add to (30)
13-30A

LAW OFFICES

BISHOP, COOK, PURCELL & REYNOLDS

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November 21, 1988

Mr. Thomas Hall
Division of Consumer Affairs
Docket H-022D
Occupational Safety & Health Administration
Room N3647
200 Constitution Avenue, N.W.
Washington, DC 20210

Supplement to NWDA's 10/28/88
Notice of Intention to Appear

Dear Mr. Hall:

My October 28 letter to you gave notice that the National Wholesale Druggists' Association would be represented in the December 6 OSHA hearing by Mr. Ronald J. Streck, Vice President of Government Affairs. Evidently in discussions with Ms. Lynn Green of NWDA, you asked for more detail on specific issues that will be addressed and the position that NWDA takes on those issues. A copy of our written comments is enclosed, which may be helpful.

In addition to this information, Mr. Streck will address the regulatory limbo in which the OSHA standard places wholesale distributors of prescription and over-the-counter drugs and consumer products. By definition, NWDA's members are not manufacturers or importers of the products they distribute. They have no independent technical expertise or capacity to determine or evaluate hazards of products they distribute in sealed containers.

In the real world of the OSHA standard, even with the pending stay of the rule insofar as FDA-regulated drugs and consumer products is concerned, distributors receive hundreds of MSDSs for materials that do not appear to warrant them. When this dilemma was raised in

legislative testimony, with examples of Pepto Bismol and Crest for Kids Super Cool Gel toothpaste, OSHA witnesses averred that no one had to prepare such MSDSs. By implication, it appears that an MSDS which need not be created also need not be distributed. In fact, however, MSDSs are being prepared and given to the distributor for products like these, and Mr. Streck's testimony will focus on the serious concern we have for the liability of the distributors put in the awkward position of making these decisions.

To illustrate this concern, and for the record, we are submitting copies of MSDSs that have been received by one of our wholesale members. Will OHSA please review these MSDSs and advise us which are required by the standard to be distributed to customers, and which are not?

Among the other questions Mr. Streck may be expected to pose to OSHA are the following:

1. Other than in response to a specific employee request, does a distributor of chemical products have to seek out and obtain MSDSs from manufacturers or importers, or need he only keep and pass on those he happens to receive?

2. Does the OSHA hazard communication standard permit a distributor who receives an MSDS from a manufacturer or importer to decide on his own <u>not</u> to pass that MSDS on to commercial customer/employers?

3. If so, given the apparent mandatory language of paragraph (i)(7) of the standard to pass on MSDSs, where in the standard is the distributor's discretion not to pass them on to be found?

4. Upon what grounds could a distributor properly determine that a chemical was not subject to the standard, if the manufacturer of that chemical apparently made the initial determination that it was covered by providing an MSDS to that distributor? In other words, if the distributor has discretion to decide what is or is not covered, in a practical sense how can he exercise that discretion?

5. Could OSHA please address the regulatory and civil liability of a chemical distributor who chooses not to pass on an MSDS for a product later alleged to be hazardous?

6. Paragraph (a)(6) of the OSHA standard exempts foods, drugs and cosmetics in a retail establishment which are packaged for sale to consumers. Are these products still exempt if their packaging is opened by a pharmacist who uses the contents to formulate prescription medicines?

7. Is a consumer product such as rubbing alcohol exempt under paragraph (a)(6)(vii) when packaged in 5-gallon drums?

8. Does a pharmacist's formulation of prescription medicines with ingredients from over-the-counter packages constitute use of a consumer product "in the same manner as normal consumer use," as that term is found in paragraph (a)(6)(vii) of the standard?

9. Is the standard as currently written sufficiently flexible and performance-oriented to permit use of alternative sources of MSDS-type information, such as the Physician's Desk Reference books or Facts and Comparisons, in place of MSDSs?

10. If a distributor or pharmacist receives two or more MSDSs from different manufacturers of the same U.S.P. material, that differ from one another in phrasing, is he obligated to maintain files on all of them or just one?

11. Paragraph (a)(4) of the standard says that in work operations where employees only handle chemicals in sealed containers which are not opened under normal circumstances, such as in cargo terminals and wholesale facilities, "the section applies to these operations only as follows," listing three limited requirements. Are all of such an employer's obligations set forth in paragraph (a)4), i.e., does such an employer have no obligation to pass on MSDSs to commercial customers under paragraph (g)(7)?

12. Is it OSHA's position that provisions on drugs and consumer products, disallowed under the OMB procedure addressed by the Third Circuit, will not be enforced with citations until the conclusion of the rule changes proposed on August 8, 1988?

NWDA's position on these issues is that they need to be resolved by OSHA, soon and without ambiguity. As a general matter, NWDA favors the comprehensible and clear position taken by OMB, that no consumer products or FDA-regulated drugs should be deemed subject to the OSHA hazard communication standard.

Please let me know if you have any questions on this supplement to the notice I filed earlier.

Sincerely,

Lawrence W. Bierlein
Counsel to NWDA

7/11/7 Bill Stratton

3M Home Products Division

3M Center
St. Paul, Minnesota 55144-1000
612/733 1110

December 29, 1987

3M

Mr. Robert W. Wilkins
Senior Vice President
Inventory Management
FOXMEYER CORPORATION
1220 Senlac Drive
Carrollton, TX 75006

File No. 8712291622232

Dear Mr. Wilkins:

Thank you for your recent request for Material Safety Data Sheets on our products.

According to Section 1910.1200 (a)(4)(iv) of Title 29, Code of Federal Regulations (CFR), the labeling requirements of the new Occupational Safety and Health Hazard Communication Standard do not apply to consumer products and hazardous substances which are subject to consumer product safety standards or labeling requirements of the Consumer Products Safety Commission. Therefore, we have not published Material Safety Data Sheets on articles such as our tapes and abrasive products which do not present chemical hazards. These products enjoy wide use, and to date, no health-related problems have arisen.

In the interest of consumer awareness we have, however, published Material Safety Data Sheets for chemical types of products such as our liquids, aerosols, adhesives and sealants.

Enclosed please find a Material Safety Data Sheet for the following products:

"SCOTCHGARD" Brand Fabric Protector
"SCOTCH" Brand Super Strength Adhesive

I trust this satisfies your request.

Sincerely,

L P Beck

Longine P. Beck
Customer Service Supervisor
HOME PRODUCTS DIVISION/3M
3M Center, Bldg. 223-4S-01
St. Paul, MN 55144-1000

3M

MATERIAL SAFETY
DATA SHEET

3M
3M CENTER
ST. PAUL, MINNESOTA
55144-1000
612/733-1110 Duns No.: 00-617-3082

DIVISION: HOME PRODUCTS
TRADE NAME: "SCOTCHGARD"(R) BRAND FABRIC PROTECTOR
3M I.D. NUMBER: 70-0701-4043-2 70-0701-4050-7 70-0701-4079-6
70-0701-6111-5 70-0701-7426-6 98-0211-0262-3
98-0211-0377-9 98-0211-0498-3
ISSUED: AUGUST 31, 1987
SUPERSEDES: JANUARY 16, 1986
DOCUMENT: 10-2520-4

1. INGREDIENTS

INGREDIENTS	C.A.S. NO.	PERCENT	EXPOSURE LIMITS	
CARBON DIOXIDE - PROPELLANT	124-38-9	3.0- 4.0	5000 PPM	1
FLUOROALIPHATIC RESIN SOLUTION	N/D	1.0- 1.1	N/D	5
1, 1, 1-TRICHLOROETHANE (AEROSOL GRADE)	71-55-6	94.5- 95.5	350 PPM	1

SOURCE OF EXPOSURE LIMIT DATA
1. ACGIH THRESHOLD LIMIT VALUES
2. FEDERAL OSHA PERMISSIBLE EXPOSURE LIMIT
3. 3M EXPOSURE GUIDELINES
4. CHEMICAL MANUFACTURER RECOMMENDED GUIDELINES
5. NONE ESTABLISHED

ABBREVIATIONS
N/D - NOT DETERMINED
N/A - NOT APPLICABLE

2. PHYSICAL DATA

BOILING POINT: 175F(LIQ.CONTENTS)
VAPOR PRESSURE: 100@20C
VAPOR DENSITY (AIR=1): 4.55
EVAPORATION RATE (BUTYL ETHER = 1): 0.4
SOLUBILITY IN WATER: NEGLIGIBLE
SP. GRAVITY (WATER=1): 1.3
PERCENT VOLATILE: 99.5
VISCOSITY: N/D
pH: N/A
APPEARANCE AND ODOR: COLORLESS LIQUID, CHLORINATED SOLVENT ODOR IN AEROSOL CAN.

3M

MATERIAL SAFETY
DATA SHEET

3M
3M CENTER
ST. PAUL, MINNESOTA
55144-1000
612/733-1110 Duns No.: 00-617-3082

DIVISION: HOME PRODUCTS
TRADE NAME: "SCOTCH-BRAND" SUPER STRENGTH ADHESIVE (CAT. 6004)
3M I.D. NUMBER: 70-0700-4869-2 70-0700-7746-9
ISSUED: FEBRUARY 24, 1986
SUPERSEDES: JULY 31, 1984
DOCUMENT: 10-2493-4

1. INGREDIENTS

INGREDIENTS	C.A.S. NO.	PERCENT	EXPOSURE LIMITS	
METHYL ETHYL KETONE	78-93-3	59.5- 60.5	200 PPM	1
EPOXY RESIN	N/D	0.0- 0.5	N/D	5
POLYURETHANE AND VINYL CHLORIDE/ACETATE COPOLYMER RESIN AND ANTIOXIDANT BLEND	N/D	35.0- 40.0	N/D	5

SOURCE OF EXPOSURE LIMIT DATA
1. ACGIH THRESHOLD LIMIT VALUES
2. FEDERAL OSHA PERMISSIBLE EXPOSURE LIMIT
3. 3M EXPOSURE GUIDELINES
4. CHEMICAL MANUFACTURER RECOMMENDED GUIDELINES
5. NONE ESTABLISHED

ABBREVIATIONS
N/D - NOT DETERMINED
N/A - NOT APPLICABLE

2. PHYSICAL DATA

BOILING POINT:	176F(MEK)	SOLUBILITY IN WATER:	VERY SLIGHT
VAPOR PRESSURE:	80@20C	SP. GRAVITY (WATER=1):	0.95
VAPOR DENSITY (AIR=1):	2.5(MEK)	PERCENT VOLATILE:	960
EVAPORATION RATE (ETHER=1):	2.7	VISCOSITY:	N/D
APPEARANCE AND ODOR:	CLEAR PASTE, KETONE ODOR		pH: N/D

3. FIRE AND EXPLOSION HAZARD DATA

FLASH POINT (CLOSED CUP): 20F
FLAMMABLE LIMITS - LEL: 1.8 UEL: 11.5

EXTINGUISHING MEDIA:
CO2, DRY CHEMICAL
SPECIAL FIRE FIGHTING PROCEDURES:

NONE

UNUSUAL FIRE AND EXPLOSION HAZARDS:
NONE

4. REACTIVITY DATA

STABILITY: STABLE

INCOMPATIBILITY - MATERIALS TO AVOID:
N/D

HAZARDOUS POLYMERIZATION: MAY NOT OCCUR

HAZARDOUS DECOMPOSITION PRODUCTS:
THERMAL DECOMPOSITION OR BURNING MAY PRODUCE CO, CO2, AND OTHER LOW MOLECULAR WEIGHT HYDROCARBONS.

5. ENVIRONMENTAL INFORMATION

SPILL RESPONSE:
OBSERVE PRECAUTIONARY INFORMATION. EXTINGUISH ALL IGNITION SOURCES. VENTILATE AREA. APPLY ABSORBENT MATERIAL TO AREA OF SPILL. CONTAIN SPILL. COLLECT SPILL. CLEAN UP RESIDUE. PLACE IN A U.S. D.O.T.-APPROVED CONTAINER AND SEAL.

RECOMMENDED DISPOSAL:
FOR BULK QUANTITIES: INCINERATE IN A PERMITTED HAZARDOUS WASTE FACILITY. SINCE REGULATIONS VARY, CONSULT APPLICABLE REGULATIONS OR AUTHORITIES BEFORE DISPOSAL. U.S.EPA HAZARDOUS WASTE NO.: D-001(IGNITABLE).

ENVIRONMENTAL DATA:
70-0700-7746-9 IS 1.0-FLUID OUNCE TUBE; 70-0700-4869-2 IS 1.85-FLUID OUNCE TUBE (U.S.). ENVIRONMENTAL DATA: N/D.

6. SUGGESTED FIRST AID

EYE CONTACT:
IMMEDIATELY FLUSH EYES WITH PLENTY OF WATER FOR TEN (10) MINUTES. CALL A PHYSICIAN.

SKIN CONTACT:
WASH WITH SOAP AND WATER. DO NOT USE SOLVENTS TO CLEANSE THE SKIN.

INHALATION:
PROVIDE FRESH AIR. IF BREATHING IS DIFFICULT, CALL A PHYSICIAN.

IF SWALLOWED:
DRINK ONE TO TWO GLASSES OF WATER AND IMMEDIATELY CALL A PHYSICIAN.

7. PRECAUTIONARY INFORMATION

KEEP AWAY FROM HEAT, SPARKS, AND FLAME. USE ONLY IN AREAS ADEQUATELY VENTILATED WITH ENOUGH AIR MOVEMENT TO REMOVE VAPORS AND PREVENT VAPOR BUILDUP. AVOID EYE CONTACT. AVOID PROLONGED BREATHING OF VAPORS AND PROLONGED OR REPEATED SKIN CONTACT. KEEP CONTAINER CLOSED. KEEP CONTAINERS OUT OF REACH OF CHILDREN.

8. HEALTH HAZARD DATA

EYE CONTACT: LIQUID IRRITATING TO THE EYES UPON DIRECT CONTACT.

SKIN CONTACT: LIQUID WAS FOUND TO BE NON-IRRITATING DERMALLY TO TEST ANIMALS. PROLONGED EXPOSURE MAY DEFAT SKIN.

INHALATION: CONCENTRATED VAPORS MAY PRODUCE RESPIRATORY SYSTEM IRRITATION, HEADACHE AND NAUSEA. DUE TO SMALL CONTAINER SIZE, NO INHALATION HAZARD IS EXPECTED UNDER LOW-VOLUME USAGE.

INGESTION: PRACTICALLY NON-TOXIC ORALLY. THE ACUTE ORAL LD50 (RAT) WAS GREATER THAN 5 GRAMS/KG BODY WEIGHT. NOTE: METHYL ETHYL KETONE IS A EMBRYO/FETOTOXIN BASED ON DATA FROM LABORATORY ANIMAL STUDIES.

Memory Technologies
Group Laboratories/3M

3M Center
St. Paul, Minnesota 55144-1000
612/733 1110

3M

January 21, 1988

Inventory Management
FoxMeyer Corporation
1220 Senlac Drive
Carrollton, TX 75006
Attn: Mr. Robert W. Wilkins

Dear Mr. Wilkins:

The 3M video tape products on your request list fall under the definition of an "Article"; see enclosed Bulletin. Articles are exempt.

I hope this information will help in meeting your needs.

Sincerely,

Paul W. Eddy
Regulatory Compliance
MTGL

PWE/can

Enclosure

The Society of the
Plastics Industry, Inc.

SPI

...Special Bulletin...Special

1025 Connecticut Avenue N.W.
Washington D.C. 20036
(202) 822-6700

OSHA Clarifies Definition of Exempt 'Articles' Under Its New Hazard Communication Standard

As most SPI members are aware, the Occupational Safety and Health Administration's Hazard Communication Standard, which requires the identification of workplace hazardous chemicals and employee training, went into effect November 25, 1985 for chemical manufacturers, importers and suppliers and will go into effect on May 25, 1986 for manufacturers who use (but do not produce) chemicals in their operations.

• • • •

The Hazard Communication Standard applies to "chemicals" but it **does not apply to any substance which is an "article"** within the meaning of the regulation.

The term "article" is defined in the new OSHA warning rule, as a manufactured item:

(1) which is formed to a specific shape or design during manufacture,
(2) which has end use function(s) dependent in whole or in part upon its shape or design during end use,
(3) which does not release, or otherwise result in exposure to, a hazardous chemical under normal conditions of use.

In the preamble to the OSHA standard as initially published in 1983, OSHA used "furniture" and "pieces of equipment" as examples of exempt articles. At the same time, the agency noted that hazardous chemicals used in the manufacture or use of an "article" would remain covered by the Standard unless otherwise excluded.

• • • •

Early in 1985, OSHA's Office of Health Compliance Assistance issued a memorandum outlining inspection procedures under the Standard, which clarifies the definition of exempt "articles." The agency stated that the key to the definition of "article" is the term "under normal conditions of use," and provides the following example:

An item may meet the definition of "article" – but produces a hazardous byproduct if burned. If burning is not considered as part of its normal conditions of use, the item would be an "article" under the Standard, and thus exempted.

The OSHA directive cites vinyl upholstery, stainless steel tables, and tires as additional examples of exempt "articles." It also lists three types of items which would not be considered "articles" under the standard

(1) Metal ingots that will be melted under normal conditions of use.
(2) Fabric treated with formaldehyde where downstream garment manufacturing employees will be exposed when making clothing.
(3) Switches with mercury in them when a certain percentage break under normal conditions of use.

In these circumstances, the agency concluded that a "release" of hazardous material would occur and that the required information must be supplied. No information needs to be provided concerning those substances which remain "bound" in an item.

• • • •

Within this framework, it appears that a number of products manufactured by SPI members may be exempt from the new OSHA standard as "articles" since, under "normal conditions of use," their utilization by purchasers and downstream workers will not result in exposure to any hazardous chemical. Manufacturers will be required to assess the status of their individual products under the standards described above. A number of other considerations, ranging from customer relations concerns to potential product liability claims, may lead some companies to take a narrow view of the "articles" exemption with respect to certain of their products. SPI members also should check to see if there are state "right to know" laws that could affect them. Such information may be obtained by contacting Pat Toner in the SPI Washington office at (202) 822-6700.

12/85

PROGRAM-ID : IF6P70 REPORT-ID : IF6070 FOXMEYER CORPORATE DATA CENTER
VENDOR ID-59401 3M CO-HOME ENTRTMNT GMP ITEM PRIMARY REPORT BY VENDOR

ITEM NO.	DESCRIPTION	NDC	UPC	F.L.	MOQ	H	M	R	HAZARD
046441	SCOTCH CART 8TK DRNG S8TR90 GM		00000000000	6-71	00	N	N	N	
050476	SCOTCH CART 8TK HGLN H8TR90 2 GM		00000000000	6-71	00	N	N	N	
499319	SCOTCH CASS TAPE BX 60/3E		05111120018	6-71	00	N	N	N	
029520	SCOTCH CASS TAPE BX 90/3E		05111120003	6-71	00	N	N	N	
499285	SCOTCH CASS TAPE BX60 CARDED		NONE	6-71	00	N	N	N	
046854	SCOTCH CASS TAPE BX60 2BAG		05111120051	6-71	00	N	N	N	
499293	SCOTCH CASS TAPE BX90 CD		NONE	6-71	00	N	N	N	
047423	SCOTCH CASS TAPE BX90 2BAG		05111120052	6-71	00	N	N	N	
499384	SCOTCH CASS TAPE CX60 CARDED		05111120011	6-71	00	N	N	N	
045872	SCOTCH CASS TAPE CX60 2BAG		05111120037	6-71	00	N	N	N	
045398	SCOTCH CASS TAPE CX90 CD		NONE	6-71	00	N	N	N	
499368	SCOTCH CASS TAPE L750CD VIDEO		00000000000	6-71	00	N	N	N	
520148	SCOTCH CASS TAPE-CX90 2 BAG		05111120038	6-71	00	N	N	N	
499350	SCOTCH*VIDEO BETA TAPE L 500CD		00000000000	6-71	00	N	N	N	
316661	SCOTCH*VIDEO TAPE K750 EG+ BETA		05111331668	6-71	00	N	N	N	
316778	SCOTCH*VIDEO TAPE-T120 EXG		05111331583	6-71	00	N	N	N	
499376	SCOTCH*VIDEO VHS TAPE T 120CD		00000000000	6-71	00	N	N	N	

TOTAL PER VENDOR - 17

*** PAGES (1) ***

3M General Offices
3M Center
St. Paul, Minnesota 55144-1000
(612) 733-1110

Duns No.: 00-617-3082

MATERIAL SAFETY
DATA SHEET

3M

DIVISION: RIKER
TRADE NAME: NORGESIC AND NORGESIC FORTE (PRESCRIPTION DRUG)
3M I.D. NUMBER: NOT ASSIGNED
ISSUED: JULY 25, 1986
SUPERSEDES: OCTOBER 11, 1985
DOCUMENT: 10-2447-0

1. INGREDIENTS

INGREDIENTS	C.A.S. NO.	PERCENT	EXPOSURE LIMITS	
ORPHENADRINE CITRATE	4682-36-4	4.0	N/D	5
CAFFEINE	58-08-2	4.0	N/D	5
ASPIRIN	50-78-2	57.0	5 MG/M3	1
EXCIPIENTS	N/D	35.0	N/D	5

SOURCE OF EXPOSURE LIMIT DATA
1. ACGIH THRESHOLD LIMIT VALUES
2. FEDERAL OSHA PERMISSIBLE EXPOSURE LIMIT
3. 3M EXPOSURE GUIDELINES
4. CHEMICAL MANUFACTURER RECOMMENDED GUIDELINES
5. NONE ESTABLISHED

ABBREVIATIONS
N/D - NOT DETERMINED
N/A - NOT APPLICABLE

2. PHYSICAL DATA

BOILING POINT: N/A
VAPOR PRESSURE: N/A
VAPOR DENSITY (AIR=1): N/A
EVAPORATION RATE (N/A = 1): N/A
SOLUBILITY IN WATER: LOW
SP. GRAVITY (WATER=1): N/D
PERCENT VOLATILE: N/A
VISCOSITY: N/D
pH: 5-6
APPEARANCE AND ODOR: YELLOW/GREEN/WHITE TABLET

3M General Offices
3M Center
St. Paul, Minnesota 55144-1000
(612) 733-1110

Duns No.: 00-617-3082

MATERIAL SAFETY
DATA SHEET

3. FIRE AND EXPLOSION HAZARD DATA

FLASH POINT (COMBUSTABLE SOLID): N/A
FLAMMABLE LIMITS - LEL: N/A UEL: N/A

EXTINGUISHING MEDIA:
WATER, CARBON DIOXIDE, DRY CHEMICAL EXTINGUISHER, FOAM
SPECIAL FIRE FIGHTING PROCEDURES:
FIRE FIGHTERS SHOULD WEAR SELF-CONTAINED BREATHING APPARATUS AND FULL PROTECTIVE CLOTHING.
UNUSUAL FIRE AND EXPLOSION HAZARDS:
NONE

4. REACTIVITY DATA

STABILITY: STABLE

INCOMPATIBILITY - MATERIALS TO AVOID:
NONE
HAZARDOUS POLYMERIZATION: MAY NOT OCCUR

HAZARDOUS DECOMPOSITION PRODUCTS:
COMBUSTION MAY PRODUCE CARBON DIOXIDE AND CARBON MONOXIDE.

5. ENVIRONMENTAL INFORMATION

SPILL RESPONSE:
COLLECT SPILL MATERIAL. PLACE IN AN APPROVED METAL CONTAINER AND SEAL.
RECOMMENDED DISPOSAL:
MIX WITH FLAMMABLE MATERIAL AND INCINERATE IN AN INDUSTRIAL OR COMMERCIAL
FACILITY. CONSULT APPLICABLE REGULATIONS OR AUTHORITIES BEFORE DISPOSAL.
ENVIRONMENTAL DATA:
N/D

6. SUGGESTED FIRST AID

EYE CONTACT:
N/A
SKIN CONTACT:
N/A
INHALATION:
N/A
IF SWALLOWED:
NOTIFY PHYSICIAN. SEE PACKAGE INSERT OR PDR.

3M General Offices
3M Center
St. Paul, Minnesota 55144-1000
(612) 733-1110

Duns No.: 00-617-3082

MATERIAL SAFETY
DATA SHEET

7. PRECAUTIONARY INFORMATION

HANDLE IN ACCORDANCE WITH GOOD INDUSTRIAL HYGIENE AND SAFETY PRACTICE. THIS PRODUCT IS APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION (FDA) FOR USE AS A PRESCRIPTION DRUG.

3M General Offices
3M Center
St. Paul, Minnesota 55144-1000
(612) 733-1110

Duns No.: 00-617-3082

MATERIAL SAFETY
DATA SHEET

8. HEALTH HAZARD DATA

EYE CONTACT: NO INFORMATION FOUND

SKIN CONTACT: NO INFORMATION FOUND

INHALATION: NO INFORMATION FOUND

INGESTION: ACUTE TOXICITY IN CONSIDERED MODERATE IN ANIMALS (ORAL LD50 OF COMPONENTS RANGE 192-1000 MG/KG)

3M General Offices
3M Center
St. Paul, Minnesota 55144-1000
(612) 733-1110

Duns No.: 00-617-3082

MATERIAL SAFETY
DATA SHEET

3M

DIVISION: RIKER
TRADE NAME: UREX (PRESCRIPTION DRUG)
3M I.D. NUMBER: NOT ASSIGNED
ISSUED: JULY 24, 1986
SUPERSEDES: APRIL 28, 1986
DOCUMENT: 10-6194-4

1. INGREDIENTS	C.A.S. NO.	PERCENT	EXPOSURE LIMITS
METHENAMINE HIPPURATE	5714-73-8	95.0	5
SACCHARIN SODIUM	128-44-9	2.0	5
EXCIPIENTS	N/D	3.0	5

SOURCE OF EXPOSURE LIMIT DATA
1. ACGIH THRESHOLD LIMIT VALUES
2. FEDERAL OSHA PERMISSIBLE EXPOSURE LIMIT
3. 3M EXPOSURE GUIDELINES
4. CHEMICAL MANUFACTURER RECOMMENDED GUIDELINES
5. NONE ESTABLISHED

ABBREVIATIONS
N/D - NOT DETERMINED
N/A - NOT APPLICABLE

2. PHYSICAL DATA

BOILING POINT: N/D
VAPOR PRESSURE: N/D
VAPOR DENSITY (AIR=1): N/D
EVAPORATION RATE (= 1): N/D
SOLUBILITY IN WATER: SOLUBLE
SP. GRAVITY (WATER=1): N/D
PERCENT VOLATILE: N/D
VISCOSITY: N/D
pH: N/D
APPEARANCE AND ODOR: WHITE SCORED TABLETS

3. FIRE AND EXPLOSION HAZARD DATA

FLASH POINT (COMBUSTABLE SOLID): N/A
FLAMMABLE LIMITS - LEL: N/A UEL: N/A

EXTINGUISHING MEDIA:
WATER, FOG OR FOAM
SPECIAL FIRE FIGHTING PROCEDURES:
NO SPECIAL PROCEDURES. USE WATER SPRAY TO COOL FIRE-EXPOSED

3M General Offices
3M Center
St. Paul, Minnesota 55144-1000
(612) 733-1110

Duns No.: 00-617-3082

MATERIAL SAFETY
DATA SHEET

CONTAINERS. FIREFIGHTERS SHOULD USE SELF-CONTAINED BREATHING APPARATUS.

UNUSUAL FIRE AND EXPLOSION HAZARDS:
POWDERS MAY FORM AN EXPLOSIVE MIXTURE WITH AIR

4. REACTIVITY DATA

STABILITY: STABLE

INCOMPATIBILITY - MATERIALS TO AVOID:
STRONG ACIDS AND BASES AVOID TEMPERATURES LESS THAN 15C (59F) AND GREATER THAN 30C (86F)

HAZARDOUS POLYMERIZATION: MAY NOT OCCUR

HAZARDOUS DECOMPOSITION PRODUCTS:
WHEN BURNING, CO, CO2, NITROUS OXIDE WILL RESULT

5. ENVIRONMENTAL INFORMATION

SPILL RESPONSE:
OBSERVE PRECAUTIONS FROM OTHER SECTIONS. AVOID DUSTING. COLLECT SPILLED MATERIAL AND PLACE INTO CLOSED CONTAINER. CLEAN UP RESIDUE WITH SOAP AND WATER.

RECOMMENDED DISPOSAL:
INCINERATE IN AN INDUSTRIAL OR COMMERCIAL FACILITY IN ACCORDANCE WITH APPLICABLE REGULATIONS

ENVIRONMENTAL DATA:
N/D

6. SUGGESTED FIRST AID

EYE CONTACT:
N/A

SKIN CONTACT:
N/A

INHALATION:
N/A

IF SWALLOWED:
NOTIFY PHYSICIAN. SEE PACKAGE INSERT OR PDR

7. PRECAUTIONARY INFORMATION

HANDLE IN ACCORDANCE WITH GOOD INDUSTRIAL HYGIENE AND SAFETY PRACTICE. THIS PRODUCT IS APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION (FDA) FOR USE AS A PRESCRIPTION DRUG.

3M General Offices
3M Center
St. Paul, Minnesota 55144-1000
(612) 733-1110

Duns No.: 00-617-3082

MATERIAL SAFETY
DATA SHEET

8. HEALTH HAZARD DATA

EYE CONTACT: NON-IRRITATING IN ANIMAL TESTS

SKIN CONTACT: NON-IRRITATING IN ANIMAL TEST. MAY BE A SKIN SENSITIZER.

INGESTION:ACUTE TOXICITY IS CONSIDERED SLIGHTLY TOXIC BASED ON ANIMAL STUDIES (ORAL LD50 >4000 MG/KG). CONTAINS AN ANIMAL CARCINOGEN (SACCARIN SODIUM) NATIONAL TOXICOLOGY PROGRAM.

INHALATION: NO EXPOSURE EXPECTED.

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Duns No.: 00-617-3082

MATERIAL SAFETY
DATA SHEET

3M

DIVISION: RIKER
TRADE NAME: THEOLAIR, THEOLAIR SR (TABLETS) (PRESCRIPTION DRUG)
3M I.D. NUMBER: NOT ASSIGNED
ISSUED: JULY 25, 1986
SUPERSEDES: JANUARY 13, 1986
DOCUMENT: 10-3091-5

1. INGREDIENTS

INGREDIENTS	C.A.S. NO.	PERCENT	EXPOSURE LIMITS	
THEOPHYLLINE ANHYDROUS	58-55-9	28.0- 50.0	N/D	5
LACTOSE HYDROUS	63-42-3	40.0	N/D	5
EXCIPIENTS	N/D	10.0- 32.0	N/D	5

SOURCE OF EXPOSURE LIMIT DATA
1. ACGIH THRESHOLD LIMIT VALUES
2. FEDERAL OSHA PERMISSIBLE EXPOSURE LIMIT
3. 3M EXPOSURE GUIDELINES
4. CHEMICAL MANUFACTURER RECOMMENDED GUIDELINES
5. NONE ESTABLISHED

ABBREVIATIONS
N/D - NOT DETERMINED
N/A - NOT APPLICABLE

2. PHYSICAL DATA

BOILING POINT: SOLID N/A
VAPOR PRESSURE: N/A
VAPOR DENSITY (AIR=1): N/A
EVAPORATION RATE (= 1): N/A
SOLUBILITY IN WATER: 0.8%
SP. GRAVITY (WATER=1): N/D
PERCENT VOLATILE: N/A
VISCOSITY: N/D
pH: SLIGHTLY ACID
APPEARANCE AND ODOR: WHITE SOLID SCORED TABLET

3. FIRE AND EXPLOSION HAZARD DATA

FLASH POINT (COMBUSTABLE SOLID): N/A
FLAMMABLE LIMITS - LEL: N/A UEL: N/A

EXTINGUISHING MEDIA:
WATER ,CARBON DIOXIDE, DRY CHEMICAL EXTINGUISHER, OR FOAM.
SPECIAL FIRE FIGHTING PROCEDURES:

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FIREFIGHTERS SHOULD WEAR TURNOUT GEAR AND SELF-CONTAINED BREATHING APPARATUS.
UNUSUAL FIRE AND EXPLOSION HAZARDS:
NONE

4. REACTIVITY DATA

STABILITY: STABLE

INCOMPATIBILITY - MATERIALS TO AVOID:
NONE
HAZARDOUS POLYMERIZATION: MAY NOT OCCUR

HAZARDOUS DECOMPOSITION PRODUCTS:
COMBUSTION MAY PRODUCE CARBON DIOXIDE, CARBON MONOXIDE, OXIDES OF NITROGEN.

5. ENVIRONMENTAL INFORMATION

SPILL RESPONSE:
OBSERVE PRECAUTIONS FROM OTHER SECTIONS. COLLECT SPILLED MATERIAL. PLACE IN A CLOSED CONTAINER.
RECOMMENDED DISPOSAL:
MIX WITH FLAMMABLE MATERIAL AND INCINERATE IN AN INDUSTRIAL OR COMMERCIAL FACILITY. SINCE REGULATIONS VARY, CONSULT APPLICABLE REGULATIONS OR AUTHORITIES BEFORE DISPOSAL.
ENVIRONMENTAL DATA:
N/D

6. SUGGESTED FIRST AID

EYE CONTACT:
N/A
SKIN CONTACT:
N/A
INHALATION:
N/A
IF SWALLOWED:
NOTIFY PHYSICIAN. SEE PACKAGE INSERT OR PDR.

7. PRECAUTIONARY INFORMATION

HANDLE IN ACCORDANCE WITH GOOD INDUSTRIAL HYGIENE AND SAFETY PRACTICE. THIS PRODUCT IS APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION (FDA) FOR USE AS A PRESCRIPTION DRUG.

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8. HEALTH HAZARD DATA

EYE CONTACT: NO INFORMATION FOUND

SKIN CONTACT: NO INFORMATION FOUND

INHALATION: NO INFORMATION FOUND

INGESTION: ACUTE TOXICITY CONSIDERED MODERATE (ORAL LD50 IN ANIMALS 600 MG/KG)

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MATERIAL SAFETY
DATA SHEET

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DIVISION: RIKER
TRADE NAME: TEPANIL/TEPANIL-TEN TAB (PRESCRIPTION DRUG)
3M I.D. NUMBER: NOT ASSIGNED
ISSUED: JULY 24, 1986
SUPERSEDES: MAY 30, 1986
DOCUMENT: 10-6776-8

1. INGREDIENTS	C.A.S. NO.	PERCENT	EXPOSURE LIMITS
DIETHYLPROPION HYDROCHLORIDE	134-80-5	10.0	5
EXCIPIENTS	N/D	90.0	5

SOURCE OF EXPOSURE LIMIT DATA
1. ACGIH THRESHOLD LIMIT VALUES
2. FEDERAL OSHA PERMISSIBLE EXPOSURE LIMIT
3. 3M EXPOSURE GUIDELINES
4. CHEMICAL MANUFACTURER RECOMMENDED GUIDELINES
5. NONE ESTABLISHED

ABBREVIATIONS
N/D - NOT DETERMINED
N/A - NOT APPLICABLE

2. PHYSICAL DATA

BOILING POINT: N/A
VAPOR PRESSURE: NIL
VAPOR DENSITY (AIR=1): UNKNOWN
EVAPORATION RATE (N/D = 1): NIL
SOLUBILITY IN WATER: 100G/L AT 20C
SP. GRAVITY (WATER=1): 500G/L
PERCENT VOLATILE: N/A
VISCOSITY: N/A
pH: N/D
APPEARANCE AND ODOR: SOLID WHITE TABLET

3. FIRE AND EXPLOSION HAZARD DATA

FLASH POINT (COMBUSTABLE SOLID): N/A
FLAMMABLE LIMITS - LEL: N/A UEL: N/A

EXTINGUISHING MEDIA:
WATER SPRAY, FOAM, DRY CHEMICAL OR CARBON DIOXIDE.
SPECIAL FIRE FIGHTING PROCEDURES:
FIRE FIGHTERS SHOULD WEAR SELF-CONTAINED BREATHING APPARATUS AND FULL PROTECTIVE CLOTHING.

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DATA SHEET

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UNUSUAL FIRE AND EXPLOSION HAZARDS:
NONE

4. REACTIVITY DATA

STABILITY: STABLE

INCOMPATIBILITY - MATERIALS TO AVOID:
ALKALI
HAZARDOUS POLYMERIZATION: MAY NOT OCCUR

HAZARDOUS DECOMPOSITION PRODUCTS:
NONE

5. ENVIRONMENTAL INFORMATION

SPILL RESPONSE:
OBSERVE PRECAUTIONS FROM OTHER SECTIONS. COLLECT SPILLED MATERIAL AND PLACE IN A APPROVED METAL CONTAINER AND SEAL.
RECOMMENDED DISPOSAL:
MIX WITH FLAMMABLE MATERIAL AND INCINERATE IN AN INDUSTRIAL OR COMMERCIAL FACILITY. CONSULT APPLICABLE REGULATIONS OR AUTHORITIES BEFORE DISPOSAL. U.S. EPA HAZARDOUS WATER NO.: NONE
ENVIRONMENTAL DATA:
NOT DETERMINED

6. SUGGESTED FIRST AID

EYE CONTACT:
N/A
SKIN CONTACT:
N/A
INHALATION:
N/A
IF SWALLOWED:
NOTIFY PHYSICIAN. SEE PACKAGE INSERT OR PHYSICIANS DESK REFERENCE

7. PRECAUTIONARY INFORMATION

HANDLE PRODUCT IN ACCORDANCE WITH GOOD INDUSTRIAL HYGIENE AND SAFETY PRACTICE. THIS PRODUCT IS APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRAITON (FDA) FOR USE AS A PRESCRIPTION DRUG.

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8. HEALTH HAZARD DATA

INGESTION: SLIGHTLY TOXIC BASED ON ANIMAL STUDIES (ORAL LD50 APPROXIMATELY 450- 500 MG/KG).

EYE CONTACT: NO INFORMATION FOUND

SKIN CONTACT: NO INFORMATION FOUND

INHALATION: NO INFORMATION FOUND

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MATERIAL SAFETY
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3M

DIVISION: RIKER
TRADE NAME: RAUWILOID (PRESCRIPTION DRUG)
3M I.D. NUMBER: NOT ASSIGNED
ISSUED: JULY 25, 1986
SUPERSEDES: OCTOBER 11, 1985
DOCUMENT: 10-2663-2

1. INGREDIENTS	C.A.S. NO.	PERCENT	EXPOSURE LIMITS	
ALSEROXYLON	50-55-1	0.1	N/D	5
PLUS RELATED ALKALOIDS	N/D	0.1	N/D	5
EXCIPIENTS	N/D	99.9	N/D	5

SOURCE OF EXPOSURE LIMIT DATA
1. ACGIH THRESHOLD LIMIT VALUES
2. FEDERAL OSHA PERMISSIBLE EXPOSURE LIMIT
3. 3M EXPOSURE GUIDELINES
4. CHEMICAL MANUFACTURER RECOMMENDED GUIDELINES
5. NONE ESTABLISHED

ABBREVIATIONS
N/D - NOT DETERMINED
N/A - NOT APPLICABLE

2. PHYSICAL DATA

BOILING POINT: N/A
VAPOR PRESSURE: NIL
VAPOR DENSITY (AIR=1): N/A
EVAPORATION RATE (N/A = 1): N/A
SOLUBILITY IN WATER: PRACTICALLY INSOLUB
SP. GRAVITY (WATER=1): UNKNOWN
PERCENT VOLATILE: N/A
VISCOSITY: N/A
pH: N/D
APPEARANCE AND ODOR: ROUND BROWN TABLET

3. FIRE AND EXPLOSION HAZARD DATA

FLASH POINT (COMBUSTABLE SOLID): N/A
FLAMMABLE LIMITS - LEL: N/A UEL: N/A

EXTINGUISHING MEDIA:
WATER, CARBON DIOXIDE, DRY CHEMICAL EXTINGUISHER, FOAM
SPECIAL FIRE FIGHTING PROCEDURES:
FIRE FIGHTERS SHOULD WEAR SELF-CONTAINED BREATHING APPARATUS AND FULL

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PROTECTIVE CLOTHING.
UNUSUAL FIRE AND EXPLOSION HAZARDS:
NONE

4. REACTIVITY DATA

STABILITY: STABLE

INCOMPATIBILITY - MATERIALS TO AVOID:
NONE
HAZARDOUS POLYMERIZATION: MAY NOT OCCUR

HAZARDOUS DECOMPOSITION PRODUCTS:
COMBUSTION MAY PRODUCE CARBON DIOXIDE AND CARBON MONOXIDE

5. ENVIRONMENTAL INFORMATION

SPILL RESPONSE:
COLLECT SPILLED MATERIAL. PLACE IN AN APPROVED METAL CONTAINER AND SEAL.
RECOMMENDED DISPOSAL:
MIX WITH FLAMMABLE MATERIAL AND INCINERATE IN AN INDUSTRIAL OR COMMERCIAL FACILITY. DISPOSAL ALTERNATIVE: DISPOSE OF WASTE PRODUCT IN A FACILITY PERMITTED TO ACCEPT CHEMICAL WASTES. SINCE REGULATIONS VARY, CONSULT APPLICABLE REGULATIONS OR AUTHORITIES BEFORE DISPOSAL.
ENVIRONMENTAL DATA:
NOT DETERMINED

6. SUGGESTED FIRST AID

EYE CONTACT:
N/A
SKIN CONTACT:
N/A
INHALATION:
N/A
IF SWALLOWED:
NOTIFY PHYSICIAN. SEE PACKAGE INSERT OR PDR.

7. PRECAUTIONARY INFORMATION

HANDLE IN ACCORDANCE WITH GOOD INDUSTRIAL HYGIENE AND SAFETY PRACTICE. THIS PRODUCT IS APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION (FDA) FOR USE AS A PRESCRIPTION DRUG.

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8. HEALTH HAZARD DATA

EYE CONTACT: NO INFORMATION FOUND

SKIN CONTACT: NO INFORMATION FOUND

INHALATION: NO INFORMATION FOUND

INGESTION: ACUTE TOXICITY CONSIDERED MODERATE (ORAL LD50-390 MG/KG IN ANIMALS)

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Duns No.: 00-617-3082

MATERIAL SAFETY
DATA SHEET

3M

DIVISION: RIKER
TRADE NAME: MEDIHALER ERGOTAMINE (PRESCRIPTION DRUG)
3M I.D. NUMBER: NOT ASSIGNED
ISSUED: AUGUST 11, 1986
SUPERSEDES: NOVEMBER 13, 1985
DOCUMENT: 10-2894-3

1. INGREDIENTS

INGREDIENTS	C.A.S. NO.	PERCENT	EXPOSURE LIMITS	
PROPELLANT 12 (DICHLORODIFLUOROMETHANE)	75-71-8	49.0	1000 PPM	1
PROPELLANT 11 (TRICHLOROFLUOROMETHANE)	75-69-4	25.0	1000 PPM	1
PROPELLANT 114 (1,2-DICHLORO-1,1,2,2-TETRAFLUOROETHANE)	76-14-2	25.0	1000 PPM	1
ERGOTAMINE TARTRATE	379-79-3	0.6	N/D	5

SOURCE OF EXPOSURE LIMIT DATA
1. ACGIH THRESHOLD LIMIT VALUES
2. FEDERAL OSHA PERMISSIBLE EXPOSURE LIMIT
3. 3M EXPOSURE GUIDELINES
4. CHEMICAL MANUFACTURER RECOMMENDED GUIDELINES
5. NONE ESTABLISHED

ABBREVIATIONS
N/D - NOT DETERMINED
N/A - NOT APPLICABLE

2. PHYSICAL DATA

BOILING POINT: -21.6F
VAPOR PRESSURE: 70 PSIG(70F)
VAPOR DENSITY (AIR=1): 6.3 G/L
EVAPORATION RATE (= 1): N/D
SOLUBILITY IN WATER: LIMITED
SP. GRAVITY (WATER=1): N/D
PERCENT VOLATILE: 98
VISCOSITY: N/D
pH: N/D
APPEARANCE AND ODOR: WHITE AEROSOL SUSPENSION IN PRESSURIZED CONTAINERS.

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3. FIRE AND EXPLOSION HAZARD DATA

FLASH POINT (): N/D
FLAMMABLE LIMITS - LEL: N/D UEL: N/D

EXTINGUISHING MEDIA:
USE EXTINGUISHING MEDIA AS APPROPRIATE FOR THE SURROUNDING MATERIALS.
SPECIAL FIRE FIGHTING PROCEDURES:
FIRE FIGHTERS SHOULD WEAR SELF-CONTAINED BREATHING APPARATUS AND FULL PROTECTIVE CLOTHING. COOL FIRE EXPOSED CONTAINERS WITH WATER SPRAY.
UNUSUAL FIRE AND EXPLOSION HAZARDS:
PRESSURIZED CONTAINERS - AVOID EXTREME HEAT.

4. REACTIVITY DATA

STABILITY: STABLE

INCOMPATIBILITY - MATERIALS TO AVOID:
EXTREME HEAT
HAZARDOUS POLYMERIZATION: MAY NOT OCCUR

HAZARDOUS DECOMPOSITION PRODUCTS:
COMBUSTION MAY PRODUCE HYDROCHLORIC ACID, HYDROFLUORIC ACID AND POSSIBLY CARBONYL FLUORIDE.

5. ENVIRONMENTAL INFORMATION

SPILL RESPONSE:
OBSERVE PRECAUTIONS FROM OTHER SECTIONS. EXTINGUISH ALL IGNITION SOURCES. VENTILATE AREA. COLLECT SPILLED MATERIAL. PLACE IN A U.S. DOT-APPROVED CONTAINER AND SEAL.
RECOMMENDED DISPOSAL:
DISPOSE OF EMPTY CANS IN A SANITARY LANDFILL. DO NOT PUNCTURE OR BURN CANS IN A HOUSEHOLD INCINERATOR. MIX WITH FLAMMABLE MATERIAL AND INCINERATE IN AN INDUSTRIAL OR COMMERCIAL FACILITY. FACILITY MUST BE CAPABLE OF HANDLING AEROSOL CANS. COMBUSTION PRODUCTS WILL INCLUDE HF AND HCL. SINCE REGULATIONS VARY, CONSULT APPLICABLE REGULATIONS OR AUTHORITIES BEFORE DISPOSAL.
ENVIRONMENTAL DATA:
N/D

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6. SUGGESTED FIRST AID

EYE CONTACT:
FLUSH WITH PLENTY OF WATER FOR AT LEAST 10 MINUTES. CALL A PHYSICIAN.
SKIN CONTACT:
WASH AFFECTED AREA WITH SOAPY WATER.
INHALATION:
REMOVE PERSON TO FRESH AIR. SEE PACKAGE INSERT OR PDR.
IF SWALLOWED:
SEE PACKAGE INSERT OR PDR. CALL A PHYSICIAN.

7. PRECAUTIONARY INFORMATION

EXPOSURE TO HEAVY CONCENTRATIONS OF PROPELLANT MAY CAUSE LIGHTHEADEDNESS, SHORTNESS OF BREATH, POSSIBLE NARCOSIS, POSSIBLE CARDIAC ARRHYTHMIAS. PERSONNEL SHOULD WEAR FACE SHIELD OR SAFETY GOGGLES FOR EYE PROTECTION, GLOVES SHOULD BE WORN WHEN HANDLING THE LIQUID, AND APPROPRIATE AIR MASKS WORN FOR HEAVY PROPELLANT CONCENTRATIONS. VENTILATE AREA- CONTROL DUSTS OR RESIDUES.

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8. HEALTH HAZARD DATA

EYE CONTACT: MAY CAUSE EYE IRRITATION. FROSTBITE MAY RESULT IF SPRAYED AT CLOSE RANGE.

SKIN CONTACT: MAY CAUSE SKIN IRRITATION. FROSTBITE MAY RESULT IF SPRAYED ON SKIN AT CLOSE RANGE.

INHALATION: VAPOR OVEREXPOSURE MAY CAUSE RESPIRATORY SYSTEM IRRITATION. OVEREXPOSURE TO PROPELLANT MAY CAUSE TEMPORARY NERVOUS SYSTEM IMPAIRMENT, DECREASED LUNG CAPACITY, CARDIAC SENSITIVITY TO ADRENALIN, AND POSSIBLE CARDIAC ARRHYTHMIAS. SYMPTOMS OF OVEREXPOSURE MAY INCLUDE DIZZINESS, GIDDINESS, WEAKNESS, SHORTNESS OF BREATH AND POSSIBLE NARCOSIS.

INGESTION: MAY CAUSE DIGESTIVE SYSTEM IRRITATION AND TEMPORARY NERVOUS SYSTEM IMPAIRMENT. SYMPTOMS MAY INCLUDE HEADACHE, WEAKNESS, NAUSEA, VOMITING, FOLLOWED BY FAINTING.

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DATA SHEET

3M

DIVISION: RIKER
TRADE NAME: NORFLEX INJECTABLE (PRESCRIPTION DRUG)
3M I.D. NUMBER: NOT ASSIGNED
ISSUED: OCTOBER 11, 1985
SUPERSEDES: INITIAL ISSUE
DOCUMENT: 10-2450-4

1. INGREDIENTS

INGREDIENTS	C.A.S. NO.	PERCENT	EXPOSURE LIMITS	
ORPHENADRINE CITRATE	4682-36-4	2.9	N/D	5
WATER	N/D	97.1	N/D	5

SOURCE OF EXPOSURE LIMIT DATA
1. ACGIH THRESHOLD LIMIT VALUES
2. FEDERAL OSHA PERMISSIBLE EXPOSURE LIMIT
3. 3M EXPOSURE GUIDELINES
4. CHEMICAL MANUFACTURER RECOMMENDED GUIDELINES
5. NONE ESTABLISHED

ABBREVIATIONS
N/D - NOT DETERMINED
N/A - NOT APPLICABLE

2. PHYSICAL DATA

BOILING POINT: N/D
VAPOR PRESSURE: N/A
VAPOR DENSITY (AIR=1): N/A
EVAPORATION RATE (= 1): N/D
SOLUBILITY IN WATER: LOW
SP. GRAVITY (WATER=1): N/D
PERCENT VOLATILE: N/D
VISCOSITY: N/D
pH: N/D
APPEARANCE AND ODOR: CLEAR LIQUID

3. FIRE AND EXPLOSION HAZARD DATA

FLASH POINT (NONCOMBUSTABLE): N/A
FLAMMABLE LIMITS - LEL: N/A UEL: N/A

EXTINGUISHING MEDIA:
USE EXTINGUISHING MEDIA AS APPROPRIATE FOR SURROUNDING MATERIALS.
SPECIAL FIRE FIGHTING PROCEDURES:
FIRE FIGHTERS SHOULD WEAR SELF-CONTAINED BREATHING APPARATUS AND FULL PROTECTIVE CLOTHING.

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UNUSUAL FIRE AND EXPLOSION HAZARDS:
NONE

4. REACTIVITY DATA

STABILITY: STABLE

INCOMPATIBILITY - MATERIALS TO AVOID:
NONE
HAZARDOUS POLYMERIZATION: MAY NOT OCCUR

HAZARDOUS DECOMPOSITION PRODUCTS:
COMBUSTION MAY PRODUCE CARBON DIOXIDE AND CARBON MONOXIDE.

5. ENVIRONMENTAL INFORMATION

SPILL RESPONSE:
COLLECT SPILL MATERIAL. PLACE IN AN APPROVED METAL CONTAINER AND SEAL.
RECOMMENDED DISPOSAL:
MIX WITH FLAMMABLE MATERIAL AND INCINERATE IN INDUSTRIAL OR COMMERCIAL FACILITY. CONSULT APPLICABLE REGULATIONS OR AUTHORITIES BEFORE DISPOSAL.
ENVIRONMENTAL DATA:
N/D

6. SUGGESTED FIRST AID

EYE CONTACT:
FLUSH WITH PLENTY OF WATER FOR AT LEAST 10 MINUTES AND NOTIFY PHYSICIAN.
SKIN CONTACT:
WASH WITH SOAP AND WATER AND NOTIFY PHYSICIAN.
INHALATION:
N/A
IF SWALLOWED:
NOTIFY PHYSICIAN. SEE PACKAGE INSERT OR PDR.

7. PRECAUTIONARY INFORMATION

HANDLE IN ACCORDANCE WITH GOOD INDUSTRIAL HYGIENE AND SAFETY PRACTICE. THIS PRODUCT IS APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION (FDA) FOR USE AS A PRESCRIPTION DRUG.

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8. HEALTH HAZARD DATA

EYE CONTACT: NO INFORMATION FOUND

SKIN CONTACT: NO INFORMATION FOUND

INHALATION: NO INFORMATION FOUND

INGESTION: ACUTE TOXICITY CONSIDERED MODERATE IN ANIMALS (ORAL LD50 150-415 MG/KG).

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MATERIAL SAFETY
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3M

DIVISION: RIKER
TRADE NAME: MEDIHALER-ISO (PRESCRIPTION DRUG)
3M I.D. NUMBER: NOT ASSIGNED
ISSUED: AUGUST 11, 1986
SUPERSEDES: NOVEMBER 13, 1985
DOCUMENT: 10-2539-4

1. INGREDIENTS

INGREDIENTS	C.A.S. NO.	PERCENT	EXPOSURE LIMITS	
PROPELLANT 12 (DICHLORODIFLUOROMETHANE)	75-71-8	50.0	1000 PPM	1
PROPELLANT 11 (TRICHLOROFLUOROMETHANE)	75-69-4	24.8	1000 PPM	1
PROPELLANT 114 (1,2-DICHLORO-1,1,2,2-TETRAFLUOROETHANE)	76-14-2	24.8	1000 PPM	1
ISOPROTERENOL SULFATE	299-95-6	0.2	N/D	5

SOURCE OF EXPOSURE LIMIT DATA
1. ACGIH THRESHOLD LIMIT VALUES
2. FEDERAL OSHA PERMISSIBLE EXPOSURE LIMIT
3. 3M EXPOSURE GUIDELINES
4. CHEMICAL MANUFACTURER RECOMMENDED GUIDELINES
5. NONE ESTABLISHED

ABBREVIATIONS
N/D - NOT DETERMINED
N/A - NOT APPLICABLE

2. PHYSICAL DATA

BOILING POINT: -21.6F
VAPOR PRESSURE: 70 PSIG (70F)
VAPOR DENSITY (AIR=1): 6.3 G/L
EVAPORATION RATE (= 1): N/D
SOLUBILITY IN WATER: LIMITED
SP. GRAVITY (WATER=1): N/D
PERCENT VOLATILE: 98
VISCOSITY: N/D
pH: N/D
APPEARANCE AND ODOR: WHITE AEROSOL SUSPENSION IN PRESSURIZED CONTAINERS.

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3. FIRE AND EXPLOSION HAZARD DATA

FLASH POINT (): N/D
FLAMMABLE LIMITS - LEL: N/D UEL: N/D

EXTINGUISHING MEDIA:
USE EXTINGUISHING MEDIA AS APPROPRIATE FOR THE SURROUNDING MATERIALS.
SPECIAL FIRE FIGHTING PROCEDURES:
FIRE FIGHTERS SHOULD WEAR SELF-CONTAINED BREATHING APPARATUS AND FULL PROTECTIVE CLOTHING. COOL FIRE EXPOSED CONTAINERS WITH WATER SPRAY.
UNUSUAL FIRE AND EXPLOSION HAZARDS:
PRESSURIZED CONTAINERS - AVOID EXTREME HEAT.

4. REACTIVITY DATA

STABILITY: STABLE

INCOMPATIBILITY - MATERIALS TO AVOID:
HIGH TEMPERATURE
HAZARDOUS POLYMERIZATION: MAY NOT OCCUR

HAZARDOUS DECOMPOSITION PRODUCTS:
COMBUSTION MAY PRODUCE HYDROCHLORIC ACID, HYDROFLUORIC ACID AND POSSIBLY CARBONYLFLUORIDE.

5. ENVIRONMENTAL INFORMATION

SPILL RESPONSE:
OBSERVE PRECAUTIONS FROM OTHER SECTIONS. EXTINGUISH ALL IGNITION SOURCES. VENTILATE AREA. COLLECT SPILLED MATERIAL. PLACE IN A U.S. DOT-APPROVED CONTAINER AND SEAL.
RECOMMENDED DISPOSAL:
DISPOSE OF EMPTY CANS IN A SANITARY LANDFILL. DO NOT PUNCTURE OR BURN CANS IN A HOUSEHOLD INCINERATOR. MIX WITH FLAMMABLE MATERIAL AND INCINERATE IN AN INDUSTRIAL OR COMMERCIAL FACILITY. FACILITY MUST BE CAPABLE OF HANDLING AEROSOL CANS. COMBUSTION PRODUCTS WILL INCLUDE HF AND HCL. SINCE REGULATIONS VARY, CONSULT APPLICABLE REGULATIONS OR AUTHORITIES BEFORE DISPOSAL.
ENVIRONMENTAL DATA:
N/D

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6. SUGGESTED FIRST AID

EYE CONTACT:
FLUSH EYES WITH PLENTY OF WATER FOR AT LEAST 10 MINUTES. NOTIFY A PHYSICIAN.
SKIN CONTACT:
WASH AFFECTED AREA WITH SOAPY WATER. NOTIFY A PHYSICIAN.
INHALATION:
REMOVE PERSON TO FRESH AIR. NOTIFY A PHYSICIAN. SEE PACKAGE INSERT OR PDR.
IF SWALLOWED:
NOTIFY A PHYSICIAN. SEE PACKAGE INSERT OR PDR.

7. PRECAUTIONARY INFORMATION

WEAR SAFETY GOGGLES FOR EYE PROTECTION. WEAR GLOVES AND SUITABLE COVERING FOR SKIN PROTECTION IN PRODUCTION. CONTROL DUSTS AND VENTILATE AREA TO PREVENT ACCUMULATION OF PROPELLANT VAPORS. WEAR APPROPRIATE AIR MASK FOR RESPIRATORY PROTECTION.

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8. HEALTH HAZARD DATA

EYE CONTACT: MAY CAUSE EYE IRRITATION. FROSTBITE MAY RESULT IF SPRAYED AT CLOSE RANGE.

SKIN CONTACT: MAY CAUSE SKIN IRRITATION. FROSTBITE MAY RESULT IF SPRAYED ON SKIN AT CLOSE RANGE.

INHALATION: VAPOR OVEREXPOSURE MAY CAUSE RESPIRATORY SYSTEM IRRITATION. ISOPROTERENOL SULFATE MAY CAUSE WHEEZING AND BREATHLESSNESS. OVEREXPOSURE TO PROPELLANT MAY CAUSE TEMPORARY NERVOUS SYSTEM IMPAIRMENT, DECREASED LUNG CAPACITY,CARDIAC SENSITIVITY TO ADRENALIN, AND POSSIBLE CARDIAC ARRHYTHMIAS. SYMPTOMS OF OVEREXPOSURE MAY INCLUDE DIZZINESS, GIDDINESS, WEAKNESS, SHORTNESS OF BREATH AND POSSIBLE NARCOSIS.

INGESTION: MAY CAUSE DIGESTIVE SYSTEM IRRITATION AND TEMPORARY NERVOUS SYSTEM IMPAIRMENT. SYMPTOMS MAY INCLUDE HEADACHE, WEAKNESS, NAUSEA VOMITING, FOLLOWED BY FAINTING.

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MATERIAL SAFETY
DATA SHEET

3M

DIVISION: RIKER
TRADE NAME: DISALCID (PRESCRIPTION DRUG)
3M I.D. NUMBER: NOT ASSIGNED
ISSUED: JULY 26, 1985
SUPERSEDES: OCTOBER 11, 1985
DOCUMENT: 10-2531-1

1. INGREDIENTS

INGREDIENTS	C.A.S. NO.	PERCENT	EXPOSURE LIMITS	
SALICYLSALICYLIC ACID	552-94-3	75.0- 84.0	N/D	5
MICROCRYSTALLINE CELLULOSE NF	9004-34-6	11.0- 15.0	N/D	5
MAGNESIUM STEARATE NF	557-04-0	0.2- 0.4	N/D	5
EXCIPIENTS	N/D	4.5- 13.0	N/D	5

SOURCE OF EXPOSURE LIMIT DATA
1. ACGIH THRESHOLD LIMIT VALUES
2. FEDERAL OSHA PERMISSIBLE EXPOSURE LIMIT
3. 3M EXPOSURE GUIDELINES
4. CHEMICAL MANUFACTURER RECOMMENDED GUIDELINES
5. NONE ESTABLISHED

ABBREVIATIONS
N/D - NOT DETERMINED
N/A - NOT APPLICABLE

2. PHYSICAL DATA

BOILING POINT: N/A SOLID
VAPOR PRESSURE: N/A
VAPOR DENSITY (AIR=1): N/A
EVAPORATION RATE (= 1): NIL
SOLUBILITY IN WATER: PRAC INSOLUBLE
SP. GRAVITY (WATER=1): N/D
PERCENT VOLATILE: N/A
VISCOSITY: N/D
pH: 5.5
APPEARANCE AND ODOR: WHITE SOLID TABLET

3. FIRE AND EXPLOSION HAZARD DATA

FLASH POINT (COMBUSTABLE SOLID): N/A
FLAMMABLE LIMITS - LEL: N/A UEL: N/A

EXTINGUISHING MEDIA:
WATER, CARBON DIOXIDE, DRY CHEMICAL EXTINGUISHER, FOAM
SPECIAL FIRE FIGHTING PROCEDURES:

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FIRE FIGHTERS SHOULD WEAR SELF-CONTAINED BREATHING APPARATUS AND FULL PROTECTIVE CLOTHING.
UNUSUAL FIRE AND EXPLOSION HAZARDS:
NONE

4. REACTIVITY DATA

STABILITY: STABLE

INCOMPATIBILITY - MATERIALS TO AVOID:
REACTION WITH STRONG BASES MAY CAUSE A MILD EXOTHERMIC REACTION.
HAZARDOUS POLYMERIZATION: MAY NOT OCCUR

HAZARDOUS DECOMPOSITION PRODUCTS:
COMBUSTION MAY PRODUCE CARBON DIOXIDE AND CARBON MONOXIDE.

5. ENVIRONMENTAL INFORMATION

SPILL RESPONSE:
COLLECT SPILLED MATERIAL. PLACE IN AN APPROVED METAL CONTAINER AND SEAL.
RECOMMENDED DISPOSAL:
MIX WITH FLAMMABLE MATERIAL AND INCINERATE IN AN INDUSTRIAL OR COMMERCIAL FACILITY. DISPOSAL ALTERNATIVE: DISPOSE OF WASTE PRODUCT IN A FACILITY PERMITTED TO ACCEPT CHEMICAL WASTES. SINCE REGULATIONS VARY, CONSULT APPLICABLE REGULATIONS OR AUTHORITIES BEFORE DISPOSAL.
ENVIRONMENTAL DATA:
N/D

6. SUGGESTED FIRST AID

EYE CONTACT:
N/A
SKIN CONTACT:
N/A
INHALATION:
N/A
IF SWALLOWED:
NOTIFY PHYSICIAN. SEE PACKAGE INSERT OR PDR.

7. PRECAUTIONARY INFORMATION

HANDLE IN ACCORDANCE IWHT GOOD INDUSTRIAL HYGIENE AND SAFETY PRACTICE. THIS PRODUCT IS APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION (FDA) FOR USE AS A PRESCRIPTION DRUG.

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8. HEALTH HAZARD DATA

EYE CONTACT: NO INFORMATION FOUND.

SKIN CONTACT: NO INFORMATION FOUND.

INHALATION: NO INFORMATION FOUND.

INGESTION: ACUTE TOXICITY IS CONSIDERED MINIMAL (ORAL LD50 IN ANIMALS >2000 MG/KG)

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MATERIAL SAFETY
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3M

DIVISION: RIKER
TRADE NAME: CALCIUM DISODIUM VERSENATE (PRESCRIPTION DRUG)
3M I.D. NUMBER: NOT ASSIGNED
ISSUED: JULY 24, 1986
SUPERSEDES: APRIL 1, 1985
DOCUMENT: 10-6196-9

1. INGREDIENTS	C.A.S. NO.	PERCENT	EXPOSURE LIMITS
CALCIUM DISODIUM EDETATE	62-33-9	20.0	5
WATER	7732-18-5	80.0	5

SOURCE OF EXPOSURE LIMIT DATA
1. ACGIH THRESHOLD LIMIT VALUES
2. FEDERAL OSHA PERMISSIBLE EXPOSURE LIMIT
3. 3M EXPOSURE GUIDELINES
4. CHEMICAL MANUFACTURER RECOMMENDED GUIDELINES
5. NONE ESTABLISHED

ABBREVIATIONS
N/D - NOT DETERMINED
N/A - NOT APPLICABLE

2. PHYSICAL DATA

BOILING POINT: N/D
VAPOR PRESSURE: N/D
VAPOR DENSITY (AIR=1): N/D
EVAPORATION RATE (= 1): N/D
SOLUBILITY IN WATER: SOLUBLE
SP. GRAVITY (WATER=1): 1
PERCENT VOLATILE: 80
VISCOSITY: N/D
pH: 6.5-8.0
APPEARANCE AND ODOR: PALE YELLOW, CLEAR SOLUTION

3. FIRE AND EXPLOSION HAZARD DATA

FLASH POINT (NONCOMBUSTABLE): N/A
FLAMMABLE LIMITS - LEL: N/A UEL: N/A

EXTINGUISHING MEDIA:
N/A
SPECIAL FIRE FIGHTING PROCEDURES:
N/A

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UNUSUAL FIRE AND EXPLOSION HAZARDS:
N/A

4. REACTIVITY DATA

STABILITY: STABLE

INCOMPATIBILITY - MATERIALS TO AVOID:
STRONG ACIDS AND BASES, TEMPERATURES LESS THAN 15C AND GREATER THAN 30C
HAZARDOUS POLYMERIZATION: MAY NOT OCCUR

HAZARDOUS DECOMPOSITION PRODUCTS:
WHEN BURNING, CO, CO2, AND NITROUS OXIDE MAY RESULT

5. ENVIRONMENTAL INFORMATION

SPILL RESPONSE:
USE ABSORBANT MATERIAL AS NEEDED IN CLEANUP PROCEDURE
RECOMMENDED DISPOSAL:
INCINERATE IN A FACILITY IN ACCORDANCE WITH APPLICALBE REGULATIONS.
ENVIRONMENTAL DATA:
N/D

6. SUGGESTED FIRST AID

EYE CONTACT:
FLUSH WITH PLENTY OF WATER FOR AT LEAST 10 MINUTES AND NOTIFY PHYSICIAN.
SKIN CONTACT:
WASH WITH SOAP AND WATER AND NOTIFY PHYSICIAN.
INHALATION:
N/A
IF SWALLOWED:
NOTIFY PHYSICIAN. SEE PACKAGE INSERT OR PDR

7. PRECAUTIONARY INFORMATION

HANDLE PRODUCT IN ACCORDANCE WITH GOOD INDUSTRIAL HYGIENE AND SAFETY PRACTICE. THIS PRODUCT IS APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION (FDA) FOR USE AS A PRESCRIPTION DRUG UNDER NDA 8922.

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8. HEALTH HAZARD DATA

EYE CONTACT: MAY CAUSE EYE IRRITATION

SKIN CONTACT: NO INFORMATION FOUND

INHALATION: NO INFORMATION FOUND

INGESTION: PRACTICALLY NON-TOXIC BASED ON ANIMAL STUDIES (ORAL LD50 >10G/KG).

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DIVISION: RIKER
TRADE NAME: NORFLEX SUSTAINED-RELEASE TABLETS
(PRESCRIPTION DRUG)
3M I.D. NUMBER: NOT ASSIGNED
ISSUED: SEPTEMBER 2, 1986
SUPERSEDES: AUGUST 11, 1986
DOCUMENT: 10-2449-6

1. INGREDIENTS

INGREDIENTS	C.A.S. NO.	PERCENT	EXPOSURE LIMITS	
ORPHENADRINE CITRATE	4682-36-4	33.0	N/D	5
EXCIPIENTS	N/D	67.0	N/D	5

SOURCE OF EXPOSURE LIMIT DATA
1. ACGIH THRESHOLD LIMIT VALUES
2. FEDERAL OSHA PERMISSIBLE EXPOSURE LIMIT
3. 3M EXPOSURE GUIDELINES
4. CHEMICAL MANUFACTURER RECOMMENDED GUIDELINES
5. NONE ESTABLISHED

ABBREVIATIONS
N/D - NOT DETERMINED
N/A - NOT APPLICABLE

2. PHYSICAL DATA

BOILING POINT: N/A
VAPOR PRESSURE: N/A
VAPOR DENSITY (AIR=1): N/D
EVAPORATION RATE (= 1): N/D
SOLUBILITY IN WATER: LOW
SP. GRAVITY (WATER=1): N/D
PERCENT VOLATILE: N/D
VISCOSITY: N/D
pH: N/D
APPEARANCE AND ODOR: WHITE TABLET PRACTICALLY ODORLESS

3. FIRE AND EXPLOSION HAZARD DATA

FLASH POINT (): N/D
FLAMMABLE LIMITS - LEL: N/D UEL: N/D

EXTINGUISHING MEDIA:
WATER, CARBON DIOXIDE, DRY CHEMICAL EXTINGUISHER, FOAM
SPECIAL FIRE FIGHTING PROCEDURES:
NONE

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MATERIAL SAFETY
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UNUSUAL FIRE AND EXPLOSION HAZARDS:
COMBUSTION, MAY PRODUCE CARBON DIOXIDE AND MONOXIDE

4. REACTIVITY DATA

STABILITY: STABLE

INCOMPATIBILITY - MATERIALS TO AVOID:
NONE
HAZARDOUS POLYMERIZATION: MAY NOT OCCUR

HAZARDOUS DECOMPOSITION PRODUCTS:
COMBUSTION MAY PRODUCE CARBON DIOXIDE AND CARBON MONOXIDE.

5. ENVIRONMENTAL INFORMATION

SPILL RESPONSE:
COLLECT SPILL MATERIAL. PLACE IN AN APPROVED METAL CONTAINER AND SEAL.
RECOMMENDED DISPOSAL:
MIX WITH FLAMMABLE MATERIAL AND INCINERATE IN INDUSTRIAL OR COMMERCIAL FACILITY. CONSULT APPLICABLE REGULATIONS OR AUTHORITIES BEFORE DISPOSAL.
ENVIRONMENTAL DATA:
N/D

6. SUGGESTED FIRST AID

EYE CONTACT:
N/A
SKIN CONTACT:
N/A
INHALATION:
N/A
IF SWALLOWED:
NOTIFY PHYSICIAN. SEE PACKAGE INSERT OR PDR.

7. PRECAUTIONARY INFORMATION

HANDLE IN ACCORDANCE WITH GOOD INDUSTRIAL HYGIENE AND SAFETY PRACTICE. THIS PRODUCT IS APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION (FDA) FOR USE AS A PRESCRIPTION DRUG.

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8. HEALTH HAZARD DATA

EYE CONTACT: EXPOSURE NOT LIKELY DUE TO THE PHYSICAL NATURE OF THE TABLET. NO RELEVANT INFORMATION FOUND

SKIN CONTACT: EXPOSURE NOT LIKELY DUE TO THE PHYSICAL NATURE OF THE TABLET. NO RELEVANT INFORMATION FOUND

INHALATION: EXPOSURE NOT LIKELY DUE TO THE PHYSICAL NATURE OF THE TABLET. NO RELEVANT INFORMATION FOUND

INGESTION: ACUTE TOXICITY CONSIDERED MODERATE BASED ON ANIMAL STUDIES (LD50 150-415 MG/KG).

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MATERIAL SAFETY
DATA SHEET

3M

DIVISION: RIKER
TRADE NAME: MEDIHALER EPI,BRONKAID MIST,PRIMATENE MIST,ASTHMAHALER
3M I.D. NUMBER: NOT ASSIGNED
ISSUED: AUGUST 11, 1986
SUPERSEDES: NOVEMBER 13, 1985
DOCUMENT: 10-2537-8

1. INGREDIENTS	C.A.S. NO.	PERCENT	EXPOSURE LIMITS	
PROPELLANT 12 (DICHLORODIFLUOROMETHANE)	75-71-8	43.0	1000 PPM	1
PROPELLANT 11 (TRICHLOROFLUOROMETHANE)	75-69-4	25.0	1000 PPM	1
PROPELLANT 114 (1,2-DICHLORO-1,1,2,2-TETRAFLUOROETHANE)	76-14-2	25.0	1000 PPM	1
EPINPHEHRINE BITARTRATE	636-89-5	0.5	N/D	5

SOURCE OF EXPOSURE LIMIT DATA
1. ACGIH THRESHOLD LIMIT VALUES
2. FEDERAL OSHA PERMISSIBLE EXPOSURE LIMIT
3. 3M EXPOSURE GUIDELINES
4. CHEMICAL MANUFACTURER RECOMMENDED GUIDELINES
5. NONE ESTABLISHED

ABBREVIATIONS
N/D - NOT DETERMINED
N/A - NOT APPLICABLE

2. PHYSICAL DATA

BOILING POINT: -21.6F
VAPOR PRESSURE: 70 PSIG(70F)
VAPOR DENSITY (AIR=1): 6.3 G/L
EVAPORATION RATE (= 1): N/D
SOLUBILITY IN WATER: LIMITED
SP. GRAVITY (WATER=1): N/D
PERCENT VOLATILE: 92
VISCOSITY: N/D
pH: N/D
APPEARANCE AND ODOR: WHITE AEROSOL SUSPEN$ION IN PRESSURIZED CONTAINERS

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3. FIRE AND EXPLOSION HAZARD DATA

FLASH POINT (): N/D
FLAMMABLE LIMITS - LEL: N/D UEL: N/D

EXTINGUISHING MEDIA:
USE EXTINGUISHING MEDIA AS APPROPRIATE FOR THE SURROUNDING MATERIALS.
SPECIAL FIRE FIGHTING PROCEDURES:
FIRE FIGHTERS SHOULD WEAR SELF-CONTAINED BREATHING APPARATUS AND FULL PROTECTIVE CLOTHING. COOL FIRE EXPOSED CONTAINERS WITH WATER SPRAY.
UNUSUAL FIRE AND EXPLOSION HAZARDS:
PRESSURIZED CONTAINERS - AVOID EXTREME HEAT.

4. REACTIVITY DATA

STABILITY: STABLE

INCOMPATIBILITY - MATERIALS TO AVOID:
HIGH TEMPERATURES
HAZARDOUS POLYMERIZATION: MAY NOT OCCUR

HAZARDOUS DECOMPOSITION PRODUCTS:
COMBUSTION MAY PRODUCE HYDROCHLORIC ACID, HYDROFLUORIC ACID AND POSSIBLY CARBONYLFLUORIDE.

5. ENVIRONMENTAL INFORMATION

SPILL RESPONSE:
OBSERVE PRECAUTIONS FROM OTHER SECTIONS. EXTINGUISH ALL IGNITION SOURCES. VENTILATE AREA. COLLECT SPILLED MATERIAL. PLACE IN A U.S. DOT-APPROVED CONTAINER AND SEAL.
RECOMMENDED DISPOSAL:
DISPOSE OF EMPTY CANS IN A SANITARY LANDFILL. DO NOT PUNCTURE OR BURN CANS IN A HOUSEHOLD INCINERATOR. MIX WITH FLAMMABLE MATERIAL AND INCINERATE IN AN INDUSTRIAL OR COMMERCIAL FACILITY. FACILITY MUST BE CAPABLE OF HANDLING AEROSOL CANS. COMBUSTION PRODUCTS WILL INCLUDE HF AND HCL. SINCE REGULATIONS VARY, CONSULT APPLICABLE REGULATIONS OR AUTHORITIES BEFORE DISPOSAL.
ENVIRONMENTAL DATA:
N/D

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6. SUGGESTED FIRST AID

EYE CONTACT:
FLUSH EYES WITH PLENTY OF WATER FOR AT LEAST 10 MINUTES. CALL A PHYSICIAN.
SKIN CONTACT:
WASH AFFECTED AREA WITH SOAPY WATER.
INHALATION:
REMOVE PERSON TO FRESH AIR. CALL A PHYSICIAN, SEE PACKAGE INSERT OR PDR.
IF SWALLOWED:
CALL A PHYSICIAN. SEE PACKAGE INSERT OR PDR.

7. PRECAUTIONARY INFORMATION

WEAR SAFETY GOGGLES IN PROCESSING. PROTECTIVE GLOVES WHEN HANDLING THE LIQUID AND USE AIR MASK IN HIGH CONCENTRATION OF PROPELLANT. VENTILATE - ESPECIALLY LOW AREAS.

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8. HEALTH HAZARD DATA

EYE CONTACT: MAY CAUSE EYE IRRITATION. FROSTBITE MAY RESULT IF SPRAYED AT CLOSE RANGE.

SKIN CONTACT: MAY CAUSE SKIN IRRITATION AND/OR RASHES. FROSTBITE MAY RESULT IF SPRAYED ON SKIN AT CLOSE RANGE.

INHALATION: MAY CAUSE RESPIRATORY SYSTEM IRRITATION. EPINEPHRINE BITARTRATE MAY CAUSE WHEEZING AND INFLAMMATION MUCOUS MEMBRANE AND TIGHTNESS IN THE THROAT. OVEREXPOSURE TO PROPELLANT MAY CAUSE TEMPORARY NERVOUS SYSTEM IMPAIRMENT, DECREASED LUNG CAPACITY, CARDIAC SENSITIVITY TO ADRENALIN, AND POSSIBLE CARDIAC ARRHYTHMIAS. SYMPTROMS OF OVEREXPOSURE MAY INCLUDE, DIZZINESS, GIDDINESS, SHORTNESS OF BREATH, WEAKNESS AND POSSIBLE NARCOSIS.

INGESTION: MAY CAUSE DIGESTIVE SYSTEM IRRITATION AND TEMPORARY NERVOUS SYSTEM IMPAIRMENT. SYMPTOMS MAY INCLUDE HEADACHE, WEAKNESS, NAUSEA, VOMITING, FOLLOWED BY FAINTING.

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DIVISION: RIKER
TRADE NAME: DUO-MEDIHALER (PRESCRIPTION DRUG)
3M I.D. NUMBER: NOT ASSIGNED
ISSUED: AUGUST 11, 1986
SUPERSEDES: NOVEMBER 13, 1985
DOCUMENT: 10-2542-8

1. INGREDIENTS

INGREDIENTS	C.A.S. NO.	PERCENT	EXPOSURE LIMITS	
PROPELLANT 12 (DICHLORODIFLUOROMETHANE)	75-71-8	49.0	1000 PPM	1
PROPELLANT 11 (TRICHLOROFLUOROMETHANE)	75-69-4	24.0	1000 PPM	1
PROPELLANT 114 (1,2-DICHLORO-1,1,2,2-TETRAFLUOROETHANE)	76-14-2	24.0	1000 PPM	1
PHENYLEPHRINE BITARTRATE	13998-27-1	0.4	N/D	5
ISOPROTERENOL HYDROCHLORIDE	51-30-9	0.3	N/D	5

SOURCE OF EXPOSURE LIMIT DATA
1. ACGIH THRESHOLD LIMIT VALUES
2. FEDERAL OSHA PERMISSIBLE EXPOSURE LIMIT
3. 3M EXPOSURE GUIDELINES
4. CHEMICAL MANUFACTURER RECOMMENDED GUIDELINES
5. NONE ESTABLISHED

ABBREVIATIONS
N/D - NOT DETERMINED
N/A - NOT APPLICABLE

2. PHYSICAL DATA

BOILING POINT: -21.6F
VAPOR PRESSURE: 70 PSIG (70F)
VAPOR DENSITY (AIR=1): 6.3 G/L
EVAPORATION RATE (= 1): N/D
SOLUBILITY IN WATER: LIMITED
SP. GRAVITY (WATER=1): N/D
PERCENT VOLATILE: 98
VISCOSITY: N/D
pH: N/D
APPEARANCE AND ODOR: WHITE AEROSOL SUSPENSION IN PRESSURIZED CONTAINERS

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3. FIRE AND EXPLOSION HAZARD DATA

FLASH POINT (): N/D
FLAMMABLE LIMITS - LEL: N/D UEL: N/D

EXTINGUISHING MEDIA:
USE EXTINGUISHING MEDIA AS APPROPRIATE FOR THE SURROUNDING MATERIALS.
SPECIAL FIRE FIGHTING PROCEDURES:
FIRE FIGHTERS SHOULD WEAR SELF-CONTAINED BREATHING APPARATUS AND FULL PROTECTIVE CLOTHING. COOL FIRE EXPOSED CONTAINERS WITH WATER SPRAY.
UNUSUAL FIRE AND EXPLOSION HAZARDS:
PRESSURIZED CONTAINERS - AVOID EXTEME HEAT

4. REACTIVITY DATA

STABILITY: STABLE

INCOMPATIBILITY - MATERIALS TO AVOID:
HIGH TEMPERATURE
HAZARDOUS POLYMERIZATION: MAY NOT OCCUR

HAZARDOUS DECOMPOSITION PRODUCTS:
COMBUSTION MAY PRODUCE HYDROCHLORIC ACID, HYDROFLUORIC ACID AND POSSIBLY CARBONYLFLUORIDE.

5. ENVIRONMENTAL INFORMATION

SPILL RESPONSE:
OBSERVE PRECAUTIONS FROM OTHER SECTIONS. EXTINGUISH ALL IGNITION SOURCES. VENTILATE AREA. COLLECT SPILLED MATERIAL. PLACE IN A U.S. DOT-APPROVED CONTAINER AND SEAL.
RECOMMENDED DISPOSAL:
DISPOSE OF EMPTY CANS IN A SANITARY LANDFILL. DO NOT PUNCTURE OR BURN CANS IN A HOUSEHOLD INCINERATOR. MIX WITH FLAMMABLE MATERIAL AND INCINERATE IN AN INDUSTRIAL OR COMMERICIAL FACILITY. FACILITY MUST BE CAPABLE OF HANDLING AEROSOL CANS. COMBUSTION PRODUCTS WILL INCLUDE HF AND HCL. SINCE REGULATIONS VARY, CONSULT APPLICABLE REGULATIONS OR AUTHORITIES BEFORE DISPOSAL.
ENVIRONMENTAL DATA:
N/D

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6. SUGGESTED FIRST AID

EYE CONTACT:
FLUSH EYES WITH PLENTY OF WATER FOR AT LEAST 10 MINUTES. NOTIFY A PHYSICIAN.
SKIN CONTACT:
WASH AFFECTED AREA WITH SOAPY WATER.
INHALATION:
REMOVE PERSON TO FRESH AIR. NOTIFY A PHYSICIAN.
IF SWALLOWED:
NOTIFY A PHYSICIAN. SEE PACKAGE INSERT OR PDR.

7. PRECAUTIONARY INFORMATION

SAFETY GOGGLES SHOULD BE WORN FOR EYE PROTECTION. WEAR GLOVES (PVC) AND SUITABLE COVERING IN PRODUCTION. USE APPROPRIATE AIR MASK FOR HEAVY PROPELLANT CONCENTRATION - DUST MASK IN FORMULATION AREAS. VENTILATE AREA TO CONTROL DUSTS AND FUMES.

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8. HEALTH HAZARD DATA

EYE CONTACT: MAY CAUSE EYE IRRITATION. FROSTBITE MAY RESULT IF SPRAYED AT CLOSE RANGE.

SKIN CONTACT: MAY CAUSE SKIN IRRITATION AND/OR RASHES. FROSTBITE MAY RESULT IF SPRAYED ON SKIN AT CLOSE RANGE.

INHALATION: VAPOR OVEREXPOSURE MAY CAUSE RESPIRATORY SYSTEM IRRITATION. PHENYLEPHRINE BITARTRATE MAY CAUSE WHEEZING AND INFLAMMATION OF MUCOUS MEMBRANE AND TIGHTNESS OF THROAT. OVEREXPOSURE TO PROPELLANT MAY CAUSE TEMPORARY NERVOUS SYSTEM IMPAIRMENT, DECREASED LUNG CAPACITY, CARDIAC SENSITIVITY TO ADRENALIN, AND POSSIBLE CARDIAC ARRHYTHMIAS. SYMPTOMS OF OVEREXPOSURE MAY INCLUSE DIZZINESS, GIDDINESS, SHORTNESS OF BREATH, AND POSSIBLE NARCOSIS.

INGESTION: MAY CAUSE DIGESTIVE SYSTEM IRRITATION AND TEMPORARY NERVOUS IMPAIRMENT. SYMPTOMS MAY INCLUDE HEADACHE, WEAKNESS, NAUSEA AND VOMITING, FOLLOWED BY FAINTING.

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Duns No.: 00-617-3082

MATERIAL SAFETY
DATA SHEET

3M

DIVISION: RIKER
TRADE NAME: DISIPAL (PRESCRIPTION DRUG)
3M I.D. NUMBER: NOT ASSIGNED
ISSUED: JULY 10, 1986
SUPERSEDES: INITIAL ISSUE
DOCUMENT: 10-8194-2

1. INGREDIENTS	C.A.S. NO.	PERCENT	EXPOSURE LIMITS
ORPHENADRINE HYDROCHLORIDE	N/D	16.0	5
EXCIPIENTS	N/D	84.0	5

SOURCE OF EXPOSURE LIMIT DATA
1. ACGIH THRESHOLD LIMIT VALUES
2. FEDERAL OSHA PERMISSIBLE EXPOSURE LIMIT
3. 3M EXPOSURE GUIDELINES
4. CHEMICAL MANUFACTURER RECOMMENDED GUIDELINES
5. NONE ESTABLISHED

ABBREVIATIONS
N/D - NOT DETERMINED
N/A - NOT APPLICABLE

2. PHYSICAL DATA

BOILING POINT: N/A
VAPOR PRESSURE: N/A
VAPOR DENSITY (AIR=1): N/A
EVAPORATION RATE (= 1): N/A
SOLUBILITY IN WATER: N/D
SP. GRAVITY (WATER=1): N/D
PERCENT VOLATILE: NIL
VISCOSITY: N/A
pH: N/D
APPEARANCE AND ODOR: SOLID ROUND GREEN TABLET

3. FIRE AND EXPLOSION HAZARD DATA

FLASH POINT (COMBUSTABLE SOLID): N/A
FLAMMABLE LIMITS - LEL: N/A UEL: N/A

EXTINGUISHING MEDIA:
WATER SPRAY,FOAM,DRY CHEMICAL OR CARBON DIOXIDE
SPECIAL FIRE FIGHTING PROCEDURES:
FIRE FIGHTERS SHOULD WEAR SELF-CONTAINED BREATHING APPARATUS AND FULL PROTECTIVE CLOTHING.

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MATERIAL SAFETY
DATA SHEET

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UNUSUAL FIRE AND EXPLOSION HAZARDS:
NONE

4. REACTIVITY DATA

STABILITY: STABLE

INCOMPATIBILITY - MATERIALS TO AVOID:
NONE
HAZARDOUS POLYMERIZATION: MAY NOT OCCUR

HAZARDOUS DECOMPOSITION PRODUCTS:
NONE

5. ENVIRONMENTAL INFORMATION

SPILL RESPONSE:

RECOMMENDED DISPOSAL:

ENVIRONMENTAL DATA:

6. SUGGESTED FIRST AID

EYE CONTACT:
N/A
SKIN CONTACT:
N/A
INHALATION:
N/A
IF SWALLOWED:
SEE PAKCAGE INSERT OR PDR

7. PRECAUTIONARY INFORMATION

HANDLE IN ACCORDANCE AS ANY OTHER PRESCRIPTION DRUG. THIS PRODUCT IS APPROVED BY FEDERAL FOOD AND DRUG ADMINISTRAITON (FDA) FOR USE AS A PRESCRIPTION DRUG.

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MATERIAL SAFETY
DATA SHEET

3M

8. HEALTH HAZARD DATA

3M General Offices
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Duns No.: 00-617-3082

MATERIAL SAFETY
DATA SHEET

3M

DIVISION: RIKER
TRADE NAME: ALU-CAP ANTACID (OTC DRUG)
3M I.D. NUMBER: NOT ASSIGNED
ISSUED: JULY 10, 1986
SUPERSEDES: INITIAL ISSUE
DOCUMENT: 10-8193-4

1. INGREDIENTS	C.A.S. NO.	PERCENT	EXPOSURE LIMITS
ALUMINUM HYDROXIDE GEL -DRIED	N/D	65.0	5
EXCIPIENTS	N/D	35.0	5

SOURCE OF EXPOSURE LIMIT DATA
1. ACGIH THRESHOLD LIMIT VALUES
2. FEDERAL OSHA PERMISSIBLE EXPOSURE LIMIT
3. 3M EXPOSURE GUIDELINES
4. CHEMICAL MANUFACTURER RECOMMENDED GUIDELINES
5. NONE ESTABLISHED

ABBREVIATIONS
N/D - NOT DETERMINED
N/A - NOT APPLICABLE

2. PHYSICAL DATA

BOILING POINT: N/A
VAPOR PRESSURE: N/A
VAPOR DENSITY (AIR=1): N/A
EVAPORATION RATE (= 1): N/A
SOLUBILITY IN WATER: MINIMAL
SP. GRAVITY (WATER=1): N/D
PERCENT VOLATILE: N/A
VISCOSITY: N/A
pH: N/D
APPEARANCE AND ODOR: GREEN AND RED CAPSULES

3. FIRE AND EXPLOSION HAZARD DATA

FLASH POINT (COMBUSTABLE SOLID): N/A
FLAMMABLE LIMITS - LEL: N/A UEL: N/A

EXTINGUISHING MEDIA:
WATER SPRAY,FOAM, DRY CHEMICAL OR CARBON DIOXIDE
SPECIAL FIRE FIGHTING PROCEDURES:
FIRE FIGHTERS SHOULD WEAR SELF-CONTAINED BREATHING APPARATUS AND FULL PROTECTIVE CLOTHING

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Duns No.: 00-617-3082

MATERIAL SAFETY
DATA SHEET

UNUSUAL FIRE AND EXPLOSION HAZARDS:
NONE

4. REACTIVITY DATA

STABILITY: STABLE

INCOMPATIBILITY - MATERIALS TO AVOID:
ACIDS
HAZARDOUS POLYMERIZATION: MAY NOT OCCUR

HAZARDOUS DECOMPOSITION PRODUCTS:
NONE

5. ENVIRONMENTAL INFORMATION

SPILL RESPONSE:

RECOMMENDED DISPOSAL:

ENVIRONMENTAL DATA:

6. SUGGESTED FIRST AID

EYE CONTACT:
N/A
SKIN CONTACT:
N/A
INHALATION:
N/A
IF SWALLOWED:
SEE PACKAGE LABEL OR PDR FOR NON-PRESCRIPTION DRUGS.

7. PRECAUTIONARY INFORMATION

HANDLE IN ACCORDANCE AS ANY OTHER OTC DRUG.

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Duns No.: 00-617-3082

MATERIAL SAFETY
DATA SHEET

3M

8. HEALTH HAZARD DATA

The information on this Data Sheet represents our current data and best opinion as to the proper use in handling of this product under normal conditions. Any use of the product which is not in conformance with this Data Sheet or which involves using the product in combination with any other product or any other process is the responsibility of the user.

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Duns No.: 00-617-3082

MATERIAL SAFETY
DATA SHEET

3M

DIVISION: RIKER
TRADE NAME: THEOLAIR PLUS TABLETS (PRESCRIPTION DRUG)
3M I.D. NUMBER: NOT ASSIGNED
ISSUED: JANUARY 13, 1986
SUPERSEDES: NOVEMBER 13, 1985
DOCUMENT: 10-3089-9

1. INGREDIENTS

INGREDIENTS	C.A.S. NO.	PERCENT	EXPOSURE LIMITS	
THEOPHYLLINE ANHYDROUS	58-55-9	34.0	N/D	5
GUIAFENESIN	93-14-1	27.0- 34.0	N/D	5
EXCIPIENTS	N/D	32.0- 39.0	N/D	5

SOURCE OF EXPOSURE LIMIT DATA
1. ACGIH THRESHOLD LIMIT VALUES
2. FEDERAL OSHA PERMISSIBLE EXPOSURE LIMIT
3. 3M EXPOSURE GUIDELINES
4. CHEMICAL MANUFACTURER RECOMMENDED GUIDELINES
5. NONE ESTABLISHED

ABBREVIATIONS
N/D - NOT DETERMINED
N/A - NOT APPLICABLE

2. PHYSICAL DATA

BOILING POINT: SOLID N/A
VAPOR PRESSURE: N/A
VAPOR DENSITY (AIR=1): N/A
EVAPORATION RATE (N/D = 1): N/A
SOLUBILITY IN WATER: LIMITED
SP. GRAVITY (WATER=1): N/D
PERCENT VOLATILE: N/A
VISCOSITY: N/D
pH: SLIGHTLY ACID
APPEARANCE AND ODOR: WHITE SOLID TABLET

3. FIRE AND EXPLOSION HAZARD DATA

FLASH POINT (COMBUSTABLE SOLID): N/A
FLAMMABLE LIMITS - LEL: N/A UEL: N/A

EXTINGUISHING MEDIA:
WATER SPRAY OR FOAM
SPECIAL FIRE FIGHTING PROCEDURES:
FIREFIGHTERS SHOULD WEAR TURNOUT GEAR AND SELF-CONTAINED BREATHING

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MATERIAL SAFETY
DATA SHEET

3M

APPARATUS.
UNUSUAL FIRE AND EXPLOSION HAZARDS:
NONE

4. REACTIVITY DATA

STABILITY: STABLE

INCOMPATIBILITY - MATERIALS TO AVOID:
NONE
HAZARDOUS POLYMERIZATION: MAY NOT OCCUR

HAZARDOUS DECOMPOSITION PRODUCTS:
COMBUSTION MAY PRODUCE CARBON DIOXIDE, CARBON MONOXIDE AND OXIDES OF NITROGEN.

5. ENVIRONMENTAL INFORMATION

SPILL RESPONSE:
OBSERVE PRECAUTIONS FROM OTHER SECTIONS. COLLECT SPILLED MATERIAL. PLACE IN A CLOSED CONTAINER.
RECOMMENDED DISPOSAL:
MIX WITH FLAMMABLE MATERIAL AND INCINERATE IN AN INDUSTRIAL OR COMMERCIAL FACILITY. SINCE REGULATIONS VARY, CONSULT APPLICABLE REGULATIONS OR AUTHORITIES BEFORE DISPOSAL.
ENVIRONMENTAL DATA:
N/D

6. SUGGESTED FIRST AID

EYE CONTACT:
N/A
SKIN CONTACT:
N/A
INHALATION:
N/A
IF SWALLOWED:
NOTIFY PHYSICIAN. SEE PACKAGRE INSERT OR PDR.

7. PRECAUTIONARY INFORMATION

HANDLE IN ACCORDANCE WITH GOOD INDUSTRIAL HYGIENE AND SAFETY PRACTICE. THIS PRODUCT IS APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION (FDA) FOR USE AS A PRESCRIPTION DRUG.

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MATERIAL SAFETY
DATA SHEET

8. HEALTH HAZARD DATA

EYE CONTACT: NO INFORMATION FOUND

SKIN CONTACT: NO INFORMATION FOUND

INHALATION: NO INFORMATION FOUND.

INGESTION: ACUTE TOXICITY CONSIDERED MODERATE (ORAL LD50 >900 MG).

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Duns No.: 00-617-3082

MATERIAL SAFETY
DATA SHEET

3M

DIVISION: RIKER
TRADE NAME: THEOLAIR PLUS LIQUID (PRESCRIPTION DRUG)
3M I.D. NUMBER: NOT ASSIGNED
ISSUED: JULY 25, 1986
SUPERSEDES: JANUARY 13, 1986
DOCUMENT: 10-3088-1

1. INGREDIENTS	C.A.S. NO.	PERCENT	EXPOSURE LIMITS	
THEOPHYLLINE ANHYDROUS	58-55-9	0.8	N/D	5
GUIATENESIN	93-14-1	0.7	N/D	5
PROPYLENE GLYCOL	57-55-6	25.0	N/D	5
SUCROSE	57-50-1	50.0	10 MG/M3	1
WATER FLAVORING EXCIPIENTS	N/D	24.0	N/D	5

SOURCE OF EXPOSURE LIMIT DATA
1. ACGIH THRESHOLD LIMIT VALUES
2. FEDERAL OSHA PERMISSIBLE EXPOSURE LIMIT
3. 3M EXPOSURE GUIDELINES
4. CHEMICAL MANUFACTURER RECOMMENDED GUIDELINES
5. NONE ESTABLISHED

ABBREVIATIONS
N/D - NOT DETERMINED
N/A - NOT APPLICABLE

2. PHYSICAL DATA

BOILING POINT: WATER SOLUTION 100 C
VAPOR PRESSURE: N/D
VAPOR DENSITY (AIR=1): N/D
EVAPORATION RATE (= 1): N/D
SOLUBILITY IN WATER: SOLUBLE
SP. GRAVITY (WATER=1): N/D
PERCENT VOLATILE: N/D
VISCOSITY: N/D
pH: N/D
APPEARANCE AND ODOR: LIQUID - PEPPERMINT ODOR

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MATERIAL SAFETY
DATA SHEET

3M

3. FIRE AND EXPLOSION HAZARD DATA

FLASH POINT (NON-FLAMMABLE): N/A
FLAMMABLE LIMITS - LEL: N/A UEL: N/A

EXTINGUISHING MEDIA:
N/A. USE EXTINGUISHING MEDIA FOR SURROUNDING MATERIALS.
SPECIAL FIRE FIGHTING PROCEDURES:
FIREFIGHTERS SHOULD WEAR TURNOUT GEAR AND SELF-CONTAINED BREATHING APPARATUS.
UNUSUAL FIRE AND EXPLOSION HAZARDS:
NONE

4. REACTIVITY DATA

STABILITY: STABLE

INCOMPATIBILITY - MATERIALS TO AVOID:
NONE
HAZARDOUS POLYMERIZATION: MAY NOT OCCUR

HAZARDOUS DECOMPOSITION PRODUCTS:
COMBUSTION MAY PRODUCE CARBON MONOXIDE, CARBON DIOXIDE, OXIDES OF NITROGEN

5. ENVIRONMENTAL INFORMATION

SPILL RESPONSE:
OBSERVE PRECAUTIONS FROM OTHER SECTIONS. CONTAIN SPILL, COVER WITH ABSORBENT MATERIAL. COLLECT SPILLED MATERIAL. CLEAN UP RESIDUE. PLACE IN A CLOSED CONTAINER. FOR SMALL AMOUNTS; COLLECT SPILLED MATERIAL. PLACE IN A CLOSED CONTAINER.
RECOMMENDED DISPOSAL:
MIX WITH FLAMMABLE MATERIAL AND INCINERATE IN AN INDUSTRIAL OR COMMERCIAL FACILITY. SINCE REGULATIONS VARY, CONSULT APPLICABLE REGULATIONS OR AUTHORITIES BEFORE DISPOSAL.
ENVIRONMENTAL DATA:
N/D

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Duns No.: 00-617-3082

MATERIAL SAFETY
DATA SHEET

6. SUGGESTED FIRST AID

EYE CONTACT:
FLUSH WITH PLENTY OF WATER FOR AT LEAST 10 MINUTES AND NOTIFY PHYSICIAN.
SKIN CONTACT:
WASH WITH SOAP AND WATER AND NOTIFY PHYSICIAN
INHALATION:
N/A
IF SWALLOWED:
NOTIFY PHYSICIAN. SEE PACKAGE INSERT OR PDR.

7. PRECAUTIONARY INFORMATION

HANDLE IN ACCORDANCE WITH GOOD INDUSTRIAL HYGIENE AND SAFETY PRACTICE. THIS PRODUCT IS APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION (FDA) FOR USE AS A PRESCRIPTION DRUG.

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Duns No.: 00-617-3082

MATERIAL SAFETY
DATA SHEET

8. HEALTH HAZARD DATA

EYE CONTACT: NO INFORMATION FOUND

SKIN CONTACT: NO INFORMATION FOUND

INHALATION: NO INFORMATION FOUND

ACUTE TOXICITY IS CONSIDERED MODERATELY TOXIC: ORAL LD50- 600 MG/KG

TAB A

MATERIAL SAFETY DATA SHEET (MSDS) EFFECTIVE 06/01/87

ALLBEE-T TABLETS NDC 0031-0688-XX

. . . SECTION 1 MANUFACTURER INFORMATION . . . . . .

A. H. ROBINS CO.,INC. 1405 CUMMINGS DRIVE RICHMOND, VA 23261-6609

EMERGENCY TELEPHONE: (804) 257-2000 (8:30 AM - 5:00 PM)
(804) 257-2000 (AFTER HOURS)

. . . SECTION 2 COMPOSITION INFORMATION . . . . . .

HAZARDOUS INGREDIENTS:
AS FORMULATED, THIS FINISHED PHARMACEUTICAL PRODUCT DOES NOT CONSTITUTE A PHYSICAL HAZARD WITHIN THE MEANING OF 29 CFR SEC 1910.1200. POTENTIAL HEALTH HAZARDS FROM INGESTION OR EXPOSURE TO THE PRODUCT ARE DISCUSSED IN SECTION 6 BELOW.

VITAMIN COMPOSITION PER TABLET:

		CAS
VITAMIN C	500MG	50-81-7
THIAMINE (VITAMIN B1)	15.5MG	532-43-4
RIBOFLAVIN (VITAMIN B2)	10MG	83-88-5
NIACIN	100MG	98-92-0
VITAMIN B6	8.2MG	58-56-0
VITAMIN B12	5MCG	68-19-9
PANTOTHENIC ACID	23MG	137-08-6

INGREDIENTS:
SODIUM ASCORBATE, DESSICATED LIVER, LACTOSE, NIACINAMIDE, CALCIUM PANTOTHENATE, HYDROXYPROPYL METHYLCELLULOSE, STEARIC ACID, POVIDONE, THIAMINE MONONITRATE, RIBOFLAVIN, ARTIFICIAL COLOR, PYRIDOXINE HYDROCHLORIDE, POLYSORBATE 20, VANILLIN, PROPYLENE GLYCOL, TITANIUM DIOXIDE, HYDROXYPROPYL CELLULOSE, GELATIN, CYANOCOBALAMIN

. . . SECTION 3 PHYSICAL/CHEMICAL CHARACTERISTICS . . . . . .

BOILING POINT	NOT APPLICABLE
VAPOR PRESSURE	NOT APPLICABLE
VAPOR DENSITY	NOT APPLICABLE
SOLUBILITY IN WATER	NOT APPLICABLE
SPECIFIC GRAVITY	NOT APPLICABLE
MELTING POINT	NOT APPLICABLE
EVAPORATION RATE	NOT APPLICABLE
APPEARANCE	AN ORANGE, CAPSULE-SHAPED TABLET ENGRAVED AHR

. . . SECTION 4 FIRE AND EXPLOSION HAZARD DATA . . . . . .

FLASH POINT	NOT APPLICABLE
METHOD USED	NOT APPLICABLE
FLAMMABLE LIMITS	
LEL	NOT APPLICABLE
UEL	NOT APPLICABLE
EXTINGUISHING MEDIA	NOT APPLICABLE
SPECIAL FIRE-FIGHTING PROCEDURES	NOT APPLICABLE
UNUSUAL FIRE AND EXPLOSION HAZARDS	NONE

. . . SECTION 5 REACTIVITY DATA . . . . . .

STABILITY	STABLE
INCOMPATABILITY	NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS	NONE KNOWN
HAZARDOUS POLYMERIZATION	WILL NOT OCCUR

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

ALLBEE-T TABLETS NDC 0031-0688-XX

. . . SECTION 6 HEALTH HAZARD DATA . . . . . .

ROUTES OF ENTRY:	INGESTION
CARCINOGENICITY:	NONE OF THE COMPONENTS IN THIS PRODUCT ARE KNOWN TO BE CARCINOGENIC
SIGNS AND SYMPTOMS OF OVEREXPOSURE: VITAMIN COMPONENTS	NO SERIOUS EFFECTS ARE EXPECTED.
EMERGENCY AND FIRST-AID PROCEDURES:	EYE CONTACT- IRRIGATE SURFACES WITH WATER FOR 15 MINUTES. SKIN CONTACT- WASH AREAS WITH SOAP AND WATER.
MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:	HYPERSENSITIVITY TO ANY OF THE COMPONENTS

. . . SECTION 7 PRECAUTIONS FOR SAFE HANDLING AND USE . . . . . .

SPILLS AND ACCIDENTAL RELEASES:	SWEEP OR SHOVEL INTO A WASTE CONTAINER
WASTE DISPOSAL METHOD:	DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. THIS IS A BIOLOGICALLY ACTIVE MATERIAL. DISPOSE OF ON SITE OR AT AN APPROVED DISPOSAL FACILITY IN ACCORDANCE WITH LOCAL, STATE, AND/OR FEDERAL REGULATIONS.
HANDLING AND STORAGE:	STORE AT ROOM TEMPERATURE, BETWEEN 59 AND 86 DEGREES F.

. . . SECTION 8 CONTROL MEASURES . . . . . .

NO SPECIAL CONTROL MEASURES ARE REQUIRED UNDER NORMAL CONDITIONS OF USE

RESPIRATORY PROTECTION	NONE REQUIRED
VENTILATION	NO SPECIAL VENTILATION IS REQUIRED
PROTECTIVE CLOTHING OR EQUIPMENT	AVOID CONTACT WITH EYES OR PROLONGED CONTACT WITH SKIN.
WORK/HYGIENIC PRACTICES	WASH THOROUGHLY AFTER HANDLING

. . . . . .

THE INFORMATION CONTAINED IN THIS MSDS IS, TO THE BEST OF A.H.ROBINS' KNOWLEDGE, COMPLETE AND ACCURATE. A.H.ROBINS, HOWEVER, USES MANY SOURCES AND REFERENCES FOR GATHERING THIS INFORMATION. THUS, A.H. ROBINS CANNOT GUARANTEE COMPLETENESS OR ACCURACY AND DISCLAIMS ALL LIABILITY FOR ITS HANDLING AND USE.

FILE/ALLBEET/TABLETS . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS) EFFECTIVE 06/11/87

ARTHRALGEN TABLETS NDC 0031-1462-XX

. . . SECTION 1 MANUFACTURER INFORMATION . . . . . .

A. H. ROBINS CO.,INC. 1405 CUMMINGS DRIVE RICHMOND, VA 23261-6609

EMERGENCY TELEPHONE: (804) 257-2000 (8:30 AM - 5:00 PM)
(804) 257-2000 (AFTER HOURS)

. . . SECTION 2 COMPOSITION INFORMATION . . . . . .

HAZARDOUS INGREDIENTS:
AS FORMULATED, THIS FINISHED PHARMACEUTICAL PRODUCT DOES NOT CONSTITUTE A PHYSICAL HAZARD WITHIN THE MEANING OF 29 CFR SEC 1910.1200. POTENTIAL HEALTH HAZARDS FROM INGESTION OR EXPOSURE TO THE PRODUCT ARE DISCUSSED IN SECTION 6 BELOW.

ACTIVE INGREDIENTS:		CAS
EACH TABLET CONTAINS:		
SALICYLAMIDE	250 MG	64-45-2
ACETAMINOPHEN, USP	250 MG	103-90-2

INACTIVE INGREDIENTS:
GUAR GUM, MICROCRYSTALLINE CELLULOSE, POVIDONE, SODIUM LAURYL SULFATE, STEARIC ACID, TALC

. . . SECTION 3 PHYSICAL/CHEMICAL CHARACTERISTICS . . . . . .

BOILING POINT	NOT APPLICABLE
VAPOR PRESSURE	NOT APPLICABLE
VAPOR DENSITY	NOT APPLICABLE
SOLUBILITY IN WATER	NOT APPLICABLE
SPECIFIC GRAVITY	NOT APPLICABLE
MELTING POINT	NOT APPLICABLE
EVAPORATION RATE	NOT APPLICABLE
APPEARANCE	WHITE SCORED TABLETS

. . . SECTION 4 FIRE AND EXPLOSION HAZARD DATA . . . . . .

FLASH POINT	NOT APPLICABLE
METHOD USED	NOT APPLICABLE
FLAMMABLE LIMITS	
LEL	NOT APPLICABLE
UEL	NOT APPLICABLE
EXTINGUISHING MEDIA	NOT APPLICABLE
SPECIAL FIRE-FIGHTING PROCEDURES	NOT APPLICABLE
UNUSUAL FIRE AND EXPLOSION HAZARDS	NONE

. . . SECTION 5 REACTIVITY DATA . . . . . .

STABILITY	STABLE
INCOMPATABILITY	NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS	NONE KNOWN
HAZARDOUS POLYMERIZATION	WILL NOT OCCUR

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

ARTHRALGEN TABLETS NDC 0031-1462-XX

. . . SECTION 6 HEALTH HAZARD DATA . . . . . .

ROUTES OF ENTRY:		INGESTION
CARCINOGENICITY:		NONE OF THE COMPONENTS IN THIS PRODUCT ARE KNOWN TO BE CARCINOGENIC
SIGNS AND SYMPTOMS OF OVER-EXPOSURE:	ACETAMINOPHEN	SEVERE OVERDOSAGE MAY PRODUCE NAUSEA, VOMITING, PERSPIRATION, AND GENERAL DISCOMFORT. MASSIVE OVERDOSAGE MAY PRODUCE DAMAGE TO LIVER, KIDNEYS, AND CENTRAL NERVOUS SYSTEM. REPEATED INGESTION OF TOXIC DOSES MAY PRODUCE CIRRHOSIS OF THE LIVER. POTENTIALLY TOXIC DOSE IS ABOUT 10 GRAMS.
	SALICYLAMIDE	CENTRAL NERVOUS SYSTEM DEPRESSION, DECREASED BLOOD PRESSURE, AND ULTIMATELY RESPIRATORY ARREST. OVERDOSAGE OF SALICYLAMIDE DOES NOT PRODUCE TYPICAL SALICYLATE SIDE-EFFECTS, SUCH AS METABOLIC ACIDOSIS (SEE ATTACHED PRODUCT LABELING FOR FULL INFORMATION ON SIDE-EFFECTS)
EMERGENCY AND FIRST-AID PROCEDURES:		EYE CONTACT- IRRIGATE SURFACES WITH WATER FOR 15 MINUTES. SKIN CONTACT- WASH AREAS WITH SOAP AND WATER. TREATMENT OF OVERDOSE: INDUCED EMESIS, LAVAGE, AND ACTIVATED CHARCOAL MAY BE HELPFUL. IF POTENTIALLY TOXIC DOSES ARE INGESTED, SERUM ACETAMINOPHEN LEVELS SHOULD BE MONITORED BEGINNING 4 HOURS AFTER INGESTION AND LIVER FUNCTION TESTS SHOULD BE SERIALLY MONITORED (THE ANTIDOTE FOR ACETAMINOPHEN, N-ACETYLCYSTEINE, SHOULD BE ADMINISTERED WITHIN 16 HOURS FOLLOWING INGESTION) SYMPTOMATIC AND SUPPORTIVE TREATMENT AS REQUIRED
MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:		HYPERSENSITIVITY TO ANY OF THE COMPONENTS; INDIVIDUALS CHRONICALLY EXPOSED TO ALCOHOL OR OTHER DRUGS MAY BE MORE SUSCEPTIBLE TO THE TOXIC EFFECTS OF ACETAMINOPHEN.

FOR COMPLETE INFORMATION ON THIS DRUG PLEASE REFER TO THE ATTACHED PRODUCT LABELING

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

ARTHRALGEN TABLETS NDC 0031-1462-XX

. . . SECTION 7 PRECAUTIONS FOR SAFE HANDLING AND USE . . . . . .

SPILLS AND ACCIDENTAL RELEASES:	SHEEP OR SHOVEL INTO A WASTE CONTAINER
WASTE DISPOSAL METHOD:	DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. THIS IS A BIOLOGICALLY ACTIVE MATERIAL. DISPOSE OF ON SITE OR AT AN APPROVED DISPOSAL FACILITY IN ACCORDANCE WITH LOCAL,STATE,AND/OR FEDERAL REGULATIONS.
HANDLING AND STORAGE:	STORE AT ROOM TEMPERATURE, BETWEEN 59 AND 86 DEGREES F.

. . . SECTION 8 CONTROL MEASURES . . . . . .

NO SPECIAL CONTROL MEASURES ARE REQUIRED UNDER NORMAL CONDITIONS OF USE

RESPIRATORY PROTECTION	NONE REQUIRED
VENTILATION	NO SPECIAL VENTILATION IS REQUIRED
PROTECTIVE CLOTHING OR EQUIPMENT	AVOID CONTACT WITH EYES OR PROLONGED CONTACT WITH SKIN.
WORK/HYGIENIC PRACTICES	WASH THOROUGHLY AFTER HANDLING

. . . . . .

THE INFORMATION CONTAINED IN THIS MSDS IS, TO THE BEST OF A.H.ROBINS' KNOWLEDGE, COMPLETE AND ACCURATE. A.H.ROBINS, HOWEVER, USES MANY SOURCES AND REFERENCES FOR GATHERING THIS INFORMATION. THUS, A.H. ROBINS CANNOT GUARANTEE COMPLETENESS OR ACCURACY AND DISCLAIMS ALL LIABILITY FOR ITS HANDLING AND USE.

FILE/ARTHRALG/TABLETS . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS) EFFECTIVE 04/23/87

DIMETANE-DC COUGH SYRUP NDC 0031-1833-XX

. . . SECTION 1 MANUFACTURER INFORMATION . . . . . .

A. H. ROBINS CO.,INC. 1405 CUMMINGS DRIVE RICHMOND, VA 23261-6609

EMERGENCY TELEPHONE: (804) 257-2000 (8:30 AM - 5:00 PM)
(804) 257-2000 (AFTER HOURS)

. . . SECTION 2 COMPOSITION INFORMATION . . . . . .

HAZARDOUS INGREDIENTS:
AS FORMULATED, THIS FINISHED PHARMACEUTICAL PRODUCT DOES NOT CONSTITUTE A PHYSICAL HAZARD WITHIN THE MEANING OF 29 CFR SEC 1910.1200. POTENTIAL HEALTH HAZARDS FROM INGESTION OR EXPOSURE TO THE PRODUCT ARE DISCUSSED IN SECTION 6 BELOW.

ACTIVE INGREDIENTS: EACH 5ML CONTAINS:		CAS
BROMPHENIRAMINE MALEATE, USP	2MG	980-71-2
PHENYLPROPANOLAMINE HCL, USP	12.5MG	154-41-6
CODEINE PHOSPHATE, USP	10MG	41444-62-6
(WARNING: MAY BE HABIT FORMING)		

INACTIVE INGREDIENTS:
ALCOHOL (0.95%), CITRIC ACID, FD&C BLUE 1, FD&C RED 40, FLAVORS, GLYCERIN, SODIUM BENZOATE, SORBITOL, WATER.

. . . SECTION 3 PHYSICAL/CHEMICAL CHARACTERISTICS . . . . . .

BOILING POINT	NOT APPLICABLE
VAPOR PRESSURE	NOT APPLICABLE
VAPOR DENSITY	NOT APPLICABLE
SOLUBILITY IN WATER	SOLUBLE
SPECIFIC GRAVITY	1.195-1.215
MELTING POINT	NOT APPLICABLE
EVAPORATION RATE	NOT APPLICABLE
APPEARANCE	LIGHT BLUISH-PINK SYRUP WITH A RASBERRY FLAVOR

. . . SECTION 4 FIRE AND EXPLOSION HAZARD DATA . . . . . .

FLASH POINT	> 230 DEGREES F
METHOD USED	ASTM 3828-81
FLAMMABLE LIMITS	
LEL	NOT APPLICABLE
UEL	NOT APPLICABLE
EXTINGUISHING MEDIA	NOT APPLICABLE
SPECIAL FIRE-FIGHTING PROCEDURES	NOT APPLICABLE
UNUSUAL FIRE AND EXPLOSION HAZARDS	NONE

. . . SECTION 5 REACTIVITY DATA . . . . . .

STABILITY	STABLE
INCOMPATABILITY	NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS	NONE KNOWN
HAZARDOUS POLYMERIZATION	WILL NOT OCCUR

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

DIMETANE-DC COUGH SYRUP NDC 0031-1833-XX

. . . SECTION 6 HEALTH HAZARD DATA . . . . . .

ROUTES OF ENTRY:		INGESTION SKIN- IT IS NOT KNOWN IF ANY OF THE INGREDIENTS IN DIMETANE-DC ARE ABSORBED THROUGH THE SKIN FROM DIMETANE-DC
CARCINOGENICITY:		NONE OF THE COMPONENTS IN THIS PRODUCT ARE KNOWN TO BE CARCINOGENIC
SIGNS AND SYMPTOMS OF OVER-EXPOSURE:	BROMPHENIRAMINE	DROWSINESS; EXCITABILITY IN SOME CASES; DRY MOUTH, GLAUCOMA (INCREASED EYE PRESSURE), DIFFICULTY IN URINATION
	CODEINE PHOSPHATE	PINPOINT PUPILS, CONSTIPATION, SLOW HEART RATE, HIGH BLOOD PRESSURE, RESPIRATORY DEPRESSION, URINARY RETENTION, MUSCLE SPASMS, ITCHING, RESPIRATORY ARREST, COMA
	PHENYLPROPANOLAMINE	EXCITEMENT, RAPID HEART BEAT, HIGH BLOOD PRESSURE, NERVOUSNESS, IRREGULAR HEART BEAT
		(SEE ATTACHED PRODUCT LABELING FOR FULL INFORMATION ON SIDE-EFFECTS)
EMERGENCY AND FIRST-AID PROCEDURES:		EYE CONTACT- IRRIGATE SURFACES WITH WATER FOR 15 MINUTES. SKIN CONTACT- WASH AREAS WITH SOAP AND WATER. TREATMENT OF OVERDOSE: INDUCED EMESIS, LAVAGE, AND ACTIVATED CHARCOAL MAY BE HELPFUL. SEVERE OPIATE EFFECTS SUCH AS RESPIRATORY DEPRESSION MAY BE REVERSED BY NALOXONE. SHORT-ACTING BARBITURATES MAY BE USED TO TREAT CASES OF SEVERE CNS HYPERACTIVITY. SYMPTOMATIC AND SUPPORTIVE TREATMENT AS REQUIRED.
MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:		HYPERSENSITIVITY TO ANY OF THE COMPONENTS

FOR COMPLETE INFORMATION ON THIS PRODUCT PLEASE REFER TO THE ATTACHED PRODUCT LABELING

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

DIMETANE-DC COUGH SYRUP NDC 0031-1833-XX

. . . SECTION 7 PRECAUTIONS FOR SAFE HANDLING AND USE . . . . . .

SPILLS AND ACCIDENTAL RELEASES:	SOAK UP ON ABSORBANT MATERIAL AND PLACE IN APPROVED WASTE CONTAINER. WASH AREAS WITH SOAP AND WATER.
WASTE DISPOSAL METHOD:	DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. THIS IS A BIOLOGICALLY ACTIVE MATERIAL. DISPOSE OF ON SITE OR AT AN APPROVED DISPOSAL FACILITY IN ACCORDANCE WITH LOCAL,STATE,AND/OR FEDERAL REGULATIONS.
HANDLING AND STORAGE:	STORE AT ROOM TEMPERATURE, BETWEEN 59 AND 86 DEGREES F.

. . . SECTION 8 CONTROL MEASURES . . . . . .

NO SPECIAL CONTROL MEASURES ARE REQUIRED UNDER NORMAL CONDITIONS OF USE

RESPIRATORY PROTECTION	NONE REQUIRED
VENTILATION	NO SPECIAL VENTILATION IS REQUIRED
PROTECTIVE CLOTHING OR EQUIPMENT	AVOID CONTACT WITH EYES OR PROLONGED CONTACT WITH SKIN.
WORK/HYGIENIC PRACTICES	WASH THOROUGHLY AFTER HANDLING

. . . . . .

THE INFORMATION CONTAINED IN THIS MSDS IS, TO THE BEST OF A.H.ROBINS' KNOWLEDGE, COMPLETE AND ACCURATE. A.H.ROBINS, HOWEVER, USES MANY SOURCES AND REFERENCES FOR GATHERING THIS INFORMATION. THUS, A.H. ROBINS CANNOT GUARANTEE COMPLETENESS OR ACCURACY AND DISCLAIMS ALL LIABILITY FOR ITS HANDLING AND USE.

FILE/DIMETANE/DC . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS) EFFECTIVE 04/23/87

DIMETANE-DX COUGH SYRUP NDC 0031-1836-XX

. . . SECTION 1 MANUFACTURER INFORMATION . . . . . .

A. H. ROBINS CO.,INC. 1405 CUMMINGS DRIVE RICHMOND, VA 23261-6609

EMERGENCY TELEPHONE: (804) 257-2000 (8:30 AM - 5:00 PM)
(804) 257-2000 (AFTER HOURS)

. . . SECTION 2 COMPOSITION INFORMATION . . . . . .

HAZARDOUS INGREDIENTS:
AS FORMULATED, THIS FINISHED PHARMACEUTICAL PRODUCT DOES NOT CONSTITUTE A PHYSICAL HAZARD WITHIN THE MEANING OF 29 CFR SEC 1910.1200. POTENTIAL HEALTH HAZARDS FROM INGESTION OR EXPOSURE TO THE PRODUCT ARE DISCUSSED IN SECTION 6 BELOW.

ACTIVE INGREDIENTS: EACH 5ML CONTAINS:		CAS
BROMPHENIRAMINE MALEATE, USP	2MG	980-71-2
PSEUDOEPHEDRINE HCL, USP	30MG	345-78-8
DEXTROMETHORPHAN HBR, USP	10MG	6700-34-1

INACTIVE INGREDIENTS:
ALCOHOL (0.95%), CITRIC ACID, FD&C RED 40, FD&C YELLOW 6, FLAVORS, GLYCERIN, SACCHARIN SODIUM, SODIUM BENZOATE, SORBITOL, WATER.

. . . SECTION 3 PHYSICAL/CHEMICAL CHARACTERISTICS . . . . . .

BOILING POINT	NOT APPLICABLE
VAPOR PRESSURE	NOT APPLICABLE
VAPOR DENSITY	NOT APPLICABLE
SOLUBILITY IN WATER	SOLUBLE
SPECIFIC GRAVITY	CA 1.18
MELTING POINT	NOT APPLICABLE
EVAPORATION RATE	NOT APPLICABLE
APPEARANCE	LIGHT RED SYRUP WITH A BUTTERSCOTCH FLAVOR

. . . SECTION 4 FIRE AND EXPLOSION HAZARD DATA . . . . . .

FLASH POINT	NOT APPLICABLE
METHOD USED	NOT APPLICABLE
FLAMMABLE LIMITS	
LEL	NOT APPLICABLE
UEL	NOT APPLICABLE
EXTINGUISHING MEDIA	NOT APPLICABLE
SPECIAL FIRE-FIGHTING PROCEDURES	NOT APPLICABLE
UNUSUAL FIRE AND EXPLOSION HAZARDS	NONE

. . . SECTION 5 REACTIVITY DATA . . . . . .

STABILITY	STABLE
INCOMPATABILITY	NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS	NONE KNOWN
HAZARDOUS POLYMERIZATION	WILL NOT OCCUR

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

DIMETANE-DX COUGH SYRUP NDC 0031-1836-XX

. . . SECTION 6 HEALTH HAZARD DATA . . . . . .

ROUTES OF ENTRY:		INGESTION SKIN- IT IS NOT KNOWN IF ANY OF THE INGREDIENTS IN DIMETANE-DX ARE ABSORBED THROUGH THE SKIN FROM DIMETANE-DX
CARCINOGENICITY:		NONE OF THE COMPONENTS IN THIS PRODUCT ARE KNOWN TO BE CARCINOGENIC
SIGNS AND SYMPTOMS OF OVER-EXPOSURE:	BROMPHENIRAMINE	DROWSINESS; EXCITABILITY IN SOME CASES; DRY MOUTH, GLAUCOMA (INCREASED EYE PRESSURE), DIFFICULTY IN URINATION
	DEXTROMETHORPHAN	DROWSINESS, UNSTEADY GAIT, NYSTAGMUS, SEVERE MUSCLE SPASMS, CONVULSIONS, ALTERED MOOD.
	PSEUDOEPHEDRINE	EXCITEMENT, RAPID HEART BEAT, HIGH BLOOD PRESSURE, NERVOUSNESS, IRREGULAR HEART BEAT
		(SEE ATTACHED PRODUCT LABELING FOR FULL INFORMATION ON SIDE-EFFECTS)
EMERGENCY AND FIRST-AID PROCEDURES:		EYE CONTACT- IRRIGATE SURFACES WITH WATER FOR 15 MINUTES. SKIN CONTACT- WASH AREAS WITH SOAP AND WATER. TREATMENT OF OVERDOSE: INDUCED EMESIS, LAVAGE, AND ACTIVATED CHARCOAL MAY BE HELPFUL. SEVERE CNS DEPRESSANT EFFECTS SUCH AS RESPIRATORY DEPRESSION MAY BE REVERSED BY NALOXONE. SHORT-ACTING BARBITURATES MAY BE USED TO TREAT CASES OF SEVERE CNS HYPERACTIVITY. SYMPTOMATIC AND SUPPORTIVE TREATMENT AS REQUIRED.
MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:		HYPERSENSITIVITY TO ANY OF THE COMPONENTS

FOR COMPLETE INFORMATION ON THIS PRODUCT PLEASE REFER TO THE ATTACHED PRODUCT LABELING

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

DIMETANE-DX COUGH SYRUP NDC 0031-1836-XX

. . . SECTION 7 PRECAUTIONS FOR SAFE HANDLING AND USE . . . . . .

SPILLS AND ACCIDENTAL RELEASES:	SOAK UP ON ABSORBANT MATERIAL AND PLACE IN APPROVED WASTE CONTAINER. WASH AREAS WITH SOAP AND WATER.
WASTE DISPOSAL METHOD:	DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. THIS IS A BIOLOGICALLY ACTIVE MATERIAL. DISPOSE OF ON SITE OR AT AN APPROVED DISPOSAL FACILITY IN ACCORDANCE WITH LOCAL,STATE,AND/OR FEDERAL REGULATIONS.
HANDLING AND STORAGE:	STORE AT ROOM TEMPERATURE, BETWEEN 59 AND 86 DEGREES F.

. . . SECTION 8 CONTROL MEASURES . . . . . .

NO SPECIAL CONTROL MEASURES ARE REQUIRED UNDER NORMAL CONDITIONS OF USE

RESPIRATORY PROTECTION	NONE REQUIRED
VENTILATION	NO SPECIAL VENTILATION IS REQUIRED
PROTECTIVE CLOTHING OR EQUIPMENT	AVOID CONTACT WITH EYES OR PROLONGED CONTACT WITH SKIN.
WORK/HYGIENIC PRACTICES	WASH THOROUGHLY AFTER HANDLING

. . . . . .

THE INFORMATION CONTAINED IN THIS MSDS IS, TO THE BEST OF A.H.ROBINS' KNOWLEDGE, COMPLETE AND ACCURATE. A.H.ROBINS, HOWEVER, USES MANY SOURCES AND REFERENCES FOR GATHERING THIS INFORMATION. THUS, A.H. ROBINS CANNOT GUARANTEE COMPLETENESS OR ACCURACY AND DISCLAIMS ALL LIABILITY FOR ITS HANDLING AND USE.

FILE/DIMETANE/DX . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS) EFFECTIVE 04/15/87

DIMETANE 10 INJECTABLE NDC 0031-1881-XX

. . . SECTION 1 MANUFACTURER INFORMATION . . . . . .

A. H. ROBINS CO.,INC. 1405 CUMMINGS DRIVE RICHMOND, VA 23261-6609

EMERGENCY TELEPHONE: (804) 257-2000 (8:30 AM - 5:00 PM)
(804) 257-2000 (AFTER HOURS)

. . . SECTION 2 COMPOSITION INFORMATION . . . . . .

HAZARDOUS INGREDIENTS:
AS FORMULATED, THIS FINISHED PHARMACEUTICAL PRODUCT DOES NOT CONSTITUTE A PHYSICAL HAZARD WITHIN THE MEANING OF 29 CFR SEC 1910.1200. POTENTIAL HEALTH HAZARDS FROM INGESTION OR EXPOSURE TO THE PRODUCT ARE DISCUSSED IN SECTION 6 BELOW.

ACTIVE INGREDIENTS:		CAS
EACH 1ML CONTAINS:		
BROMPHENIRAMINE MALEATE, USP	10 MG	980-71-2

INACTIVE INGREDIENTS:
WATER FOR INJECTION USP; PH ADJUSTED WITH SODIUM HYDROXIDE

. . . SECTION 3 PHYSICAL/CHEMICAL CHARACTERISTICS . . . . . .

BOILING POINT	CA 100 DEGREES C.
VAPOR PRESSURE	NOT APPLICABLE
VAPOR DENSITY	NOT APPLICABLE
SOLUBILITY IN WATER	SOLUBLE
SPECIFIC GRAVITY	CA 1.00
MELTING POINT	NOT APPLICABLE
EVAPORATION RATE	NOT APPLICABLE
APPEARANCE	AMPULES CONTAINING A CLEAR, COLORLESS, ODORLESS LIQUID

. . . SECTION 4 FIRE AND EXPLOSION HAZARD DATA . . . . . .

FLASH POINT	NOT APPLICABLE
METHOD USED	NOT APPLICABLE
FLAMMABLE LIMITS	
LEL	NOT APPLICABLE
UEL	NOT APPLICABLE
EXTINGUISHING MEDIA	NOT APPLICABLE
SPECIAL FIRE-FIGHTING PROCEDURES	NOT APPLICABLE
UNUSUAL FIRE AND EXPLOSION HAZARDS	NONE

. . . SECTION 5 REACTIVITY DATA . . . . . .

STABILITY	STABLE
INCOMPATABILITY	NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS	NONE KNOWN
HAZARDOUS POLYMERIZATION	WILL NOT OCCUR

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

DIMETANE 10 INJECTABLE NDC 0031-1881-XX

. . . SECTION 6 HEALTH HAZARD DATA . . . . . .

	ROUTES OF ENTRY:	INGESTION SKIN- IT IS NOT KNOWN IF BROMPHENIRAMINE MALEATE IS ABSORBED THROUGH THE SKIN FROM DIMETANE INJECTABLE
	CARCINOGENICITY:	NONE OF THE COMPONENTS IN THIS PRODUCT ARE KNOWN TO BE CARCINOGENIC
SIGNS AND SYMPTOMS OF OVER-EXPOSURE:	BROMPHENIRAMINE	DROWSINESS; EXCITABILITY IN SOME CASES; DRY MOUTH, GLAUCOMA (INCREASED EYE PRESSURE), DIFFICULTY IN URINATION (SEE ATTACHED PRODUCT LABELING FOR FULL INFORMATION ON SIDE-EFFECTS)
	EMERGENCY AND FIRST-AID PROCEDURES:	EYE CONTACT- IRRIGATE SURFACES WITH WATER FOR 15 MINUTES. SKIN CONTACT- WASH AREAS WITH SOAP AND WATER. TREATMENT OF OVERDOSE: INDUCED EMESIS, LAVAGE, AND ACTIVATED CHARCOAL MAY BE HELPFUL. SYMPTOMATIC AND SUPPORTIVE TREATMENT AS REQUIRED.
	MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:	HYPERSENSITIVITY TO ANY OF THE COMPONENTS; GLAUCOMA; URINARY RETENTION

FOR COMPLETE INFORMATION ON THIS DRUG PLEASE REFER TO THE ATTACHED PRODUCT LABELING

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

DIMETANE 10 INJECTABLE NDC 0031-1881-XX

. . . SECTION 7 PRECAUTIONS FOR SAFE HANDLING AND USE . . . . . .

SPILLS AND ACCIDENTAL RELEASES:	SOAK UP ON ABSORBANT MATERIAL AND PLACE IN APPROVED WASTE CONTAINER. WASH AREAS WITH SOAP AND WATER.
WASTE DISPOSAL METHOD:	DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. THIS IS A BIOLOGICALLY ACTIVE MATERIAL. DISPOSE OF ON SITE OR AT AN APPROVED DISPOSAL FACILITY IN ACCORDANCE WITH LOCAL,STATE,AND/OR FEDERAL REGULATIONS.
HANDLING AND STORAGE:	STORE AT ROOM TEMPERATURE, BETWEEN 59 AND 86 DEGREES F.

. . . SECTION 8 CONTROL MEASURES . . . . . .

NO SPECIAL CONTROL MEASURES ARE REQUIRED UNDER NORMAL CONDITIONS OF USE

RESPIRATORY PROTECTION	NONE REQUIRED
VENTILATION	NO SPECIAL VENTILATION IS REQUIRED
PROTECTIVE CLOTHING OR EQUIPMENT	AVOID CONTACT WITH EYES OR PROLONGED CONTACT WITH SKIN.
WORK/HYGIENIC PRACTICES	WASH THOROUGHLY AFTER HANDLING

. . . . . .

THE INFORMATION CONTAINED IN THIS MSDS IS, TO THE BEST OF A.H.ROBINS' KNOWLEDGE, COMPLETE AND ACCURATE. A.H.ROBINS, HOWEVER, USES MANY SOURCES AND REFERENCES FOR GATHERING THIS INFORMATION. THUS, A.H. ROBINS CANNOT GUARANTEE COMPLETENESS OR ACCURACY AND DISCLAIMS ALL LIABILITY FOR ITS HANDLING AND USE.

FILE/DIMETANE/INJECT. . . . . .

MATERIAL SAFETY DATA SHEET (MSDS) EFFECTIVE 03/10/87

DONNAGEL-PG NDC 0031-3083-XX

. . . SECTION 1 MANUFACTURER INFORMATION . . . . . .

A. H. ROBINS CO.,INC. 1405 CUMMINGS DRIVE RICHMOND, VA 23261-6609

EMERGENCY TELEPHONE: (804) 257-2000 (8:30 AM - 5:00 PM)
(804) 257-2000 (AFTER HOURS)

. . . SECTION 2 COMPOSITION INFORMATION . . . . . .

HAZARDOUS INGREDIENTS:
AS FORMULATED, THIS FINISHED PHARMACEUTICAL PRODUCT DOES NOT CONSTITUTE A PHYSICAL HAZARD WITHIN THE MEANING OF 29 CFR SEC 1910.1200. POTENTIAL HEALTH HAZARDS FROM INGESTION OR EXPOSURE TO THE PRODUCT ARE DISCUSSED IN SECTION 6 BELOW.

ACTIVE INGREDIENTS:			CAS
EACH FLUID OUNCE (2 TABLESPOONFULS) CONTAINS			
POWDERED OPIUM, USP (OR EQUIV)	24.0	MG	-
(WARNING: MAY BE HABIT FORMING)			
KAOLIN, USP	6	G	-
PECTIN, USP	142.8	MG	9000-69-5
HYOSCYAMINE SULFATE, USP	0.1037	MG	6835-16-1
ATROPINE SULFATE, USP	0.0194	MG	55-48-1
SCOPOLOMINE HYDROBROMIDE, USP	0.0065	MG	114-49-8

INACTIVE INGREDIENTS:
SODIUM BENZOATE NF 60 MG/FLUID OUNCE (PRESERVATIVE), ALCOHOL 5.0%, CITRIC ACID, D&C YELLOW 10, FLAVORS, HIGH FRUCTOSE CORN SYRUP, SODIUM CARBOXYMETHYLCELLULOSE, SODIUM CHLORIDE, WATER.

. . . SECTION 3 PHYSICAL/CHEMICAL CHARACTERISTICS . . . . . .

BOILING POINT	NOT APPLICABLE
VAPOR PRESSURE	NOT APPLICABLE
VAPOR DENSITY	NOT APPLICABLE
SOLUBILITY IN WATER	NOT APPLICABLE
SPECIFIC GRAVITY	1.18
MELTING POINT	NOT APPLICABLE
EVAPORATION RATE	NOT APPLICABLE
APPEARANCE	A LIGHT YELLOW, BANANA-FLAVORED SUSPENSION

. . . SECTION 4 FIRE AND EXPLOSION HAZARD DATA . . . . . .

FLASH POINT	NOT APPLICABLE
METHOD USED	NOT APPLICABLE
FLAMMABLE LIMITS	
LEL	NOT APPLICABLE
UEL	NOT APPLICABLE
EXTINGUISHING MEDIA	NOT APPLICABLE
SPECIAL FIRE-FIGHTING PROCEDURES	NOT APPLICABLE
UNUSUAL FIRE AND EXPLOSION HAZARDS	NONE

. . . SECTION 5 REACTIVITY DATA . . . . . .

STABILITY	STABLE
INCOMPATABILITY	NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS	NONE KNOWN
HAZARDOUS POLYMERIZATION	WILL NOT OCCUR

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

DONNAGEL-PG NDC 0031-3083-XX

. . . SECTION 6 HEALTH HAZARD DATA . . . . . .

ROUTES OF ENTRY:		INGESTION SKIN- IT IS NOT KNOWN IF ANY OF THE INGREDIENTS IN DONNAGEL-PG ARE ABSORBED THROUGH THE SKIN FROM DONNAGEL-PG SUSPENSION
CARCINOGENICITY:		NONE OF THE COMPONENTS IN THIS PRODUCT ARE KNOWN TO BE CARCINOGENIC
SIGNS AND SYMPTOMS OF OVER-EXPOSURE:	POWDERED OPIUM	PINPOINT PUPILS, CONSTIPATION, SLOW HEART RATE, HIGH BLOOD PRESSURE, RESPIRATORY DEPRESSION, URINARY RETENTION, MUSCLE SPASMS, ITCHING, RESPIRATORY ARREST, COMA
	KAOLIN, PECTIN	NO SERIOUS EFFECTS ARE EXPECTED
	ATROPINE, HYOSCYAMINE, AND SCOPOLOMINE	DRY MOUTH, THIRST, FIXED DILATED PUPILS, FLUSHED FACE, FEVER, HOT DRY RED SKIN, TACHYCARDIA, BLURRED VISION, DELIRIUM, TREMORS, CONVULSIONS, COMA, RESPIRATORY FAILURE, CARDIOVASCULAR COLLAPSE
EMERGENCY AND FIRST-AID PROCEDURES:		EYE CONTACT- IRRIGATE SURFACES WITH WATER FOR 15 MINUTES. SKIN CONTACT- WASH AREAS WITH SOAP AND WATER. TREATMENT OF OVERDOSE: INDUCED EMESIS, LAVAGE, AND ACTIVATED CHARCOAL MAY BE HELPFUL. PHYSOSTIGMINE DRAMATICALLY REVERSES THE CENTRAL AND PERIPHERAL SIGNS OF ANTICHOLINERGIC TOXICITY. SEVERE OPIATE EFFECTS SUCH AS RESPIRATORY DEPRESSION MAY BE REVERSED BY NALOXONE. SYMPTOMATIC AND SUPPORTIVE TREATMENT AS REQUIRED.
MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:		HYPERSENSITIVITY TO ANY OF THE COMPONENTS; GLAUCOMA; URINARY RETENTION

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

DONNAGEL-PG NDC 0031-3083-XX

. . . SECTION 7 PRECAUTIONS FOR SAFE HANDLING AND USE . . . . . .

SPILLS AND ACCIDENTAL RELEASES:	SOAK UP ON ABSORBANT MATERIAL AND PLACE IN APPROVED WASTE CONTAINER. WASH AREAS WITH SOAP AND WATER.
WASTE DISPOSAL METHOD:	DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. THIS IS A BIOLOGICALLY ACTIVE MATERIAL. DISPOSE OF ON SITE OR AT AN APPROVED DISPOSAL FACILITY IN ACCORDANCE WITH LOCAL,STATE,AND/OR FEDERAL REGULATIONS.
HANDLING AND STORAGE:	STORE AT ROOM TEMPERATURE, BETWEEN 59 AND 86 DEGREES F.

. . . SECTION 8 CONTROL MEASURES . . . . . .

NO SPECIAL CONTROL MEASURES ARE REQUIRED UNDER NORMAL CONDITIONS OF USE

RESPIRATORY PROTECTION	NONE REQUIRED
VENTILATION	NO SPECIAL VENTILATION IS REQUIRED
PROTECTIVE CLOTHING OR EQUIPMENT	AVOID CONTACT WITH EYES OR PROLONGED CONTACT WITH SKIN.
WORK/HYGIENIC PRACTICES	WASH THOROUGHLY AFTER HANDLING

. . . . . .

THE INFORMATION CONTAINED IN THIS MSDS IS, TO THE BEST OF A.H.ROBINS' KNOWLEDGE, COMPLETE AND ACCURATE. A.H.ROBINS, HOWEVER, USES MANY SOURCES AND REFERENCES FOR GATHERING THIS INFORMATION. THUS, A.H. ROBINS CANNOT GUARANTEE COMPLETENESS OR ACCURACY AND DISCLAIMS ALL LIABILITY FOR ITS HANDLING AND USE.

FILE/DONNAGEL/PG . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS) EFFECTIVE 04/09/87

DONNATAL CAPSULES NDC 0031-4207-XX

. . . SECTION 1 MANUFACTURER INFORMATION . . . . . .

A. H. ROBINS CO.,INC. 1405 CUMMINGS DRIVE RICHMOND, VA 23261-6609

EMERGENCY TELEPHONE: (804) 257-2000 (8:30 AM - 5:00 PM)
(804) 257-2000 (AFTER HOURS)

. . . SECTION 2 COMPOSITION INFORMATION . . . . . .

HAZARDOUS INGREDIENTS:
AS FORMULATED, THIS FINISHED PHARMACEUTICAL PRODUCT DOES NOT CONSTITUTE A PHYSICAL HAZARD WITHIN THE MEANING OF 29 CFR SEC 1910.1200. POTENTIAL HEALTH HAZARDS FROM INGESTION OR EXPOSURE TO THE PRODUCT ARE DISCUSSED IN SECTION 6 BELOW.

ACTIVE INGREDIENTS:		CAS
EACH CAPSULE CONTAINS:		
PHENOBARBITAL, USP	16.2 MG	50-06-6
(WARNING: MAY BE HABIT FORMING)		
HYOSCYAMINE SULFATE, USP	0.1037 MG	6835-16-1
ATROPINE SULFATE, USP	0.0194 MG	55-48-1
SCOPOLOMINE HYDROBROMIDE, USP	0.0065 MG	114-49-8

INACTIVE INGREDIENTS:
CORN STARCH, EDIBLE INK, D&C YELLOW 10 AND FD&C GREEN 3 OR FD&C BLUE 1 AND FD&C YELLOW 6, FD&C BLUE 2 ALUMINUM LAKE, GELATIN, LACTOSE, SUCROSE; MAY CONTAIN FD&C RED 40 AND YELLOW 6 ALUMINUM LAKES

. . . SECTION 3 PHYSICAL/CHEMICAL CHARACTERISTICS . . . . . .

BOILING POINT	NOT APPLICABLE
VAPOR PRESSURE	NOT APPLICABLE
VAPOR DENSITY	NOT APPLICABLE
SOLUBILITY IN WATER	NOT APPLICABLE
SPECIFIC GRAVITY	NOT APPLICABLE
MELTING POINT	NOT APPLICABLE
EVAPORATION RATE	NOT APPLICABLE
APPEARANCE	GREEN AND WHITE CAPSULES MONOGRAMMED "AHR" AND "4207"

. . . SECTION 4 FIRE AND EXPLOSION HAZARD DATA . . . . . .

FLASH POINT	NOT APPLICABLE
METHOD USED	NOT APPLICABLE
FLAMMABLE LIMITS	
LEL	NOT APPLICABLE
UEL	NOT APPLICABLE
EXTINGUISHING MEDIA	NOT APPLICABLE
SPECIAL FIRE-FIGHTING PROCEDURES	NOT APPLICABLE
UNUSUAL FIRE AND EXPLOSION HAZARDS	NONE

. . . SECTION 5 REACTIVITY DATA . . . . . .

STABILITY	STABLE
INCOMPATABILITY	NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS	NONE KNOWN
HAZARDOUS POLYMERIZATION	WILL NOT OCCUR

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

DONNATAL CAPSULES NDC 0031-4207-XX

. . . SECTION 6 HEALTH HAZARD DATA . . . . . .

	ROUTES OF ENTRY:	INGESTION
	CARCINOGENICITY:	NONE OF THE COMPONENTS IN THIS PRODUCT ARE KNOWN TO BE CARCINOGENIC
SIGNS AND SYMPTOMS OF OVER-EXPOSURE:	PHENOBARBITAL	DROWSINESS, DIZZINESS, WEAKNESS, SEDATION
	ATROPINE, HYOSCYAMINE, AND SCOPOLOMINE	DRY MOUTH, THIRST, FIXED DILATED PUPILS, FLUSHED FACE, FEVER, HOT DRY RED SKIN, TACHYCARDIA (RAPID HEART BEAT), BLURRED VISION, DELIRIUM, TREMORS, CONVULSIONS, COMA, RESPIRATORY FAILURE, CARDIOVASCULAR COLLAPSE
	EMERGENCY AND FIRST-AID PROCEDURES:	EYE CONTACT- IRRIGATE SURFACES WITH WATER FOR 15 MINUTES. SKIN CONTACT- WASH AREAS WITH SOAP AND WATER. TREATMENT OF OVERDOSE: INDUCED EMESIS, LAVAGE, AND ACTIVATED CHARCOAL MAY BE HELPFUL. PHYSOSTIGMINE DRAMATICALLY REVERSES THE CENTRAL AND PERIPHERAL SIGNS OF ANTICHOLINERGIC TOXICITY. SYMPTOMATIC AND SUPPORTIVE TREATMENT AS REQUIRED.
	MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:	HYPERSENSITIVITY TO ANY OF THE COMPONENTS; GLAUCOMA; URINARY RETENTION

FOR COMPLETE INFORMATION ON THIS DRUG PLEASE REFER TO THE ATTACHED PRODUCT LABELING

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

DONNATAL CAPSULES NDC 0031-4207-XX

. . . SECTION 7 PRECAUTIONS FOR SAFE HANDLING AND USE . . . . . .

SPILLS AND ACCIDENTAL RELEASES:	SWEEP OR SHOVEL INTO A WASTE CONTAINER
WASTE DISPOSAL METHOD:	DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. THIS IS A BIOLOGICALLY ACTIVE MATERIAL. DISPOSE OF ON SITE OR AT AN APPROVED DISPOSAL FACILITY IN ACCORDANCE WITH LOCAL, STATE, AND/OR FEDERAL REGULATIONS.
HANDLING AND STORAGE:	STORE AT ROOM TEMPERATURE, BETWEEN 59 AND 86 DEGREES F.

. . . SECTION 8 CONTROL MEASURES . . . . . .

NO SPECIAL CONTROL MEASURES ARE REQUIRED UNDER NORMAL CONDITIONS OF USE

RESPIRATORY PROTECTION	NONE REQUIRED
VENTILATION	NO SPECIAL VENTILATION IS REQUIRED
PROTECTIVE CLOTHING OR EQUIPMENT	AVOID CONTACT WITH EYES OR PROLONGED CONTACT WITH SKIN.
WORK/HYGIENIC PRACTICES	WASH THOROUGHLY AFTER HANDLING

. . . . . .

THE INFORMATION CONTAINED IN THIS MSDS IS, TO THE BEST OF A.H.ROBINS' KNOWLEDGE, COMPLETE AND ACCURATE. A.H.ROBINS, HOWEVER, USES MANY SOURCES AND REFERENCES FOR GATHERING THIS INFORMATION. THUS, A.H. ROBINS CANNOT GUARANTEE COMPLETENESS OR ACCURACY AND DISCLAIMS ALL LIABILITY FOR ITS HANDLING AND USE.

FILE/DONNATAL/CAPSULES. . . . . .

MATERIAL SAFETY DATA SHEET (MSDS) EFFECTIVE 04/09/87

DONNATAL ELIXIR NDC 0031-4221-XX

. . . SECTION 1 MANUFACTURER INFORMATION . . . . . .

A. H. ROBINS CO.,INC. 1405 CUMMINGS DRIVE RICHMOND, VA 23261-6609

EMERGENCY TELEPHONE: (804) 257-2000 (8:30 AM - 5:00 PM)
(804) 257-2000 (AFTER HOURS)

. . . SECTION 2 COMPOSITION INFORMATION . . . . . .

HAZARDOUS INGREDIENTS:
AS FORMULATED, THIS FINISHED PHARMACEUTICAL PRODUCT DOES NOT CONSTITUTE A PHYSICAL HAZARD WITHIN THE MEANING OF 29 CFR SEC 1910.1200. POTENTIAL HEALTH HAZARDS FROM INGESTION OR EXPOSURE TO THE PRODUCT ARE DISCUSSED IN SECTION 6 BELOW.

ACTIVE INGREDIENTS: EACH 5ML CONTAINS:		CAS
PHENOBARBITAL, USP (WARNING: MAY BE HABIT FORMING)	16.2 MG	56-06-6
HYOSCYAMINE SULFATE, USP	0.1037 MG	6835-16-1
ATROPINE SULFATE, USP	0.0194 MG	55-48-1
SCOPOLOMINE HYDROBROMIDE, USP	0.0065 MG	114-49-8

INACTIVE INGREDIENTS:
D&C YELLOW 10, FD&C BLUE 1, FD&C YELLOW 6, FLAVORS, GLUCOSE, SACCHARIN SODIUM, WATER, ALCOHOL (23%)

. . . SECTION 3 PHYSICAL/CHEMICAL CHARACTERISTICS . . . . . .

BOILING POINT	NOT APPLICABLE
VAPOR PRESSURE	NOT APPLICABLE
VAPOR DENSITY	NOT APPLICABLE
SOLUBILITY IN WATER	SOLUBLE
SPECIFIC GRAVITY	CA 1.09
MELTING POINT	NOT APPLICABLE
EVAPORATION RATE	NOT APPLICABLE
APPEARANCE	GREEN, CITRUS FLAVORED LIQUID

. . . SECTION 4 FIRE AND EXPLOSION HAZARD DATA . . . . . .

FLASH POINT	NOT APPLICABLE
METHOD USED	NOT APPLICABLE
FLAMMABLE LIMITS	
LEL	NOT APPLICABLE
UEL	NOT APPLICABLE
EXTINGUISHING MEDIA	NOT APPLICABLE
SPECIAL FIRE-FIGHTING PROCEDURES	NOT APPLICABLE
UNUSUAL FIRE AND EXPLOSION HAZARDS	NONE

. . . SECTION 5 REACTIVITY DATA . . . . . .

STABILITY	STABLE
INCOMPATABILITY	NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS	NONE KNOWN
HAZARDOUS POLYMERIZATION	WILL NOT OCCUR

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

DONNATAL ELIXIR NDC 0031-4221-XX

. . . SECTION 6 HEALTH HAZARD DATA . . . . . .

	ROUTES OF ENTRY:	INGESTION SKIN- IT IS NOT KNOWN IF ANY OF THE INGREDIENTS IN DONNATAL ELIXIR ARE ABSORBED THROUGH THE SKIN FROM DONNATAL ELIXIR
	CARCINOGENICITY:	NONE OF THE COMPONENTS IN THIS PRODUCT ARE KNOWN TO BE CARCINOGENIC
SIGNS AND SYMPTOMS OF OVER-EXPOSURE:	PHENOBARBITAL	DROWSINESS, DIZZINESS, WEAKNESS, SEDATION
	ATROPINE, HYOSCYAMINE, AND SCOPOLOMINE	DRY MOUTH, THIRST, FIXED DILATED PUPILS, FLUSHED FACE, FEVER, HOT DRY RED SKIN, TACHYCARDIA (RAPID HEART BEAT), BLURRED VISION, DELIRIUM, TREMORS, CONVULSIONS, COMA, RESPIRATORY FAILURE, CARDIOVASCULAR COLLAPSE
	EMERGENCY AND FIRST-AID PROCEDURES:	EYE CONTACT- IRRIGATE SURFACES WITH WATER FOR 15 MINUTES. SKIN CONTACT- WASH AREAS WITH SOAP AND WATER. TREATMENT OF OVERDOSE: INDUCED EMESIS, LAVAGE, AND ACTIVATED CHARCOAL MAY BE HELPFUL. PHYSOSTIGMINE DRAMATICALLY REVERSES THE CENTRAL AND PERIPHERAL SIGNS OF ANTICHOLINERGIC TOXICITY. SYMPTOMATIC AND SUPPORTIVE TREATMENT AS REQUIRED.
	MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:	HYPERSENSITIVITY TO ANY OF THE COMPONENTS; GLAUCOMA; URINARY RETENTION

FOR COMPLETE INFORMATION ON THIS DRUG PLEASE REFER TO THE ATTACHED PRODUCT LABELING

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

DONNATAL ELIXIR NDC 0031-4221-XX

. . . SECTION 7 PRECAUTIONS FOR SAFE HANDLING AND USE . . . . . .

SPILLS AND ACCIDENTAL RELEASES:	SOAK UP ON ABSORBANT MATERIAL AND PLACE IN APPROVED WASTE CONTAINER. WASH AREAS WITH SOAP AND WATER.
WASTE DISPOSAL METHOD:	DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. THIS IS A BIOLOGICALLY ACTIVE MATERIAL. DISPOSE OF ON SITE OR AT AN APPROVED DISPOSAL FACILITY IN ACCORDANCE WITH LOCAL,STATE,AND/OR FEDERAL REGULATIONS.
HANDLING AND STORAGE:	STORE AT ROOM TEMPERATURE, BETWEEN 59 AND 86 DEGREES F.

. . . SECTION 8 CONTROL MEASURES . . . . . .

NO SPECIAL CONTROL MEASURES ARE REQUIRED UNDER NORMAL CONDITIONS OF USE

RESPIRATORY PROTECTION	NONE REQUIRED
VENTILATION	NO SPECIAL VENTILATION IS REQUIRED
PROTECTIVE CLOTHING OR EQUIPMENT	AVOID CONTACT WITH EYES OR PROLONGED CONTACT WITH SKIN.
WORK/HYGIENIC PRACTICES	WASH THOROUGHLY AFTER HANDLING

. . . . . .

THE INFORMATION CONTAINED IN THIS MSDS IS, TO THE BEST OF A.H.ROBINS' KNOWLEDGE, COMPLETE AND ACCURATE. A.H.ROBINS, HOWEVER, USES MANY SOURCES AND REFERENCES FOR GATHERING THIS INFORMATION. THUS, A.H. ROBINS CANNOT GUARANTEE COMPLETENESS OR ACCURACY AND DISCLAIMS ALL LIABILITY FOR ITS HANDLING AND USE.

FILE/DONNATAL/ELIXIR. . . . . .

MATERIAL SAFETY DATA SHEET (MSDS) EFFECTIVE 04/09/87

DONNATAL EXTENTABS NDC 0031-4235-XX

. . . SECTION 1 MANUFACTURER INFORMATION . . . . . .

A. H. ROBINS CO.,INC. 1405 CUMMINGS DRIVE RICHMOND, VA 23261-6609

EMERGENCY TELEPHONE: (804) 257-2000 (8:30 AM - 5:00 PM)
(804) 257-2000 (AFTER HOURS)

. . . SECTION 2 COMPOSITION INFORMATION . . . . . .

HAZARDOUS INGREDIENTS:
AS FORMULATED, THIS FINISHED PHARMACEUTICAL PRODUCT DOES NOT CONSTITUTE A PHYSICAL HAZARD WITHIN THE MEANING OF 29 CFR SEC 1910.1200. POTENTIAL HEALTH HAZARDS FROM INGESTION OR EXPOSURE TO THE PRODUCT ARE DISCUSSED IN SECTION 6 BELOW.

ACTIVE INGREDIENTS: EACH TABLET CONTAINS:		CAS
PHENOBARBITAL, USP (WARNING: MAY BE HABIT FORMING)	48.6 MG	56-06-6
HYOSCYAMINE SULFATE, USP	0.3111 MG	6835-16-1
ATROPINE SULFATE, USP	0.0582 MG	55-48-1
SCOPOLOMINE HYDROBROMIDE, USP	0.0195 MG	114-49-8

INACTIVE INGREDIENTS:
ACACIA, ACETYLATED MONOGLYCERIDES, CALCIUM SULFATE, CARNUBA WAX, D&C YELLOW 10, EDIBLE INK, FD&C BLUE 1, FD&C BLUE 2 ALUMINUM LAKE, FD&C YELLOW 6, GELATIN, GUAR GUM, MAGNESIUM STEARATE, POLYSORBATES, SHELLAC, SODIUM PHOSPHATE, SUCROSE, TITANIUM DIOXIDE, WHEAT FLOUR, WHITE WAX, AND OTHER INGREDIENTS, ONE OF WHICH IS A CORN DERIVATIVE; MAY INCLUDE FD&C RED 40 AND YELLOW 6 ALUMINUM LAKES

. . . SECTION 3 PHYSICAL/CHEMICAL CHARACTERISTICS . . . . . .

BOILING POINT	NOT APPLICABLE
VAPOR PRESSURE	NOT APPLICABLE
VAPOR DENSITY	NOT APPLICABLE
SOLUBILITY IN WATER	NOT APPLICABLE
SPECIFIC GRAVITY	NOT APPLICABLE
MELTING POINT	NOT APPLICABLE
EVAPORATION RATE	NOT APPLICABLE
APPEARANCE	PALE GREEN, COATED TABLETS, MONOGRAMMED AHR AND DONNATAL EXTENTAB

. . . SECTION 4 FIRE AND EXPLOSION HAZARD DATA . . . . . .

FLASH POINT	NOT APPLICABLE
METHOD USED	NOT APPLICABLE
FLAMMABLE LIMITS	
LEL	NOT APPLICABLE
UEL	NOT APPLICABLE
EXTINGUISHING MEDIA	NOT APPLICABLE
SPECIAL FIRE-FIGHTING PROCEDURES	NOT APPLICABLE
UNUSUAL FIRE AND EXPLOSION HAZARDS	NONE

. . . SECTION 5 REACTIVITY DATA . . . . . .

STABILITY	STABLE
INCOMPATABILITY	NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS	NONE KNOWN
HAZARDOUS POLYMERIZATION	WILL NOT OCCUR

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

DONNATAL EXTENTABS NDC 0031-4235-XX

. . . SECTION 6 HEALTH HAZARD DATA . . . . . .

	ROUTES OF ENTRY:	INGESTION
	CARCINOGENICITY:	NONE OF THE COMPONENTS IN THIS PRODUCT ARE KNOWN TO BE CARCINOGENIC
SIGNS AND SYMPTOMS OF OVER-EXPOSURE:	PHENOBARBITAL	DROWSINESS, DIZZINESS, WEAKNESS, SEDATION
	ATROPINE, HYOSCYAMINE, AND SCOPOLOMINE	DRY MOUTH, THIRST, FIXED DILATED PUPILS, FLUSHED FACE, FEVER, HOT DRY RED SKIN, TACHYCARDIA (RAPID HEART BEAT), BLURRED VISION, DELIRIUM, TREMORS, CONVULSIONS, COMA, RESPIRATORY FAILURE, CARDIOVASCULAR COLLAPSE
	EMERGENCY AND FIRST-AID PROCEDURES:	EYE CONTACT- IRRIGATE SURFACES WITH WATER FOR 15 MINUTES. SKIN CONTACT- WASH AREAS WITH SOAP AND WATER. TREATMENT OF OVERDOSE: INDUCED EMESIS, LAVAGE, ACTIVATED CHARCOAL AND SALINE CATHARTICS MAY BE HELPFUL. PHYSOSTIGMINE DRAMATICALLY REVERSES THE CENTRAL AND PERIPHERAL SIGNS OF ANTICHOLINERGIC TOXICITY. SYMPTOMATIC AND SUPPORTIVE TREATMENT AS REQUIRED.
	MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:	HYPERSENSITIVITY TO ANY OF THE COMPONENTS; GLAUCOMA; URINARY RETENTION

FOR COMPLETE INFORMATION ON THIS DRUG PLEASE REFER TO THE ATTACHED PRODUCT LABELING

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

DONNATAL EXTENTABS NDC 0031-4235-XX

. . . SECTION 7 PRECAUTIONS FOR SAFE HANDLING AND USE . . . . . .

SPILLS AND ACCIDENTAL RELEASES:	SWEEP OR SHOVEL INTO A WASTE CONTAINER
WASTE DISPOSAL METHOD:	DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. THIS IS A BIOLOGICALLY ACTIVE MATERIAL. DISPOSE OF ON SITE OR AT AN APPROVED DISPOSAL FACILITY IN ACCORDANCE WITH LOCAL,STATE,AND/OR FEDERAL REGULATIONS.
HANDLING AND STORAGE:	STORE AT ROOM TEMPERATURE, BETWEEN 59 AND 86 DEGREES F.

. . . SECTION 8 CONTROL MEASURES . . . . . .

NO SPECIAL CONTROL MEASURES ARE REQUIRED UNDER NORMAL CONDITIONS OF USE

RESPIRATORY PROTECTION	NONE REQUIRED
VENTILATION	NO SPECIAL VENTILATION IS REQUIRED
PROTECTIVE CLOTHING OR EQUIPMENT	AVOID CONTACT WITH EYES OR PROLONGED CONTACT WITH SKIN.
WORK/HYGIENIC PRACTICES	WASH THOROUGHLY AFTER HANDLING

. . . . . .

THE INFORMATION CONTAINED IN THIS MSDS IS, TO THE BEST OF A.H.ROBINS' KNOWLEDGE, COMPLETE AND ACCURATE. A.H.ROBINS, HOWEVER, USES MANY SOURCES AND REFERENCES FOR GATHERING THIS INFORMATION. THUS, A.H. ROBINS CANNOT GUARANTEE COMPLETENESS OR ACCURACY AND DISCLAIMS ALL LIABILITY FOR ITS HANDLING AND USE.

FILE/DONNATAL/EXTENTAB. . . . . .

MATERIAL SAFETY DATA SHEET (MSDS) EFFECTIVE 04/09/87

DONNATAL TABLETS NDC 0031-4250-XX

. . . SECTION 1 MANUFACTURER INFORMATION . . . . . .

A. H. ROBINS CO.,INC. 1405 CUMMINGS DRIVE RICHMOND, VA 23261-6609

EMERGENCY TELEPHONE: (804) 257-2000 (8:30 AM - 5:00 PM)
(804) 257-2000 (AFTER HOURS)

. . . SECTION 2 COMPOSITION INFORMATION . . . . . .

HAZARDOUS INGREDIENTS:
AS FORMULATED, THIS FINISHED PHARMACEUTICAL PRODUCT DOES NOT CONSTITUTE A PHYSICAL HAZARD WITHIN THE MEANING OF 29 CFR SEC 1910.1200. POTENTIAL HEALTH HAZARDS FROM INGESTION OR EXPOSURE TO THE PRODUCT ARE DISCUSSED IN SECTION 6 BELOW.

ACTIVE INGREDIENTS: EACH TABLET CONTAINS:			CAS
PHENOBARBITAL, USP (WARNING: MAY BE HABIT FORMING)	16.2	MG	50-06-6
HYOSCYAMINE SULFATE, USP	0.1037	MG	6835-16-1
ATROPINE SULFATE, USP	0.0194	MG	55-48-1
SCOPOLOMINE HYDROBROMIDE, USP	0.0065	MG	114-49-8

INACTIVE INGREDIENTS:
DIBASIC CALCIUM PHOSPHATE, MAGNESIUM STEARATE, MICROCRYSTALLINE CELLULOSE, SILICON DIOXIDE, SODIUM STARCH GLYCOLATE, STEARIC ACID, SUCROSE; MAY CONTAIN CORN STARCH, DEXTROSE, OR INVERT SUGAR

. . . SECTION 3 PHYSICAL/CHEMICAL CHARACTERISTICS . . . . . .

BOILING POINT	NOT APPLICABLE
VAPOR PRESSURE	NOT APPLICABLE
VAPOR DENSITY	NOT APPLICABLE
SOLUBILITY IN WATER	NOT APPLICABLE
SPECIFIC GRAVITY	NOT APPLICABLE
MELTING POINT	NOT APPLICABLE
EVAPORATION RATE	NOT APPLICABLE
APPEARANCE	WHITE, COMPRESSED TABLET, SCORED AND EMBOSSED "R"

. . . SECTION 4 FIRE AND EXPLOSION HAZARD DATA . . . . . .

FLASH POINT	NOT APPLICABLE
METHOD USED	NOT APPLICABLE
FLAMMABLE LIMITS	
LEL	NOT APPLICABLE
UEL	NOT APPLICABLE
EXTINGUISHING MEDIA	NOT APPLICABLE
SPECIAL FIRE-FIGHTING PROCEDURES	NOT APPLICABLE
UNUSUAL FIRE AND EXPLOSION HAZARDS	NONE

. . . SECTION 5 REACTIVITY DATA . . . . . .

STABILITY	STABLE
INCOMPATABILITY	NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS	NONE KNOWN
HAZARDOUS POLYMERIZATION	WILL NOT OCCUR

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

DONNATAL TABLETS NDC 0031-4250-XX

. . . SECTION 6 HEALTH HAZARD DATA . . . . . .

ROUTES OF ENTRY:		INGESTION
CARCINOGENICITY:		NONE OF THE COMPONENTS IN THIS PRODUCT ARE KNOWN TO BE CARCINOGENIC
SIGNS AND SYMPTOMS OF OVER-EXPOSURE:	PHENOBARBITAL	DROWSINESS, DIZZINESS, WEAKNESS, SEDATION
	ATROPINE, HYOSCYAMINE, AND SCOPOLOMINE	DRY MOUTH, THIRST, FIXED DILATED PUPILS, FLUSHED FACE, FEVER, HOT DRY RED SKIN, TACHYCARDIA (RAPID HEART BEAT), BLURRED VISION, DELIRIUM, TREMORS, CONVULSIONS, COMA, RESPIRATORY FAILURE, CARDIOVASCULAR COLLAPSE
EMERGENCY AND FIRST-AID PROCEDURES:		EYE CONTACT- IRRIGATE SURFACES WITH WATER FOR 15 MINUTES. SKIN CONTACT- WASH AREAS WITH SOAP AND WATER. TREATMENT OF OVERDOSE: INDUCED EMESIS, LAVAGE, AND ACTIVATED CHARCOAL MAY BE HELPFUL. PHYSOSTIGMINE DRAMATICALLY REVERSES THE CENTRAL AND PERIPHERAL SIGNS OF ANTICHOLINERGIC TOXICITY. SYMPTOMATIC AND SUPPORTIVE TREATMENT AS REQUIRED.
MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:		HYPERSENSITIVITY TO ANY OF THE COMPONENTS; GLAUCOMA; URINARY RETENTION

FOR COMPLETE INFORMATION ON THIS DRUG PLEASE REFER TO THE ATTACHED PRODUCT LABELING

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

DONNATAL TABLETS NDC 0031-4250-XX

. . . SECTION 7 PRECAUTIONS FOR SAFE HANDLING AND USE . . . . . .

SPILLS AND ACCIDENTAL RELEASES:	SWEEP OR SHOVEL INTO A WASTE CONTAINER
WASTE DISPOSAL METHOD:	DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. THIS IS A BIOLOGICALLY ACTIVE MATERIAL. DISPOSE OF ON SITE OR AT AN APPROVED DISPOSAL FACILITY IN ACCORDANCE WITH LOCAL, STATE, AND/OR FEDERAL REGULATIONS.
HANDLING AND STORAGE:	STORE AT ROOM TEMPERATURE, BETWEEN 59 AND 86 DEGREES F.

. . . SECTION 8 CONTROL MEASURES . . . . . .

NO SPECIAL CONTROL MEASURES ARE REQUIRED UNDER NORMAL CONDITIONS OF USE

RESPIRATORY PROTECTION	NONE REQUIRED
VENTILATION	NO SPECIAL VENTILATION IS REQUIRED
PROTECTIVE CLOTHING OR EQUIPMENT	AVOID CONTACT WITH EYES OR PROLONGED CONTACT WITH SKIN.
WORK/HYGIENIC PRACTICES	WASH THOROUGHLY AFTER HANDLING

. . . . . .

THE INFORMATION CONTAINED IN THIS MSDS IS, TO THE BEST OF A.H.ROBINS' KNOWLEDGE, COMPLETE AND ACCURATE. A.H.ROBINS, HOWEVER, USES MANY SOURCES AND REFERENCES FOR GATHERING THIS INFORMATION. THUS, A.H. ROBINS CANNOT GUARANTEE COMPLETENESS OR ACCURACY AND DISCLAIMS ALL LIABILITY FOR ITS HANDLING AND USE.

FILE/DONNATAL/TABLETS . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS) EFFECTIVE 04/09/87

DONNATAL NO. 2 TABLETS NDC 0031-4264-XX

. . . SECTION 1 MANUFACTURER INFORMATION . . . . . .

A. H. ROBINS CO.,INC. 1405 CUMMINGS DRIVE RICHMOND, VA 23261-6609

EMERGENCY TELEPHONE: (804) 257-2000 (8:30 AM - 5:00 PM)
(804) 257-2000 (AFTER HOURS)

. . . SECTION 2 COMPOSITION INFORMATION . . . . . .

HAZARDOUS INGREDIENTS:
AS FORMULATED, THIS FINISHED PHARMACEUTICAL PRODUCT DOES NOT CONSTITUTE A PHYSICAL HAZARD WITHIN THE MEANING OF 29 CFR SEC 1910.1200. POTENTIAL HEALTH HAZARDS FROM INGESTION OR EXPOSURE TO THE PRODUCT ARE DISCUSSED IN SECTION 6 BELOW.

ACTIVE INGREDIENTS:			CAS
EACH TABLET CONTAINS:			
PHENOBARBITAL, USP (WARNING: MAY BE HABIT FORMING)	32.4	MG	56-06-6
MYOSCYAMINE SULFATE, USP	0.1037	MG	6835-16-1
ATROPINE SULFATE, USP	0.0194	MG	55-48-1
SCOPOLOMINE HYDROBROMIDE, USP	0.0065	MG	114-49-8

INACTIVE INGREDIENTS:
CALCIUM STEARATE, CORN STARCH, D&C YELLOW 10, FD&C YELLOW 1, FD&C YELLOW 6, LACTOSE, SUCROSE

. . . SECTION 3 PHYSICAL/CHEMICAL CHARACTERISTICS . . . . . .

BOILING POINT	NOT APPLICABLE
VAPOR PRESSURE	NOT APPLICABLE
VAPOR DENSITY	NOT APPLICABLE
SOLUBILITY IN WATER	NOT APPLICABLE
SPECIFIC GRAVITY	NOT APPLICABLE
MELTING POINT	NOT APPLICABLE
EVAPORATION RATE	NOT APPLICABLE
APPEARANCE	PALE GREEN COMPRESSED TABLETS SCORED AND EMBOSSED "R"

. . . SECTION 4 FIRE AND EXPLOSION HAZARD DATA . . . . . .

FLASH POINT	NOT APPLICABLE
METHOD USED	NOT APPLICABLE
FLAMMABLE LIMITS	
LEL	NOT APPLICABLE
UEL	NOT APPLICABLE
EXTINGUISHING MEDIA	NOT APPLICABLE
SPECIAL FIRE-FIGHTING PROCEDURES	NOT APPLICABLE
UNUSUAL FIRE AND EXPLOSION HAZARDS	NONE

. . . SECTION 5 REACTIVITY DATA . . . . . .

STABILITY	STABLE
INCOMPATABILITY	NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS	NONE KNOWN
HAZARDOUS POLYMERIZATION	WILL NOT OCCUR

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

DONNATAL NO. 2 TABLETS NDC 0031-4264-XX

. . . SECTION 6 HEALTH HAZARD DATA . . . . . .

ROUTES OF ENTRY:		INGESTION
CARCINOGENICITY:		NONE OF THE COMPONENTS IN THIS PRODUCT ARE KNOWN TO BE CARCINOGENIC
SIGNS AND SYMPTOMS OF OVER-EXPOSURE:	PHENOBARBITAL	DROWSINESS, DIZZINESS, WEAKNESS, SEDATION
	ATROPINE, HYOSCYAMINE, AND SCOPOLOMINE	DRY MOUTH, THIRST, FIXED DILATED PUPILS, FLUSHED FACE, FEVER, HOT DRY RED SKIN, TACHYCARDIA (RAPID HEART BEAT), BLURRED VISION, DELIRIUM, TREMORS, CONVULSIONS, COMA, RESPIRATORY FAILURE, CARDIOVASCULAR COLLAPSE
EMERGENCY AND FIRST-AID PROCEDURES:		EYE CONTACT- IRRIGATE SURFACES WITH WATER FOR 15 MINUTES. SKIN CONTACT- WASH AREAS WITH SOAP AND WATER. TREATMENT OF OVERDOSE: INDUCED EMESIS, LAVAGE, AND ACTIVATED CHARCOAL MAY BE HELPFUL. PHYSOSTIGMINE DRAMATICALLY REVERSES THE CENTRAL AND PERIPHERAL SIGNS OF ANTICHOLINERGIC TOXICITY. SYMPTOMATIC AND SUPPORTIVE TREATMENT AS REQUIRED.
MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:		HYPERSENSITIVITY TO ANY OF THE COMPONENTS; GLAUCOMA; URINARY RETENTION

FOR COMPLETE INFORMATION ON THIS DRUG PLEASE REFER TO THE ATTACHED PRODUCT LABELING

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

DONNATAL NO. 2 TABLETS NDC 0031-4264-XX

. . . SECTION 7 PRECAUTIONS FOR SAFE HANDLING AND USE . . . . . .

SPILLS AND ACCIDENTAL RELEASES:	SWEEP OR SHOVEL INTO A WASTE CONTAINER
WASTE DISPOSAL METHOD:	DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. THIS IS A BIOLOGICALLY ACTIVE MATERIAL. DISPOSE OF ON SITE OR AT AN APPROVED DISPOSAL FACILITY IN ACCORDANCE WITH LOCAL, STATE, AND/OR FEDERAL REGULATIONS.
HANDLING AND STORAGE:	STORE AT ROOM TEMPERATURE, BETWEEN 59 AND 86 DEGREES F.

. . . SECTION 8 CONTROL MEASURES . . . . . .

NO SPECIAL CONTROL MEASURES ARE REQUIRED UNDER NORMAL CONDITIONS OF USE

RESPIRATORY PROTECTION	NONE REQUIRED
VENTILATION	NO SPECIAL VENTILATION IS REQUIRED
PROTECTIVE CLOTHING OR EQUIPMENT	AVOID CONTACT WITH EYES OR PROLONGED CONTACT WITH SKIN.
WORK/HYGIENIC PRACTICES	WASH THOROUGHLY AFTER HANDLING

. . . . . .

THE INFORMATION CONTAINED IN THIS MSDS IS, TO THE BEST OF A.H.ROBINS' KNOWLEDGE, COMPLETE AND ACCURATE. A.H.ROBINS, HOWEVER, USES MANY SOURCES AND REFERENCES FOR GATHERING THIS INFORMATION. THUS, A.H. ROBINS CANNOT GUARANTEE COMPLETENESS OR ACCURACY AND DISCLAIMS ALL LIABILITY FOR ITS HANDLING AND USE.

FILE/DONNATAL/2TABLETS. . . . . .

MATERIAL SAFETY DATA SHEET (MSDS) EFFECTIVE 06/24/87

DONNAZYME TABLETS NDC 0031-4649-XX

. . . SECTION 1 MANUFACTURER INFORMATION . . . . . .

A. H. ROBINS CO.,INC. 1405 CUMMINGS DRIVE RICHMOND, VA 23261-6609

EMERGENCY TELEPHONE: (804) 257-2000 (8:30 AM - 5:00 PM)
(804) 257-2000 (AFTER HOURS)

. . . SECTION 2 COMPOSITION INFORMATION . . . . . .

HAZARDOUS INGREDIENTS:
AS FORMULATED, THIS FINISHED PHARMACEUTICAL PRODUCT DOES NOT CONSTITUTE A PHYSICAL HAZARD WITHIN THE MEANING OF 29 CFR SEC 1910.1200. POTENTIAL HEALTH HAZARDS FROM INGESTION OR EXPOSURE TO THE PRODUCT ARE DISCUSSED IN SECTION 6 BELOW.

ACTIVE INGREDIENTS: EACH TABLET CONTAINS:		CAS
PANCREATIN, USP EQUIVALENT	300 MG	8049-47-6
PEPSIN	150 MG	9001-75-6
BILE SALTS	150 MG	
PHENOBARBITAL, USP (WARNING: MAY BE HABIT FORMING)	8.1 MG	50-06-6
HYOSCYAMINE SULFATE, USP	0.0518 MG	6835-16-1
ATROPINE SULFATE, USP	0.0097 MG	55-48-1
SCOPOLOMINE HYDROBROMIDE, USP	0.0033 MG	114-49-8

INACTIVE INGREDIENTS:
ACACIA, ACETYLATED MONOGLYCERIDES, CALCIUM SULFATE, CARNAUBA WAX, CELLULOSE ACETATE PHTHALATE, CORN STARCH, D&C YELLOW 10 ALUMINUM LAKE, DIETHYL PHTHALATE, EDIBLE INK, FD&C BLUE 1 ALUMINUM LAKE, FD&C YELLOW 6 ALUMINUM LAKE, GELATIN, METHYLPARABEN, MICROCRYSTALLINE CELLULOSE, POLYSORBATES, POVIDONE, PROPYLPARABEN, SHELLAC, SODIUM BENZOATE, STEARIC ACID, SUCROSE, TARTARIC ACID, TITANIUM DIOXIDE, WHEAT FLOUR, WHITE WAX, MAY CONTAIN DOCUSATE SODIUM

. . . SECTION 3 PHYSICAL/CHEMICAL CHARACTERISTICS . . . . . .

BOILING POINT	NOT APPLICABLE
VAPOR PRESSURE	NOT APPLICABLE
VAPOR DENSITY	NOT APPLICABLE
SOLUBILITY IN WATER	NOT APPLICABLE
SPECIFIC GRAVITY	NOT APPLICABLE
MELTING POINT	NOT APPLICABLE
EVAPORATION RATE	NOT APPLICABLE
APPEARANCE	ROUND, GREEN-COATED TABLETS, MONOGRAMMED AHR-4649

. . . SECTION 4 FIRE AND EXPLOSION HAZARD DATA . . . . . .

FLASH POINT	NOT APPLICABLE
METHOD USED	NOT APPLICABLE
FLAMMABLE LIMITS	
LEL	NOT APPLICABLE
UEL	NOT APPLICABLE
EXTINGUISHING MEDIA	NOT APPLICABLE
SPECIAL FIRE-FIGHTING PROCEDURES	NOT APPLICABLE
UNUSUAL FIRE AND EXPLOSION HAZARDS	NONE

. . . SECTION 5 REACTIVITY DATA . . . . . .

STABILITY	STABLE
INCOMPATABILITY	NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS	NONE KNOWN
HAZARDOUS POLYMERIZATION	WILL NOT OCCUR

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

DONNAZYME TABLETS NDC 0031-4649-XX

. . . SECTION 6 HEALTH HAZARD DATA . . . . . .

ROUTES OF ENTRY:		INGESTION
CARCINOGENICITY:		NONE OF THE COMPONENTS IN THIS PRODUCT ARE KNOWN TO BE CARCINOGENIC
SIGNS AND SYMPTOMS OF OVER-EXPOSURE:	PHENOBARBITAL	DROWSINESS, DIZZINESS, WEAKNESS, SEDATION
	ATROPINE, HYOSCYAMINE, AND SCOPOLOMINE	DRY MOUTH, THIRST, FIXED DILATED PUPILS, FLUSHED FACE, FEVER, HOT DRY RED SKIN, TACHYCARDIA (RAPID HEART BEAT), BLURRED VISION, DELIRIUM, TREMORS, CONVULSIONS, COMA, RESPIRATORY FAILURE, CARDIOVASCULAR COLLAPSE
	PANCREATIN, PEPSIN, AND BILE SALTS	SKIN RASH. HIGH DOSES MAY PRODUCE A LAXATIVE EFFECT; SYSTEMIC TOXICITY IS NOT EXPECTED.
		(SEE ATTACHED PRODUCT LABELING FOR FULL INFORMATION ON SIDE-EFFECTS)
EMERGENCY AND FIRST-AID PROCEDURES:		EYE CONTACT- IRRIGATE SURFACES WITH WATER FOR 15 MINUTES. SKIN CONTACT- WASH AREAS WITH SOAP AND WATER. TREATMENT OF OVERDOSE: INDUCED EMESIS, LAVAGE, AND ACTIVATED CHARCOAL MAY BE HELPFUL. PHYSOSTIGMINE DRAMATICALLY REVERSES THE CENTRAL AND PERIPHERAL SIGNS OF ANTICHOLINERGIC TOXICITY. SYMPTOMATIC AND SUPPORTIVE TREATMENT AS REQUIRED.
MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:		HYPERSENSITIVITY TO ANY OF THE COMPONENTS; GLAUCOMA; URINARY RETENTION

FOR COMPLETE INFORMATION ON THIS DRUG PLEASE REFER TO THE ATTACHED PRODUCT LABELING

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

DONNAZYME TABLETS NDC 0031-4649-XX

. . . SECTION 7 PRECAUTIONS FOR SAFE HANDLING AND USE . . . . . .

SPILLS AND ACCIDENTAL RELEASES:	SWEEP OR SHOVEL INTO A WASTE CONTAINER
WASTE DISPOSAL METHOD:	DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. THIS IS A BIOLOGICALLY ACTIVE MATERIAL. DISPOSE OF ON SITE OR AT AN APPROVED DISPOSAL FACILITY IN ACCORDANCE WITH LOCAL,STATE,AND/OR FEDERAL REGULATIONS.
HANDLING AND STORAGE:	STORE AT ROOM TEMPERATURE, BETWEEN 59 AND 86 DEGREES F.

. . . SECTION 8 CONTROL MEASURES . . . . . .

NO SPECIAL CONTROL MEASURES ARE REQUIRED UNDER NORMAL CONDITIONS OF USE

RESPIRATORY PROTECTION	NONE REQUIRED
VENTILATION	NO SPECIAL VENTILATION IS REQUIRED
PROTECTIVE CLOTHING OR EQUIPMENT	AVOID CONTACT WITH EYES OR PROLONGED CONTACT WITH SKIN.
WORK/HYGIENIC PRACTICES	WASH THOROUGHLY AFTER HANDLING

. . . . . .

THE INFORMATION CONTAINED IN THIS MSDS IS, TO THE BEST OF A.H.ROBINS' KNOWLEDGE, COMPLETE AND ACCURATE. A.H.ROBINS, HOWEVER, USES MANY SOURCES AND REFERENCES FOR GATHERING THIS INFORMATION. THUS, A.H. ROBINS CANNOT GUARANTEE COMPLETENESS OR ACCURACY AND DISCLAIMS ALL LIABILITY FOR ITS HANDLING AND USE.

FILE/DONNAZYM/TABLETS . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS) EFFECTIVE 05/28/87

DOPRAM INJECTABLE NDC 0031-4849-XX

. . . SECTION 1 MANUFACTURER INFORMATION . . . . . .

A. H. ROBINS CO.,INC. 1405 CUMMINGS DRIVE RICHMOND, VA 23261-6609

EMERGENCY TELEPHONE: (804) 257-2000 (8:30 AM - 5:00 PM)
(804) 257-2000 (AFTER HOURS)

. . . SECTION 2 COMPOSITION INFORMATION . . . . . .

HAZARDOUS INGREDIENTS:
AS FORMULATED, THIS FINISHED PHARMACEUTICAL PRODUCT DOES NOT CONSTITUTE A PHYSICAL HAZARD WITHIN THE MEANING OF 29 CFR SEC 1910.1200. POTENTIAL HEALTH HAZARDS FROM INGESTION OR EXPOSURE TO THE PRODUCT ARE DISCUSSED IN SECTION 6 BELOW.

ACTIVE INGREDIENTS:		CAS
EACH ML CONTAINS:		
DOXAPRAM HCL, USP	20MG	7081-53-0

INACTIVE INGREDIENTS:
EACH ML CONTAINS:
WATER FOR INJECTION USP, BENZYL ALCOHOL AS PRESERVATIVE (0.9%)

. . . SECTION 3 PHYSICAL/CHEMICAL CHARACTERISTICS . . . . . .

BOILING POINT	CA 100 DEGREES C.
VAPOR PRESSURE	NOT APPLICABLE
VAPOR DENSITY	NOT APPLICABLE
SOLUBILITY IN WATER	SOLUBLE
SPECIFIC GRAVITY	CA 1.0
MELTING POINT	NOT APPLICABLE
EVAPORATION RATE	NOT APPLICABLE
APPEARANCE	A CLEAR, COLORLESS, SOLUTION

. . . SECTION 4 FIRE AND EXPLOSION HAZARD DATA . . . . . .

FLASH POINT	NOT APPLICABLE
METHOD USED	NOT APPLICABLE
FLAMMABLE LIMITS	
LEL	NOT APPLICABLE
UEL	NOT APPLICABLE
EXTINGUISHING MEDIA	NOT APPLICABLE
SPECIAL FIRE-FIGHTING PROCEDURES	NOT APPLICABLE
UNUSUAL FIRE AND EXPLOSION HAZARDS	NONE

. . . SECTION 5 REACTIVITY DATA . . . . . .

STABILITY	STABLE
INCOMPATABILITY	NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS	NONE KNOWN
HAZARDOUS POLYMERIZATION	WILL NOT OCCUR

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

DOPRAM INJECTABLE NDC 0031-4849-XX

. . . SECTION 6 HEALTH HAZARD DATA . . . . . .

ROUTES OF ENTRY:		INGESTION SKIN- IT IS NOT KNOWN IF DOXAPRAM IS ABSORBED THROUGH THE SKIN FROM DOPRAM INJECTABLE
CARCINOGENICITY:		NONE OF THE COMPONENTS IN THIS PRODUCT ARE KNOWN TO BE CARCINOGENIC
SIGNS AND SYMPTOMS OF OVER-EXPOSURE:	DOXAPRAM	OVERDOSAGE MAY PRODUCE EXAGGERATION OF THE EFFECTS SEEN WHEN THE DRUG IS ADMINISTERED FOR TREATMENT. HIGH BLOOD PRESSURE, RAPID HEART BEAT, EXAGGERATED MUSCLE MOVEMENTS AND REFLEXES MAY BE EARLY SIGNS OF OVERDOSAGE (SEE ATTACHED PRODUCT LABELING FOR FULL INFORMATION ON SIDE-EFFECTS)
EMERGENCY AND FIRST-AID PROCEDURES:		EYE CONTACT- IRRIGATE SURFACES WITH WATER FOR 15 MINUTES. SKIN CONTACT- WASH AREAS WITH SOAP AND WATER. TREATMENT OF OVERDOSE: SYMPTOMATIC AND SUPPORTIVE TREATMENT AS REQUIRED. SHORT-ACTING IV BARBITURATES, OXYGEN, AND RESUSCITATIVE EQUIPMENT SHOULD BE USED AS NEEDED
MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:		HYPERSENSITIVITY TO ANY OF THE COMPONENTS

FOR COMPLETE INFORMATION ON THIS DRUG PLEASE REFER TO THE ATTACHED PRODUCT LABELING

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

DOPRAM INJECTABLE NDC 0031-4849-XX

. . . SECTION 7 PRECAUTIONS FOR SAFE HANDLING AND USE . . . . . .

SPILLS AND ACCIDENTAL RELEASES:	SOAK UP ON ABSORBANT MATERIAL AND PLACE IN APPROVED WASTE CONTAINER. WASH AREAS WITH SOAP AND WATER.
WASTE DISPOSAL METHOD:	DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. THIS IS A BIOLOGICALLY ACTIVE MATERIAL. DISPOSE OF ON SITE OR AT AN APPROVED DISPOSAL FACILITY IN ACCORDANCE WITH LOCAL,STATE,AND/OR FEDERAL REGULATIONS.
HANDLING AND STORAGE:	STORE AT ROOM TEMPERATURE, BETWEEN 59 AND 86 DEGREES F.

. . . SECTION 8 CONTROL MEASURES . . . . . .

NO SPECIAL CONTROL MEASURES ARE REQUIRED UNDER NORMAL CONDITIONS OF USE

RESPIRATORY PROTECTION	NONE REQUIRED
VENTILATION	NO SPECIAL VENTILATION IS REQUIRED
PROTECTIVE CLOTHING OR EQUIPMENT	AVOID CONTACT WITH EYES OR PROLONGED CONTACT WITH SKIN.
WORK/HYGIENIC PRACTICES	WASH THOROUGHLY AFTER HANDLING

. . . . . .

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FILE/DOPRAM/INJECT. . . . . .

MATERIAL SAFETY DATA SHEET (MSDS) EFFECTIVE 01/04/88

ENTOLASE CAPSULES NDC 0031-5025-XX

. . . SECTION 1 MANUFACTURER INFORMATION . . . . . .

A. H. ROBINS CO.,INC. 1405 CUMMINGS DRIVE RICHMOND, VA 23261-6609

EMERGENCY TELEPHONE: (804) 257-2000 (8:30 AM - 5:00 PM)
(804) 257-2000 (AFTER HOURS)

. . . SECTION 2 COMPOSITION INFORMATION . . . . . .

HAZARDOUS INGREDIENTS:
AS FORMULATED, THIS FINISHED PHARMACEUTICAL PRODUCT DOES NOT CONSTITUTE A PHYSICAL HAZARD WITHIN THE MEANING OF 29 CFR SEC 1910.1200. POTENTIAL HEALTH HAZARDS FROM INGESTION OR EXPOSURE TO THE PRODUCT ARE DISCUSSED IN SECTION 6 BELOW.

ACTIVE INGREDIENTS: EACH TABLET CONTAINS:		CAS
PANCRELIPASE, USP (EQUIVALENT TO THE FOLLOWING):		53608-75-6
LIPASE, USP	4,000 UNITS	
PROTEASE, USP	25,000 UNITS	
AMYLASE, USP	20,000 UNITS	

INACTIVE INGREDIENTS:
CELLULOSE ACETATE PHTHALATE, CORN STARCH, EDIBLE INKS, GELATIN, POVIDONE, SIMETHICONE, SODIUM CHLORIDE, STEARIC ACID, SUCROSE, TALC, TITANIUM DIOXIDE.

. . . SECTION 3 PHYSICAL/CHEMICAL CHARACTERISTICS . . . . . .

BOILING POINT	NOT APPLICABLE
VAPOR PRESSURE	NOT APPLICABLE
VAPOR DENSITY	NOT APPLICABLE
SOLUBILITY IN WATER	NOT APPLICABLE
SPECIFIC GRAVITY	NOT APPLICABLE
MELTING POINT	NOT APPLICABLE
EVAPORATION RATE	NOT APPLICABLE
APPEARANCE	MICROBEADS CONTAINED IN WHITE AND CLEAR CAPSULES, MONOGRAMMED ENTOLASE AND AHR

. . . SECTION 4 FIRE AND EXPLOSION HAZARD DATA . . . . . .

FLASH POINT	NOT APPLICABLE
METHOD USED	NOT APPLICABLE
FLAMMABLE LIMITS	
LEL	NOT APPLICABLE
UEL	NOT APPLICABLE
EXTINGUISHING MEDIA	NOT APPLICABLE
SPECIAL FIRE-FIGHTING PROCEDURES	NOT APPLICABLE
UNUSUAL FIRE AND EXPLOSION HAZARDS	NONE

. . . SECTION 5 REACTIVITY DATA . . . . . .

STABILITY	STABLE
INCOMPATABILITY	NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS	NONE KNOWN
HAZARDOUS POLYMERIZATION	WILL NOT OCCUR

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

ENTOLASE CAPSULES NDC 0031-5025-XX

. . . SECTION 6 HEALTH HAZARD DATA . . . . . .

ROUTES OF ENTRY:	INGESTION
CARCINOGENICITY:	NONE OF THE COMPONENTS IN THIS PRODUCT ARE KNOWN TO BE CARCINOGENIC
SIGNS AND SYMPTOMS OF OVEREXPOSURE: PANCRELIPASE	OVERDOSAGE MAY CAUSE DIARRHEA OR TRANSIENT INTESTINAL UPSET. (SEE ATTACHED PRODUCT LABELING FOR FULL INFORMATION ON SIDE-EFFECTS)
EMERGENCY AND FIRST-AID PROCEDURES:	EYE CONTACT- IRRIGATE SURFACES WITH WATER FOR 15 MINUTES. SKIN CONTACT- WASH AREAS WITH SOAP AND WATER. TREATMENT OF OVERDOSE: SYMPTOMATIC TREATMENT, AS REQUIRED
MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:	HYPERSENSITIVITY TO ANY OF THE COMPONENTS, ESPECIALLY TO PORK PROTEIN

FOR COMPLETE INFORMATION ON THIS DRUG PLEASE REFER TO THE ATTACHED PRODUCT LABELING

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

ENTOLASE CAPSULES NDC 0031-5025-XX

. . . SECTION 7 PRECAUTIONS FOR SAFE HANDLING AND USE . . . . . .

SPILLS AND ACCIDENTAL RELEASES:	SWEEP OR SHOVEL INTO A WASTE CONTAINER
WASTE DISPOSAL METHOD:	DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. THIS IS A BIOLOGICALLY ACTIVE MATERIAL. DISPOSE OF ON SITE OR AT AN APPROVED DISPOSAL FACILITY IN ACCORDANCE WITH LOCAL,STATE,AND/OR FEDERAL REGULATIONS.
HANDLING AND STORAGE:	STORE AT ROOM TEMPERATURE, BETWEEN 59 AND 86 DEGREES F.

. . . SECTION 8 CONTROL MEASURES . . . . . .

NO SPECIAL CONTROL MEASURES ARE REQUIRED UNDER NORMAL CONDITIONS OF USE

RESPIRATORY PROTECTION	NONE REQUIRED
VENTILATION	NO SPECIAL VENTILATION IS REQUIRED
PROTECTIVE CLOTHING OR EQUIPMENT	AVOID CONTACT WITH EYES OR PROLONGED CONTACT WITH SKIN.
WORK/HYGIENIC PRACTICES	WASH THOROUGHLY AFTER HANDLING

. . . . . .

THE INFORMATION CONTAINED IN THIS MSDS IS, TO THE BEST OF A.H.ROBINS' KNOWLEDGE, COMPLETE AND ACCURATE. A.H.ROBINS, HOWEVER, USES MANY SOURCES AND REFERENCES FOR GATHERING THIS INFORMATION. THUS, A.H. ROBINS CANNOT GUARANTEE COMPLETENESS OR ACCURACY AND DISCLAIMS ALL LIABILITY FOR ITS HANDLING AND USE.

FILE/ENTOLASE/CAPSULES . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS) EFFECTIVE 01/04/88

ENTOLASE-HP CAPSULES NDC 0031-5035-XX

. . . SECTION 1 MANUFACTURER INFORMATION . . . . . .

A. H. ROBINS CO.,INC. 1405 CUMMINGS DRIVE RICHMOND, VA 23261-6609

EMERGENCY TELEPHONE: (804) 257-2000 (8:30 AM - 5:00 PM)
(804) 257-2000 (AFTER HOURS)

. . . SECTION 2 COMPOSITION INFORMATION . . . . . .

HAZARDOUS INGREDIENTS:
AS FORMULATED, THIS FINISHED PHARMACEUTICAL PRODUCT DOES NOT CONSTITUTE A PHYSICAL HAZARD WITHIN THE MEANING OF 29 CFR SEC 1910.1200. POTENTIAL HEALTH HAZARDS FROM INGESTION OR EXPOSURE TO THE PRODUCT ARE DISCUSSED IN SECTION 6 BELOW.

ACTIVE INGREDIENTS: EACH TABLET CONTAINS:		CAS
PANCRELIPASE, USP (EQUIVALENT TO THE FOLLOWING):		53608-75-6
LIPASE, USP	8,000 UNITS	
PROTEASE, USP	50,000 UNITS	
AMYLASE, USP	40,000 UNITS	

INACTIVE INGREDIENTS:
CELLULOSE ACETATE PHTHALATE, CORN STARCH, EDIBLE INKS, GELATIN, IRON OXIDE, POVIDONE, SIMETHICONE, SODIUM CHLORIDE, STEARIC ACID, SUCROSE, TALC, TITANIUM DIOXIDE.

. . . SECTION 3 PHYSICAL/CHEMICAL CHARACTERISTICS . . . . . .

BOILING POINT	NOT APPLICABLE
VAPOR PRESSURE	NOT APPLICABLE
VAPOR DENSITY	NOT APPLICABLE
SOLUBILITY IN WATER	NOT APPLICABLE
SPECIFIC GRAVITY	NOT APPLICABLE
MELTING POINT	NOT APPLICABLE
EVAPORATION RATE	NOT APPLICABLE
APPEARANCE	MICROBEADS CONTAINED IN BROWN AND CLEAR CAPSULES, MONOGRAMMED ENTOLASE HP AND AMR

. . . SECTION 4 FIRE AND EXPLOSION HAZARD DATA . . . . . .

FLASH POINT	NOT APPLICABLE
METHOD USED	NOT APPLICABLE
FLAMMABLE LIMITS	
LEL	NOT APPLICABLE
UEL	NOT APPLICABLE
EXTINGUISHING MEDIA	NOT APPLICABLE
SPECIAL FIRE-FIGHTING PROCEDURES	NOT APPLICABLE
UNUSUAL FIRE AND EXPLOSION HAZARDS	NONE

. . . SECTION 5 REACTIVITY DATA . . . . . .

STABILITY	STABLE
INCOMPATABILITY	NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS	NONE KNOWN
HAZARDOUS POLYMERIZATION	WILL NOT OCCUR

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

ENTOLASE-HP CAPSULES NDC 0031-5035-XX

. . . SECTION 6 HEALTH HAZARD DATA . . . . . .

ROUTES OF ENTRY:	INGESTION
CARCINOGENICITY:	NONE OF THE COMPONENTS IN THIS PRODUCT ARE KNOWN TO BE CARCINOGENIC
SIGNS AND SYMPTOMS OF OVEREXPOSURE: PANCRELIPASE	OVERDOSAGE MAY CAUSE DIARRHEA OR TRANSIENT INTESTINAL UPSET. (SEE ATTACHED PRODUCT LABELING FOR FULL INFORMATION ON SIDE-EFFECTS)
EMERGENCY AND FIRST-AID PROCEDURES:	EYE CONTACT- IRRIGATE SURFACES WITH WATER FOR 15 MINUTES. SKIN CONTACT- WASH AREAS WITH SOAP AND WATER. TREATMENT OF OVERDOSE: SYMPTOMATIC TREATMENT, AS REQUIRED
MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:	HYPERSENSITIVITY TO ANY OF THE COMPONENTS, ESPECIALLY TO PORK PROTEIN

FOR COMPLETE INFORMATION ON THIS DRUG PLEASE REFER TO THE ATTACHED PRODUCT LABELING

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

ENTOLASE-HP CAPSULES NDC 0031-5035-XX

. . . SECTION 7 PRECAUTIONS FOR SAFE HANDLING AND USE . . . . . .

SPILLS AND ACCIDENTAL RELEASES:	SWEEP OR SHOVEL INTO A WASTE CONTAINER
WASTE DISPOSAL METHOD:	DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. THIS IS A BIOLOGICALLY ACTIVE MATERIAL. DISPOSE OF ON SITE OR AT AN APPROVED DISPOSAL FACILITY IN ACCORDANCE WITH LOCAL,STATE,AND/OR FEDERAL REGULATIONS.
HANDLING AND STORAGE:	STORE AT ROOM TEMPERATURE, BETWEEN 59 AND 86 DEGREES F.

. . . SECTION 8 CONTROL MEASURES . . . . . .

NO SPECIAL CONTROL MEASURES ARE REQUIRED UNDER NORMAL CONDITIONS OF USE

RESPIRATORY PROTECTION	NONE REQUIRED
VENTILATION	NO SPECIAL VENTILATION IS REQUIRED
PROTECTIVE CLOTHING OR EQUIPMENT	AVOID CONTACT WITH EYES OR PROLONGED CONTACT WITH SKIN.
WORK/HYGIENIC PRACTICES	WASH THOROUGHLY AFTER HANDLING

. . . . . .

THE INFORMATION CONTAINED IN THIS MSDS IS, TO THE BEST OF A.H.ROBINS' KNOWLEDGE, COMPLETE AND ACCURATE. A.H.ROBINS, HOWEVER, USES MANY SOURCES AND REFERENCES FOR GATHERING THIS INFORMATION. THUS, A.H. ROBINS CANNOT GUARANTEE COMPLETENESS OR ACCURACY AND DISCLAIMS ALL LIABILITY FOR ITS HANDLING AND USE.

FILE/ENTOLASE/HPCAPS . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS) EFFECTIVE 06/24/87

ENTOZYME TABLETS NDC 0031-5049-XX

. . . SECTION 1 MANUFACTURER INFORMATION . . . .

A. H. ROBINS CO.,INC. 1405 CUMMINGS DRIVE RICHMOND, VA 23261-6609

EMERGENCY TELEPHONE: (804) 257-2000 (8:30 AM - 5:00 PM)
(804) 257-2000 (AFTER HOURS)

. . . SECTION 2 COMPOSITION INFORMATION . . . .

HAZARDOUS INGREDIENTS:
AS FORMULATED, THIS FINISHED PHARMACEUTICAL PRODUCT DOES NOT CONSTITUTE A PHYSICAL HAZARD WITHIN THE MEANING OF 29 CFR SEC 1910.1200. POTENTIAL HEALTH HAZARDS FROM INGESTION OR EXPOSURE TO THE PRODUCT ARE DISCUSSED IN SECTION 6 BELOW.

ACTIVE INGREDIENTS: EACH TABLET CONTAINS:		CAS
PANCREATIN, USP EQUIVALENT	300 MG	8049-47-6
PEPSIN	250 MG	9001-75-6
BILE SALTS	150 MG	-

INACTIVE INGREDIENTS:
ACACIA, ACETYLATED MONOGLYCERIDES, CALCIUM CARBONATE, CALCIUM SULFATE, CARNAUBA WAX, CELLULOSE ACETATE PHTHALATE, CORN STARCH, DIETHYL PHTHALATE, EDIBLE INK, FD&C BLUE 2 ALUMINUM LAKE, GELATIN, MICROCRYSTALLINE CELLULOSE, POLYSORBATES, SHELLAC, STEARIC ACID, SUCROSE, TARTARIC ACID, TITANIUM DIOXIDE, WHITE WAX, MAY CONTAIN FD&C RED 40 AND YELLOW 6 ALUMINUM LAKES

. . . SECTION 3 PHYSICAL/CHEMICAL CHARACTERISTICS . . . .

BOILING POINT	NOT APPLICABLE
VAPOR PRESSURE	NOT APPLICABLE
VAPOR DENSITY	NOT APPLICABLE
SOLUBILITY IN WATER	NOT APPLICABLE
SPECIFIC GRAVITY	NOT APPLICABLE
MELTING POINT	NOT APPLICABLE
EVAPORATION RATE	NOT APPLICABLE
APPEARANCE	WHITE TABLETS MONOGRAMMED AHR AND 5049

. . . SECTION 4 FIRE AND EXPLOSION HAZARD DATA . . . .

FLASH POINT	NOT APPLICABLE
METHOD USED	NOT APPLICABLE
FLAMMABLE LIMITS	
LEL	NOT APPLICABLE
UEL	NOT APPLICABLE
EXTINGUISHING MEDIA	NOT APPLICABLE
SPECIAL FIRE-FIGHTING PROCEDURES	NOT APPLICABLE
UNUSUAL FIRE AND EXPLOSION HAZARDS	NONE

. . . SECTION 5 REACTIVITY DATA . . . .

STABILITY	STABLE
INCOMPATABILITY	NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS	NONE KNOWN
HAZARDOUS POLYMERIZATION	WILL NOT OCCUR

. . . . . CONTINUED . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

ENTOZYME TABLETS NDC 0031-5049-XX

. . . SECTION 6 HEALTH HAZARD DATA . . . . . .

ROUTES OF ENTRY:	INGESTION
CARCINOGENICITY:	NONE OF THE COMPONENTS IN THIS PRODUCT ARE KNOWN TO BE CARCINOGENIC
SIGNS AND SYMPTOMS OF OVEREXPOSURE: ENTOZYME	SKIN RASH. HIGH DOSES MAY PRODUCE A LAXATIVE EFFECT; SYSTEMIC TOXICITY IS NOT EXPECTED.
EMERGENCY AND FIRST-AID PROCEDURES:	EYE CONTACT- IRRIGATE SURFACES WITH WATER FOR 15 MINUTES. SKIN CONTACT- WASH AREAS WITH SOAP AND WATER. TREATMENT OF OVERDOSE: SYMPTOMATIC AND SUPPORTIVE TREATMENT AS REQUIRED.
MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:	HYPERSENSITIVITY TO ANY OF THE COMPONENTS

FOR COMPLETE INFORMATION ON THIS DRUG PLEASE REFER TO THE ATTACHED PRODUCT LABELING

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

ENTOZYME TABLETS NDC 0031-5049-XX

. . . SECTION 7 PRECAUTIONS FOR SAFE HANDLING AND USE . . . . . .

SPILLS AND ACCIDENTAL RELEASES:	SWEEP OR SHOVEL INTO A WASTE CONTAINER
WASTE DISPOSAL METHOD:	DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. THIS IS A BIOLOGICALLY ACTIVE MATERIAL. DISPOSE OF ON SITE OR AT AN APPROVED DISPOSAL FACILITY IN ACCORDANCE WITH LOCAL,STATE,AND/OR FEDERAL REGULATIONS.
HANDLING AND STORAGE:	STORE AT ROOM TEMPERATURE, BETWEEN 59 AND 86 DEGREES F.

. . . SECTION 8 CONTROL MEASURES . . . . . .

NO SPECIAL CONTROL MEASURES ARE REQUIRED UNDER NORMAL CONDITIONS OF USE

RESPIRATORY PROTECTION	NONE REQUIRED
VENTILATION	NO SPECIAL VENTILATION IS REQUIRED
PROTECTIVE CLOTHING OR EQUIPMENT	AVOID CONTACT WITH EYES OR PROLONGED CONTACT WITH SKIN.
WORK/HYGIENIC PRACTICES	WASH THOROUGHLY AFTER HANDLING

. . . . . .

THE INFORMATION CONTAINED IN THIS MSDS IS, TO THE BEST OF A.H.ROBINS' KNOWLEDGE, COMPLETE AND ACCURATE. A.H.ROBINS, HOWEVER, USES MANY SOURCES AND REFERENCES FOR GATHERING THIS INFORMATION. THUS, A.H. ROBINS CANNOT GUARANTEE COMPLETENESS OR ACCURACY AND DISCLAIMS ALL LIABILITY FOR ITS HANDLING AND USE.

FILE/ENTOZYME/TABLETS . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS) EFFECTIVE 05/28/87

EXNA NDC 0031-5449-XX

. . . SECTION 1 MANUFACTURER INFORMATION . . . . . .

A. H. ROBINS CO.,INC. 1405 CUMMINGS DRIVE RICHMOND, VA 23261-6609

EMERGENCY TELEPHONE: (804) 257-2000 (8:30 AM - 5:00 PM)
(804) 257-2000 (AFTER HOURS)

. . . SECTION 2 COMPOSITION INFORMATION . . . . . .

HAZARDOUS INGREDIENTS:
AS FORMULATED, THIS FINISHED PHARMACEUTICAL PRODUCT DOES NOT CONSTITUTE A PHYSICAL HAZARD WITHIN THE MEANING OF 29 CFR SEC 1910.1200. POTENTIAL HEALTH HAZARDS FROM INGESTION OR EXPOSURE TO THE PRODUCT ARE DISCUSSED IN SECTION 6 BELOW.

ACTIVE INGREDIENTS:		CAS
BENZTHIAZIDE, USP	50MG	91-33-8

INACTIVE INGREDIENTS:
CORN STARCH, DIBASIC CALCIUM PHOSPHATE, FD&C YELLOW 5, LACTOSE, MAGNESIUM STEARATE, POLYETHYLENE GLYCOL, SODIUM LARYL SULFATE

. . . SECTION 3 PHYSICAL/CHEMICAL CHARACTERISTICS . . . . . .

BOILING POINT	NOT APPLICABLE
VAPOR PRESSURE	NOT APPLICABLE
VAPOR DENSITY	NOT APPLICABLE
SOLUBILITY IN WATER	NOT APPLICABLE
SPECIFIC GRAVITY	NOT APPLICABLE
MELTING POINT	NOT APPLICABLE
EVAPORATION RATE	NOT APPLICABLE
APPEARANCE	ROUND, YELLOW, SCORED TABLETS ENGRAVED AHR AND 5449

. . . SECTION 4 FIRE AND EXPLOSION HAZARD DATA . . . . . .

FLASH POINT	NOT APPLICABLE
METHOD USED	NOT APPLICABLE
FLAMMABLE LIMITS	
LEL	NOT APPLICABLE
UEL	NOT APPLICABLE
EXTINGUISHING MEDIA	NOT APPLICABLE
SPECIAL FIRE-FIGHTING PROCEDURES	NOT APPLICABLE
UNUSUAL FIRE AND EXPLOSION HAZARDS	NONE

. . . SECTION 5 REACTIVITY DATA . . . . . .

STABILITY	STABLE
INCOMPATABILITY	NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS	NONE KNOWN
HAZARDOUS POLYMERIZATION	WILL NOT OCCUR

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

EXNA NDC 0031-5449-XX

. . . SECTION 6 HEALTH HAZARD DATA . . . . . .

	ROUTES OF ENTRY:	INGESTION
	CARCINOGENICITY:	NONE OF THE COMPONENTS IN THIS PRODUCT ARE KNOWN TO BE CARCINOGENIC
SIGNS AND SYMPTOMS OF OVER-EXPOSURE:	BENZTHIAZIDE	CONFUSION, DIZZINESS, MUSCULAR WEAKNESS, AND GASTOINTESTINAL DISTURBANCES, AS MIGHT BE SEEN IN ELECTROLYTE IMBALANCE OR POTASSIUM DEFICIENCY (SEE ATTACHED PRODUCT LABELING FOR FULL INFORMATION ON SIDE-EFFECTS)
	EMERGENCY AND FIRST-AID PROCEDURES:	EYE CONTACT- IRRIGATE SURFACES WITH WATER FOR 15 MINUTES. SKIN CONTACT- WASH AREAS WITH SOAP AND WATER. TREATMENT OF OVERDOSE: SYMPTOMATIC AND SUPPORTIVE TREATMENT AS REQUIRED. REPLACEMENT OF FLUIDS AND ELECTROLYTES MAY BE INDICATED
	MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:	HYPERSENSITIVITY TO ANY OF THE COMPONENTS. THIS PRODUCT CONTAINS FD&C YELLOW 5 (TARTRAZINE), AND SHOULD BE AVOIDED BY INDIVIDUALS ALLERGIC TO TARTRAZINE OR ASPIRIN.

FOR COMPLETE INFORMATION ON THIS DRUG PLEASE REFER TO THE ATTACHED PRODUCT LABELING

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

EXNA NDC 0031-5449-XX

. . . SECTION 7 PRECAUTIONS FOR SAFE HANDLING AND USE . . . . . .

SPILLS AND ACCIDENTAL RELEASES:	SWEEP OR SHOVEL INTO A WASTE CONTAINER
WASTE DISPOSAL METHOD:	DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. THIS IS A BIOLOGICALLY ACTIVE MATERIAL. DISPOSE OF ON SITE OR AT AN APPROVED DISPOSAL FACILITY IN ACCORDANCE WITH LOCAL,STATE,AND/OR FEDERAL REGULATIONS.
HANDLING AND STORAGE:	STORE AT ROOM TEMPERATURE, BETWEEN 59 AND 86 DEGREES F.

. . . SECTION 8 CONTROL MEASURES . . . . . .

NO SPECIAL CONTROL MEASURES ARE REQUIRED UNDER NORMAL CONDITIONS OF USE

RESPIRATORY PROTECTION	NONE REQUIRED
VENTILATION	NO SPECIAL VENTILATION IS REQUIRED
PROTECTIVE CLOTHING OR EQUIPMENT	AVOID CONTACT WITH EYES OR PROLONGED CONTACT WITH SKIN.
WORK/HYGIENIC PRACTICES	WASH THOROUGHLY AFTER HANDLING

. . . . . .

THE INFORMATION CONTAINED IN THIS MSDS IS, TO THE BEST OF A.H.ROBINS' KNOWLEDGE, COMPLETE AND ACCURATE. A.H.ROBINS, HOWEVER, USES MANY SOURCES AND REFERENCES FOR GATHERING THIS INFORMATION. THUS, A.H. ROBINS CANNOT GUARANTEE COMPLETENESS OR ACCURACY AND DISCLAIMS ALL LIABILITY FOR ITS HANDLING AND USE.

FILE/EXNA/TABLETS . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS) EFFECTIVE 03/10/87

MICRO-K EXTENCAPS, 750MG (10 MEQ) NDC 0031-5730-XX

. . . SECTION 1 MANUFACTURER INFORMATION . . . . . .

A. H. ROBINS CO.,INC. 1405 CUMMINGS DRIVE RICHMOND, VA 23261-6609

EMERGENCY TELEPHONE: (804) 257-2000 (8:30 AM - 5:00 PM)
(804) 257-2000 (AFTER HOURS)

. . . SECTION 2 COMPOSITION INFORMATION . . . . . .

HAZARDOUS INGREDIENTS:
AS FORMULATED, THIS FINISHED PHARMACEUTICAL PRODUCT DOES NOT CONSTITUTE A PHYSICAL HAZARD WITHIN THE MEANING OF 29 CFR SEC 1910.1200. POTENTIAL HEALTH HAZARDS FROM INGESTION OR EXPOSURE TO THE PRODUCT ARE DISCUSSED IN SECTION 6 BELOW.

ACTIVE INGREDIENTS:		CAS
POTASSIUM CHLORIDE	750MG (10 MEQ POTASSIUM)	7447-40-7

INACTIVE INGREDIENTS:
EDIBLE INK, ETHYLCELLULOSE, FD&C BLUE 2 ALUMINUM LAKE, FD&C YELLOW 6, GELATIN, MAGNESIUM STEARATE, SODIUM LAURYL SULFATE, TITANIUM DIOXIDE. MAY CONTAIN FD&C RED 40 AND YELLOW 6 ALUMINUM LAKES.

. . . SECTION 3 PHYSICAL/CHEMICAL CHARACTERISTICS . . . . . .

BOILING POINT	NOT APPLICABLE
VAPOR PRESSURE	NOT APPLICABLE
VAPOR DENSITY	NOT APPLICABLE
SOLUBILITY IN WATER	NOT APPLICABLE
SPECIFIC GRAVITY	NOT APPLICABLE
MELTING POINT	NOT APPLICABLE
EVAPORATION RATE	NOT APPLICABLE
APPEARANCE	PALE ORANGE AND OPAQUE WHITE HARD GELATIN CAPSULES MONOGRAMMED MICRO-K 10 AND AHR/5730

. . . SECTION 4 FIRE AND EXPLOSION HAZARD DATA . . . . . .

FLASH POINT	NOT APPLICABLE
METHOD USED	NOT APPLICABLE
FLAMMABLE LIMITS	
LEL	NOT APPLICABLE
UEL	NOT APPLICABLE
EXTINGUISHING MEDIA	NOT APPLICABLE
SPECIAL FIRE-FIGHTING PROCEDURES	NOT APPLICABLE
UNUSUAL FIRE AND EXPLOSION HAZARDS	NONE

. . . SECTION 5 REACTIVITY DATA . . . . . .

STABILITY	STABLE
INCOMPATABILITY	NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS	NONE KNOWN
HAZARDOUS POLYMERIZATION	WILL NOT OCCUR

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

MICRO-K EXTENCAPS, 750MG (10 MEQ) NDC 0031-5730-XX

. . . SECTION 6 HEALTH HAZARD DATA . . . . . .

ROUTES OF ENTRY:		INGESTION
CARCINOGENICITY:		NONE OF THE COMPONENTS IN THIS PRODUCT ARE KNOWN TO BE CARCINOGENIC
SIGNS AND SYMPTOMS OF OVER-EXPOSURE:	POTASSIUM CHLORIDE	HYPERKALEMIA IS USUALLY ASYMPTOMATIC AND MAY BE MANIFESTED ONLY BY AN INCREASED SERUM POTASSIUM CONCENTRATION AND CHARACTERISTIC ECG CHANGES (PEAKING OF T WAVES, LOSS OF P WAVE, DEPRESSION OF ST SEGMENT, AND PROLONGATION OF THE QT INTERVAL). LATE MANIFESTATIONS INCLUDE MUSCLE PARALYSIS AND CARDIOVASCULAR COLLAPSE FROM CARDIAC ARREST. THE MOST COMMON ADVERSE REACTIONS TO POTASSIUM SALTS ARE NAUSEA, VOMITING, ABDOMINAL DISCOMFORT, AND DIARRHEA. (SEE ATTACHED PRODUCT LABELING FOR FULL INFORMATION ON SIDE-EFFECTS)
EMERGENCY AND FIRST-AID PROCEDURES:		EYE CONTACT- IRRIGATE SURFACES WITH WATER FOR 15 MINUTES. SKIN CONTACT- WASH AREAS WITH SOAP AND WATER. TREATMENT OF OVERDOSE: INTRAVENOUS ADMINISTRATION OF 300 - 500 ML PER HOUR OF 10% DEXTROSE SOLUTION CONTAINING 10 TO 20 UNITS OF INSULIN PER 1000ML; CORRECTION OF ACIDOSIS, IF PRESENT, WITH INTRAVENOUS SODIUM BICARBONATE; USE OF EXCHANGE RESINS, HEMODIALYSIS, OR PERITONEAL DIALYSIS.
MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:		HYPERSENSITIVITY TO ANY OF THE COMPONENTS; IN PATIENTS WITH IMPAIRED MECHANISMS FOR EXCRETING POTASSIUM THE INGESTION OF POTASSIUM SALTS CAN PRODUCE HYPERKALEMIA AND CARDIAC ARREST.

FOR COMPLETE INFORMATION ON THIS DRUG PLEASE REFER TO THE ATTACHED PRODUCT LABELING

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

MICRO-K EXTENCAPS, 750MG (10 MEQ) NDC 0031-5730-XX

. . . SECTION 7 PRECAUTIONS FOR SAFE HANDLING AND USE . . . . . .

SPILLS AND ACCIDENTAL RELEASES:	SWEEP OR SHOVEL INTO A WASTE CONTAINER
WASTE DISPOSAL METHOD:	DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. THIS IS A BIOLOGICALLY ACTIVE MATERIAL. DISPOSE OF ON SITE OR AT AN APPROVED DISPOSAL FACILITY IN ACCORDANCE WITH LOCAL, STATE, AND/OR FEDERAL REGULATIONS.
HANDLING AND STORAGE:	STORE AT ROOM TEMPERATURE, BETWEEN 59 AND 86 DEGREES F.

. . . SECTION 8 CONTROL MEASURES . . . . . .

NO SPECIAL CONTROL MEASURES ARE REQUIRED UNDER NORMAL CONDITIONS OF USE

RESPIRATORY PROTECTION	NONE REQUIRED
VENTILATION	NO SPECIAL VENTILATION IS REQUIRED
PROTECTIVE CLOTHING OR EQUIPMENT	AVOID CONTACT WITH EYES OR PROLONGED CONTACT WITH SKIN.
WORK/HYGIENIC PRACTICES	WASH THOROUGHLY AFTER HANDLING

. . . . . .

THE INFORMATION CONTAINED IN THIS MSDS IS, TO THE BEST OF A.H.ROBINS' KNOWLEDGE, COMPLETE AND ACCURATE. A.H.ROBINS, HOWEVER, USES MANY SOURCES AND REFERENCES FOR GATHERING THIS INFORMATION. THUS, A.H. ROBINS CANNOT GUARANTEE COMPLETENESS OR ACCURACY AND DISCLAIMS ALL LIABILITY FOR ITS HANDLING AND USE.

FILE/MICROK10/CAPSULES . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS) EFFECTIVE 03/10/87

MICRO-K EXTENCAPS, 600MG (8 MEQ) NDC 0031-5720-XX

. . . SECTION 1 MANUFACTURER INFORMATION . . . . . .

A. H. ROBINS CO.,INC. 1405 CUMMINGS DRIVE RICHMOND, VA 23261-6609

EMERGENCY TELEPHONE: (804) 257-2000 (8:30 AM - 5:00 PM)
(804) 257-2000 (AFTER HOURS)

. . . SECTION 2 COMPOSITION INFORMATION . . . . . .

HAZARDOUS INGREDIENTS:
AS FORMULATED, THIS FINISHED PHARMACEUTICAL PRODUCT DOES NOT CONSTITUTE A PHYSICAL HAZARD WITHIN THE MEANING OF 29 CFR SEC 1910.1200. POTENTIAL HEALTH HAZARDS FROM INGESTION OR EXPOSURE TO THE PRODUCT ARE DISCUSSED IN SECTION 6 BELOW.

ACTIVE INGREDIENTS:		CAS
POTASSIUM CHLORIDE	600MG (8 MEQ POTASSIUM)	7447-40-7

INACTIVE INGREDIENTS:
EDIBLE INK, ETHYLCELLULOSE, FD&C BLUE 2 ALUMINUM LAKE, FD&C YELLOW 6, GELATIN, MAGNESIUM STEARATE, SODIUM LAURYL SULFATE, TITANIUM DIOXIDE. MAY CONTAIN FD&C RED 40 AND YELLOW 6 ALUMINUM LAKES.

. . . SECTION 3 PHYSICAL/CHEMICAL CHARACTERISTICS . . . . . .

BOILING POINT	NOT APPLICABLE
VAPOR PRESSURE	NOT APPLICABLE
VAPOR DENSITY	NOT APPLICABLE
SOLUBILITY IN WATER	NOT APPLICABLE
SPECIFIC GRAVITY	NOT APPLICABLE
MELTING POINT	NOT APPLICABLE
EVAPORATION RATE	NOT APPLICABLE
APPEARANCE	PALE ORANGE, HARD GELATIN CAPSULES MONOGRAMMED MICRO-K AND AHR/5720

. . . SECTION 4 FIRE AND EXPLOSION HAZARD DATA . . . . . .

FLASH POINT	NOT APPLICABLE
METHOD USED	NOT APPLICABLE
FLAMMABLE LIMITS	
LEL	NOT APPLICABLE
UEL	NOT APPLICABLE
EXTINGUISHING MEDIA	NOT APPLICABLE
SPECIAL FIRE-FIGHTING PROCEDURES	NOT APPLICABLE
UNUSUAL FIRE AND EXPLOSION HAZARDS	NONE

. . . SECTION 5 REACTIVITY DATA . . . . . .

STABILITY	STABLE
INCOMPATABILITY	NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS	NONE KNOWN
HAZARDOUS POLYMERIZATION	WILL NOT OCCUR

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

MICRO-K EXTENCAPS, 600MG (8 MEQ) NDC 0031-5720-XX

. . . SECTION 6 HEALTH HAZARD DATA . . . . . .

	ROUTES OF ENTRY:	INGESTION
	CARCINOGENICITY:	NONE OF THE COMPONENTS IN THIS PRODUCT ARE KNOWN TO BE CARCINOGENIC
SIGNS AND SYMPTOMS OF OVER-EXPOSURE:	POTASSIUM CHLORIDE	HYPERKALEMIA IS USUALLY ASYMPTOMATIC AND MAY BE MANIFESTED ONLY BY AN INCREASED SERUM POTASSIUM CONCENTRATION AND CHARACTERISTIC ECG CHANGES (PEAKING OF T WAVES, LOSS OF P WAVE, DEPRESSION OF ST SEGMENT, AND PROLONGATION OF THE QT INTERVAL). LATE MANIFESTATIONS INCLUDE MUSCLE PARALYSIS AND CARDIOVASCULAR COLLAPSE FROM CARDIAC ARREST. THE MOST COMMON ADVERSE REACTIONS TO POTASSIUM SALTS ARE NAUSEA, VOMITING, ABDOMINAL DISCOMFORT, AND DIARRHEA. (SEE ATTACHED PRODUCT LABELING FOR FULL INFORMATION ON SIDE-EFFECTS)
	EMERGENCY AND FIRST-AID PROCEDURES:	EYE CONTACT- IRRIGATE SURFACES WITH WATER FOR 15 MINUTES. SKIN CONTACT- WASH AREAS WITH SOAP AND WATER. TREATMENT OF OVERDOSE: INTRAVENOUS ADMINISTRATION OF 300 - 500 ML PER HOUR OF 10% DEXTROSE SOLUTION CONTAINING 10 TO 20 UNITS OF INSULIN PER 1000ML; CORRECTION OF ACIDOSIS, IF PRESENT, WITH INTRAVENOUS SODIUM BICARBONATE; USE OF EXCHANGE RESINS, HEMODIALYSIS, OR PERITONEAL DIALYSIS.
	MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:	HYPERSENSITIVITY TO ANY OF THE COMPONENTS; IN PATIENTS WITH IMPAIRED MECHANISMS FOR EXCRETING POTASSIUM THE INGESTION OF POTASSIUM SALTS CAN PRODUCE HYPERKALEMIA AND CARDIAC ARREST.

FOR COMPLETE INFORMATION ON THIS DRUG PLEASE REFER TO THE ATTACHED PRODUCT LABELING

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

MICRO-K EXTENCAPS, 600MG (8 MEQ) NDC 0031-5720-XX

. . . SECTION 7 PRECAUTIONS FOR SAFE HANDLING AND USE . . . . . .

SPILLS AND ACCIDENTAL RELEASES:	SWEEP OR SHOVEL INTO A WASTE CONTAINER
WASTE DISPOSAL METHOD:	DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. THIS IS A BIOLOGICALLY ACTIVE MATERIAL. DISPOSE OF ON SITE OR AT AN APPROVED DISPOSAL FACILITY IN ACCORDANCE WITH LOCAL, STATE, AND/OR FEDERAL REGULATIONS.
HANDLING AND STORAGE:	STORE AT ROOM TEMPERATURE, BETWEEN 59 AND 86 DEGREES F.

. . . SECTION 8 CONTROL MEASURES . . . . . .

NO SPECIAL CONTROL MEASURES ARE REQUIRED UNDER NORMAL CONDITIONS OF USE

RESPIRATORY PROTECTION	NONE REQUIRED
VENTILATION	NO SPECIAL VENTILATION IS REQUIRED
PROTECTIVE CLOTHING OR EQUIPMENT	AVOID CONTACT WITH EYES OR PROLONGED CONTACT WITH SKIN.
WORK/HYGIENIC PRACTICES	WASH THOROUGHLY AFTER HANDLING

. . . . . .

THE INFORMATION CONTAINED IN THIS MSDS IS, TO THE BEST OF A.H.ROBINS' KNOWLEDGE, COMPLETE AND ACCURATE. A.H.ROBINS, HOWEVER, USES MANY SOURCES AND REFERENCES FOR GATHERING THIS INFORMATION. THUS, A.H. ROBINS CANNOT GUARANTEE COMPLETENESS OR ACCURACY AND DISCLAIMS ALL LIABILITY FOR ITS HANDLING AND USE.

FILE/MICROKB/CAPSULES . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS) EFFECTIVE 03/10/87

MITROLAN TABLETS NDC 0031-1535-XX

. . . SECTION 1 MANUFACTURER INFORMATION . . . . . .

A. H. ROBINS CO.,INC. 1405 CUMMINGS DRIVE RICHMOND, VA 23261-6609

EMERGENCY TELEPHONE: (804) 257-2000 (8:30 AM - 5:00 PM)
(804) 257-2000 (AFTER HOURS)

. . . SECTION 2 COMPOSITION INFORMATION . . . . . .

HAZARDOUS INGREDIENTS:
AS FORMULATED, THIS FINISHED PHARMACEUTICAL PRODUCT DOES NOT CONSTITUTE A PHYSICAL HAZARD WITHIN THE MEANING OF 29 CFR SEC 1910.1200. POTENTIAL HEALTH HAZARDS FROM INGESTION OR EXPOSURE TO THE PRODUCT ARE DISCUSSED IN SECTION 6 BELOW.

ACTIVE INGREDIENTS:	CAS
CALCIUM POLYCARBOPHIL, EQUIVALENT TO 500MG OF POLYCARBOPHIL, USP	9003-97-8

INACTIVE INGREDIENTS:
AMINOACETIC ACID, CORN STARCH, D&C YELLOW 10 ALUMINUM LAKE, FLAVORS, MAGNESIUM STEARATE, MANNITOL, POVIDONE, SUCROSE

. . . SECTION 3 PHYSICAL/CHEMICAL CHARACTERISTICS . . . . . .

BOILING POINT	NOT APPLICABLE
VAPOR PRESSURE	NOT APPLICABLE
VAPOR DENSITY	NOT APPLICABLE
SOLUBILITY IN WATER	NOT APPLICABLE
SPECIFIC GRAVITY	NOT APPLICABLE
MELTING POINT	NOT APPLICABLE
EVAPORATION RATE	NOT APPLICABLE
APPEARANCE	ROUND, YELLOW, TABLETS ENGRAVED AHR 1535

. . . SECTION 4 FIRE AND EXPLOSION HAZARD DATA . . . . . .

FLASH POINT	NOT APPLICABLE
METHOD USED	NOT APPLICABLE
FLAMMABLE LIMITS	
LEL	NOT APPLICABLE
UEL	NOT APPLICABLE
EXTINGUISHING MEDIA	NOT APPLICABLE
SPECIAL FIRE-FIGHTING PROCEDURES	NOT APPLICABLE
UNUSUAL FIRE AND EXPLOSION HAZARDS	NONE

. . . SECTION 5 REACTIVITY DATA . . . . . .

STABILITY	STABLE
INCOMPATABILITY	NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS	NONE KNOWN
HAZARDOUS POLYMERIZATION	WILL NOT OCCUR

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

MITROLAN TABLETS NDC 0031-1535-XX

. . . SECTION 6 HEALTH HAZARD DATA . . . . . .

ROUTES OF ENTRY:	INGESTION
CARCINOGENICITY:	NONE OF THE COMPONENTS IN THIS PRODUCT ARE KNOWN TO BE CARCINOGENIC
SIGNS AND SYMPTOMS OF OVEREXPOSURE: CALCIUM POLYCARBOPHIL	SYSTEMIC SIDE-EFFECTS WOULD NOT BE EXPECTED. ABDOMINAL FULLNESS MAY BE NOTED. (SEE ATTACHED PRODUCT LABELING FOR FULL INFORMATION ON SIDE-EFFECTS)
EMERGENCY AND FIRST-AID PROCEDURES:	EYE CONTACT- IRRIGATE SURFACES WITH WATER FOR 15 MINUTES. SKIN CONTACT- WASH AREAS WITH SOAP AND WATER. TREATMENT OF OVERDOSE: SYMPTOMATIC TREATMENT, AS REQUIRED
MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:	HYPERSENSITIVITY TO ANY OF THE COMPONENTS

FOR COMPLETE INFORMATION ON THIS DRUG PLEASE REFER TO THE ATTACHED PRODUCT LABELING

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

MITROLAN TABLETS NDC 0031-1535-XX

. . . SECTION 7 PRECAUTIONS FOR SAFE HANDLING AND USE . . . . . .

SPILLS AND ACCIDENTAL RELEASES:	SWEEP OR SHOVEL INTO A WASTE CONTAINER
WASTE DISPOSAL METHOD:	DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. THIS IS A BIOLOGICALLY ACTIVE MATERIAL. DISPOSE OF ON SITE OR AT AN APPROVED DISPOSAL FACILITY IN ACCORDANCE WITH LOCAL,STATE,AND/OR FEDERAL REGULATIONS.
HANDLING AND STORAGE:	STORE AT ROOM TEMPERATURE, BETWEEN 59 AND 86 DEGREES F.

. . . SECTION 8 CONTROL MEASURES . . . . . .

NO SPECIAL CONTROL MEASURES ARE REQUIRED UNDER NORMAL CONDITIONS OF USE

RESPIRATORY PROTECTION	NONE REQUIRED
VENTILATION	NO SPECIAL VENTILATION IS REQUIRED
PROTECTIVE CLOTHING OR EQUIPMENT	AVOID CONTACT WITH EYES OR PROLONGED CONTACT WITH SKIN.
WORK/HYGIENIC PRACTICES	WASH THOROUGHLY AFTER HANDLING

. . . . . .

THE INFORMATION CONTAINED IN THIS MSDS IS, TO THE BEST OF A.H.ROBINS' KNOWLEDGE, COMPLETE AND ACCURATE. A.H.ROBINS, HOWEVER, USES MANY SOURCES AND REFERENCES FOR GATHERING THIS INFORMATION. THUS, A.H. ROBINS CANNOT GUARANTEE COMPLETENESS OR ACCURACY AND DISCLAIMS ALL LIABILITY FOR ITS HANDLING AND USE.

FILE/MITROLAN/TABLETS . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS) EFFECTIVE 06/11/87

PABALATE-SF NDC 0031-5883-XX

. . . SECTION 1 MANUFACTURER INFORMATION . . . . . .

A. H. ROBINS CO.,INC. 1405 CUMMINGS DRIVE RICHMOND, VA 23261-6609

EMERGENCY TELEPHONE: (804) 257-2000 (8:30 AM - 5:00 PM)
(804) 257-2000 (AFTER HOURS)

. . . SECTION 2 COMPOSITION INFORMATION . . . . . .

HAZARDOUS INGREDIENTS:
AS FORMULATED, THIS FINISHED PHARMACEUTICAL PRODUCT DOES NOT CONSTITUTE A PHYSICAL HAZARD WITHIN THE MEANING OF 29 CFR SEC 1910.1200. POTENTIAL HEALTH HAZARDS FROM INGESTION OR EXPOSURE TO THE PRODUCT ARE DISCUSSED IN SECTION 6 BELOW.

ACTIVE INGREDIENTS:		CAS
EACH ENTERIC-COATED TABLET CONTAINS:		
POTASSIUM SALICYLATE	300MG	578-36-9
POTASSIUM AMINOBENZOATE	300MG	138-84-1

INACTIVE INGREDIENTS:
ACACIA, ACETYLATED MONOGLYCERIDES, CALCIUM CARBONATE, CALCIUM SULFATE, CARNAUBA WAX, CELLULOSE ACETATE PHTHALATE, DIETHYL PHTHALATE, DOCUSATE SODIUM, EDIBLE INK, FD&C BLUE 1 ALUMINUM LAKE, FD&C BLUE 2 ALUMINUM LAKE, FD&C RED 3 ALUMINUM LAKE, GELATIN, MAGNESIUM STEARATE, POLYSORBATES, SHELLAC, STEARIC ACID, SUCROSE, TALC, TITANIUM DIOXIDE, WHEAT FLOUR, WHITE WAX; MAY CONTAIN FD&C RED 40 AND YELLOW 6 ALUMINUM LAKES

. . . SECTION 3 PHYSICAL/CHEMICAL CHARACTERISTICS . . . . . .

BOILING POINT	NOT APPLICABLE
VAPOR PRESSURE	NOT APPLICABLE
VAPOR DENSITY	NOT APPLICABLE
SOLUBILITY IN WATER	NOT APPLICABLE
SPECIFIC GRAVITY	NOT APPLICABLE
MELTING POINT	NOT APPLICABLE
EVAPORATION RATE	NOT APPLICABLE
APPEARANCE	PERSIAN ROSE ENTERIC-COATED TABLETS, MONOGRAMMED AHR AND 5883

. . . SECTION 4 FIRE AND EXPLOSION HAZARD DATA . . . . . .

FLASH POINT	NOT APPLICABLE
METHOD USED	NOT APPLICABLE
FLAMMABLE LIMITS	
LEL	NOT APPLICABLE
UEL	NOT APPLICABLE
EXTINGUISHING MEDIA	NOT APPLICABLE
SPECIAL FIRE-FIGHTING PROCEDURES	NOT APPLICABLE
UNUSUAL FIRE AND EXPLOSION HAZARDS	NONE

. . . SECTION 5 REACTIVITY DATA . . . . . .

STABILITY	STABLE
INCOMPATABILITY	NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS	NONE KNOWN
HAZARDOUS POLYMERIZATION	WILL NOT OCCUR

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

PABALATE-SF NDC 0031-5883-XX

. . . SECTION 6 HEALTH HAZARD DATA . . . . . .

ROUTES OF ENTRY: INGESTION

CARCINOGENICITY: NONE OF THE COMPONENTS IN THIS PRODUCT ARE KNOWN TO BE CARCINOGENIC

SIGNS AND SYMPTOMS OF OVER-EXPOSURE:

POTASSIUM SALICYLATE: CENTRAL NERVOUS SYSTEM STIMULATION WITH VOMITING, RAPID BREATHING, HYPERACTIVITY AND POSSIBLY CONVULSIONS. THIS PROGRESSES QUICKLY TO DEPRESSION, COMA, RESPIRATORY FAILURE, AND COLLAPSE, AND IS ACCOMPANIED BY SEVERE ELECTROLYTE DISTURBANCES.

POTASSIUM AMINOBENZOATE: NAUSEA, VOMITING, ACIDOSIS, ITCHING, RASH, FEVER, METHEMOGLOBINEMIA, AND POSSIBLY HEPATITIS

HYPERKALEMIA IS USUALLY ASYMPTOMATIC AND MAY BE MANIFESTED ONLY BY AN INCREASED SERUM POTASSIUM CONCENTRATION AND CHARACTERISTIC ECG CHANGES (PEAKING OF T WAVES, LOSS OF P WAVE, DEPRESSION OF ST SEGMENT, AND PROLONGATION OF THE QT INTERVAL). LATE MANIFESTATIONS INCLUDE MUSCLE PARALYSIS AND CARDIOVASCULAR COLLAPSE FROM CARDIAC ARREST.
THE MOST COMMON ADVERSE REACTIONS TO POTASSIUM SALTS ARE NAUSEA, VOMITING, ABDOMINAL DISCOMFORT, AND DIARRHEA.

(SEE ATTACHED PRODUCT LABELING FOR FULL INFORMATION ON SIDE EFFECTS)

EMERGENCY AND FIRST-AID PROCEDURES: EYE CONTACT- IRRIGATE SURFACES WITH WATER FOR 15 MINUTES. SKIN CONTACT- WASH AREAS WITH SOAP AND WATER. TREATMENT OF OVERDOSE: SYMPTOMATIC AND SUPPORTIVE TREATMENT AS REQUIRED. ACTIVATED CHARCOAL, INDUCED EMESIS AND GASTRIC LAVAGE. MONITOR PLASMA SALICYLATE LEVELS

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: HYPERSENSITIVITY TO ANY OF THE COMPONENTS; IN PATIENTS WITH IMPAIRED MECHANISMS FOR EXCRETING POTASSIUM THE INGESTION OF POSTASSIUM SALTS CAN PRODUCE HYPERKALEMIA AND CARDIAC ARREST.

FOR COMPLETE INFORMATION ON THIS DRUG PLEASE REFER TO THE ATTACHED PRODUCT LABELING

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

PABALATE-SF NDC 0031-5883-XX

. . . SECTION 7 PRECAUTIONS FOR SAFE HANDLING AND USE . . . . . .

SPILLS AND ACCIDENTAL RELEASES:	SWEEP OR SHOVEL INTO A WASTE CONTAINER
WASTE DISPOSAL METHOD:	DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. THIS IS A BIOLOGICALLY ACTIVE MATERIAL. DISPOSE OF ON SITE OR AT AN APPROVED DISPOSAL FACILITY IN ACCORDANCE WITH LOCAL,STATE,AND/OR FEDERAL REGULATIONS.
HANDLING AND STORAGE:	STORE AT ROOM TEMPERATURE, BETWEEN 59 AND 86 DEGREES F.

. . . SECTION 8 CONTROL MEASURES . . . . . .

NO SPECIAL CONTROL MEASURES ARE REQUIRED UNDER NORMAL CONDITIONS OF USE

RESPIRATORY PROTECTION	NONE REQUIRED
VENTILATION	NO SPECIAL VENTILATION IS REQUIRED
PROTECTIVE CLOTHING OR EQUIPMENT	AVOID CONTACT WITH EYES OR PROLONGED CONTACT WITH SKIN.
WORK/HYGIENIC PRACTICES	WASH THOROUGHLY AFTER HANDLING

. . . . . .

THE INFORMATION CONTAINED IN THIS MSDS IS, TO THE BEST OF A.H.ROBINS' KNOWLEDGE, COMPLETE AND ACCURATE. A.H.ROBINS, HOWEVER, USES MANY SOURCES AND REFERENCES FOR GATHERING THIS INFORMATION. THUS, A.H. ROBINS CANNOT GUARANTEE COMPLETENESS OR ACCURACY AND DISCLAIMS ALL LIABILITY FOR ITS HANDLING AND USE.

FILE/PABALATE/SF . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS) EFFECTIVE 06/11/87

PABALATE NDC 0031-5816-XX

. . . SECTION 1 MANUFACTURER INFORMATION . . . . . .

A. H. ROBINS CO.,INC. 1405 CUMMINGS DRIVE RICHMOND, VA 23261-6609

EMERGENCY TELEPHONE: (804) 257-2000 (8:30 AM - 5:00 PM)
(804) 257-2000 (AFTER HOURS)

. . . SECTION 2 COMPOSITION INFORMATION . . . . . .

HAZARDOUS INGREDIENTS:
AS FORMULATED, THIS FINISHED PHARMACEUTICAL PRODUCT DOES NOT CONSTITUTE A PHYSICAL HAZARD WITHIN THE MEANING OF 29 CFR SEC 1910.1200. POTENTIAL HEALTH HAZARDS FROM INGESTION OR EXPOSURE TO THE PRODUCT ARE DISCUSSED IN SECTION 6 BELOW.

ACTIVE INGREDIENTS: EACH ENTERIC-COATED TABLET CONTAINS:		CAS
SODIUM SALICYLATE, USP	300MG	54-21-7
SODIUM AMINOBENZOATE	300MG	54287-22-8

INACTIVE INGREDIENTS:
ACACIA, ACETYLATED MONOGLYCERIDES, CALCIUM CARBONATE, CALCIUM SULFATE, CARNAUBA WAX, CELLULOSE ACETATE PHTHALATE, D&C YELLOW 10, DIETHYL PHTHALATE, EDIBLE INK, FD&C BLUE 2 ALUMINUM LAKE, FD&C YELLOW 6, GELATIN, MAGNESIUM STEARATE, POLYSORBATES, SHELLAC, STEARIC ACID, SUCROSE, TALC, TITANIUM DIOXIDE, WHEAT FLOUR, WHITE WAX; MAY CONTAIN FD&C RED 40 AND YELLOW 6 ALUMINUM LAKES

. . . SECTION 3 PHYSICAL/CHEMICAL CHARACTERISTICS . . . . . .

BOILING POINT	NOT APPLICABLE
VAPOR PRESSURE	NOT APPLICABLE
VAPOR DENSITY	NOT APPLICABLE
SOLUBILITY IN WATER	NOT APPLICABLE
SPECIFIC GRAVITY	NOT APPLICABLE
MELTING POINT	NOT APPLICABLE
EVAPORATION RATE	NOT APPLICABLE
APPEARANCE	YELLOW, ENTERIC-COATED TABLETS, MONOGRAMMED AHR AND 5816

. . . SECTION 4 FIRE AND EXPLOSION HAZARD DATA . . . . . .

FLASH POINT	NOT APPLICABLE
METHOD USED	NOT APPLICABLE
FLAMMABLE LIMITS	
LEL	NOT APPLICABLE
UEL	NOT APPLICABLE
EXTINGUISHING MEDIA	NOT APPLICABLE
SPECIAL FIRE-FIGHTING PROCEDURES	NOT APPLICABLE
UNUSUAL FIRE AND EXPLOSION HAZARDS	NONE

. . . SECTION 5 REACTIVITY DATA . . . . . .

STABILITY	STABLE
INCOMPATABILITY	NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS	NONE KNOWN
HAZARDOUS POLYMERIZATION	WILL NOT OCCUR

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

PABALATE NDC 0031-5816-XX

. . . SECTION 6 HEALTH HAZARD DATA . . . . . .

ROUTES OF ENTRY:		INGESTION
CARCINOGENICITY:		NONE OF THE COMPONENTS IN THIS PRODUCT ARE KNOWN TO BE CARCINOGENIC
SIGNS AND SYMPTOMS OF OVER-EXPOSURE:	SODIUM SALICYLATE	CENTRAL NERVOUS SYSTEM STIMULATION WITH VOMITING, RAPID BREATHING, HYPERACTIVITY AND POSSIBLY CONVULSIONS. THIS PROGRESSES QUICKLY TO DEPRESSION, COMA, RESPIRATORY FAILURE, AND COLLAPSE, AND IS ACCOMPANIED BY SEVERE ELECTROLYTE DISTURBANCES.
	SODIUM AMINOBENZOATE	NAUSEA, VOMITING, ACIDOSIS, ITCHING, RASH, FEVER, METHEMOGLOBINEMIA, AND POSSIBLY HEPATITIS
		(SEE ATTACHED PRODUCT LABELING FOR FULL INFORMATION ON SIDE EFFECTS)
EMERGENCY AND FIRST-AID PROCEDURES:		EYE CONTACT- IRRIGATE SURFACES WITH WATER FOR 15 MINUTES. SKIN CONTACT- WASH AREAS WITH SOAP AND WATER. TREATMENT OF OVERDOSE: SYMPTOMATIC AND SUPPORTIVE TREATMENT AS REQUIRED. ACTIVATED CHARCOAL, INDUCED EMESIS AND GASTRIC LAVAGE. MONITOR PLASMA SALICYLATE LEVELS
MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:		HYPERSENSITIVITY TO ANY OF THE COMPONENTS

FOR COMPLETE INFORMATION ON THIS DRUG PLEASE REFER TO THE ATTACHED PRODUCT LABELING

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

PABALATE NDC 0031-5816-XX

. . . SECTION 7 PRECAUTIONS FOR SAFE HANDLING AND USE . . . . . .

SPILLS AND ACCIDENTAL RELEASES:	SWEEP OR SHOVEL INTO A WASTE CONTAINER
WASTE DISPOSAL METHOD:	DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. THIS IS A BIOLOGICALLY ACTIVE MATERIAL. DISPOSE OF ON SITE OR AT AN APPROVED DISPOSAL FACILITY IN ACCORDANCE WITH LOCAL,STATE,AND/OR FEDERAL REGULATIONS.
HANDLING AND STORAGE:	STORE AT ROOM TEMPERATURE, BETWEEN 59 AND 86 DEGREES F.

. . . SECTION 8 CONTROL MEASURES . . . . . .

NO SPECIAL CONTROL MEASURES ARE REQUIRED UNDER NORMAL CONDITIONS OF USE

RESPIRATORY PROTECTION	NONE REQUIRED
VENTILATION	NO SPECIAL VENTILATION IS REQUIRED
PROTECTIVE CLOTHING OR EQUIPMENT	AVOID CONTACT WITH EYES OR PROLONGED CONTACT WITH SKIN.
WORK/HYGIENIC PRACTICES	WASH THOROUGHLY AFTER HANDLING

. . . . . .

THE INFORMATION CONTAINED IN THIS MSDS IS, TO THE BEST OF A.H.ROBINS' KNOWLEDGE, COMPLETE AND ACCURATE. A.H.ROBINS, HOWEVER, USES MANY SOURCES AND REFERENCES FOR GATHERING THIS INFORMATION. THUS, A.H. ROBINS CANNOT GUARANTEE COMPLETENESS OR ACCURACY AND DISCLAIMS ALL LIABILITY FOR ITS HANDLING AND USE.

FILE/PABALATE/TABLETS . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS) EFFECTIVE 01/04/88

PHENAPHEN CAPLETS NDC 0031-6209-XX

. . . SECTION 1 MANUFACTURER INFORMATION . . . . . .

A. H. ROBINS CO.,INC. 1405 CUMMINGS DRIVE RICHMOND, VA 23261-6609

EMERGENCY TELEPHONE: (804) 257-2000 (8:30 AM - 5:00 PM)
(804) 257-2000 (AFTER HOURS)

. . . SECTION 2 COMPOSITION INFORMATION . . . . . .

HAZARDOUS INGREDIENTS:
AS FORMULATED, THIS FINISHED PHARMACEUTICAL PRODUCT DOES NOT CONSTITUTE A PHYSICAL HAZARD WITHIN THE MEANING OF 29 CFR SEC 1910.1200. POTENTIAL HEALTH HAZARDS FROM INGESTION OR EXPOSURE TO THE PRODUCT ARE DISCUSSED IN SECTION 6 BELOW.

ACTIVE INGREDIENTS:		CAS
EACH CAPLET CONTAINS:		
ACETAMINOPHEN, USP	325 MG	103-90-2

INACTIVE INGREDIENTS:
CORN STARCH, FD&C BLUE 1, FLAVOR, HYDROXYPROPYL METHYLCELLULOSE, MAGNESIUM STEARATE, METHACRYLIC ACID COPOLYMER, METHYLPARABEN, MICROCRYSTALLINE CELLULOSE, POLYSORBATE 20, POTASSIUM SORBATE, POVIDONE, PROPYLENE GLYCOL, PROPYLPARABEN, SACCHARIN SODIUM, STEARIC ACID, TITANIUM DIOXIDE, TRIETHYL CITRATE, XANTHAN GUM.

. . . SECTION 3 PHYSICAL/CHEMICAL CHARACTERISTICS . . . . . .

BOILING POINT	NOT APPLICABLE
VAPOR PRESSURE	NOT APPLICABLE
VAPOR DENSITY	NOT APPLICABLE
SOLUBILITY IN WATER	NOT APPLICABLE
SPECIFIC GRAVITY	NOT APPLICABLE
MELTING POINT	NOT APPLICABLE
EVAPORATION RATE	NOT APPLICABLE
APPEARANCE	WHITE, CAPSULE-SHAPED, FILM-COATED TABLET ENGRAVED 6209 ON ONE SIDE AND AHR ON THE OTHER

. . . SECTION 4 FIRE AND EXPLOSION HAZARD DATA . . . . . .

FLASH POINT	NOT APPLICABLE
METHOD USED	NOT APPLICABLE
FLAMMABLE LIMITS	
LEL	NOT APPLICABLE
UEL	NOT APPLICABLE
EXTINGUISHING MEDIA	NOT APPLICABLE
SPECIAL FIRE-FIGHTING PROCEDURES	NOT APPLICABLE
UNUSUAL FIRE AND EXPLOSION HAZARDS	NONE

. . . SECTION 5 REACTIVITY DATA . . . . . .

STABILITY	STABLE
INCOMPATABILITY	NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS	NONE KNOWN
HAZARDOUS POLYMERIZATION	WILL NOT OCCUR

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

PHENAPHEN CAPLETS NDC 0031-6209-XX

. . . SECTION 6 HEALTH HAZARD DATA . . . . . .

	ROUTES OF ENTRY:	INGESTION
	CARCINOGENICITY:	NONE OF THE COMPONENTS IN THIS PRODUCT ARE KNOWN TO BE CARCINOGENIC
SIGNS AND SYMPTOMS OF OVER-EXPOSURE:	ACETAMINOPHEN	SEVERE OVERDOSAGE MAY PRODUCE NAUSEA, VOMITING, PERSPIRATION, AND GENERAL DISCOMFORT. MASSIVE OVERDOSAGE MAY PRODUCE DAMAGE TO LIVER, KIDNEYS, AND CENTRAL NERVOUS SYSTEM. REPEATED INGESTION OF TOXIC DOSES MAY PRODUCE CIRRHOSIS OF THE LIVER. POTENTIALLY TOXIC DOSE IS ABOUT 10 GRAMS. (SEE ATTACHED PRODUCT LABELING FOR FULL INFORMATION ON SIDE-EFFECTS)
	EMERGENCY AND FIRST-AID PROCEDURES:	EYE CONTACT- IRRIGATE SURFACES WITH WATER FOR 15 MINUTES. SKIN CONTACT- WASH AREAS WITH SOAP AND WATER. TREATMENT OF OVERDOSE: INDUCED EMESIS, LAVAGE, AND ACTIVATED CHARCOAL MAY BE HELPFUL. IF POTENTIALLY TOXIC DOSES ARE INGESTED, SERUM ACETAMINOPHEN LEVELS SHOULD BE MONITORED BEGINNING 4 HOURS AFTER INGESTION AND LIVER FUNCTION TESTS SHOULD BE SERIALLY MONITORED. THE ANTIDOTE, N-ACETYLCYSTEINE, SHOULD BE ADMINISTERED WITHIN 16 HOURS FOLLOWING INGESTION. SYMPTOMATIC AND SUPPORTIVE TREATMENT AS REQUIRED
	MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:	HYPERSENSITIVITY TO ANY OF THE COMPONENTS; INDIVIDUALS CHRONICALLY EXPOSED TO ALCOHOL OR OTHER DRUGS MAY BE MORE SUSCEPTIBLE TO THE TOXIC EFFECTS OF ACETAMINOPHEN.

FOR COMPLETE INFORMATION ON THIS DRUG PLEASE REFER TO THE ATTACHED PRODUCT LABELING

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

PHENAPHEN CAPLETS NDC 0031-6209-XX

. . . SECTION 7 PRECAUTIONS FOR SAFE HANDLING AND USE . . . . . .

SPILLS AND ACCIDENTAL RELEASES:	SWEEP OR SHOVEL INTO A WASTE CONTAINER
WASTE DISPOSAL METHOD:	DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. THIS IS A BIOLOGICALLY ACTIVE MATERIAL. DISPOSE OF ON SITE OR AT AN APPROVED DISPOSAL FACILITY IN ACCORDANCE WITH LOCAL,STATE,AND/OR FEDERAL REGULATIONS.
HANDLING AND STORAGE:	STORE AT ROOM TEMPERATURE, BETWEEN 59 AND 86 DEGREES F.

. . . SECTION 8 CONTROL MEASURES . . . . . .

NO SPECIAL CONTROL MEASURES ARE REQUIRED UNDER NORMAL CONDITIONS OF USE

RESPIRATORY PROTECTION	NONE REQUIRED
VENTILATION	NO SPECIAL VENTILATION IS REQUIRED
PROTECTIVE CLOTHING OR EQUIPMENT	AVOID CONTACT WITH EYES OR PROLONGED CONTACT WITH SKIN.
WORK/HYGIENIC PRACTICES	WASH THOROUGHLY AFTER HANDLING

. . . . . .

THE INFORMATION CONTAINED IN THIS MSDS IS, TO THE BEST OF A.H.ROBBINS' KNOWLEDGE, COMPLETE AND ACCURATE. A.H.ROBBINS, HOWEVER, USES MANY SOURCES AND REFERENCES FOR GATHERING THIS INFORMATION. THUS, A.H. ROBBINS CANNOT GUARANTEE COMPLETENESS OR ACCURACY AND DISCLAIMS ALL LIABILITY FOR ITS HANDLING AND USE.

FILE/PHENAPHN/CAPLETS . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS) EFFECTIVE 05/14/87

PHENAPHEN WITH CODEINE NO. 2 NDC 0031-6242-XX

. . . SECTION 1 MANUFACTURER INFORMATION . . . . . .

A. H. ROBINS CO.,INC. 1405 CUMMINGS DRIVE RICHMOND, VA 23261-6609

EMERGENCY TELEPHONE: (804) 257-2000 (8:30 AM - 5:00 PM)
(804) 257-2000 (AFTER HOURS)

. . . SECTION 2 COMPOSITION INFORMATION . . . . . .

HAZARDOUS INGREDIENTS:
AS FORMULATED, THIS FINISHED PHARMACEUTICAL PRODUCT DOES NOT CONSTITUTE A PHYSICAL HAZARD WITHIN THE MEANING OF 29 CFR SEC 1910.1200. POTENTIAL HEALTH HAZARDS FROM INGESTION OR EXPOSURE TO THE PRODUCT ARE DISCUSSED IN SECTION 6 BELOW.

ACTIVE INGREDIENTS: EACH CAPSULE CONTAINS:		CAS
ACETAMINOPHEN, USP	325 MG	103-90-2
CODEINE PHOSPHATE, USP	15 MG	41444-62-6
(WARNING: MAY BE HABIT FORMING)		

INACTIVE INGREDIENTS:
CORN STARCH, D&C YELLOW 10, EDIBLE INK, FD&C BLUE 1, FD&C RED 3 OR 40, FD&C YELLOW 6, GELATIN, MAGNESIUM STEARATE, SODIUM STARCH GLYCOLATE, STEARIC ACID.

. . . SECTION 3 PHYSICAL/CHEMICAL CHARACTERISTICS . . . . . .

BOILING POINT	NOT APPLICABLE
VAPOR PRESSURE	NOT APPLICABLE
VAPOR DENSITY	NOT APPLICABLE
SOLUBILITY IN WATER	NOT APPLICABLE
SPECIFIC GRAVITY	NOT APPLICABLE
MELTING POINT	NOT APPLICABLE
EVAPORATION RATE	NOT APPLICABLE
APPEARANCE	BLACK AND YELLOW CAPSULES

. . . SECTION 4 FIRE AND EXPLOSION HAZARD DATA . . . . . .

FLASH POINT	NOT APPLICABLE
METHOD USED	NOT APPLICABLE
FLAMMABLE LIMITS	
LEL	NOT APPLICABLE
UEL	NOT APPLICABLE
EXTINGUISHING MEDIA	NOT APPLICABLE
SPECIAL FIRE-FIGHTING PROCEDURES	NOT APPLICABLE
UNUSUAL FIRE AND EXPLOSION HAZARDS	NONE

. . . SECTION 5 REACTIVITY DATA . . . . . .

STABILITY	STABLE
INCOMPATABILITY	NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS	NONE KNOWN
HAZARDOUS POLYMERIZATION	WILL NOT OCCUR

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

PHENAPHEN WITH CODEINE NO. 2 NDC 0031-6242-XX

. . . SECTION 6 HEALTH HAZARD DATA . . . . . .

	ROUTES OF ENTRY:	INGESTION
	CARCINOGENICITY:	NONE OF THE COMPONENTS IN THIS PRODUCT ARE KNOWN TO BE CARCINOGENIC
SIGNS AND SYMPTOMS OF OVER-EXPOSURE:	ACETAMINOPHEN	SEVERE OVERDOSAGE MAY PRODUCE NAUSEA, VOMITING, PERSPIRATION, AND GENERAL DISCOMFORT. MASSIVE OVERDOSAGE MAY PRODUCE DAMAGE TO LIVER, KIDNEYS, AND CENTRAL NERVOUS SYSTEM. REPEATED INGESTION OF TOXIC DOSES MAY PRODUCE CIRRHOSIS OF THE LIVER. POTENTIALLY TOXIC DOSE IS ABOUT 10 GRAMS.
	CODEINE PHOSPHATE	PINPOINT PUPILS, CONSTIPATION, SLOW HEART RATE, HIGH BLOOD PRESSURE, RESPIRATORY DEPRESSION, URINARY RETENTION, MUSCLE SPASMS, ITCHING, RESPIRATORY ARREST, COMA
	EMERGENCY AND FIRST-AID PROCEDURES:	EYE CONTACT- IRRIGATE SURFACES WITH WATER FOR 15 MINUTES. SKIN CONTACT- WASH AREAS WITH SOAP AND WATER. TREATMENT OF OVERDOSE: INDUCED EMESIS, LAVAGE, AND ACTIVATED CHARCOAL MAY BE HELPFUL. IF POTENTIALLY TOXIC DOSES ARE INGESTED, SERUM ACETAMINOPHEN LEVELS SHOULD BE MONITORED BEGINNING 4 HOURS AFTER INGESTION AND LIVER FUNCTION TESTS SHOULD BE SERIALLY MONITORED. THE ANTIDOTE FOR ACETAMINOPHEN, N-ACETYLCYSTEINE, SHOULD BE ADMINISTERED WITHIN 16 HOURS FOLLOWING INGESTION. SEVERE OPIATE EFFECTS SUCH AS RESPIRATORY DEPRESSION MAY BE REVERSED BY NALOXONE. SYMPTOMATIC AND SUPPORTIVE TREATMENT AS REQUIRED
	MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:	HYPERSENSITIVITY TO ANY OF THE COMPONENTS; INDIVIDUALS CHRONICALLY EXPOSED TO ALCOHOL OR OTHER DRUGS MAY BE MORE SUSCEPTIBLE TO THE TOXIC EFFECTS OF ACETAMINOPHEN.

FOR COMPLETE INFORMATION ON THIS DRUG PLEASE REFER TO THE ATTACHED PRODUCT LABELING

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

PHENAPHEN WITH CODEINE NO. 2 NDC 0031-6242-XX

. . . SECTION 7 PRECAUTIONS FOR SAFE HANDLING AND USE . . . . . .

SPILLS AND ACCIDENTAL RELEASES:	SWEEP OR SHOVEL INTO A WASTE CONTAINER
WASTE DISPOSAL METHOD:	DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. THIS IS A BIOLOGICALLY ACTIVE MATERIAL. DISPOSE OF ON SITE OR AT AN APPROVED DISPOSAL FACILITY IN ACCORDANCE WITH LOCAL,STATE,AND/OR FEDERAL REGULATIONS.
HANDLING AND STORAGE:	STORE AT ROOM TEMPERATURE, BETWEEN 59 AND 86 DEGREES F.

. . . SECTION 8 CONTROL MEASURES . . . . . .

NO SPECIAL CONTROL MEASURES ARE REQUIRED UNDER NORMAL CONDITIONS OF USE

RESPIRATORY PROTECTION	NONE REQUIRED
VENTILATION	NO SPECIAL VENTILATION IS REQUIRED
PROTECTIVE CLOTHING OR EQUIPMENT	AVOID CONTACT WITH EYES OR PROLONGED CONTACT WITH SKIN.
WORK/HYGIENIC PRACTICES	WASH THOROUGHLY AFTER HANDLING

. . . . . .

THE INFORMATION CONTAINED IN THIS MSDS IS, TO THE BEST OF A.H.ROBINS' KNOWLEDGE, COMPLETE AND ACCURATE. A.H.ROBINS, HOWEVER, USES MANY SOURCES AND REFERENCES FOR GATHERING THIS INFORMATION. THUS, A.H. ROBINS CANNOT GUARANTEE COMPLETENESS OR ACCURACY AND DISCLAIMS ALL LIABILITY FOR ITS HANDLING AND USE.

FILE/PHENAPHN/NO2 . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS) EFFECTIVE 05/14/87

PHENAPHEN WITH CODEINE NO. 3 NDC 0031-6257-XX

. . . SECTION 1 MANUFACTURER INFORMATION . . . . . .

A. H. ROBINS CO.,INC. 1405 CUMMINGS DRIVE RICHMOND, VA 23261-6609

EMERGENCY TELEPHONE: (804) 257-2000 (8:30 AM - 5:00 PM)
(804) 257-2000 (AFTER HOURS)

. . . SECTION 2 COMPOSITION INFORMATION . . . . . .

HAZARDOUS INGREDIENTS:
AS FORMULATED, THIS FINISHED PHARMACEUTICAL PRODUCT DOES NOT CONSTITUTE A PHYSICAL HAZARD WITHIN THE MEANING OF 29 CFR SEC 1910.1200. POTENTIAL HEALTH HAZARDS FROM INGESTION OR EXPOSURE TO THE PRODUCT ARE DISCUSSED IN SECTION 6 BELOW.

ACTIVE INGREDIENTS:		CAS
EACH CAPSULE CONTAINS:		
ACETAMINOPHEN, USP	325 MG	103-90-2
CODEINE PHOSPHATE, USP	30 MG	41444-62-6
(WARNING: MAY BE HABIT FORMING)		

INACTIVE INGREDIENTS:
D&C YELLOW 10, EDIBLE INK, FD&C BLUE 1, (FD&C GREEN 3 AND RED 40) OR RED 3, FD&C YELLOW 6, GELATIN, LACTOSE, MAGNESIUM STEARATE, SODIUM STARCH GLYCOLATE, STEARIC ACID.

. . . SECTION 3 PHYSICAL/CHEMICAL CHARACTERISTICS . . . . . .

BOILING POINT	NOT APPLICABLE
VAPOR PRESSURE	NOT APPLICABLE
VAPOR DENSITY	NOT APPLICABLE
SOLUBILITY IN WATER	NOT APPLICABLE
SPECIFIC GRAVITY	NOT APPLICABLE
MELTING POINT	NOT APPLICABLE
EVAPORATION RATE	NOT APPLICABLE
APPEARANCE	BLACK AND GREEN CAPSULES

. . . SECTION 4 FIRE AND EXPLOSION HAZARD DATA . . . . . .

FLASH POINT	NOT APPLICABLE
METHOD USED	NOT APPLICABLE
FLAMMABLE LIMITS	
LEL	NOT APPLICABLE
UEL	NOT APPLICABLE
EXTINGUISHING MEDIA	NOT APPLICABLE
SPECIAL FIRE-FIGHTING PROCEDURES	NOT APPLICABLE
UNUSUAL FIRE AND EXPLOSION HAZARDS	NONE

. . . SECTION 5 REACTIVITY DATA . . . . . .

STABILITY	STABLE
INCOMPATABILITY	NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS	NONE KNOWN
HAZARDOUS POLYMERIZATION	WILL NOT OCCUR

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

PHENAPHEN WITH CODEINE NO. 3 NDC 0031-6257-XX

. . . SECTION 6 HEALTH HAZARD DATA . . . . . .

ROUTES OF ENTRY:		INGESTION
CARCINOGENICITY:		NONE OF THE COMPONENTS IN THIS PRODUCT ARE KNOWN TO BE CARCINOGENIC
SIGNS AND SYMPTOMS OF OVER-EXPOSURE:	ACETAMINOPHEN	SEVERE OVERDOSAGE MAY PRODUCE NAUSEA, VOMITING, PERSPIRATION, AND GENERAL DISCOMFORT. MASSIVE OVERDOSAGE MAY PRODUCE DAMAGE TO LIVER, KIDNEYS, AND CENTRAL NERVOUS SYSTEM. REPEATED INGESTION OF TOXIC DOSES MAY PRODUCE CIRRHOSIS OF THE LIVER. POTENTIALLY TOXIC DOSE IS ABOUT 10 GRAMS.
	CODEINE PHOSPHATE	PINPOINT PUPILS, CONSTIPATION, SLOW HEART RATE, HIGH BLOOD PRESSURE, RESPIRATORY DEPRESSION, URINARY RETENTION, MUSCLE SPASMS, ITCHING, RESPIRATORY ARREST, COMA
EMERGENCY AND FIRST-AID PROCEDURES:		EYE CONTACT- IRRIGATE SURFACES WITH WATER FOR 15 MINUTES. SKIN CONTACT- WASH AREAS WITH SOAP AND WATER. TREATMENT OF OVERDOSE: INDUCED EMESIS, LAVAGE, AND ACTIVATED CHARCOAL MAY BE HELPFUL. IF POTENTIALLY TOXIC DOSES ARE INGESTED, SERUM ACETAMINOPHEN LEVELS SHOULD BE MONITORED BEGINNING 4 HOURS AFTER INGESTION AND LIVER FUNCTION TESTS SHOULD BE SERIALLY MONITORED. THE ANTIDOTE FOR ACETAMINOPHEN, N-ACETYLCYSTEINE, SHOULD BE ADMINISTERED WITHIN 16 HOURS FOLLOWING INGESTION. SEVERE OPIATE EFFECTS SUCH AS REPIRATORY DEPRESSION MAY BE REVERSED BY NALOXONE. SYMPTOMATIC AND SUPPORTIVE TREATMENT AS REQUIRED
MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:		HYPERSENSITIVITY TO ANY OF THE COMPONENTS; INDIVIDUALS CHRONICALLY EXPOSED TO ALCOHOL OR OTHER DRUGS MAY BE MORE SUSCEPTIBLE TO THE TOXIC EFFECTS OF ACETAMINOPHEN.

FOR COMPLETE INFORMATION ON THIS DRUG PLEASE REFER TO THE ATTACHED PRODUCT LABELING

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

PHENAPHEN WITH CODEINE NO. 3 NDC 0031-6257-XX

. . . SECTION 7 PRECAUTIONS FOR SAFE HANDLING AND USE . . . . . .

SPILLS AND ACCIDENTAL RELEASES:	SWEEP OR SHOVEL INTO A WASTE CONTAINER
WASTE DISPOSAL METHOD:	DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. THIS IS A BIOLOGICALLY ACTIVE MATERIAL. DISPOSE OF ON SITE OR AT AN APPROVED DISPOSAL FACILITY IN ACCORDANCE WITH LOCAL,STATE,AND/OR FEDERAL REGULATIONS.
HANDLING AND STORAGE:	STORE AT ROOM TEMPERATURE, BETWEEN 59 AND 86 DEGREES F.

. . . SECTION 8 CONTROL MEASURES . . . . . .

NO SPECIAL CONTROL MEASURES ARE REQUIRED UNDER NORMAL CONDITIONS OF USE

RESPIRATORY PROTECTION	NONE REQUIRED
VENTILATION	NO SPECIAL VENTILATION IS REQUIRED
PROTECTIVE CLOTHING OR EQUIPMENT	AVOID CONTACT WITH EYES OR PROLONGED CONTACT WITH SKIN.
WORK/HYGIENIC PRACTICES	WASH THOROUGHLY AFTER HANDLING

. . . . . .

THE INFORMATION CONTAINED IN THIS MSDS IS, TO THE BEST OF A.H.ROBINS' KNOWLEDGE, COMPLETE AND ACCURATE. A.H.ROBINS, HOWEVER, USES MANY SOURCES AND REFERENCES FOR GATHERING THIS INFORMATION. THUS, A.H. ROBINS CANNOT GUARANTEE COMPLETENESS OR ACCURACY AND DISCLAIMS ALL LIABILITY FOR ITS HANDLING AND USE.

FILE/PHENAPHN/NO3 . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS) EFFECTIVE 05/14/87

PHENAPHEN WITH CODEINE NO. 4 NDC 0031-6274-XX

. . . SECTION 1 MANUFACTURER INFORMATION . . . . . .

A. H. ROBINS CO.,INC. 1405 CUMMINGS DRIVE RICHMOND, VA 23261-6609

EMERGENCY TELEPHONE: (804) 257-2000 (8:30 AM - 5:00 PM)
(804) 257-2000 (AFTER HOURS)

. . . SECTION 2 COMPOSITION INFORMATION . . . . . .

HAZARDOUS INGREDIENTS:
AS FORMULATED, THIS FINISHED PHARMACEUTICAL PRODUCT DOES NOT CONSTITUTE A PHYSICAL HAZARD WITHIN THE MEANING OF 29 CFR SEC 1910.1200. POTENTIAL HEALTH HAZARDS FROM INGESTION OR EXPOSURE TO THE PRODUCT ARE DISCUSSED IN SECTION 6 BELOW.

ACTIVE INGREDIENTS:		CAS
EACH CAPSULE CONTAINS:		
ACETAMINOPHEN, USP	325 MG	103-90-2
CODEINE PHOSPHATE, USP	60 MG	41444-62-6
(WARNING: MAY BE HABIT FORMING)		

INACTIVE INGREDIENTS:
CORN STARCH, D&C YELLOW 10, EDIBLE INK, FD&C GREEN 3 OR BLUE 1, FD&C YELLOW 6, GELATIN, LACTOSE, MAGNESIUM STEARATE, SODIUM STARCH GLYCOLATE, STEARIC ACID.

. . . SECTION 3 PHYSICAL/CHEMICAL CHARACTERISTICS . . . . . .

BOILING POINT	NOT APPLICABLE
VAPOR PRESSURE	NOT APPLICABLE
VAPOR DENSITY	NOT APPLICABLE
SOLUBILITY IN WATER	NOT APPLICABLE
SPECIFIC GRAVITY	NOT APPLICABLE
MELTING POINT	NOT APPLICABLE
EVAPORATION RATE	NOT APPLICABLE
APPEARANCE	GREEN AND WHITE CAPSULES

. . . SECTION 4 FIRE AND EXPLOSION HAZARD DATA . . . . . .

FLASH POINT	NOT APPLICABLE
METHOD USED	NOT APPLICABLE
FLAMMABLE LIMITS	
LEL	NOT APPLICABLE
UEL	NOT APPLICABLE
EXTINGUISHING MEDIA	NOT APPLICABLE
SPECIAL FIRE-FIGHTING PROCEDURES	NOT APPLICABLE
UNUSUAL FIRE AND EXPLOSION HAZARDS	NONE

. . . SECTION 5 REACTIVITY DATA . . . . . .

STABILITY	STABLE
INCOMPATABILITY	NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS	NONE KNOWN
HAZARDOUS POLYMERIZATION	WILL NOT OCCUR

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

PHENAPHEN WITH CODEINE NO. 4 NDC 0031-6274-XX

. . . SECTION 6 HEALTH HAZARD DATA . . . . . .

	ROUTES OF ENTRY:	INGESTION
	CARCINOGENICITY:	NONE OF THE COMPONENTS IN THIS PRODUCT ARE KNOWN TO BE CARCINOGENIC
SIGNS AND SYMPTOMS OF OVER-EXPOSURE:	ACETAMINOPHEN	SEVERE OVERDOSAGE MAY PRODUCE NAUSEA, VOMITING, PERSPIRATION, AND GENERAL DISCOMFORT. MASSIVE OVERDOSAGE MAY PRODUCE DAMAGE TO LIVER, KIDNEYS, AND CENTRAL NERVOUS SYSTEM. REPEATED INGESTION OF TOXIC DOSES MAY PRODUCE CIRRHOSIS OF THE LIVER. POTENTIALLY TOXIC DOSE IS ABOUT 10 GRAMS.
	CODEINE PHOSPHATE	PINPOINT PUPILS, CONSTIPATION, SLOW HEART RATE, HIGH BLOOD PRESSURE, RESPIRATORY DEPRESSION, URINARY RETENTION, MUSCLE SPASMS, ITCHING, RESPIRATORY ARREST, COMA
	EMERGENCY AND FIRST-AID PROCEDURES:	EYE CONTACT- IRRIGATE SURFACES WITH WATER FOR 15 MINUTES. SKIN CONTACT- WASH AREAS WITH SOAP AND WATER. TREATMENT OF OVERDOSE: INDUCED EMESIS, LAVAGE, AND ACTIVATED CHARCOAL MAY BE HELPFUL. IF POTENTIALLY TOXIC DOSES ARE INGESTED, SERUM ACETAMINOPHEN LEVELS SHOULD BE MONITORED BEGINNING 4 HOURS AFTER INGESTION AND LIVER FUNCTION TESTS SHOULD BE SERIALLY MONITORED. THE ANTIDOTE FOR ACETAMINOPHEN, N-ACETYLCYSTEINE, SHOULD BE ADMINISTERED WITHIN 16 HOURS FOLLOWING INGESTION. SEVERE OPIATE EFFECTS SUCH AS RESPIRATORY DEPRESSION MAY BE REVERSED BY NALOXONE. SYMPTOMATIC AND SUPPORTIVE TREATMENT AS REQUIRED
	MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:	HYPERSENSITIVITY TO ANY OF THE COMPONENTS; INDIVIDUALS CHRONICALLY EXPOSED TO ALCOHOL OR OTHER DRUGS MAY BE MORE SUSCEPTIBLE TO THE TOXIC EFFECTS OF ACETAMINOPHEN.

FOR COMPLETE INFORMATION ON THIS DRUG PLEASE REFER TO THE ATTACHED PRODUCT LABELING

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

PHENAPHEN WITH CODEINE NO. 4 NDC 0031-6274-XX

. . . SECTION 7 PRECAUTIONS FOR SAFE HANDLING AND USE . . . . . .

SPILLS AND ACCIDENTAL RELEASES:	SHEEP OR SHOVEL INTO A WASTE CONTAINER
WASTE DISPOSAL METHOD:	DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. THIS IS A BIOLOGICALLY ACTIVE MATERIAL. DISPOSE OF ON SITE OR AT AN APPROVED DISPOSAL FACILITY IN ACCORDANCE WITH LOCAL,STATE,AND/OR FEDERAL REGULATIONS.
HANDLING AND STORAGE:	STORE AT ROOM TEMPERATURE, BETWEEN 59 AND 86 DEGREES F.

. . . SECTION 8 CONTROL MEASURES . . . . . .

NO SPECIAL CONTROL MEASURES ARE REQUIRED UNDER NORMAL CONDITIONS OF USE

RESPIRATORY PROTECTION	NONE REQUIRED
VENTILATION	NO SPECIAL VENTILATION IS REQUIRED
PROTECTIVE CLOTHING OR EQUIPMENT	AVOID CONTACT WITH EYES OR PROLONGED CONTACT WITH SKIN.
WORK/HYGIENIC PRACTICES	WASH THOROUGHLY AFTER HANDLING

. . . . . .

THE INFORMATION CONTAINED IN THIS MSDS IS, TO THE BEST OF A.H.ROBINS' KNOWLEDGE, COMPLETE AND ACCURATE. A.H.ROBINS, HOWEVER, USES MANY SOURCES AND REFERENCES FOR GATHERING THIS INFORMATION. THUS, A.H. ROBINS CANNOT GUARANTEE COMPLETENESS OR ACCURACY AND DISCLAIMS ALL LIABILITY FOR ITS HANDLING AND USE.

FILE/PHENAPHN/ND4 . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS) EFFECTIVE 05/14/87

PHENAPHEN-650 WITH CODEINE NDC 0031-6251-XX

. . . SECTION 1 MANUFACTURER INFORMATION . . . . . .

A. H. ROBINS CO.,INC. 1405 CUMMINGS DRIVE RICHMOND, VA 23261-6609

EMERGENCY TELEPHONE: (804) 257-2000 (8:30 AM - 5:00 PM)
(804) 257-2000 (AFTER HOURS)

. . . SECTION 2 COMPOSITION INFORMATION . . . . . .

HAZARDOUS INGREDIENTS:
AS FORMULATED, THIS FINISHED PHARMACEUTICAL PRODUCT DOES NOT CONSTITUTE A PHYSICAL HAZARD WITHIN THE MEANING OF 29 CFR SEC 1910.1200. POTENTIAL HEALTH HAZARDS FROM INGESTION OR EXPOSURE TO THE PRODUCT ARE DISCUSSED IN SECTION 6 BELOW.

ACTIVE INGREDIENTS: EACH TABLET CONTAINS:		CAS
ACETAMINOPHEN, USP	650 MG	103-90-2
CODEINE PHOSPHATE, USP	30 MG	41444-62-6
(WARNING: MAY BE HABIT FORMING)		

INACTIVE INGREDIENTS:
CALCIUM SULFATE, CORN STARCH, MICROCRYSTALLINE CELLULOSE, POLYETHYLENE GLYCOL, POVIDONE, SILICON DIOXIDE, SODIUM BISULFITE, SODIUM STARCH GLYCOLATE, STEARIC ACID.

. . . SECTION 3 PHYSICAL/CHEMICAL CHARACTERISTICS . . . . . .

BOILING POINT	NOT APPLICABLE
VAPOR PRESSURE	NOT APPLICABLE
VAPOR DENSITY	NOT APPLICABLE
SOLUBILITY IN WATER	NOT APPLICABLE
SPECIFIC GRAVITY	NOT APPLICABLE
MELTING POINT	NOT APPLICABLE
EVAPORATION RATE	NOT APPLICABLE
APPEARANCE	A SCORED, WHITE, CAPSULE-SHAPED COMPRESSED TABLET ENGRAVED AHR AND 6251

. . . SECTION 4 FIRE AND EXPLOSION HAZARD DATA . . . . . .

FLASH POINT	NOT APPLICABLE
METHOD USED	NOT APPLICABLE
FLAMMABLE LIMITS	
LEL	NOT APPLICABLE
UEL	NOT APPLICABLE
EXTINGUISHING MEDIA	NOT APPLICABLE
SPECIAL FIRE-FIGHTING PROCEDURES	NOT APPLICABLE
UNUSUAL FIRE AND EXPLOSION HAZARDS	NONE

. . . SECTION 5 REACTIVITY DATA . . . . . .

STABILITY	STABLE
INCOMPATABILITY	NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS	NONE KNOWN
HAZARDOUS POLYMERIZATION	WILL NOT OCCUR

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

PHENAPHEN-650 WITH CODEINE NDC 0031-6251-XX

. . . SECTION 7 PRECAUTIONS FOR SAFE HANDLING AND USE . . . . . .

SPILLS AND ACCIDENTAL RELEASES:	SWEEP OR SHOVEL INTO A WASTE CONTAINER
WASTE DISPOSAL METHOD:	DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. THIS IS A BIOLOGICALLY ACTIVE MATERIAL. DISPOSE OF ON SITE OR AT AN APPROVED DISPOSAL FACILITY IN ACCORDANCE WITH LOCAL,STATE,AND/OR FEDERAL REGULATIONS.
HANDLING AND STORAGE:	STORE AT ROOM TEMPERATURE, BETWEEN 59 AND 86 DEGREES F.

. . . SECTION 8 CONTROL MEASURES . . . . . .

NO SPECIAL CONTROL MEASURES ARE REQUIRED UNDER NORMAL CONDITIONS OF USE

RESPIRATORY PROTECTION	NONE REQUIRED
VENTILATION	NO SPECIAL VENTILATION IS REQUIRED
PROTECTIVE CLOTHING OR EQUIPMENT	AVOID CONTACT WITH EYES OR PROLONGED CONTACT WITH SKIN.
WORK/HYGIENIC PRACTICES	WASH THOROUGHLY AFTER HANDLING

. . . . . .

THE INFORMATION CONTAINED IN THIS MSDS IS, TO THE BEST OF A.H.ROBINS' KNOWLEDGE, COMPLETE AND ACCURATE. A.H.ROBINS, HOWEVER, USES MANY SOURCES AND REFERENCES FOR GATHERING THIS INFORMATION. THUS, A.H. ROBINS CANNOT GUARANTEE COMPLETENESS OR ACCURACY AND DISCLAIMS ALL LIABILITY FOR ITS HANDLING AND USE.

FILE/PHENAPHN/650CDD. . . . . .

MATERIAL SAFETY DATA SHEET (MSDS) EFFECTIVE 05/28/87

PONDIMIN NDC 0031-6447-XX

. . . SECTION 1 MANUFACTURER INFORMATION . . . . . .

A. H. ROBINS CO.,INC. 1405 CUMMINGS DRIVE RICHMOND, VA 23261-6609

EMERGENCY TELEPHONE: (804) 257-2000 (8:30 AM - 5:00 PM)
(804) 257-2000 (AFTER HOURS)

. . . SECTION 2 COMPOSITION INFORMATION . . . . . .

HAZARDOUS INGREDIENTS:
AS FORMULATED, THIS FINISHED PHARMACEUTICAL PRODUCT DOES NOT CONSTITUTE A PHYSICAL HAZARD WITHIN THE MEANING OF 29 CFR SEC 1910.1200. POTENTIAL HEALTH HAZARDS FROM INGESTION OR EXPOSURE TO THE PRODUCT ARE DISCUSSED IN SECTION 6 BELOW.

ACTIVE INGREDIENTS:		CAS
FENFLURAMINE HCL	20MG	404-82-0

INACTIVE INGREDIENTS:
CORN STARCH, FD&C YELLOW 6, MAGNESIUM STEARATE, MICROCRYSTALLINE CELLULOSE, SILICON DIOXIDE, SODIUM LAURYL SULFATE

. . . SECTION 3 PHYSICAL/CHEMICAL CHARACTERISTICS . . . . . .

BOILING POINT	NOT APPLICABLE
VAPOR PRESSURE	NOT APPLICABLE
VAPOR DENSITY	NOT APPLICABLE
SOLUBILITY IN WATER	NOT APPLICABLE
SPECIFIC GRAVITY	NOT APPLICABLE
MELTING POINT	NOT APPLICABLE
EVAPORATION RATE	NOT APPLICABLE
APPEARANCE	ORANGE, SCORED, COMPRESSED TABLETS MONOGRAMMED AHR AND 6447

. . . SECTION 4 FIRE AND EXPLOSION HAZARD DATA . . . . . .

FLASH POINT	NOT APPLICABLE
METHOD USED	NOT APPLICABLE
FLAMMABLE LIMITS	
LEL	NOT APPLICABLE
UEL	NOT APPLICABLE
EXTINGUISHING MEDIA	NOT APPLICABLE
SPECIAL FIRE-FIGHTING PROCEDURES	NOT APPLICABLE
UNUSUAL FIRE AND EXPLOSION HAZARDS	NONE

. . . SECTION 5 REACTIVITY DATA . . . . . .

STABILITY	STABLE
INCOMPATABILITY	NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS	NONE KNOWN
HAZARDOUS POLYMERIZATION	WILL NOT OCCUR

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS) EFFECTIVE 06/01/87

ALLBEE-T TABLETS NDC 0031-0688-XX

. . . SECTION 1 MANUFACTURER INFORMATION . . . . . .

A. H. ROBINS CO.,INC. 1405 CUMMINGS DRIVE RICHMOND, VA 23261-6609

EMERGENCY TELEPHONE: (804) 257-2000 (8:30 AM - 5:00 PM)
(804) 257-2000 (AFTER HOURS)

. . . SECTION 2 COMPOSITION INFORMATION . . . . . .

HAZARDOUS INGREDIENTS:
AS FORMULATED, THIS FINISHED PHARMACEUTICAL PRODUCT DOES NOT CONSTITUTE A PHYSICAL HAZARD WITHIN THE MEANING OF 29 CFR SEC 1910.1200. POTENTIAL HEALTH HAZARDS FROM INGESTION OR EXPOSURE TO THE PRODUCT ARE DISCUSSED IN SECTION 6 BELOW.

VITAMIN COMPOSITION PER TABLET:		CAS
VITAMIN C	500MG	50-81-7
THIAMINE (VITAMIN B1)	15.5MG	532-43-4
RIBOFLAVIN (VITAMIN B2)	10MG	83-88-5
NIACIN	100MG	98-92-0
VITAMIN B6	8.2MG	58-56-0
VITAMIN B12	5MCG	68-19-9
PANTOTHENIC ACID	23MG	137-08-6

INGREDIENTS:
SODIUM ASCORBATE, DESSICATED LIVER, LACTOSE, NIACINAMIDE, CALCIUM PANTOTHENATE, HYDROXYPROPYL METHYLCELLULOSE, STEARIC ACID, POVIDONE, THIAMINE MONONITRATE, RIBOFLAVIN, ARTIFICIAL COLOR, PYRIDOXINE HYDROCHLORIDE, POLYSORBATE 20, VANILLIN, PROPYLENE GLYCOL, TITANIUM DIOXIDE, HYDROXYPROPYL CELLULOSE, GELATIN, CYANOCOBALAMIN

. . . SECTION 3 PHYSICAL/CHEMICAL CHARACTERISTICS . . . . . .

BOILING POINT	NOT APPLICABLE
VAPOR PRESSURE	NOT APPLICABLE
VAPOR DENSITY	NOT APPLICABLE
SOLUBILITY IN WATER	NOT APPLICABLE
SPECIFIC GRAVITY	NOT APPLICABLE
MELTING POINT	NOT APPLICABLE
EVAPORATION RATE	NOT APPLICABLE
APPEARANCE	AN ORANGE, CAPSULE-SHAPED TABLET ENGRAVED AHR

. . . SECTION 4 FIRE AND EXPLOSION HAZARD DATA . . . . . .

FLASH POINT	NOT APPLICABLE
METHOD USED	NOT APPLICABLE
FLAMMABLE LIMITS	
LEL	NOT APPLICABLE
UEL	NOT APPLICABLE
EXTINGUISHING MEDIA	NOT APPLICABLE
SPECIAL FIRE-FIGHTING PROCEDURES	NOT APPLICABLE
UNUSUAL FIRE AND EXPLOSION HAZARDS	NONE

. . . SECTION 5 REACTIVITY DATA . . . . . .

STABILITY	STABLE
INCOMPATABILITY	NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS	NONE KNOWN
HAZARDOUS POLYMERIZATION	WILL NOT OCCUR

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

ALLBEE-T TABLETS NDC 0031-0688-XX

. . . SECTION 6 HEALTH HAZARD DATA . . . . . .

ROUTES OF ENTRY:	INGESTION
CARCINOGENICITY:	NONE OF THE COMPONENTS IN THIS PRODUCT ARE KNOWN TO BE CARCINOGENIC
SIGNS AND SYMPTOMS OF OVEREXPOSURE: VITAMIN COMPONENTS	NO SERIOUS EFFECTS ARE EXPECTED.
EMERGENCY AND FIRST-AID PROCEDURES:	EYE CONTACT- IRRIGATE SURFACES WITH WATER FOR 15 MINUTES. SKIN CONTACT- WASH AREAS WITH SOAP AND WATER.
MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:	HYPERSENSITIVITY TO ANY OF THE COMPONENTS

. . . SECTION 7 PRECAUTIONS FOR SAFE HANDLING AND USE . . . . . .

SPILLS AND ACCIDENTAL RELEASES:	SWEEP OR SHOVEL INTO A WASTE CONTAINER
WASTE DISPOSAL METHOD:	DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. THIS IS A BIOLOGICALLY ACTIVE MATERIAL. DISPOSE OF ON SITE OR AT AN APPROVED DISPOSAL FACILITY IN ACCORDANCE WITH LOCAL, STATE, AND/OR FEDERAL REGULATIONS.
HANDLING AND STORAGE:	STORE AT ROOM TEMPERATURE, BETWEEN 59 AND 86 DEGREES F.

. . . SECTION 8 CONTROL MEASURES . . . . . .

NO SPECIAL CONTROL MEASURES ARE REQUIRED UNDER NORMAL CONDITIONS OF USE

RESPIRATORY PROTECTION	NONE REQUIRED
VENTILATION	NO SPECIAL VENTILATION IS REQUIRED
PROTECTIVE CLOTHING OR EQUIPMENT	AVOID CONTACT WITH EYES OR PROLONGED CONTACT WITH SKIN.
WORK/HYGIENIC PRACTICES	WASH THOROUGHLY AFTER HANDLING

. . . . . .

THE INFORMATION CONTAINED IN THIS MSDS IS, TO THE BEST OF A.H.ROBINS' KNOWLEDGE, COMPLETE AND ACCURATE. A.H.ROBINS, HOWEVER, USES MANY SOURCES AND REFERENCES FOR GATHERING THIS INFORMATION. THUS, A.H. ROBINS CANNOT GUARANTEE COMPLETENESS OR ACCURACY AND DISCLAIMS ALL LIABILITY FOR ITS HANDLING AND USE.

FILE/ALLBEET/TABLETS . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS) EFFECTIVE 06/11/87

ARTHRALGEN TABLETS NDC 0031-1462-XX

. . . SECTION 1 MANUFACTURER INFORMATION . . . . . .

A. H. ROBINS CO.,INC. 1405 CUMMINGS DRIVE RICHMOND, VA 23261-6609

EMERGENCY TELEPHONE: (804) 257-2000 (8:30 AM - 5:00 PM)
(804) 257-2000 (AFTER HOURS)

. . . SECTION 2 COMPOSITION INFORMATION . . . . . .

HAZARDOUS INGREDIENTS:
AS FORMULATED, THIS FINISHED PHARMACEUTICAL PRODUCT DOES NOT CONSTITUTE A PHYSICAL HAZARD WITHIN THE MEANING OF 29 CFR SEC 1910.1200. POTENTIAL HEALTH HAZARDS FROM INGESTION OR EXPOSURE TO THE PRODUCT ARE DISCUSSED IN SECTION 6 BELOW.

ACTIVE INGREDIENTS: EACH TABLET CONTAINS:		CAS
SALICYLAMIDE	250 MG	64-45-2
ACETAMINOPHEN, USP	250 MG	103-90-2

INACTIVE INGREDIENTS:
GUAR GUM, MICROCRYSTALLINE CELLULOSE, POVIDONE, SODIUM LAURYL SULFATE, STEARIC ACID, TALC

. . . SECTION 3 PHYSICAL/CHEMICAL CHARACTERISTICS . . . . . .

BOILING POINT	NOT APPLICABLE
VAPOR PRESSURE	NOT APPLICABLE
VAPOR DENSITY	NOT APPLICABLE
SOLUBILITY IN WATER	NOT APPLICABLE
SPECIFIC GRAVITY	NOT APPLICABLE
MELTING POINT	NOT APPLICABLE
EVAPORATION RATE	NOT APPLICABLE
APPEARANCE	WHITE SCORED TABLETS

. . . SECTION 4 FIRE AND EXPLOSION HAZARD DATA . . . . . .

FLASH POINT	NOT APPLICABLE
METHOD USED	NOT APPLICABLE
FLAMMABLE LIMITS	
LEL	NOT APPLICABLE
UEL	NOT APPLICABLE
EXTINGUISHING MEDIA	NOT APPLICABLE
SPECIAL FIRE-FIGHTING PROCEDURES	NOT APPLICABLE
UNUSUAL FIRE AND EXPLOSION HAZARDS	NONE

. . . SECTION 5 REACTIVITY DATA . . . . . .

STABILITY	STABLE
INCOMPATABILITY	NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS	NONE KNOWN
HAZARDOUS POLYMERIZATION	WILL NOT OCCUR

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

ARTHRALGEN TABLETS NDC 0031-1462-XX

. . . SECTION 6 HEALTH HAZARD DATA . . . . . .

	ROUTES OF ENTRY:	INGESTION
	CARCINOGENICITY:	NONE OF THE COMPONENTS IN THIS PRODUCT ARE KNOWN TO BE CARCINOGENIC
SIGNS AND SYMPTOMS OF OVER-EXPOSURE:	ACETAMINOPHEN	SEVERE OVERDOSAGE MAY PRODUCE NAUSEA, VOMITING, PERSPIRATION, AND GENERAL DISCOMFORT. MASSIVE OVERDOSAGE MAY PRODUCE DAMAGE TO LIVER, KIDNEYS, AND CENTRAL NERVOUS SYSTEM. REPEATED INGESTION OF TOXIC DOSES MAY PRODUCE CIRRHOSIS OF THE LIVER. POTENTIALLY TOXIC DOSE IS ABOUT 10 GRAMS.
	SALICYLAMIDE	CENTRAL NERVOUS SYSTEM DEPRESSION, DECREASED BLOOD PRESSURE, AND ULTIMATELY RESPIRATORY ARREST. OVERDOSAGE OF SALICYLAMIDE DOES NOT PRODUCE TYPICAL SALICYLATE SIDE-EFFECTS, SUCH AS METABOLIC ACIDOSIS (SEE ATTACHED PRODUCT LABELING FOR FULL INFORMATION ON SIDE-EFFECTS)
	EMERGENCY AND FIRST-AID PROCEDURES:	EYE CONTACT- IRRIGATE SURFACES WITH WATER FOR 15 MINUTES. SKIN CONTACT- WASH AREAS WITH SOAP AND WATER. TREATMENT OF OVERDOSE: INDUCED EMESIS, LAVAGE, AND ACTIVATED CHARCOAL MAY BE HELPFUL. IF POTENTIALLY TOXIC DOSES ARE INGESTED, SERUM ACETAMINOPHEN LEVELS SHOULD BE MONITORED BEGINNING 4 HOURS AFTER INGESTION AND LIVER FUNCTION TESTS SHOULD BE SERIALLY MONITORED (THE ANTIDOTE FOR ACETAMINOPHEN, N-ACETYLCYSTEINE, SHOULD BE ADMINISTERED WITHIN 16 HOURS FOLLOWING INGESTION) SYMPTOMATIC AND SUPPORTIVE TREATMENT AS REQUIRED
	MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:	HYPERSENSITIVITY TO ANY OF THE COMPONENTS; INDIVIDUALS CHRONICALLY EXPOSED TO ALCOHOL OR OTHER DRUGS MAY BE MORE SUSCEPTIBLE TO THE TOXIC EFFECTS OF ACETAMINOPHEN.

FOR COMPLETE INFORMATION ON THIS DRUG PLEASE REFER TO THE ATTACHED PRODUCT LABELING

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

ARTHRALGEN TABLETS NDC 0031-1462-XX

. . . SECTION 7 PRECAUTIONS FOR SAFE HANDLING AND USE . . . . . .

SPILLS AND ACCIDENTAL RELEASES:	SWEEP OR SHOVEL INTO A WASTE CONTAINER
WASTE DISPOSAL METHOD:	DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. THIS IS A BIOLOGICALLY ACTIVE MATERIAL. DISPOSE OF ON SITE OR AT AN APPROVED DISPOSAL FACILITY IN ACCORDANCE WITH LOCAL,STATE,AND/OR FEDERAL REGULATIONS.
HANDLING AND STORAGE:	STORE AT ROOM TEMPERATURE, BETWEEN 59 AND 86 DEGREES F.

. . . SECTION 8 CONTROL MEASURES . . . . . .

NO SPECIAL CONTROL MEASURES ARE REQUIRED UNDER NORMAL CONDITIONS OF USE

RESPIRATORY PROTECTION	NONE REQUIRED
VENTILATION	NO SPECIAL VENTILATION IS REQUIRED
PROTECTIVE CLOTHING OR EQUIPMENT	AVOID CONTACT WITH EYES OR PROLONGED CONTACT WITH SKIN.
WORK/HYGIENIC PRACTICES	WASH THOROUGHLY AFTER HANDLING

. . . . . .

THE INFORMATION CONTAINED IN THIS MSDS IS, TO THE BEST OF A.H.ROBINS' KNOWLEDGE, COMPLETE AND ACCURATE. A.H.ROBINS, HOWEVER, USES MANY SOURCES AND REFERENCES FOR GATHERING THIS INFORMATION. THUS, A.H. ROBINS CANNOT GUARANTEE COMPLETENESS OR ACCURACY AND DISCLAIMS ALL LIABILITY FOR ITS HANDLING AND USE.

FILE/ARTHRALG/TABLETS . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS) EFFECTIVE 04/23/87

DIMETANE-DC COUGH SYRUP NDC 0031-1833-XX

. . . SECTION 1 MANUFACTURER INFORMATION . . . . . .

A. H. ROBINS CO.,INC. 1405 CUMMINGS DRIVE RICHMOND, VA 23261-6609

EMERGENCY TELEPHONE: (804) 257-2000 (8:30 AM - 5:00 PM)
(804) 257-2000 (AFTER HOURS)

. . . SECTION 2 COMPOSITION INFORMATION . . . . . .

HAZARDOUS INGREDIENTS:
AS FORMULATED, THIS FINISHED PHARMACEUTICAL PRODUCT DOES NOT CONSTITUTE A PHYSICAL HAZARD WITHIN THE MEANING OF 29 CFR SEC 1910.1200. POTENTIAL HEALTH HAZARDS FROM INGESTION OR EXPOSURE TO THE PRODUCT ARE DISCUSSED IN SECTION 6 BELOW.

ACTIVE INGREDIENTS: EACH 5ML CONTAINS:		CAS
BROMPHENIRAMINE MALEATE, USP	2MG	980-71-2
PHENYLPROPANOLAMINE HCL, USP	12.5MG	154-41-6
CODEINE PHOSPHATE, USP	10MG	41444-62-6
(WARNING: MAY BE HABIT FORMING)		

INACTIVE INGREDIENTS:
ALCOHOL (0.95%), CITRIC ACID, FD&C BLUE 1, FD&C RED 40, FLAVORS, GLYCERIN, SODIUM BENZOATE, SORBITOL, WATER.

. . . SECTION 3 PHYSICAL/CHEMICAL CHARACTERISTICS . . . . . .

BOILING POINT	NOT APPLICABLE
VAPOR PRESSURE	NOT APPLICABLE
VAPOR DENSITY	NOT APPLICABLE
SOLUBILITY IN WATER	SOLUBLE
SPECIFIC GRAVITY1.195-1.215	
MELTING POINT	NOT APPLICABLE
EVAPORATION RATE	NOT APPLICABLE
APPEARANCE	LIGHT BLUISH-PINK SYRUP WITH A RASBERRY FLAVOR

. . . SECTION 4 FIRE AND EXPLOSION HAZARD DATA . . . . . .

FLASH POINT	> 230 DEGREES F
METHOD USED	ASTM 3828-81
FLAMMABLE LIMITS	
LEL	NOT APPLICABLE
UEL	NOT APPLICABLE
EXTINGUISHING MEDIA	NOT APPLICABLE
SPECIAL FIRE-FIGHTING PROCEDURES	NOT APPLICABLE
UNUSUAL FIRE AND EXPLOSION HAZARDS	NONE

. . . SECTION 5 REACTIVITY DATA . . . . . .

STABILITY	STABLE
INCOMPATABILITY	NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS	NONE KNOWN
HAZARDOUS POLYMERIZATION	WILL NOT OCCUR

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

DIMETANE-DC COUGH SYRUP NDC 0031-1833-XX

. . . SECTION 6 HEALTH HAZARD DATA . . . . . .

ROUTES OF ENTRY:		INGESTION SKIN- IT IS NOT KNOWN IF ANY OF THE INGREDIENTS IN DIMETANE-DC ARE ABSORBED THROUGH THE SKIN FROM DIMETANE-DC
CARCINOGENICITY:		NONE OF THE COMPONENTS IN THIS PRODUCT ARE KNOWN TO BE CARCINOGENIC
SIGNS AND SYMPTOMS OF OVER-EXPOSURE:	BROMPHENIRAMINE	DROWSINESS; EXCITABILITY IN SOME CASES; DRY MOUTH, GLAUCOMA (INCREASED EYE PRESSURE), DIFFICULTY IN URINATION
	CODEINE PHOSPHATE	PINPOINT PUPILS, CONSTIPATION, SLOW HEART RATE, HIGH BLOOD PRESSURE, RESPIRATORY DEPRESSION, URINARY RETENTION, MUSCLE SPASMS, ITCHING, RESPIRATORY ARREST, COMA
	PHENYLPROPANOLAMINE	EXCITEMENT, RAPID HEART BEAT, HIGH BLOOD PRESSURE, NERVOUSNESS, IRREGULAR HEART BEAT
		(SEE ATTACHED PRODUCT LABELING FOR FULL INFORMATION ON SIDE-EFFECTS)
EMERGENCY AND FIRST-AID PROCEDURES:		EYE CONTACT- IRRIGATE SURFACES WITH WATER FOR 15 MINUTES. SKIN CONTACT- WASH AREAS WITH SOAP AND WATER. TREATMENT OF OVERDOSE: INDUCED EMESIS, LAVAGE, AND ACTIVATED CHARCOAL MAY BE HELPFUL. SEVERE OPIATE EFFECTS SUCH AS RESPIRATORY DEPRESSION MAY BE REVERSED BY NALOXONE. SHORT-ACTING BARBITURATES MAY BE USED TO TREAT CASES OF SEVERE CNS HYPERACTIVITY. SYMPTOMATIC AND SUPPORTIVE TREATMENT AS REQUIRED.
MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:		HYPERSENSITIVITY TO ANY OF THE COMPONENTS

FOR COMPLETE INFORMATION ON THIS PRODUCT PLEASE REFER TO THE ATTACHED PRODUCT LABELING

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

DIMETANE-DC COUGH SYRUP NDC 0031-1833-XX

. . . SECTION 7 PRECAUTIONS FOR SAFE HANDLING AND USE . . . . . .

SPILLS AND ACCIDENTAL RELEASES:	SOAK UP ON ABSORBANT MATERIAL AND PLACE IN APPROVED WASTE CONTAINER. WASH AREAS WITH SOAP AND WATER.
WASTE DISPOSAL METHOD:	DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. THIS IS A BIOLOGICALLY ACTIVE MATERIAL. DISPOSE OF ON SITE OR AT AN APPROVED DISPOSAL FACILITY IN ACCORDANCE WITH LOCAL,STATE,AND/OR FEDERAL REGULATIONS.
HANDLING AND STORAGE:	STORE AT ROOM TEMPERATURE, BETWEEN 59 AND 86 DEGREES F.

. . . SECTION 8 CONTROL MEASURES . . . . . .

NO SPECIAL CONTROL MEASURES ARE REQUIRED UNDER NORMAL CONDITIONS OF USE

RESPIRATORY PROTECTION	NONE REQUIRED
VENTILATION	NO SPECIAL VENTILATION IS REQUIRED
PROTECTIVE CLOTHING OR EQUIPMENT	AVOID CONTACT WITH EYES OR PROLONGED CONTACT WITH SKIN.
WORK/HYGIENIC PRACTICES	WASH THOROUGHLY AFTER HANDLING

. . . . . .

THE INFORMATION CONTAINED IN THIS MSDS IS, TO THE BEST OF A.H.ROBINS' KNOWLEDGE, COMPLETE AND ACCURATE. A.H.ROBINS, HOWEVER, USES MANY SOURCES AND REFERENCES FOR GATHERING THIS INFORMATION. THUS, A.H. ROBINS CANNOT GUARANTEE COMPLETENESS OR ACCURACY AND DISCLAIMS ALL LIABILITY FOR ITS HANDLING AND USE.

FILE/DIMETANE/DC . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS) EFFECTIVE 04/23/87

DIMETANE-DX COUGH SYRUP NDC 0031-1836-XX

. . . SECTION 1 MANUFACTURER INFORMATION . . . . . .

A. H. ROBINS CO.,INC. 1405 CUMMINGS DRIVE RICHMOND, VA 23261-6609

EMERGENCY TELEPHONE: (804) 257-2000 (8:30 AM - 5:00 PM)
(804) 257-2000 (AFTER HOURS)

. . . SECTION 2 COMPOSITION INFORMATION . . . . . .

HAZARDOUS INGREDIENTS:
AS FORMULATED, THIS FINISHED PHARMACEUTICAL PRODUCT DOES NOT CONSTITUTE A PHYSICAL HAZARD WITHIN THE MEANING OF 29 CFR SEC 1910.1200. POTENTIAL HEALTH HAZARDS FROM INGESTION OR EXPOSURE TO THE PRODUCT ARE DISCUSSED IN SECTION 6 BELOW.

ACTIVE INGREDIENTS: EACH 5ML CONTAINS:		CAS
BROMPHENIRAMINE MALEATE, USP	2MG	980-71-2
PSEUDOEPHEDRINE HCL, USP	30MG	345-78-8
DEXTROMETHORPHAN HBR, USP	10MG	6700-34-1

INACTIVE INGREDIENTS:
ALCOHOL (0.95%), CITRIC ACID, FD&C RED 40, FD&C YELLOW 6, FLAVORS, GLYCERIN, SACCHARIN SODIUM, SODIUM BENZOATE, SORBITOL, WATER.

. . . SECTION 3 PHYSICAL/CHEMICAL CHARACTERISTICS . . . . . .

BOILING POINT	NOT APPLICABLE
VAPOR PRESSURE	NOT APPLICABLE
VAPOR DENSITY	NOT APPLICABLE
SOLUBILITY IN WATER	SOLUBLE
SPECIFIC GRAVITY	CA 1.18
MELTING POINT	NOT APPLICABLE
EVAPORATION RATE	NOT APPLICABLE
APPEARANCE	LIGHT RED SYRUP WITH A BUTTERSCOTCH FLAVOR

. . . SECTION 4 FIRE AND EXPLOSION HAZARD DATA . . . . . .

FLASH POINT	NOT APPLICABLE
METHOD USED	NOT APPLICABLE
FLAMMABLE LIMITS	
LEL	NOT APPLICABLE
UEL	NOT APPLICABLE
EXTINGUISHING MEDIA	NOT APPLICABLE
SPECIAL FIRE-FIGHTING PROCEDURES	NOT APPLICABLE
UNUSUAL FIRE AND EXPLOSION HAZARDS	NONE

. . . SECTION 5 REACTIVITY DATA . . . . . .

STABILITY	STABLE
INCOMPATABILITY	NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS	NONE KNOWN
HAZARDOUS POLYMERIZATION	WILL NOT OCCUR

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

DIMETANE-DX COUGH SYRUP NDC 0031-1836-XX

. . . SECTION 6 HEALTH HAZARD DATA . . . . . .

ROUTES OF ENTRY:		INGESTION SKIN- IT IS NOT KNOWN IF ANY OF THE INGREDIENTS IN DIMETANE-DX ARE ABSORBED THROUGH THE SKIN FROM DIMETANE-DX
CARCINOGENICITY:		NONE OF THE COMPONENTS IN THIS PRODUCT ARE KNOWN TO BE CARCINOGENIC
SIGNS AND SYMPTOMS OF OVER-EXPOSURE:	BROMPHENIRAMINE	DROWSINESS; EXCITABILITY IN SOME CASES; DRY MOUTH, GLAUCOMA (INCREASED EYE PRESSURE), DIFFICULTY IN URINATION
	DEXTROMETHORPHAN	DROWSINESS, UNSTEADY GAIT, NYSTAGMUS, SEVERE MUSCLE SPASMS, CONVULSIONS, ALTERED MOOD.
	PSEUDOEPHEDRINE	EXCITEMENT, RAPID HEART BEAT, HIGH BLOOD PRESSURE, NERVOUSNESS, IRREGULAR HEART BEAT
		(SEE ATTACHED PRODUCT LABELING FOR FULL INFORMATION ON SIDE-EFFECTS)
EMERGENCY AND FIRST-AID PROCEDURES:		EYE CONTACT- IRRIGATE SURFACES WITH WATER FOR 15 MINUTES. SKIN CONTACT- WASH AREAS WITH SOAP AND WATER. TREATMENT OF OVERDOSE: INDUCED EMESIS, LAVAGE, AND ACTIVATED CHARCOAL MAY BE HELPFUL. SEVERE CNS DEPRESSANT EFFECTS SUCH AS RESPIRATORY DEPRESSION MAY BE REVERSED BY NALOXONE. SHORT-ACTING BARBITURATES MAY BE USED TO TREAT CASES OF SEVERE CNS HYPERACTIVITY. SYMPTOMATIC AND SUPPORTIVE TREATMENT AS REQUIRED.
MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:		HYPERSENSITIVITY TO ANY OF THE COMPONENTS

FOR COMPLETE INFORMATION ON THIS PRODUCT PLEASE REFER TO THE ATTACHED PRODUCT LABELING

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

DIMETANE-DX COUGH SYRUP NDC 0031-1836-XX

. . . SECTION 7 PRECAUTIONS FOR SAFE HANDLING AND USE . . . . . .

SPILLS AND ACCIDENTAL RELEASES:	SOAK UP ON ABSORBANT MATERIAL AND PLACE IN APPROVED WASTE CONTAINER. WASH AREAS WITH SOAP AND WATER.
WASTE DISPOSAL METHOD:	DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. THIS IS A BIOLOGICALLY ACTIVE MATERIAL. DISPOSE OF ON SITE OR AT AN APPROVED DISPOSAL FACILITY IN ACCORDANCE WITH LOCAL,STATE,AND/OR FEDERAL REGULATIONS.
HANDLING AND STORAGE:	STORE AT ROOM TEMPERATURE, BETWEEN 59 AND 86 DEGREES F.

. . . SECTION 8 CONTROL MEASURES . . . . . .

NO SPECIAL CONTROL MEASURES ARE REQUIRED UNDER NORMAL CONDITIONS OF USE

RESPIRATORY PROTECTION	NONE REQUIRED
VENTILATION	NO SPECIAL VENTILATION IS REQUIRED
PROTECTIVE CLOTHING OR EQUIPMENT	AVOID CONTACT WITH EYES OR PROLONGED CONTACT WITH SKIN.
WORK/HYGIENIC PRACTICES	WASH THOROUGHLY AFTER HANDLING

. . . . . .

THE INFORMATION CONTAINED IN THIS MSDS IS, TO THE BEST OF A.H.ROBINS' KNOWLEDGE, COMPLETE AND ACCURATE. A.H.ROBINS, HOWEVER, USES MANY SOURCES AND REFERENCES FOR GATHERING THIS INFORMATION. THUS, A.H. ROBINS CANNOT GUARANTEE COMPLETENESS OR ACCURACY AND DISCLAIMS ALL LIABILITY FOR ITS HANDLING AND USE.

FILE/DIMETANE/DX . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS) EFFECTIVE 04/15/87

DIMETANE 10 INJECTABLE NDC 0031-1881-XX

. . . SECTION 1 MANUFACTURER INFORMATION . . . . . .

A. H. ROBINS CO.,INC. 1405 CUMMINGS DRIVE RICHMOND, VA 23261-6609

EMERGENCY TELEPHONE: (804) 257-2000 (8:30 AM - 5:00 PM)
(804) 257-2000 (AFTER HOURS)

. . . SECTION 2 COMPOSITION INFORMATION . . . . . .

HAZARDOUS INGREDIENTS:
AS FORMULATED, THIS FINISHED PHARMACEUTICAL PRODUCT DOES NOT CONSTITUTE A PHYSICAL HAZARD WITHIN THE MEANING OF 29 CFR SEC 1910.1200. POTENTIAL HEALTH HAZARDS FROM INGESTION OR EXPOSURE TO THE PRODUCT ARE DISCUSSED IN SECTION 6 BELOW.

ACTIVE INGREDIENTS:		CAS
EACH 1ML CONTAINS:		
BROMPHENIRAMINE MALEATE, USP	10 MG	980-71-2

INACTIVE INGREDIENTS:
WATER FOR INJECTION USP; PH ADJUSTED WITH SODIUM HYDROXIDE

. . . SECTION 3 PHYSICAL/CHEMICAL CHARACTERISTICS . . . . . .

BOILING POINT	CA 100 DEGREES C.
VAPOR PRESSURE	NOT APPLICABLE
VAPOR DENSITY	NOT APPLICABLE
SOLUBILITY IN WATER	SOLUBLE
SPECIFIC GRAVITY	CA 1.00
MELTING POINT	NOT APPLICABLE
EVAPORATION RATE	NOT APPLICABLE
APPEARANCE	AMPULES CONTAINING A CLEAR, COLORLESS, ODORLESS LIQUID

. . . SECTION 4 FIRE AND EXPLOSION HAZARD DATA . . . . . .

FLASH POINT	NOT APPLICABLE
METHOD USED	NOT APPLICABLE
FLAMMABLE LIMITS	
LEL	NOT APPLICABLE
UEL	NOT APPLICABLE
EXTINGUISHING MEDIA	NOT APPLICABLE
SPECIAL FIRE-FIGHTING PROCEDURES	NOT APPLICABLE
UNUSUAL FIRE AND EXPLOSION HAZARDS	NONE

. . . SECTION 5 REACTIVITY DATA . . . . . .

STABILITY	STABLE
INCOMPATABILITY	NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS	NONE KNOWN
HAZARDOUS POLYMERIZATION	WILL NOT OCCUR

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

DIMETANE 10 INJECTABLE NDC 0031-1881-XX

. . . SECTION 6 HEALTH HAZARD DATA . . . . . .

ROUTES OF ENTRY:		INGESTION SKIN- IT IS NOT KNOWN IF BROMPHENIRAMINE MALEATE IS ABSORBED THROUGH THE SKIN FROM DIMETANE INJECTABLE
CARCINOGENICITY:		NONE OF THE COMPONENTS IN THIS PRODUCT ARE KNOWN TO BE CARCINOGENIC
SIGNS AND SYMPTOMS OF OVER-EXPOSURE:	BROMPHENIRAMINE	DROWSINESS; EXCITABILITY IN SOME CASES; DRY MOUTH, GLAUCOMA (INCREASED EYE PRESSURE), DIFFICULTY IN URINATION (SEE ATTACHED PRODUCT LABELING FOR FULL INFORMATION ON SIDE-EFFECTS)
EMERGENCY AND FIRST-AID PROCEDURES:		EYE CONTACT- IRRIGATE SURFACES WITH WATER FOR 15 MINUTES. SKIN CONTACT- WASH AREAS WITH SOAP AND WATER. TREATMENT OF OVERDOSE: INDUCED EMESIS, LAVAGE, AND ACTIVATED CHARCOAL MAY BE HELPFUL. SYMPTOMATIC AND SUPPORTIVE TREATMENT AS REQUIRED.
MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:		HYPERSENSITIVITY TO ANY OF THE COMPONENTS; GLAUCOMA; URINARY RETENTION

FOR COMPLETE INFORMATION ON THIS DRUG PLEASE REFER TO THE ATTACHED PRODUCT LABELING

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

DIMETANE 10 INJECTABLE NDC 0031-1881-XX

. . . SECTION 7 PRECAUTIONS FOR SAFE HANDLING AND USE . . . . . .

SPILLS AND ACCIDENTAL RELEASES:	SOAK UP ON ABSORBANT MATERIAL AND PLACE IN APPROVED WASTE CONTAINER. WASH AREAS WITH SOAP AND WATER.
WASTE DISPOSAL METHOD:	DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. THIS IS A BIOLOGICALLY ACTIVE MATERIAL. DISPOSE OF ON SITE OR AT AN APPROVED DISPOSAL FACILITY IN ACCORDANCE WITH LOCAL,STATE,AND/OR FEDERAL REGULATIONS.
HANDLING AND STORAGE:	STORE AT ROOM TEMPERATURE, BETWEEN 59 AND 86 DEGREES F.

. . . SECTION 8 CONTROL MEASURES . . . . . .

NO SPECIAL CONTROL MEASURES ARE REQUIRED UNDER NORMAL CONDITIONS OF USE

RESPIRATORY PROTECTION	NONE REQUIRED
VENTILATION	NO SPECIAL VENTILATION IS REQUIRED
PROTECTIVE CLOTHING OR EQUIPMENT	AVOID CONTACT WITH EYES OR PROLONGED CONTACT WITH SKIN.
WORK/HYGIENIC PRACTICES	WASH THOROUGHLY AFTER HANDLING

. . . . . .

THE INFORMATION CONTAINED IN THIS MSDS IS, TO THE BEST OF A.H.ROBINS' KNOWLEDGE, COMPLETE AND ACCURATE. A.H.ROBINS, HOWEVER, USES MANY SOURCES AND REFERENCES FOR GATHERING THIS INFORMATION. THUS, A.H. ROBINS CANNOT GUARANTEE COMPLETENESS OR ACCURACY AND DISCLAIMS ALL LIABILITY FOR ITS HANDLING AND USE.

FILE/DIMETANE/INJECT. . . . . .

MATERIAL SAFETY DATA SHEET (MSDS) EFFECTIVE 03/10/87

DONNAGEL-PG NDC 0031-3083-XX

. . . SECTION 1 MANUFACTURER INFORMATION . . . . . .

A. H. ROBINS CO.,INC. 1405 CUMMINGS DRIVE RICHMOND, VA 23261-6609

EMERGENCY TELEPHONE: (804) 257-2000 (8:30 AM - 5:00 PM)
(804) 257-2000 (AFTER HOURS)

. . . SECTION 2 COMPOSITION INFORMATION . . . . . .

HAZARDOUS INGREDIENTS:
AS FORMULATED, THIS FINISHED PHARMACEUTICAL PRODUCT DOES NOT CONSTITUTE A PHYSICAL HAZARD WITHIN THE MEANING OF 29 CFR SEC 1910.1200. POTENTIAL HEALTH HAZARDS FROM INGESTION OR EXPOSURE TO THE PRODUCT ARE DISCUSSED IN SECTION 6 BELOW.

ACTIVE INGREDIENTS:

EACH FLUID OUNCE (2 TABLESPOONFULS) CONTAINS		CAS
POWDERED OPIUM, USP (OR EQUIV) (WARNING: MAY BE HABIT FORMING)	24.0 MG	-
KAOLIN, USP	6 G	-
PECTIN, USP	142.8 MG	9000-69-5
HYOSCYAMINE SULFATE, USP	0.1037 MG	6835-16-1
ATROPINE SULFATE, USP	0.0194 MG	55-48-1
SCOPOLOMINE HYDROBROMIDE, USP	0.0065 MG	114-49-8

INACTIVE INGREDIENTS:
SODIUM BENZOATE NF 60 MG/FLUID OUNCE (PRESERVATIVE), ALCOHOL 5.0%, CITRIC ACID, D&C YELLOW 10, FLAVORS, HIGH FRUCTOSE CORN SYRUP, SODIUM CARBOXYMETHYLCELLULOSE, SODIUM CHLORIDE, WATER.

. . . SECTION 3 PHYSICAL/CHEMICAL CHARACTERISTICS . . . . . .

BOILING POINT	NOT APPLICABLE
VAPOR PRESSURE	NOT APPLICABLE
VAPOR DENSITY	NOT APPLICABLE
SOLUBILITY IN WATER	NOT APPLICABLE
SPECIFIC GRAVITY	1.18
MELTING POINT	NOT APPLICABLE
EVAPORATION RATE	NOT APPLICABLE
APPEARANCE	A LIGHT YELLOW, BANANA-FLAVORED SUSPENSION

. . . SECTION 4 FIRE AND EXPLOSION HAZARD DATA . . . . . .

FLASH POINT	NOT APPLICABLE
METHOD USED	NOT APPLICABLE
FLAMMABLE LIMITS	
LEL	NOT APPLICABLE
UEL	NOT APPLICABLE
EXTINGUISHING MEDIA	NOT APPLICABLE
SPECIAL FIRE-FIGHTING PROCEDURES	NOT APPLICABLE
UNUSUAL FIRE AND EXPLOSION HAZARDS	NONE

. . . SECTION 5 REACTIVITY DATA . . . . . .

STABILITY	STABLE
INCOMPATABILITY	NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS	NONE KNOWN
HAZARDOUS POLYMERIZATION	WILL NOT OCCUR

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

DONNAGEL-PG NDC 0031-3083-XX

. . . SECTION 6 HEALTH HAZARD DATA . . . . . .

ROUTES OF ENTRY:		INGESTION SKIN- IT IS NOT KNOWN IF ANY OF THE INGREDIENTS IN DONNAGEL-PG ARE ABSORBED THROUGH THE SKIN FROM DONNAGEL-PG SUSPENSION
CARCINOGENICITY:		NONE OF THE COMPONENTS IN THIS PRODUCT ARE KNOWN TO BE CARCINOGENIC
SIGNS AND SYMPTOMS OF OVER-EXPOSURE:	POWDERED OPIUM	PINPOINT PUPILS, CONSTIPATION, SLOW HEART RATE, HIGH BLOOD PRESSURE, RESPIRATORY DEPRESSION, URINARY RETENTION, MUSCLE SPASMS, ITCHING, RESPIRATORY ARREST, COMA
	KAOLIN, PECTIN	NO SERIOUS EFFECTS ARE EXPECTED
	ATROPINE, HYOSCYAMINE, AND SCOPOLOMINE	DRY MOUTH, THIRST, FIXED DILATED PUPILS, FLUSHED FACE, FEVER, HOT DRY RED SKIN, TACHYCARDIA, BLURRED VISION, DELIRIUM, TREMORS, CONVULSIONS, COMA, RESPIRATORY FAILURE, CARDIOVASCULAR COLLAPSE
EMERGENCY AND FIRST-AID PROCEDURES:		EYE CONTACT- IRRIGATE SURFACES WITH WATER FOR 15 MINUTES. SKIN CONTACT- WASH AREAS WITH SOAP AND WATER. TREATMENT OF OVERDOSE: INDUCED EMESIS, LAVAGE, AND ACTIVATED CHARCOAL MAY BE HELPFUL. PHYSOSTIGMINE DRAMATICALLY REVERSES THE CENTRAL AND PERIPHERAL SIGNS OF ANTICHOLINERGIC TOXICITY. SEVERE OPIATE EFFECTS SUCH AS RESPIRATORY DEPRESSION MAY BE REVERSED BY NALOXONE. SYMPTOMATIC AND SUPPORTIVE TREATMENT AS REQUIRED.
MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:		HYPERSENSITIVITY TO ANY OF THE COMPONENTS; GLAUCOMA; URINARY RETENTION

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

DONNAGEL-PG NDC 0031-3083-XX

. . . SECTION 7 PRECAUTIONS FOR SAFE HANDLING AND USE . . . . . .

SPILLS AND ACCIDENTAL RELEASES:	SOAK UP ON ABSORBANT MATERIAL AND PLACE IN APPROVED WASTE CONTAINER. WASH AREAS WITH SOAP AND WATER.
WASTE DISPOSAL METHOD:	DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. THIS IS A BIOLOGICALLY ACTIVE MATERIAL. DISPOSE OF ON SITE OR AT AN APPROVED DISPOSAL FACILITY IN ACCORDANCE WITH LOCAL,STATE,AND/OR FEDERAL REGULATIONS.
HANDLING AND STORAGE:	STORE AT ROOM TEMPERATURE, BETWEEN 59 AND 86 DEGREES F.

. . . SECTION 8 CONTROL MEASURES . . . . . .

NO SPECIAL CONTROL MEASURES ARE REQUIRED UNDER NORMAL CONDITIONS OF USE

RESPIRATORY PROTECTION	NONE REQUIRED
VENTILATION	NO SPECIAL VENTILATION IS REQUIRED
PROTECTIVE CLOTHING OR EQUIPMENT	AVOID CONTACT WITH EYES OR PROLONGED CONTACT WITH SKIN.
WORK/HYGIENIC PRACTICES	WASH THOROUGHLY AFTER HANDLING

. . . . . .

THE INFORMATION CONTAINED IN THIS MSDS IS, TO THE BEST OF A.H.ROBINS' KNOWLEDGE, COMPLETE AND ACCURATE. A.H.ROBINS, HOWEVER, USES MANY SOURCES AND REFERENCES FOR GATHERING THIS INFORMATION. THUS, A.H. ROBINS CANNOT GUARANTEE COMPLETENESS OR ACCURACY AND DISCLAIMS ALL LIABILITY FOR ITS HANDLING AND USE.

FILE/DONNAGEL/PG . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS) EFFECTIVE 04/09/87

DONNATAL CAPSULES NDC 0031-4207-XX

. . . SECTION 1 MANUFACTURER INFORMATION . . . . . .

A. H. ROBINS CO.,INC. 1405 CUMMINGS DRIVE RICHMOND, VA 23261-6609

EMERGENCY TELEPHONE: (804) 257-2000 (8:30 AM - 5:00 PM)
(804) 257-2000 (AFTER HOURS)

. . . SECTION 2 COMPOSITION INFORMATION . . . . . .

HAZARDOUS INGREDIENTS:
AS FORMULATED, THIS FINISHED PHARMACEUTICAL PRODUCT DOES NOT CONSTITUTE A PHYSICAL HAZARD WITHIN THE MEANING OF 29 CFR SEC 1910.1200. POTENTIAL HEALTH HAZARDS FROM INGESTION OR EXPOSURE TO THE PRODUCT ARE DISCUSSED IN SECTION 6 BELOW.

ACTIVE INGREDIENTS:

EACH CAPSULE CONTAINS:			CAS
PHENOBARBITAL, USP	16.2	MG	50-06-6
(WARNING: MAY BE HABIT FORMING)			
HYOSCYAMINE SULFATE, USP	0.1037	MG	6835-16-1
ATROPINE SULFATE, USP	0.0194	MG	55-48-1
SCOPOLOMINE HYDROBROMIDE, USP	0.0065	MG	114-49-8

INACTIVE INGREDIENTS:
CORN STARCH, EDIBLE INK, D&C YELLOW 10 AND FD&C GREEN 3 OR FD&C BLUE 1 AND FD&C YELLOW 6, FD&C BLUE 2 ALUMINUM LAKE, GELATIN, LACTOSE, SUCROSE; MAY CONTAIN FD&C RED 40 AND YELLOW 6 ALUMINUM LAKES

. . . SECTION 3 PHYSICAL/CHEMICAL CHARACTERISTICS . . . . . .

BOILING POINT	NOT APPLICABLE
VAPOR PRESSURE	NOT APPLICABLE
VAPOR DENSITY	NOT APPLICABLE
SOLUBILITY IN WATER	NOT APPLICABLE
SPECIFIC GRAVITY	NOT APPLICABLE
MELTING POINT	NOT APPLICABLE
EVAPORATION RATE	NOT APPLICABLE
APPEARANCE	GREEN AND WHITE CAPSULES MONOGRAMMED "AHR" AND "4207"

. . . SECTION 4 FIRE AND EXPLOSION HAZARD DATA . . . . . .

FLASH POINT	NOT APPLICABLE
METHOD USED	NOT APPLICABLE
FLAMMABLE LIMITS	
LEL	NOT APPLICABLE
UEL	NOT APPLICABLE
EXTINGUISHING MEDIA	NOT APPLICABLE
SPECIAL FIRE-FIGHTING PROCEDURES	NOT APPLICABLE
UNUSUAL FIRE AND EXPLOSION HAZARDS	NONE

. . . SECTION 5 REACTIVITY DATA . . . . . .

STABILITY	STABLE
INCOMPATABILITY	NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS	NONE KNOWN
HAZARDOUS POLYMERIZATION	WILL NOT OCCUR

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

DONNATAL CAPSULES NDC 0031-4207-XX

. . . SECTION 6 HEALTH HAZARD DATA . . . . . .

	ROUTES OF ENTRY:	INGESTION
	CARCINOGENICITY:	NONE OF THE COMPONENTS IN THIS PRODUCT ARE KNOWN TO BE CARCINOGENIC
SIGNS AND SYMPTOMS OF OVER-EXPOSURE:	PHENOBARBITAL	DROWSINESS, DIZZINESS, WEAKNESS, SEDATION
	ATROPINE, HYOSCYAMINE, AND SCOPOLOMINE	DRY MOUTH, THIRST, FIXED DILATED PUPILS, FLUSHED FACE, FEVER, HOT DRY RED SKIN, TACHYCARDIA (RAPID HEART BEAT), BLURRED VISION, DELIRIUM, TREMORS, CONVULSIONS, COMA, RESPIRATORY FAILURE, CARDIOVASCULAR COLLAPSE
	EMERGENCY AND FIRST-AID PROCEDURES:	EYE CONTACT- IRRIGATE SURFACES WITH WATER FOR 15 MINUTES. SKIN CONTACT- WASH AREAS WITH SOAP AND WATER. TREATMENT OF OVERDOSE: INDUCED EMESIS, LAVAGE, AND ACTIVATED CHARCOAL MAY BE HELPFUL. PHYSOSTIGMINE DRAMATICALLY REVERSES THE CENTRAL AND PERIPHERAL SIGNS OF ANTICHOLINERGIC TOXICITY. SYMPTOMATIC AND SUPPORTIVE TREATMENT AS REQUIRED.
	MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:	HYPERSENSITIVITY TO ANY OF THE COMPONENTS; GLAUCOMA; URINARY RETENTION

FOR COMPLETE INFORMATION ON THIS DRUG PLEASE REFER TO THE ATTACHED PRODUCT LABELING

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

DONNATAL CAPSULES NDC 0031-4207-XX

. . . SECTION 7 PRECAUTIONS FOR SAFE HANDLING AND USE . . . . . .

SPILLS AND ACCIDENTAL RELEASES:	SWEEP OR SHOVEL INTO A WASTE CONTAINER
WASTE DISPOSAL METHOD:	DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. THIS IS A BIOLOGICALLY ACTIVE MATERIAL. DISPOSE OF ON SITE OR AT AN APPROVED DISPOSAL FACILITY IN ACCORDANCE WITH LOCAL,STATE,AND/OR FEDERAL REGULATIONS.
HANDLING AND STORAGE:	STORE AT ROOM TEMPERATURE, BETWEEN 59 AND 86 DEGREES F.

. . . SECTION 8 CONTROL MEASURES . . . . . .

NO SPECIAL CONTROL MEASURES ARE REQUIRED UNDER NORMAL CONDITIONS OF USE

RESPIRATORY PROTECTION	NONE REQUIRED
VENTILATION	NO SPECIAL VENTILATION IS REQUIRED
PROTECTIVE CLOTHING OR EQUIPMENT	AVOID CONTACT WITH EYES OR PROLONGED CONTACT WITH SKIN.
WORK/HYGIENIC PRACTICES	WASH THOROUGHLY AFTER HANDLING

. . . . . .

THE INFORMATION CONTAINED IN THIS MSDS IS, TO THE BEST OF A.H.ROBINS' KNOWLEDGE, COMPLETE AND ACCURATE. A.H.ROBINS, HOWEVER, USES MANY SOURCES AND REFERENCES FOR GATHERING THIS INFORMATION. THUS, A.H. ROBINS CANNOT GUARANTEE COMPLETENESS OR ACCURACY AND DISCLAIMS ALL LIABILITY FOR ITS HANDLING AND USE.

FILE/DONNATAL/CAPSULES. . . . . .

MATERIAL SAFETY DATA SHEET (MSDS) EFFECTIVE 04/09/87

DONNATAL ELIXIR NDC 0031-4221-XX

. . . SECTION 1 MANUFACTURER INFORMATION . . . . . .

A. H. ROBINS CO.,INC. 1405 CUMMINGS DRIVE RICHMOND, VA 23261-6609

EMERGENCY TELEPHONE: (804) 257-2000 (8:30 AM - 5:00 PM)
(804) 257-2000 (AFTER HOURS)

. . . SECTION 2 COMPOSITION INFORMATION . . . . . .

HAZARDOUS INGREDIENTS:
AS FORMULATED, THIS FINISHED PHARMACEUTICAL PRODUCT DOES NOT CONSTITUTE A PHYSICAL HAZARD WITHIN THE MEANING OF 29 CFR SEC 1910.1200. POTENTIAL HEALTH HAZARDS FROM INGESTION OR EXPOSURE TO THE PRODUCT ARE DISCUSSED IN SECTION 6 BELOW.

ACTIVE INGREDIENTS:

EACH 5ML CONTAINS:		CAS
PHENOBARBITAL, USP (WARNING: MAY BE HABIT FORMING)	16.2 MG	56-06-6
HYOSCYAMINE SULFATE, USP	0.1037 MG	6835-16-1
ATROPINE SULFATE, USP	0.0194 MG	55-48-1
SCOPOLOMINE HYDROBROMIDE, USP	0.0065 MG	114-49-8

INACTIVE INGREDIENTS:
D&C YELLOW 10, FD&C BLUE 1, FD&C YELLOW 6, FLAVORS, GLUCOSE, SACCHARIN SODIUM, WATER, ALCOHOL (23%)

. . . SECTION 3 PHYSICAL/CHEMICAL CHARACTERISTICS . . . . . .

BOILING POINT	NOT APPLICABLE
VAPOR PRESSURE	NOT APPLICABLE
VAPOR DENSITY	NOT APPLICABLE
SOLUBILITY IN WATER	SOLUBLE
SPECIFIC GRAVITY	CA 1.09
MELTING POINT	NOT APPLICABLE
EVAPORATION RATE	NOT APPLICABLE
APPEARANCE	GREEN, CITRUS FLAVORED LIQUID

. . . SECTION 4 FIRE AND EXPLOSION HAZARD DATA . . . . . .

FLASH POINT	NOT APPLICABLE
METHOD USED	NOT APPLICABLE
FLAMMABLE LIMITS	
LEL	NOT APPLICABLE
UEL	NOT APPLICABLE
EXTINGUISHING MEDIA	NOT APPLICABLE
SPECIAL FIRE-FIGHTING PROCEDURES	NOT APPLICABLE
UNUSUAL FIRE AND EXPLOSION HAZARDS	NONE

. . . SECTION 5 REACTIVITY DATA . . . . . .

STABILITY	STABLE
INCOMPATABILITY	NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS	NONE KNOWN
HAZARDOUS POLYMERIZATION	WILL NOT OCCUR

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

DONNATAL ELIXIR NDC 0031-4221-XX

. . . SECTION 6 HEALTH HAZARD DATA . . . . . .

ROUTES OF ENTRY:		INGESTION SKIN- IT IS NOT KNOWN IF ANY OF THE INGREDIENTS IN DONNATAL ELIXIR ARE ABSORBED THROUGH THE SKIN FROM DONNATAL ELIXIR
CARCINOGENICITY:		NONE OF THE COMPONENTS IN THIS PRODUCT ARE KNOWN TO BE CARCINOGENIC
SIGNS AND SYMPTOMS OF OVER-EXPOSURE:	PHENOBARBITAL	DROWSINESS, DIZZINESS, WEAKNESS, SEDATION
	ATROPINE, HYOSCYAMINE, AND SCOPOLOMINE	DRY MOUTH, THIRST, FIXED DILATED PUPILS, FLUSHED FACE, FEVER, HOT DRY RED SKIN, TACHYCARDIA (RAPID HEART BEAT), BLURRED VISION, DELIRIUM, TREMORS, CONVULSIONS, COMA, RESPIRATORY FAILURE, CARDIOVASCULAR COLLAPSE
EMERGENCY AND FIRST-AID PROCEDURES:		EYE CONTACT- IRRIGATE SURFACES WITH WATER FOR 15 MINUTES. SKIN CONTACT- WASH AREAS WITH SOAP AND WATER. TREATMENT OF OVERDOSE: INDUCED EMESIS, LAVAGE, AND ACTIVATED CHARCOAL MAY BE HELPFUL. PHYSOSTIGMINE DRAMATICALLY REVERSES THE CENTRAL AND PERIPHERAL SIGNS OF ANTICHOLINERGIC TOXICITY. SYMPTOMATIC AND SUPPORTIVE TREATMENT AS REQUIRED.
MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:		HYPERSENSITIVITY TO ANY OF THE COMPONENTS; GLAUCOMA; URINARY RETENTION

FOR COMPLETE INFORMATION ON THIS DRUG PLEASE REFER TO THE ATTACHED PRODUCT LABELING

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

DONNATAL ELIXIR NDC 0031-4221-XX

. . . SECTION 7 PRECAUTIONS FOR SAFE HANDLING AND USE . . . . . .

SPILLS AND ACCIDENTAL RELEASES:	SOAK UP ON ABSORBANT MATERIAL AND PLACE IN APPROVED WASTE CONTAINER. WASH AREAS WITH SOAP AND WATER.
WASTE DISPOSAL METHOD:	DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. THIS IS A BIOLOGICALLY ACTIVE MATERIAL. DISPOSE OF ON SITE OR AT AN APPROVED DISPOSAL FACILITY IN ACCORDANCE WITH LOCAL,STATE,AND/OR FEDERAL REGULATIONS.
HANDLING AND STORAGE:	STORE AT ROOM TEMPERATURE, BETWEEN 59 AND 86 DEGREES F.

. . . SECTION 8 CONTROL MEASURES . . . . . .

NO SPECIAL CONTROL MEASURES ARE REQUIRED UNDER NORMAL CONDITIONS OF USE

RESPIRATORY PROTECTION	NONE REQUIRED
VENTILATION	NO SPECIAL VENTILATION IS REQUIRED
PROTECTIVE CLOTHING OR EQUIPMENT	AVOID CONTACT WITH EYES OR PROLONGED CONTACT WITH SKIN.
WORK/HYGIENIC PRACTICES	WASH THOROUGHLY AFTER HANDLING

. . . . . .

THE INFORMATION CONTAINED IN THIS MSDS IS, TO THE BEST OF A.H.ROBINS' KNOWLEDGE, COMPLETE AND ACCURATE. A.H.ROBINS, HOWEVER, USES MANY SOURCES AND REFERENCES FOR GATHERING THIS INFORMATION. THUS, A.H. ROBINS CANNOT GUARANTEE COMPLETENESS OR ACCURACY AND DISCLAIMS ALL LIABILITY FOR ITS HANDLING AND USE.

FILE/DONNATAL/ELIXIR. . . . . .

MATERIAL SAFETY DATA SHEET (MSDS) EFFECTIVE 04/09/87

DONNATAL EXTENTABS NDC 0031-4235-XX

. . . SECTION 1 MANUFACTURER INFORMATION . . . . .

A. H. ROBINS CO.,INC. 1405 CUMMINGS DRIVE RICHMOND, VA 23261-6609

EMERGENCY TELEPHONE: (804) 257-2000 (8:30 AM - 5:00 PM)
(804) 257-2000 (AFTER HOURS)

. . . SECTION 2 COMPOSITION INFORMATION . . . . .

HAZARDOUS INGREDIENTS:
AS FORMULATED, THIS FINISHED PHARMACEUTICAL PRODUCT DOES NOT CONSTITUTE A PHYSICAL HAZARD WITHIN THE MEANING OF 29 CFR SEC 1910.1200. POTENTIAL HEALTH HAZARDS FROM INGESTION OR EXPOSURE TO THE PRODUCT ARE DISCUSSED IN SECTION 6 BELOW.

ACTIVE INGREDIENTS: EACH TABLET CONTAINS:			CAS
PHENOBARBITAL, USP (WARNING: MAY BE HABIT FORMING)	48.6	MG	56-06-6
HYOSCYAMINE SULFATE, USP	0.3111	MG	6835-16-1
ATROPINE SULFATE, USP	0.0582	MG	55-48-1
SCOPOLOMINE HYDROBROMIDE, USP	0.0195	MG	114-49-8

INACTIVE INGREDIENTS:
ACACIA, ACETYLATED MONOGLYCERIDES, CALCIUM SULFATE, CARNUBA WAX, D&C YELLOW 10, EDIBLE INK, FD&C BLUE 1, FD&C BLUE 2 ALUMINUM LAKE, FD&C YELLOW 6, GELATIN, GUAR GUM, MAGNESIUM STEARATE, POLYSORBATES, SHELLAC, SODIUM PHOSPHATE, SUCROSE, TITANIUM DIOXIDE, WHEAT FLOUR, WHITE WAX, AND OTHER INGREDIENTS, ONE OF WHICH IS A CORN DERIVATIVE; MAY INCLUDE FD&C RED 40 AND YELLOW 6 ALUMINUM LAKES

. . . SECTION 3 PHYSICAL/CHEMICAL CHARACTERISTICS . . . . .

BOILING POINT	NOT APPLICABLE
VAPOR PRESSURE	NOT APPLICABLE
VAPOR DENSITY	NOT APPLICABLE
SOLUBILITY IN WATER	NOT APPLICABLE
SPECIFIC GRAVITY	NOT APPLICABLE
MELTING POINT	NOT APPLICABLE
EVAPORATION RATE	NOT APPLICABLE
APPEARANCE	PALE GREEN, COATED TABLETS, MONOGRAMMED AHR AND DONNATAL EXTENTAB

. . . SECTION 4 FIRE AND EXPLOSION HAZARD DATA . . . . .

FLASH POINT	NOT APPLICABLE
METHOD USED	NOT APPLICABLE
FLAMMABLE LIMITS	
LEL	NOT APPLICABLE
UEL	NOT APPLICABLE
EXTINGUISHING MEDIA	NOT APPLICABLE
SPECIAL FIRE-FIGHTING PROCEDURES	NOT APPLICABLE
UNUSUAL FIRE AND EXPLOSION HAZARDS	NONE

. . . SECTION 5 REACTIVITY DATA . . . . .

STABILITY	STABLE
INCOMPATABILITY	NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS	NONE KNOWN
HAZARDOUS POLYMERIZATION	WILL NOT OCCUR

. . . . . CONTINUED . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

DONNATAL EXTENTABS NDC 0031-4235-XX

. . . SECTION 6 HEALTH HAZARD DATA . . . . . .

ROUTES OF ENTRY: INGESTION

CARCINOGENICITY: NONE OF THE COMPONENTS IN THIS PRODUCT ARE KNOWN TO BE CARCINOGENIC

SIGNS AND SYMPTOMS OF OVER-EXPOSURE:

PHENOBARBITAL: DROWSINESS, DIZZINESS, WEAKNESS, SEDATION

ATROPINE, HYOSCYAMINE, AND SCOPOLOMINE: DRY MOUTH, THIRST, FIXED DILATED PUPILS, FLUSHED FACE, FEVER, HOT DRY RED SKIN, TACHYCARDIA (RAPID HEART BEAT), BLURRED VISION, DELIRIUM, TREMORS, CONVULSIONS, COMA, RESPIRATORY FAILURE, CARDIOVASCULAR COLLAPSE

EMERGENCY AND FIRST-AID PROCEDURES: EYE CONTACT- IRRIGATE SURFACES WITH WATER FOR 15 MINUTES.
SKIN CONTACT- WASH AREAS WITH SOAP AND WATER.
TREATMENT OF OVERDOSE: INDUCED EMESIS, LAVAGE, ACTIVATED CHARCOAL AND SALINE CATHARTICS MAY BE HELPFUL. PHYSOSTIGMINE DRAMATICALLY REVERSES THE CENTRAL AND PERIPHERAL SIGNS OF ANTICHOLINERGIC TOXICITY.
SYMPTOMATIC AND SUPPORTIVE TREATMENT AS REQUIRED.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: HYPERSENSITIVITY TO ANY OF THE COMPONENTS; GLAUCOMA; URINARY RETENTION

FOR COMPLETE INFORMATION ON THIS DRUG PLEASE REFER TO THE ATTACHED PRODUCT LABELING

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

DONNATAL EXTENTABS NDC 0031-4235-XX

. . . SECTION 7 PRECAUTIONS FOR SAFE HANDLING AND USE . . . . . .

SPILLS AND ACCIDENTAL RELEASES:	SWEEP OR SHOVEL INTO A WASTE CONTAINER
WASTE DISPOSAL METHOD:	DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. THIS IS A BIOLOGICALLY ACTIVE MATERIAL. DISPOSE OF ON SITE OR AT AN APPROVED DISPOSAL FACILITY IN ACCORDANCE WITH LOCAL,STATE,AND/OR FEDERAL REGULATIONS.
HANDLING AND STORAGE:	STORE AT ROOM TEMPERATURE, BETWEEN 59 AND 86 DEGREES F.

. . . SECTION 8 CONTROL MEASURES . . . . . .

NO SPECIAL CONTROL MEASURES ARE REQUIRED UNDER NORMAL CONDITIONS OF USE

RESPIRATORY PROTECTION	NONE REQUIRED
VENTILATION	NO SPECIAL VENTILATION IS REQUIRED
PROTECTIVE CLOTHING OR EQUIPMENT	AVOID CONTACT WITH EYES OR PROLONGED CONTACT WITH SKIN.
WORK/HYGIENIC PRACTICES	WASH THOROUGHLY AFTER HANDLING

. . . . . .

THE INFORMATION CONTAINED IN THIS MSDS IS, TO THE BEST OF A.H.ROBINS' KNOWLEDGE, COMPLETE AND ACCURATE. A.H.ROBINS, HOWEVER, USES MANY SOURCES AND REFERENCES FOR GATHERING THIS INFORMATION. THUS, A.H. ROBINS CANNOT GUARANTEE COMPLETENESS OR ACCURACY AND DISCLAIMS ALL LIABILITY FOR ITS HANDLING AND USE.

FILE/DONNATAL/EXTENTAB. . . . . .

MATERIAL SAFETY DATA SHEET (MSDS) EFFECTIVE 04/09/87

DONNATAL TABLETS NDC 0031-4250-XX

. . . SECTION 1 MANUFACTURER INFORMATION . . . . . .

A. H. ROBINS CO.,INC. 1405 CUMMINGS DRIVE RICHMOND, VA 23261-6609

EMERGENCY TELEPHONE: (804) 257-2000 (8:30 AM - 5:00 PM)
(804) 257-2000 (AFTER HOURS)

. . . SECTION 2 COMPOSITION INFORMATION . . . . . .

HAZARDOUS INGREDIENTS:
AS FORMULATED, THIS FINISHED PHARMACEUTICAL PRODUCT DOES NOT CONSTITUTE A PHYSICAL HAZARD WITHIN THE MEANING OF 29 CFR SEC 1910.1200. POTENTIAL HEALTH HAZARDS FROM INGESTION OR EXPOSURE TO THE PRODUCT ARE DISCUSSED IN SECTION 6 BELOW.

ACTIVE INGREDIENTS: EACH TABLET CONTAINS:		CAS
PHENOBARBITAL, USP (WARNING: MAY BE HABIT FORMING)	16.2 MG	50-06-6
HYOSCYAMINE SULFATE, USP	0.1037 MG	6835-16-1
ATROPINE SULFATE, USP	0.0194 MG	55-48-1
SCOPOLOMINE HYDROBROMIDE, USP	0.0065 MG	114-49-8

INACTIVE INGREDIENTS:
DIBASIC CALCIUM PHOSPHATE, MAGNESIUM STEARATE, MICROCRYSTALLINE CELLULOSE, SILICON DIOXIDE, SODIUM STARCH GLYCOLATE, STEARIC ACID, SUCROSE; MAY CONTAIN CORN STARCH, DEXTROSE, OR INVERT SUGAR

. . . SECTION 3 PHYSICAL/CHEMICAL CHARACTERISTICS . . . . . .

BOILING POINT	NOT APPLICABLE
VAPOR PRESSURE	NOT APPLICABLE
VAPOR DENSITY	NOT APPLICABLE
SOLUBILITY IN WATER	NOT APPLICABLE
SPECIFIC GRAVITY	NOT APPLICABLE
MELTING POINT	NOT APPLICABLE
EVAPORATION RATE	NOT APPLICABLE
APPEARANCE	WHITE, COMPRESSED TABLET, SCORED AND EMBOSSED "R"

. . . SECTION 4 FIRE AND EXPLOSION HAZARD DATA . . . . . .

FLASH POINT	NOT APPLICABLE
METHOD USED	NOT APPLICABLE
FLAMMABLE LIMITS	
LEL	NOT APPLICABLE
UEL	NOT APPLICABLE
EXTINGUISHING MEDIA	NOT APPLICABLE
SPECIAL FIRE-FIGHTING PROCEDURES	NOT APPLICABLE
UNUSUAL FIRE AND EXPLOSION HAZARDS	NONE

. . . SECTION 5 REACTIVITY DATA . . . . . .

STABILITY	STABLE
INCOMPATABILITY	NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS	NONE KNOWN
HAZARDOUS POLYMERIZATION	WILL NOT OCCUR

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

DONNATAL TABLETS NDC 0031-4250-XX

. . . SECTION 6 HEALTH HAZARD DATA . . . . . .

ROUTES OF ENTRY:		INGESTION
CARCINOGENICITY:		NONE OF THE COMPONENTS IN THIS PRODUCT ARE KNOWN TO BE CARCINOGENIC
SIGNS AND SYMPTOMS OF OVER-EXPOSURE:	PHENOBARBITAL	DROWSINESS, DIZZINESS, WEAKNESS, SEDATION
	ATROPINE, HYOSCYAMINE, AND SCOPOLOMINE	DRY MOUTH, THIRST, FIXED DILATED PUPILS, FLUSHED FACE, FEVER, HOT DRY RED SKIN, TACHYCARDIA (RAPID HEART BEAT), BLURRED VISION, DELIRIUM, TREMORS, CONVULSIONS, COMA, RESPIRATORY FAILURE, CARDIOVASCULAR COLLAPSE
EMERGENCY AND FIRST-AID PROCEDURES:		EYE CONTACT- IRRIGATE SURFACES WITH WATER FOR 15 MINUTES. SKIN CONTACT- WASH AREAS WITH SOAP AND WATER. TREATMENT OF OVERDOSE: INDUCED EMESIS, LAVAGE, AND ACTIVATED CHARCOAL MAY BE HELPFUL. PHYSOSTIGMINE DRAMATICALLY REVERSES THE CENTRAL AND PERIPHERAL SIGNS OF ANTICHOLINERGIC TOXICITY. SYMPTOMATIC AND SUPPORTIVE TREATMENT AS REQUIRED.
MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:		HYPERSENSITIVITY TO ANY OF THE COMPONENTS; GLAUCOMA; URINARY RETENTION

FOR COMPLETE INFORMATION ON THIS DRUG PLEASE REFER TO THE ATTACHED PRODUCT LABELING

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

DONNATAL TABLETS NDC 0031-4250-XX

. . . SECTION 7 PRECAUTIONS FOR SAFE HANDLING AND USE . . . . . .

SPILLS AND ACCIDENTAL RELEASES:	SWEEP OR SHOVEL INTO A WASTE CONTAINER
WASTE DISPOSAL METHOD:	DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. THIS IS A BIOLOGICALLY ACTIVE MATERIAL. DISPOSE OF ON SITE OR AT AN APPROVED DISPOSAL FACILITY IN ACCORDANCE WITH LOCAL,STATE,AND/OR FEDERAL REGULATIONS.
HANDLING AND STORAGE:	STORE AT ROOM TEMPERATURE, BETWEEN 59 AND 86 DEGREES F.

. . . SECTION 8 CONTROL MEASURES . . . . . .

NO SPECIAL CONTROL MEASURES ARE REQUIRED UNDER NORMAL CONDITIONS OF USE

RESPIRATORY PROTECTION	NONE REQUIRED
VENTILATION	NO SPECIAL VENTILATION IS REQUIRED
PROTECTIVE CLOTHING OR EQUIPMENT	AVOID CONTACT WITH EYES OR PROLONGED CONTACT WITH SKIN.
WORK/HYGIENIC PRACTICES	WASH THOROUGHLY AFTER HANDLING

. . . . . .

THE INFORMATION CONTAINED IN THIS MSDS IS, TO THE BEST OF A.H.ROBINS' KNOWLEDGE, COMPLETE AND ACCURATE. A.H.ROBINS, HOWEVER, USES MANY SOURCES AND REFERENCES FOR GATHERING THIS INFORMATION. THUS, A.H. ROBINS CANNOT GUARANTEE COMPLETENESS OR ACCURACY AND DISCLAIMS ALL LIABILITY FOR ITS HANDLING AND USE.

FILE/DONNATAL/TABLETS . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS) EFFECTIVE 04/09/87

DONNATAL NO. 2 TABLETS NDC 0031-4264-XX

. . . SECTION 1 MANUFACTURER INFORMATION . . . . . .

A. H. ROBINS CO.,INC. 1405 CUMMINGS DRIVE RICHMOND, VA 23261-6609

EMERGENCY TELEPHONE: (804) 257-2000 (8:30 AM - 5:00 PM)
(804) 257-2000 (AFTER HOURS)

. . . SECTION 2 COMPOSITION INFORMATION . . . . . .

HAZARDOUS INGREDIENTS:
AS FORMULATED, THIS FINISHED PHARMACEUTICAL PRODUCT DOES NOT CONSTITUTE A PHYSICAL HAZARD WITHIN THE MEANING OF 29 CFR SEC 1910.1200. POTENTIAL HEALTH HAZARDS FROM INGESTION OR EXPOSURE TO THE PRODUCT ARE DISCUSSED IN SECTION 6 BELOW.

ACTIVE INGREDIENTS: EACH TABLET CONTAINS:		CAS
PHENOBARBITAL, USP (WARNING: MAY BE HABIT FORMING)	32.4 MG	56-06-6
HYOSCYAMINE SULFATE, USP	0.1037 MG	6835-16-1
ATROPINE SULFATE, USP	0.0194 MG	55-48-1
SCOPOLOMINE HYDROBROMIDE, USP	0.0065 MG	114-49-8

INACTIVE INGREDIENTS:
CALCIUM STEARATE, CORN STARCH, D&C YELLOW 10, FD&C YELLOW 1, FD&C YELLOW 6, LACTOSE, SUCROSE

. . . SECTION 3 PHYSICAL/CHEMICAL CHARACTERISTICS . . . . . .

BOILING POINT	NOT APPLICABLE
VAPOR PRESSURE	NOT APPLICABLE
VAPOR DENSITY	NOT APPLICABLE
SOLUBILITY IN WATER	NOT APPLICABLE
SPECIFIC GRAVITY	NOT APPLICABLE
MELTING POINT	NOT APPLICABLE
EVAPORATION RATE	NOT APPLICABLE
APPEARANCE	PALE GREEN COMPRESSED TABLETS SCORED AND EMBOSSED "R"

. . . SECTION 4 FIRE AND EXPLOSION HAZARD DATA . . . . . .

FLASH POINT	NOT APPLICABLE
METHOD USED	NOT APPLICABLE
FLAMMABLE LIMITS	
LEL	NOT APPLICABLE
UEL	NOT APPLICABLE
EXTINGUISHING MEDIA	NOT APPLICABLE
SPECIAL FIRE-FIGHTING PROCEDURES	NOT APPLICABLE
UNUSUAL FIRE AND EXPLOSION HAZARDS	NONE

. . . SECTION 5 REACTIVITY DATA . . . . . .

STABILITY	STABLE
INCOMPATABILITY	NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS	NONE KNOWN
HAZARDOUS POLYMERIZATION	WILL NOT OCCUR

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

DONNATAL NO. 2 TABLETS NDC 0031-4264-XX

. . . SECTION 6 HEALTH HAZARD DATA . . . . . .

	ROUTES OF ENTRY:	INGESTION
	CARCINOGENICITY:	NONE OF THE COMPONENTS IN THIS PRODUCT ARE KNOWN TO BE CARCINOGENIC
SIGNS AND SYMPTOMS OF OVER-EXPOSURE:	PHENOBARBITAL	DROWSINESS, DIZZINESS, WEAKNESS, SEDATION
	ATROPINE, HYOSCYAMINE, AND SCOPOLOMINE	DRY MOUTH, THIRST, FIXED DILATED PUPILS, FLUSHED FACE, FEVER, HOT DRY RED SKIN, TACHYCARDIA (RAPID HEART BEAT), BLURRED VISION, DELIRIUM, TREMORS, CONVULSIONS, COMA, RESPIRATORY FAILURE, CARDIOVASCULAR COLLAPSE
	EMERGENCY AND FIRST-AID PROCEDURES:	EYE CONTACT- IRRIGATE SURFACES WITH WATER FOR 15 MINUTES. SKIN CONTACT- WASH AREAS WITH SOAP AND WATER. TREATMENT OF OVERDOSE: INDUCED EMESIS, LAVAGE, AND ACTIVATED CHARCOAL MAY BE HELPFUL. PHYSOSTIGMINE DRAMATICALLY REVERSES THE CENTRAL AND PERIPHERAL SIGNS OF ANTICHOLINERGIC TOXICITY. SYMPTOMATIC AND SUPPORTIVE TREATMENT AS REQUIRED.
	MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:	HYPERSENSITIVITY TO ANY OF THE COMPONENTS; GLAUCOMA; URINARY RETENTION

FOR COMPLETE INFORMATION ON THIS DRUG PLEASE REFER TO THE ATTACHED PRODUCT LABELING

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

DONNATAL NO. 2 TABLETS NDC 0031-4264-XX

. . . SECTION 7 PRECAUTIONS FOR SAFE HANDLING AND USE . . . . . .

SPILLS AND ACCIDENTAL RELEASES:	SWEEP OR SHOVEL INTO A WASTE CONTAINER
WASTE DISPOSAL METHOD:	DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. THIS IS A BIOLOGICALLY ACTIVE MATERIAL. DISPOSE OF ON SITE OR AT AN APPROVED DISPOSAL FACILITY IN ACCORDANCE WITH LOCAL,STATE,AND/OR FEDERAL REGULATIONS.
HANDLING AND STORAGE:	STORE AT ROOM TEMPERATURE, BETWEEN 59 AND 86 DEGREES F.

. . . SECTION 8 CONTROL MEASURES . . . . . .

NO SPECIAL CONTROL MEASURES ARE REQUIRED UNDER NORMAL CONDITIONS OF USE

RESPIRATORY PROTECTION	NONE REQUIRED
VENTILATION	NO SPECIAL VENTILATION IS REQUIRED
PROTECTIVE CLOTHING OR EQUIPMENT	AVOID CONTACT WITH EYES OR PROLONGED CONTACT WITH SKIN.
WORK/HYGIENIC PRACTICES	WASH THOROUGHLY AFTER HANDLING

. . . . . .

THE INFORMATION CONTAINED IN THIS MSDS IS, TO THE BEST OF A.H.ROBINS' KNOWLEDGE, COMPLETE AND ACCURATE. A.H.ROBINS, HOWEVER, USES MANY SOURCES AND REFERENCES FOR GATHERING THIS INFORMATION. THUS, A.H. ROBINS CANNOT GUARANTEE COMPLETENESS OR ACCURACY AND DISCLAIMS ALL LIABILITY FOR ITS HANDLING AND USE.

FILE/DONNATAL/2TABLETS. . . . . .

MATERIAL SAFETY DATA SHEET (MSDS) EFFECTIVE 06/24/87

DONNAZYME TABLETS NDC 0031-4649-XX

. . . SECTION 1 MANUFACTURER INFORMATION . . . . . .

A. H. ROBINS CO.,INC. 1405 CUMMINGS DRIVE RICHMOND, VA 23261-6609

EMERGENCY TELEPHONE: (804) 257-2000 (8:30 AM - 5:00 PM)
(804) 257-2000 (AFTER HOURS)

. . . SECTION 2 COMPOSITION INFORMATION . . . . . .

HAZARDOUS INGREDIENTS:
AS FORMULATED, THIS FINISHED PHARMACEUTICAL PRODUCT DOES NOT CONSTITUTE A PHYSICAL HAZARD WITHIN THE MEANING OF 29 CFR SEC 1910.1200. POTENTIAL HEALTH HAZARDS FROM INGESTION OR EXPOSURE TO THE PRODUCT ARE DISCUSSED IN SECTION 6 BELOW.

ACTIVE INGREDIENTS: EACH TABLET CONTAINS:		CAS
PANCREATIN, USP EQUIVALENT	300 MG	8049-47-6
PEPSIN	150 MG	9001-75-6
BILE SALTS	150 MG	
PHENOBARBITAL, USP (WARNING: MAY BE HABIT FORMING)	8.1 MG	50-06-6
HYOSCYAMINE SULFATE, USP	0.0518 MG	6835-16-1
ATROPINE SULFATE, USP	0.0097 MG	55-48-1
SCOPOLOMINE HYDROBROMIDE, USP	0.0033 MG	114-49-8

INACTIVE INGREDIENTS:
ACACIA, ACETYLATED MONOGLYCERIDES, CALCIUM SULFATE, CARNAUBA WAX, CELLULOSE ACETATE PHTHALATE, CORN STARCH, D&C YELLOW 10 ALUMINUM LAKE, DIETHYL PHTHALATE, EDIBLE INK, FD&C BLUE 1 ALUMINUM LAKE, FD&C YELLOW 6 ALUMINUM LAKE, GELATIN, METHYLPARABEN, MICROCRYSTALLINE CELLULOSE, POLYSORBATES, POVIDONE, PROPYLPARABEN, SHELLAC, SODIUM BENZOATE, STEARIC ACID, SUCROSE, TARTARIC ACID, TITANIUM DIOXIDE, WHEAT FLOUR, WHITE WAX, MAY CONTAIN DOCUSATE SODIUM

. . . SECTION 3 PHYSICAL/CHEMICAL CHARACTERISTICS . . . . . .

BOILING POINT	NOT APPLICABLE
VAPOR PRESSURE	NOT APPLICABLE
VAPOR DENSITY	NOT APPLICABLE
SOLUBILITY IN WATER	NOT APPLICABLE
SPECIFIC GRAVITY	NOT APPLICABLE
MELTING POINT	NOT APPLICABLE
EVAPORATION RATE	NOT APPLICABLE
APPEARANCE	ROUND, GREEN-COATED TABLETS, MONOGRAMMED AHR-4649

. . . SECTION 4 FIRE AND EXPLOSION HAZARD DATA . . . . . .

FLASH POINT	NOT APPLICABLE
METHOD USED	NOT APPLICABLE
FLAMMABLE LIMITS	
LEL	NOT APPLICABLE
UEL	NOT APPLICABLE
EXTINGUISHING MEDIA	NOT APPLICABLE
SPECIAL FIRE-FIGHTING PROCEDURES	NOT APPLICABLE
UNUSUAL FIRE AND EXPLOSION HAZARDS	NONE

. . . SECTION 5 REACTIVITY DATA . . . . . .

STABILITY	STABLE
INCOMPATABILITY	NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS	NONE KNOWN
HAZARDOUS POLYMERIZATION	WILL NOT OCCUR

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

DONNAZYME TABLETS NDC 0031-4649-XX

. . . SECTION 6 HEALTH HAZARD DATA . . . . . .

ROUTES OF ENTRY:		INGESTION
CARCINOGENICITY:		NONE OF THE COMPONENTS IN THIS PRODUCT ARE KNOWN TO BE CARCINOGENIC
SIGNS AND SYMPTOMS OF OVER-EXPOSURE:	PHENOBARBITAL	DROWSINESS, DIZZINESS, WEAKNESS, SEDATION
	ATROPINE, HYOSCYAMINE, AND SCOPOLOMINE	DRY MOUTH, THIRST, FIXED DILATED PUPILS, FLUSHED FACE, FEVER, HOT DRY RED SKIN, TACHYCARDIA (RAPID HEART BEAT), BLURRED VISION, DELIRIUM, TREMORS, CONVULSIONS, COMA, RESPIRATORY FAILURE, CARDIOVASCULAR COLLAPSE
	PANCREATIN, PEPSIN, AND BILE SALTS	SKIN RASH. HIGH DOSES MAY PRODUCE A LAXATIVE EFFECT; SYSTEMIC TOXICITY IS NOT EXPECTED.
		(SEE ATTACHED PRODUCT LABELING FOR FULL INFORMATION ON SIDE-EFFECTS)
EMERGENCY AND FIRST-AID PROCEDURES:		EYE CONTACT- IRRIGATE SURFACES WITH WATER FOR 15 MINUTES. SKIN CONTACT- WASH AREAS WITH SOAP AND WATER. TREATMENT OF OVERDOSE: INDUCED EMESIS, LAVAGE, AND ACTIVATED CHARCOAL MAY BE HELPFUL. PHYSOSTIGMINE DRAMATICALLY REVERSES THE CENTRAL AND PERIPHERAL SIGNS OF ANTICHOLINERGIC TOXICITY. SYMPTOMATIC AND SUPPORTIVE TREATMENT AS REQUIRED.
MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:		HYPERSENSITIVITY TO ANY OF THE COMPONENTS; GLAUCOMA; URINARY RETENTION

FOR COMPLETE INFORMATION ON THIS DRUG PLEASE REFER TO THE ATTACHED PRODUCT LABELING

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

DONNAZYME TABLETS NDC 0031-4649-XX

. . . SECTION 7 PRECAUTIONS FOR SAFE HANDLING AND USE . . . . . .

SPILLS AND ACCIDENTAL RELEASES:	SWEEP OR SHOVEL INTO A WASTE CONTAINER
WASTE DISPOSAL METHOD:	DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. THIS IS A BIOLOGICALLY ACTIVE MATERIAL. DISPOSE OF ON SITE OR AT AN APPROVED DISPOSAL FACILITY IN ACCORDANCE WITH LOCAL,STATE,AND/OR FEDERAL REGULATIONS.
HANDLING AND STORAGE:	STORE AT ROOM TEMPERATURE, BETWEEN 59 AND 86 DEGREES F.

. . . SECTION 8 CONTROL MEASURES . . . . . .

NO SPECIAL CONTROL MEASURES ARE REQUIRED UNDER NORMAL CONDITIONS OF USE

RESPIRATORY PROTECTION	NONE REQUIRED
VENTILATION	NO SPECIAL VENTILATION IS REQUIRED
PROTECTIVE CLOTHING OR EQUIPMENT	AVOID CONTACT WITH EYES OR PROLONGED CONTACT WITH SKIN.
WORK/HYGIENIC PRACTICES	WASH THOROUGHLY AFTER HANDLING

. . . . . .

THE INFORMATION CONTAINED IN THIS MSDS IS, TO THE BEST OF A.H.ROBINS' KNOWLEDGE, COMPLETE AND ACCURATE. A.H.ROBINS, HOWEVER, USES MANY SOURCES AND REFERENCES FOR GATHERING THIS INFORMATION. THUS, A.H. ROBINS CANNOT GUARANTEE COMPLETENESS OR ACCURACY AND DISCLAIMS ALL LIABILITY FOR ITS HANDLING AND USE.

FILE/DONNAZYM/TABLETS . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS) EFFECTIVE 05/28/87

DOPRAM INJECTABLE NDC 0031-4849-XX

. . . SECTION 1 MANUFACTURER INFORMATION . . . . . .

A. H. ROBINS CO.,INC. 1405 CUMMINGS DRIVE RICHMOND, VA 23261-6609

EMERGENCY TELEPHONE: (804) 257-2000 (8:30 AM - 5:00 PM)
(804) 257-2000 (AFTER HOURS)

. . . SECTION 2 COMPOSITION INFORMATION . . . . . .

HAZARDOUS INGREDIENTS:
AS FORMULATED, THIS FINISHED PHARMACEUTICAL PRODUCT DOES NOT CONSTITUTE A PHYSICAL HAZARD WITHIN THE MEANING OF 29 CFR SEC 1910.1200. POTENTIAL HEALTH HAZARDS FROM INGESTION OR EXPOSURE TO THE PRODUCT ARE DISCUSSED IN SECTION 6 BELOW.

ACTIVE INGREDIENTS:		CAS
EACH ML CONTAINS:		
DOXAPRAM HCL, USP	20MG	7081-53-0

INACTIVE INGREDIENTS:
EACH ML CONTAINS:
WATER FOR INJECTION USP, BENZYL ALCOHOL AS PRESERVATIVE (0.9%)

. . . SECTION 3 PHYSICAL/CHEMICAL CHARACTERISTICS . . . . . .

BOILING POINT	CA 100 DEGREES C.
VAPOR PRESSURE	NOT APPLICABLE
VAPOR DENSITY	NOT APPLICABLE
SOLUBILITY IN WATER	SOLUBLE
SPECIFIC GRAVITY	CA 1.0
MELTING POINT	NOT APPLICABLE
EVAPORATION RATE	NOT APPLICABLE
APPEARANCE	A CLEAR, COLORLESS, SOLUTION

. . . SECTION 4 FIRE AND EXPLOSION HAZARD DATA . . . . . .

FLASH POINT	NOT APPLICABLE
METHOD USED	NOT APPLICABLE
FLAMMABLE LIMITS	
LEL	NOT APPLICABLE
UEL	NOT APPLICABLE
EXTINGUISHING MEDIA	NOT APPLICABLE
SPECIAL FIRE-FIGHTING PROCEDURES	NOT APPLICABLE
UNUSUAL FIRE AND EXPLOSION HAZARDS	NONE

. . . SECTION 5 REACTIVITY DATA . . . . . .

STABILITY	STABLE
INCOMPATABILITY	NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS	NONE KNOWN
HAZARDOUS POLYMERIZATION	WILL NOT OCCUR

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

DOPRAM INJECTABLE NDC 0031-4849-XX

. . . SECTION 6 HEALTH HAZARD DATA . . . . . .

ROUTES OF ENTRY:		INGESTION SKIN- IT IS NOT KNOWN IF DOXAPRAM IS ABSORBED THROUGH THE SKIN FROM DOPRAM INJECTABLE
CARCINOGENICITY:		NONE OF THE COMPONENTS IN THIS PRODUCT ARE KNOWN TO BE CARCINOGENIC
SIGNS AND SYMPTOMS OF OVER-EXPOSURE:	DOXAPRAM	OVERDOSAGE MAY PRODUCE EXAGGERATION OF THE EFFECTS SEEN WHEN THE DRUG IS ADMINISTERED FOR TREATMENT. HIGH BLOOD PRESSURE, RAPID HEART BEAT, EXAGGERATED MUSCLE MOVEMENTS AND REFLEXES MAY BE EARLY SIGNS OF OVERDOSAGE (SEE ATTACHED PRODUCT LABELING FOR FULL INFORMATION ON SIDE-EFFECTS)
EMERGENCY AND FIRST-AID PROCEDURES:		EYE CONTACT- IRRIGATE SURFACES WITH WATER FOR 15 MINUTES. SKIN CONTACT- WASH AREAS WITH SOAP AND WATER. TREATMENT OF OVERDOSE: SYMPTOMATIC AND SUPPORTIVE TREATMENT AS REQUIRED. SHORT-ACTING IV BARBITURATES, OXYGEN, AND RESUSCITATIVE EQUIPMENT SHOULD BE USED AS NEEDED
MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:		HYPERSENSITIVITY TO ANY OF THE COMPONENTS

FOR COMPLETE INFORMATION ON THIS DRUG PLEASE REFER TO THE ATTACHED PRODUCT LABELING

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

DOPRAM INJECTABLE NDC 0031-4849-XX

. . . SECTION 7 PRECAUTIONS FOR SAFE HANDLING AND USE . . . . . .

SPILLS AND ACCIDENTAL RELEASES:	SOAK UP ON ABSORBANT MATERIAL AND PLACE IN APPROVED WASTE CONTAINER. WASH AREAS WITH SOAP AND WATER.
WASTE DISPOSAL METHOD:	DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. THIS IS A BIOLOGICALLY ACTIVE MATERIAL. DISPOSE OF ON SITE OR AT AN APPROVED DISPOSAL FACILITY IN ACCORDANCE WITH LOCAL,STATE,AND/OR FEDERAL REGULATIONS.
HANDLING AND STORAGE:	STORE AT ROOM TEMPERATURE, BETWEEN 59 AND 86 DEGREES F.

. . . SECTION 8 CONTROL MEASURES . . . . . .

NO SPECIAL CONTROL MEASURES ARE REQUIRED UNDER NORMAL CONDITIONS OF USE

RESPIRATORY PROTECTION	NONE REQUIRED
VENTILATION	NO SPECIAL VENTILATION IS REQUIRED
PROTECTIVE CLOTHING OR EQUIPMENT	AVOID CONTACT WITH EYES OR PROLONGED CONTACT WITH SKIN.
WORK/HYGIENIC PRACTICES	WASH THOROUGHLY AFTER HANDLING

. . . . . .

THE INFORMATION CONTAINED IN THIS MSDS IS, TO THE BEST OF A.H.ROBINS' KNOWLEDGE, COMPLETE AND ACCURATE. A.H.ROBINS, HOWEVER, USES MANY SOURCES AND REFERENCES FOR GATHERING THIS INFORMATION. THUS, A.H. ROBINS CANNOT GUARANTEE COMPLETENESS OR ACCURACY AND DISCLAIMS ALL LIABILITY FOR ITS HANDLING AND USE.

FILE/DOPRAM/INJECT. . . . . .

MATERIAL SAFETY DATA SHEET (MSDS) EFFECTIVE 01/04/88

ENTOLASE CAPSULES NDC 0031-5025-XX

. . . SECTION 1 MANUFACTURER INFORMATION . . . . . .

A. H. ROBINS CO.,INC. 1405 CUMMINGS DRIVE RICHMOND, VA 23261-6609

EMERGENCY TELEPHONE: (804) 257-2000 (8:30 AM - 5:00 PM)
(804) 257-2000 (AFTER HOURS)

. . . SECTION 2 COMPOSITION INFORMATION . . . . . .

HAZARDOUS INGREDIENTS:
AS FORMULATED, THIS FINISHED PHARMACEUTICAL PRODUCT DOES NOT CONSTITUTE A PHYSICAL HAZARD WITHIN THE MEANING OF 29 CFR SEC 1910.1200. POTENTIAL HEALTH HAZARDS FROM INGESTION OR EXPOSURE TO THE PRODUCT ARE DISCUSSED IN SECTION 6 BELOW.

ACTIVE INGREDIENTS: EACH TABLET CONTAINS:		CAS
PANCRELIPASE, USP (EQUIVALENT TO THE FOLLOWING):		53608-75-6
LIPASE, USP	4,000 UNITS	
PROTEASE, USP	25,000 UNITS	
AMYLASE, USP	20,000 UNITS	

INACTIVE INGREDIENTS:
CELLULOSE ACETATE PHTHALATE, CORN STARCH, EDIBLE INKS, GELATIN, POVIDONE, SIMETHICONE, SODIUM CHLORIDE, STEARIC ACID, SUCROSE, TALC, TITANIUM DIOXIDE.

. . . SECTION 3 PHYSICAL/CHEMICAL CHARACTERISTICS . . . . . .

BOILING POINT	NOT APPLICABLE
VAPOR PRESSURE	NOT APPLICABLE
VAPOR DENSITY	NOT APPLICABLE
SOLUBILITY IN WATER	NOT APPLICABLE
SPECIFIC GRAVITY	NOT APPLICABLE
MELTING POINT	NOT APPLICABLE
EVAPORATION RATE	NOT APPLICABLE
APPEARANCE	MICROBEADS CONTAINED IN WHITE AND CLEAR CAPSULES, MONOGRAMMED ENTOLASE AND AHR

. . . SECTION 4 FIRE AND EXPLOSION HAZARD DATA . . . . . .

FLASH POINT	NOT APPLICABLE
METHOD USED	NOT APPLICABLE
FLAMMABLE LIMITS	
LEL	NOT APPLICABLE
UEL	NOT APPLICABLE
EXTINGUISHING MEDIA	NOT APPLICABLE
SPECIAL FIRE-FIGHTING PROCEDURES	NOT APPLICABLE
UNUSUAL FIRE AND EXPLOSION HAZARDS	NONE

. . . SECTION 5 REACTIVITY DATA . . . . . .

STABILITY	STABLE
INCOMPATABILITY	NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS	NONE KNOWN
HAZARDOUS POLYMERIZATION	WILL NOT OCCUR

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

ENTOLASE CAPSULES NDC 0031-5025-XX

. . . SECTION 6 HEALTH HAZARD DATA . . . . . .

	ROUTES OF ENTRY:	INGESTION
	CARCINOGENICITY:	NONE OF THE COMPONENTS IN THIS PRODUCT ARE KNOWN TO BE CARCINOGENIC
SIGNS AND SYMPTOMS OF OVEREXPOSURE:	PANCRELIPASE	OVERDOSAGE MAY CAUSE DIARRHEA OR TRANSIENT INTESTINAL UPSET. (SEE ATTACHED PRODUCT LABELING FOR FULL INFORMATION ON SIDE-EFFECTS)
	EMERGENCY AND FIRST-AID PROCEDURES:	EYE CONTACT- IRRIGATE SURFACES WITH WATER FOR 15 MINUTES. SKIN CONTACT- WASH AREAS WITH SOAP AND WATER. TREATMENT OF OVERDOSE: SYMPTOMATIC TREATMENT, AS REQUIRED
	MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:	HYPERSENSITIVITY TO ANY OF THE COMPONENTS, ESPECIALLY TO PORK PROTEIN

FOR COMPLETE INFORMATION ON THIS DRUG PLEASE REFER TO THE ATTACHED PRODUCT LABELING

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

ENTOLASE CAPSULES NDC 0031-5025-XX

. . . SECTION 7 PRECAUTIONS FOR SAFE HANDLING AND USE . . . . . .

SPILLS AND ACCIDENTAL RELEASES:	SWEEP OR SHOVEL INTO A WASTE CONTAINER
WASTE DISPOSAL METHOD:	DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. THIS IS A BIOLOGICALLY ACTIVE MATERIAL. DISPOSE OF ON SITE OR AT AN APPROVED DISPOSAL FACILITY IN ACCORDANCE WITH LOCAL, STATE, AND/OR FEDERAL REGULATIONS.
HANDLING AND STORAGE:	STORE AT ROOM TEMPERATURE, BETWEEN 59 AND 86 DEGREES F.

. . . SECTION 8 CONTROL MEASURES . . . . . .

NO SPECIAL CONTROL MEASURES ARE REQUIRED UNDER NORMAL CONDITIONS OF USE

RESPIRATORY PROTECTION	NONE REQUIRED
VENTILATION	NO SPECIAL VENTILATION IS REQUIRED
PROTECTIVE CLOTHING OR EQUIPMENT	AVOID CONTACT WITH EYES OR PROLONGED CONTACT WITH SKIN.
WORK/HYGIENIC PRACTICES	WASH THOROUGHLY AFTER HANDLING

. . . . . .

THE INFORMATION CONTAINED IN THIS MSDS IS, TO THE BEST OF A.H.ROBINS' KNOWLEDGE, COMPLETE AND ACCURATE. A.H.ROBINS, HOWEVER, USES MANY SOURCES AND REFERENCES FOR GATHERING THIS INFORMATION. THUS, A.H. ROBINS CANNOT GUARANTEE COMPLETENESS OR ACCURACY AND DISCLAIMS ALL LIABILITY FOR ITS HANDLING AND USE.

FILE/ENTOLASE/CAPSULES . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS) EFFECTIVE 01/04/88

ENTOLASE-HP CAPSULES NDC 0031-5035-XX

. . . SECTION 1 MANUFACTURER INFORMATION . . . . . .

A. H. ROBINS CO.,INC. 1405 CUMMINGS DRIVE RICHMOND, VA 23261-6609

EMERGENCY TELEPHONE: (804) 257-2000 (8:30 AM - 5:00 PM)
(804) 257-2000 (AFTER HOURS)

. . . SECTION 2 COMPOSITION INFORMATION . . . . . .

HAZARDOUS INGREDIENTS:
AS FORMULATED, THIS FINISHED PHARMACEUTICAL PRODUCT DOES NOT CONSTITUTE A PHYSICAL HAZARD WITHIN THE MEANING OF 29 CFR SEC 1910.1200. POTENTIAL HEALTH HAZARDS FROM INGESTION OR EXPOSURE TO THE PRODUCT ARE DISCUSSED IN SECTION 6 BELOW.

ACTIVE INGREDIENTS:		CAS
EACH TABLET CONTAINS:		
PANCRELIPASE, USP (EQUIVALENT TO THE FOLLOWING):		53608-75-6
LIPASE, USP	8,000 UNITS	
PROTEASE, USP	50,000 UNITS	
AMYLASE, USP	40,000 UNITS	

INACTIVE INGREDIENTS:
CELLULOSE ACETATE PHTHALATE, CORN STARCH, EDIBLE INKS, GELATIN, IRON OXIDE, POVIDONE, SIMETHICONE, SODIUM CHLORIDE, STEARIC ACID, SUCROSE, TALC, TITANIUM DIOXIDE.

. . . SECTION 3 PHYSICAL/CHEMICAL CHARACTERISTICS . . . . . .

BOILING POINT	NOT APPLICABLE
VAPOR PRESSURE	NOT APPLICABLE
VAPOR DENSITY	NOT APPLICABLE
SOLUBILITY IN WATER	NOT APPLICABLE
SPECIFIC GRAVITY	NOT APPLICABLE
MELTING POINT	NOT APPLICABLE
EVAPORATION RATE	NOT APPLICABLE
APPEARANCE	MICROBEADS CONTAINED IN BROWN AND CLEAR CAPSULES, MONOGRAMMED ENTOLASE HP AND AHR

. . . SECTION 4 FIRE AND EXPLOSION HAZARD DATA . . . . . .

FLASH POINT	NOT APPLICABLE *
METHOD USED	NOT APPLICABLE
FLAMMABLE LIMITS	
LEL	NOT APPLICABLE
UEL	NOT APPLICABLE
EXTINGUISHING MEDIA	NOT APPLICABLE
SPECIAL FIRE-FIGHTING PROCEDURES	NOT APPLICABLE
UNUSUAL FIRE AND EXPLOSION HAZARDS	NONE

. . . SECTION 5 REACTIVITY DATA . . . . . .

STABILITY	STABLE
INCOMPATABILITY	NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS	NONE KNOWN
HAZARDOUS POLYMERIZATION	WILL NOT OCCUR

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

ENTOLASE-HP CAPSULES NDC 0031-5035-XX

. . . SECTION 6 HEALTH HAZARD DATA . . . . . .

ROUTES OF ENTRY:	INGESTION
CARCINOGENICITY:	NONE OF THE COMPONENTS IN THIS PRODUCT ARE KNOWN TO BE CARCINOGENIC
SIGNS AND SYMPTOMS OF OVEREXPOSURE: PANCRELIPASE	OVERDOSAGE MAY CAUSE DIARRHEA OR TRANSIENT INTESTINAL UPSET. (SEE ATTACHED PRODUCT LABELING FOR FULL INFORMATION ON SIDE-EFFECTS)
EMERGENCY AND FIRST-AID PROCEDURES:	EYE CONTACT- IRRIGATE SURFACES WITH WATER FOR 15 MINUTES. SKIN CONTACT- WASH AREAS WITH SOAP AND WATER. TREATMENT OF OVERDOSE: SYMPTOMATIC TREATMENT, AS REQUIRED
MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:	HYPERSENSITIVITY TO ANY OF THE COMPONENTS, ESPECIALLY TO PORK PROTEIN

FOR COMPLETE INFORMATION ON THIS DRUG PLEASE REFER TO THE ATTACHED PRODUCT LABELING

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

ENTOLASE-HP CAPSULES NDC 0031-5035-XX

. . . SECTION 7 PRECAUTIONS FOR SAFE HANDLING AND USE . . . . . .

SPILLS AND ACCIDENTAL RELEASES:	SWEEP OR SHOVEL INTO A WASTE CONTAINER
WASTE DISPOSAL METHOD:	DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. THIS IS A BIOLOGICALLY ACTIVE MATERIAL. DISPOSE OF ON SITE OR AT AN APPROVED DISPOSAL FACILITY IN ACCORDANCE WITH LOCAL, STATE, AND/OR FEDERAL REGULATIONS.
HANDLING AND STORAGE:	STORE AT ROOM TEMPERATURE, BETWEEN 59 AND 86 DEGREES F.

. . . SECTION 8 CONTROL MEASURES . . . . . .

NO SPECIAL CONTROL MEASURES ARE REQUIRED UNDER NORMAL CONDITIONS OF USE

RESPIRATORY PROTECTION	NONE REQUIRED
VENTILATION	NO SPECIAL VENTILATION IS REQUIRED
PROTECTIVE CLOTHING OR EQUIPMENT	AVOID CONTACT WITH EYES OR PROLONGED CONTACT WITH SKIN.
WORK/HYGIENIC PRACTICES	WASH THOROUGHLY AFTER HANDLING

. . . . . .

THE INFORMATION CONTAINED IN THIS MSDS IS, TO THE BEST OF A.H.ROBINS' KNOWLEDGE, COMPLETE AND ACCURATE. A.H.ROBINS, HOWEVER, USES MANY SOURCES AND REFERENCES FOR GATHERING THIS INFORMATION. THUS, A.H. ROBINS CANNOT GUARANTEE COMPLETENESS OR ACCURACY AND DISCLAIMS ALL LIABILITY FOR ITS HANDLING AND USE.

FILE/ENTOLASE/HPCAPS . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS) EFFECTIVE 06/24/87

ENTOZYME TABLETS NDC 0031-5049-XX

. . . SECTION 1 MANUFACTURER INFORMATION . . . . . .

A. H. ROBINS CO.,INC. 1405 CUMMINGS DRIVE RICHMOND, VA 23261-6609

EMERGENCY TELEPHONE: (804) 257-2000 (8:30 AM - 5:00 PM)
(804) 257-2000 (AFTER HOURS)

. . . SECTION 2 COMPOSITION INFORMATION . . . . . .

HAZARDOUS INGREDIENTS:
AS FORMULATED, THIS FINISHED PHARMACEUTICAL PRODUCT DOES NOT CONSTITUTE A PHYSICAL HAZARD WITHIN THE MEANING OF 29 CFR SEC 1910.1200. POTENTIAL HEALTH HAZARDS FROM INGESTION OR EXPOSURE TO THE PRODUCT ARE DISCUSSED IN SECTION 6 BELOW.

ACTIVE INGREDIENTS: EACH TABLET CONTAINS:		CAS
PANCREATIN, USP EQUIVALENT	300 MG	8049-47-6
PEPSIN	250 MG	9001-75-6
BILE SALTS	150 MG	-

INACTIVE INGREDIENTS:
ACACIA, ACETYLATED MONOGLYCERIDES, CALCIUM CARBONATE, CALCIUM SULFATE, CARNAUBA WAX, CELLULOSE ACETATE PHTHALATE, CORN STARCH, DIETHYL PHTHALATE, EDIBLE INK, FD&C BLUE 2 ALUMINUM LAKE, GELATIN, MICROCRYSTALLINE CELLULOSE, POLYSORBATES, SHELLAC, STEARIC ACID, SUCROSE, TARTARIC ACID, TITANIUM DIOXIDE, WHITE WAX, MAY CONTAIN FD&C RED 40 AND YELLOW 6 ALUMINUM LAKES

. . . SECTION 3 PHYSICAL/CHEMICAL CHARACTERISTICS . . . . . .

BOILING POINT	NOT APPLICABLE
VAPOR PRESSURE	NOT APPLICABLE
VAPOR DENSITY	NOT APPLICABLE
SOLUBILITY IN WATER	NOT APPLICABLE
SPECIFIC GRAVITY	NOT APPLICABLE
MELTING POINT	NOT APPLICABLE
EVAPORATION RATE	NOT APPLICABLE
APPEARANCE	WHITE TABLETS MONOGRAMMED AHR AND 5049

. . . SECTION 4 FIRE AND EXPLOSION HAZARD DATA . . . . . .

FLASH POINT	NOT APPLICABLE
METHOD USED	NOT APPLICABLE
FLAMMABLE LIMITS	
LEL	NOT APPLICABLE
UEL	NOT APPLICABLE
EXTINGUISHING MEDIA	NOT APPLICABLE
SPECIAL FIRE-FIGHTING PROCEDURES	NOT APPLICABLE
UNUSUAL FIRE AND EXPLOSION HAZARDS	NONE

. . . SECTION 5 REACTIVITY DATA . . . . . .

STABILITY	STABLE
INCOMPATABILITY	NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS	NONE KNOWN
HAZARDOUS POLYMERIZATION	WILL NOT OCCUR

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

ENTOZYME TABLETS NDC 0031-5049-XX

. . . SECTION 6 HEALTH HAZARD DATA . . . . . .

ROUTES OF ENTRY:	INGESTION
CARCINOGENICITY:	NONE OF THE COMPONENTS IN THIS PRODUCT ARE KNOWN TO BE CARCINOGENIC
SIGNS AND SYMPTOMS OF OVEREXPOSURE: ENTOZYME	SKIN RASH. HIGH DOSES MAY PRODUCE A LAXATIVE EFFECT; SYSTEMIC TOXICITY IS NOT EXPECTED.
EMERGENCY AND FIRST-AID PROCEDURES:	EYE CONTACT- IRRIGATE SURFACES WITH WATER FOR 15 MINUTES. SKIN CONTACT- WASH AREAS WITH SOAP AND WATER. TREATMENT OF OVERDOSE: SYMPTOMATIC AND SUPPORTIVE TREATMENT AS REQUIRED.
MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:	HYPERSENSITIVITY TO ANY OF THE COMPONENTS

FOR COMPLETE INFORMATION ON THIS DRUG PLEASE REFER TO THE ATTACHED PRODUCT LABELING

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

ENTOZYME TABLETS NDC 0031-5049-XX

. . . SECTION 7 PRECAUTIONS FOR SAFE HANDLING AND USE . . . . . .

SPILLS AND ACCIDENTAL RELEASES:	SWEEP OR SHOVEL INTO A WASTE CONTAINER
WASTE DISPOSAL METHOD:	DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. THIS IS A BIOLOGICALLY ACTIVE MATERIAL. DISPOSE OF ON SITE OR AT AN APPROVED DISPOSAL FACILITY IN ACCORDANCE WITH LOCAL,STATE,AND/OR FEDERAL REGULATIONS.
HANDLING AND STORAGE:	STORE AT ROOM TEMPERATURE, BETWEEN 59 AND 86 DEGREES F.

. . . SECTION 8 CONTROL MEASURES . . . . . .

NO SPECIAL CONTROL MEASURES ARE REQUIRED UNDER NORMAL CONDITIONS OF USE

RESPIRATORY PROTECTION	NONE REQUIRED
VENTILATION	NO SPECIAL VENTILATION IS REQUIRED
PROTECTIVE CLOTHING OR EQUIPMENT	AVOID CONTACT WITH EYES OR PROLONGED CONTACT WITH SKIN.
WORK/HYGIENIC PRACTICES	WASH THOROUGHLY AFTER HANDLING

. . . . . .

THE INFORMATION CONTAINED IN THIS MSDS IS, TO THE BEST OF A.H.ROBINS' KNOWLEDGE, COMPLETE AND ACCURATE. A.H.ROBINS, HOWEVER, USES MANY SOURCES AND REFERENCES FOR GATHERING THIS INFORMATION. THUS, A.H. ROBINS CANNOT GUARANTEE COMPLETENESS OR ACCURACY AND DISCLAIMS ALL LIABILITY FOR ITS HANDLING AND USE.

FILE/ENTOZYME/TABLETS . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS) EFFECTIVE 03/10/87

MICRO-K EXTENCAPS, 750MG (10 MEQ) NDC 0031-5730-XX

. . . SECTION 1 MANUFACTURER INFORMATION . . . . . .

A. H. ROBINS CO.,INC. 1405 CUMMINGS DRIVE RICHMOND, VA 23261-6609

EMERGENCY TELEPHONE: (804) 257-2000 (8:30 AM - 5:00 PM)
(804) 257-2000 (AFTER HOURS)

. . . SECTION 2 COMPOSITION INFORMATION . . . . . .

HAZARDOUS INGREDIENTS:
AS FORMULATED, THIS FINISHED PHARMACEUTICAL PRODUCT DOES NOT CONSTITUTE A PHYSICAL HAZARD WITHIN THE MEANING OF 29 CFR SEC 1910.1200. POTENTIAL HEALTH HAZARDS FROM INGESTION OR EXPOSURE TO THE PRODUCT ARE DISCUSSED IN SECTION 6 BELOW.

ACTIVE INGREDIENTS:		CAS
POTASSIUM CHLORIDE	750MG (10 MEQ POTASSIUM)	7447-40-7

INACTIVE INGREDIENTS:
EDIBLE INK, ETHYLCELLULOSE, FD&C BLUE 2 ALUMINUM LAKE, FD&C YELLOW 6, GELATIN, MAGNESIUM STEARATE, SODIUM LAURYL SULFATE, TITANIUM DIOXIDE. MAY CONTAIN FD&C RED 40 AND YELLOW 6 ALUMINUM LAKES.

. . . SECTION 3 PHYSICAL/CHEMICAL CHARACTERISTICS . . . . . .

BOILING POINT	NOT APPLICABLE
VAPOR PRESSURE	NOT APPLICABLE
VAPOR DENSITY	NOT APPLICABLE
SOLUBILITY IN WATER	NOT APPLICABLE
SPECIFIC GRAVITY	NOT APPLICABLE
MELTING POINT	NOT APPLICABLE
EVAPORATION RATE	NOT APPLICABLE
APPEARANCE	PALE ORANGE AND OPAQUE WHITE HARD GELATIN CAPSULES MONOGRAMMED MICRO-K 10 AND AHR/5730

. . . SECTION 4 FIRE AND EXPLOSION HAZARD DATA . . . . . .

FLASH POINT	NOT APPLICABLE
METHOD USED	NOT APPLICABLE
FLAMMABLE LIMITS	
LEL	NOT APPLICABLE
UEL	NOT APPLICABLE
EXTINGUISHING MEDIA	NOT APPLICABLE
SPECIAL FIRE-FIGHTING PROCEDURES	NOT APPLICABLE
UNUSUAL FIRE AND EXPLOSION HAZARDS	NONE

. . . SECTION 5 REACTIVITY DATA . . . . . .

STABILITY	STABLE
INCOMPATABILITY	NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS	NONE KNOWN
HAZARDOUS POLYMERIZATION	WILL NOT OCCUR

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

MICRO-K EXTENCAPS, 750MG (10 MEQ) NDC 0031-5730-XX

. . . SECTION 6 HEALTH HAZARD DATA . . . . . .

	ROUTES OF ENTRY:	INGESTION
	CARCINOGENICITY:	NONE OF THE COMPONENTS IN THIS PRODUCT ARE KNOWN TO BE CARCINOGENIC
SIGNS AND SYMPTOMS OF OVER-EXPOSURE:	POTASSIUM CHLORIDE	HYPERKALEMIA IS USUALLY ASYMPTOMATIC AND MAY BE MANIFESTED ONLY BY AN INCREASED SERUM POTASSIUM CONCENTRATION AND CHARACTERISTIC ECG CHANGES (PEAKING OF T WAVES, LOSS OF P WAVE, DEPRESSION OF ST SEGMENT, AND PROLONGATION OF THE QT INTERVAL). LATE MANIFESTATIONS INCLUDE MUSCLE PARALYSIS AND CARDIOVASCULAR COLLAPSE FROM CARDIAC ARREST. THE MOST COMMON ADVERSE REACTIONS TO POTASSIUM SALTS ARE NAUSEA, VOMITING, ABDOMINAL DISCOMFORT, AND DIARRHEA. (SEE ATTACHED PRODUCT LABELING FOR FULL INFORMATION ON SIDE-EFFECTS)
	EMERGENCY AND FIRST-AID PROCEDURES:	EYE CONTACT- IRRIGATE SURFACES WITH WATER FOR 15 MINUTES. SKIN CONTACT- WASH AREAS WITH SOAP AND WATER. TREATMENT OF OVERDOSE: INTRAVENOUS ADMINISTRATION OF 300 - 500 ML PER HOUR OF 10% DEXTROSE SOLUTION CONTAINING 10 TO 20 UNITS OF INSULIN PER 1000ML; CORRECTION OF ACIDOSIS, IF PRESENT, WITH INTRAVENOUS SODIUM BICARBONATE; USE OF EXCHANGE RESINS, HEMODIALYSIS, OR PERITONEAL DIALYSIS.
	MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:	HYPERSENSITIVITY TO ANY OF THE COMPONENTS; IN PATIENTS WITH IMPAIRED MECHANISMS FOR EXCRETING POTASSIUM THE INGESTION OF POTASSIUM SALTS CAN PRODUCE HYPERKALEMIA AND CARDIAC ARREST.

FOR COMPLETE INFORMATION ON THIS DRUG PLEASE REFER TO THE ATTACHED PRODUCT LABELING

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

MICRO-K EXTENCAPS, 750MG (10 MEQ) NDC 0031-5730-XX

. . . SECTION 7 PRECAUTIONS FOR SAFE HANDLING AND USE . . . . . .

SPILLS AND ACCIDENTAL RELEASES:	SWEEP OR SHOVEL INTO A WASTE CONTAINER
WASTE DISPOSAL METHOD:	DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. THIS IS A BIOLOGICALLY ACTIVE MATERIAL. DISPOSE OF ON SITE OR AT AN APPROVED DISPOSAL FACILITY IN ACCORDANCE WITH LOCAL, STATE, AND/OR FEDERAL REGULATIONS.
HANDLING AND STORAGE:	STORE AT ROOM TEMPERATURE, BETWEEN 59 AND 86 DEGREES F.

. . . SECTION 8 CONTROL MEASURES . . . . . .

NO SPECIAL CONTROL MEASURES ARE REQUIRED UNDER NORMAL CONDITIONS OF USE

RESPIRATORY PROTECTION	NONE REQUIRED
VENTILATION	NO SPECIAL VENTILATION IS REQUIRED
PROTECTIVE CLOTHING OR EQUIPMENT	AVOID CONTACT WITH EYES OR PROLONGED CONTACT WITH SKIN.
WORK/HYGIENIC PRACTICES	WASH THOROUGHLY AFTER HANDLING

. . . . . .

THE INFORMATION CONTAINED IN THIS MSDS IS, TO THE BEST OF A.H.ROBINS' KNOWLEDGE, COMPLETE AND ACCURATE. A.H.ROBINS, HOWEVER, USES MANY SOURCES AND REFERENCES FOR GATHERING THIS INFORMATION. THUS, A.H. ROBINS CANNOT GUARANTEE COMPLETENESS OR ACCURACY AND DISCLAIMS ALL LIABILITY FOR ITS HANDLING AND USE.

FILE/MICROK10/CAPSULES . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS) EFFECTIVE 03/10/87

MICRO-K EXTENCAPS, 600MG (8 MEQ) NDC 0031-5720-XX

. . . SECTION 1 MANUFACTURER INFORMATION . . . . . .

A. H. ROBINS CO.,INC. 1405 CUMMINGS DRIVE RICHMOND, VA 23261-6609

EMERGENCY TELEPHONE: (804) 257-2000 (8:30 AM - 5:00 PM)
(804) 257-2000 (AFTER HOURS)

. . . SECTION 2 COMPOSITION INFORMATION . . . . . .

HAZARDOUS INGREDIENTS:
AS FORMULATED, THIS FINISHED PHARMACEUTICAL PRODUCT DOES NOT CONSTITUTE A PHYSICAL HAZARD WITHIN THE MEANING OF 29 CFR SEC 1910.1200. POTENTIAL HEALTH HAZARDS FROM INGESTION OR EXPOSURE TO THE PRODUCT ARE DISCUSSED IN SECTION 6 BELOW.

ACTIVE INGREDIENTS:		CAS
POTASSIUM CHLORIDE	600MG (8 MEQ POTASSIUM)	7447-40-7

INACTIVE INGREDIENTS:
EDIBLE INK, ETHYLCELLULOSE, FD&C BLUE 2 ALUMINUM LAKE, FD&C YELLOW 6, GELATIN, MAGNESIUM STEARATE, SODIUM LAURYL SULFATE, TITANIUM DIOXIDE. MAY CONTAIN FD&C RED 40 AND YELLOW 6 ALUMINUM LAKES.

. . . SECTION 3 PHYSICAL/CHEMICAL CHARACTERISTICS . . . . . .

BOILING POINT	NOT APPLICABLE
VAPOR PRESSURE	NOT APPLICABLE
VAPOR DENSITY	NOT APPLICABLE
SOLUBILITY IN WATER	NOT APPLICABLE
SPECIFIC GRAVITY	NOT APPLICABLE
MELTING POINT	NOT APPLICABLE
EVAPORATION RATE	NOT APPLICABLE
APPEARANCE	PALE ORANGE, HARD GELATIN CAPSULES MONOGRAMMED MICRO-K AND AHR/5720

. . . SECTION 4 FIRE AND EXPLOSION HAZARD DATA . . . . . .

FLASH POINT	NOT APPLICABLE
METHOD USED	NOT APPLICABLE
FLAMMABLE LIMITS	
LEL	NOT APPLICABLE
UEL	NOT APPLICABLE
EXTINGUISHING MEDIA	NOT APPLICABLE
SPECIAL FIRE-FIGHTING PROCEDURES	NOT APPLICABLE
UNUSUAL FIRE AND EXPLOSION HAZARDS	NONE

. . . SECTION 5 REACTIVITY DATA . . . . . .

STABILITY	STABLE
INCOMPATABILITY	NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS	NONE KNOWN
HAZARDOUS POLYMERIZATION	WILL NOT OCCUR

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

MICRO-K EXTENCAPS, 600MG (8 MEQ) NDC 0031-5720-XX

. . . SECTION 6 HEALTH HAZARD DATA . . . . . .

	ROUTES OF ENTRY:	INGESTION
	CARCINOGENICITY:	NONE OF THE COMPONENTS IN THIS PRODUCT ARE KNOWN TO BE CARCINOGENIC
SIGNS AND SYMPTOMS OF OVER-EXPOSURE:	POTASSIUM CHLORIDE	HYPERKALEMIA IS USUALLY ASYMPTOMATIC AND MAY BE MANIFESTED ONLY BY AN INCREASED SERUM POTASSIUM CONCENTRATION AND CHARACTERISTIC ECG CHANGES (PEAKING OF T WAVES, LOSS OF P WAVE, DEPRESSION OF ST SEGMENT, AND PROLONGATION OF THE QT INTERVAL). LATE MANIFESTATIONS INCLUDE MUSCLE PARALYSIS AND CARDIOVASCULAR COLLAPSE FROM CARDIAC ARREST. THE MOST COMMON ADVERSE REACTIONS TO POTASSIUM SALTS ARE NAUSEA, VOMITING, ABDOMINAL DISCOMFORT, AND DIARRHEA. (SEE ATTACHED PRODUCT LABELING FOR FULL INFORMATION ON SIDE-EFFECTS)
	EMERGENCY AND FIRST-AID PROCEDURES:	EYE CONTACT- IRRIGATE SURFACES WITH WATER FOR 15 MINUTES. SKIN CONTACT- WASH AREAS WITH SOAP AND WATER. TREATMENT OF OVERDOSE: INTRAVENOUS ADMINISTRATION OF 300 - 500 ML PER HOUR OF 10% DEXTROSE SOLUTION CONTAINING 10 TO 20 UNITS OF INSULIN PER 1000ML; CORRECTION OF ACIDOSIS, IF PRESENT, WITH INTRAVENOUS SODIUM BICARBONATE; USE OF EXCHANGE RESINS, HEMODIALYSIS, OR PERITONEAL DIALYSIS.
	MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:	HYPERSENSITIVITY TO ANY OF THE COMPONENTS; IN PATIENTS WITH IMPAIRED MECHANISMS FOR EXCRETING POTASSIUM THE INGESTION OF POTASSIUM SALTS CAN PRODUCE HYPERKALEMIA AND CARDIAC ARREST.

FOR COMPLETE INFORMATION ON THIS DRUG PLEASE REFER TO THE ATTACHED PRODUCT LABELING

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

MICRO-K EXTENCAPS, 600MG (8 MEQ) NDC 0031-5720-XX

. . . SECTION 7 PRECAUTIONS FOR SAFE HANDLING AND USE . . . . . .

SPILLS AND ACCIDENTAL RELEASES:	SWEEP OR SHOVEL INTO A WASTE CONTAINER
WASTE DISPOSAL METHOD:	DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. THIS IS A BIOLOGICALLY ACTIVE MATERIAL. DISPOSE OF ON SITE OR AT AN APPROVED DISPOSAL FACILITY IN ACCORDANCE WITH LOCAL, STATE, AND/OR FEDERAL REGULATIONS.
HANDLING AND STORAGE:	STORE AT ROOM TEMPERATURE, BETWEEN 59 AND 86 DEGREES F.

. . . SECTION 8 CONTROL MEASURES . . . . . .

NO SPECIAL CONTROL MEASURES ARE REQUIRED UNDER NORMAL CONDITIONS OF USE

RESPIRATORY PROTECTION	NONE REQUIRED
VENTILATION	NO SPECIAL VENTILATION IS REQUIRED
PROTECTIVE CLOTHING OR EQUIPMENT	AVOID CONTACT WITH EYES OR PROLONGED CONTACT WITH SKIN.
WORK/HYGIENIC PRACTICES	WASH THOROUGHLY AFTER HANDLING

. . . . . .

THE INFORMATION CONTAINED IN THIS MSDS IS, TO THE BEST OF A.H.ROBINS' KNOWLEDGE, COMPLETE AND ACCURATE. A.H.ROBINS, HOWEVER, USES MANY SOURCES AND REFERENCES FOR GATHERING THIS INFORMATION. THUS, A.H. ROBINS CANNOT GUARANTEE COMPLETENESS OR ACCURACY AND DISCLAIMS ALL LIABILITY FOR ITS HANDLING AND USE.

FILE/MICROK8/CAPSULES . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS) EFFECTIVE 03/10/87

MITROLAN TABLETS NDC 0031-1535-XX

. . . SECTION 1 MANUFACTURER INFORMATION . . . . . .

A. H. ROBINS CO.,INC. 1405 CUMMINGS DRIVE RICHMOND, VA 23261-6609

EMERGENCY TELEPHONE: (804) 257-2000 (8:30 AM - 5:00 PM)
(804) 257-2000 (AFTER HOURS)

. . . SECTION 2 COMPOSITION INFORMATION . . . . . .

HAZARDOUS INGREDIENTS:
AS FORMULATED, THIS FINISHED PHARMACEUTICAL PRODUCT DOES NOT CONSTITUTE A PHYSICAL HAZARD WITHIN THE MEANING OF 29 CFR SEC 1910.1200. POTENTIAL HEALTH HAZARDS FROM INGESTION OR EXPOSURE TO THE PRODUCT ARE DISCUSSED IN SECTION 6 BELOW.

ACTIVE INGREDIENTS:	CAS
CALCIUM POLYCARBOPHIL, EQUIVALENT TO 500MG OF POLYCARBOPHIL, USP	9003-97-8

INACTIVE INGREDIENTS:
AMINOACETIC ACID, CORN STARCH, D&C YELLOW 10 ALUMINUM LAKE, FLAVORS, MAGNESIUM STEARATE, MANNITOL, POVIDONE, SUCROSE

. . . SECTION 3 PHYSICAL/CHEMICAL CHARACTERISTICS . . . . . .

BOILING POINT	NOT APPLICABLE
VAPOR PRESSURE	NOT APPLICABLE
VAPOR DENSITY	NOT APPLICABLE
SOLUBILITY IN WATER	NOT APPLICABLE
SPECIFIC GRAVITY	NOT APPLICABLE
MELTING POINT	NOT APPLICABLE
EVAPORATION RATE	NOT APPLICABLE
APPEARANCE	ROUND, YELLOW, TABLETS ENGRAVED AHR 1535

. . . SECTION 4 FIRE AND EXPLOSION HAZARD DATA . . . . . .

FLASH POINT	NOT APPLICABLE
METHOD USED	NOT APPLICABLE
FLAMMABLE LIMITS	
LEL	NOT APPLICABLE
UEL	NOT APPLICABLE
EXTINGUISHING MEDIA	NOT APPLICABLE
SPECIAL FIRE-FIGHTING PROCEDURES	NOT APPLICABLE
UNUSUAL FIRE AND EXPLOSION HAZARDS	NONE

. . . SECTION 5 REACTIVITY DATA . . . . . .

STABILITY	STABLE
INCOMPATABILITY	NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS	NONE KNOWN
HAZARDOUS POLYMERIZATION	WILL NOT OCCUR

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

MITROLAN TABLETS NDC 0031-1535-XX

. . . SECTION 6 HEALTH HAZARD DATA . . . . . .

ROUTES OF ENTRY:	INGESTION
CARCINOGENICITY:	NONE OF THE COMPONENTS IN THIS PRODUCT ARE KNOWN TO BE CARCINOGENIC
SIGNS AND SYMPTOMS OF OVEREXPOSURE: CALCIUM POLYCARBOPHIL	SYSTEMIC SIDE-EFFECTS WOULD NOT BE EXPECTED. ABDOMINAL FULLNESS MAY BE NOTED. (SEE ATTACHED PRODUCT LABELING FOR FULL INFORMATION ON SIDE-EFFECTS)
EMERGENCY AND FIRST-AID PROCEDURES:	EYE CONTACT- IRRIGATE SURFACES WITH WATER FOR 15 MINUTES. SKIN CONTACT- WASH AREAS WITH SOAP AND WATER. TREATMENT OF OVERDOSE: SYMPTOMATIC TREATMENT, AS REQUIRED
MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:	HYPERSENSITIVITY TO ANY OF THE COMPONENTS

FOR COMPLETE INFORMATION ON THIS DRUG PLEASE REFER TO THE ATTACHED PRODUCT LABELING

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

MITROLAN TABLETS NDC 0031-1535-XX

. . . SECTION 7 PRECAUTIONS FOR SAFE HANDLING AND USE . . . . . .

SPILLS AND ACCIDENTAL RELEASES:	SWEEP OR SHOVEL INTO A WASTE CONTAINER
WASTE DISPOSAL METHOD:	DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. THIS IS A BIOLOGICALLY ACTIVE MATERIAL. DISPOSE OF ON SITE OR AT AN APPROVED DISPOSAL FACILITY IN ACCORDANCE WITH LOCAL,STATE,AND/OR FEDERAL REGULATIONS.
HANDLING AND STORAGE:	STORE AT ROOM TEMPERATURE, BETWEEN 59 AND 86 DEGREES F.

. . . SECTION 8 CONTROL MEASURES . . . . . .

NO SPECIAL CONTROL MEASURES ARE REQUIRED UNDER NORMAL CONDITIONS OF USE

RESPIRATORY PROTECTION	NONE REQUIRED
VENTILATION	NO SPECIAL VENTILATION IS REQUIRED
PROTECTIVE CLOTHING OR EQUIPMENT	AVOID CONTACT WITH EYES OR PROLONGED CONTACT WITH SKIN.
WORK/HYGIENIC PRACTICES	WASH THOROUGHLY AFTER HANDLING

. . . . . .

THE INFORMATION CONTAINED IN THIS MSDS IS, TO THE BEST OF A.H.ROBINS' KNOWLEDGE, COMPLETE AND ACCURATE. A.H.ROBINS, HOWEVER, USES MANY SOURCES AND REFERENCES FOR GATHERING THIS INFORMATION. THUS, A.H. ROBINS CANNOT GUARANTEE COMPLETENESS OR ACCURACY AND DISCLAIMS ALL LIABILITY FOR ITS HANDLING AND USE.

FILE/MITROLAN/TABLETS . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS) EFFECTIVE 06/11/87

PABALATE-SF NDC 0031-5883-XX

. . . SECTION 1 MANUFACTURER INFORMATION . . . . . .

A. H. ROBINS CO.,INC. 1405 CUMMINGS DRIVE RICHMOND, VA 23261-6609

EMERGENCY TELEPHONE: (804) 257-2000 (8:30 AM - 5:00 PM)
(804) 257-2000 (AFTER HOURS)

. . . SECTION 2 COMPOSITION INFORMATION . . . . . .

HAZARDOUS INGREDIENTS:
AS FORMULATED, THIS FINISHED PHARMACEUTICAL PRODUCT DOES NOT CONSTITUTE A PHYSICAL HAZARD WITHIN THE MEANING OF 29 CFR SEC 1910.1200. POTENTIAL HEALTH HAZARDS FROM INGESTION OR EXPOSURE TO THE PRODUCT ARE DISCUSSED IN SECTION 6 BELOW.

ACTIVE INGREDIENTS:

EACH ENTERIC-COATED TABLET CONTAINS:		CAS
POTASSIUM SALICYLATE	300MG	578-36-9
POTASSIUM AMINOBENZOATE	300MG	138-84-1

INACTIVE INGREDIENTS:
ACACIA, ACETYLATED MONOGLYCERIDES, CALCIUM CARBONATE, CALCIUM SULFATE, CARNAUBA WAX, CELLULOSE ACETATE PHTHALATE, DIETHYL PHTHALATE, DOCUSATE SODIUM, EDIBLE INK, FD&C BLUE 1 ALUMINUM LAKE, FD&C BLUE 2 ALUMINUM LAKE, FD&C RED 3 ALUMINUM LAKE, GELATIN, MAGNESIUM STEARATE, POLYSORBATES, SHELLAC, STEARIC ACID, SUCROSE, TALC, TITANIUM DIOXIDE, WHEAT FLOUR, WHITE WAX; MAY CONTAIN FD&C RED 40 AND YELLOW 6 ALUMINUM LAKES

. . . SECTION 3 PHYSICAL/CHEMICAL CHARACTERISTICS . . . . . .

BOILING POINT	NOT APPLICABLE
VAPOR PRESSURE	NOT APPLICABLE
VAPOR DENSITY	NOT APPLICABLE
SOLUBILITY IN WATER	NOT APPLICABLE
SPECIFIC GRAVITY	NOT APPLICABLE
MELTING POINT	NOT APPLICABLE
EVAPORATION RATE	NOT APPLICABLE
APPEARANCE	PERSIAN ROSE ENTERIC-COATED TABLETS, MONOGRAMMED AHR AND 5883

. . . SECTION 4 FIRE AND EXPLOSION HAZARD DATA . . . . . .

FLASH POINT	NOT APPLICABLE
METHOD USED	NOT APPLICABLE
FLAMMABLE LIMITS	
LEL	NOT APPLICABLE
UEL	NOT APPLICABLE
EXTINGUISHING MEDIA	NOT APPLICABLE
SPECIAL FIRE-FIGHTING PROCEDURES	NOT APPLICABLE
UNUSUAL FIRE AND EXPLOSION HAZARDS	NONE

. . . SECTION 5 REACTIVITY DATA . . . . . .

STABILITY	STABLE
INCOMPATABILITY	NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS	NONE KNOWN
HAZARDOUS POLYMERIZATION	WILL NOT OCCUR

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

PABALATE-SF NDC 0031-5883-XX

. . . SECTION 6 HEALTH HAZARD DATA . . . . . .

ROUTES OF ENTRY: INGESTION

CARCINOGENICITY: NONE OF THE COMPONENTS IN THIS PRODUCT ARE KNOWN TO BE CARCINOGENIC

SIGNS AND SYMPTOMS OF OVER-EXPOSURE:

POTASSIUM SALICYLATE: CENTRAL NERVOUS SYSTEM STIMULATION WITH VOMITING, RAPID BREATHING, HYPERACTIVITY AND POSSIBLY CONVULSIONS. THIS PROGRESSES QUICKLY TO DEPRESSION, COMA, RESPIRATORY FAILURE, AND COLLAPSE, AND IS ACCOMPANIED BY SEVERE ELECTROLYTE DISTURBANCES.

POTASSIUM AMINOBENZOATE: NAUSEA, VOMITING, ACIDOSIS, ITCHING, RASH, FEVER, METHEMOGLOBINEMIA, AND POSSIBLY HEPATITIS

HYPERKALEMIA IS USUALLY ASYMPTOMATIC AND MAY BE MANIFESTED ONLY BY AN INCREASED SERUM POTASSIUM CONCENTRATION AND CHARACTERISTIC ECG CHANGES (PEAKING OF T WAVES, LOSS OF P WAVE, DEPRESSION OF ST SEGMENT, AND PROLONGATION OF THE QT INTERVAL). LATE MANIFESTATIONS INCLUDE MUSCLE PARALYSIS AND CARDIOVASCULAR COLLAPSE FROM CARDIAC ARREST.
THE MOST COMMON ADVERSE REACTIONS TO POTASSIUM SALTS ARE NAUSEA, VOMITING, ABDOMINAL DISCOMFORT, AND DIARRHEA.

(SEE ATTACHED PRODUCT LABELING FOR FULL INFORMATION ON SIDE EFFECTS)

EMERGENCY AND FIRST-AID PROCEDURES: EYE CONTACT- IRRIGATE SURFACES WITH WATER FOR 15 MINUTES.
SKIN CONTACT- WASH AREAS WITH SOAP AND WATER.
TREATMENT OF OVERDOSE: SYMPTOMATIC AND SUPPORTIVE TREATMENT AS REQUIRED. ACTIVATED CHARCOAL, INDUCED EMESIS AND GASTRIC LAVAGE. MONITOR PLASMA SALICYLATE LEVELS

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: HYPERSENSITIVITY TO ANY OF THE COMPONENTS; IN PATIENTS WITH IMPAIRED MECHANISMS FOR EXCRETING POTASSIUM THE INGESTION OF POSTASSIUM SALTS CAN PRODUCE HYPERKALEMIA AND CARDIAC ARREST.

FOR COMPLETE INFORMATION ON THIS DRUG PLEASE REFER TO THE ATTACHED PRODUCT LABELING

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

PABALATE-SF NDC 0031-5883-XX

. . . SECTION 7 PRECAUTIONS FOR SAFE HANDLING AND USE . . . . . .

SPILLS AND ACCIDENTAL RELEASES:	SWEEP OR SHOVEL INTO A WASTE CONTAINER
WASTE DISPOSAL METHOD:	DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. THIS IS A BIOLOGICALLY ACTIVE MATERIAL. DISPOSE OF ON SITE OR AT AN APPROVED DISPOSAL FACILITY IN ACCORDANCE WITH LOCAL,STATE,AND/OR FEDERAL REGULATIONS.
HANDLING AND STORAGE:	STORE AT ROOM TEMPERATURE, BETWEEN 59 AND 86 DEGREES F.

. . . SECTION 8 CONTROL MEASURES . . . . . .

NO SPECIAL CONTROL MEASURES ARE REQUIRED UNDER NORMAL CONDITIONS OF USE

RESPIRATORY PROTECTION	NONE REQUIRED
VENTILATION	NO SPECIAL VENTILATION IS REQUIRED
PROTECTIVE CLOTHING OR EQUIPMENT	AVOID CONTACT WITH EYES OR PROLONGED CONTACT WITH SKIN.
WORK/HYGIENIC PRACTICES	WASH THOROUGHLY AFTER HANDLING

. . . . . .

THE INFORMATION CONTAINED IN THIS MSDS IS, TO THE BEST OF A.H.ROBINS' KNOWLEDGE, COMPLETE AND ACCURATE. A.H.ROBINS, HOWEVER, USES MANY SOURCES AND REFERENCES FOR GATHERING THIS INFORMATION. THUS, A.H. ROBINS CANNOT GUARANTEE COMPLETENESS OR ACCURACY AND DISCLAIMS ALL LIABILITY FOR ITS HANDLING AND USE.

FILE/PABALATE/SF . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS) EFFECTIVE 06/11/87

PABALATE NDC 0031-5816-XX

. . . SECTION 1 MANUFACTURER INFORMATION . . . . . .

A. H. ROBINS CO.,INC. 1405 CUMMINGS DRIVE RICHMOND, VA 23261-6609

EMERGENCY TELEPHONE: (804) 257-2000 (8:30 AM - 5:00 PM)
(804) 257-2000 (AFTER HOURS)

. . . SECTION 2 COMPOSITION INFORMATION . . . . . .

HAZARDOUS INGREDIENTS:
AS FORMULATED, THIS FINISHED PHARMACEUTICAL PRODUCT DOES NOT CONSTITUTE A PHYSICAL HAZARD WITHIN THE MEANING OF 29 CFR SEC 1910.1200. POTENTIAL HEALTH HAZARDS FROM INGESTION OR EXPOSURE TO THE PRODUCT ARE DISCUSSED IN SECTION 6 BELOW.

ACTIVE INGREDIENTS:		CAS
EACH ENTERIC-COATED TABLET CONTAINS:		
SODIUM SALICYLATE, USP	300MG	54-21-7
SODIUM AMINOBENZOATE	300MG	54287-22-8

INACTIVE INGREDIENTS:
ACACIA, ACETYLATED MONOGLYCERIDES, CALCIUM CARBONATE, CALCIUM SULFATE, CARNAUBA WAX, CELLULOSE ACETATE PHTHALATE, D&C YELLOW 10, DIETHYL PHTHALATE, EDIBLE INK, FD&C BLUE 2 ALUMINUM LAKE, FD&C YELLOW 6, GELATIN, MAGNESIUM STEARATE, POLYSORBATES, SHELLAC, STEARIC ACID, SUCROSE, TALC, TITANIUM DIOXIDE, WHEAT FLOUR, WHITE WAX; MAY CONTAIN FD&C RED 40 AND YELLOW 6 ALUMINUM LAKES

. . . SECTION 3 PHYSICAL/CHEMICAL CHARACTERISTICS . . . . . .

BOILING POINT	NOT APPLICABLE
VAPOR PRESSURE	NOT APPLICABLE
VAPOR DENSITY	NOT APPLICABLE
SOLUBILITY IN WATER	NOT APPLICABLE
SPECIFIC GRAVITY	NOT APPLICABLE
MELTING POINT	NOT APPLICABLE
EVAPORATION RATE	NOT APPLICABLE
APPEARANCE	YELLOW, ENTERIC-COATED TABLETS, MONOGRAMMED AHR AND 5816

. . . SECTION 4 FIRE AND EXPLOSION HAZARD DATA . . . . . .

FLASH POINT	NOT APPLICABLE
METHOD USED	NOT APPLICABLE
FLAMMABLE LIMITS	
LEL	NOT APPLICABLE
UEL	NOT APPLICABLE
EXTINGUISHING MEDIA	NOT APPLICABLE
SPECIAL FIRE-FIGHTING PROCEDURES	NOT APPLICABLE
UNUSUAL FIRE AND EXPLOSION HAZARDS	NONE

. . . SECTION 5 REACTIVITY DATA . . . . . .

STABILITY	STABLE
INCOMPATABILITY	NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS	NONE KNOWN
HAZARDOUS POLYMERIZATION	WILL NOT OCCUR

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

PABALATE NDC 0031-5816-XX

. . . SECTION 6 HEALTH HAZARD DATA . . . . . .

	ROUTES OF ENTRY:	INGESTION
	CARCINOGENICITY:	NONE OF THE COMPONENTS IN THIS PRODUCT ARE KNOWN TO BE CARCINOGENIC
SIGNS AND SYMPTOMS OF OVER-EXPOSURE:	SODIUM SALICYLATE	CENTRAL NERVOUS SYSTEM STIMULATION WITH VOMITING, RAPID BREATHING, HYPERACTIVITY AND POSSIBLY CONVULSIONS. THIS PROGRESSES QUICKLY TO DEPRESSION, COMA, RESPIRATORY FAILURE, AND COLLAPSE, AND IS ACCOMPANIED BY SEVERE ELECTROLYTE DISTURBANCES.
	SODIUM AMINOBENZOATE	NAUSEA, VOMITING, ACIDOSIS, ITCHING, RASH, FEVER, METHEMOGLOBINEMIA, AND POSSIBLY HEPATITIS
		(SEE ATTACHED PRODUCT LABELING FOR FULL INFORMATION ON SIDE EFFECTS)
	EMERGENCY AND FIRST-AID PROCEDURES:	EYE CONTACT- IRRIGATE SURFACES WITH WATER FOR 15 MINUTES. SKIN CONTACT- WASH AREAS WITH SOAP AND WATER. TREATMENT OF OVERDOSE: SYMPTOMATIC AND SUPPORTIVE TREATMENT AS REQUIRED. ACTIVATED CHARCOAL, INDUCED EMESIS AND GASTRIC LAVAGE. MONITOR PLASMA SALICYLATE LEVELS
	MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:	HYPERSENSITIVITY TO ANY OF THE COMPONENTS

FOR COMPLETE INFORMATION ON THIS DRUG PLEASE REFER TO THE ATTACHED PRODUCT LABELING

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

PABALATE NDC 0031-5816-XX

. . . SECTION 7 PRECAUTIONS FOR SAFE HANDLING AND USE . . . . . .

SPILLS AND ACCIDENTAL RELEASES:	SWEEP OR SHOVEL INTO A WASTE CONTAINER
WASTE DISPOSAL METHOD:	DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. THIS IS A BIOLOGICALLY ACTIVE MATERIAL. DISPOSE OF ON SITE OR AT AN APPROVED DISPOSAL FACILITY IN ACCORDANCE WITH LOCAL,STATE,AND/OR FEDERAL REGULATIONS.
HANDLING AND STORAGE:	STORE AT ROOM TEMPERATURE, BETWEEN 59 AND 86 DEGREES F.

. . . SECTION 8 CONTROL MEASURES . . . . . .

NO SPECIAL CONTROL MEASURES ARE REQUIRED UNDER NORMAL CONDITIONS OF USE

RESPIRATORY PROTECTION	NONE REQUIRED
VENTILATION	NO SPECIAL VENTILATION IS REQUIRED
PROTECTIVE CLOTHING OR EQUIPMENT	AVOID CONTACT WITH EYES OR PROLONGED CONTACT WITH SKIN.
WORK/HYGIENIC PRACTICES	WASH THOROUGHLY AFTER HANDLING

. . . . . .

THE INFORMATION CONTAINED IN THIS MSDS IS, TO THE BEST OF A.H.ROBINS' KNOWLEDGE, COMPLETE AND ACCURATE. A.H.ROBINS, HOWEVER, USES MANY SOURCES AND REFERENCES FOR GATHERING THIS INFORMATION. THUS, A.H. ROBINS CANNOT GUARANTEE COMPLETENESS OR ACCURACY AND DISCLAIMS ALL LIABILITY FOR ITS HANDLING AND USE.

FILE/PABALATE/TABLETS . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS) EFFECTIVE 01/04/88

PHENAPHEN CAPLETS NDC 0031-6209-XX

. . . SECTION 1 MANUFACTURER INFORMATION . . . . . .

A. H. ROBINS CO.,INC. 1405 CUMMINGS DRIVE RICHMOND, VA 23261-6609

EMERGENCY TELEPHONE: (804) 257-2000 (8:30 AM - 5:00 PM)
(804) 257-2000 (AFTER HOURS)

. . . SECTION 2 COMPOSITION INFORMATION . . . . . .

HAZARDOUS INGREDIENTS:
AS FORMULATED, THIS FINISHED PHARMACEUTICAL PRODUCT DOES NOT CONSTITUTE A PHYSICAL HAZARD WITHIN THE MEANING OF 29 CFR SEC 1910.1200. POTENTIAL HEALTH HAZARDS FROM INGESTION OR EXPOSURE TO THE PRODUCT ARE DISCUSSED IN SECTION 6 BELOW.

ACTIVE INGREDIENTS:		CAS
EACH CAPLET CONTAINS:		
ACETAMINOPHEN, USP	325 MG	103-90-2

INACTIVE INGREDIENTS:
CORN STARCH, FD&C BLUE 1, FLAVOR, HYDROXYPROPYL METHYLCELLULOSE, MAGNESIUM STEARATE, METHACRYLIC ACID COPOLYMER, METHYLPARABEN, MICROCRYSTALLINE CELLULOSE, POLYSORBATE 20, POTASSIUM SORBATE, POVIDONE, PROPYLENE GLYCOL, PROPYLPARABEN, SACCHARIN SODIUM, STEARIC ACID, TITANIUM DIOXIDE, TRIETHYL CITRATE, XANTHAN GUM.

. . . SECTION 3 PHYSICAL/CHEMICAL CHARACTERISTICS . . . . . .

BOILING POINT	NOT APPLICABLE
VAPOR PRESSURE	NOT APPLICABLE
VAPOR DENSITY	NOT APPLICABLE
SOLUBILITY IN WATER	NOT APPLICABLE
SPECIFIC GRAVITY	NOT APPLICABLE
MELTING POINT	NOT APPLICABLE
EVAPORATION RATE	NOT APPLICABLE
APPEARANCE	WHITE, CAPSULE-SHAPED, FILM-COATED TABLET ENGRAVED 6209 ON ONE SIDE AND AHR ON THE OTHER

. . . SECTION 4 FIRE AND EXPLOSION HAZARD DATA . . . . . .

FLASH POINT	NOT APPLICABLE
METHOD USED	NOT APPLICABLE
FLAMMABLE LIMITS	
LEL	NOT APPLICABLE
UEL	NOT APPLICABLE
EXTINGUISHING MEDIA	NOT APPLICABLE
SPECIAL FIRE-FIGHTING PROCEDURES	NOT APPLICABLE
UNUSUAL FIRE AND EXPLOSION HAZARDS	NONE

. . . SECTION 5 REACTIVITY DATA . . . . . .

STABILITY	STABLE
INCOMPATABILITY	NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS	NONE KNOWN
HAZARDOUS POLYMERIZATION	WILL NOT OCCUR

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

PHENAPHEN CAPLETS NDC 0031-6209-XX

. . . SECTION 6 HEALTH HAZARD DATA . . . . . .

	ROUTES OF ENTRY:	INGESTION
	CARCINOGENICITY:	NONE OF THE COMPONENTS IN THIS PRODUCT ARE KNOWN TO BE CARCINOGENIC
SIGNS AND SYMPTOMS OF OVER-EXPOSURE:	ACETAMINOPHEN	SEVERE OVERDOSAGE MAY PRODUCE NAUSEA, VOMITING, PERSPIRATION, AND GENERAL DISCOMFORT. MASSIVE OVERDOSAGE MAY PRODUCE DAMAGE TO LIVER, KIDNEYS, AND CENTRAL NERVOUS SYSTEM. REPEATED INGESTION OF TOXIC DOSES MAY PRODUCE CIRRHOSIS OF THE LIVER. POTENTIALLY TOXIC DOSE IS ABOUT 10 GRAMS. (SEE ATTACHED PRODUCT LABELING FOR FULL INFORMATION ON SIDE-EFFECTS)
	EMERGENCY AND FIRST-AID PROCEDURES:	EYE CONTACT- IRRIGATE SURFACES WITH WATER FOR 15 MINUTES. SKIN CONTACT- WASH AREAS WITH SOAP AND WATER. TREATMENT OF OVERDOSE: INDUCED EMESIS, LAVAGE, AND ACTIVATED CHARCOAL MAY BE HELPFUL. IF POTENTIALLY TOXIC DOSES ARE INGESTED, SERUM ACETAMINOPHEN LEVELS SHOULD BE MONITORED BEGINNING 4 HOURS AFTER INGESTION AND LIVER FUNCTION TESTS SHOULD BE SERIALLY MONITORED. THE ANTIDOTE, N-ACETYLCYSTEINE, SHOULD BE ADMINISTERED WITHIN 16 HOURS FOLLOWING INGESTION. SYMPTOMATIC AND SUPPORTIVE TREATMENT AS REQUIRED
	MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:	HYPERSENSITIVITY TO ANY OF THE COMPONENTS; INDIVIDUALS CHRONICALLY EXPOSED TO ALCOHOL OR OTHER DRUGS MAY BE MORE SUSCEPTIBLE TO THE TOXIC EFFECTS OF ACETAMINOPHEN.

FOR COMPLETE INFORMATION ON THIS DRUG PLEASE REFER TO THE ATTACHED PRODUCT LABELING

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

PHENAPHEN CAPLETS NDC 0031-6209-XX

. . . SECTION 7 PRECAUTIONS FOR SAFE HANDLING AND USE . . . . . .

SPILLS AND ACCIDENTAL RELEASES:	SWEEP OR SHOVEL INTO A WASTE CONTAINER
WASTE DISPOSAL METHOD:	DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. THIS IS A BIOLOGICALLY ACTIVE MATERIAL. DISPOSE OF ON SITE OR AT AN APPROVED DISPOSAL FACILITY IN ACCORDANCE WITH LOCAL,STATE,AND/OR FEDERAL REGULATIONS.
HANDLING AND STORAGE:	STORE AT ROOM TEMPERATURE, BETWEEN 59 AND 86 DEGREES F.

. . . SECTION 8 CONTROL MEASURES . . . . . .

NO SPECIAL CONTROL MEASURES ARE REQUIRED UNDER NORMAL CONDITIONS OF USE

RESPIRATORY PROTECTION	NONE REQUIRED
VENTILATION	NO SPECIAL VENTILATION IS REQUIRED
PROTECTIVE CLOTHING OR EQUIPMENT	AVOID CONTACT WITH EYES OR PROLONGED CONTACT WITH SKIN.
WORK/HYGIENIC PRACTICES	WASH THOROUGHLY AFTER HANDLING

. . . . . .

THE INFORMATION CONTAINED IN THIS MSDS IS, TO THE BEST OF A.H.ROBINS' KNOWLEDGE, COMPLETE AND ACCURATE. A.H.ROBINS, HOWEVER, USES MANY SOURCES AND REFERENCES FOR GATHERING THIS INFORMATION. THUS, A.H. ROBINS CANNOT GUARANTEE COMPLETENESS OR ACCURACY AND DISCLAIMS ALL LIABILITY FOR ITS HANDLING AND USE.

FILE/PHENAPHN/CAPLETS . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS) EFFECTIVE 05/14/87

PHENAPHEN WITH CODEINE NO. 2 NDC 0031-6242-XX

. . . SECTION 1 MANUFACTURER INFORMATION . . . . . .

A. H. ROBINS CO.,INC. 1405 CUMMINGS DRIVE RICHMOND, VA 23261-6609

EMERGENCY TELEPHONE: (804) 257-2000 (8:30 AM - 5:00 PM)
(804) 257-2000 (AFTER HOURS)

. . . SECTION 2 COMPOSITION INFORMATION . . . . . .

HAZARDOUS INGREDIENTS:
AS FORMULATED, THIS FINISHED PHARMACEUTICAL PRODUCT DOES NOT CONSTITUTE A PHYSICAL HAZARD WITHIN THE MEANING OF 29 CFR SEC 1910.1200. POTENTIAL HEALTH HAZARDS FROM INGESTION OR EXPOSURE TO THE PRODUCT ARE DISCUSSED IN SECTION 6 BELOW.

ACTIVE INGREDIENTS: EACH CAPSULE CONTAINS:		CAS
ACETAMINOPHEN, USP	325 MG	103-90-2
CODEINE PHOSPHATE, USP	15 MG	41444-62-6
(WARNING: MAY BE HABIT FORMING)		

INACTIVE INGREDIENTS:
CORN STARCH, D&C YELLOW 10, EDIBLE INK, FD&C BLUE 1, FD&C RED 3 OR 40, FD&C YELLOW 6, GELATIN, MAGNESIUM STEARATE, SODIUM STARCH GLYCOLATE, STEARIC ACID.

. . . SECTION 3 PHYSICAL/CHEMICAL CHARACTERISTICS . . . . . .

BOILING POINT	NOT APPLICABLE
VAPOR PRESSURE	NOT APPLICABLE
VAPOR DENSITY	NOT APPLICABLE
SOLUBILITY IN WATER	NOT APPLICABLE
SPECIFIC GRAVITY	NOT APPLICABLE
MELTING POINT	NOT APPLICABLE
EVAPORATION RATE	NOT APPLICABLE
APPEARANCE	BLACK AND YELLOW CAPSULES

. . . SECTION 4 FIRE AND EXPLOSION HAZARD DATA . . . . . .

FLASH POINT	NOT APPLICABLE
METHOD USED	NOT APPLICABLE
FLAMMABLE LIMITS	
LEL	NOT APPLICABLE
UEL	NOT APPLICABLE
EXTINGUISHING MEDIA	NOT APPLICABLE
SPECIAL FIRE-FIGHTING PROCEDURES	NOT APPLICABLE
UNUSUAL FIRE AND EXPLOSION HAZARDS	NONE

. . . SECTION 5 REACTIVITY DATA . . . . . .

STABILITY	STABLE
INCOMPATABILITY	NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS	NONE KNOWN
HAZARDOUS POLYMERIZATION	WILL NOT OCCUR

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

PHENAPHEN WITH CODEINE NO. 2 NDC 0031-6242-XX

. . . SECTION 6 HEALTH HAZARD DATA . . . . . .

	ROUTES OF ENTRY:	INGESTION
	CARCINOGENICITY:	NONE OF THE COMPONENTS IN THIS PRODUCT ARE KNOWN TO BE CARCINOGENIC
SIGNS AND SYMPTOMS OF OVER-EXPOSURE:	ACETAMINOPHEN	SEVERE OVERDOSAGE MAY PRODUCE NAUSEA, VOMITING, PERSPIRATION, AND GENERAL DISCOMFORT. MASSIVE OVERDOSAGE MAY PRODUCE DAMAGE TO LIVER, KIDNEYS, AND CENTRAL NERVOUS SYSTEM. REPEATED INGESTION OF TOXIC DOSES MAY PRODUCE CIRRHOSIS OF THE LIVER. POTENTIALLY TOXIC DOSE IS ABOUT 10 GRAMS.
	CODEINE PHOSPHATE	PINPOINT PUPILS, CONSTIPATION, SLOW HEART RATE, HIGH BLOOD PRESSURE, RESPIRATORY DEPRESSION, URINARY RETENTION, MUSCLE SPASMS, ITCHING, RESPIRATORY ARREST, COMA
	EMERGENCY AND FIRST-AID PROCEDURES:	EYE CONTACT- IRRIGATE SURFACES WITH WATER FOR 15 MINUTES. SKIN CONTACT- WASH AREAS WITH SOAP AND WATER. TREATMENT OF OVERDOSE: INDUCED EMESIS, LAVAGE, AND ACTIVATED CHARCOAL MAY BE HELPFUL. IF POTENTIALLY TOXIC DOSES ARE INGESTED, SERUM ACETAMINOPHEN LEVELS SHOULD BE MONITORED BEGINNING 4 HOURS AFTER INGESTION AND LIVER FUNCTION TESTS SHOULD BE SERIALLY MONITORED. THE ANTIDOTE FOR ACETAMINOPHEN, N-ACETYLCYSTEINE, SHOULD BE ADMINISTERED WITHIN 16 HOURS FOLLOWING INGESTION. SEVERE OPIATE EFFECTS SUCH AS RESPIRATORY DEPRESSION MAY BE REVERSED BY NALOXONE. SYMPTOMATIC AND SUPPORTIVE TREATMENT AS REQUIRED
	MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:	HYPERSENSITIVITY TO ANY OF THE COMPONENTS; INDIVIDUALS CHRONICALLY EXPOSED TO ALCOHOL OR OTHER DRUGS MAY BE MORE SUSCEPTIBLE TO THE TOXIC EFFECTS OF ACETAMINOPHEN.

FOR COMPLETE INFORMATION ON THIS DRUG PLEASE REFER TO THE ATTACHED PRODUCT LABELING

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

PHENAPHEN WITH CODEINE NO. 2 NDC 0031-6242-XX

. . . SECTION 7 PRECAUTIONS FOR SAFE HANDLING AND USE . . . . . .

SPILLS AND ACCIDENTAL RELEASES:	SWEEP OR SHOVEL INTO A WASTE CONTAINER
WASTE DISPOSAL METHOD:	DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. THIS IS A BIOLOGICALLY ACTIVE MATERIAL. DISPOSE OF ON SITE OR AT AN APPROVED DISPOSAL FACILITY IN ACCORDANCE WITH LOCAL,STATE,AND/OR FEDERAL REGULATIONS.
HANDLING AND STORAGE:	STORE AT ROOM TEMPERATURE, BETWEEN 59 AND 86 DEGREES F.

. . . SECTION 8 CONTROL MEASURES . . . . . .

NO SPECIAL CONTROL MEASURES ARE REQUIRED UNDER NORMAL CONDITIONS OF USE

RESPIRATORY PROTECTION	NONE REQUIRED
VENTILATION	NO SPECIAL VENTILATION IS REQUIRED
PROTECTIVE CLOTHING OR EQUIPMENT	AVOID CONTACT WITH EYES OR PROLONGED CONTACT WITH SKIN.
WORK/HYGIENIC PRACTICES	WASH THOROUGHLY AFTER HANDLING

. . . . . .

THE INFORMATION CONTAINED IN THIS MSDS IS, TO THE BEST OF A.H.ROBINS' KNOWLEDGE, COMPLETE AND ACCURATE. A.H.ROBINS, HOWEVER, USES MANY SOURCES AND REFERENCES FOR GATHERING THIS INFORMATION. THUS, A.H. ROBINS CANNOT GUARANTEE COMPLETENESS OR ACCURACY AND DISCLAIMS ALL LIABILITY FOR ITS HANDLING AND USE.

FILE/PHENAPHN/NO2 . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS) EFFECTIVE 05/14/87

PHENAPHEN WITH CODEINE NO. 3 NDC 0031-6257-XX

. . . SECTION 1 MANUFACTURER INFORMATION . . . . . .

A. H. ROBINS CO.,INC. 1405 CUMMINGS DRIVE RICHMOND, VA 23261-6609

EMERGENCY TELEPHONE: (804) 257-2000 (8:30 AM - 5:00 PM)
(804) 257-2000 (AFTER HOURS)

. . . SECTION 2 COMPOSITION INFORMATION . . . . . .

HAZARDOUS INGREDIENTS:
AS FORMULATED, THIS FINISHED PHARMACEUTICAL PRODUCT DOES NOT CONSTITUTE A PHYSICAL HAZARD WITHIN THE MEANING OF 29 CFR SEC 1910.1200. POTENTIAL HEALTH HAZARDS FROM INGESTION OR EXPOSURE TO THE PRODUCT ARE DISCUSSED IN SECTION 6 BELOW.

ACTIVE INGREDIENTS:			CAS
EACH CAPSULE CONTAINS:			
ACETAMINOPHEN, USP	325	MG	103-90-2
CODEINE PHOSPHATE, USP	30	MG	41444-62-6
(WARNING: MAY BE HABIT FORMING)			

INACTIVE INGREDIENTS:
D&C YELLOW 10, EDIBLE INK, FD&C BLUE 1, (FD&C GREEN 3 AND RED 40) OR RED 3, FD&C YELLOW 6, GELATIN, LACTOSE, MAGNESIUM STEARATE, SODIUM STARCH GLYCOLATE, STEARIC ACID.

. . . SECTION 3 PHYSICAL/CHEMICAL CHARACTERISTICS . . . . . .

BOILING POINT	NOT APPLICABLE
VAPOR PRESSURE	NOT APPLICABLE
VAPOR DENSITY	NOT APPLICABLE
SOLUBILITY IN WATER	NOT APPLICABLE
SPECIFIC GRAVITY	NOT APPLICABLE
MELTING POINT	NOT APPLICABLE
EVAPORATION RATE	NOT APPLICABLE
APPEARANCE	BLACK AND GREEN CAPSULES

. . . SECTION 4 FIRE AND EXPLOSION HAZARD DATA . . . . . .

FLASH POINT	NOT APPLICABLE
METHOD USED	NOT APPLICABLE
FLAMMABLE LIMITS	
LEL	NOT APPLICABLE
UEL	NOT APPLICABLE
EXTINGUISHING MEDIA	NOT APPLICABLE
SPECIAL FIRE-FIGHTING PROCEDURES	NOT APPLICABLE
UNUSUAL FIRE AND EXPLOSION HAZARDS	NONE

. . . SECTION 5 REACTIVITY DATA . . . . . .

STABILITY	STABLE
INCOMPATABILITY	NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS	NONE KNOWN
HAZARDOUS POLYMERIZATION	WILL NOT OCCUR

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

PHENAPHEN WITH CODEINE NO. 3 NDC 0031-6257-XX

. . . SECTION 6 HEALTH HAZARD DATA . . . . . .

ROUTES OF ENTRY: INGESTION

CARCINOGENICITY: NONE OF THE COMPONENTS IN THIS PRODUCT ARE KNOWN TO BE CARCINOGENIC

SIGNS AND SYMPTOMS OF OVER-EXPOSURE:

ACETAMINOPHEN: SEVERE OVERDOSAGE MAY PRODUCE NAUSEA, VOMITING, PERSPIRATION, AND GENERAL DISCOMFORT. MASSIVE OVERDOSAGE MAY PRODUCE DAMAGE TO LIVER, KIDNEYS, AND CENTRAL NERVOUS SYSTEM. REPEATED INGESTION OF TOXIC DOSES MAY PRODUCE CIRRHOSIS OF THE LIVER. POTENTIALLY TOXIC DOSE IS ABOUT 10 GRAMS.

CODEINE PHOSPHATE: PINPOINT PUPILS, CONSTIPATION, SLOW HEART RATE, HIGH BLOOD PRESSURE, RESPIRATORY DEPRESSION, URINARY RETENTION, MUSCLE SPASMS, ITCHING, RESPIRATORY ARREST, COMA

EMERGENCY AND FIRST-AID PROCEDURES:
EYE CONTACT- IRRIGATE SURFACES WITH WATER FOR 15 MINUTES.
SKIN CONTACT- WASH AREAS WITH SOAP AND WATER.
TREATMENT OF OVERDOSE: INDUCED EMESIS, LAVAGE, AND ACTIVATED CHARCOAL MAY BE HELPFUL. IF POTENTIALLY TOXIC DOSES ARE INGESTED, SERUM ACETAMINOPHEN LEVELS SHOULD BE MONITORED BEGINNING 4 HOURS AFTER INGESTION AND LIVER FUNCTION TESTS SHOULD BE SERIALLY MONITORED. THE ANTIDOTE FOR ACETAMINOPHEN, N-ACETYLCYSTEINE, SHOULD BE ADMINISTERED WITHIN 16 HOURS FOLLOWING INGESTION.
SEVERE OPIATE EFFECTS SUCH AS REPIRATORY DEPRESSION MAY BE REVERSED BY NALOXONE.
SYMPTOMATIC AND SUPPORTIVE TREATMENT AS REQUIRED

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: HYPERSENSITIVITY TO ANY OF THE COMPONENTS; INDIVIDUALS CHRONICALLY EXPOSED TO ALCOHOL OR OTHER DRUGS MAY BE MORE SUSCEPTIBLE TO THE TOXIC EFFECTS OF ACETAMINOPHEN.

FOR COMPLETE INFORMATION ON THIS DRUG PLEASE REFER TO THE ATTACHED PRODUCT LABELING

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

PHENAPHEN WITH CODEINE NO. 3 NDC 0031-6257-XX

. . . SECTION 7 PRECAUTIONS FOR SAFE HANDLING AND USE . . . . . .

SPILLS AND ACCIDENTAL RELEASES:	SWEEP OR SHOVEL INTO A WASTE CONTAINER
WASTE DISPOSAL METHOD:	DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. THIS IS A BIOLOGICALLY ACTIVE MATERIAL. DISPOSE OF ON SITE OR AT AN APPROVED DISPOSAL FACILITY IN ACCORDANCE WITH LOCAL,STATE,AND/OR FEDERAL REGULATIONS.
HANDLING AND STORAGE:	STORE AT ROOM TEMPERATURE, BETWEEN 59 AND 86 DEGREES F.

. . . SECTION 8 CONTROL MEASURES . . . . . .

NO SPECIAL CONTROL MEASURES ARE REQUIRED UNDER NORMAL CONDITIONS OF USE

RESPIRATORY PROTECTION	NONE REQUIRED
VENTILATION	NO SPECIAL VENTILATION IS REQUIRED
PROTECTIVE CLOTHING OR EQUIPMENT	AVOID CONTACT WITH EYES OR PROLONGED CONTACT WITH SKIN.
WORK/HYGIENIC PRACTICES	WASH THOROUGHLY AFTER HANDLING

. . . . . .

THE INFORMATION CONTAINED IN THIS MSDS IS, TO THE BEST OF A.H.ROBINS' KNOWLEDGE, COMPLETE AND ACCURATE. A.H.ROBINS, HOWEVER, USES MANY SOURCES AND REFERENCES FOR GATHERING THIS INFORMATION. THUS, A.H. ROBINS CANNOT GUARANTEE COMPLETENESS OR ACCURACY AND DISCLAIMS ALL LIABILITY FOR ITS HANDLING AND USE.

FILE/PHENAPHN/NO3 . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS) EFFECTIVE 05/14/87

PHENAPHEN WITH CODEINE NO. 4 NDC 0031-6274-XX

. . . SECTION 1 MANUFACTURER INFORMATION . . . . . .

A. H. ROBINS CO.,INC. 1405 CUMMINGS DRIVE RICHMOND, VA 23261-6609

EMERGENCY TELEPHONE: (804) 257-2000 (8:30 AM - 5:00 PM)
(804) 257-2000 (AFTER HOURS)

. . . SECTION 2 COMPOSITION INFORMATION . . . . . .

HAZARDOUS INGREDIENTS:
AS FORMULATED, THIS FINISHED PHARMACEUTICAL PRODUCT DOES NOT CONSTITUTE A PHYSICAL HAZARD WITHIN THE MEANING OF 29 CFR SEC 1910.1200. POTENTIAL HEALTH HAZARDS FROM INGESTION OR EXPOSURE TO THE PRODUCT ARE DISCUSSED IN SECTION 6 BELOW.

ACTIVE INGREDIENTS:		CAS
EACH CAPSULE CONTAINS:		
ACETAMINOPHEN, USP	325 MG	103-90-2
CODEINE PHOSPHATE, USP	60 MG	41444-62-6
(WARNING: MAY BE HABIT FORMING)		

INACTIVE INGREDIENTS:
CORN STARCH, D&C YELLOW 10, EDIBLE INK, FD&C GREEN 3 OR BLUE 1, FD&C YELLOW 6, GELATIN, LACTOSE, MAGNESIUM STEARATE, SODIUM STARCH GLYCOLATE, STEARIC ACID.

. . . SECTION 3 PHYSICAL/CHEMICAL CHARACTERISTICS . . . . . .

BOILING POINT	NOT APPLICABLE
VAPOR PRESSURE	NOT APPLICABLE
VAPOR DENSITY	NOT APPLICABLE
SOLUBILITY IN WATER	NOT APPLICABLE
SPECIFIC GRAVITY	NOT APPLICABLE
MELTING POINT	NOT APPLICABLE
EVAPORATION RATE	NOT APPLICABLE
APPEARANCE	GREEN AND WHITE CAPSULES

. . . SECTION 4 FIRE AND EXPLOSION HAZARD DATA . . . . . .

FLASH POINT	NOT APPLICABLE
METHOD USED	NOT APPLICABLE
FLAMMABLE LIMITS	
LEL	NOT APPLICABLE
UEL	NOT APPLICABLE
EXTINGUISHING MEDIA	NOT APPLICABLE
SPECIAL FIRE-FIGHTING PROCEDURES	NOT APPLICABLE
UNUSUAL FIRE AND EXPLOSION HAZARDS	NONE

. . . SECTION 5 REACTIVITY DATA . . . . . .

STABILITY	STABLE
INCOMPATABILITY	NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS	NONE KNOWN
HAZARDOUS POLYMERIZATION	WILL NOT OCCUR

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

PHENAPHEN WITH CODEINE NO. 4 NDC 0031-6274-XX

. . . SECTION 6 HEALTH HAZARD DATA . . . . . .

ROUTES OF ENTRY:		INGESTION
CARCINOGENICITY:		NONE OF THE COMPONENTS IN THIS PRODUCT ARE KNOWN TO BE CARCINOGENIC
SIGNS AND SYMPTOMS OF OVER-EXPOSURE:	ACETAMINOPHEN	SEVERE OVERDOSAGE MAY PRODUCE NAUSEA, VOMITING, PERSPIRATION, AND GENERAL DISCOMFORT. MASSIVE OVERDOSAGE MAY PRODUCE DAMAGE TO LIVER, KIDNEYS, AND CENTRAL NERVOUS SYSTEM. REPEATED INGESTION OF TOXIC DOSES MAY PRODUCE CIRRHOSIS OF THE LIVER. POTENTIALLY TOXIC DOSE IS ABOUT 10 GRAMS.
	CODEINE PHOSPHATE	PINPOINT PUPILS, CONSTIPATION, SLOW HEART RATE, HIGH BLOOD PRESSURE, RESPIRATORY DEPRESSION, URINARY RETENTION, MUSCLE SPASMS, ITCHING, RESPIRATORY ARREST, COMA
EMERGENCY AND FIRST-AID PROCEDURES:		EYE CONTACT- IRRIGATE SURFACES WITH WATER FOR 15 MINUTES. SKIN CONTACT- WASH AREAS WITH SOAP AND WATER. TREATMENT OF OVERDOSE: INDUCED EMESIS, LAVAGE, AND ACTIVATED CHARCOAL MAY BE HELPFUL. IF POTENTIALLY TOXIC DOSES ARE INGESTED, SERUM ACETAMINOPHEN LEVELS SHOULD BE MONITORED BEGINNING 4 HOURS AFTER INGESTION AND LIVER FUNCTION TESTS SHOULD BE SERIALLY MONITORED. THE ANTIDOTE FOR ACETAMINOPHEN, N-ACETYLCYSTEINE, SHOULD BE ADMINISTERED WITHIN 16 HOURS FOLLOWING INGESTION. SEVERE OPIATE EFFECTS SUCH AS RESPIRATORY DEPRESSION MAY BE REVERSED BY NALOXONE. SYMPTOMATIC AND SUPPORTIVE TREATMENT AS REQUIRED
MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:		HYPERSENSITIVITY TO ANY OF THE COMPONENTS; INDIVIDUALS CHRONICALLY EXPOSED TO ALCOHOL OR OTHER DRUGS MAY BE MORE SUSCEPTIBLE TO THE TOXIC EFFECTS OF ACETAMINOPHEN.

FOR COMPLETE INFORMATION ON THIS DRUG PLEASE REFER TO THE ATTACHED PRODUCT LABELING

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

PHENAPHEN WITH CODEINE NO. 4 NDC 0031-6274-XX

. . . SECTION 7 PRECAUTIONS FOR SAFE HANDLING AND USE . . . . . .

SPILLS AND ACCIDENTAL RELEASES:	SWEEP OR SHOVEL INTO A WASTE CONTAINER
WASTE DISPOSAL METHOD:	DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. THIS IS A BIOLOGICALLY ACTIVE MATERIAL. DISPOSE OF ON SITE OR AT AN APPROVED DISPOSAL FACILITY IN ACCORDANCE WITH LOCAL,STATE,AND/OR FEDERAL REGULATIONS.
HANDLING AND STORAGE:	STORE AT ROOM TEMPERATURE, BETWEEN 59 AND 86 DEGREES F.

. . . SECTION 8 CONTROL MEASURES . . . . . .

NO SPECIAL CONTROL MEASURES ARE REQUIRED UNDER NORMAL CONDITIONS OF USE

RESPIRATORY PROTECTION	NONE REQUIRED
VENTILATION	NO SPECIAL VENTILATION IS REQUIRED
PROTECTIVE CLOTHING OR EQUIPMENT	AVOID CONTACT WITH EYES OR PROLONGED CONTACT WITH SKIN.
WORK/HYGIENIC PRACTICES	WASH THOROUGHLY AFTER HANDLING

. . . . . .

THE INFORMATION CONTAINED IN THIS MSDS IS, TO THE BEST OF A.H.ROBINS' KNOWLEDGE, COMPLETE AND ACCURATE. A.H.ROBINS, HOWEVER, USES MANY SOURCES AND REFERENCES FOR GATHERING THIS INFORMATION. THUS, A.H. ROBINS CANNOT GUARANTEE COMPLETENESS OR ACCURACY AND DISCLAIMS ALL LIABILITY FOR ITS HANDLING AND USE.

FILE/PHENAPHN/NO4 . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS) EFFECTIVE 05/14/87

PHENAPHEN-650 WITH CODEINE NDC 0031-6251-XX

. . . SECTION 1 MANUFACTURER INFORMATION . . . . . .

A. H. ROBINS CO.,INC. 1405 CUMMINGS DRIVE RICHMOND, VA 23261-6609

EMERGENCY TELEPHONE: (804) 257-2000 (8:30 AM - 5:00 PM)
(804) 257-2000 (AFTER HOURS)

. . . SECTION 2 COMPOSITION INFORMATION . . . . . .

HAZARDOUS INGREDIENTS:
AS FORMULATED, THIS FINISHED PHARMACEUTICAL PRODUCT DOES NOT CONSTITUTE A PHYSICAL HAZARD WITHIN THE MEANING OF 29 CFR SEC 1910.1200. POTENTIAL HEALTH HAZARDS FROM INGESTION OR EXPOSURE TO THE PRODUCT ARE DISCUSSED IN SECTION 6 BELOW.

ACTIVE INGREDIENTS: EACH TABLET CONTAINS:		CAS
ACETAMINOPHEN, USP	650 MG	103-90-2
CODEINE PHOSPHATE, USP (WARNING: MAY BE HABIT FORMING)	30 MG	41444-62-6

INACTIVE INGREDIENTS:
CALCIUM SULFATE, CORN STARCH, MICROCRYSTALLINE CELLULOSE, POLYETHYLENE GLYCOL, POVIDONE, SILICON DIOXIDE, SODIUM BISULFITE, SODIUM STARCH GLYCOLATE, STEARIC ACID.

. . . SECTION 3 PHYSICAL/CHEMICAL CHARACTERISTICS . . . . . .

BOILING POINT	NOT APPLICABLE
VAPOR PRESSURE	NOT APPLICABLE
VAPOR DENSITY	NOT APPLICABLE
SOLUBILITY IN WATER	NOT APPLICABLE
SPECIFIC GRAVITY	NOT APPLICABLE
MELTING POINT	NOT APPLICABLE
EVAPORATION RATE	NOT APPLICABLE
APPEARANCE	A SCORED, WHITE, CAPSULE-SHAPED COMPRESSED TABLET ENGRAVED AHR AND 6251

. . . SECTION 4 FIRE AND EXPLOSION HAZARD DATA . . . . . .

FLASH POINT	NOT APPLICABLE
METHOD USED	NOT APPLICABLE
FLAMMABLE LIMITS	
LEL	NOT APPLICABLE
UEL	NOT APPLICABLE
EXTINGUISHING MEDIA	NOT APPLICABLE
SPECIAL FIRE-FIGHTING PROCEDURES	NOT APPLICABLE
UNUSUAL FIRE AND EXPLOSION HAZARDS	NONE

. . . SECTION 5 REACTIVITY DATA . . . . . .

STABILITY	STABLE
INCOMPATABILITY	NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS	NONE KNOWN
HAZARDOUS POLYMERIZATION	WILL NOT OCCUR

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

PHENAPHEN-650 WITH CODEINE NDC 0031-6251-XX

. . . SECTION 6 HEALTH HAZARD DATA . . . . . .

	ROUTES OF ENTRY:	INGESTION
	CARCINOGENICITY:	NONE OF THE COMPONENTS IN THIS PRODUCT ARE KNOWN TO BE CARCINOGENIC
SIGNS AND SYMPTOMS OF OVER-EXPOSURE:	ACETAMINOPHEN	SEVERE OVERDOSAGE MAY PRODUCE NAUSEA, VOMITING, PERSPIRATION, AND GENERAL DISCOMFORT. MASSIVE OVERDOSAGE MAY PRODUCE DAMAGE TO LIVER, KIDNEYS, AND CENTRAL NERVOUS SYSTEM. REPEATED INGESTION OF TOXIC DOSES MAY PRODUCE CIRRHOSIS OF THE LIVER. POTENTIALLY TOXIC DOSE IS ABOUT 10 GRAMS.
	CODEINE PHOSPHATE	PINPOINT PUPILS, CONSTIPATION, SLOW HEART RATE, HIGH BLOOD PRESSURE, RESPIRATORY DEPRESSION, URINARY RETENTION, MUSCLE SPASMS, ITCHING, RESPIRATORY ARREST, COMA
	EMERGENCY AND FIRST-AID PROCEDURES:	EYE CONTACT- IRRIGATE SURFACES WITH WATER FOR 15 MINUTES. SKIN CONTACT- WASH AREAS WITH SOAP AND WATER. TREATMENT OF OVERDOSE: INDUCED EMESIS, LAVAGE, AND ACTIVATED CHARCOAL MAY BE HELPFUL. IF POTENTIALLY TOXIC DOSES ARE INGESTED, SERUM ACETAMINOPHEN LEVELS SHOULD BE MONITORED BEGINNING 4 HOURS AFTER INGESTION AND LIVER FUNCTION TESTS SHOULD BE SERIALLY MONITORED. THE ANTIDOTE FOR ACETAMINOPHEN, N-ACETYLCYSTEINE, SHOULD BE ADMINISTERED WITHIN 16 HOURS FOLLOWING INGESTION. SEVERE OPIATE EFFECTS SUCH AS RESPIRATORY DEPRESSION MAY BE REVERSED BY NALOXONE. SYMPTOMATIC AND SUPPORTIVE TREATMENT AS REQUIRED
	MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:	HYPERSENSITIVITY TO ANY OF THE COMPONENTS; INDIVIDUALS CHRONICALLY EXPOSED TO ALCOHOL OR OTHER DRUGS MAY BE MORE SUSCEPTIBLE TO THE TOXIC EFFECTS OF ACETAMINOPHEN.

FOR COMPLETE INFORMATION ON THIS DRUG PLEASE REFER TO THE ATTACHED PRODUCT LABELING

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

PHENAPHEN-650 WITH CODEINE NDC 0031-6251-XX

. . . SECTION 7 PRECAUTIONS FOR SAFE HANDLING AND USE . . . . . .

SPILLS AND ACCIDENTAL RELEASES:	SWEEP OR SHOVEL INTO A WASTE CONTAINER
WASTE DISPOSAL METHOD:	DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. THIS IS A BIOLOGICALLY ACTIVE MATERIAL. DISPOSE OF ON SITE OR AT AN APPROVED DISPOSAL FACILITY IN ACCORDANCE WITH LOCAL,STATE,AND/OR FEDERAL REGULATIONS.
HANDLING AND STORAGE:	STORE AT ROOM TEMPERATURE, BETWEEN 59 AND 86 DEGREES F.

. . . SECTION 8 CONTROL MEASURES . . . . . .

NO SPECIAL CONTROL MEASURES ARE REQUIRED UNDER NORMAL CONDITIONS OF USE

RESPIRATORY PROTECTION	NONE REQUIRED
VENTILATION	NO SPECIAL VENTILATION IS REQUIRED
PROTECTIVE CLOTHING OR EQUIPMENT	AVOID CONTACT WITH EYES OR PROLONGED CONTACT WITH SKIN.
WORK/HYGIENIC PRACTICES	WASH THOROUGHLY AFTER HANDLING

. . . . . .

THE INFORMATION CONTAINED IN THIS MSDS IS, TO THE BEST OF A.H.ROBINS' KNOWLEDGE, COMPLETE AND ACCURATE. A.H.ROBINS, HOWEVER, USES MANY SOURCES AND REFERENCES FOR GATHERING THIS INFORMATION. THUS, A.H. ROBINS CANNOT GUARANTEE COMPLETENESS OR ACCURACY AND DISCLAIMS ALL LIABILITY FOR ITS HANDLING AND USE.

FILE/PHENAPHN/650COD. . . . . .

MATERIAL SAFETY DATA SHEET (MSDS) EFFECTIVE 05/28/87

PONDIMIN NDC 0031-6447-XX

. . . SECTION 1 MANUFACTURER INFORMATION . . . . . .

A. H. ROBINS CO.,INC. 1405 CUMMINGS DRIVE RICHMOND, VA 23261-6609

EMERGENCY TELEPHONE: (804) 257-2000 (8:30 AM - 5:00 PM)
(804) 257-2000 (AFTER HOURS)

. . . SECTION 2 COMPOSITION INFORMATION . . . . . .

HAZARDOUS INGREDIENTS:
AS FORMULATED, THIS FINISHED PHARMACEUTICAL PRODUCT DOES NOT CONSTITUTE A PHYSICAL HAZARD WITHIN THE MEANING OF 29 CFR SEC 1910.1200. POTENTIAL HEALTH HAZARDS FROM INGESTION OR EXPOSURE TO THE PRODUCT ARE DISCUSSED IN SECTION 6 BELOW.

ACTIVE INGREDIENTS:		CAS
FENFLURAMINE HCL	20MG	404-82-0

INACTIVE INGREDIENTS:
CORN STARCH, FD&C YELLOW 6, MAGNESIUM STEARATE, MICROCRYSTALLINE CELLULOSE, SILICON DIOXIDE, SODIUM LAURYL SULFATE

. . . SECTION 3 PHYSICAL/CHEMICAL CHARACTERISTICS . . . . . .

BOILING POINT	NOT APPLICABLE
VAPOR PRESSURE	NOT APPLICABLE
VAPOR DENSITY	NOT APPLICABLE
SOLUBILITY IN WATER	NOT APPLICABLE
SPECIFIC GRAVITY	NOT APPLICABLE
MELTING POINT	NOT APPLICABLE
EVAPORATION RATE	NOT APPLICABLE
APPEARANCE	ORANGE, SCORED, COMPRESSED TABLETS MONOGRAMMED AHR AND 6447

. . . SECTION 4 FIRE AND EXPLOSION HAZARD DATA . . . . . .

FLASH POINT	NOT APPLICABLE
METHOD USED	NOT APPLICABLE
FLAMMABLE LIMITS	
LEL	NOT APPLICABLE
UEL	NOT APPLICABLE
EXTINGUISHING MEDIA	NOT APPLICABLE
SPECIAL FIRE-FIGHTING PROCEDURES	NOT APPLICABLE
UNUSUAL FIRE AND EXPLOSION HAZARDS	NONE

. . . SECTION 5 REACTIVITY DATA . . . . . .

STABILITY	STABLE
INCOMPATABILITY	NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS	NONE KNOWN
HAZARDOUS POLYMERIZATION	WILL NOT OCCUR

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

PONDIMIN NDC 0031-6447-XX

. . . SECTION 6 HEALTH HAZARD DATA . . . . . .

	ROUTES OF ENTRY:	INGESTION
	CARCINOGENICITY:	NONE OF THE COMPONENTS IN THIS PRODUCT ARE KNOWN TO BE CARCINOGENIC
SIGNS AND SYMPTOMS OF OVER-EXPOSURE:	FENFLURAMINE	DROWSINESS, DIARRHEA, AND DRY MOUTH ARE THE MOST COMMON ADVERSE REACTIONS. IN OVERDOSAGE, THE FOLLOWING MAY BE SEEN: AGITATION OR DROWSINESS, CONFUSION, FLUSHING, SHIVERING, SWEATING, ABDOMINAL PAIN, OVERBREATHING, DILATED PUPILS, RAPID HEART BEAT, CONVULSIONS, COMA, IRREGULAR HEART BEAT, OR CARDIAC ARREST (SEE ATTACHED PRODUCT LABELING FOR FULL INFORMATION ON SIDE-EFFECTS)
	EMERGENCY AND FIRST-AID PROCEDURES:	EYE CONTACT- IRRIGATE SURFACES WITH WATER FOR 15 MINUTES. SKIN CONTACT- WASH AREAS WITH SOAP AND WATER. TREATMENT OF OVERDOSE: GASTRIC LAVAGE AND ACTIVATED CHARCOAL MAY BE HELPFUL; SYMPTOMATIC AND SUPPORTIVE TREATMENT AS REQUIRED. (SEE ATTACHED PRODUCT LABELING FOR A DETAILED DESCRIPTION OF THE MANAGEMENT OF FENFLURAMINE OVERDOSAGE)
	MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:	HYPERSENSITIVITY TO ANY OF THE COMPONENTS

FOR COMPLETE INFORMATION ON THIS DRUG PLEASE REFER TO THE ATTACHED PRODUCT LABELING

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

PONDIMIN NDC 0031-6447-XX

. . . SECTION 7 PRECAUTIONS FOR SAFE HANDLING AND USE . . . . . .

SPILLS AND ACCIDENTAL RELEASES:	SWEEP OR SHOVEL INTO A WASTE CONTAINER
WASTE DISPOSAL METHOD:	DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. THIS IS A BIOLOGICALLY ACTIVE MATERIAL. DISPOSE OF ON SITE OR AT AN APPROVED DISPOSAL FACILITY IN ACCORDANCE WITH LOCAL,STATE,AND/OR FEDERAL REGULATIONS.
HANDLING AND STORAGE:	STORE AT ROOM TEMPERATURE, BETWEEN 59 AND 86 DEGREES F.

. . . SECTION 8 CONTROL MEASURES . . . . . .

NO SPECIAL CONTROL MEASURES ARE REQUIRED UNDER NORMAL CONDITIONS OF USE

RESPIRATORY PROTECTION	NONE REQUIRED
VENTILATION	NO SPECIAL VENTILATION IS REQUIRED
PROTECTIVE CLOTHING OR EQUIPMENT	AVOID CONTACT WITH EYES OR PROLONGED CONTACT WITH SKIN.
WORK/HYGIENIC PRACTICES	WASH THOROUGHLY AFTER HANDLING

. . . . . .

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FILE/PONDIMIN/TABLETS . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS) EFFECTIVE 07/10/87

QUINIDEX EXTENTABS NDC 0031-6649-XX

. . . SECTION 1 MANUFACTURER INFORMATION . . . . . .

A. H. ROBINS CO.,INC. 1405 CUMMINGS DRIVE RICHMOND, VA 23261-6609

EMERGENCY TELEPHONE: (804) 257-2000 (8:30 AM - 5:00 PM)
(804) 257-2000 (AFTER HOURS)

. . . SECTION 2 COMPOSITION INFORMATION . . . . . .

HAZARDOUS INGREDIENTS:
AS FORMULATED, THIS FINISHED PHARMACEUTICAL PRODUCT DOES NOT CONSTITUTE A PHYSICAL HAZARD WITHIN THE MEANING OF 29 CFR SEC 1910.1200. POTENTIAL HEALTH HAZARDS FROM INGESTION OR EXPOSURE TO THE PRODUCT ARE DISCUSSED IN SECTION 6 BELOW.

ACTIVE INGREDIENTS:		CAS
EACH TABLET CONTAINS:		
QUINIDINE SULFATE, USP	300MG	6591-63-5

INACTIVE INGREDIENTS:
ACACIA, ACETYLATED MONOGLYCERIDES, CALCIUM SULFATE, CARNAUBA WAX, EDIBLE INK, FD&C BLUE 2, GELATIN, GUAR GUM, MAGNESIUM OXIDE, MAGNESIUM STEARATE, POLYSORBATES, SHELLAC, SUCROSE, TITANIUM DIOXIDE, WHITE WAX, AND OTHER INGREDIENTS, ONE OF WHICH IS A CORN DERIVATIVE. MAY CONTAIN FD&C RED 40 AND YELLOW 6 ALUMINUM LAKES.

. . . SECTION 3 PHYSICAL/CHEMICAL CHARACTERISTICS . . . . . .

BOILING POINT	NOT APPLICABLE
VAPOR PRESSURE	NOT APPLICABLE
VAPOR DENSITY	NOT APPLICABLE
SOLUBILITY IN WATER	NOT APPLICABLE
SPECIFIC GRAVITY	NOT APPLICABLE
MELTING POINT	NOT APPLICABLE
EVAPORATION RATE	NOT APPLICABLE
APPEARANCE	WHITE, SUGAR-COATED TABLET MONOGRAMMED QUINIDEX AND AHR

. . . SECTION 4 FIRE AND EXPLOSION HAZARD DATA . . . . . .

FLASH POINT	NOT APPLICABLE
METHOD USED	NOT APPLICABLE
FLAMMABLE LIMITS	
LEL	NOT APPLICABLE
UEL	NOT APPLICABLE
EXTINGUISHING MEDIA	NOT APPLICABLE
SPECIAL FIRE-FIGHTING PROCEDURES	NOT APPLICABLE
UNUSUAL FIRE AND EXPLOSION HAZARDS	NONE

. . . SECTION 5 REACTIVITY DATA . . . . . .

STABILITY	STABLE
INCOMPATABILITY	NONE KNOWN
HAZARDOUS DECOMPOSITION OR BYPRODUCTS	NONE KNOWN
HAZARDOUS POLYMERIZATION	WILL NOT OCCUR

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

QUINIDEX EXTENTABS NDC 0031-6649-XX

. . . SECTION 6 HEALTH HAZARD DATA . . . . . .

ROUTES OF ENTRY:		INGESTION
CARCINOGENICITY:		NONE OF THE COMPONENTS IN THIS PRODUCT ARE KNOWN TO BE CARCINOGENIC
SIGNS AND SYMPTOMS OF OVER-EXPOSURE:	QUINIDINE SULFATE	RINGING IN THE EARS, HEARING LOSS, DIZZINESS, LIGHT-HEADEDNESS, ITCHING, RASH, ALLERGIC REACTIONS, HEADACHE, NAUSEA, DISTURBED VISION, IRREGULAR HEARTBEAT, FEVER, MUSCLE AND JOINT PAIN, RAPID HEARTBEAT, LOWERED BLOOD PRESSURE, RESPIRATORY DEPRESSION, FLUID IN LUNGS, DECREASED BLOOD PLATELETS, FAINTING, SEIZURES, COMA (SEE ATTACHED PRODUCT LABELING FOR FULL INFORMATION ON SIDE-EFFECTS)
EMERGENCY AND FIRST-AID PROCEDURES:		EYE CONTACT- IRRIGATE SURFACES WITH WATER FOR 15 MINUTES. SKIN CONTACT- WASH AREAS WITH SOAP AND WATER. TREATMENT OF OVERDOSE: GASTRIC LAVAGE AND ACTIVATED CHARCOAL MAY BE HELPFUL; SYMPTOMATIC AND SUPPORTIVE TREATMENT AS REQUIRED. (SEE ATTACHED PRODUCT LABELING FOR A DETAILED DESCRIPTION OF THE MANAGEMENT OF QUINIDEX OVERDOSAGE)
MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:		HYPERSENSITIVITY TO ANY OF THE COMPONENTS

FOR COMPLETE INFORMATION ON THIS DRUG PLEASE REFER TO THE ATTACHED PRODUCT LABELING

. . . . . CONTINUED . . . . . .

MATERIAL SAFETY DATA SHEET (MSDS)

QUINIDEX EXTENTABS NDC 0031-6649-XX

. . . SECTION 7 PRECAUTIONS FOR SAFE HANDLING AND USE . . . . . .

SPILLS AND ACCIDENTAL RELEASES:	SWEEP OR SHOVEL INTO A WASTE CONTAINER
WASTE DISPOSAL METHOD:	DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. THIS IS A BIOLOGICALLY ACTIVE MATERIAL. DISPOSE OF ON SITE OR AT AN APPROVED DISPOSAL FACILITY IN ACCORDANCE WITH LOCAL,STATE,AND/OR FEDERAL REGULATIONS.
HANDLING AND STORAGE:	STORE AT ROOM TEMPERATURE, BETWEEN 59 AND 86 DEGREES F.

. . . SECTION 8 CONTROL MEASURES . . . . . .

NO SPECIAL CONTROL MEASURES ARE REQUIRED UNDER NORMAL CONDITIONS OF USE

RESPIRATORY PROTECTION	NONE REQUIRED
VENTILATION	NO SPECIAL VENTILATION IS REQUIRED
PROTECTIVE CLOTHING OR EQUIPMENT	AVOID CONTACT WITH EYES OR PROLONGED CONTACT WITH SKIN.
WORK/HYGIENIC PRACTICES	WASH THOROUGHLY AFTER HANDLING

. . . . . .

THE INFORMATION CONTAINED IN THIS MSDS IS, TO THE BEST OF A.H.ROBINS' KNOWLEDGE, COMPLETE AND ACCURATE. A.H.ROBINS, HOWEVER, USES MANY SOURCES AND REFERENCES FOR GATHERING THIS INFORMATION. THUS, A.H. ROBINS CANNOT GUARANTEE COMPLETENESS OR ACCURACY AND DISCLAIMS ALL LIABILITY FOR ITS HANDLING AND USE.

FILE/QUINIDEX/EXTENTAB . . . . . .

Rev. May 1987

Dimetane®-DC Cough Syrup

Description: Dimetane-DC Cough Syrup is a light bluish-pink syrup with a raspberry flavor.

Each 5 ml (1 teaspoonful) contains:

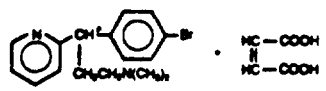
Brompheniramine Maleate, USP	2.0 mg
Phenylpropanolamine Hydrochloride, USP	12.5 mg
Codeine Phosphate, USP	10.0 mg

(Warning: May be habit forming)

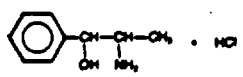
Alcohol 0.95 percent

In a palatable aromatic vehicle.

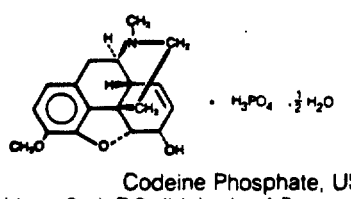
Inactive Ingredients: Citric Acid, FD&C Blue 1, FD&C Red 40, Flavors, Glycerin, Sodium Benzoate, Sorbitol, Water.



Brompheniramine Maleate, USP
2-Pyridinepropanamine, γ-(4-bromophenyl)-N,N-dimethyl-,(Z)-butenedioate (1:1).



Phenylpropanolamine Hydrochloride, USP
Benzenemethanol, α-(1-aminoethyl)-, hydrochloride, (R*S*)-, (±)



Codeine Phosphate, USP
Morphinan-6-ol, 7,8-didehydro-4,5-epoxy-3-methoxy-17-methyl-, (5α,6α)-, phosphate (1:1) (salt), hemihydrate

Antihistamine/Nasal Decongestant/Antitussive syrup for oral administration.

Clinical Pharmacology: Brompheniramine maleate is a histamine antagonist, specifically an H_1-receptor-blocking agent belonging to the alkylamine class of antihistamines. Antihistamines appear to compete with histamine for receptor sites on effector cells. Brompheniramine also has anticholinergic (drying) and sedative effects. Among the antihistaminic effects, it antagonizes the allergic response (vasodilatation, increased vascular permeability, increased mucus secretion) of nasal tissue. Brompheniramine is well absorbed from the gastrointestinal tract, with peak plasma concentration after a single oral dose of 4 mg reached in 5 hours; urinary excretion is the major route of elimination, mostly as products of biodegradation; the liver is assumed to be the main site of metabolic transformation.

Phenylpropanolamine hydrochloride is a sympathomimetic drug which is readily absorbed from the gastrointestinal tract and produces nasal vasoconstriction (decongestion). Phenylpropanolamine stimulates both α and β-adrenergic receptors, similar to ephedrine. Part of its peripheral action is indirect and is due to the displacement of norepinephrine from storage sites, but it also has direct effect on the adrenergic receptors.

Codeine is an opiate analgesic and antitussive. Codeine calms the cough control center.

Indications and Usage: For relief of coughs and upper respiratory symptoms, including nasal congestion, associated with allergy or the common cold.

Contraindications: Hypersensitivity to any of the ingredients. Do not use in the newborn, in premature infants, in nursing mothers, in patients with severe hypertension or severe coronary artery disease, or in those receiving monoamine oxidase (MAO) inhibitors.

Antihistamines should not be used to treat lower respiratory tract conditions including asthma.

Warnings: Especially in infants and small children, antihistamines in overdosage may cause hallucinations, convulsions, death. Codeine may cause or aggravate constipation.

Antihistamines may diminish mental alertness. In the young child, they may produce excitation.

Precautions: *General:* Because of its antihistamine component, Dimetane-DC Cough Syrup should be used with caution in patients with a history of bronchial asthma, narrow angle glaucoma, gastrointestinal obstruction, or urinary bladder neck obstruction. Because of its sympathomimetic component, Dimetane-DC Cough Syrup should be used with caution in patients with diabetes, hypertension, heart disease, or thyroid disease.

Information for Patients: Patients should be warned about engaging in activities requiring mental alertness, such as driving a car or operating dangerous machinery.

Drug Interactions: Antihistamines have additive effects with alcohol and other CNS depressants (hypnotics, sedatives, tranquilizers, antianxiety agents, etc.). MAO inhibitors prolong and intensify the anticholinergic (drying) effects of antihistamines. MAO inhibitors may enhance the effect of phenylpropanolamine. Sympathomimetics may reduce the effects of antihypertensive drugs.

Carcinogenesis, Mutagenesis: Long-term studies in animals to evaluate carcinogenic and mutagenic potential have not been performed.

Pregnancy Category C: Animal reproduction studies have not been conducted with Dimetane-DC Cough Syrup. It is also not known whether Dimetane-DC Cough Syrup can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Dimetane-DC Cough Syrup should be given to a pregnant woman only if clearly needed.

Reproduction studies of brompheniramine maleate (one of the components of the Dimetane formulations) in rats and mice at doses up to 16 times the maximum human dose have revealed no evidence of impaired fertility or harm to the fetus.

Nursing Mothers: Because of the higher risk of intolerance of antihistamines in small infants generally, and in newborns and premature in particular, and the fact that codeine appears in human milk, Dimetane-DC Cough Syrup is contraindicated in nursing mothers.

Adverse Reactions: The most frequent adverse reactions to Dimetane-DC Cough Syrup are: sedation; dryness of mouth, nose and throat; thickening of bronchial secretions; dizziness. Other adverse reactions may include:

Dermatologic: Urticaria, drug rash, photosensitivity, pruritus.

Cardiovascular System: Hypotension, hypertension, cardiac arrhythmias

CNS: Disturbed coordination, tremor, irritability, insomnia, visual disturbances, weakness, nervousness, convulsions, headache, euphoria, and dysphoria.

G. U. System: Urinary frequency, difficult urination.

G. I. System: Epigastric discomfort, anorexia, nausea, vomiting, diarrhea, constipation.

Respiratory System: Tightness of chest and wheezing, shortness of breath. At higher doses, codeine has most of the disadvantages of morphine including respiratory depression.

Hematologic System: Hemolytic anemia, thrombocytopenia, agranulocytosis.

Drug Abuse and Dependence: Codeine can produce drug dependence of the morphine type, and therefore has the potential for being abused. Psychic dependence, physical dependence and tolerance may develop upon repeated administration of this drug, and it should be prescribed and administered with the same degree of caution appropriate to the use of other oral narcotic medications.

Dimetane-DC Cough Syrup is subject to the Federal Controlled Substances Act (Schedule V).

Overdosage: *Signs and Symptoms:* Serious overdose with codeine is characterized by respiratory depression, extreme somnolence progressing to stupor or coma. In severe overdosage, apnea, circulatory collapse, cardiac arrest and death may occur. The central nervous system effects from overdosage of brompheniramine may vary from depression to stimulation. Anticholinergic effects may also occur. Overdosage of phenylpropanolamine may be associated with tachycardia, hypertension, and cardiac arrhythmias.

Toxic Doses: Doses of 800 mg or more of codeine have caused partial loss of consciousness, delirium, restlessness, excitement, tremors, convulsions and collapse; or respiratory paralysis with such sequelae as mydriasis, marked vasodilatation, and finally death. A 2½-year-old child survived a dose of 300–900 mg of brompheniramine; the lethal dose of phenylpropanolamine is in the range of 50 mg/kg.

Treatment: Respiratory depression should be treated promptly. Oxygen, intravenous fluids, vasopressors and other supportive measures should be employed as indicated. If necessary, reestablishment of adequate respiratory exchange through provision of a patent airway and the institution of assisted or controlled ventilation must be provided. The narcotic antagonist, naloxone, is a specific antidote to codeine-induced respiratory depression, and should be administered by the intravenous route if appropriate

(see package insert for naloxone). Since the duration of action of codeine may exceed that of the antagonist, the patient should be kept under constant surveillance.

Gastric emptying may be useful in removing unabsorbed drug, either by inducing emesis or lavage; precautions against aspiration must be taken. Stimulants or depressants should be used cautiously and only when specifically indicated. If marked excitement is present, one of the short-acting barbiturates or chloral hydrate may be used.

Dosage and Administration: Adults and children 12 years of age and over: 2 teaspoonfuls every 4 hours. Children 6 to under 12 years: 1 teaspoonful every 4 hours. Children 2 to under 6 years: ½ teaspoonful every 4 hours. Children 6 months to under 2 years: Dosage to be established by physician.

Do not exceed 6 doses during a 24-hour period.

How Supplied: Dimetane-DC Cough Syrup is a light bluish-pink syrup containing in each 5 ml (1 teaspoonful): brompheniramine maleate 2 mg, phenylpropanolamine HCl 12.5 mg, and codeine phosphate 10 mg; available in pints (NDC 0031-1833-25) and gallons (NDC 0031-1833-29).

Store at controlled room temperature, between 15°C and 30°C (59°F and 86°F).

Dispense in tight, light-resistant container.

Rev. May 1987

Rev. May 1987

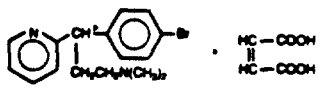
Dimetane®-DX Cough Syrup

Description: Dimetane-DX Cough Syrup is a light-red syrup with a butterscotch flavor. Each 5 mL (1 teaspoonful) contains:

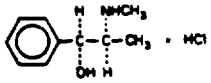
Brompheniramine Maleate, USP	2 mg
Pseudoephedrine Hydrochloride, USP	30 mg
Dextromethorphan Hydrobromide, USP	10 mg
Alcohol 0.95 percent	

In a palatable, aromatic vehicle.

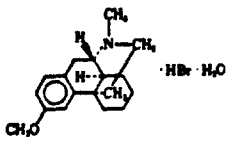
Inactive Ingredients: Citric Acid, FD&C Red 40, FD&C Yellow 6, Flavors, Glycerin, Saccharin Sodium, Sodium Benzoate, Sorbitol, Water.



Brompheniramine Maleate, USP
2-Pyridinepropanamine, γ-(4-bromophenyl)-N,N-dimethyl-,(Z)-butenedioate (1:1).



Pseudoephedrine Hydrochloride, USP
Benzenemethanol, α-[1-(methylamino)ethyl]-, [S-(R*,R*)-, hydrochloride.



Dextromethorphan Hydrobromide, USP
Morphinan, 3-methoxy-17-methyl-,(9α, 13α, 14α)-, hydrobromide, monohydrate.

Antihistamine/Nasal Decongestant/Antitussive syrup for oral administration.

Clinical Pharmacology: Brompheniramine maleate is a histamine antagonist, specifically an H_1-receptor-blocking agent belonging to the alkylamine class of antihistamines. Antihistamines appear to compete with histamine for receptor sites on effector cells. Brompheniramine also has anticholinergic (drying) and sedative effects. Among the antihistaminic effects, it antagonizes the allergic response (vasodilatation, increased vascular permeability, increased mucus secretion) of nasal tissue. Brompheniramine is well absorbed from the gastrointestinal tract, with peak plasma concentration after single, oral dose of 4 mg reached in 5 hours; urinary excretion is the major route of elimination, mostly as products of biodegradation; the liver is assumed to be the main site of metabolic transformation.

Pseudoephedrine acts on sympathetic nerve endings and also on smooth muscle, making it useful as a nasal decongestant. The nasal decongestant effect is mediated by the action of pseudoephedrine on α-sympathetic receptors, producing vasoconstriction of the dilated nasal arterioles. Following oral administration, effects are noted within 30 minutes with peak activity occurring at approximately one hour.

Dextromethorphan acts centrally to elevate the threshold for coughing. It has no analgesic or addictive properties. The onset of antitussive action occurs in 15 to 30 minutes after administration and is of long duration.

Indications and Usage: For relief of coughs and upper respiratory symptoms, including nasal congestion, associated with allergy or the common cold.

Contraindications: Hypersensitivity to any of the ingredients. Do not use in the newborn, in premature infants, in nursing mothers, in patients with severe hypertension or severe coronary artery disease, or in those receiving monoamine oxidase (MAO) inhibitors.

Antihistamines should not be used to treat lower respiratory tract conditions including asthma.

Warnings: Especially in infants and small children, antihistamines in overdosage may cause hallucinations, convulsions, and death.

Antihistamines may diminish mental alertness. In the young child, they may produce excitation.

Precautions: ***General:*** Because of its antihistamine component, Dimetane-DX Cough Syrup should be used with caution in patients with a history of bronchial asthma, narrow angle glaucoma, gastrointestinal obstruction, or urinary bladder neck obstruction. Because of its sympathomimetic component, Dimetane-DX Cough Syrup should be used with caution in patients with diabetes, hypertension, heart disease, or thyroid disease.

Information for Patients: Patients should be warned about engaging in activities requiring mental alertness, such as driving a car or operating dangerous machinery.

Drug Interactions: Antihistamines have additive effects with alcohol and other CNS depressants (hypnotics, sedatives, tranquilizers, antianxiety agents, etc.). MAO inhibitors prolong and intensify the anticholinergic (drying) effects of antihistamines. MAO inhibitors may enhance the effect of pseudoephedrine. Sympathomimetics may reduce the effects of antihypertensive drugs.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Animal studies of Dimetane-DX Cough Syrup to assess the carcinogenic and mutagenic potential or the effect on fertility have not been performed.

Pregnancy

Teratogenic Effects–Pregnancy Category C

Animal reproduction studies have not been conducted with Dimetane-DX Cough Syrup. It is also not known whether Dimetane-DX Cough Syrup can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Dimetane-DX Cough Syrup should be given to a pregnant woman only if clearly needed.

Reproduction studies of brompheniramine maleate (a component of Dimetane-DX Cough Syrup) in rats and mice at doses up to 16 times the maximum human dose have revealed no evidence of impaired fertility or harm to the fetus.

Nursing Mothers: Because of the higher risk of intolerance of antihistamines in small infants generally, and in newborns and premature in particular, Dimetane-DX Cough Syrup is contraindicated in nursing mothers.

Adverse Reactions: The most frequent adverse reactions to Dimetane-DX Cough Syrup are: sedation; dryness of mouth, nose and throat; thickening of bronchial secretions; dizziness. Other adverse reactions may include:

Dermatologic: Urticaria, drug rash, photosensitivity, pruritus.

Cardiovascular System: Hypotension, hypertension, cardiac arrhythmias, palpitation.

CNS: Disturbed coordination, tremor, irritability, insomnia, visual disturbances, weakness, nervousness, convulsions, headache, euphoria, and dysphoria.

G. U. System: Urinary frequency, difficult urination.

G. I. System: Epigastric discomfort, anorexia, nausea, vomiting, diarrhea, constipation.

Respiratory System: Tightness of chest and wheezing, shortness of breath.

Hematologic System: Hemolytic anemia, thrombocytopenia, agranulocytosis.

Overdosage: ***Signs and Symptoms:*** Central nervous system effects from overdosage of brompheniramine may vary from depression to stimulation, especially in children. Anticholinergic effects may be noted. Toxic doses of pseudoephedrine may result in CNS stimulation, tachycardia, hypertension, and cardiac arrhythmias; signs of CNS depression may occasionally be seen. Dextromethorphan in toxic doses will cause drowsiness, ataxia, nystagmus, opisthotonos, and convulsive seizures.

Toxic Doses: Data suggest that individuals may respond in an unexpected manner to apparently small amounts of a particular

drug. A 2½-year-old child survived the ingestion of 21 mg/kg of dextromethorphan exhibiting only ataxia, drowsiness, and fever, but seizures have been reported in 2 children following the ingestion of 13–17 mg/kg. Another 2½-year-old child survived a dose of 300–900 mg of brompheniramine. The toxic dose of pseudoephedrine should be less than that of ephedrine, which is estimated to be 50 mg/kg.

Treatment: Induce emesis if patient is alert and is seen prior to 6 hours following ingestion. Precautions against aspiration must be taken, especially in infants and small children. Gastric lavage may be carried out, although in some instances tracheostomy may be necessary prior to lavage. Naloxone hydrochloride 0.005 mg/kg intravenously may be of value in reversing the CNS depression that may occur from an overdose of dextromethorphan. CNS stimulants may counter CNS depression. Should CNS hyperactivity or convulsive seizures occur, intravenous short-acting barbiturates may be indicated. Hypertensive responses and/or tachycardia should be treated appropriately. Oxygen, intravenous fluids, and other supportive measures should be employed as indicated.

Dosage and Administration: Adults and children 12 years of age and over: 2 teaspoonfuls every 4 hours. Children 6 to under 12 years: 1 teaspoonful every 4 hours. Children 2 to under 6 years: ½ teaspoonful every 4 hours. Children 6 months to under 2 years: Dosage to be established by physician.

Do not exceed 6 doses during a 24-hour period.

How Supplied: Dimetane-DX Cough Syrup is a light-red syrup containing in each 5 mL (1 teaspoonful) brompheniramine maleate 2 mg, pseudoephedrine hydrochloride 30 mg and dextromethorphan hydrobromide 10 mg, available in pints (NDC 0031-1836-25) and gallons (NDC 0031-1836-29).

Store at controlled room temperature, between 15°C and 30°C (59°F and 86°F).

Dispense in tight, light-resistant container.

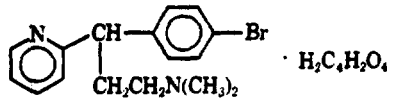
Rev. May 1987

Rev. April 1983
ANTIHISTAMINE

Dimetane®-Ten Injectable

brand of
Brompheniramine Maleate Injection, USP

Description: Dimetane®-Ten Injectable is a clear, colorless, odorless liquid intended for intravenous, intramuscular, or subcutaneous injection.
Each 1 ml contains:
Brompheniramine Maleate, USP ..... 10 mg
Water for Injection, USP ..... q.s.
pH adjusted to 6.8–7.0
with sodium hydroxide
Dimetane (brompheniramine maleate) is an antihistamine with the following structural formula:



γ-(4-bromophenyl)-(N,N-dimethyl-2-pyridinepropanamine (Z)-butenedioate(1:1)

Clinical Pharmacology: Brompheniramine is a histamine antagonist, specifically an H_1-receptor blocking agent belonging to the alkylamine class of antihistamines. Antihistamines appear to compete with histamine for receptor sites on effector cells antagonizing the allergic response which consists of vasodilatation, increased vascular permeability, and increased mucus secretion. Brompheniramine also has anticholinergic (drying) and sedative effects. Brompheniramine is well absorbed from the gastrointestinal tract, with peak plasma concentration reached in 5 hours after a single oral dose of 4 mg, and having an excretory half-life on the order of 24 hours. Urinary excretion is the major route of elimination; most as products of bio-degradation. The liver is assumed to be the main site of metabolic transformation.
Indications and Usage: For use in the following conditions when administration of the oral form of the drug is impractical: Amelioration of allergic reactions to blood or plasma.

In anaphylaxis as an adjunct to epinephrine and other standard measures after the acute symptoms have been controlled.

For other uncomplicated allergic conditions of the immediate type when oral therapy is impossible or contraindicated.
Contraindications: Do not use in the newborn or premature infants; in patients known to be hypersensitive to brompheniramine maleate; or in patients receiving monoamine oxidase inhibitor therapy.

Antihistamines should not be used to treat lower respiratory tract conditions including acute bronchial asthma.
Warnings: In the young child, antihistamines may produce excitation. In the elderly (approximately 60 years or older), antihistamines are more likely to cause dizziness, sedation, and hypotension.
Precautions: *General:* Because Dimetane-Ten Injectable is an antihistamine, it should be administered with caution to patients with a history of bronchial asthma, narrow angle glaucoma, gastrointestinal obstruction, or prostatic hypertrophy.

Information for Patients: Patients should be warned about engaging in activities requiring mental alertness, such as driving a car or operating dangerous machinery until the extent of individual tolerance has been established.

Drug Interactions: Antihistamines have an additive effect with alcohol and other CNS depressants (hypnotics, sedatives, tranquilizers, antianxiety agents, etc.). MAO inhibitors prolong and intensify the anticholinergic (drying) effects of antihistamines.

Carcinogenesis, mutagenesis: Long-term studies in animals to evaluate carcinogenic or mutagenic potential have not been performed.

Pregnancy: Pregnancy Category B. Reproduction studies have been performed in rats and mice at doses up to 16 times the maximum human dose and have revealed no evidence of impaired fertility or harm to the fetus due to brompheniramine maleate. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Dimetane-Ten Injectable is administered to a nursing mother.

Pediatric use: Dimetane-Ten Injectable should not be used in newborn or premature infants. In infants and children, especially, antihistamines in overdosage may cause hallucinations, convulsions, or death.
Adverse Reactions: The most frequent adverse reactions are italicized:

General: Urticaria, drug rash, anaphylactic shock, photosensitivity, excessive perspiration, chills, dryness of mouth, nose, and throat.

Cardiovascular system: Hypotension, headache, palpitations, tachycardia, extrasystoles.

Hematologic system: Hemolytic anemia, thrombocytopenia, agranulocytosis.

Nervous system: Sedation, sleepiness, dizziness, disturbed coordination, fatigue, confusion, restlessness, excitation, nervousness, tremor, irritability, insomnia, euphoria, paresthesias, blurred vision, diplopia, vertigo, tinnitus, acute labyrinthitis, hysteria, neuritis, convulsions.

G. I. system: Epigastric distress, anorexia, nausea, vomiting, diarrhea, constipation.

G. U. system: Urinary frequency, difficult urination, urinary retention, early menses.

Respiratory System: Thickening of bronchial secretions, tightness of chest and wheezing, nasal stuffiness.
Overdosage: *Signs and symptoms:* Central nervous system depression is usually the dominant action in adults; it is evidenced by drowsiness, lethargy, fatigue, hypnosis, and coma. Related symptoms include vertigo, ataxia, tinnitus, and blurred vision.

Central nervous hyperexcitability often follows initial sedation; in children excitement is often the first evidence of overdosage. The stimulant phase may include tremors, anxiety, insomnia, excitement, hallucinations, delirium, toxic psychosis, and convulsions. Hyperpyrexia may occur in children.

The terminal phase is one of severe central nervous depression with death from respiratory arrest or cardiovascular collapse.

LD_{50}

Species	Route	LD_{50} mg/kg	Range mg/kg
Rat	PO	372	324-428
Rat	PO	207	179-239
Mice	IP	110	100-121
Mice	PO	195	167-228
Dogs	IV	97	85-126

Toxic dosage in humans: There are no absolute figures relative to the toxic dosage of brompheniramine in humans. There have been no reports of Dimetane overdosage in adults.

Removal: There is no information regarding the usefulness of forced diuresis or dialysis in the management of overdosage. Brompheniramine is 80-85% bound to protein in plasma and tissues.

Treatment: There is no specific therapy or known antidote, and treatment is along general symptomatic and supportive lines. Mechanical ventilation and oxygen therapy may be used if indicated. Care should be taken to avoid or carefully control medications which are likely to potentiate the effects of the antihistamine. If convulsions develop, they are best countered by a short-acting depressant such as thiopental, to provide a rapid, transient, and controllable effect. Diazepam is also worthy of a trial. Stimulants should not be used. Vasopressors may be used to treat hypotension.

In view of the anticholinergic manifestation of antihistamines, especially in overdosage, physostigmine may be useful in reversing such symptoms as severe agitation, delirium, and tachycardia.
Dosage and Administration: DOSAGE SHOULD BE INDIVIDUALIZED ACCORDING TO THE NEEDS AND THE RESPONSE OF THE PATIENTS.

Adults: The usual dose is 10 mg. The dosage range is 5 mg to 20 mg. The period of protection is 3 to 12 hours, and twice daily administration is usually all that is necessary. The maximum recommended dose for 24 hours is 40 mg.

Children under 12 years: 0.5 mg per kg per 24 hours, or 15 mg per M^2 per 24 hours, divided into 3–4 doses.

NOTE: Dimetane-Ten Injectable may be administered without further dilution intramuscularly or subcutaneously. It may also be administered intravenously either undiluted or diluted 1 to 10 with sterile saline for injection. If given intravenously, the drug should be given slowly, preferably with the patient in a recumbent position. If desired,

(Dimetane-Ten, continued)

Dimetane-Ten Injectable may be added to normal saline or 5% glucose or whole blood for intravenous administration.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

How Supplied: Dimetane-Ten Injectable is supplied in 1 ml ampuls, in cartons of 25 (NDC 0031-1881-11), each ampul containing 10 mg brompheniramine maleate.

Caution: To protect from light, Dimetane-Ten Injectable should be stored in carton until used.

Store at controlled room temperature, between 15°C and 30°C (50°F and 86°F).

Cooling below 32°F may produce brompheniramine crystals; if present, dissolve by warming to 85°F before using.

Rev. April 1983

Rev. Feb. 1987
ANTIDIARRHEAL

Donnagel®-PG

Donnagel-PG
Description:
Each fluid ounce (2 tablespoonfuls) contains: Powdered Opium, USP or equivalent 24.0 mg (Warning: May be habit forming), Kaolin, USP 6.0 g, Pectin, USP 142.8 mg, Hyoscyamine Sulfate, USP 0.1037 mg, Atropine Sulfate, USP 0.0194 mg, Scopolamine Hydrobromide, USP 0.0065 mg, Sodium Benzoate, NF 60.0 mg (preservative), Alcohol 5.0 percent.

Inactive Ingredients: Citric Acid, D&C Yellow 10, Flavors, High Fructose Corn Syrup, Sodium Carboxymethylcellulose, Sodium Chloride, Water.

Donnagel-PG combines the effects of kaolin, pectin and the natural belladonna alkaloids with the efficacy of powdered opium (or equivalent). The opium content in 1 fluid ounce of Donnagel-PG is equivalent to 5 mL of paregoric.

Actions: Donnagel-PG contains a paregoric equivalent for more complete symptomatic control of acute, non-specific diarrheas. This combination of drugs affords a more complete approach for stopping diarrhea and relieving tenesmus and pain. The belladonna alkaloids partly antagonize the occasional cramping effect of opium upon the colon.

Indications: Donnagel-PG is indicated for the treatment of diarrhea.

Contraindications: Glaucoma, advanced renal or hepatic disease or hypersensitivity to any of the ingredients.

Cautions: As with all preparations containing belladonna alkaloids, Donnagel-PG must be administered cautiously to patients with incipient glaucoma or urinary bladder neck obstruction as in prostatic hypertrophy. Caution should be exercised when prescribing this or any other medication for pregnant or nursing patients.

Warnings to Patient: Diarrhea may be serious. Do not use for more than two days or in the presence of high fever unless prescribed by a physician. Not to be used by persons having glaucoma or excessive pressure within the eye, by elderly persons (where undiagnosed glaucoma or excessive pressure within the eye occurs most frequently), or by children under 6 years of age, unless directed by a physician. Discontinue use if blurring of vision, rapid pulse, or dizziness occurs. Do not exceed recommended dosage. Not for frequent or prolonged use. If dryness of the mouth occurs, decrease dosage. If eye pain occurs, discontinue use and see your physician immediately as this may indicate undiagnosed glaucoma.

Adverse Reactions: Blurred vision, dry mouth; difficult urination or flushing and dryness of the skin may occur at higher dosage levels, rarely at the usual dose.

Dosage and Administration: ***Adults and children 12 years of age and over:*** two tablespoonfuls (one fl. oz.) initially, followed by 1 tablespoonful every 3 hours.

Children 6 to under 12 years: two teaspoonfuls initially and 1 or 2 teaspoonfuls every 3 hours thereafter.

Pediatric Dosage Recommendations (For Physician Use Only):

Body Weight	Initial Dosage
10 lb.	½ teaspoonful (2.5 mL)
20 lb.	1 teaspoonful (5 mL)
30 lb. and over	1–2 teaspoonfuls (5–10 mL)

Do not administer more than 4 doses in any 24-hour period.

How Supplied: Donnagel-PG (light yellow, banana-flavored suspension) in 6 fl. oz. (NDC 0031-3083-15) and pint (NDC 0031-3083-25).

Rev. Feb. 1987

Rev. October 1985

Donnatal®

Description: Each Donnatal tablet, capsule or 5 mL (teaspoonful) of elixir (23% alcohol) contains:

Phenobarbital, USP (¼ gr) ..... (Warning: May be habit forming)	16.2 mg
Hyoscyamine Sulfate, USP	0.1037 mg
Atropine Sulfate, USP	0.0194 mg
Scopolamine Hydrobromide, USP	0.0065 mg

Inactive Ingredients:

TABLETS: Dibasic Calcium Phosphate, Magnesium Stearate, Microcrystalline Cellulose, Silicon Dioxide, Sodium Starch Glycolate, Stearic Acid, Sucrose. May contain Corn Starch, Dextrose, or Invert Sugar.

CAPSULES: Corn Starch, Edible Ink, D&C Yellow 10 and FD&C Green 3 or FD&C Blue 1 and FD&C Yellow 6, FD&C Blue 2 Aluminum Lake, Gelatin, Lactose, Sucrose. May contain FD&C Red 40 and Yellow 6 Aluminum Lakes.

ELIXIR: D&C Yellow 10, FD&C Blue 1, FD&C Yellow 6, Flavors, Glucose, Saccharin Sodium, Water.

Actions: This drug combination provides natural belladonna alkaloids in a specific, fixed ratio combined with phenobarbital to provide peripheral anticholinergic/antispasmodic action and mild sedation.

INDICATIONS

Based on a review of this drug by the National Academy of Sciences—National Research Council and/or other information, FDA has classified the following indications as "possibly" effective:

For use as adjunctive therapy in the treatment of irritable bowel syndrome (irritable colon, spastic colon, mucous colitis) and acute enterocolitis.

May also be useful as adjunctive therapy in the treatment of duodenal ulcer. IT HAS NOT BEEN SHOWN CONCLUSIVELY WHETHER ANTICHOLINERGIC/ANTISPASMODIC DRUGS AID IN THE HEALING OF A DUODENAL ULCER, DECREASE THE RATE OF RECURRENCES OR PREVENT COMPLICATIONS.

Contraindications: Glaucoma, obstructive uropathy (for example, bladder neck obstruction due to prostatic hypertrophy); obstructive disease of the gastrointestinal tract (as in achalasia, pyloroduodenal stenosis, etc.); paralytic ileus, intestinal atony of the elderly or debilitated patient; unstable cardiovascular status in acute hemorrhage; severe ulcerative colitis especially if complicated by toxic megacolon; myasthenia gravis; hiatal hernia associated with reflux esophagitis.

Donnatal is contraindicated in patients with known hypersensitivity to any of the ingredients. Phenobarbital is contraindicated in acute intermittent porphyria and in those patients in whom phenobarbital produces restlessness and/or excitement.

Warnings: In the presence of a high environmental temperature, heat prostration can occur with belladonna alkaloids (fever and heatstroke due to decreased sweating).

Diarrhea may be an early symptom of incomplete intestinal obstruction, especially in patients with ileostomy or colostomy. In this instance treatment with this drug would be inappropriate and possibly harmful.

Donnatal may produce drowsiness or blurred vision. The patient should be warned, should these occur, not to engage in activities requiring mental alertness, such as operating a motor vehicle or other machinery, and not to perform hazardous work.

Phenobarbital may decrease the effect of anticoagulants and necessitate larger doses of the anticoagulant for optimal effect. When the phenobarbital is discontinued, the dose of the anticoagulant may have to be decreased.

Phenobarbital may be habit forming and should not be administered to individuals known to be addiction prone or to those with a history of physical and/or psychological dependence upon drugs.

Since barbiturates are metabolized in the liver, they should be used with caution and initial doses should be small in patients with hepatic dysfunction.

Precautions: Use with caution in patients with: autonomic neuropathy, hepatic or renal disease, hyperthyroidism, coronary heart disease, congestive heart failure, cardiac arrhythmias, tachycardia, and hypertension.

Belladonna alkaloids may produce a delay in gastric emptying (antral stasis) which would complicate the management of gastric ulcer.

Theoretically, with overdosage, a curare-like action may occur.

Carcinogenesis, mutagenesis. Long-term studies in animals have not been performed to evaluate carcinogenic potential.

Pregnancy Category C. Animal reproduction studies have not been conducted with Donnatal. It is not known whether Donnatal can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Donnatal should be given to a pregnant woman only if clearly needed.

Nursing mothers. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Donnatal is administered to a nursing mother.

Adverse Reactions: Adverse reactions may include xerostomia; urinary hesitancy and retention; blurred vision; tachycardia; palpitation; mydriasis; cycloplegia; increased ocular tension; loss of taste sense; headache; nervousness; drowsiness; weakness; dizziness; insomnia; nausea; vomiting; impotence; suppression of lactation; constipation; bloated feeling; musculoskeletal pain; severe allergic reaction or drug idiosyncrasies, including anaphylaxis, urticaria and other dermal manifestations; and decreased sweating. Elderly patients may react with symptoms of excitement, agitation, drowsiness, and other untoward manifestations to even small doses of the drug.

Phenobarbital may produce excitement in some patients, rather than a sedative effect. In patients habituated to barbiturates, abrupt withdrawal may produce delirium or convulsions.

Dosage and Administration: The dosage of Donnatal should be adjusted to the needs of the individual patient to assure symptomatic control with a minimum of adverse effects.

Donnatal Tablets or Capsules. Adults: One or two Donnatal tablets or capsules three or four times a day according to condition and severity of symptoms.

Donnatal Elixir. Adults: One or two teaspoonfuls of elixir three or four times a day according to conditions and severity of symptoms.

Children (Elixir)—may be dosed every 4 or 6 hours:

Body Weight	Starting Dosage q4h	Starting Dosage q6h
10 lb (4.5 kg)	0.5 mL	0.75 mL
20 lb (9.1 kg)	1.0 mL	1.5 mL
30 lb (13.6 kg)	1.5 mL	2.0 mL
50 lb (22.7 kg)	½ tsp	¾ tsp
75 lb (34.0 kg)	¾ tsp	1 tsp
100 lb (45.4 kg)	1 tsp	1½ tsp

Overdosage: The signs and symptoms of overdose are headache, nausea, vomiting, blurred vision, dilated pupils, hot and dry skin, dizziness, dryness of mouth, difficulty in swallowing, CNS stimulation. Treatment should consist of gastric lavage, emetics, and activated charcoal. If indicated, parenteral cholinergic agents such as physostigmine or bethanechol chloride should be added.

How Supplied: *Donnatal Tablets.* White, compressed, scored and embossed "R"; in bottles of 100 (NDC 0031-4250-63), 1000 (NDC 0031-4250-74) and Dis-Co® Unit Dose Packs of 100 (NDC 0031-4250-64).

Donnatal Capsules. Green and white, monogrammed "AHR" and "4207"; in bottles of 100 (NDC 0031-4207-63) and 1000 (NDC 0031-4207-74).

Donnatal Elixir. Green, citrus flavored, in 4 fl. oz., (NDC 0031-4221-12), pints (NDC 0031-4221-25), gallons (NDC 0031-4221-29) and 5 mL Dis-Co® Unit Dose Packs (4 x 25s) (NDC 0031-4221-13).

Store at controlled room temperature, between 15°C and 30°C (59°F and 86°F).

Dispense in tight, light-resistant container.

Rev. October 1985

Rev. Feb. 1985

Donnatal® No. 2

Description: Each Donnatal No. 2 Tablet contains:

Phenobarbital, USP (½ gr) ..... 32.4 mg
(Warning: May be habit forming)
Hyoscyamine Sulfate, USP ..... 0.1037 mg
Atropine Sulfate, USP ..... 0.0194 mg
Scopolamine Hydrobromide, USP ..... 0.0065 mg

Inactive Ingredients: Calcium Stearate, Corn Starch, D&C Yellow 10, FD&C Blue 1, FD&C Yellow 6, Lactose, Sucrose.

Actions: This drug combination provides natural belladonna alkaloids in a specific, fixed ratio combined with phenobarbital to provide peripheral anticholinergic/antispasmodic action and mild sedation.

INDICATIONS

Based on a review of this drug by the National Academy of Sciences—National Research Council and/or other information, FDA has classified the following indications as "possibly" effective:

For use as adjunctive therapy in the treatment of irritable bowel syndrome (irritable colon, spastic colon, mucous colitis) and acute enterocolitis.

May also be useful as adjunctive therapy in the treatment of duodenal ulcer. IT HAS NOT BEEN SHOWN CONCLUSIVELY WHETHER ANTICHOLINERGIC/ANTISPASMODIC DRUGS AID IN THE HEALING OF A DUODENAL ULCER, DECREASE THE RATE OF RECURRENCES OR PREVENT COMPLICATIONS.

Contraindications: Glaucoma, obstructive uropathy (for example, bladder neck obstruction due to prostatic hypertrophy); obstructive disease of the gastrointestinal tract (as in achalasia, pyloroduodenal stenosis, etc.); paralytic ileus, intestinal atony of the elderly or debilitated patient; unstable cardiovascular status in acute hemorrhage; severe ulcerative colitis especially if complicated by toxic megacolon; myasthenia gravis; hiatal hernia associated with reflux esophagitis.

Donnatal No. 2 is contraindicated in patients with known hypersensitivity to any of the ingredients. Phenobarbital is contraindicated in acute intermittent porphyria and in those patients in whom phenobarbital produces restlessness and/or excitement.

Warnings: The use of Donnatal No. 2 in pregnancy, lactation, or in women of childbearing age, should be limited to those patients for whom the physician expects the benefits to outweigh the potential hazards to the mother and child.

In the presence of a high environmental temperature, heat prostration can occur with belladonna alkaloids (fever and heatstroke due to decreased sweating).

Diarrhea may be an early symptom of incomplete intestinal obstruction, especially in patients with ileostomy or colostomy. In this instance treatment with this drug would be inappropriate and possibly harmful.

Donnatal No. 2 may produce drowsiness or blurred vision. The patient should be warned, should these occur, not to engage in activities requiring mental alertness, such as operating a motor vehicle or other machinery, and not to perform hazardous work.

Phenobarbital may decrease the effect of anticoagulants and necessitate larger doses of the anticoagulant for optimal effect. When the phenobarbital is discontinued, the dose of the anticoagulant may have to be decreased.

Phenobarbital may be habit forming and should not be administered to individuals known to be addiction prone or to those with a history of physical and/or psychological dependence upon drugs.

Since barbiturates are metabolized in the liver, they should be used with caution and initial doses should be small in patients with hepatic dysfunction.

Precautions: Use with caution in patients with: autonomic neuropathy, hepatic or renal disease, hyperthyroidism, coronary heart disease, congestive heart failure, cardiac arrhythmias, tachycardia, and hypertension.

Belladonna alkaloids may produce a delay in gastric emptying (antral stasis) which would complicate the management of gastric ulcer.

Theoretically, with overdosage, a curare-like action may occur.

Carcinogenesis, mutagenesis. Long-term studies in animals have not been performed to evaluate carcinogenic potential.

Pregnancy Category C. Animal reproduction studies have not been conducted with Donnatal No. 2. It is not known whether Donnatal No. 2 can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Donnatal No. 2 should be given to a pregnant woman only if clearly needed.

Nursing mothers. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Donnatal No. 2 is administered to a nursing mother.

Adverse Reactions: Adverse reactions may include xerostomia; urinary hesitancy and retention; blurred vision; tachycardia; palpitation; mydriasis; cycloplegia; increased ocular tension; loss of taste sense; headache; nervousness; drowsiness; weakness; dizziness; insomnia; nausea; vomiting; impotence; suppression of lactation; constipation; bloated feeling; musculoskeletal pain; severe allergic reaction or drug idiosyncrasies, including anaphylaxis, urticaria and other dermal manifestations; and decreased sweating. Elderly patients may react with symptoms of excitement, agitation, drowsiness, and other untoward manifestations to even small doses of the drug.

Phenobarbital may produce excitement in some patients, rather than a sedative effect. In patients habituated to barbiturates, abrupt withdrawal may produce delirium or convulsions.

Dosage and Administration: The dosage of Donnatal No. 2 should be adjusted to the needs of the individual patient to assure symptomatic control with a minimum of adverse effects.

Adults: One or two tablets three times a day according to condition and severity of symptoms.

Overdosage: The signs and symptoms of overdose are headache, nausea, vomiting, blurred vision, dilated pupils, hot and dry skin, dizziness, dryness of mouth, difficulty in swallowing, CNS stimulation. Treatment should consist of gastric lavage, emetics, and activated charcoal. If indicated, parenteral cholinergic agents such as physostigmine or bethanechol chloride should be added.

How Supplied: Pale green, compressed, scored and embossed "R", in bottles of 100 (NDC 0031-4264-63), and 1000 (NDC 0031-4264-74).

Store at controlled room temperature, between 15°C and 30°C (59°F and 86°F).

Dispense in tight, light-resistant container.

Rev. February 1985

Rev. February 1985

Donnatal Extentabs®

Description: Each Donnatal Extentabs tablet contains:

Phenobarbital, USP (¾ gr)....	48.6 mg
(Warning: May be habit forming)	
Hyoscyamine Sulfate, USP....	0.3111 mg
Atropine Sulfate, USP.....	0.0582 mg
Scopolamine Hydrobromide, USP.....	0.0195 mg

Each Donnatal Extentabs tablet contains the equivalent of three Donnatal tablets. Extentabs are designed to release the ingredients gradually to provide effects for up to twelve (12) hours.

Inactive Ingredients: Acacia, Acetylated Monoglycerides, Calcium Sulfate, Carnauba Wax, D&C Yellow 10, Edible Ink, FD&C Blue 1, FD&C Blue 2 Aluminum Lake, FD&C Yellow 6, Gelatin, Guar Gum, Magnesium Stearate, Polysorbates, Shellac, Sodium Phosphate, Sucrose, Titanium Dioxide, Wheat Flour, White Wax and other ingredients, one of which is a corn derivative. May include FD&C Red 40 and Yellow 6 Aluminum Lakes.

Actions: This drug combination provides natural belladonna alkaloids in a specific, fixed ratio combined with phenobarbital to provide peripheral anticholinergic/antispasmodic action and mild sedation.

INDICATIONS

Based on a review of this drug by the National Academy of Sciences—National Research Council and/or other information, FDA has classified the following indications as "possibly" effective:

For use as adjunctive therapy in the treatment of irritable bowel syndrome (irritable colon, spastic colon, mucous colitis) and acute enterocolitis.

May also be useful as adjunctive therapy in the treatment of duodenal ulcer. IT HAS NOT BEEN SHOWN CONCLUSIVELY WHETHER ANTICHOLINERGIC / ANTISPASMODIC DRUGS AID IN THE HEALING OF A DUODENAL ULCER, DECREASE THE RATE OF RECURRENCES OR PREVENT COMPLICATIONS.

Contraindications: Glaucoma, obstructive uropathy (for example, bladder neck obstruction due to prostatic hypertrophy); obstructive disease of the gastrointestinal tract (as in achalasia, pyloroduodenal stenosis, etc.); paralytic ileus, intestinal atony of the elderly or debilitated patient; unstable cardiovascular status in acute hemorrhage; severe ulcerative colitis especially if complicated by toxic megacolon; myasthenia gravis; hiatal hernia associated with reflux esophagitis.

Donnatal is contraindicated in patients with known hypersensitivity to any of the ingredients. Phenobarbital is contraindicated in acute intermittent porphyria and in those patients in whom phenobarbital produces restlessness and/or excitement.

Warnings: In the presence of a high environmental temperature, heat prostration can occur with belladonna alkaloids (fever and heatstroke due to decreased sweating).

Diarrhea may be an early symptom of incomplete intestinal obstruction, especially in patients with ileostomy or colostomy. In this instance treatment with this drug would be inappropriate and possibly harmful.

Donnatal may produce drowsiness or blurred vision. The patient should be warned, should these occur, not to engage in activities requiring mental alertness, such as operating a motor vehicle or other machinery, and not to perform hazardous work.

Phenobarbital may decrease the effect of anticoagulants and necessitate larger doses of the anticoagulant for optimal effect. When the phenobarbital is discontinued, the dose of the anticoagulant may have to be decreased.

Phenobarbital may be habit forming and should not be administered to individuals known to be addiction prone or to those with a history of physical and/or psychological dependence upon drug.

Since barbiturates are metabolized in the liver, they should be used with caution and initial doses should be small in patients with hepatic dysfunction.

Precautions: Use with caution in patients with: autonomic neuropathy, hepatic or renal disease, hyperthyroidism, coronary heart disease, congestive heart failure, cardiac arrhythmias, tachycardia, and hypertension.

Belladonna alkaloids may produce a delay in gastric emptying (antral stasis) which would complicate the management of gastric ulcer.

Theoretically, with overdosage, a curare-like action may occur.

Carcinogenesis, mutagenesis. Long-term studies in animals have not been performed to evaluate carcinogenic potential.

Pregnancy Category C. Animal reproduction studies have not been conducted with Donnatal. It is not known whether Donnatal can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Donnatal should be given to a pregnant woman only if clearly needed.

Nursing mothers. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Donnatal is administered to a nursing mother.

Adverse Reactions: Adverse reactions may include xerostomia; urinary hesitancy and retention; blurred vision; tachycardia; palpitation; mydriasis; cycloplegia; increased ocular tension; loss of taste sense; headache; nervousness; drowsiness; weakness; dizziness; insomnia; nausea; vomiting; impotence; suppression of lactation; constipation; bloated feeling; musculoskeletal pain; severe allergic reaction or drug idiosyncrasies, including anaphylaxis, urticaria and other dermal manifestations; and decreased sweating. Elderly patients may react with symptoms of excitement, agitation, drowsiness, and other untoward manifestations to even small doses of the drug.

Phenobarbital may produce excitement in some patients, rather than a sedative effect. In patients habituated to barbiturates, abrupt withdrawal may produce delirium or convulsions.

Dosage and Administration: The dosage of Donnatal Extentabs should be adjusted to the needs of the individual patient to assure symptomatic control with a minimum of adverse reactions. The usual dose is one tablet every twelve (12) hours. If indicated, one tablet every eight (8) hours may be given.

Overdosage: The signs and symptoms of overdose are headache, nausea, vomiting, blurred vision, dilated pupils; hot and dry skin, dizziness, dryness of the mouth, difficulty in swallowing, CNS stimulation. Treatment should consist of gastric lavage, emetics, and activated charcoal. If indicated, parenteral cholinergic agents such as physostigmine or bethanechol chloride should be added.

How Supplied: Pale green, coated tablets, monogrammed AHR and Donnatal Extentab in bottles of 100 (NDC 0031-4235-63) and 500 (NDC 0031-4235-70); and Dis-Co® Unit Dose Packs of 100 (NDC 0031-4235-64).

Store at controlled room temperature, between 15°C and 30°C (59°F and 86°F).

Dispense in well-closed, light-resistant container.

Rev. February 1985

Rev. February 1985

Donnazyme®

Description: Donnazyme tablets are available for oral administration. Each tablet contains:

Pancreatin, USP equivalent ...	300 mg
Pepsin	150 mg
Bile Salts	150 mg
Hyoscyamine Sulfate, USP ..	0.0518 mg
Atropine Sulfate, USP	0.0097 mg
Scopolamine Hydrobromide, USP	0.0033 mg
Phenobarbital, USP (⅛ gr) ...	8.1 mg

(Warning: may be habit forming)

Inactive Ingredients: Acacia, Acetylated Monoglycerides, Calcium Sulfate, Carnauba Wax, Cellulose Acetate Phthalate, Corn Starch, D&C Yellow 10 Aluminum Lake, Diethyl Phthalate, Edible Ink, FD&C Blue 1 Aluminum Lake, FD&C Yellow 6 Aluminum Lake, Gelatin, Methylparaben, Microcrystalline Cellulose, Polysorbates, Povidone, Propylparaben, Shellac, Sodium Benzoate, Stearic Acid, Sucrose, Tartaric Acid, Titanium Dioxide, Wheat Flour, White Wax. May contain Docusate Sodium.

The combination of anticholinergic/antispasmodic/sedative components with natural digestive enzymes plus bile salts makes it useful for symptomatic relief of functional G.I. disorders.

Clinical Pharmacology: The outer layer of Donnazyme tablets is gastric-soluble and contains the belladonna alkaloids, phenobarbital and pepsin. These ingredients rapidly become available for absorption as the tablet begins disintegrating in the stomach. The pepsin supplements the stomach's digestive secretions by aiding the breakdown of proteins into proteoses and peptones. Spasmolysis and sedation are produced as the belladonna alkaloids and phenobarbital are absorbed.

The core of the tablet contains pancreatin and bile salts. It is designed to disintegrate in the alkaline medium of the duodenum where it releases the active enzyme components of pancreatin (trypsin, amylase and lipase), along with the bile salts. Trypsin breaks down larger protein fractions into peptides; amylase converts starch into maltose; lipase splits fat into fatty acids and glycerin; and bile salts enhance the fat-splitting action of the lipase and aid in the emulsification of fats and the absorption of fatty acids.

Indications and Usage: Donnazyme is indicated for the relief of symptoms associated with "nervous indigestion" and other functional G.I. disorders in the absence of organic pathology. Some of these conditions are chronic pancreatitis, chronic gastritis, postcholecystectomy syndrome, and chronic biliary disorders. Donnazyme may prove especially useful in patients with decreased digestive enzyme secretory activity, which is frequently suspect in older patients with visceral complaints.

Contraindications: Glaucoma, obstructive uropathy (for example, bladder neck obstruction due to prostatic hypertrophy); obstructive disease of the gastrointestinal tract (as in achalasia, pyloroduodenal stenosis, etc.); paralytic ileus, intestinal atony of the elderly or debilitated patient; unstable cardiovascular status in acute hemorrhage; severe ulcerative colitis especially if complicated by toxic megacolon; myasthenia gravis; hiatal hernia associated with reflux esophagitis.

Donnazyme is contraindicated in patients with known hypersensitivity to any of the ingredients. Phenobarbital is contraindicated in acute intermittent porphyria and in those patients in whom phenobarbital produces restlessness and/or excitement.

Warnings: In the presence of a high environmental temperature, heat prostration can occur with belladonna alkaloids (fever and heatstroke due to decreased sweating).

Diarrhea may be an early symptom of incomplete intestinal obstruction, especially in patients with ileostomy or colostomy. In this instance, treatment with this drug would be inappropriate and possibly harmful.

Donnazyme may produce drowsiness or blurred vision. The patient should be warned, should these occur, not to engage in activities requiring mental alertness, such as operating a motor vehicle or other machinery, and not to perform hazardous work.

Phenobarbital may decrease the effect of anticoagulants and necessitate larger doses of the anticoagulant for optimal effect. When the phenobarbital is discontinued, the dose of the anticoagulant may have to be decreased.

Phenobarbital may be habit forming and should not be administered to individuals known to be addiction prone or to those with a history of physical and/or psychological dependence upon drugs.

Since barbiturates are metabolized in the liver, they should be used with caution and initial small doses in patients with hepatic dysfunction.

Precautions: ***General.*** Use with caution in patients with: autonomic neuropathy, hepatic or renal disease, hyperthyroidism, coronary heart disease, congestive heart failure, cardiac arrhythmias, tachycardia, and hypertension.

Belladonna alkaloids may produce a delay in gastric emptying (antral stasis) which would complicate the management of gastric ulcer.

Theoretically, with overdosage, a curare-like action may occur.

Carcinogenesis, mutagenesis. Long-term studies in animals have not been performed to evaluate carcinogenic potential.

Pregnancy Category C. Animal reproduction studies have not been conducted with Donnazyme. It is not known whether Donnazyme can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Donnazyme should be given to a pregnant woman only if clearly needed.

Nursing mothers. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Donnazyme is administered to a nursing mother.

Pediatric Use: Safety and effectiveness in children have not been established.

Adverse Reactions: Adverse reactions may include xerostomia; urinary hesitancy and retention; blurred vision; tachycardia; palpitation; mydriasis; cycloplegia; increased ocular tension; loss of taste sense; headache; nervousness; drowsiness; weakness; dizziness; insomnia; nausea; vomiting; impotence; suppression of lactation; constipation; bloated feeling; musculoskeletal pain; severe allergic reaction or drug idiosyncrasies, including "anaphylaxis, urticaria and other dermal manifestations; and decreased sweating." Elderly patients may react with symptoms of excitement, agitation, drowsiness, and other untoward manifestations to even small doses of the drug.

Phenobarbital may produce excitement in some patients, rather than a sedative effect. In patients habituated to barbiturates, abrupt withdrawal may produce delirium or convulsions.

Overdosage: The signs and symptoms of overdose are headache, nausea, vomiting, blurred vision, dilated pupils, hot and dry skin, dizziness, dryness of mouth, difficulty in swallowing, CNS stimulation. Treatment should consist of gastric lavage, emetics, and activated charcoal. If indicated, parenteral cholinergic agents, such as physostigmine or bethanechol chloride should be added.

Dosage and Administration: Adult dosage: Two tablets after each meal.

How Supplied: Kelly green tablets in bottles of 100 (NDC 0031-4649-63) and 500 (NDC 0031-4649-70). Store at controlled room temperature, between 15°C and 30°C (59°F and 86°F). Dispense in tight container.

Rev. February 1985

Rev. April 1986

Dopram® Injectable

brand of

Doxapram Hydrochloride Injection, USP

DESCRIPTION: Dopram Injectable (Doxapram Hydrochloride Injection, USP) is a clear, colorless, sterile, nonpyrogenic, aqueous solution with pH 3.5–5.0, for intravenous administration.

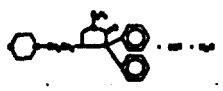
Each 1 mL contains:

Doxapram Hydrochloride, USP	20 mg
Benzyl Alcohol, NF (as preservative)	0.9%
Water for Injection, USP	q.s.

Due to its benzyl alcohol content, Dopram Injectable should not be used in newborns.

Dopram Injectable is a respiratory stimulant.

Doxapram hydrochloride is a white to off-white, crystalline powder, sparingly soluble in water, alcohol and chloroform. It has the following chemical structure and name:



1-ethyl-4-[2-(4-morpholinyl)ethyl]-3,3-diphenyl-2-pyrrolidinone monohydrochloride, monohydrate.

CLINICAL PHARMACOLOGY:

Doxapram hydrochloride produces respiratory stimulation mediated through the peripheral carotid chemoreceptors. As the dosage level is increased, the central respiratory centers in the medulla are stimulated with progressive stimulation of other parts of the brain and spinal cord.

The onset of respiratory stimulation following the recommended single intravenous injection of doxapram hydrochloride usually occurs in 20–40 seconds with peak effect at 1–2 minutes. The duration of effect may vary from 5–12 minutes.

The respiratory stimulant action is manifested by an increase in tidal volume associated with a slight increase in respiratory rate.

A pressor response may result following doxapram administration. Provided there is no impairment of cardiac function, the pressor effect is more marked in hypovolemic than in normovolemic states. The pressor response is due to the improved cardiac output rather than peripheral vasoconstriction. Following doxapram administration, an increased release of catecholamines has been noted.

Although opiate induced respiratory depression is antagonized by doxapram, the analgesic effect is not affected.

INDICATIONS

1. *Postanesthesia.*
   a. When the possibility of airway obstruction and/or hypoxia have been eliminated, doxapram may be used to stimulate respiration in patients with drug-induced postanesthesia respiratory depression or apnea other than that due to muscle relaxant drugs.
   b. To pharmacologically stimulate deep breathing in the so-called "stir-up" regimen in the postoperative patient. (Simultaneous administration of oxygen is desirable.)
2. *Drug-induced central nervous system depression.* Exercising care to prevent vomiting and aspiration, doxapram may be used to stimulate respiration, hasten arousal, and to encourage the return of laryngopharyngeal reflexes in patients with mild to moderate respiratory and CNS depression due to drug overdosage.
3. *Chronic pulmonary disease associated with acute hypercapnia.* Doxapram is indicated as a temporary measure in hospitalized patients with acute respiratory insufficiency superimposed on chronic obstructive pulmonary disease. Its use should be for a short period of time (approximately 2 hours) as an aid in the prevention of elevation of arterial CO_2 tension during the administration of oxygen. It should not be used in conjunction with mechanical ventilation.

CONTRAINDICATIONS

Due to its benzyl alcohol content, Dopram Injectable should not be used in newborns.

Doxapram should not be used in patients with epilepsy or other convulsive disorders.

Doxapram is contraindicated in patients with mechanical disorders of ventilation such as mechanical obstruction, muscle paresis, flail chest, pneumothorax, acute bronchial asthma, pulmonary fibrosis or other conditions resulting in restriction of chest wall, muscles of respiration or alveolar expansion.

Doxapram is contraindicated in patients with evidence of head injury or cerebral vascular accident and in those with significant cardiovascular impairment, severe hypertension, or known hypersensitivity to the drug.

WARNINGS

1. *In postanesthetic use.*
   a. Doxapram is neither an antagonist to muscle relaxant drugs nor a specific narcotic antagonist. Adequacy of airway and oxygenation must be assured prior to doxapram administration.
   b. Doxapram should be administered with great care and only under careful supervision to patients with hypermetabolic states such as hyperthyroidism or pheochromocytoma.
   c. Since narcosis may recur after stimulation with doxapram, care should be taken to maintain close observation until the patient has been fully alert for ½ to 1 hour.
2. *In drug-induced CNS and respiratory depression.* Doxapram alone may not stimulate adequate spontaneous breathing or provide sufficient arousal in patients who are severely depressed either due to respiratory failure or to CNS depressant drugs, but should be used as an adjunct to established supportive measures and resuscitative techniques.
3. *In chronic obstructive pulmonary disease.*
   a. Because of the associated increased work of breathing, do not increase the rate of infusion of doxapram in severely ill patients in an attempt to lower pCO_2.
   b. Doxapram should not be used in conjunction with mechanical ventilation.

PRECAUTIONS

1. *General.*
   a. An adequate airway is essential.
   b. Recommended dosages of doxapram should be employed and maximum total dosages should not be exceeded. In order to avoid side effects, it is advisable to use the minimum effective dosage.
   c. Monitoring of the blood pressure and deep tendon reflexes is recommended to prevent overdosage.
   d. Vascular extravasation or use of a single injection site over an extended period should be avoided since either may lead to thrombophlebitis or local skin irritation.
   e. Rapid infusion may result in hemolysis.
   f. Lowered pCO_2 induced by hyperventilation produces cerebral vasoconstriction and slowing of the cerebral circulation. This should be taken into consideration on an individual basis.
   g. Intravenous short-acting barbiturates, oxygen and resuscitative equipment should be readily available to manage overdosage manifested by excessive central nervous system stimulation. Slow administration of the drug and careful observation of the patient during administration and for some time subsequently are advisable. These precautions are to assure that the protective reflexes have been restored and to prevent possible post-hyperventilation hypoventilation.
   h. Doxapram should be administered cautiously to patients receiving sympathomimetic or monoamine oxidase inhibiting drugs, since an additive pressor effect may occur.
   i. Blood pressure increases are generally modest but significant increases have been noted in some patients. Because of this doxapram is not recommended for use in severe hypertension (see Contraindications).
   j. If sudden hypotension or dyspnea develops, doxapram should be stopped.
2. *In postanesthetic use.*
   a. The same consideration to pre-existing disease states should be exercised as in non-anesthetized individuals. See Contraindications and Warnings covering use in hypertension, asthma, disturbances of respiratory mechanics including airway obstruction, CNS disorders including increased cerebrospinal fluid pressure, convulsive disorders, acute agitation, and profound metabolic disorders.
   b. See Drug Interactions.
3. *In chronic obstructive pulmonary disease.*
   a. Arrhythmias seen in some patients in acute respiratory failure secondary to chronic obstructive pulmonary disease are probably the result of hypoxia. Doxapram should be used with caution in these patients.
   b. Arterial blood gases should be drawn prior to the initiation of doxapram infusion and oxygen administration, then at least every ½ hour. Doxapram administration does not diminish the need for careful monitoring of the patient or the need for supplemental oxygen in patients with acute respiratory failure. Doxapram should be stopped if the arterial blood gases deteriorate, and mechanical ventilation initiated.

Drug Interactions: Administration of doxapram to patients who are receiving sympathomimetic or monoamine oxidase inhibiting drugs may result in an additive pressor effect. (See Precautions).

In patients who have received muscle relaxants, doxapram may temporarily mask the residual effects of muscle relaxant drugs.

In patients who have received anesthetics known to sensitize the myocardium to catecholamines, such as halothane, cyclopropane and enflurane, initiation of doxapram therapy should be delayed for at least 10 minutes following discontinuance of anesthesia, since an increase in epinephrine release has been noted with doxapram.

Carcinogenesis, mutagenesis, impairment of fertility. No carcinogenic or mutagenic studies have been performed using doxapram. Doxapram did not adversely affect the breeding performance of rats.

Pregnancy Category B. Reproduction studies have been performed in rats at doses up to 1.6 times the human dose and have revealed no evidence of impaired fertility or harm to the fetus due to doxapram. There are, however, no adequate and well-controlled studies in pregnant women. Since the animals in the reproduction studies were dosed by the IM and oral routes and animal reproduction studies, in general, are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing mothers. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when doxapram hydrochloride is administered to a nursing mother.

Pediatric use. The use of the preservative benzyl alcohol in the newborn has been associated with metabolic, CNS, respiratory, circulatory, and renal dysfunction. Safety and effectiveness in children below the age of 12 years have not been established.

ADVERSE REACTIONS

The following adverse reactions have been reported:

1. *Central and autonomic nervous systems.* Pyrexia, flushing, sweating; pruritus and paresthesia, such as a feeling of warmth, burning, or hot sensation, especially in the area of genitalia and perineum; apprehension, disorientation, pupillary dilatation, headache, dizziness, hyperactivity, involuntary movements, muscle spasticity, increased deep tendon reflexes, clonus, bilateral Babinski, and convulsions.
2. *Respiratory.* Dyspnea, cough, tachypnea, laryngospasm, bronchospasm, hiccough, and rebound hypoventilation.
3. *Cardiovascular.* Phlebitis; variations in heart rate, lowered T-waves, arrhythmias, chest pain, tightness in chest. A mild to moderate increase in blood pressure is commonly noted and may be of concern in patients with severe cardiovascular diseases.
4. *Gastrointestinal.* Nausea, vomiting, diarrhea, desire to defecate.
5. *Genitourinary.* Stimulation of urinary bladder with spontaneous voiding; urinary retention.
6. *Laboratory determinations.* A decrease in hemoglobin, hematocrit, or red blood cell count has been observed in postoperative patients. In the presence of pre-existing leukopenia, a further decrease in WBC has been observed following anesthesia and treatment with doxapram hydrochloride. Elevation of BUN and albuminuria have also been observed. As some of the patients cited above had received multiple drugs concomitantly, a cause and effect relationship could not be determined.

OVERDOSAGE

Signs and Symptoms. Symptoms of overdosage are extensions of the pharmacologic effects of the drug. Excessive pressor effect, tachycardia, skeletal muscle hyperactivity, and enhanced deep tendon reflexes may be early signs of overdosage. Therefore, the blood pressure, pulse rate and deep tendon reflexes should be evaluated periodically and the dosage or infusion rate adjusted accordingly.

Convulsive seizures are unlikely at recommended dosages. In unanesthetized animals, the convulsant dose is 70 times greater than the respiratory stimulant dose. Intravenous LD_{50} values in the mouse and rat were approximately 75 mg/kg and in the cat and dog were 40–80 mg/kg.

Except for management of chronic obstructive pulmonary disease associated with acute hypercapnia, the maximum recommended dosage is 3 GRAMS/24 HOURS. (See Dosage and Administration.)

Management. There is no specific antidote for doxapram. Management should be symptomatic. Short-acting intravenous barbiturates, oxygen and resuscitative equipment should be used as needed for supportive treatment.

There is no evidence that doxapram is dialyzable; further, the half-life of doxapram makes it unlikely that dialysis would be appropriate in managing overdose with this drug.

DOSAGE AND ADMINISTRATION

1. Doxapram hydrochloride is compatible with 5% and 10% dextrose in water or normal saline. ADMIXTURE OF DOXAPRAM WITH ALKALINE SOLUTIONS SUCH AS 2.5% THIOPENTAL SODIUM, BICARBONATE, OR AMINOPHYLLINE WILL RESULT IN PRECIPITATION OR GAS FORMATION.
2. *In postanesthetic use.*
   a. By I.V. injection (see Table I. Dosage for postanesthetic use—I.V.) Slow administration of the drug and careful observation of the patient during administration and for some time subsequently are advisable.

Table I. Dosage for postanesthetic use.—I.V.

I.V. Administration	Recommended dosage mg/kg	Recommended dosage mg/lb	Maximum dose per single injection mg/kg	Maximum dose per single injection mg/lb	Maximum total dose mg/kg	Maximum total dose mg/lb
Single injection	0.5-1.0	0.25-0.5	1.5	0.70	1.5	0.70
Repeat injections (5 min intervals)	0.5-1.0	0.25-0.5	1.5	0.70	2.0	1.0
Infusion	0.5-1.0	0.25-0.5	–	–	4.0	2.0

   b. By infusion. The solution is prepared by adding 250 mg of doxapram (12.5 mL) to 250 mL of dextrose or saline solution. The infusion is initiated at a rate of approximately 5 mg/minute until a satisfactory respiratory response is observed, and maintained at a rate of 1-3 mg/minute. The rate of infusion should be adjusted to sustain the desired level of respiratory stimulation with a minimum of side effects. The recommended total dosage by infusion is 4 mg/kg (2.0 mg/lb), or approximately 300 mg for the average adult.
3. *In the management of drug-induced CNS depression.)* (See Table II. Dosage for drug-induced CNS depression.)

(Dopram Injectable, continued)

Table II. Dosage for drug-induced CNS depression.

Level of Depression	METHOD ONE Priming dose single/repeat I.V. injection mg/kg	mg/lb	METHOD TWO Rate of intermittent I.V. infusion mg/kg/hr	mg/lb/hr
Mild*	1.0	0.5	1.0-2.0	0.5-1.0
Moderate†	2.0	1.0	2.0-3.0	1.0-1.5

*Mild Depression
Class 0: Asleep, but can be aroused and can answer questions.
Class 1: Comatose, will withdraw from painful stimuli, reflexes intact.

†Moderate Depression
Class 2: Comatose, will not withdraw from painful stimuli, reflexes intact.
Class 3: Comatose, reflexes absent, no depression of circulation or respiration.

METHOD ONE
Using Single and/or Repeat Single I.V. *Injections.*
a. Give priming dose of 1.0 mg/lb (2.0 mg/kg) body weight and repeat in 5 minutes.
b. Repeat same dose q1–2h until patient wakens. Watch for relapse into unconsciousness or development of respiratory depression, since Dopram does not affect the metabolism of CNS-depressant drugs.
c. If relapse occurs, resume injections q1–2h until arousal is sustained, or total maximum daily dose (3 grams) is given. Allow patient to sleep until 24 hours have elapsed from first injection of Dopram, using assisted or automatic respiration if necessary.
d. Repeat procedure the following day until patient breathes spontaneously and sustains desired level of consciousness, or until maximum dosage (3 grams) is given.
e. Repetitive doses should be administered only to patients who have shown response to the initial dose.
f. Failure to respond appropriately indicates the need for neurologic evaluation for a possible central nervous system source of sustained coma.

METHOD TWO
By Intermittent I.V. *Infusion.*
a. Give priming dose as in Method One.
b. If patient wakens, watch for relapse; if no response, continue general supportive treatment for 1–2 hours and repeat Dopram. If some respiratory stimulation occurs, prepare I.V. infusion by adding 250 mg of Dopram (12.5 mL) to 250 mL of saline or dextrose solution. Deliver at rate of 1–3 mg/min (60–180 mL/hr) according to size of patient and depth of coma. Discontinue Dopram if patient begins to waken or at end of 2 hours.
c. Continue supportive treatment for ½ to 2 hours and repeat Step b.
d. Do not exceed 3 grams/day.
4. *Chronic obstructive pulmonary disease associated with acute hypercapnia.*
a. One vial of doxapram (400 mg) should be mixed with 180 mL of dextrose or saline solution (concentration of 2.0 mg/mL). The infusion should be started at 1–2 mg/minute (½–1 mL/minute); if indicated, increase to a maximum of 3 mg/minute. Arterial blood gases should be determined prior to the onset of doxapram's administration and at least every half hour during the two hours of infusion to insure against the insidious development of CO_2-RETENTION AND ACIDOSIS. Alteration of oxygen concentration or flow rate may necessitate adjustment in the rate of doxapram infusion.
b. Predictable blood gas patterns are more readily established with a continuous infusion of doxapram. If the blood gases show evidence of deterioration, the infusion of doxapram should be discontinued.
c. ADDITIONAL INFUSIONS BEYOND THE SINGLE MAXIMUM TWO HOUR ADMINISTRATION PERIOD ARE NOT RECOMMENDED. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

HOW SUPPLIED
Dopram Injectable (Doxapram Hydrochloride Injection) is available in 20 mL multiple dose vials containing 20 mg of doxapram hydrochloride per mL with benzyl alcohol 0.9% as the preservative (NDC 0031-4849-83).

Store at Controlled Room Temperature, Between 15°C and 30°C (59°F and 86°F).

Manufactured for PHARMACEUTICAL DIVISION, A. H. ROBINS CO., Richmond, VA 23220 by ELKINS-SINN, INC. Cherry Hill, NJ 08034, a subsidiary of A. H. Robins.
Rev. April 1986

October 1987

Entolase®-HP Capsules
(Pancrelipase)
Enteric-Coated Microbeads

Entolase® Capsules
(Pancrelipase)
Enteric-Coated Microbeads

Description: Dye-free Entolase-HP and Entolase Capsules (Pancrelipase) are pancreatic enzyme concentrates of porcine origin containing standardized lipase, protease, and amylase as well as other pancreatic enzymes. They are available as enteric-coated microbeads of pancrelipase in hard gelatin capsules for oral administration. The enzyme potencies of Entolase-HP and Entolase Capsules are no less than:

	Each Entolase-HP Capsule	Each Entolase Capsule
Lipase USP Units	8 000	4 000
Protease USP Units	50 000	25 000
Amylase USP Units	40 000	20 000

Inactive Ingredients: Entolase-HP Capsules—cellulose acetate phthalate, corn starch, edible inks, gelatin, iron oxide, povidone, simethicone, sodium chloride, stearic acid, sucrose, talc, titanium dioxide.

Entolase Capsules—cellulose acetate phthalate, corn starch, edible inks, gelatin, povidone, simethicone, sodium chloride, stearic acid, sucrose, talc, titanium dioxide.

Clinical Pharmacology: The natural digestive enzymes in Entolase-HP and Entolase Capsules hydrolyze fats into fatty acids and glycerol, split protein into peptides and amino acids, and convert carbohydrates to dextrins and short chain sugars.

Under conditions of the USP test method (*in vitro*), the Entolase products have the following total digestive capacity:

	Each Entolase-HP Capsule	Each Entolase Capsule
Dietary Fat grams	28	14
Dietary Protein grams	50	25
Dietary Starch grams	40	20

The digestive capacity of a pancreatic enzyme concentrate depends on the amount that passes through the stomach unchanged and is available at the site of action in the small intestine. The pancrelipase in Entolase-HP and Entolase Capsules is contained within enteric-coated microbeads as a safeguard against inactivation of the enzymes in the acid medium of the stomach.

Indications: Entolase (Pancrelipase) is indicated in the treatment of exocrine pancreatic insufficiency as associated with but not limited to:

- cystic fibrosis
- chronic pancreatitis
- post-pancreatectomy
- post-gastrointestinal bypass surgery (e.g., Billroth II gastroenterostomy)
- obstruction of the pancreatic ducts.

Contraindications: Do not use in patients hypersensitive to pork protein.

Precautions: ***General:*** Individuals previously sensitized to trypsin, pancreatin, or pancrelipase may have allergic manifestations to the Entolase products.

Information for Patients: Patients should be advised to avoid chewing or crushing the enteric-coated microbeads. Where swallowing of capsules is difficult, capsules may be opened and the enteric-coated microbeads sprinkled over soft food which does not require chewing (e.g., applesauce, gelatin, etc.) and swallowed immediately. Prolonged contact of microbeads with food of pH greater than 5.5 may dissolve the protective enteric coating.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Long-term studies in animals have not been performed to evaluate carcinogenic potential.

Pregnancy Category C: Animal reproduction studies have not been conducted with the Entolase products. It is also not known whether these products can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Entolase products should be given to a pregnant woman only if clearly needed.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Entolase products are administered to a nursing mother.

Adverse Reactions: Extremely high doses of exogenous pancreatic enzymes have been associated with hyperuricemia and hyperuricosuria. Diarrhea or transient intestinal upset may occur with pancreatic enzyme concentrate. Allergic manifestations (see precautions).

Overdosage: Acute toxicity determinations in animals have not been possible since the maximum dose that could be given orally produced no toxic reaction.

Dosage and Administration: The requirement for replacement digestive enzymes varies from patient to patient. To provide dosage flexibility, Entolase is available in two strengths.

Entolase-HP Capsules and Entolase Capsules: One (1) to three (3) or more capsules with meals as directed by physician depending on patient requirements.

How Supplied: Entolase-HP Capsules, enteric-coated microbeads in brown and clear No. 00 capsules monogrammed Entolase HP and AHR in bottles of 100 (NDC 0031-5035-63) and 250 (NDC 0031-5035-67).

Entolase Capsules, enteric-coated microbeads in white and clear No. 1 capsules, monogrammed Entolase and AHR in bottles of 100 (NDC 0031-5025-63) and 500 (NDC 0031-5025-70).

Store in a tightly closed container in a dry place at controlled room temperature between 15°C and 30°C (59°F and 86°F). Do not refrigerate.

Dispense Entolase-HP Capsules and Entolase Capsules in tight container, preferably with a desiccant.

October 1987

Rev. Feb. 1985

Entozyme®

Description: Entozyme tablets are available for oral administration. Each tablet contains:

Pancreatin, USP equivalent	300 mg
Pepsin	250 mg
Bile salts	150 mg

Natural Digestive Enzymes

Inactive Ingredients: Acacia, Acetylated Monoglycerides, Calcium Carbonate, Calcium Sulfate, Carnauba Wax, Cellulose Acetate Phthalate, Corn Starch, Diethyl Phthalate, Edible Ink, FD&C Blue 2 Aluminum Lake, Gelatin, Microcrystalline Cellulose, Polysorbates, Shellac, Stearic Acid, Sucrose, Tartaric Acid, Titanium Dioxide, White wax. May contain FD&C Red 40 and Yellow 6 Aluminum Lakes.

Construction: Entozyme is a specially constructed tablet. The outer layer dissolves in the stomach and releases pepsin. The "inner tablet" is protected by an enteric coating that disintegrates in the alkaline medium of the small intestine and releases pancreatin and bile salts, thus preserving the digestive potency of the pancreatin as it passes through the stomach.

Clinical Pharmacology: Entozyme should be considered a form of nutritional therapy since it is made up of naturally-occurring digestive enzymes. Entozyme enhances proteolysis by its peptic and tryptic activity, carbohydrate digestion by amylolytic activity, and fat emulsification and transport by lipolytic activity and the action of the bile salts. The components of six Entozyme tablets will digest 60 grams of fat, 48 grams of protein and 48 grams of carbohydrate, amounts of food that yield nearly 1,000 calories (one-third to one-half the daily caloric intake for many patients).

Indications and Usage: Entozyme is indicated for the relief of steatorrhea, pyrosis, flatulence, and belching associated with incomplete digestion of food due to a deficiency of digestive enzymes.

By effectively supplementing the patient's secretion of digestive enzymes, Entozyme promotes more complete digestion of carbohydrates, proteins and fats.

Contraindications: Biliary tract obstruction or hypersensitivity to any of the ingredients.

Warnings: Do not administer to patients who are allergic to pork products.

Precautions: ***Carcinogenesis, mutagenesis.*** Long-term studies in animals have not been performed to evaluate carcinogenic potential.

Pregnancy Category C. Animal reproduction studies have not been conducted with Entozyme. It is not known whether Entozyme can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Entozyme should be given to a pregnant woman only if clearly needed.

Nursing mothers. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Entozyme is administered to a nursing woman.

Pediatric Use. Safety and effectiveness in children have not been established.

Adverse Reactions: Skin rash is the most frequently reported adverse reaction to Entozyme, and appears to be associated with hypersensitivity to pork protein in the pancreatin. At high doses, a laxative effect may occur.

Overdosage: Excessive dosage may produce a laxative effect. Systemic toxicity does not occur.

Dosage and Administration: Two tablets with each meal and 1 or 2 tablets with each snack. The dose may be increased as necessary to achieve adequate digestion. Entozyme tablets should be swallowed whole and crushed or chewed.

How Supplied: White, coated tablets, monogrammed AHR and 5049 in bottles of 100 (NDC 0031-5049-63) and 500 (NDC 0031-5049-70).

Store at controlled room temperature, between 15°C and 30°C (59°F and 86°F). Dispense in tight container.

Rev. Feb. 1985

Rev. January 1986

Exna®

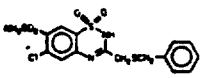
brand of

Benzthiazide Tablets, USP

Description: Exna (benzthiazide) is a diuretic available in round, yellow, scored tablets engraved AHR and 5449 for oral administration. Each tablet contains 50 mg benzthiazide.

Inactive Ingredients: Corn Starch, Dibasic Calcium Phosphate, FD&C Yellow 5, Lactose, Magnesium Stearate, Polyethylene Glycol, Sodium Lauryl Sulfate.

Benzthiazide is a white, crystalline powder with a characteristic odor, freely soluble in alkaline solution. The chemical structure is:



6-chloro-3-[[(phenylmethyl)thio]methyl]-2H-1,2,4-benzothiadiazine-7-sulfonamide 1,1-dioxide

Clinical Pharmacology: Exna is a diuretic and antihypertensive. It affects the renal tubular mechanism of electrolyte reabsorption. At maximal therapeutic dosage, all thiazides are approximately equal in their diuretic potency. The mechanism whereby thiazides function in the control of hypertension is unknown. Exna increases excretion of sodium and chloride in approximately equivalent amounts. Natriuresis may be accompanied by some loss of potassium and bicarbonate.

In humans, benzthiazide is excreted in the urine almost entirely unchanged. Following a single oral dose of Exna Tablets or benzthiazide solution, 1% and 4.3% of the respective doses were recovered in the urine in 24 hr. The relative bioavailability of Exna Tablets was determined to be about 25% in reference to benzthiazide solution.

Indications and Usage: Exna (benzthiazide) is indicated as adjunctive therapy in edema associated with congestive heart failure, hepatic cirrhosis and corticosteroid and estrogen therapy.

Exna has also been found useful in edema due to various forms of renal dysfunction as: nephrotic syndrome; acute glomerulonephritis; and chronic renal failure.

Exna is indicated in the management of hypertension either as the sole therapeutic agent or to enhance the effectiveness of other antihypertensive drugs in the more severe forms of hypertension.

Use in Pregnancy: The routine use of diuretics in an otherwise healthy woman is inappropriate and exposes mother and fetus to unnecessary hazard. Diuretics do not prevent development of toxemia of pregnancy, and there is no satisfactory evidence that they are useful in the treatment of developed toxemia.

Edema during pregnancy may arise from pathological causes or from the physiologic and mechanical consequences of pregnancy. Thiazides are indicated in pregnancy when edema is due to pathologic causes, just as they are in the absence of pregnancy (however, see Warnings, below). Dependent edema in pregnancy, resulting from restriction of venous return by the expanded uterus, is properly treated through elevation of the lower extremities and use of support hose; use of diuretics to lower intravascular volume in this case is illogical and unnecessary. There is hypervolemia during normal pregnancy which is harmful to neither the fetus nor the mother (in the absence of cardiovascular disease), but which is associated with edema, including generalized edema, in the majority of pregnant women. If this edema produces discomfort, increased recumbency will often provide relief. In rare instances, this edema may cause extreme discomfort which is not relieved by rest. In these cases, a short course of diuretics may provide relief and may be appropriate.

Contraindications: Anuria. Hypersensitivity to this or other sulfonamide-derived drugs.

Warnings: Thiazides should be used with caution in severe renal disease. In patients with renal disease, thiazides may precipitate azotemia. Cumulative effects of the drug may develop in patients with impaired renal function.

Thiazides should be used with caution in patients with impaired hepatic function or progressive liver disease, since minor alterations of fluid and electrolyte balance may precipitate hepatic coma.

Sensitivity reactions may occur in patients with a history of allergy or bronchial asthma.

The possibility of exacerbation or activation of systemic lupus erythematosus has been reported.

Latent diabetes mellitus may become manifest during thiazide administration; hyperuricemia or frank gout may also be precipitated in certain patients. The antihypertensive effect of the drug may be enhanced in the postsympathectomy patient.

Precautions: *General:* All patients receiving thiazide therapy should be observed for clinical signs of fluid or electrolyte imbalance; namely, hyponatremia, hypochloremic alkalosis, and hypokalemia.

Dilutional hyponatremia may occur in edematous patients in hot weather; appropriate therapy is water restriction, rather than administration of salt except in rare instances when hyponatremia is life threatening.

In actual salt depletion, appropriate replacement is the therapy of choice. Any chloride deficit is generally mild and usually does not require specific treatment except under extraordinary circumstances (as in liver disease or renal disease).

Hypokalemia may develop with thiazides as with any other potent diuretic especially with brisk diuresis. Inadequate oral electrolyte intake will also contribute to hypokalemia.

This product contains FD&C Yellow No. 5 (tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible individuals. Although the overall incidence of FD&C Yellow No. 5 (tartrazine) sensitivity in the general population is low, it is frequently seen in patients who have aspirin hypersensitivity.

Information for patients: Warning signs of electrolyte imbalance are: dryness of mouth, thirst, weakness, lethargy, drowsiness, restlessness, muscle pains or cramps, muscular fatigue, hypotension, oliguria, tachycardia, and gastrointestinal disturbances such as nausea and vomiting.

Laboratory tests: Periodic determination of serum electrolytes to detect possible electrolyte imbalance should be performed at appropriate intervals. When the patient is vomiting excessively or receiving parenteral fluids, serum and urine electrolyte determinations are particularly important.

In patients with renal impairment, nonprotein nitrogen or blood urea nitrogen level should be tested periodically; rising values would indicate progressive renal impairment and careful reappraisal of therapy is necessary with consideration given to withholding or discontinuing diuretic therapy.

Drug interaction: Thiazides may add to or potentiate the action of other hypotensive drugs. Potentiation occurs with ganglionic or peripheral adrenergic-blocking drugs.

Thiazides may increase the responsiveness to tubocurarine.

Thiazides may decrease arterial responsiveness to norepinephrine. This diminution is not sufficient to preclude effectiveness of the pressor agent for therapeutic use.

Insulin requirement in diabetic patients may be increased, decreased, or unchanged.

Medication such as digitalis may also influence serum electrolytes. Digitalis therapy may exaggerate metabolic effects of hypokalemia especially with reference to myocardial activity.

Drug/Laboratory Tests Interactions: Thiazides may decrease serum PBI levels without signs of thyroid disturbance.

Carcinogenesis, mutagenesis, impairment of fertility: No animal carcinogenicity or mutagenesis studies on benzthiazide are known.

Pregnancy-teratogenic effects: Pregnancy Category C. Benzthiazide has an embryocidal effect in rats when given in doses several hundred times the human dose. Exna (benzthiazide) can cause fetal harm when administered to a pregnant woman. Fetal or neonatal jaundice has been reported. Thrombocytopenia and possibly other adverse reactions have occurred in the adult. If this drug is used during pregnancy, or if patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus.

Thiazides cross the placental barrier and appear in cord blood.

Nursing mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Exna is administered to a nursing mother.

Pediatric use: Safety and effectiveness in children have not been established.

Adverse Reactions: The following adverse reactions have been observed, but there is not enough systematic collection of data to support an estimate of their frequency.

Gastrointestinal System: jaundice (intrahepatic cholestatic jaundice); pancreatitis; gastric irritation; vomiting; cramping; nausea; anorexia; diarrhea; constipation.

Central Nervous System: dizziness; restlessness; paresthesia; headache; xanthopsia.

Hematologic: aplastic anemia; thrombocytopenia; agranulocytosis; leukopenia.

Dermatologic-Hypersensitivity: necrotizing angiitis (vasculitis) (cutaneous vasculitis); purpura; urticaria; rash; photosensitivity.

Cardiovascular: Orthostatic hypotension may occur and may be aggravated by alcohol, barbiturates or narcotics.

Other: hyperglycemia, glycosuria; hyperuricemia; weakness; muscle spasm.

Whenever adverse reactions are moderate or severe, thiazide dosage should be reduced or therapy withdrawn.

Overdosage: Symptoms of overdosage include electrolyte imbalance and signs of potassium deficiency such as confusion, dizziness, muscular weakness, and gastrointestinal disturbances. General supportive measures including replacement of fluids and electrolytes may be indicated in treatment of overdosage.

Dosage and Administration: Therapy should be individualized according to patient response. This therapy should be titrated to gain maximal therapeutic response as well as the minimal dose possible to maintain that therapeutic response.

	Diuretic	Antihypertensive
Benzthiazide	50 to 200 mg	50 to 200 mg

Edema: ***Initiation of diuresis.*** 50 to 200 mg daily should be used for several days, or until dry weight is attained. With 100 mg or more daily, it is generally preferable to administer benzthiazide in two doses, following morning and evening meals.

Maintenance of diuresis. 50 to 150 mg daily depending upon the patient's response. To maintain effectiveness, reduction to minimal effective dosage should be gradual.

Hypertension: ***Initiation of antihypertensive therapy.*** 50 to 100 mg daily is the average dose. It may be given in two doses of 25 mg or 50 mg each after breakfast and after lunch. This dosage may be continued until a therapeutic drop in blood pressure occurs.

Maintenance of antihypertensive therapy. Dosage should be adjusted according to the patient response, either upward to as much as 50 mg q.i.d. or downward to the minimal effective dosage level.

How Supplied: Exna (benzthiazide) is supplied in 50 mg round, yellow, scored tablets engraved AHR and 5449, packaged in bottles of 100 (NDC 0031-5449-63).

Store at controlled room temperature, between 15°C and 30°C (59°F and 86°F).

Dispense in tight container.

Rev. Jan. 1986

Rev. Feb. 1985

Micro-K Extencaps® Micro-K 10 Extencaps®

brand of

Potassium Chloride

Description: Micro-K Extencaps are pale orange, hard gelatin capsules, each containing 600 mg of dispersible, small crystalline particles of potassium chloride (equivalent to 8 mEq K), monogrammed Micro-K and AHR/5720.

Micro-K 10 Extencaps are pale orange and opaque white, hard gelatin capsules, each containing 750 mg of dispersible, small crystalline particles of potassium chloride (equivalent to 10 mEq K) monogrammed Micro-K 10 and AHR/5730. Each particle of potassium chloride (KCl) is microencapsulated by a patented process with a polymeric coating which allows for the controlled release of potassium and chloride ions over an eight- to ten-hour period. The dispersibility of the microcapsules and the controlled release of ions are intended to minimize the likelihood of high localized concentrations of potassium chloride and resultant mucosal ulceration within the gastrointestinal tract.

The polymeric coating forming the microcapsules functions as a water-permeable membrane. Fluids pass through the membrane and gradually dissolve the potassium chloride within the microcapsules. The resulting potassium chloride solution slowly diffuses outward through the membrane.

Inactive Ingredients: Edible Ink, Ethylcellulose, FD&C Blue 2 Aluminum Lake, FD&C Yellow 6, Gelatin, Magnesium Stearate, Sodium Lauryl Sulfate, Titanium Dioxide. May contain FD&C Red 40 and Yellow 6 Aluminum Lakes.

Actions: Potassium ion is the principal intracellular cation of most body tissues. Potassium ions participate in a number of essential physiological processes, including the maintenance of intracellular tonicity, the transmission of nerve impulses, the contraction of cardiac, skeletal, and smooth muscle and the maintenance of normal renal function.

Potassium depletion may occur whenever the rate of potassium loss through renal excretion and/or loss from the gastrointestinal tract exceeds the rate of potassium intake. Such depletion usually develops slowly as a consequence of prolonged therapy with oral diuretics, primary or secondary hyperaldosteronism, diabetic ketoacidosis, severe diarrhea, or inadequate replacement of potassium in patients on prolonged parenteral nutrition. Potassium depletion due to these causes is usually accompanied by a concomitant deficiency of chloride and is manifested by hypokalemia and metabolic alkalosis. Potassium depletion may produce weakness, fatigue, disturbances of cardiac rhythm (primarily ectopic beats), prominent U-waves in the electrocardiogram, and in advanced cases, flaccid paralysis and/or impaired ability to concentrate urine.

Potassium depletion associated with metabolic alkalosis is managed by correcting the fundamental causes of the deficiency whenever possible and administering supplemental potassium chloride, in the form of high potassium food or potassium chloride solution, capsules or tablets. In rare circumstances (e.g., patients with renal tubular acidosis) potassium depletion may be associated with metabolic acidosis and hyperchloremia. In such patients potassium replacement should be accomplished with potassium salts other than the chloride, such as potassium bicarbonate, potassium citrate, or potassium acetate.

INDICATIONS: BECAUSE OF REPORTS OF INTESTINAL AND GASTRIC ULCERATION AND BLEEDING WITH SLOW-RELEASE POTASSIUM CHLORIDE PREPARATIONS, THESE DRUGS SHOULD BE RESERVED FOR THOSE PATIENTS WHO CANNOT TOLERATE OR REFUSE TO TAKE LIQUID OR EFFERVESCENT POTASSIUM PREPARATIONS OR FOR PATIENTS IN WHOM THERE IS A PROBLEM OF COMPLIANCE WITH THESE PREPARATIONS.

1. For therapeutic use in patients with hypokalemia with or without metabolic alkalosis; in digitalis intoxication and in patients with hypokalemic familial periodic paralysis.
2. For prevention of potassium depletion when the dietary intake of potassium is inadequate in the following conditions: patients receiving digitalis and diuretics for congestive heart failure; hepatic cirrhosis with ascites; states of aldosterone excess with normal renal function; potassium-losing nephropathy, and certain diarrheal states.
3. The use of potassium salts in patients receiving diuretics for uncomplicated essential hypertension is often unnecessary when such patients have a normal dietary pattern. Serum potassium should be checked periodically, however, and, if hypokalemia occurs, dietary supplementation with potassium-containing foods may be adequate to control milder cases. In more severe cases, supplementation with potassium salts may be indicated.

Contraindications: Potassium supplements are contraindicated in patients with hyperkalemia since a further increase in serum potassium concentration in such patients can produce cardiac arrest. Hyperkalemia may complicate any of the following conditions: chronic renal failure, systemic acidosis such as diabetic acidosis, acute dehydration, extensive tissue breakdown as in severe burns, adrenal insufficiency, or the administration of a potassium-sparing diuretic (e.g., spironolactone, triamterene).

Wax-matrix potassium chloride preparations have produced esophageal ulceration in certain cardiac patients with esophageal compression due to an enlarged left atrium.

All solid dosage forms of potassium supplements are contraindicated in any patient in whom there is cause for arrest or delay in tablet passage through the gastrointestinal tract. In these instances, potassium supplementation should be with a liquid preparation.

Warnings: ***Hyperkalemia.*** In patients with impaired mechanisms for excreting potassium, the administration of potassium salts can produce hyperkalemia and cardiac arrest. This occurs most commonly in patients given potassium by the intravenous route but may also occur in patients given potassium orally. Potentially fatal hyperkalemia can develop rapidly and be asymptomatic.

The use of potassium salts in patients with chronic renal disease, or any other condition which impairs potassium excretion, requires particularly careful monitoring of the serum potassium concentration and appropriate dosage adjustments.

Interaction with Potassium-Sparing Diuretics. Hypokalemia should not be treated by the concomitant administration of potassium salts and a potassium-sparing diuretic (e.g., spironolactone or triamterene), since the simultaneous administration of these agents can produce severe hyperkalemia.

Gastrointestinal lesions. Potassium chloride tablets have produced stenotic and/or ulcerative lesions of the small bowel and deaths, in addition to upper gastrointestinal bleeding. These lesions are caused by a high localized concentration of potassium ion in the region of a rapidly dissolving tablet which injures the bowel wall and thereby produces obstruction, hemorrhage, or perforation.

Micro-K Extencaps contain microcapsules which disperse upon dissolution of the hard gelatin capsule. The microcapsules are formulated to provide a controlled release of potassium chloride. The dispersibility of the microcapsules and the controlled release of ions from the microcapsules are intended to minimize the possibility of a high local concentration near the gastrointestinal mucosa and the ability of the KCl to cause stenosis or ulceration. Other means of accomplishing this (e.g., incorporation of KCl into a wax matrix) have reduced the frequency of such lesions to less than one per 100,000 patient years (compared to 40–50 per 100,000 patient years with enteric-coated KCl), but have not eliminated them. The frequency of GI lesions with Micro-K Extencaps is, at present, unknown. Micro-K Extencaps should be discontinued immediately and the possibility of bowel obstruction or perforation considered if severe vomiting, abdominal pain, distention, or gastrointestinal bleeding occurs.

Metabolic Acidosis. Hypokalemia in patients with metabolic *acidosis* should be treated with an alkalinizing potassium salt such as potassium bicarbonate, potassium citrate, or potassium acetate.

Precautions: The diagnosis of potassium depletion is ordinarily made by demonstrating hypokalemia in a patient with a clinical history suggesting some cause for potassium depletion. In interpreting the serum potassium level, the physician should bear in mind that acute alkalosis per se can produce hypokalemia in the absence of a deficit in total body potassium, while acute acidosis per se can increase the serum potassium concentration into the normal range even in the presence of a reduced total body potas-

sium. The treatment of potassium depletion, particularly in the presence of cardiac disease, renal disease, or acidosis, requires careful attention to acid-base balance and appropriate monitoring of serum electrolytes, the electrocardiogram, and the clinical status of the patient.

Adverse Reactions: The most common adverse reactions to oral potassium salts are nausea, vomiting, abdominal discomfort, and diarrhea. These symptoms are due to irritation of the gastrointestinal tract and may be minimized by taking the dose with meals or by reducing the dose.

Intestinal bleeding, ulceration, perforation and obstruction have been reported in patients treated with solid dosage forms of potassium salts and may occur with Micro-K Extencaps (see Contraindications and Warnings).

One of the most severe adverse effects of potassium supplementation is hyperkalemia (see Contraindications, Warnings, and Overdosage).

Skin rash has been reported rarely with potassium preparations.

Overdosage: The administration of oral potassium salts to persons with normal excretory mechanisms for potassium rarely causes serious hyperkalemia. However, if excretory mechanisms are impaired or if potassium is administered too rapidly intravenously, potentially fatal hyperkalemia can result (see Contraindications and Warnings). It is important to recognize that hyperkalemia is usually asymptomatic and may be manifested only by an increased serum potassium concentration and characteristic electrocardiogram changes (peaking of T-waves, loss of P-wave, depression of S-T segment, and prolongation of the QT interval). Late manifestations include muscle paralysis and cardiovascular collapse from cardiac arrest.

Treatment measures for hyperkalemia include the following: (1) elimination of foods and medications containing potassium and of potassium-sparing diuretics; (2) intravenous administration of 300 to 500 mL/hr of 10% dextrose solution containing 10–20 units of insulin per 1,000 mL; (3) correction of acidosis, if present, with intravenous sodium bicarbonate; (4) use of exchange resins, hemodialysis, or peritoneal dialysis.

In treating hyperkalemia, it should be recalled that in patients who have been stabilized on digitalis, too rapid a lowering of the serum potassium concentration can produce digitalis toxicity.

Dosage and Administration: The usual dietary intake of potassium by the average adult is 40 to 80 mEq per day. Potassium depletion sufficient to cause hypokalemia usually requires the loss of 200 or more mEq of potassium from the total body store.

Dosage must be adjusted to the individual needs of each patient, but typically is around 20 mEq per day for the prevention of hypokalemia and 40 to 100 mEq per day for the treatment of potassium depletion.

	For Prevention	For Treatment
Micro-K Extencaps (8 mEq K)	2 or 3 Extencaps/day (16–24 mEq K)	5 to 12 Extencaps/day (40–96 mEq K)
Micro-K Extencaps (10 mEq K)	2 Extencaps/day (20 mEq K)	4 to 10 Extencaps/day (40–100 mEq K)

If more than 2 Extencaps are prescribed per day, the total daily dosage should be divided into two or more separate doses. Those patients having difficulty swallowing the capsules may be advised to sprinkle the contents onto a spoonful of soft food to facilitate ingestion.

How Supplied: Micro-K Extencaps® are pale orange capsules monogrammed Micro-K and AHR/5720, each containing 600 mg microencapsulated potassium chloride (equivalent to 8 mEq K), in bottles of 100 (NDC 0031-5720-63), 500 (NDC 0031-5720-70) and Dis-Co® unit dose packs of 100 (NDC 0031-5720-64).

Micro-K 10 Extencaps® are pale orange and opaque white capsules monogrammed Micro-K 10 and AHR/5730, each containing 750 mg microencapsulated potassium chloride (equivalent to 10 mEq K), in bottles of 100 (NDC 0031-5730-63), 500 (NDC 0031-5730-70), and Dis-Co® unit dose packs of 100 (NDC 0031-5730-64).

Animal Toxicology: The ulcerogenic potential of microencapsulated KCl was studied in anesthetized cats by direct applications on exteriorized gastric mucosa. The microcapsules of KCl were found to be non-ulcerogenic and significantly less irritating than wax-matrix tablets and 20% solution of KCl.

In groups of monkeys (up to 8 monkeys per group) receiving different formulations of potassium chloride at equivalent daily dosage (2400 mg KCl) for four and one-half days, Micro-K Extencaps showed no tendency to cause intestinal ulceration (similar to liquid KCl and a wax-matrix preparation but in contrast to an enteric-coated KCl tablet) and minimal gastric irritation (less than a wax-matrix preparation).

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Rev. February 1986
ANALGESIC

Pabalate®-SF

Pabalate®-Sodium Free

Description: Pabalate®-SF tablets are intended for oral administration.
Each enteric-coated tablet contains:
Potassium Salicylate ..... 0.3 g
Potassium Aminobenzoate..... 0.3 g
Potassium content per tablet: 131.5 mg (3.4 mEq)

Inactive Ingredients: Acacia, Acetylated Monoglycerides, Calcium Carbonate, Calcium Sulfate, Carnauba Wax, Cellulose Acetate Phthalate, Diethyl Phthalate, Docusate Sodium, Edible Ink, FD&C Blue 1 Aluminum Lake, FD&C Blue 2 Aluminum Lake, FD&C Red 3 Aluminum Lake, Gelatin, Magnesium Stearate, Polysorbates, Shellac, Stearic Acid, Sucrose, Talc, Titanium Dioxide, Wheat Flour, White Wax. May contain FD&C Red 40 and Yellow 6 Aluminum Lakes.
Analgesic Drug Product.

The components have the following chemical structures:

Clinical Pharmacology: Potassium salicylate is a mild analgesic with antiinflammatory and antipyretic activity. Compared to aspirin, potassium salicylate has substantially less effect on platelet adhesiveness. In large doses, however, it has a hypoprothrombinemic effect. Potassium salicylate in conventional dosage form dissolves in the stomach and is absorbed as un-ionized salicylic acid. However, in Pabalate-SF, the enteric coating delays release of the salicylate until the tablet reaches the alkaline medium of the intestine. After absorption, salicylic acid is extensively bound to plasma protein, and the bound portion is in equilibrium with the free salicylate in the plasma. The action of potassium aminobenzoate in this formulation has not been established.

Indications: Pabalate-SF tablets are indicated for the temporary relief of mild to moderate pain complicated by conditions in which the restriction of sodium intake may be desirable, such as: congestive heart failure, essential hypertension and glomerulonephritis.

Contraindications: Hypersensitivity to any of the ingredients. Presence of an active ulcer, hypoprothrombinemia, Vitamin K deficiency, severe hepatic or renal damage, hemophilia, or hyperkalemia. Do not administer to patients who are receiving a potassium-sparing diuretic.

Warnings: Salicylates have been reported to be associated with the development of Reye syndrome in children and teenagers with chicken pox, influenza, and influenza-like infections.

There have been several reports, published and unpublished, concerning non-specific small bowel lesions consisting of stenosis with or without ulceration, associated with the administration of enteric-coated thiazides with potassium salts. These lesions may occur with enteric-coated potassium tablets alone or when they are used with nonenteric-coated thiazides, or certain other oral diuretics.

These small bowel lesions have caused obstruction, hemorrhage, and perforation. Surgery was frequently required and deaths have occurred.

Based on a large survey of physicians and hospitals, both American and foreign, the incidence of these lesions is low, and a causal relationship in man has not been definitely established.

Available information tends to implicate enteric-coated potassium salts although lesions of this type also occur spontaneously. Therefore, coated potassium-containing formulations should be administered only when indicated, and should be discontinued immediately if abdominal pain, distension, nausea, vomiting, or gastrointestinal bleeding occur.

When prescribing Pabalate-SF for patients who are receiving concurrent potassium supplementation (e.g., to replace potassium excreted during thiazide therapy), it should be kept in mind that each Pabalate-SF tablet contains 131.5 mg (3.4 mEq) of potassium. A decrease in supplemental potassium dosage should be considered in order to avoid hyperkalemia.

The use of potassium salts in patients with chronic renal disease, or any other condition which impairs potassium excretion, requires particularly careful monitoring of the serum potassium concentration and appropriate dosage adjustment.

Precautions: ***General:*** Treatment with salicylates may interfere with blood clotting; therefore, salicylate therapy should be stopped at least one week prior to surgery.

Drug Interaction: This product contains aminobenzoic acid which inhibits the bacteriostatic action of sulfonamides when the two are administered concurrently.

Carcinogenesis, mutagenesis: Long-term studies in animals have not been performed to evaluate carcinogenic potential.

Pregnancy Category C: Animal reproduction studies have not been conducted with Pabalate-SF.

Safe use of Pabalate-SF has not been established with regard to possible adverse effects upon fetal development. Therefore, Pabalate-SF should not be used in women who are or may become pregnant and particularly during early pregnancy unless in the judgment of the physician the potential benefits outweigh the possible hazards.

Nursing Mothers: Salicylates appear in human milk in moderate amounts. They can produce a bleeding tendency by decreasing the amount of prothrombin in the infant's blood. As a general rule, nursing should not be undertaken while a patient is on this drug.

Pediatric Use: Safety and effectiveness in children below the age of 12 have not been established.

Adverse Reactions: Hyperkalemia is a potential adverse effect (see Contraindications and Warnings). The most frequent adverse reactions to products such as Pabalate-SF which contain potassium and/or salicylates are nausea and gastrointestinal upset. Fine rash with or without pruritus and urticaria occur less frequently. The occasional occurrence of mild salicylism may require adjustment in dosage.

Overdosage: Overdose may cause symptoms of hyperkalemia and/or salicylate intoxication. Mild chronic overdosage, termed salicylism, may cause symptoms such as tinnitus, nausea, headache, hyperventilation, dizziness, drowsiness, mental confusion, dimness of vision, sweating, thirst, and occasionally diarrhea. Withdrawal of salicylates and supportive therapy may be sufficient treatment.

A more severe degree of salicylate intoxication may occur with acute massive overdosage or the chronic administration of more moderate overdoses, especially in infants and children. CNS effects are more pronounced and may progress to dilirium, hallucinations, generalized convulsions and coma. A variety of cutaneous lesions may be observed.

A most important feature of salicylate intoxication is a disturbance of acid-base balance and plasma electrolytes. Careful monitoring of these laboratory parameters along with plasma glucose concentration is essential. The type and quantity of repair solutions used will depend upon interpretation of the laboratory data. Bicarbonate solution should be administered IV in order to produce alkaline diuresis. Correction of hypoglycemia and ketosis by the administration of glucose is essential.

Since hyperthermia and dehydration are immediate threats to life, external sponging and the administration of adequate quantities of IV fluids are important first steps to correct these conditions and maintain adequate renal function.

If hemorrhagic phenomena (petechiae, thrombocytopenia) occur, whole blood transfusions and vitamin K may be necessary.

The gastrointestinal tract should be emptied either by emesis or purging to remove undissolved tablets in cases of acute ingestion of a large single dose. Since enteric-coated tablets do not disintegrate in the stomach, they cannot be removed by lavage.

Rapid and immediate removal of salicylate from the body by alkaline diuresis is essential. In more severe cases, extrarenal measures such as peritoneal dialysis, hemodialysis, hemoperfusion or exchange transfusion may be required.

Dosage and Administration: The average adult dose is two tablets every 4 hours. Due to the enteric coating, tablets should not be taken within one hour of ingesting milk or antacids. For Chicken Pox or Flu, see Warnings.

How Supplied: Persian rose, enteric-coated tablets, monogrammed AHR and 5883 in bottles of 100 (NDC 0031-5883-63) and 500 (NDC 0031-5883-70).

Store at Controlled Room Temperature, Between 15°C and 30°C (59°F and 86°F).

Dispense in well-closed container.

Also Available: Pabalate® Tablets (yellow) in bottles of 100 (NDC 0031-5816-63) and 500 (NDC 0031-5816-70).

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ANALGESIC

Phenaphen® with Codeine

Description:
Each Phenaphen® with Codeine No. 2 capsule contains:
Codeine Phosphate, USP ..... 15 mg
(Warning: May be habit forming)
Acetaminophen, USP ..... 325 mg
Inactive Ingredients: Corn Starch, D&C Yellow 10, Edible Ink, FD&C Blue 1, FD&C Red 3 or 40, FD&C Yellow 6, Gelatin, Magnesium Stearate, Sodium Starch Glycolate, Stearic Acid.

Each Phenaphen® with Codeine No. 3 capsule contains:
Codeine Phosphate, USP ..... 30 mg
(Warning: May be habit forming)
Acetaminophen, USP ..... 325 mg
Inactive Ingredients: D&C Yellow 10, Edible Ink, FD&C Blue 1, (FD&C Green 3 *and* Red 40) or Red 3, FD&C Yellow 6, Gelatin, Magnesium Stearate, Sodium Starch Glycolate, Stearic Acid.

Each Phenaphen® with Codeine No. 4 capsule contains:
Codeine Phosphate, USP ..... 60 mg
(Warning: May be habit forming)
Acetaminophen, USP ..... 325 mg
Inactive Ingredients: Corn Starch, D&C Yellow 10, Edible Ink, FD&C Green 3 or Blue 1, FD&C Yellow 6, Gelatin, Lactose, Magnesium Stearate, Sodium Starch Glycolate, Stearic Acid.

Acetaminophen occurs as a white, odorless, crystalline powder possessing a slightly bitter taste. Codeine is an alkaloid, obtained from opium or prepared from morphine by methylation. Codeine phosphate occurs as fine, white, needle-shaped crystals, or white, crystalline powder. It is affected by light.

Clinical Pharmacology: ***Phenaphen with Codeine*** combines the analgesic effects of a centrally acting analgesic, codeine, with a peripherally acting analgesic, acetaminophen. Both ingredients are well absorbed orally. The plasma elimination half-life ranges from 1 to 4 hours for acetaminophen, and from 2.5 to 3 hours for codeine.

Codeine retains at least one-half of its analgesic activity when administered orally. A reduced first-pass metabolism of codeine by the liver accounts for the greater oral efficacy of codeine when compared to most other morphine-like narcotics. Following absorption, codeine is metabolized by the liver and metabolic products are excreted in the urine. Approximately 10 percent of the administered codeine is demethylated to morphine, which may account for its analgesic activity.

Acetaminophen is distributed throughout most fluids of the body, and is metabolized primarily in the liver. Little unchanged drug is excreted in the urine, but most metabolic products appear in the urine within 24 hours.

Indications and Usage: Phenaphen with Codeine capsules are indicated for the relief of mild to moderately severe pain.

Contraindications: Acetaminophen and codeine phosphate should not be administered to patients who have previously exhibited hypersensitivity to codeine or acetaminophen.

Precautions: ***General:***

Head injury and increased intracranial pressure. The respiratory depressant effects of narcotics and their capacity to elevate cerebrospinal fluid pressure may be markedly exaggerated in the presence of head injury, other intracranial lesions or a pre-existing increase in intracranial pressure. Furthermore, narcotics produce adverse reactions which may obscure the clinical course of patients with head injuries.

Acute abdominal conditions. The administration of products containing codeine or other narcotics may obscure the diagnosis or clinical course in patients with acute abdominal conditions.

Special risk patients. Acetaminophen with codeine should be given with caution to certain patients such as the elderly or debilitated, and those with severe impairment of hepatic or renal function, hypothyroidism, Addison's disease, and prostatic hypertrophy or urethral stricture.

Information for Patients. Codeine may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks such as driving a car or operating machinery. The patient taking this drug should be cautioned accordingly.

Drug Interactions. Patients receiving other narcotic analgesics, antipsychotics, anti-anxiety agents, or other CNS depressants (including alcohol) concomitantly with acetaminophen and codeine may exhibit additive CNS depression due to the codeine component. When such therapy is contemplated, the dose of one or both agents should be reduced.

The use of monoamine oxidase inhibitors or tricyclic antidepressants with codeine preparations may increase the effect of either the antidepressant or codeine.

The concurrent use of anticholinergics with codeine may produce paralytic ileus.

Carcinogenesis, Mutagenesis, Impairment of Fertility: No long-term studies in animals have been performed with acetaminophen or codeine to determine carcinogenic potential or effects on fertility.

Acetaminophen and codeine have been found to have no mutagenic potential using the Ames Salmonella-Microsomal Activation test, the Basc test on Drosophila germ cells, and the Micronucleus test on mouse bone marrow.

Teratogenic Effects: Pregnancy Category C. Codeine has been shown to be teratogenic in mice when given in doses 17 times the maximum human daily dose. There are no adequate and well controlled studies in pregnant women. Acetaminophen and codeine phosphate should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: It is not known whether the components of this drug are excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when acetaminophen with codeine is administered to a nursing woman.

Adverse Reactions: The most frequently observed adverse reactions include lightheadedness, dizziness, sedation; shortness of breath, nausea and vomiting. These effects seem to be more prominent in ambulatory than in nonambulatory patients, and some of these adverse reactions may be alleviated if the patient lies down.

Other adverse reactions include allergic reactions, euphoria, dysphoria, constipation and pruritus.

At higher doses, codeine has most of the disadvantages of morphine including respiratory depression.

Drug Abuse and Dependence: Acetaminophen and Codeine Phosphate capsules are a Schedule III controlled substance.

Codeine can produce drug dependence of the morphine type, and therefore has the potential for being abused. Psychic dependence, physical dependence and tolerance may develop upon repeated administration of this drug, and it should be prescribed and administered with the same degree of caution appropriate to the use of other oral narcotic-containing medications.

Overdosage:
Acetaminophen:

Signs and Symptoms: Acetaminophen in massive overdosage may cause hepatic toxicity in some patients. In cases of suspected overdosage you may wish to call your regional poison center for assistance in diagnosis and for directions in the use of N-acetylcysteine as an antidote.

In adults, hepatic toxicity has rarely been reported with acute overdoses of less than 10 grams and fatalities with less than 15 grams. Importantly, young children seem to be more resistant than adults to the hepatotoxic effect of an acetaminophen overdose. Despite this, the measures outlined below

should be initiated in any adult or child suspected of having ingested an acetaminophen overdose.

Early symptoms following a potentially hepatotoxic overdose may include: nausea, vomiting, diaphoresis and general malaise. Clinical and laboratory evidence of hepatic toxicity may not be apparent until 48 to 72 hours post-ingestion.

Treatment: The stomach should be emptied promptly by lavage or by induction of emesis with syrup of ipecac. Patient's estimates of the quantity of a drug ingested are notoriously unreliable. Therefore, if an acetaminophen overdose is suspected, a serum acetaminophen assay should be obtained as early as possible, but no sooner than four hours following ingestion. Liver function studies should be obtained initially and repeated at 24-hour intervals.

The antidote, N-acetylcysteine, should be administered as early as possible, preferably within 16 hours of the overdose ingestion for optimal results, but in any case, within 24 hours. Following recovery, there are no residual, structural or functional hepatic abnormalities.

Codeine:

Signs and Symptoms: Serious overdose with codeine is characterized by respiratory depression (a decrease in respiratory rate and/or tidal volume, Cheyne-Stokes respiration, cyanosis), extreme somnolence progressing to stupor or coma, skeletal muscle flaccidity, cold and clammy skin, and sometimes bradycardia and hypotension. In severe overdosage, apnea, circulatory collapse, cardiac arrest and death may occur.

Treatment: Primary attention should be given to the reestablishment of adequate respiratory exchange through provision of a patent airway and the institution of assisted or controlled ventilation. The narcotic antagonist naloxone is a specific antidote against respiratory depression which may result from overdosage or unusual sensitivity to narcotics, including codeine. Therefore, an appropriate dose of naloxone (see package insert) should be administered, preferably by the intravenous route, and simultaneously with efforts at respiratory resuscitation. Since the duration of action of codeine may exceed that of the antagonist, the patient should be kept under continued surveillance and repeated doses of the antagonist should be administered as needed to maintain adequate respiration.

An antagonist should not be administered in the absence of clinically significant respiratory or cardiovascular depression. Oxygen, intravenous fluids, vasopressors and other supportive measures should be employed as indicated.

Gastric emptying may be useful in removing unabsorbed drug.

Dosage and Administration: Dosage should be adjusted according to severity of pain and response of the patient. The usual dosage is: Adults: Codeine Phosphate 15 mg to 60 mg. Acetaminophen 325 mg to 650 mg. Children: Codeine Phosphate 0.5 mg/kg. Doses may be repeated up to every 4 hours. The usual adult dose for Phenaphen with Codeine No. 2 and Phenaphen with Codeine No. 3 is one or two capsules every 4 hours as required. The usual adult dose for Phenaphen with Codeine No. 4 is one capsule every 4 hours as required.

It should be kept in mind, however, that tolerance to codeine can develop with continued use and that the incidence of untoward effects is dose related.

Adult doses of codeine higher than 60 mg fail to give commensurate relief of pain but merely prolong analgesia and are associated with an appreciably increased incidence of undesirable side effects. Equivalently high doses in children would have similar effects.

How Supplied: ***Phenaphen with Codeine No. 2,*** black and yellow capsules in bottles of 100 (NDC 0031-6242-63) and 500 (NDC 0031-6242-70) and Dis-Co® Unit Dose Packs (4x25's) (6242-61).

Phenaphen with Codeine No. 3, black and green capsules in bottles of 100 (NDC 0031-6257-63) and 500 (NDC 0031-6257-70) and Dis-Co® Unit Dose Packs (4x25's) (6257-61).

Phenaphen with Codeine No. 4, green and white capsules in bottles of 100 (NDC 0031-6274-63) and 500 (NDC 0031-6274-70) and Dis-Co® Unit Dose Packs (4x25's) (6274-61).

Store at controlled room temperature, between 15°C and 30°C (59°F and 86°F).

Dispense capsules in tight, light-resistant container.

Rev. November 1986

Rev. April 1987
ANALGESIC

Phenaphen®-650 with Codeine (III)

(Acetaminophen and Codeine Phosphate Tablets)

Description:
Each Phenaphen®-650 with Codeine tablet contains:
Codeine Phosphate, USP ..... 30 mg
(Warning: May be habit forming)
Acetaminophen, USP ..... 650 mg
Inactive Ingredients: Calcium Sulfate, Corn Starch, Microcrystalline Cellulose, Polyethylene Glycol, Povidone, Silicon Dioxide, Sodium Bisulfite, Sodium Starch Glycolate, Stearic Acid.

Acetaminophen occurs as a white, odorless, crystalline powder, possessing a slightly bitter taste. Codeine is an alkaloid, obtained from opium or prepared from morphine by methylation. Codeine phosphate occurs as fine, white, needle-shaped crystals, or white, crystalline powder. It is affected by light.

Clinical Pharmacology: Phenaphen-650 with Codeine combines the analgesic effects of a centrally acting analgesic, codeine, with a peripherally acting analgesic, acetaminophen. Both ingredients are well absorbed orally. The plasma elimination half-life ranges from 1 to 4 hours for acetaminophen, and from 2.5 to 3 hours for codeine.

Codeine retains at least one-half of its analgesic activity when administered orally. A reduced first-pass metabolism of codeine by the liver accounts for the greater oral efficacy of codeine when compared to most other morphine-like narcotics. Following absorption, codeine is metabolized by the liver and metabolic products are excreted in the urine. Approximately 10 percent of the administered codeine is demethylated to morphine, which may account for its analgesic activity.

Acetaminophen is distributed throughout most fluids of the body, and is metabolized primarily in the liver. Little unchanged drug is excreted in the urine, but most metabolic products appear in the urine within 24 hours.

Indications and Usage: Phenaphen-650 with Codeine Tablets are indicated for the relief of mild to moderately severe pain.

Contraindications: Acetaminophen and codeine phosphate should not be administered to patients who have previously exhibited hypersensitivity to codeine or acetaminophen.

Warnings: Contains sodium bisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in nonasthmatic people.

Precautions: *General:*

Head Injury and increased intracranial pressure. The respiratory depressant effects of narcotics and their capacity to elevate cerebrospinal fluid pressure may be markedly exaggerated in the presence of head injury, other intracranial lesions or a pre-existing increase in intracranial pressure. Furthermore, narcotics produce adverse reactions which may obscure the clinical course of patients with head injuries.

Acute abdominal conditions. The administration of this product or other narcotics may obscure the diagnosis or clinical course in patients with acute abdominal conditions.

Special risk patients. This drug should be given with caution to certain patients such as the elderly or debilitated, and those with severe impairment of hepatic or renal function, hypothyroidism, Addison's disease, and prostatic hypertrophy or urethral stricture.

Information for Patients. Codeine may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks such as driving a car or operating machinery. The patient using this drug should be cautioned accordingly.

Drug Interactions. Patients receiving other narcotic analgesics, antipsychotics, anti-anxiety agents, or other CNS depressants (including alcohol) concomitantly with acetaminophen and codeine phosphate may exhibit additive CNS depression due to the codeine component. When such therapy is contemplated, the dose of one or both agents should be reduced.

The use of monoamine oxidase inhibitors or tricyclic antidepressants with codeine preparations may increase the effect of either the antidepressant or codeine.

The concurrent use of anticholinergics with codeine may produce paralytic ileus.

Carcinogenesis, Mutagenesis, Impairment of Fertility: No long-term studies in animals have been performed with acetaminophen or codeine to determine carcinogenic potential or effects on fertility.

Acetaminophen and codeine have been found to have no mutagenic potential using the Ames Salmonella-Microsomal Activation test, the Basc test on Drosophila germ cells, and the Micronucleus test on mouse bone marrow.

Teratogenic Effects: Pregnancy Category C: Codeine has been shown to be teratogenic in mice when given in doses 17 times the maximum human daily dose. There are no adequate and well controlled studies in pregnant women. Acetaminophen and codeine phosphate should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers. It is not known whether the components of this drug are excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when acetaminophen with codeine phosphate is administered to a nursing woman.

Adverse Reactions: The most frequently observed adverse reactions include lightheadedness, dizziness, sedation; shortness of breath, nausea and vomiting. These effects seem to be more prominent in ambulatory than nonambulatory patients, and some of these adverse reactions may be alleviated if the patient lies down.

Other adverse reactions include allergic reactions, euphoria, dysphoria, constipation and pruritus.

At higher doses, codeine has most of the disadvantages of morphine including respiratory depression.

Drug Abuse and Dependence: Phenaphen-650 with Codeine Tablets are a Schedule III controlled substance.

Codeine can produce drug dependence of the morphine type, and, therefore, has the potential for being abused. Psychic dependence, physical dependence and tolerance may develop upon repeated administration of this drug and it should be prescribed and administered with the same degree of caution appropriate to the use of other oral narcotic medications.

Overdosage:
Acetaminophen:

Signs and Symptoms: Acetaminophen in massive overdosage may cause hepatic toxicity in some patients. In all cases of suspected overdose, you may wish to call your regional poison center for assistance in diagnosis and for directions in the use of N-acetylcysteine as an antidote.

In adults, hepatic toxicity has rarely been reported with acute overdoses of less than 10 grams and fatalities with less than 15 grams. Importantly, young children seem to be more resistant than adults to the hepatotoxic effect of an acetaminophen overdose. Despite this, the measures outlined below should be initiated in any adult or child suspected of having ingested an acetaminophen overdose.

Early symptoms following a potentially hepatotoxic overdose may include: nausea, vomiting, diaphoresis and general malaise. Clinical and laboratory evidence of hepatic toxicity may not be apparent until 48 to 72 hours post-ingestion.

Treatment: The stomach should be emptied promptly by lavage or by induction of emesis with syrup of ipecac. Patient's estimates of the quantity of a drug ingested are notoriously unreliable. Therefore, if an acetaminophen overdose is suspected, a serum acetaminophen assay should be obtained as early as possible, but no sooner than four hours following ingestion. Liver function studies should be obtained initially and repeated at 24-hour intervals.

The antidote, N-acetylcysteine, should be

administered as early as possible, preferably within 16 hours of the overdose ingestion for optimal results, but in any case, within 24 hours. Following recovery, there are no residual, structural or functional hepatic abnormalities.

Codeine:

Signs and Symptoms: Serious overdose with codeine is characterized by respiratory depression (a decrease in respiratory rate and/or tidal volume, Cheyne-Stokes respiration, cyanosis), extreme somnolence progressing to stupor or coma, skeletal muscle flaccidity, cold and clammy skin, and sometimes bradycardia and hypotension. In severe overdosage, apnea, circulatory collapse, cardiac arrest and death may occur.

Treatment: Primary attention should be given to the reestablishment of adequate respiratory exchange through provision of a patent airway and the institution of assisted or controlled ventilation. The narcotic antagonist naloxone is a specific antidote against respiratory depression which may result from overdosage or unusual sensitivity to narcotics, including codeine. Therefore, an appropriate dose of naloxone (see package insert) should be administered, preferably by the intravenous route, and simultaneously with efforts at respiratory resuscitation. Since the duration of action of codeine may exceed that of the antagonist, the patient should be kept under continued surveillance and repeated doses of the antagonist should be administered as needed to maintain adequate respiration.

An antagonist should not be administered in the absence of clinically significant respiratory or cardiovascular depression. Oxygen, intravenous fluids, vasopressors and other supportive measures should be employed as indicated.

Gastric emptying may be useful in removing unabsorbed drug.

Dosage and Administration: Dosage should be adjusted according to severity of pain and response of the patient.

The usual dosage is:

Adults: Codeine Phosphate 15 mg to 60 mg; Acetaminophen 325 mg to 650 mg

Children: Codeine Phosphate 0.5 mg/kg.

Doses may be repeated up to every 4 hours. It should be kept in mind, however, that tolerance to codeine can develop with continued use and that the incidence of untoward effects is dose related. Adult doses of codeine higher than 60 mg fail to give commensurate relief of pain but merely prolong analgesia and are associated with an appreciably increased incidence of undesirable side effects. Equivalently high doses in children would have similar effects.

How Supplied: ***Phenaphen-650 with Codeine*** is available as a scored, white, capsule-shaped compressed tablet, engraved AHR and 6251 in bottles of 50 (NDC 0031-6251-60).

Store at controlled room temperature, between 15°C and 30°C (59°F and 86°F).

Dispense tablets in tight, light-resistant container.

Rev. April 1987

Rev. July 1987

Pondimin®

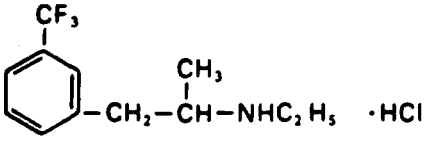
brand of

Fenfluramine Hydrochloride Tablets–20 mg

Description: Pondimin (fenfluramine hydrochloride) is an anorectic drug for oral administration. Immediate release tablets containing 20 mg fenfluramine hydrochloride are orange, scored, compressed tablets engraved AHR and 6447.

Inactive Ingredients: Corn Starch, FD&C Yellow 6, Magnesium Stearate, Microcrystalline Cellulose, Silicon Dioxide, Sodium Lauryl Sulfate.

Pondimin has the following chemical structure and name:



N-ethyl-α-methyl-3-(trifluoromethyl) benzeneethanamine hydrochloride

Clinical Pharmacology: Fenfluramine is a sympathomimetic amine, the pharmacologic activity of which differs somewhat from that of the prototype drugs of this class used in obesity, the amphetamines, in appearing to produce more central nervous system depression than stimulation.

The mechanism of action of Pondimin is unclear but may be related to brain levels (or turnover rates) of serotonin or to increased glucose utilization. The antiappetite effects of Pondimin are suppressed by serotonin-blocking drugs and by drugs that lower brain levels of the amine. Furthermore, decreased serotonin levels produced by selective brain lesions suppress the action of Pondimin.

In a study of 20 normal males, fenfluramine increased glucose utilization, resulting in decreased blood glucose levels. Experimental work in animals suggested that increased glucose utilization activated the satiety center and decreased the activity of the feeding center. Perhaps by this mechanism Pondimin inhibits appetite. The relationship between glucose utilization and serotonin has not been clarified.

Fenfluramine is well-absorbed from the gastrointestinal tract, and a maximal anorectic effect is generally seen after 2 to 4 hours. In man, fenfluramine is de-ethylated to norfenfluramine which is subsequently oxidized to m-trifluoromethyl benzoic acid and excreted as the glycine conjugate, m-trifluoromethylhippuric acid. Other compounds found in the urine include unchanged fenfluramine and norfenfluramine.

The rate of excretion of fenfluramine is pH dependent, with much smaller amounts appearing in an alkaline than in an acid urine.

The half-life of fenfluramine is said to be about 20 hours, compared with 5 hours for amphetamines; however, if urinary excretion is rapid and the pH maintained in the acidic range (below pH 5), half-life can be reduced to 11 hours. Fenfluramine and norfenfluramine reach steady state concentrations in plasma within 3 to 4 days following chronic dosage.

The greatest weight loss is seen in those patients who maintain the highest levels of Pondimin. A 2-to-3-kg weight loss over 6 weeks is associated with a plasma level of 0.1 mcg/mL (or 10 mcg/100 mL).

Fenfluramine is widely distributed in almost all body tissues. It is soluble in lipids and crosses the blood-brain barrier. Fenfluramine crosses the placenta readily in monkeys.

Indications and Usage: Pondimin is indicated in the management of exogenous obesity as a short-term (a few weeks) adjunct in a regimen of weight reduction based on caloric restriction.

Drugs of this class used in obesity are commonly known as "anorectics" or "anorexigenics." It has not been established, however, that the action of such drugs in treating obesity is primarily one of appetite suppression. Other central nervous system actions or metabolic effects may be involved.

Adult obese subjects instructed in dietary management and treated with "anorectic" drugs, lose more weight on the average than those treated with placebo and diet, as determined in relatively short-term trials.

The average magnitude of increased weight loss of drug-treated patients over placebo-treated is only a fraction of a pound a week. The rate of weight loss is greatest in the first weeks of therapy for both drug and placebo subjects and tends to decrease in succeeding weeks. The possible origins of the increased weight loss due to the various drug effects are not established. The average amount of weight loss associated with the use of an "anorectic" drug varies from trial to trial, and the increased weight loss appears to be related in part to variables other than the drug prescribed such as the physician-investigator, the population treated and the diet prescribed. Studies do not permit conclusions as to the relative importance of the drug and non-drug factors on weight loss.

The natural history of obesity is measured in years, whereas the studies cited are restricted to a few weeks duration; thus, the total impact of drug-induced weight loss over that of diet alone must be considered clinically limited.

Contraindications: Fenfluramine is contraindicated in patients with glaucoma or with hypersensitivity to fenfluramine or other sympathomimetic amines. Do not administer fenfluramine during or within 14 days following the administration of monoamine oxidase inhibitors, since hypertensive crises may result. Patients with a history of drug abuse should not receive this drug.

Do not administer fenfluramine to patients with alcoholism since psychiatric symptoms (paranoia, depression, psychosis) have been reported in a few such patients who had been administered this drug.

Fenfluramine should also generally be avoided in patients with psychotic illness. There have been reports of schizophrenic patients who have become agitated, delusional, and assaultive.

A fatal cardiac arrest has been reported shortly after the induction of anesthesia in a patient who had been taking fenfluramine prior to surgery. Fenfluramine may have a catecholamine-depleting effect when administered for prolonged periods of time; therefore, potent anesthetic agents should be administered with caution to patients taking fenfluramine. If general anesthesia cannot be avoided, full cardiac monitoring and facilities for instant resuscitative measures are a minimum necessity.

Warnings: When tolerance to the "anorectic" effect develops, the maximum recommended dose should not be exceeded in an attempt to increase the effect; rather, the drug should be discontinued.

Precautions: ***General.*** Fenfluramine differs in its pharmacological profile from other "anorectic" drugs with which the prescribing practitioner may be familiar. Correspondingly, there are possible adverse effects not associated with other "anorectics"; such effects include those of diarrhea, sedation, and depression. The possibility of these effects should be weighed against the possible advantage of decreased central nervous system stimulation and/or abuse potential.

There have been four cases of pulmonary hypertension reported in association with fenfluramine use. Two cases were apparently reversible after discontinuation of fenfluramine, but evidence of pulmonary hypertension recurred in one of these patients upon rechallenge with fenfluramine. A third patient was initially improved with nifedipine treatment, but was noted to have increased pulmonary arterial pressure again at a four month follow up visit. Finally, an irreversible and fatal case of pulmonary hypertension has been reported in a patient who had seven 1-month courses of fenfluramine in the twelve years prior to death. Patients taking fenfluramine should be advised to report immediately any deterioration in exercise tolerance.

Use only with caution in hypertension, with monitoring of blood pressure, since evidence is insufficient to rule out a possible adverse effect on blood pressure in some hypertensive patients. The drug is not recommended in severely hypertensive patients. The drug is not recommended for patients with symptomatic cardiovascular disease including arrhythmias.

Caution should be exercised in prescribing fenfluramine for patients with a history of mental depression. Further depression of mood may become evident while the patient is on fenfluramine or following withdrawal of fenfluramine. Symptoms of depression occurring immediately following abrupt withdrawal can be readily controlled by reinstituting Pondimin, followed by a gradual tapering off of the daily dose.

Information for Patients. Fenfluramine may impair the ability of the patient to engage in potentially hazardous activities such as operating machinery or driving a motor vehicle (see "Adverse Reactions"); the patient should be cautioned accordingly. Patient should also be advised to avoid alcoholic beverages while taking Pondimin.

Drug Interactions. Fenfluramine may increase slightly the effect of antihypertensive drugs, e.g., guanethidine, methyldopa.

serpine.

Other CNS depressant drugs should be used with caution in patients taking fenfluramine, since the effects may be additive.

Carcinogenesis, Mutagenesis. No carcinogenic studies or mutagenic studies have been undertaken with this drug.

Pregnancy Category C. Pondimin was shown to produce a questionable embryotoxic effect in rats and a reduced conception rate when given in a dose of 20 times the human dose. However, additional reproduction studies in rats, rabbits, mice, and monkeys at doses up to, respectively, 5 times, 20 times, 1 time, and 5 times the human dose yielded negative results.

There are no adequate and well-controlled studies in pregnant women. Pondimin should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Labor and Delivery. The effect of fenfluramine during labor or delivery on the mother and the fetus is unknown. The effect on later growth, development, and functional maturation of the child is unknown.

Nursing Mothers. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when fenfluramine is administered to a nursing mother.

Pediatric Use. Safety and effectiveness in children below the age of 12 years have not been established.

Adverse Reactions: The most common adverse reactions of fenfluramine are drowsiness, diarrhea, and dry mouth. Less frequent adverse reactions reported in association with fenfluramine are:

Central nervous system. Dizziness; confusion; incoordination; headache; elevated mood, depression; anxiety, nervousness, or tension; insomnia; weakness or fatigue; increased or decreased libido; agitation; dysarthria.

Gastrointestinal. Constipation; abdominal pain; nausea.

Autonomic. Sweating; chills; blurred vision.

Genitourinary. Dysuria; urinary frequency.

Cardiovascular. Palpitation; hypotension, hypertension; fainting; pulmonary hypertension.

Skin. Rash; urticaria; burning sensation.

Miscellaneous. Eye irritation; myalgia, fever; chest pain; bad taste.

Drug Abuse and Dependence: Pondimin (fenfluramine hydrochloride) is a controlled substance in Schedule IV. Fenfluramine is related chemically to the amphetamines, although it differs somewhat pharmacologically. The amphetamines and related stimulant drugs have been extensively abused and can produce tolerance and severe psychological dependence, as well as other adverse organic and mental changes. In this regard, there has been a report of abuse of fenfluramine by subjects with a history of abuse of other drugs. Abuse of 80 to 400 milligrams of the drug has been reported to be associated with euphoria, derealization, and perceptual changes. Fenfluramine did not produce signs of dependence in animals and appears to produce sedation more often than CNS stimulation at therapeutic doses. Its abuse potential appears qualitatively different from that of amphetamines. The possibility that fenfluramine may induce dependence should be kept in mind when evaluating the desirability of including the drug in the weight reduction programs of individual patients.

Overdosage: ***Signs and Symptoms:*** Only limited data have been reported concerning clinical effects and management of overdosage of fenfluramine.

Agitation and drowsiness, confusion, flushing, tremor (or shivering), fever, sweating, abdominal pain, hyperventilation and dilated non-reactive pupils seem frequent in fenfluramine overdosage. Reflexes may be either exaggerated or depressed and some patients may have rotary nystagmus. Tachycardia may be present, but blood pressure may be normal or only slightly elevated. Convulsions, coma, and ventricular extrasystoles, culminating in ventricular fibrillation, and cardiac arrest, may occur at higher dosages.

Human Toxicity. Less than 5 mg/kg are toxic to humans. Five-ten mg/kg may produce coma and convulsions. Reported single overdoses have ranged from 300 to 2000 mg, the lowest reported fatal dose was a few hundred mg in a small child, and the highest reported nonfatal dose was 1800 mg in an adult. Most deaths were apparently due to respiratory failure and cardiac arrest.

Toxic effects will appear within 30 to 60 minutes and may progress rapidly to potentially fatal complications in 90 to 240 minutes. Symptoms may persist for extended periods depending upon the dose ingested.

Management. After overdosage, only a small percentage of the drug is excreted in the urine. Forced acid diuresis has been recommended only in extreme cases in which the patient survives the early hours of intoxication but fails to show decisive improvement from other measures. Hemodialysis and peritoneal dialysis are of theoretical advantage but have not been used clinically.

Reportedly the treatment of fenfluramine intoxication should include:

- ***Gastric lavage*** (but not drug-induced emesis because the patient may become unconscious at a very early stage.)
- In the event that gastric lavage is not feasible due to trismus, consult an anesthesiologist for endotracheal intubation after administration of muscle relaxants; only then gastric evacuation should be tried.
- Administration of activated charcoal after emesis or lavage may reduce absorption of drug.
- ***Monitoring of vital functions.*** If necessary, mechanical respiration, defibrillation, or "cardioversion" should be instituted.
- ***Drug therapy.*** Diazepam or phenobarbital for convulsions or muscular hyperactivity. In the presence of extreme tachycardia: propranolol; in the presence of ventricular extrasystoles: lidocaine; in the presence of hyperpyrexia: chlorpromazine.

Since fenfluramine has been shown to have a slight lowering effect on blood sugar in some patients, the theoretical possibility of hypoglycemia should be borne in mind although this effect has not been reported in cases of clinical overdosage.

Dosage and Administration: The usual dose is one 20 mg tablet three times daily before meals. Depending on the degree of effectiveness and side effects, the dosage may be increased at weekly intervals by one tablet (20 mg) daily until a maximum dosage of two tablets three times daily is attained. Total dosage of fenfluramine should not exceed 120 mg per day.

How Supplied: Pondimin is available in 20 mg orange, scored, compressed tablets monogrammed AHR and 6447, in bottles of 100 (NDC 0031-6447-63) and 500 (NDC 0031-6447-70).

Store at controlled room temperature, between 15°C and 30° (59°F and 86°F).

Dispense in well-closed container.

Rev. July 1987

Rev. October 1987

Quinidex Extentabs®

brand of

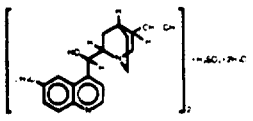
Quinidine Sulfate Extended-release Tablets, USP

300 mg in each Quinidex Extentabs tablet.

Description: Quinidex Extentabs (quinidine sulfate extended-release tablets) are constructed to release one-third of their alkaloidal salt, quinidine sulfate (100 mg), on reaching the stomach, to begin absorption in the upper intestinal tract. The remaining two-thirds of the active drug (200 mg) is evenly distributed throughout a homogeneous core which slowly dissolves as it moves along the intestinal tract, releasing the quinidine sulfate for continuous absorption over an 8–12 hour period.

Each Quinidex Extentabs tablet contains 300 mg of quinidine sulfate, the equivalent of 248.6 mg of the anhydrous quinidine alkaloid.

Chemically, quinidine sulfate is cinchonan-9-ol,6'-methoxy-,(9s)-sulfate(2:1) (salt) dihydrate.



Inactive Ingredients: Acacia, Acetylated Monoglycerides, Calcium Sulfate, Carnauba Wax, Edible Ink, FD&C Blue 2, Gelatin, Guar Gum, Magnesium Oxide, Magnesium Stearate, Polysorbates, Shellac, Sucrose, Titanium Dioxide, White Wax and other ingredients, one of which is a corn derivative. May contain FD&C Red 40 and Yellow 6 Aluminum Lakes.

Action: The action of quinidine in preventing aberrant cardiac rhythms of atrial and ventricular origin resides in its ability to (a) depress excitability of cardiac muscle, (b) slow the rate of spontaneous rhythm, (c) decrease vagal tone, and (d) prolong conduction and effective refractory period.

Indications and Usage: Quinidex Extentabs are indicated for the treatment of:

- Premature atrial and ventricular contractions.
- Paroxysmal atrial tachycardia.
- Paroxysmal A-V junctional rhythm.
- Atrial flutter.
- Paroxysmal atrial fibrillation.
- Established atrial fibrillation when therapy is appropriate.
- Paroxysmal ventricular tachycardia when not associated with complete heartblock.
- Maintenance therapy after electrical conversion of atrial fibrillation and/or flutter.

Contraindications: Intraventricular conduction defects. Complete A-V block. A-V conduction disorders caused by digitalis intoxication. Aberrant impulses and abnormal rhythms due to escape mechanisms. Idiosyncrasy or hypersensitivity to quinidine or related cinchona derivatives. Myasthenia gravis.

Warnings: In the treatment of atrial flutter, reversion to sinus rhythm may be preceded by a progressive reduction in the degree of A-V block to a 1:1 ratio, resulting in an extremely rapid ventricular rate. This possible hazard may be reduced by digitalization prior to administration of quinidine.

Reports in the literature indicate that serum concentrations of digoxin may increase and may even double when quinidine is administered concurrently. Patients on concomitant therapy should be carefully monitored for digitalis toxicity. Reduction of digoxin dosage may have to be considered.

Manifestations of quinidine cardiotoxicity such as excessive prolongation of the QT interval, widening of the QRS complex and ventricular tachyarrhythmias mandate immediate discontinuation of the drug and/or close clinical and electrocardiographic monitoring.

In susceptible individuals, such as those with marginally compensated cardiovascular disease, quinidine may produce clinically important depression of cardiac function manifested by hypotension, bradycardia, or heartblock. Quinidine therapy should be carefully monitored in such individuals.

Quinidine should be used with extreme caution in patients with incomplete AV block since complete AV block and asystole may be produced. Quinidine may cause abnormalities of cardiac rhythm in digitalized patients and therefore should be used with caution in the presence of digitalis intoxication.

Quinidine should be used with caution in patients exhibiting renal, cardiac or hepatic insufficiency because of potential accumulation of quinidine in serum, leading to toxicity.

Patients taking quinidine occasionally have syncopal episodes which usually result from ventricular tachycardia or fibrillation. This syndrome has not been shown to be related to dose or serum levels. Syncopal episodes frequently terminate spontaneously or in response to treatment, but sometimes are fatal.

Cases of hepatotoxicity, including granulomatous hepatitis, due to quinidine hypersensitivity have been reported. Unexplained fever and/or elevation of hepatic enzymes, particularly in the early stages of therapy, warrant consideration of possible hepatotoxicity. Monitoring liver function during the first 4–8 weeks should be considered. Cessation of quinidine in these cases usually results in the disappearance of toxicity.

Precautions: *General*—All the precautions applying to regular quinidine therapy apply to this product. Hypersensitivity or anaphylactoid reactions to quinidine, although rare, should be considered, especially during the first weeks of therapy. Hospitalization for close clinical observation, electrocardiographic monitoring, and determination of serum quinidine levels are indicated when large doses of quinidine are used or with patients who present an increased risk.

Information for Patients—As with all solid dosage medications, Quinidex Extentabs should be taken with an adequate amount of fluid, preferably with the patient in an upright position to facilitate swallowing. They should be swallowed whole in order to preserve the controlled-release mechanism.

Laboratory Tests—Periodic blood counts and liver and kidney function tests should be performed during long-term therapy; the drug should be discontinued if blood dyscrasias or evidence of hepatic or renal dysfunction occurs.

Drug Interactions

Drug	Effect
Quinidine with anticholinergic drugs	Additive vagolytic effect
Quinidine with cholinergic drugs	Antagonism of cholinergic effects
Quinidine with carbonic anhydrase inhibitors, sodium bicarbonate, thiazide diuretics	Alkalinization of urine resulting in decreased excretion of quinidine
Quinidine with coumarin anticoagulants	Reduction of clotting factor concentrations
Quinidine with tubocurare, succinylcholine and decamethonium	Potentiation of neuromuscular blockade
Quinidine with phenothiazines and reserpine	Additive cardiac depressive effects
Quinidine with hepatic enzyme inducing drugs (phenobarbital, phenytoin, rifampin)	Decreased plasma half-life of quinidine
Quinidine with digoxin	Increased serum concentration of digoxin (See Warnings)
Quinidine with amiodarone	Increased serum concentration of quinidine
Quinidine with cimetidine	Prolonged quinidine half-life and an increase in serum quinidine level
Quinidine with ranitidine	Premature ventricular contractions and/or bigeminy
Quinidine with verapamil	Increased quinidine half-life and an increase in serum quinidine level, potential hypotensive reactions
Quinidine with nifedipine	Decreased serum concentrations of quinidine

Carcinogenesis: Studies in animals have not been performed to evaluate the carcinogenic potential of quinidine.

Pregnancy, Teratogenic Effects: Pregnancy Category C. Animal reproduction studies have not been conducted with quinidine. There are no adequate and well-controlled studies in pregnant women. Quinidex Extentabs should be administered to a pregnant woman only if clearly indicated.

Nonteratogenic Effects: Like quinine, quinidine has been reported to have oxytocic properties. The significance of this property in the clinical setting has not been established.

Labor and Delivery—There is no known use for Quinidex Extentabs in labor and delivery. However, quinidine has been reported to have oxytocic properties. The significance of this property in the clinical setting has not been established.

Nursing Mothers—Because of passage of the drug into breast milk, caution should be exercised when Quinidex Extentabs are administered to a nursing woman.

Pediatric Use—There are no adequate and well-controlled studies establishing the safety and effectiveness of Quinidex Extentabs in children.

Adverse Reactions: Symptoms of cinchonism, such as ringing in the ears, loss of hearing, dizziness, lightheadedness, headache, nausea, and/or disturbed vision may appear in sensitive patients after a single dose of the drug. The most frequently encountered side effects to quinidine are gastrointestinal

(Quinidex Extentabs, continued)

Gastrointestinal—Nausea, vomiting, abdominal pain, diarrhea, anorexia, granulomatous hepatitis (which may be preceded by fever), esophagitis.

Cardiovascular—Ventricular extrasystoles occurring at a rate of one or more every 6 normal beats, widening of the QRS complex and prolonged QT interval, complete A-V block, ventricular tachycardia and fibrillation; ventricular flutter, torsade de pointes; arterial embolism; hypotension; syncope.

Central Nervous System—Headache, vertigo, apprehension, excitement, confusion, delirium, dementia, ataxia, depression.

Ophthalmologic and Otologic—Disturbed hearing (tinnitus, decreased auditory acuity), disturbed vision (mydriasis, blurred vision, disturbed color perception, photophobia, diplopia, night blindness, scotomata), optic neuritis, reduced visual field.

Dermatologic—Cutaneous flushing with intense pruritus, photosensitivity, urticaria, rash, eczema, exfoliative eruptions, psoriasis, abnormalities of pigmentation.

Hypersensitivity—Angioedema, acute asthmatic episode, vascular collapse, respiratory arrest, hepatotoxicity, granulomatous hepatitis (See Warnings), purpura, vasculitis

Hematologic—Thrombocytopenia, thrombocytopenic purpura, agranulocytosis, acute hemolytic anemia, hypoprothrombinemia, leukocytosis, shift to left in WBC differential, neutropenia.

Immunologic—Systemic lupus erythematosus, lupus nephritis

Miscellaneous—Fever, increase in serum skeletal muscle creatine phosphokinase, arthralgia, myalgia.

Overdosage: ***Symptoms***—Overdosage of quinidine can lead to accelerated idioventricular rhythm, morphologic appearance of QRS complexes, prolonged QT intervals, intermittent sinus capture beats, paroxysms of tachycardia, ventricular arrhythmias, hypotension, oliguria, respiratory depression, pulmonary edema, acidosis, seizures, and coma.

Treatment—Early treatment to empty the stomach using syrup of ipecac and/or gastric lavage is recommended. Since Quinidex Extentabs cannot be removed through a nasogastric tube, gastric lavage should be followed by saline cathartics. Administration of activated charcoal may reduce absorption. Other general supportive measures should be employed as indicated by patient response. In severe cases, circulation should be stabilized and measurements of pulmonary capillary wedge pressure should be performed to assure adequate left ventricular filling pressure. Electrolyte and blood gas abnormalities should be corrected. In quinidine-induced vasodilation, catecholamines and other alpha-adrenergic agonists may be tried. Arrhythmias may be treated with lidocaine, pacing, and cardioversion. Administration of sodium lactate reportedly reduces the cardiotoxicity of quinidine, however, sodium lactate is contraindicated in the presence of alkalosis as increased urinary pH can lead to an increase in the renal tubular absorption of quinidine. Acidification of the urine may enhance the urinary excretion of quinidine.

Dosage and Administration: One or two Quinidex Extentabs tablets every 8 to 12 hours as may be required to achieve the desired therapeutic effect.

How Supplied: White, sugar-coated Extentabs tablets, monogrammed QUINIDEX and AHR, in bottles of 100 (NDC 0031-6649-63) and 250 (NDC 0031-6649-67), and Dis-Co® Unit Dose packs of 100 (NDC 0031-6649-64)

Store at controlled room temperature between 15°C and 30°C (59°F and 86°F). Dispense in well-closed, light-resistant container.

Rev. October 1987

Rev. July 1987

Reglan®

(Metoclopramide Hydrochloride)

Tablets, Syrup and Injectable

Description: For oral administration, Reglan (metoclopramide hydrochloride) Tablets and Syrup are available. **Reglan Tablets 10 mg** are pink, scored, capsule-shaped tablets engraved Reglan on one side and AHR 10 on the opposite side.

Each tablet contains:

Metoclopramide base 10 mg
(as the monohydrochloride monohydrate)

Inactive Ingredients: FD&C Red 3 Aluminum Lake, FD&C Yellow 6 Aluminum Lake, Magnesium Stearate, Mannitol, Microcrystalline Cellulose, Stearic Acid.

Reglan Tablets 5 mg are green, elliptical-shaped tablets engraved Reglan 5 on one side and AHR on the opposite side.

Each tablet contains:

Metoclopramide base 5 mg
(as the monohydrochloride monohydrate)

Inactive Ingredients: Corn Starch, D&C Yellow 10 Lake, FD&C Blue 1 Aluminum Lake, Lactose, Microcrystalline Cellulose, Silicon Dioxide, Stearic Acid.

Reglan Syrup is an orange-colored, palatable, aromatic, sugar-free liquid.

Each 5 mL (1 teaspoonful) contains:

Metoclopramide base 5 mg
(as the monohydrochloride monohydrate)

Inactive Ingredients: Citric Acid, FD&C Yellow 6, Flavors, Glycerin, Methylparaben, Propylparaben, Sorbitol, Water.

Reglan Injectable is a clear, colorless, sterile solution with a pH of 4.5–6.5 for intravenous or intramuscular administration.

SINGLE DOSE VIALS AND AMPULS WHICH CONTAIN NO PRESERVATIVE.

2 mL and 10 mL **single dose** vials/ampuls; 30 mL **single dose** vial

Each 1 mL contains:

Metoclopramide base 5 mg
(as the monohydrochloride monohydrate)

Sodium Chloride, USP 8.5 mg, Water for Injection, USP q.s.

pH adjusted, when necessary, with hydrochloric acid and/or sodium hydroxide.

1 mL AND 2 mL STERILE SYRINGES CONTAINING BENZYL ALCOHOL: NOT FOR USE IN NEWBORNS.

Each 1 mL contains:

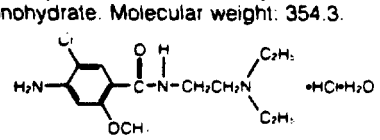
Metoclopramide base 10 mg
(as the monohydrochloride monohydrate)

Sodium Chloride, USP 5 mg, Water for Injection, USP q.s.

Benzyl Alcohol, NF 0.9% (preservative).

pH adjusted when necessary with hydrochloric acid and/or sodium hydroxide.

Metoclopramide hydrochloride is a white crystalline, odorless substance, freely soluble in water. Chemically, it is 4-amino-5-chloro-N-[2-(diethylamino)ethyl]-2-methoxy benzamide monohydrochloride monohydrate. Molecular weight: 354.3.



Clinical Pharmacology: Metoclopramide stimulates motility of the upper gastrointestinal tract without stimulating gastric, biliary, or pancreatic secretions. Its mode of action is unclear. It seems to sensitize tissues to the action of acetylcholine. The effect of metoclopramide on motility is not dependent on intact vagal innervation, but it can be abolished by anticholinergic drugs.

Metoclopramide increases the tone and amplitude of gastric (especially antral) contractions, relaxes the pyloric sphincter and the duodenal bulb, and increases peristalsis of the duodenum and jejunum resulting in accelerated gastric emptying and intestinal transit. It increases the resting tone of the lower esophageal sphincter. It has little, if any effect on the motility of the colon or gallbladder.

In patients with gastroesophageal reflux and low LESP (lower esophageal sphincter pressure), single oral doses of metoclopramide produce dose-related increases in LESP. Effects begin at about 5 mg and increase through 20 mg (the largest dose tested). The increase in LESP from a 5 mg dose lasts about 45 minutes and that of 20 mg lasts between 2 and 3 hours. Increased rate of stomach emptying has been observed with single oral doses of 10 mg.

The antiemetic properties of metoclopramide appear to be a result of its antagonism of central and peripheral dopamine receptors. Dopamine produces nausea and vomiting by stimulation of the medullary chemoreceptor trigger zone (CTZ), and metoclopramide blocks stimulation of the CTZ by agents like l-dopa or apomorphine which are known to increase dopamine levels or to possess dopamine-like effects. Metoclopramide also abolishes the slowing of gastric emptying caused by apomorphine.

Like the phenothiazines and related drugs, which are also dopamine antagonists, metoclopramide produces sedation and may produce extrapyramidal reactions, although these are comparatively rare (See Warnings). Metoclopramide inhibits the central and peripheral effects of apomorphine, induces release of prolactin and causes a transient increase in circulating aldosterone levels, which may be associated with transient fluid retention.

The onset of pharmacological action of metoclopramide is 1 to 3 minutes following an intravenous dose, 10 to 15 minutes following intramuscular administration, and 30 to 60 minutes following an oral dose; pharmacological effects persist for 1 to 2 hours.

Pharmacokinetics: Metoclopramide is rapidly and well absorbed. Relative to an intravenous dose of 20 mg, the absolute oral bioavailability of metoclopramide is 80% ± 15.5% as demonstrated in a crossover study of 18 subjects. Peak plasma concentrations occur at about 1–2 hr after a single oral dose. Similar time to peak is observed after individual doses at steady state.

In a single dose study of 12 subjects the area under the drug concentration-time curve increases linearly with doses from 20 to 100 mg. Peak concentrations increase linearly with dose; time to peak concentrations remains the same; whole body clearance is unchanged; and the elimination rate remains the same. The average elimination half-life in individuals with normal renal function is 5–6 hr. Linear kinetic processes adequately describe the absorption and elimination of metoclopramide.

Approximately 85% of the radioactivity of an orally administered dose appears in the urine within 72 hr. Of the 85% eliminated in the urine, about half is present as free or conjugated metoclopramide.

The drug is not extensively bound to plasma proteins (about 30%). The whole body volume of distribution is high (about 3.5 L/kg) which suggests extensive distribution of drug to the tissues.

Renal impairment affects the clearance of metoclopramide. In a study with patients with varying degrees of renal impairment, a reduction in creatinine clearance was correlated with a reduction in plasma clearance, renal clearance, non-renal clearance, and increase in elimination half-life. The kinetics of metoclopramide in the presence of renal impairment remained linear however. The reduction in clearance as a result of renal impairment suggests that adjustment downward of maintenance dosage should be done to avoid drug cumulation.

Indications and Usage: ***Symptomatic gastroesophageal reflux:*** Reglan Tablets and Syrup are indicated for short-term (4 to 12 weeks) therapy for adults with symptomatic, documented gastroesophageal reflux who fail to respond to conventional therapy.

The principal effect of metoclopramide is on symptoms of postprandial and daytime heartburn with less observed effect on nocturnal symptoms. If symptoms are confined to particular situations, such as following the evening meal, use of metoclopramide as single doses prior to the provocative situation should be considered, rather than using the drug throughout the day. Healing of esophageal ulcers and erosions has been endoscopically demonstrated at the end of a 12-week trial using doses of 15 mg q.i.d. As there is no documented correlation between symptoms and healing of esophageal lesions, patients with documented lesions should be monitored endoscopically.

Diabetic gastroparesis (diabetic gastric stasis). Reglan (metoclopramide hydrochloride) is indicated for the relief of symptoms associated with acute and recurrent diabetic gastric stasis. The usual manifestations of delayed gastric emptying (e.g., nausea, vomiting, heartburn, persistent fullness after meals and anorexia) appear to respond to Reglan within different time intervals. Significant relief of nausea occurs early and continues to improve over a three-week period. Relief of vomiting and anorexia may precede the relief of abdominal fullness by one week or more.

The prevention of nausea and vomiting associated with emetogenic cancer chemotherapy. Reglan Injectable is indicated for the prophylaxis of vomiting associated with emetogenic cancer chemotherapy.

The prevention of postoperative nausea and vomiting. Reglan Injectable is indicated for the prophylaxis of postoperative nausea and vomiting in those circumstances where nasogastric suction is undesirable.

Small bowel intubation. Reglan Injectable may be used to facilitate small bowel intuba-

tion in adults and children in whom the tube does not pass the pylorus with conventional maneuvers.

Radiological examination. Reglan Injectable may be used to stimulate gastric emptying and intestinal transit of barium in cases where delayed emptying interferes with radiological examination of the stomach and/or small intestine.

Contraindications: Metoclopramide should not be used whenever stimulation of gastrointestinal motility might be dangerous, e.g., in the presence of gastrointestinal hemorrhage, mechanical obstruction, or perforation.

Reglan Injectable containing benzyl alcohol should not be used in newborns.

Metoclopramide is contraindicated in patients with pheochromocytoma because the drug may cause a hypertensive crisis, probably due to release of catecholamines from the tumor. Such hypertensive crises may be controlled by phentolamine.

Metoclopramide is contraindicated in patients with known sensitivity or intolerance to the drug.

Metoclopramide should not be used in epileptics or patients receiving other drugs which are likely to cause extrapyramidal reactions, since the frequency and severity of seizures or extrapyramidal reactions may be increased.

Warnings: Depression bearing a temporal relationship to Reglan administration has been reported.

Extrapyramidal symptoms, manifested primarily as acute dystonic reactions, occur in approximately 1 in 500 patients treated with the usual adult dosages of 30–40 mg/day of metoclopramide. These usually are seen during the first 24–48 hours of treatment with metoclopramide, occur more frequently in children and young adults, and are even more frequent at the higher doses used in prophylaxis of vomiting due to cancer chemotherapy. These symptoms may include involuntary movements of limbs and facial grimacing, torticollis, oculogyric crisis, rhythmic protrusion of tongue, bulbar type of speech, trismus, or dystonic reactions resembling tetanus. Rarely, dystonic reactions may present as stridor and dyspnea, possibly due to laryngospasm. If these symptoms should occur, inject 50 mg Benadryl® (diphenhydramine hydrochloride) intramuscularly, and they usually will subside. Cogentin® (benztropine mesylate), 1 to 2 mg intramuscularly, may also be used to reverse these reactions.

Parkinsonian-like symptoms have occurred, more commonly within the first 6 months after beginning treatment with metoclopramide, but occasionally after longer periods. These symptoms generally subside within 2–3 months following discontinuance of metoclopramide.

Tardive Dyskinesia: Tardive dyskinesia, a syndrome consisting of potentially irreversible, involuntary, dyskinetic movements may develop in patients treated with metoclopramide. Although the prevalence of the syndrome appears to be highest among the elderly, especially elderly women, it is impossible to predict which patients are likely to develop the syndrome. Both the risk of developing the syndrome and the likelihood that it will become irreversible are believed to increase with the duration of treatment and the total cumulative dose.

Less commonly, the syndrome can develop after relatively brief treatment periods at low doses; in these cases, symptoms appear more likely to be reversible.

There is no known treatment for established cases of tardive dyskinesia although the syndrome may remit, partially or completely, within several weeks-to-months after metoclopramide is withdrawn. Metoclopramide itself, however, may suppress (or partially suppress) the signs of tardive dyskinesia, thereby masking the underlying disease process. The effect of this symptomatic suppression upon the long-term course of the syndrome is unknown. Therefore, the use of metoclopramide for the symptomatic control of tardive dyskinesia is not recommended.

Precautions: ***General.*** In one study in hypertensive patients, intravenously administered metoclopramide was shown to release catecholamines; hence, caution should be exercised when metoclopramide is used in patients with hypertension.

Intravenous injections of undiluted metoclopramide should be made slowly allowing 1 to 2 minutes for 10 mg since a transient but intense feeling of anxiety and restlessness, followed by drowsiness, may occur with rapid administration.

Intravenous administration of Reglan Injectable diluted in a parenteral solution should be made slowly over a period of not less than 15 minutes.

Giving a promotility drug such as metoclopramide theoretically could put increased pressure on suture lines following a gut anastomosis or closure. Although adverse events related to this possibility have not been reported to date, the possibility should be considered and weighed when deciding whether to use metoclopramide or nasogastric suction in the prevention of postoperative nausea and vomiting.

Information for patients: Metoclopramide may impair the mental and/or physical abilities required for the performance of hazardous tasks such as operating machinery or driving a motor vehicle. The ambulatory patient should be cautioned accordingly.

Drug Interactions. The effects of metoclopramide on gastrointestinal motility are antagonized by anticholinergic drugs and narcotic analgesics. Additive sedative effects can occur when metoclopramide is given with alcohol, sedatives, hypnotics, narcotics or tranquilizers.

The finding that metoclopramide releases catecholamines in patients with essential hypertension suggests that it should be used cautiously, if at all, in patients receiving monoamine oxidase inhibitors.

Absorption of drugs from the stomach may be diminished (e.g., digoxin) by metoclopramide, whereas absorption of drugs from the small bowel may be accelerated (e.g., acetaminophen, tetracycline, levodopa, ethanol).

Gastroparesis (gastric stasis) may be responsible for poor diabetic control in some patients. Exogenously administered insulin may begin to act before food has left the stomach and lead to hypoglycemia. Because the action of metoclopramide will influence the delivery of food to the intestines and thus the rate of absorption, insulin dosage or timing of dosage may require adjustment.

Carcinogenesis, Mutagenesis, Impairment of Fertility: A 77-week study was conducted in rats with oral doses up to about 40 times the maximum recommended human daily dose. Metoclopramide elevates prolactin levels and the elevation persists during chronic administration. Tissue culture experiments indicate that approximately one-third of human breast cancers are prolactin-dependent *in vitro*, a factor of potential importance if the prescription of metoclopramide is contemplated in a patient with previously detected breast cancer. Although disturbances such as galactorrhea, amenorrhea, gynecomastia, and impotence have been reported with prolactin-elevating drugs, the clinical significance of elevated serum prolactin levels is unknown for most patients. An increase in mammary neoplasms has been found in rodents after chronic administration of prolactin-stimulating neuroleptic drugs and metoclopramide. Neither clinical studies nor epidemiologic studies conducted to date, however, have shown an association between chronic administration of these drugs and mammary tumorigenesis; the available evidence is too limited to be conclusive at this time.

An Ames mutagenicity test performed on metoclopramide was negative.

Pregnancy Category B. Reproduction studies performed in rats, mice, and rabbits by the i.v., i.m., s.c. and oral routes at maximum levels ranging from 12 to 250 times the human dose have demonstrated no impairment of fertility or significant harm to the fetus due to metoclopramide. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers. Metoclopramide is excreted in human milk. Caution should be exercised when metoclopramide is administered to a nursing mother.

Adverse Reactions: In general, the incidence of adverse reactions correlates with the dose and duration of metoclopramide administration. The following reactions have been reported, although in most instances, data do not permit an estimate of frequency:

CNS Effects. Restlessness, drowsiness, fatigue and lassitude occur in approximately 10% of patients receiving the most commonly prescribed dosage of 10 mg q.i.d. (see Precautions). Insomnia, headache, confusion, dizziness or depression (see Warnings) occur less frequently. In cancer chemotherapy patients being treated with 1–2 mg/kg per dose, incidence of drowsiness is about 70%. There are isolated reports of convulsive seizures without clear-cut relationship to metoclopramide. Rarely, hallucinations have been reported.

Extrapyramidal Reactions (EPS). Acute dystonic reactions, the most common type of EPS associated with metoclopramide, occur in approximately 0.2% of patients (1 in 500)

treated with 30 to 40 mg of metoclopramide per day. In cancer chemotherapy patients receiving 1–2 mg/kg per dose, the incidence is 2% in patients over the ages of 30–35, and 25% or higher in children and young adults who have not had prophylactic administration of diphenhydramine. Symptoms include involuntary movements of limbs, facial grimacing, torticollis, oculogyric crisis, rhythmic protrusion of tongue, bulbar type of speech, trismus, opisthotonus (tetanus-like reactions) and rarely, stridor and dyspnea possibly due to laryngospasm; ordinarily these symptoms are readily reversed by diphenhydramine (see Warnings).

Parkinsonian-like symptoms may include bradykinesia, tremor, cogwheel rigidity, mask-like facies (see Warnings).

Tardive dyskinesia most frequently is characterized by involuntary movements of the tongue, face, mouth or jaw, and sometimes by involuntary movements of the trunk and/or extremities (see Warnings).

Motor restlessness (akathisia) may consist of feelings of anxiety, agitation, jitteriness, and insomnia, as well as inability to sit still, pacing, foot-tapping. These symptoms may disappear spontaneously or respond to a reduction in dosage.

Endocrine Disturbances. Galactorrhea, amenorrhea, gynecomastia, impotence secondary to hyperprolactinemia (see Precautions). Fluid retention secondary to transient elevation of aldosterone (see Clinical Pharmacology).

Cardiovascular. Hypotension, hypertension and a single instance of supraventricular tachycardia (see Contraindications, Precautions).

Gastrointestinal. Nausea and bowel disturbances, primarily diarrhea.

Hepatic. Rarely, cases of hepatotoxicity, characterized by such findings as jaundice and altered liver function tests, when metoclopramide was administered with other drugs with known hepatotoxic potential.

Renal. Urinary frequency and incontinence.

Hematologic. A few cases of neutropenia, leukopenia, or agranulocytosis, generally without clearcut relationship to metoclopramide.

Allergic Reactions. A few cases of rash, urticaria, or bronchospasm, especially in patients with a history of asthma. Rarely, angioneurotic edema, including glossal or laryngeal edema.

Miscellaneous. Visual disturbances. Porphyria. Rare occurrences of neuroleptic malignant syndrome (NMS) have been reported. This potentially fatal syndrome is comprised of the symptom complex of hyperthermia, altered consciousness, muscular rigidity and autonomic dysfunction.

Transient flushing of the face and upper body, without alterations in vital signs, following high doses intravenously.

Overdosage: Symptoms of overdosage may include drowsiness, disorientation and extrapyramidal reactions. Anticholinergic or antiparkinson drugs or antihistamines with anticholinergic properties may be helpful in controlling the extrapyramidal reactions. Symptoms are self-limiting and usually disappear within 24 hours.

Hemodialysis removes relatively little metoclopramide, probably because of the small amount of the drug in blood relative to tissues. Similarly, continuous ambulatory peritoneal dialysis does not remove significant amounts of drug. It is unlikely that dosage would need to be adjusted to compensate for losses through dialysis. Dialysis is not likely to be an effective method of drug removal in overdose situations.

Literature reports describe methemoglobinemia in premature and full term neonates who were given metoclopramide intramuscularly, 1–2 mg/kg/day for 3 or more days. Methemoglobinemia has not been reported in similar infants treated with 0.5 mg/kg/day in divided doses. Methemoglobinemia can be reversed by the intravenous administration of methylene blue.

Dosage and Administration: ***For the relief of symptomatic gastroesophageal reflux:*** Administer from 10 mg to 15 mg Reglan orally up to q.i.d. 30 minutes before each meal and at bedtime, depending upon symptoms being treated and clinical response (see Clinical Pharmacology and Indications). If symptoms occur only intermittently or at specific times of the day, use of metoclopramide in single doses up to 20 mg prior to the provoking situation may be preferred rather than continuous treatment. Occasionally, patients (such as elderly patients) who are more sensitive to the therapeutic or adverse effects of metoclopramide will require only 5 mg per dose.

Experience with esophageal erosions and ulcerations is limited, but healing has thus far been documented in one controlled trial using q.i.d. therapy at 15 mg/dose, and this regimen should be used when lesions are present, so long as it is tolerated (see Adverse Reactions). Because of the poor correlation between symptoms and endoscopic appearance of the esophagus, therapy directed at esophageal lesions is best guided by endoscopic evaluation.

Therapy longer than 12 weeks has not been evaluated and cannot be recommended.

For the relief of symptoms associated with diabetic gastroparesis (diabetic gastric stasis): Administer 10 mg of metoclopramide 30 minutes before each meal and at bedtime for two to eight weeks, depending upon response and the likelihood of continued well-being upon drug discontinuation.

The initial route of administration should be determined by the severity of the presenting symptoms. If only the earliest manifestations of diabetic gastric stasis are present, oral administration of Reglan may be initiated. However, if severe symptoms are present, therapy should begin with Reglan Injectable (I.M. or I.V.). Doses of 10 mg may be administered slowly by the intravenous route over a 1- to 2-minute period.

Administration of Reglan Injectable up to 10 days may be required before symptoms subside, at which time oral administration may be instituted. Since diabetic gastric stasis is frequently recurrent, Reglan therapy should be reinstituted at the earliest manifestation.

For the prevention of nausea and vomiting associated with emetogenic cancer chemotherapy: For doses in excess of 10 mg, Reglan Injectable should be diluted in 50 mL of a parenteral solution.

The preferred parenteral solution is Sodium Chloride Injection (normal saline), which when combined with Reglan Injectable, can be stored frozen for up to 4 weeks. Reglan Injectable is degraded when admixed and frozen with Dextrose-5% in Water. Reglan Injectable diluted in Sodium Chloride Injection, Dextrose-5% in Water, Dextrose-5% in 0.45% Sodium Chloride, Ringer's Injection or Lactated Ringer's Injection may be stored up to 48 hours (without freezing) after preparation if protected from light. All dilutions may be stored unprotected from light under normal light conditions up to 24 hours after preparation.

Intravenous infusions should be made slowly over a period of not less than 15 minutes, 30 minutes before beginning cancer chemotherapy and repeated every 2 hours for two doses, then every 3 hours for three doses.

The initial two doses should be 2 mg/kg if highly emetogenic drugs such as cisplatin or dacarbazine are used alone or in combination. For less emetogenic regimens, 1 mg/kg per dose may be adequate.

If extrapyramidal symptoms should occur, inject 50 mg Benadryl® (diphenhydramine hydrochloride) intramuscularly, and EPS usually will subside.

For the prevention of postoperative nausea and vomiting: Reglan Injectable should be given intramuscularly near the end of surgery. The usual adult dose is 10 mg; however, doses of 20 mg may be used. Dosing may be repeated every 4 to 6 hours.

To facilitate small bowel intubation: If the tube has not passed the pylorus with conventional maneuvers in 10 minutes, a single dose (undiluted) may be administered slowly by the intravenous route over a 1- to 2-minute period.

The recommended single dose is: Adults—10 mg metoclopramide base. Children (6-14 years of age)—2.5 to 5 mg metoclopramide base; (under 6 years of age)—0.1 mg/kg metoclopramide base.

To aid in radiological examinations: In patients where delayed gastric emptying interferes with radiological examination of the stomach and/or small intestine, a single dose may be admistered slowly by the trave For dosage, see intubation above.

Use in Patients with Renal or Hepatic Impairment: Since metoclopramide is excreted principally through the kidneys, in those patients whose creatinine clearance is below 40 mL/min, therapy should be initiated at approximately one-half the recommended dosage. Depending upon clinical efficacy and safety considerations, the dosage may be increased or decreased as appropriate.

See Overdosage section for information regarding dialysis.

Metoclopramide undergoes minimal hepatic metabolism, except for simple conjugation. Its safe use has been described in patients with advanced liver disease whose renal function was normal.

NOTE: Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, when-

ever solution and container permit.

Admixture Compatibilities. Reglan (metoclopramide hydrochloride) Injectable is compatible for mixing and injection with the following dosage forms to the extent indicated below:

Physically and Chemically Compatible up to 48 hours. Cimetidine Hydrochloride (SK&F), Mannitol, USP (Abbott), Potassium Acetate, USP (Invenex), Potassium Chloride, USP (ESI), Potassium Phosphate, USP (Invenex).

Physically Compatible up to 48 hours. Ascorbic Acid, USP (Abbott), Benztropine Mesylate, USP (MS&D), Cytarabine, USP (Upjohn), Dexamethasone Sodium Phosphate, USP (ESI, MS&D), Diphenhydramine Hydrochloride, USP (Parke-Davis), Doxorubicin Hydrochloride, USP (Adria), Heparin Sodium, USP (ESI), Hydrocortisone Sodium Phosphate (MS&D), Lidocaine Hydrochloride, USP (ESI), Magnesium Sulfate, USP (ESI), Multi-Vitamin Infusion (must be refrigerated-USV), Vitamin B Complex with Ascorbic Acid (Roche).

Physically Compatible up to 24 hours (Do not use if precipitation occurs). Aminophylline, USP (ESI), Clindamycin Phosphate, USP (Upjohn), Cyclophosphamide, USP (Mead-Johnson), Insulin, USP (Lilly), Methylprednisolone Sodium Succinate, USP (ESI).

Conditionally Compatible (Use within one hour after mixing or may be infused directly into the same running IV line). Ampicillin Sodium, USP (Bristol), Calcium Gluconate, USP (ESI), Cisplatin (Bristol), Erythromycin Lactobionate, USP (Abbott), Methotrexate Sodium, USP (Lederle), Penicillin G Potassium, USP (Squibb), Tetracycline Hydrochloride, USP (Lederle).

Incompatible (Do Not Mix). Cephalothin Sodium, USP (Lilly), Chloramphenicol Sodium, USP (Parke-Davis), Sodium Bicarbonate, USP (Abbott).

How Supplied: Each pink, capsule-shaped, scored Reglan® Tablet contains 10 mg metoclopramide base (as the monohydrochloride monohydrate). Available in bottles of 100 (NDC 0031-6701-63), and 500 tablets (NDC 0031- 6701-70) and Dis-Co® Unit Dose Packs of 100 tablets (NDC 0031-6701-64).

Each green, elliptical-shaped Reglan® Tablet contains 5 mg metoclopramide base (as the monohydrochloride monohydrate). Available in bottles of 100 (NDC 0031-6705-63) and Dis-Co® Unit Dose Packs of 100 tablets (NDC 0031-6705-64). Dispense tablets in tight container.

Reglan® Syrup, 5 mg metoclopramide base (as the monohydrochloride monohydrate) per 5 mL, available in pints (NDC 0031-6706-25) and 10 mL Dis-Co® Unit Dose Packs (10 x 10s) (NDC 0031-6706-26). Dispense syrup in well-closed container.

Preservative-free:

Reglan® Injectable **5 mg** metoclopramide base (as the monohydrochloride monohydrate) **per mL;** available in 2 mL single dose vials in cartons of 25 (NDC 0031-6709-72), 10 mL single dose vials in cartons of 25 (NDC 0031-6709-78), 30 mL single dose vials in cartons of 6 (NDC 0031-6709-85) and in cartons of 25 (NDC 0031-6709-24), 2 mL ampuls in cartons of 5 (NDC 0031-6709-90) and 25 (NDC 0031-6709-95), 10 mL ampuls in cartons of 25 (NDC 0031-6709-94).

Contains Preservative:

Reglan® Injectable, **10 mg** metoclopramide base (as the monohydrochloride monohydrate) **per mL;** available in 1 mL sterile syringes in cartons of 10 (NDC 0031-6704-41) and in 2 mL sterile syringes in cartons of 10 (NDC 0031-6704-42).

NOT FOR USE IN NEWBORNS BECAUSE OF BENZYL ALCOHOL CONTENT.

Container	Total Contents #	Concentration #	Administration
* 2 mL single dose vial ampul	10 mg	5 mg/mL	FOR IV or IM ADMINISTRATION
** 1 mL sterile syringe	10 mg	10 mg/mL	FOR IV or IM ADMINISTRATION
** 2 mL sterile syringe	20 mg	10 mg/mL	FOR IV or IM ADMINISTRATION
* 10 mL single dose vial ampul	50 mg	5 mg/mL	FOR IV INFUSION ONLY DILUTE BEFORE USING
* 30 mL single dose vial	150 mg	5 mg/mL	FOR IV INFUSION ONLY DILUTE BEFORE USING

Metoclopramide base (as the monohydrochloride monohydrate)
* Preservative-free
** Contains 0.9% Benzyl Alcohol DO NOT USE IN NEWBORNS

Store vials and ampuls in carton until used. Do not store open single dose vials or ampuls for later use, as they contain no preservative.

Protect syringes from light; store in carton until used.

Dilutions may be stored unprotected from light under normal light conditions up to 24 hours after preparation.

TABLETS, SYRUP AND INJECTABLE SHOULD BE STORED AT CONTROLLED ROOM TEMPERATURE BETWEEN 15°C and 30°C (59°F and 86°F).

Reglan Injectable is manufactured for Pharmaceutical Division, A. H. Robins Company, Richmond, Virginia 23220 by Elkins-Sinn, Inc., Cherry Hill, NJ 08003, a subsidiary of A. H. Robins. Rev. July 1987

Rev. May 1985

Robaxin®

brand of

Methocarbamol Tablets, USP

500 mg per tablet

Robaxin®-750

brand of

Methocarbamol Tablets, USP

750 mg per tablet

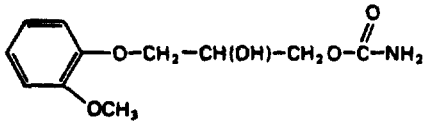
Description:

Inactive ingredients:

ROBAXIN—Corn Starch, FD&C Yellow 6 Aluminum Lake, Hydroxypropyl Cellulose, Hydroxypropyl Methylcellulose, Magnesium Stearate, Polysorbate 20, Povidone, Propylene Glycol, Saccharin Sodium, Sodium Lauryl Sulfate, Sodium Starch Glycolate, Stearic Acid, Titanium Dioxide.

ROBAXIN-750—Corn Starch, D&C Yellow 10 Aluminum Lake, FD&C Yellow 6 Aluminum Lake, Hydroxypropyl Cellulose, Hydroxypropyl Methylcellulose, Magnesium Stearate, Polysorbate 20, Povidone, Propylene Glycol, Saccharin Sodium, Sodium Lauryl Sulfate, Sodium Starch Glycolate, Stearic Acid, Titanium Dioxide.

Methocarbamol has the following structural formula:



3-(2-methoxyphenoxy)-1,2-propanediol 1-carbamate, or methocarbamol

Actions: The mechanism of action of methocarbamol in humans has not been established, but may be due to general central nervous system depression. It has no direct action on the contractile mechanism of striated muscle, the motor end plate or the nerve fiber.

Indications: Robaxin (methocarbamol) is indicated as an adjunct to rest, physical therapy, and other measures for the relief of discomforts associated with acute, painful musculoskeletal conditions. The mode of action of this drug has not been clearly identified, but may be related to its sedative properties. Methocarbamol does not directly relax tense skeletal muscles in man.

Contraindications: Robaxin is contraindicated in patients hypersensitive to any of the ingredients.

Warnings: Since methocarbamol may possess a general central nervous system depressant effect, patients receiving Robaxin/Robaxin-750 (methocarbamol tablets) should be cautioned about combined effects with alcohol and other CNS depressants.

Safe use of methocarbamol has not been established with regard to possible adverse effects upon fetal development. Therefore, methocarbamol tablets should not be used in women who are or may become pregnant and particularly during early pregnancy unless in the judgment of the physician the potential benefits outweigh the possible hazards.

Precautions: Safety and effectiveness in children below the age of 12 years have not been established.

It is not known whether this drug is secreted in human milk. As a general rule, nursing should not be undertaken while a patient is on a drug since many drugs are excreted in human milk.

Methocarbamol may cause a color interference in certain screening tests for 5-hydroxyindoleacetic acid (5-HIAA) and vanilmandelic acid (VMA).

Adverse Reactions: Lightheadedness, dizziness, drowsiness, nausea, allergic manifestations such as urticaria, pruritus, rash, conjunctivitis with nasal congestion, blurred vision, headache, fever.

Dosage and Administration: Robaxin (methocarbamol), 500 mg—Adults: initial dosage, 3 tablets q.i.d., maintenance dosage, 2 tablets q.i.d.

Robaxin-750 (methocarbamol), 750 mg—Adults: initial dosage, 2 tablets q.i.d., maintenance dosage, 1 tablet q.4h. or 2 tablets t.i.d.

Six grams a day are recommended for the first 48 to 72 hours of treatment. (For severe conditions 8 grams a day may be administered). Thereafter, the dosage can usually be reduced to approximately 4 grams a day.

How Supplied: Robaxin—light orange, round, film-coated tablets monogrammed Robaxin and AHR in bottles of 100 (NDC 0031-7429-63), 500 (NDC 0031-7429-70), and Dis-Co® unit dose packs of 100 (NDC 0031-7429-64).

Robaxin-750—orange, capsule-shaped, film-coated tablets monogrammed Robaxin-750 and AHR in bottles of 100 (NDC 0031-7449-63), 500 (NDC 0031-7449-70), and Dis-Co® unit dose packs of 100 (NDC 0031-7449-64).

Store at Controlled Room Temperature, between 15°C and 30°C (59°F and 86°F).

Dispense in tight container.

Also available in the injectable form, 1 g methocarbamol in each 10 ml vial (NDC 0031-7409). Rev. May 1985

Rev. Dec. 1981

Robaxin® Injectable

brand of

Methocarbamol Injection, USP

Description: Methocarbamol has the following chemical name:

3-(2-methoxyphenoxy)-1,2-propanediol 1-carbamate, or methocarbamol

Robaxin Injectable is a parenteral dosage form.

Each ml contains:

Methocarbamol, USP **100 mg;** Polyethylene Glycol 300, NF 0.5 ml; Water for Injection, USP q. s. pH adjusted, when necessary, with hydrochloric acid and/or sodium hydroxide. AFTER MIXING WITH I. V. INFUSION FLUIDS, **DO NOT REFRIGERATE.**

Actions: The mechanism of action of methocarbamol in humans has not been established, but may be due to general central nervous system depression. It has no direct action on the contractile mechanism of striated muscle, the motor end plate or the nerve fiber.

Indications: The injectable form of methocarbamol is indicated as an adjunct to rest, physical therapy, and other measures for the relief of discomfort associated with acute, painful musculoskeletal conditions. The mode of action of this drug has not been clearly identified, but may be related to its sedative properties. Methocarbamol does not directly relax tense skeletal muscles in man.

Contraindications: Robaxin Injectable should not be administered to patients with known or suspected renal pathology. This caution is necessary because of the presence of polyethylene glycol 300 in the vehicle.

A much larger amount of polyethylene glycol 300 than is present in recommended doses of Robaxin Injectable is known to have increased pre-existing acidosis and urea retention in patients with renal impairment. Although the amount present in this preparation is well within the limits of safety, caution dictates this contraindication.

Robaxin Injectable is contraindicated in patients hypersensitive to any of the ingredients.

Warnings: Since methocarbamol may possess a general central nervous system depressant effect, patients receiving Robaxin Injectable (methocarbamol injection) should be cautioned about combined effects with alcohol and other CNS depressants.

Safe use of Robaxin Injectable has not been established with regard to possible adverse effects upon fetal development. Therefore, Robaxin Injectable should not be used in women who are or may become pregnant and particularly during early pregnancy unless in the judgment of the physician the potential benefits outweigh the possible hazards.

Precautions: As with other agents administered either intravenously or intramuscularly, careful supervision of dose and rate of injection should be observed. Rate of injection should not exceed 3 ml per minute—i.e., one 10 ml vial in approximately three minutes. Since Robaxin Injectable is hypertonic, vascular extravasation must be avoided. A recumbent position will reduce the likelihood of side reactions.

Blood aspirated into the syringe does not mix with the hypertonic solution. This phenomenon occurs with many other intravenous preparations. The blood may be safely injected with the methocarbamol, or the injection may be stopped when the plunger reaches the blood, whichever the physician prefers.

The total dosage should not exceed 30 ml (three vials) a day for more than three consecutive days except in the treatment of tetanus.

Caution should be observed in using the injectable form in suspected or known epileptic patients.

Safety and effectiveness in children below the age of 12 years have not been established except in tetanus. See special directions for use in tetanus.

It is not known whether this drug is secreted in human milk. As a general rule, nursing should not be undertaken while a patient is on a drug since many drugs are excreted in human milk.

Methocarbamol may cause a color interference in certain screening tests for 5-hydroxyindoleacetic acid (5-HIAA) and vanillylmandelic acid (VMA).

Adverse Reactions: Dizziness, lightheadedness, drowsiness, vertigo, fainting, syncope, hypotension, gastrointestinal upset, metallic taste, thrombophlebitis, sloughing at the site of injection, pain at the site of injection, anaphylactic reaction, urticaria, pruritus, rash, conjunctivitis with nasal congestion, flushing, nystagmus, diplopia, mild muscular incoordination, bradycardia, blurred vision, headache, fever. In most cases of syncope there was spontaneous recovery. In others, epinephrine, injectable steroids and/or injectable antihistamines were employed to hasten recovery. Certain of these complaints may have been due to an overly rapid rate of intravenous injection.

The onset of convulsive seizures during intravenous administration has been reported, including instances in known epileptics. The psychic trauma of the procedure may have been a contributing factor. Although several observers have reported success in terminating epileptiform seizures with Robaxin Injectable, its administration to patients with epilepsy is not recommended.

Dosage and Administration: *For Intravenous and Intramuscular Use Only.* Total adult dosage should not exceed 30 ml (3 vials) a day for more than 3 consecutive days except in the treatment of tetanus. A like course may be repeated after a lapse of 48 hours if the condition persists. Dosage and frequency of injection should be based on the severity of the condition being treated and therapeutic response noted.

For the relief of symptoms of moderate degree, 10 ml (one vial) may be adequate. Ordinarily this injection need not be repeated, as the administration of the oral form will usually sustain the relief initiated by the injection. For the severest cases or in postoperative conditions in which oral administration is not feasible, 20 to 30 ml (two to three vials) may be required.

Directions for Intravenous Use. Robaxin Injectable may be administered undiluted directly into the vein at a *maximum rate of three ml per minute.* It may also be added to an intravenous drip of Sodium Chloride Injection (Sterile Isotonic Sodium Chloride Solution for Parenteral Use) or five per cent Dextrose Injection (Sterile 5 per cent Dextrose Solution); one vial given as a single dose should not be diluted to more than 250 ml for I.V. infusion. Care should be exercised to avoid vascular extravasation of this hypertonic solution which may result in thrombophlebitis. It is preferable that the patient be in a recumbent position during and for at least 10 to 15 minutes following the injection.

Directions for Intramuscular Use. When the intramuscular route is indicated, not more than five ml (one-half vial) should be injected into each gluteal region. The injections may be repeated at eight hour intervals, if necessary. When satisfactory relief of symptoms is achieved, it can usually be maintained with tablets.

Not Recommended for Subcutaneous Administration.

Special Directions for Use in Tetanus: There is clinical evidence which suggests that methocarbamol may have a beneficial effect in the control of the neuromuscular manifestations of tetanus. It does not, however, replace the usual procedure of debridement, tetanus antitoxin, penicillin, tracheotomy, attention to fluid balance, and supportive care. Robaxin Injectable should be added to the regimen as soon as possible.

For adults: Inject one or two vials directly into the tubing of the previously inserted indwelling needle. An additional 10 ml or 20 ml may be added to the infusion bottle so that a total of up to 30 ml (three vials) is given as the initial dose (note Precautions). This procedure should be repeated every six hours until conditions allow for the insertion of a nasogastric tube. Crushed Robaxin (methocarbamol) tablets suspended in water or saline may then be given through this tube. Total daily oral doses up to 24 grams may be required as judged by patient response.

For children: A minimum initial dose of 15 mg/kg is recommended. This dosage may be repeated every six hours as indicated. The maintenance dosage may be given by injection into the tubing or by I.V. infusion with an appropriate quantity of fluid. See directions for I.V. use.

How Supplied: Robaxin Injectable—10 ml single dose vials in packages of 5 (NDC 0031-7409-87) and 25 (NDC 0031-7409-94). Manufactured for PHARMACEUTICAL DIVISION, A. H. ROBINS CO., Richmond, VA 23220, by ELKINS-SINN, INC., Cherry Hill, NJ 08034, a subsidiary of A. H. Robins.

Rev. March 1985

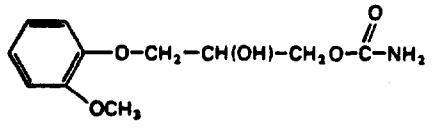
Robaxisal®

Description: For oral administration, Robaxisal is available as a pink and white laminated tablet containing:

Methocarbamol, USP ..... 400 mg
Aspirin, USP ..... 325 mg

Inactive Ingredients: Corn Starch, FD&C Red 3, Magnesium Stearate, Povidone, Sodium Lauryl Sulfate, Sodium Starch Glycolate, Stearic Acid.

Methocarbamol has the following structural formula and chemical name:



3-(2-Methoxyphenoxy)-1,2-propanediol 1-Carbamate

Actions: Robaxisal provides a double approach to the management of discomforts associated with musculoskeletal disorders.

Methocarbamol. The mechanism of action of methocarbamol in humans has not been established, but may be due to general central nervous system depression. It has no direct action on the contractile mechanism of striated muscle, the motor end plate or the nerve fiber.

Aspirin. Aspirin is a mild analgesic with anti-inflammatory and antipyretic activity.

Indications: Robaxisal is indicated as an adjunct to rest, physical therapy, and other measures for the relief of discomfort associated with acute, painful musculoskeletal conditions. The mode of action of methocarbamol has not been clearly identified but may be related to its sedative properties. Methocarbamol does not directly relax tense skeletal muscles in man.

Contraindications: Hypersensitivity to methocarbamol or aspirin.

Warnings: Since methocarbamol may possess a general central nervous system depressant effect, patients receiving Robaxisal should be cautioned about combined effects with alcohol and other CNS depressants.

Precautions: Products containing aspirin should be administered with caution to patients with gastritis or peptic ulceration, or those receiving hypoprothrombinemic anticoagulants.

Methocarbamol may cause a color interference in certain screening tests for 5-hydroxyindoleacetic acid (5-HIAA) and vanilmandelic acid (VMA).

Pregnancy. Safe use of Robaxisal has not been established with regard to possible adverse effects upon fetal development. Therefore, Robaxisal should not be used in women who are or may become pregnant and particularly during early pregnancy unless in the judgment of the physician the potential benefits outweigh the possible hazards.

Nursing mothers. It is not known whether methocarbamol is secreted in human milk; however, aspirin does appear in human milk in moderate amounts. It can produce a bleeding tendency either by interfering with the function of the infant's platelets or by decreasing the amount of prothrombin in the blood. The risk is minimal if the mother takes the aspirin just after nursing and if the infant has an adequate store of vitamin K. As a general rule, nursing should not be undertaken while a patient is on a drug.

Pediatric Use. Safety and effectiveness in children 12 years of age and below have not been established.

Use in Activities Requiring Mental Alertness. Robaxisal may rarely cause drowsiness. Until the patient's response has been determined, he should be cautioned against the operation of motor vehicles or dangerous machinery.

Adverse Reactions: The most frequent adverse reaction to methocarbamol is dizziness or lightheadedness and nausea. This occurs in about one in 20-25 patients. Less frequent reactions are drowsiness, blurred vision, headache, fever, allergic manifestations such as urticaria, pruritus, and rash.

Adverse reactions that have been associated with the use of aspirin include: nausea and other gastrointestinal discomfort, gastritis, gastric erosion, vomiting, constipation, diarrhea, angio-edema, asthma, rash, pruritus, urticaria.

Gastrointestinal discomfort may be minimized by taking Robaxisal with food.

Dosage and Administration: Adults and children over 12 years of age: Two tablets four times daily. Three tablets four times daily may be used in severe conditions for one to three days in patients who are able to tolerate salicylates. These dosage recommendations provide respectively 3.2 and 4.8 grams of methocarbamol per day.

Overdosage: Toxicity due to overdosage of methocarbamol is unlikely; however, acute overdosage of aspirin may cause symptoms of salicylate intoxication.

Treatment of Overdosage. Supportive therapy for 24 hours, as methocarbamol is excreted within that time. If salicylate intoxication occurs, especially in children, the hyperpnea may be controlled with sodium bicarbonate. Judicious use of 5% CO_2 with 95% O_2 may be of benefit. Abnormal electrolyte patterns should be corrected with appropriate fluid therapy.

How Supplied: Robaxisal® is supplied as pink and white laminated, compressed tablets in bottles of 100 (NDC 0031-7469-63), 500 (NDC 0031-7469-70) and Dis-Co® Unit Dose Packs of 100 (NDC 0031-7469-64).

Store at controlled room temperature, between 15°C and 30°C (59°F and 86°F).

Dispense in well-closed container.

Rev. March 1985

Rev. April 1985

Robicillin VK Robitabs®

brand of

Penicillin V Potassium Tablets, USP

250 mg and 500 mg
For oral administration.

Description: Penicillin V is the phenoxymethyl analog of penicillin G. The chemical formula is $C_{16}H_{18}N_2O_5S$.

Inactive Ingredients: Dibasic Calcium Phosphate, Magnesium Stearate, Microcrystalline Cellulose, Sodium Citrate.

Action and Pharmacology: Penicillin V exerts a bactericidal action against penicillin sensitive microorganisms during the stage of active multiplication. It acts through the inhibition of biosynthesis of cell wall mucopeptide. It is not active against the penicillinase producing bacteria, which include many strains of staphylococci. The drug exerts high in vitro activity against staphylococci (except penicillinase-producing strains), streptococci (groups A, C, G, H, L, and M) and pneumococci. Other organisms sensitive in vitro to penicillin V are ***Corynebacterium diphtheriae, Bacillus anthracis,*** Clostridia, ***Actinomyces bovis, Streptobacillus moniliformis, Listeria monocytogenes,*** Leptospira and ***N. gonorrhoeae. Treponema pallidum*** is extremely sensitive.

Penicillin V has the distinct advantage over penicillin G in resistance to inactivation by gastric acid. It may be given with meals; however, blood levels are slightly higher when the drug is given on an empty stomach. Average blood levels are two to five times higher than the levels following the same dose of oral penicillin G and also show much less individual variation.

Once absorbed, penicillin V is about 80% bound to serum protein. Tissue levels are highest in the kidneys, with lesser amounts in the liver, skin and intestines. Small amounts are found in all other body tissues and the cerebrospinal fluid. The drug is excreted as rapidly as it is absorbed in individuals with normal kidney function; however, recovery of the drug from the urine indicates that only about 25% of the dose given is absorbed. In neonates, young infants and individuals with impaired kidney function, excretion is considerably delayed.

Indications: Penicillin V is indicated in the treatment of mild to moderately severe infections due to penicillin-G sensitive microorganisms that are sensitive to the low serum levels common to this particular dosage form. Therapy should be guided by bacteriological studies (including sensitivity tests) and by clinical response.

Note: Severe pneumonia, empyema, bacteremia, pericarditis, meningitis, and arthritis should not be treated with penicillin V during the acute stage.

Indicated surgical procedures should be performed.

The following infections will usually respond to adequate dosage of penicillin V.

Streptococcal infections (without bacteremia). Mild to moderate infections of the upper respiratory tract, scarlet fever, and mild erysipelas.

Note: Streptococci in groups A, C, G, H, L, and M are very sensitive to penicillin. Other groups, including group D (enterococcus) are resistant.

Pneumococcal infections. Mild to moderately severe infections of the respiratory tract.

Staphylococcal infections—penicillin G sensitive. Mild infections of the skin and soft tissues.

Note: Reports indicate an increasing number of strains of staphylococci resistant to penicillin G, emphasizing the need for culture and sensitivity studies in treating suspected staphylococcal infections.

Fusospirochetosis (Vincent's gingivitis and pharyngitis)—Mild to moderately severe infections of the oropharynx usually respond to therapy with oral penicillin.

Note: Nedessary dental care should be accomplished in infections involving the gum tissue.

Medical conditions in which oral penicillin therapy is indicated as prophylaxis:

For the prevention of recurrence following rheumatic fever and/or chorea.

Prophylaxis with oral penicillin on a continuing basis has proven effective in preventing recurrence of these conditions.

Although no controlled clinical efficacy studies have been conducted, penicillin V has been suggested by the American Heart Association and the American Dental Association for use as part of a parenteral-oral regimen and as an alternative oral regimen for prophylaxis against bacterial endocarditis in patients with congenital and/or rheumatic or other acquired valvular heart disease when they undergo dental procedures and surgical procedures of the respiratory tract.[1] Since it may happen that *alpha* hemolytic streptococci relatively resistant to penicillin may be found when patients are receiving continuous oral penicillin for secondary prevention of rheumatic fever, prophylactic agents other than penicillin may be chosen for these patients and prescribed in addition to their continuous rheumatic fever prophylactic regimen. Oral penicillin should not be used as adjunctive prophylaxis for genitourinary instrumentation or surgery, lower intestinal tract surgery, sigmoidoscopy, and childbirth.

Note: When selecting antibiotics for the prevention of bacterial endocarditis, the physician or dentist should read the full joint statement of the American Heart Association and the American Dental Association.[1]

Contraindications: A previous hypersensitivity reaction to any penicillin is a contraindication.

Warnings: Serious and occasionally fatal hypersensitivity (anaphylactoid) reactions have been reported in patients on penicillin therapy. Although anaphylaxis is more frequent following parenteral therapy it has occurred in patients on oral penicillin. These reactions are more apt to occur in individuals with a history of sensitivity to multiple allergens.

There have been well documented reports of individuals with a history of penicillin hypersensitivity reactions who have experienced severe hypersensitivity reactions when treated with a cephalosporin. Before therapy with a penicillin, careful inquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins, and other allergens. If an allergic reaction occurs, the drug should be discontinued and the patient treated with the usual agents e.g., pressor amines, antihistamines and corticosteroids.

Precautions: Penicillin should be used with caution in individuals with histories of significant allergies and/or asthma.

The oral route of administration should not be relied upon in patients with severe illness, or with nausea, vomiting, gastric dilatation, cardiospasm or intestinal hypermotility.

Occasionally patients will not absorb therapeutic amounts of orally administered penicillin.

In streptococcal infections, therapy must be sufficient to eliminate the organism (10 days minimum); otherwise the sequelae of streptococcal disease may occur. Cultures should be taken following completion of treatment to determine whether streptococci have been eradicated.

Prolonged use of antibiotics may promote the overgrowth of non-susceptible organisms, including fungi. Should superinfection occur, appropriate measures should be taken.

Adverse Reactions: Although the incidence of reactions to oral penicillins has been reported with much less frequency than following parenteral therapy, it should be remembered that all degrees of hypersensitivity including fatal anaphylaxis, have been reported with oral penicillin.

The most common reactions to oral penicillin are nausea, vomiting, epigastric distress, diarrhea, and black hairy tongue. The hypersensitivity reactions reported are skin eruptions (maculo-papular to exfoliative dermatitis), urticaria and other serum sickness reactions, laryngeal edema and anaphylaxis. Fever and eosinophilia may frequently be the only reaction observed.

(Robicillin VK, continued)

Hemolytic anemia, leucopenia, thrombocytopenia, neuropathy, and nephropathy are infrequent reactions and usually associated with high doses of parenteral penicillin.

Dosage and Administration: The dosage of penicillin V should be determined according to the sensitivity of the causative microorganisms and the severity of infection, and adjusted to the clinical response of the patient.

The usual dosage recommendations for adults and children 12 years and over are as follows:

Streptococcal infections—mild to moderately severe—of the upper respiratory tract and including scarlet fever, and mild erysipelas; 125 mg (200,000 units) every 6–8 hours for 10 days for mild infections; 250–500 mg (400,000–800,000 units) every 8 hours for 10 days for moderately severe infections.

Pneumococcal infections—mild to moderately severe—of the respiratory tract, including otitis media: 250–500 mg (400,000–800,000 units) every 6 hours until the patient has been afebrile for at least 2 days.

Staphylococcal infections—mild infections of skin and soft tissue (culture and sensitivity tests should be performed): 250–500 mg (400,000–800,000 units) every 6–8 hours.

Fusospirochetosis (Vincent's infection) of the oropharynx. Mild to moderately severe infections: 250 mg (400,000 units) every 6–8 hours.

For the prevention of recurrence following rheumatic fever and/or chorea: 125 mg (200,000 units) twice daily on a continuing basis.

For prophylaxis against bacterial endocarditis[1] in patients with rheumatic, congenital or other acquired valvular heart disease when undergoing dental procedures or surgical procedures of the upper respiratory tract, one of two regimens may be selected.

1. For the oral regimen, give 2.0 Gm of penicillin V (1.0 Gm for children under 60 lbs) ½ to 1 hour before the procedure, and then, 500 mg (250 mg for children under 60 lbs) every 6 hours for 8 doses; or
2. For the combined parenteral-oral regimen, give one million units of aqueous crystalline penicillin G (30,000 units/kg in children) intramuscularly mixed with 600,000 units procaine penicillin G (600,000 units for children) ½ to 1 hour before the procedure, and then oral penicillin V, 500 mg (250 mg for children less than 60 lbs) every 6 hours for 8 doses. Doses for children should not exceed recommendations for adults for a single dose or for a 24-hour period.

Note: Therapy for children under 12 years of age is calculated on the basis of body weight. For infants and small children the suggested dose is 25,000 to 90,000 units per kg per day in three to six divided doses.

How Supplied:

Penicillin V Potassium Tablets, USP

250 mg (400,000 Units)—bottles of 100 (NDC 0031-8217-63) and 1,000 tablets (NDC 0031-8217-74).

500 mg (800,000 Units)—bottles of 100 (NDC 0031-8227-63) and 500 tablets (NDC 0031-8227-70).

[1]American Heart Association. 1977. Prevention of bacterial endocarditis. Circulation. 56:139A–143A

Rev. April 1985

Rev. April 1985

Robimycin Robitabs®

brand of

Erythromycin Tablets, USP enteric-coated 250 mg erythromycin base For Oral Administration.

Description: Erythromycin is produced by a strain of ***Streptomyces erythraeus*** and belongs to the macrolide group of antibiotics. It is basic and readily forms salts with acids. The base, the stearate salt, and the esters are poorly soluble in water and are suitable for oral administration. Robimycin Robitabs®, brand of Erythromycin Tablets, USP (enteric-coated), are specially coated to protect the antibiotic from the inactivating effects of gastric acidity and to permit efficient absorption in the small intestine.

Inactive Ingredients: Cellulose Acetate Phthalate, Corn Starch, D&C Yellow 10 Aluminum Lake, Diethyl Phthalate, FD&C Blue 1 Aluminum Lake, FD&C Yellow 6 Aluminum Lake, Hydroxypropyl Cellulose, Lactose, Magnesium Stearate, Silicon Dioxide, Sodium Cholate, Sodium Citrate, Sodium Lauryl Sulfate, Stearic Acid, Talc, Titanium Dioxide.

Actions: The mode of action of erythromycin is inhibition of protein synthesis without affecting nucleic acid synthesis. Resistance to erythromycin of some strains of ***Haemophilus influenzae*** and staphylococci has been demonstrated. Culture and susceptibility testing should be done. If the Kirby-Bauer method of disc susceptibility is used, a 15 mcg erythromycin disc should give a zone diameter of at least 18 mm when tested against an erythromycin susceptible organism.

Robimycin Robitabs®, brand of Erythromycin Tablets, USP (enteric-coated), are absorbed either when administered with meals or when given between meals on an empty stomach. However, absorption may be temporarily delayed by the presence of food. Some interpatient variability in absorption of orally-administered erythromycin has been observed.

After absorption, erythromycin diffuses readily into most body fluids. In the absence of meningeal inflammation, low concentrations are normally achieved in the spinal fluid but passage of the drug across the blood-brain barrier increases in meningitis. In the presence of normal hepatic function, erythromycin is concentrated in the liver and excreted in the bile; the effect of hepatic dysfunction on excretion of erythromycin by the liver into the bile is not known. After oral administration, less than 5 percent of the activity of the administered dose can be recovered in the urine.

Erythromycin crosses the placental barrier but fetal plasma levels are low.

Indications: Robimycin is indicated in the treatment of infections due to the following microorganisms:

Streptococcus pyogenes (Group A beta hemolytic streptococcus): For upper and lower respiratory tract, skin, and soft tissue infections of mild to moderate severity.

Injectable benzathine penicillin G is considered by the American Heart Association to be the drug of choice in the treatment and prevention of streptococcal pharyngitis and in long-term prophylaxis of rheumatic fever.

When oral medication is preferred for treatment of the above conditions, penicillin G, V, or erythromycin are alternate drugs of choice.

When oral medication is given, the importance of strict adherence by the patient to the prescribed dosage regimen must be stressed. A therapeutic dose should be administered for at least 10 days.

Alpha-hemolytic streptococci (viridans group): Although no controlled clinical efficacy trials have been conducted, oral erythromycin has been suggested by the American Heart Association and the American Dental Association for use in a regimen for prophylaxis of bacterial endocarditis in patients hypersensitive to penicillin who have congenital and/or rheumatic or other acquired valvular heart disease when they undergo dental procedures and surgical procedures of the upper respiratory tract.[1] Erythromycin is not suitable prior to genitourinary or gastrointestinal tract surgery.

NOTE: When selecting antibiotics for the prevention of bacterial endocarditis, the physician or dentist should read the full joint statement of the American Heart Association and the American Dental Association.[1]

Staphylococcus aureus: For acute infections of skin and soft tissue of mild to moderate severity. Resistant organisms may emerge during treatment.

Streptococcus pneumoniae (Diplococcus pneumoniae): For upper respiratory tract infections (e.g., Otitis media, pharyngitis) and lower respiratory tract infections (e.g., pneumonia) of mild to moderate degree.

Mycoplasma pneumoniae (Eaton agent, PPLO): For respiratory infections due to this organism.

Hemophilus influenzae: For upper respiratory tract infections of mild to moderate severity when used concomitantly with adequate doses of sulfonamides. Not all strains of this organism are susceptible at the erythromycin concentrations ordinarily achieved (see appropriate sulfonamide labeling for prescribing information).

Treponema pallidum: Erythromycin (oral forms only) is an alternate choice of treatment for primary syphilis in patients allergic to the penicillins. In treatment of primary syphilis, spinal fluid examinations should be done before treatment and as part of follow-up after therapy.

Corynebacterium diphtheriae and *C. minutissimum:* As an adjunct to antitoxin, to prevent establishment of carriers, and to eradicate the organism in carriers.

In the treatment of erythrasma.

Entamoeba histolytica: In the treatment of intestinal amebiasis only. Extraenteric amebiasis requires treatment with other agents.

Listeria monocytogenes: Infections due to this organism.

Neisseria gonorrhoeae: Erythromycin lactobionate for injection in conjunction with erythromycin stearate or base orally, as an alternative drug in treatment of acute pelvic inflammatory disease caused by ***N. gonorrhoeae*** in female patients with a history of sensitivity to penicillin. Before treatment of gonorrhea, patients who are suspected of also having syphilis should have a microscopic examination for ***T. pallidum*** (by immunofluorescence or darkfield) before receiving erythromycin, and monthly serologic tests for a minimum of 4 months.

Legionnaires' Disease: Although no controlled clinical efficacy studies have been conducted, *in vitro* and limited preliminary clinical data suggest that erythromycin may be effective in treating Legionnaires' Disease.

Chlamydia trachomatis: Urogenital infections during pregnancy. When tetracyclines are contraindicated or not tolerated, erythromycin is indicated for the treatment of uncomplicated urethral, endocervical, or rectal infections in adults due to ***Chlamydia trachomatis.***[2]

Contraindications: Erythromycin is contraindicated in patients with known hypersensitivity to this antibiotic.

Warnings: Usage in pregnancy: Safety for use in pregnancy has not been established.

Precautions: Erythromycin is principally excreted by the liver. Caution should be exercised in administering the antibiotic to patients with impaired hepatic function.

There have been reports of hepatic dysfunction, with or without jaundice, occurring in patients receiving oral erythromycin products. Although the majority of these cases have been associated with erythromycin estolate, there have been some reports of hepatic dysfunctions in conjunction with the erythromycin base, stearate and ethylsuccinate.

Recent data from studies of erythromycin reveal that its use in patients who are receiving high doses of theophylline may be associated with an increase of serum theophylline levels and potential theophylline toxicity. In case of theophylline toxicity and/or elevated serum theophylline levels, the dose of theophylline should be reduced while the patient is receiving concomitant erythromycin therapy.

Surgical procedures should be performed when indicated.

Adverse Reactions: The most frequent side effects of erythromycin preparations are gastrointestinal, such as abdominal cramping and discomfort, and are dose-related. Nausea, vomiting, and diarrhea occur infrequently with usual oral doses.

During prolonged or repeated therapy, there is a possibility of overgrowth of nonsusceptible bacteria or fungi. If such infections occur, the drug should be discontinued and appropriate therapy instituted.

Mild allergic reactions such as urticaria and other skin rashes have occurred. Serious allergic reactions, including anaphylaxis have been reported.

There have been isolated reports of reversible hearing loss occurring chiefly in patients with renal insufficiency and in patients

receiving high doses of erythromycin.

Dosage and Administration: Robimycin Robitabs®, brand of Erythromycin Tablets, USP (enteric-coated), may be administered orally without regard to meals, i.e., with meals or on an empty stomach.

Adults: 250 mg every 6 hours is the usual dose. Dosage may be increased up to 4 or more grams per day according to the severity of the infection.

Children: Age, weight, and severity of the infection are important factors in determining the proper dosage. 30–50 mg/kg/day, in divided doses, is the usual dose. For more severe infections this dose may be doubled.

If dosage is desired on a twice-a-day schedule in either adults or children, one-half of the total daily dose may be given every 12 hours. Twice-a-day dosing is not recommended when doses larger than 1 gram daily are administered.

In the treatment of streptococcal infections, a therapeutic dosage of erythromycin should be administered for at least 10 days. In continuous ***prophylaxis*** of streptococcal infections in persons with a history of rheumatic heart disease, the dose is 250 mg twice a day.

For prophylaxis of bacterial endocarditis[1] in patients with rheumatic, congenital, or other acquired valvular heart disease when undergoing dental procedures or surgical procedures of the upper respiratory tract, give 1.0 Gm (20 mg/kg for children) orally 1½-2 hours before the procedure, and then 500 mg (10 mg/kg for children) orally every 6 hours for 8 doses.

For treatment of primary syphilis: 30–40 grams given in divided doses over a period of 10–15 days.

For treatment of acute pelvic inflammatory disease caused by N. gonorrhoeae: After initial treatment with erythromycin lactobionate for injection (500 mg every 6 hours for 3 days), the oral dosage recommendation is 250 mg every 6 hours for 7 days.

For dysenteric amebiasis: 250 mg four times daily for 10 to 14 days, for adults; 30–50 mg/kg/day in divided doses for 10 to 14 days, for children.

For treatment of Legionnaires' Disease: Although optimal doses have not been established, doses utilized in reported clinical data were those recommended above (1 to 4 grams erythromycin base daily in divided doses).

Urogenital infections during pregnancy due to ***Chlamydia trachomatis:*** Although the optimal dose and duration of therapy have not been established, the suggested treatment is erythromycin 500 mg, by mouth, 4 times a day for at least 7 days. For women who cannot tolerate this regimen, a decreased dose of 250 mg, by mouth, 4 times a day should be used for at least 14 days.[2]

For adults with uncomplicated urethral, endocervical, or rectal infections caused by ***Chlamydia trachomatis*** in whom tetracyclines are contraindicated or not tolerated: 500 mg, by mouth, 4 times a day for at least 7 days.[2]

How Supplied: Robimycin Robitabs®†, brand of Erythromycin Tablets, USP (enteric-coated), 250 mg (pale green, round) are available in bottles of 100 (NDC 0031-8317-63) and 500 (NDC 0031-8317-70).

References:

[1]American Heart Association. 1977. Prevention of bacterial endocarditis. Circulation. 56:139A-143A.

[2]CDC Sexually Transmitted Diseases Treatment Guidelines. 1982.

Rev. April 1985

†Robitabs® is A. H. Robins' registered trademark for tablets.

Robinul®

Rev. Feb. 1985
ANTICHOLINERGIC

and

Robinul® Forte

brand of
Glycopyrrolate Tablets, USP

Description: Robinul and Robinul Forte tablets contain the synthetic anticholinergic, glycopyrrolate. Glycopyrrolate is a quaternary ammonium compound with the following chemical name:
3-[(cyclopentylhydroxyphenylacetyl)oxy]-1, 1-dimethylpyrrolidinium bromide.

Robinul tablets are scored, compressed pink tablets engraved AHR. Each tablet contains:
Glycopyrrolate, USP ..... 1 mg

Robinul Forte tablets are scored, compressed pink tablets engraved AHR. Each tablet contains:
Glycopyrrolate, USP ..... 2 mg

Inactive Ingredients: Dibasic Calcium Phosphate, FD&C Red 3 Aluminum Lake, Lactose, Magnesium Stearate, Povidone, Sodium Starch Glycolate.

Actions: Glycopyrrolate, like other anticholinergic (antimuscarinic) agents, inhibits the action of acetylcholine on structures innervated by postganglionic cholinergic nerves and on smooth muscles that respond to acetylcholine but lack cholinergic innervation. These peripheral cholinergic receptors are present in the autonomic effector cells of smooth muscle, cardiac muscle, the sino-atrial node, the atrioventricular node, exocrine glands, and, to a limited degree, in the autonomic ganglia. Thus, it diminishes the volume and free acidity of gastric secretions and controls excessive pharyngeal, tracheal, and bronchial secretions.

Glycopyrrolate antagonizes muscarinic symptoms (e.g., bronchorrhea, bronchospasm, bradycardia, and intestinal hypermotility) induced by cholinergic drugs such as the anticholinesterases.

The highly polar quaternary ammonium group of glycopyrrolate limits its passage across lipid membranes, such as the blood-brain barrier, in contrast to atropine sulfate and scopolamine hydrobromide, which are non-polar tertiary amines which penetrate lipid barriers easily.

Indications: For use as adjunctive therapy in the treatment of peptic ulcer.

Contraindications: Glaucoma; obstructive uropathy (for example, bladder neck obstruction due to prostatic hypertrophy); obstructive disease of the gastrointestinal tract (as in achalasia, pyloroduodenal stenosis, etc.); paralytic ileus; intestinal atony of the elderly or debilitated patient; unstable cardiovascular status in acute hemorrhage; severe ulcerative colitis; toxic megacolon complicating ulcerative colitis; myasthenia gravis. Robinul (glycopyrrolate) tablets are contraindicated in those patients with a hypersensitivity to glycopyrrolate.

Warnings: In the presence of a high environmental temperature, heat prostration (fever and heat stroke due to decreased sweating) can occur with use of Robinul.

Diarrhea may be an early symptom of incomplete intestinal obstruction, especially in patients with ileostomy or colostomy. In this instance treatment with this drug would be inappropriate and possibly harmful.

Robinul (glycopyrrolate) may produce drowsiness or blurred vision. In this event, the patient should be warned not to engage in activities requiring mental alertness such as operating a motor vehicle or other machinery, or performing hazardous work while taking this drug.

Theoretically, with overdosage, a curare-like action may occur, i.e., neuromuscular blockade leading to muscular weakness and possible paralysis.

Pregnancy. The safety of this drug during pregnancy has not been established. The use of any drug during pregnancy requires that the potential benefits of the drug be weighed against possible hazards to mother and child. Reproduction studies in rats revealed no teratogenic effects from glycopyrrolate; however, the potent anticholinergic action of this agent resulted in diminished rates of conception and of survival at weaning, in a dose-related manner. Other studies in dogs suggest that this may be due to diminished seminal secretion which is evident at high doses of glycopyrrolate. Information on possible adverse effects in the pregnant female is limited to uncontrolled data derived from marketing experience. Such experience has revealed no reports of teratogenic or other fetus-damaging potential. No controlled studies to establish the safety of the drug in pregnancy have been performed.

Nursing mothers. It is not known whether this drug is excreted in human milk. As a general rule, nursing should not be undertaken while a patient is on a drug since many drugs are excreted in human milk.

Pediatric Use. Since there is no adequate experience in children who have received this drug, safety and efficacy in children have not been established.

Precautions: Use Robinul with caution in the elderly and in all patients with:

- Autonomic neuropathy.
- Hepatic or renal disease.
- Ulcerative colitis—large doses may suppress intestinal motility to the point of producing a paralytic ileus and for this reason may precipitate or aggravate "toxic megacolon," a serious complication of the disease.
- Hyperthyroidism, coronary heart disease, congestive heart failure, cardiac tachyarrhythmias, tachycardia, hypertension and prostatic hypertrophy.
- Hiatal hernia associated with reflux esophagitis, since anticholinergic drugs may aggravate this condition.

Adverse Reactions: Anticholinergics produce certain effects, most of which are extensions of their fundamental pharmacological actions. Adverse reactions to anticholinergics in general may include xerostomia; decreased sweating; urinary hesitancy and retention; blurred vision; tachycardia; palpitations; dilatation of the pupil; cycloplegia; increased ocular tension; loss of taste; headaches; nervousness; mental confusion; drowsiness; weakness; dizziness; insomnia; nausea; vomiting; constipation; bloated feeling; impotence; suppression of lactation; severe allergic reaction or drug idiosyncrasies including anaphylaxis, urticaria and other dermal manifestations.

Robinul (glycopyrrolate) is chemically a quaternary ammonium compound; hence, its passage across lipid membranes, such as the blood-brain barrier, is limited in contrast to atropine sulfate and scopolamine hydrobromide. For this reason the occurrence of CNS related side effects is lower, in comparison to their incidence following administration of anticholinergics which are chemically tertiary amines that can cross this barrier readily.

Overdosage: The symptoms of overdosage of glycopyrrolate are peripheral in nature rather than central.

1. To guard against further absorption of the drug—use gastric lavage, cathartics and/or enemas.
2. To combat peripheral anticholinergic effects (residual mydriasis, dry mouth, etc.)—utilize a quaternary ammonium anticholinesterase, such as neostigmine methylsulfate.
3. To combat hypotension—use pressor amines (norepinephrine, metaraminol) i.v.; and supportive care.
4. To combat respiratory depression—administer oxygen; utilize a respiratory stimulant such as Dopram® i.v.; artificial respiration.

Dosage and Administration: ***The dosage of Robinul or Robinul Forte should be adjusted to the needs of the individual patient to assure symptomatic control with a minimum of adverse reactions. The presently recommended maximum daily dosage of glycopyrrolate is 8 mg.***

Robinul (glycopyrrolate, 1 mg) tablets. The recommended initial dosage of Robinul for adults is one tablet three times daily (in the morning, early afternoon, and at bedtime). Some patients may require two tablets at bedtime to assure overnight control of symptoms. For maintenance, a dosage of one tablet twice a day is frequently adequate.

Robinul Forte (glycopyrrolate, 2 mg) tablets. The recommended dosage of Robinul Forte for adults is one tablet two or three times daily at equally spaced intervals.

Robinul tablets are not recommended for use in children under the age of 12 years.

Drug Interactions: There are no known drug interactions.

How Supplied: Robinul (glycopyrrolate, 1 mg) tablets in bottles of 100 (NDC 0031-7824-63) and 500 (NDC 0031-7824-70).

Robinul Forte (glycopyrrolate, 2 mg) tablets in bottles of 100 (NDC 0031-7840-63).

Rev. February 1985

Rev. Dec. 1981

Robinul® Injectable

brand of

Glycopyrrolate Injection, USP

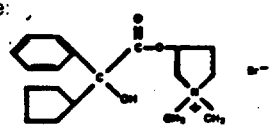
Description: Robinul (glycopyrrolate) is a synthetic anticholinergic agent. Each 1 ml contains:

Glycopyrrolate, USP ..... 0.2 mg
Water for Injection, USP ..... q.s.
Benzyl Alcohol, NF 0.9%
(preservative)

pH adjusted, when necessary, with hydrochloric acid and/or sodium hydroxide.

For intramuscular or intravenous administration.

Glycopyrrolate is a quaternary ammonium compound with the following chemical structure:



3[(cyclopentylhydroxyphenylacetyl)oxy]-1,1-dimethyl pyrrolidinium bromide.

Unlike atropine, glycopyrrolate is completely ionized at physiological pH values.

Robinul Injectable is a clear, colorless, sterile liquid; pH 2.0-3.0.

Clinical Pharmacology: Glycopyrrolate, like other anticholinergic (antimuscarinic) agents, inhibits the action of acetylcholine on structures innervated by postganglionic cholinergic nerves and on smooth muscles that respond to acetylcholine but lack cholinergic innervation. These peripheral cholinergic receptors are present in the autonomic effector cells of smooth muscle, cardiac muscle, the sinoatrial node, the atrioventricular node, exocrine glands, and, to a limited degree, in the autonomic ganglia. Thus, it diminishes the volume and free acidity of gastric secretions and controls excessive pharyngeal, tracheal, and bronchial secretions.

Glycopyrrolate antagonizes muscarinic symptoms (e.g., bronchorrhea, bronchospasm, bradycardia, and intestinal hypermotility) induced by cholinergic drugs such as the anticholinesterases.

The highly polar quaternary ammonium group of glycopyrrolate limits its passage across lipid membranes, such as the blood-brain barrier, in contrast to atropine sulfate and scopolamine hydrobromide, which are non-polar tertiary amines which penetrate lipid barriers easily.

Peak effects occur approximately 30 to 45 minutes after intramuscular administration. The vagal blocking effects persist for 2 to 3 hours and the antisialagogue effects persist up to 7 hours, periods longer than for atropine. With intravenous injection, the onset of action is generally evident within one minute.

Indications and Usage:

In Anesthesia: Robinul (glycopyrrolate) Injectable is indicated for use as a preoperative antimuscarinic to reduce salivary, tracheobronchial, and pharyngeal secretions; to reduce the volume and free acidity of gastric secretions; and, to block cardiac vagal inhibitory reflexes during induction of anesthesia and intubation. When indicated, Robinul Injectable may be used intraoperatively to counteract drug-induced or vagal traction reflexes with the associated arrhythmias. Glycopyrrolate protects against the peripheral muscarinic effects (e.g., bradycardia and excessive secretions) of cholinergic agents such as neostigmine and pyridostigmine given to reverse the neuromuscular blockade due to nondepolarizing muscle relaxants.

In Peptic Ulcer: For use in adults as adjunctive therapy for the treatment of peptic ulcer when rapid anticholinergic effect is desired or when oral medication is not tolerated.

Contraindications: Known hypersensitivity to glycopyrrolate.

In addition, in the management of *peptic ulcer* patients, because of the longer duration of therapy, Robinul Injectable may be contraindicated in patients with concurrent glaucoma; obstructive uropathy (for example, bladder neck obstruction due to prostatic hypertrophy); obstructive disease of the gastrointestinal tract (as in achalasia, pyloroduodenal stenosis, etc.); paralytic ileus, intestinal atony of the elderly or debilitated patient; unstable cardiovascular status in acute hemorrhage; severe ulcerative colitis; toxic megacolon complicating ulcerative colitis; myasthenia gravis.

Warnings: This drug should be used with great caution, if at all, in patients with glaucoma or asthma.

In the ambulatory patient, Robinul (glycopyrrolate) may produce drowsiness or blurred vision. The patient should be cautioned regarding activities requiring mental alertness such as operating a motor vehicle or other machinery or performing hazardous work while taking this drug.

In addition, in the presence of a high environmental temperature, heat prostration (fever and heat stroke due to decreased sweating) can occur with use of Robinul (glycopyrrolate).

Diarrhea may be an early symptom of incomplete intestinal obstruction, especially in patients with ileostomy or colostomy. In this instance treatment with Robinul (glycopyrrolate) would be inappropriate and possibly harmful.

Precautions: *General.*

Investigate any tachycardia before giving glycopyrrolate since an increase in the heart rate may occur.

Use with caution in patients with: coronary artery disease; congestive heart failure; cardiac arrhythmias; hypertension; hyperthyroidism.

In managing ulcer patients, use Robinul with caution in the elderly and in all patients with autonomic neuropathy, hepatic or renal disease, ulcerative colitis or hiatal hernia, since anticholinergic drugs may aggravate these conditions.

With overdosage, a curare-like action may occur.

Drug Interactions. The intravenous administration of any anticholinergic in the presence of cyclopropane anesthesia can result in ventricular arrhythmias; therefore, caution should be observed if Robinul (glycopyrrolate) Injectable is used during cyclopropane anesthesia. If the drug is given in small incremental doses of 0.1 mg or less, the likelihood of producing ventricular arrhythmias is reduced.

Carcinogenesis, mutagenesis, impairment of fertility. Long-term studies in animals have not been performed to evaluate carcinogenic potential. In the teratology studies, diminished rates of conception and of survival at weaning were observed in rats, in a dose-related manner. Studies in dogs suggest that this may be due to diminished seminal secretion which is evident at high doses of glycopyrrolate.

Pregnancy Category B. Reproduction studies have been performed in rats and rabbits up to 1000 times the human dose and have revealed no teratogenic effects from glycopyrrolate. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Robinul is administered to a nursing woman.

Pediatric Use. Safety and effectiveness in children below the age of 12 years have not been established for the management of peptic ulcer.

Adverse Reactions: Anticholinergics produce certain effects, most of which are extensions of their pharmacologic actions. Adverse reactions to anticholinergics in general may include dry mouth; urinary hesitancy and retention; blurred vision due to mydriasis; increased ocular tension; tachycardia; palpitation; decreased sweating; loss of taste; headache; nervousness; drowsiness; weakness; dizziness; insomnia; nausea; vomiting; impotence; suppression of lactation; constipation; bloated feeling; severe allergic reaction or drug idiosyncrasies including anaphylaxis; urticaria and other dermal manifestations; some degree of mental confusion and/or excitement, especially in elderly persons.

Robinul is chemically a quaternary ammonium compound; hence, its passage across lipid membranes, such as the blood-brain barrier is limited in contrast to atropine sulfate and scopolamine hydrobromide. For this reason the occurrence of CNS related side effects is lower, in comparison to their incidence following administration of anticholinergics which are chemically tertiary amines that can cross this barrier readily.

Overdosage: To combat peripheral anticholinergic effects, a quaternary ammonium anticholinesterase such as neostigmine methylsulfate (which does not cross the blood-brain barrier) may be given intravenously in increments of 0.25 mg in adults. This dosage may be repeated every five to ten minutes until anticholinergic over-activity is reversed or up to a maximum of 2.5 mg. Proportionately smaller doses should be used in children. Indication for repetitive doses of neostigmine should be based on close monitoring of the decrease in heart rate and the return of bowel sounds.

In the unlikely event that CNS symptoms (excitement, restlessness, convulsions, psychotic behavior) occur, physostigmine (which does cross the blood-brain barrier) should be used. Physostigmine 0.5 to 2 mg

should be slowly administered intravenously and repeated as necessary up to a total of 5 mg in adults. Proportionately smaller doses should be used in children.

Fever should be treated symptomatically. In the event of a curare-like effect on respiratory muscles, artificial respiration should be instituted and maintained until effective respiratory action returns.

Dosage and Administration: Robinul (glycopyrrolate) Injectable may be administered intramuscularly, or intravenously, without dilution, in the following indications.

Adults: *Preanesthetic Medication.* The recommended dose of Robinul (glycopyrrolate) Injectable is 0.002 mg (0.01 ml) per pound of body weight by intramuscular injection, given 30 to 60 minutes prior to the anticipated time of induction of anesthesia or at the time the preanesthetic narcotic and/or sedative are administered.

Intraoperative Medication. Robinul (glycopyrrolate) Injectable may be used during surgery to counteract drug induced or vagal traction reflexes with the associated arrhythmias (e.g., bradycardia). It should be administered intravenously as single doses of 0.1 mg (0.5 ml) and repeated, as needed, at intervals of 2-3 minutes. The usual attempts should be made to determine the etiology of the arrhythmia, and the surgical or anesthetic manipulations necessary to correct parasympathetic imbalance should be performed.

Reversal of Neuromuscular Blockade. The recommended dose of Robinul (glycopyrrolate) Injectable is 0.2 mg (1.0 ml) for each 1.0 mg of neostigmine or 5.0 mg of pyridostigmine. In order to minimize the appearance of cardiac side effects, the drugs may be administered simultaneously by intravenous injection and may be mixed in the same syringe.

Children: *Preanesthetic Medication.* The recommended dose of Robinul (glycopyrrolate) Injectable in children to 12 years of age is 0.002 mg (0.01 ml) per pound of body weight intramuscularly, given 30 to 60 minutes prior to the anticipated time of induction of anesthesia or at the time the preanesthetic narcotic and/or sedative are administered.

Children under 2 years of age may require up to 0.004 mg (0.02 ml) per pound of body weight.

Intraoperative Medication. Because of the long duration of action of Robinul (glycopyrrolate) if used as preanesthetic medication, additional Robinul (glycopyrrolate) Injectable for anticholinergic effect intraoperatively is rarely needed; in the event it is required the recommended pediatric dose is 0.002 mg (0.01 ml) per pound of body weight intravenously, not to exceed 0.1 mg (0.5 ml) in a single dose which may be repeated, as needed, at intervals of 2-3 minutes. The usual attempts should be made to determine the etiology of the arrhythmia, and the surgical or anesthetic manipulations necessary to correct parasympathetic imbalance should be performed.

Reversal of Neuromuscular Blockade. The recommended pediatric dose of Robinul (glycopyrrolate) Injectable is 0.2 mg (1.0 ml) for each 1.0 mg of neostigmine or 5.0 mg of pyridostigmine. In order to minimize the appearance of cardiac side effects, the drugs may be administered simultaneously by intravenous injection and may be mixed in the same syringe.

Adults: *Peptic Ulcer.* The usual recommended dose of Robinul Injectable is 0.1 mg (0.5 ml) administered at 4-hour intervals, 3 or 4 times daily intravenously or intramuscularly. Where more profound effect is required, 0.2 mg (1.0 ml) may be given. Some patients may need only a single dose, and frequency of administration should be dictated by patient response up to a maximum of four times daily.

Robinul Injectable is not recommended for peptic ulcer in children under 12 years of age. (See Precautions).

NOTE: Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.

Admixture Compatibilities. Robinul (glycopyrrolate) Injectable is compatible for mixing and injection with the following injectable dosage forms: 5% and 10% glucose in water or saline; atropine sulfate, USP; Antilirium® (physostigmine salicylate); Benadryl® (diphenhydramine HCl); codeine phosphate, USP; Emete-Con® (benzquinamide HCl); hydromorphone HCl, USP; Inapsine® (droperidol); Innovar® (droperidol and fentabyl citrate); Largon® (propiomazine HCl); Levo-Dromoran® (levorphanol tartrate); lidocaine, USP; Mepergan® (meperidine and promethazine HCls); meperidine HCl, USP; Mestinon®/Regonol® (pyridostigmine bromide); morphine sulfate, USP; Nisentil® (alphaprodine HCl); Nubain® (nalbuphine HCl); Numorphan® (oxymorphone HCl); Pantopon® (opium alkaloids HCls); procaine HCl, USP; promethazine HCl, USP; Prostigmin® (neostigmine methylsulfate, USP); scopolamine HBr, USP; Sparine® (promazine HCl); Stadol® (butorphanol tartrate); Sublimaze® (fentanyl citrate); Talwin® (pentazocine lactate); Tigan® (trimethobenzamide HCl); Vesprin® (triflupromazine HCl); and Vistaril® (hydroxyzine HCl). Robinul Injectable may be administered via the tubing of a running infusion of physiological saline or lactated Ringer's solution.

Since the stability of glycopyrrolate is questionable above a pH of 6.0 do *not* combine Robinul Injectable in the same syringe with Brevital® (methohexital Na); Chloromycetin® (chloramphenicol Na succinate); Dramamine® (dimenhydrinate); Nembutal® (pentobarbital Na); Pentothal® (thiopental Na); Seconal® (secobarbital Na); sodium bicarbonate (Abbott); or Valium® (diazepam). A gas will evolve or a precipitate may form. Mixing with Decadron® (dexamethazone Na phosphate) or a buffered solution of lactated Ringer's solution will result in a pH higher than 6.0. Mixing chlorpromazine HCl, USP, or Compazine® (prochlorperazine) with other agents in a syringe is not recommended by the manufacturer, although the mixture with Robinul Injectable is physically compatible.

How Supplied: Robinul (glycopyrrolate) Injectable, 0.2 mg/ml, is available in 1 ml single dose vials packaged in 5's (NDC 0031-7890-87), and 25's (NDC 0031-7890-11), 2 ml single dose vials packaged in 25's (NDC 0031-7890-95), 5 ml multiple dose vials packaged individually (NDC 0031-7890-93) and in 25's (NDC 0031-7890-06), and 20 ml (NDC 0031-7890-83) multiple dose vials.

Store at controlled room temperature, between 15°C and 30°C (59°F and 86°F).

Manufactured for PHARMACEUTICAL DIVISION, A. H. ROBINS CO., Richmond, VA 23220, by ELKINS-SINN, INC., Cherry Hill, NJ 08034.

Rev. Dec. 1981

Rev. March 1985
BROAD-SPECTRUM
ANTIBIOTIC

Robitet Robicaps®

Robitet® `250´
hydrochloride Robicaps
(Tetracycline Hydrochloride Capsules, USP)

Robitet® `500´
hydrochloride Robicaps
(Tetracycline Hydrochloride Capsules, USP)

Description: Tetracycline is a broad-spectrum antibiotic prepared from the cultures of certain streptomyces species. Robitet '250' Robicaps are pink and brown hard gelatin capsules each containing 250 mg tetracycline hydrochloride.
Robitet '500' Robicaps are cream and brown hard gelatin capsules each containing 500 mg tetracycline hydrochloride.

Inactive Ingredients: Robitet '250' Robicaps: D&C Yellow 10, Edible Ink, FD&C Blue 1, FD&C Red 3, Gelatin, Lactose, Magnesium Stearate, Sodium Lauryl Sulfate, Titanium Dioxide. May contain FD&C Yellow 6.

Robitet '500' Robicaps: Corn Starch, D&C Red 33, D&C Yellow 10, Edible Ink, FD&C Blue 1, FD&C Blue 2 Aluminum Lake, FD&C Red 3, Gelatin, Magnesium Stearate, Stearic Acid, Titanium Dioxide. May contain FD&C Red 40 and Yellow 6 Aluminum Lakes.

Actions: The tetracyclines are primarily bacteriostatic and are thought to exert their antimicrobial effect by the inhibition of protein synthesis. Tetracyclines are active against a wide range of gram-negative and gram-positive organisms.

The drugs in the tetracycline class have closely similar antimicrobial spectra, and cross-resistance among them is common. Micro-organisms may be considered susceptible if the MIC (minimum inhibitory concentration) is not more than 4.0 mcg/mL and intermediate if the MIC is 4.0 to 12.5 mcg/mL.

Susceptibility plate testing: A tetracycline disc may be used to determine microbial susceptibility to drugs in the tetracycline class. If the Kirby-Bauer method of disc susceptibility testing is used, a 30 mcg tetracycline disc should give a zone of at least 19 mm when tested against a tetracycline-susceptible bacterial strain.

Tetracyclines are readily absorbed and are bound to plasma proteins in varying degree. They are concentrated by the liver in the bile and excreted in the urine and feces at high concentrations and in a biologically active form.

Indications: Tetracycline is indicated in infections caused by the following micro-organisms: Rickettsiae (Rocky Mountain spotted fever, typhus fever and the typhus group, Q fever, rickettsialpox and tick fevers), *Mycoplasma pneumoniae* (PPLO, Eaton Agent). Agents of psittacosis and ornithosis, Agents of lymphogranuloma venereum and granuloma inguinale, The spirochetal agent of relapsing fever (*Borrelia recurrentis*).

The following gram-negative microorganisms: *Haemophilus ducreyi* (chancroid), *Pasteurella pestis* and *Pasteurella tularensis, Bartonella bacilliformis, Bacteroides* species, *Vibrio comma* and *Vibrio fetus, Brucella* species (in conjunction with streptomycin).

Because many strains of the following groups of micro-organisms have been shown to be resistant to tetracyclines, culture and susceptibility testing are recommended.

Tetracycline is indicated for treatment of infections caused by the following gram-negative micro-organisms, when bacteriologic testing indicates appropriate susceptibility to the drug: *Escherichia coli, Enterobacter aerogenes* (formerly *Aerobacter aerogenes*), *Shigella* species, *Mima* species and *Herellea* species, *Haemophilus influenzae* (respiratory infections), *Klebsiella* species (respiratory and urinary infections).

Tetracycline is indicated for treatment of infections caused by the following gram-positive micro-organisms when bacteriologic testing indicates appropriate susceptibility to the drug. Streptococcus species: Up to 44 percent of strains of *Streptococcus pyogenes* and 74 percent of *Streptococcus faecalis* have been found to be resistant to tetracycline drugs. Therefore, tetracyclines should not be used for streptococcal disease unless the organism has been demonstrated to be sensitive. For upper respiratory infections due to group A beta-hemolytic streptococci, penicillin is the usual drug of choice, including prophylaxis of rheumatic fever. *Diplococcus pneumoniae, Staphylococcus aureus,* skin and soft tissue infections. Tetracyclines are not the drugs of choice in the treatment of any type of staphylococcal infections.

When penicillin is contraindicated, tetracyclines are alternative drugs in the treatment of infections due to: *Neisseria gonorrhoeae, Treponema pallidum* and *Treponema pertenue* (syphilis and yaws), *Listeria monocytogenes, Clostridium* species, *Bacillus anthracis, Fusobacterium fusiforme* (Vincent's infection), *Actinomyces* species.

In acute intestinal amebiasis, the tetracyclines may be a useful adjunct to amebicides.

In severe acne, the tetracyclines may be useful adjunctive therapy.

Tetracycline hydrochloride is indicated for the treatment of uncomplicated urethral, endocervical or rectal infections in adults caused by *Chlamydia trachomatis.*[1]

Tetracyclines are indicated in the treatment of trachoma, although the infectious agent is not always eliminated, as judged by immunofluorescence.

Inclusion conjunctivitis may be treated with oral tetracyclines or with a combination of oral and topical agents.

Contraindication: This drug is contraindicated in persons who have shown hypersensitivity to any of the tetracyclines.

Warnings: THE USE OF DRUGS OF THE TETRACYCLINE CLASS DURING TOOTH DEVELOPMENT (LAST HALF OF PREGNANCY, INFANCY AND CHILDHOOD TO THE AGE OF 8 YEARS) MAY CAUSE PERMANENT DISCOLORATION OF THE TEETH (YELLOW-GRAY-BROWN). This adverse reaction is more common during long-term use of the drugs but has been observed following repeated short-term courses. Enamel hypoplasia has also been reported. TETRACYCLINE DRUGS, THEREFORE, SHOULD NOT BE USED IN THIS AGE GROUP UNLESS OTHER DRUGS ARE NOT LIKELY TO BE EFFECTIVE OR ARE CONTRAINDICATED.

If renal impairment exists, even usual oral or parenteral doses may lead to excessive systemic accumulation of the drug and possible liver toxicity. Under such conditions, lower than usual total doses are indicated and, if therapy is prolonged, serum level determinations of the drug may be advisable.

Photosensitivity manifested by an exaggerated sunburn reaction has been observed in some individuals taking tetracyclines. Patients apt to be exposed to direct sunlight or ultraviolet light should be advised that this reaction can occur with tetracycline drugs, and treatment should be discontinued at the first evidence of skin erythema.

The anti-anabolic action of the tetracyclines may cause an increase in BUN. While this is not a problem in those with normal renal function, in patients with significantly impaired function, higher serum levels of tetracycline may lead to azotemia, hyperphosphatemia, and acidosis.

Usage in pregnancy. (See above "Warnings" about use during tooth development.)

Results of animal studies indicate that tetracyclines cross the placenta, are found in fetal tissues and can have toxic effects on the developing fetus (often related to retardation of skeletal development). Evidence of embryotoxicity has also been noted in animals treated early in pregnancy.

Usage in newborns, infants, and children. (See above "Warnings" about use during tooth development.)

All tetracyclines form a stable calcium complex in any bone forming tissue. A decrease in the fibula growth rate has been observed in prematures given oral tetracycline in doses of 25 mg/kg every 6 hours. This reaction was shown to be reversible when the drug was discontinued.

Tetracyclines are present in the milk of lactating women who are taking a drug in this class.

Precautions: As with other antibiotic preparations, use of this drug may result in overgrowth of nonsusceptible organisms, including fungi. If superinfection occurs, the antibiotic should be discontinued and appropriate therapy instituted.

In venereal diseases when coexistent syphilis is suspected, darkfield examination should be done before treatment is started and the blood serology repeated monthly for at least 4 months.

Because tetracyclines have been shown to depress plasma prothrombin activity, patients who are on anticoagulant therapy may require downward adjustment of their

anticoagulant dosage.

In long-term therapy, periodic laboratory evaluation of organ systems, including hematopoietic, renal and hepatic studies should be performed.

All infections due to Group A beta-hemolytic streptococci should be treated for at least 10 days.

Since bacteriostatic drugs may interfere with the bactericidal action of penicillin, it is advisable to avoid giving tetracycline in conjunction with penicillin.

Adverse Reactions: Gastrointestinal: Anorexia, nausea, vomiting, diarrhea, glossitis, dysphagia, enterocolitis, and inflammatory lesions (with monilial overgrowth) in the anogenital region. These reactions have been caused by both the oral and parenteral administration of tetracyclines.

Skin: maculopapular and erythematous rashes. Exfoliative dermatitis has been reported but is uncommon. Photosensitivity is discussed above. (See "Warnings.")

Renal toxicity: Rise in BUN has been reported and is apparently dose related. (See "Warnings.")

Hypersensitivity reactions: urticaria, angioneurotic edema, anaphylaxis, anaphylactoid purpura, pericarditis and exacerbation of systemic lupus erythematosis.

Bulging fontanels have been reported in young infants following full therapeutic dosage. This sign disappeared rapidly when the drug was discontinued.

Blood: Hemolytic anemia, thrombocytopenia, neutropenia and eosinophilia have been reported.

When given over prolonged periods, tetracyclines have been reported to produce brown-black microscopic discoloration of thyroid glands. No abnormalities of thyroid function studies are known to occur.

Dosage and Administration: Therapy should be continued for at least 24–48 hours after symptoms and fever have subsided.

Concomitant therapy: Antacids containing aluminum, calcium, or magnesium impair absorption and should not be given to patients taking oral tetracycline.

Food and some dairy products also interfere with absorption. Oral forms of tetracycline should be given 1 hour before or 2 hours after meals. Pediatric oral dosage forms should not be given with milk formulas and should be given at least 1 hour prior to feeding.

In patients with renal impairment: (See "Warnings.") Total dosage should be decreased by reduction of recommended individual doses and/or by extending time intervals between doses.

In the treatment of streptococcal infections, a therapeutic dose of tetracycline should be administered for at least 10 days.

ADULTS: Usual daily dose, 1–2 gm divided in two or four equal doses, depending on the severity of the infection.

FOR CHILDREN ABOVE EIGHT YEARS OF AGE: Usual daily dose, 10–20 mg (25–50 mg/kg) per pound of body weight divided in four equal doses.

For treatment of brucellosis, 500 mg tetracycline four times daily for 3 weeks should be accompanied by streptomycin, 1 gram intramuscularly twice daily the first week, and once daily the second week.

For treatment of syphilis, a total of 30–40 grams in equally divided doses over a period of 10–15 days should be given. Close followup, including laboratory tests, is recommended.

Treatment of uncomplicated gonorrhea: When penicillin is contraindicated, tetracycline may be used for the treatment of both males and females in the following divided dosage schedule: 1.5 grams initially followed by 0.5 grams q.i.d. for a total of 9.0 grams.

For treatment of uncomplicated urethral, endocervical, or rectal infections in adults caused by ***Chlamydia trachomatis:*** 500 mg, by mouth, 4 times a day for at least 7 days.[1]

How Supplied: Robitet Robicaps® (Tetracycline Hydrochloride Capsules, USP), 250 mg in bottles of 100 (NDC 0031-8417-63) and 1000 (NDC 0031-8417-74); 500 mg in bottles of 100 (NDC 0031-8427-63) and 500 (NDC 0031-8427-70).

Store at Controlled Room Temperature, Between 15°C and 30°C (59°F and 86°F).

Dispense in tight, light-resistant container.

Rev. March 1985

[1]CDC Sexually Transmitted Diseases Treatment Guidelines 1982."

†Robicaps® is A. H. Robins' registered trademark for capsules

Rev. April 1987
EXPECTORANT
ANTITUSSIVE

Robitussin A-C®

Robitussin and codeine
Each 5 mL (1 teaspoonful) contains:
Guaifenesin, USP ..... 100 mg
Codeine Phosphate, USP ..... 10 mg
(Warning: May be habit forming)
Alcohol 3.5 percent
In a palatable, aromatic syrup

Inactive Ingredients: Caramel, Citric Acid, FD&C Red 40, Flavors, Glycerin, Saccharin Sodium, Sodium Benzoate, Sorbitol, Water.

Actions: Robitussin-AC combines the expectorant, guaifenesin, with the cough suppressant, codeine. Guaifenesin enhances the output of lower respiratory tract fluid (RTF). The enhanced flow of less viscid secretions promotes ciliary action and facilitates the removal of inspissated mucus. As a result, dry, unproductive coughs become more productive and less frequent.

Codeine phosphate is favored for its efficacy in low dosage. Robitussin A-C is especially useful when concurrent expectorant and cough suppressant actions are desired.

Indications: Robitussin A-C is useful in combating coughs associated with the common cold, bronchitis, laryngitis, tracheitis, pharyngitis, pertussis, influenza, and measles.

Contraindications: Hypersensitivity to any of the ingredients.

Warnings: Use this product with caution in children under 2 years or in children taking another drug. Prescribe cautiously for patients with persistent or chronic cough such as occurs with smoking, asthma, emphysema, or where cough is accompanied by excessive secretions. In patients with chronic pulmonary disease or shortness of breath, this product should be administered with caution. This product may cause or aggravate constipation. Caution should be exercised when prescribing this or any other medication for pregnant or nursing patients.

Note: Guaifenesin has been shown to produce a color interference with certain clinical laboratory determinations of 5-hydroxyindoleacetic acid (5-HIAA) and vanillylmandelic acid (VMA).

Adverse Reactions: Rarely, nausea, gastrointestinal upset, constipation, and drowsiness may occur. No serious side effects from guaifenesin have been reported.

Dosage: Adults and children 12 years of age and over: 2 teaspoonfuls every four hours, not to exceed 12 teaspoonfuls in a 24-hour period; children 6 to under 12 years: 1 teaspoonful every four hours, not to exceed 6 teaspoonfuls in a 24-hour period; children 2 to under 6 years: ½ teaspoonful every four hours, not to exceed 3 teaspoonfuls in a 24-hour period; children under 2 years: use as directed by physician.

How Supplied: Bottles of 2 fl. ounces (NDC 0031-8674-05), 4 fl. ounces (NDC 0031-8674-12), one pint (NDC 0031-8674-25), and one gallon (NDC 0031-8674-29).

Also Available: Robitussin®, Robitussin-CF®—Robitussin with phenylpropanolamine and dextromethorphan. Robitussin-DM®—Robitussin with dextromethorphan. Cough Calmers® lozenges (Robitussin-DM in solid form). Robitussin-PE®— Robitussin with pseudoephedrine. Robitussin®- DAC—Robitussin with pseudoephedrine and codeine.

Rev. April 1987
EXPECTORANT
NASAL DECONGESTANT
ANTITUSSIVE

Robitussin®-DAC

Each 5 mL (1 teaspoonful) contains:

Guaifenesin, USP	100 mg
Pseudoephedrine Hydrochloride, USP	30 mg
Codeine Phosphate, USP	10 mg

(Warning: May be habit forming)
In a palatable aromatic syrup
Alcohol 1.9 percent

Inactive Ingredients: Caramel, Citric Acid, FD&C Red 40, Flavors, Glycerin, Saccharin Sodium, Sodium Benzoate, Sorbitol, Water.

Indications: For the temporary relief of cough and nasal congestion as may occur with the common cold or with inhaled irritants.

Contains the expectorant, guaifenesin, which relieves irritated membranes in the respiratory passageways by preventing dryness through increased mucus flow. The nasal decongestant, pseudoephedrine, reduces the swelling of nasal passages. The antitussive, codeine, calms the cough control center and relieves coughing.

Contraindications: Hypersensitivity to any of the ingredients, marked hypertension, hyperthyroidism, or in patients who are receiving MAO inhibitors or antihypertensive medication.

Warnings: Use this product with caution in children under 2 years or in children taking another drug. Prescribe cautiously for patients with persistent or chronic cough such as occurs with smoking, asthma, emphysema, or where cough is accompanied by excessive secretions. Caution should be taken in administering this drug to patients with high blood pressure, heart disease or diabetes. In patients with chronic pulmonary disease or shortness of breath, this product should be administered with caution. As with all products containing sympathomimetic amines, use with caution in patients with prostatic hypertrophy or glaucoma. Do not exceed recommended dosage because at higher doses nervousness, dizziness or sleeplessness may occur. May cause or aggravate constipation. Caution should be exercised when prescribing this or any other medication for pregnant or nursing patients.

Note: Guaifenesin has been shown to produce a color interference with certain clinical laboratory determinations of 5-hydroxyindoleacetic acid (5-HIAA) and vanillylmandelic acid (VMA).

Adverse Reactions: Agitation, dizziness, insomnia or palpitations may occur. In such cases, reduction in frequency and/or quantity of dose is indicated. Rarely, nausea, gastrointestinal upset and constipation may occur.

Recommended Dosage: Adults and children 12 years of age and over: 1 or 2 teaspoonfuls every four hours, not to exceed 8 teaspoonfuls in a 24-hour period; children 6 to under 12 years: 1 teaspoonful every four hours, not to exceed 4 teaspoonfuls in a 24-hour period; children 2 to under 6 years: ½ teaspoonful every four hours, not to exceed 2 teaspoonfuls in a 24-hour period; children under 2 years: use as directed by physician.

How Supplied: Bottles of 4 fl. ounces (NDC 0031-8680-12) and one pint (NDC 0031-8680-25).

Also Available: Robitussin®. Robitussin A-C®—Robitussin with codeine. Robitussin-CF®—Robitussin with phenylpropanolamine and dextromethorphan. Robitussin-DM®—Robitussin with dextromethorphan. Cough Calmers® lozenges (Robitussin-DM in solid form). Robitussin-PE®—Robitussin with pseudoephedrine.

Rev. April 1987

October 1986

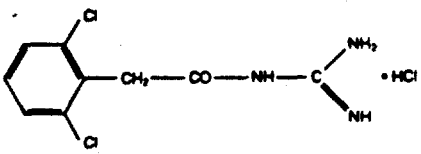
Tenex®

(Guanfacine Hydrochloride)

1 mg Tablets

Description: Tenex (guanfacine hydrochloride) is a centrally acting antihypertensive with α_2-adrenoceptor agonist properties. It is supplied as a light pink diamond shaped tablet for oral administration embossed with a 1 and engraved AHR on one side and engraved TENEX on the other side. Each tablet contains guanfacine base 1 mg (as the hydrochloride salt).

The chemical name of Tenex (guanfacine hydrochloride) is N-amidino-2-(2,6-dichlorophenyl) acetamide hydrochloride and its molecular weight is 282.56. Its structural formula is:



Guanfacine hydrochloride is a white to off-white powder; sparingly soluble in water and alcohol and slightly soluble in acetone. The tablets contain the following inactive ingredients: FD&C Red No. 40 aluminum lake, Lactose, Microcrystalline cellulose, Povidone, Stearic Acid.

Clinical Pharmacology: Tenex (guanfacine hydrochloride) is an orally active antihypertensive agent whose principal mechanism of action appears to be stimulation of central α_2-adrenergic receptors. By stimulating these receptors, guanfacine reduces sympathetic nerve impulses from the vasomotor center to the heart and blood vessels. This results in a decrease in peripheral vascular resistance and a reduction in heart rate.

Controlled clinical trials in patients with mild to moderate hypertension who were receiving a thiazide-type diuretic have defined the dose-response relationship for blood pressure response and adverse reactions of guanfacine given at bedtime and have shown that the blood pressure response to guanfacine can persist for 24 hours after a single dose. In the dose-response study, patients were randomized to placebo or to doses of 0.5, 1, 2, and 3 mg of guanfacine, each given at bedtime. The observed mean changes from baseline, tabulated below, indicate the similarity of response for placebo and the 0.5 mg dose. Doses of 1, 2, and 3 mg resulted in decreased blood pressure in the sitting position with no real differences among the three doses. In the standing position there was some increase in response with dose.

Mean Decrease in Seated and Standing Blood Pressure (BP) by Guanfacine Dosage Group

Week Data	n =	Placebo	0.5 mg	1 mg	2 mg	3 mg
		83	82	84	80	80
Change in Systolic BP (seated)		−5	−5	−14	−12	−16
Change in Diastolic BP (seated)		−7	−6	−13	−13	−13
Change in Systolic BP (standing)		−3	−5	−11	−9	−15
Change in Diastolic BP (standing)		−5	−4	−9	−10	−12

While most of the effectiveness of guanfacine was present at 1 mg, adverse reactions at this dose were not clearly distinguishable from those associated with placebo. Adverse reactions were clearly present at 2 and 3 mg (see Adverse Reactions).

In a placebo-controlled study of Tenex (guanfacine hydrochloride) a significant decrease in blood pressure was maintained for a full 24 hours after dosing. While there was no significant difference between the 12 and 24 hour blood pressure readings, the fall in blood pressure at 24 hours was numerically smaller, suggesting possible escape of blood pressure in some patients and the need for individualization of therapy.

In a double-blind, randomized trial, either guanfacine or clonidine was given at recommended doses with 25 mg chlorthalidone for 24 weeks and then abruptly discontinued. Results showed equal degrees of blood pressure reduction with the two drugs and there was no tendency for blood pressures to increase despite maintenance of the same daily dose of the two drugs. Signs and symptoms of rebound phenomena were infrequent upon discontinuation of either drug. Abrupt withdrawal of clonidine produced a rapid return of diastolic and especially, systolic blood pressure to approximately pre-treatment levels, with occasional values significantly greater than baseline, whereas guanfacine withdrawal produced a more gradual increase to pre-treatment levels, but also with occasional values significantly greater than baseline.

Pharmacodynamics: Hemodynamic studies in man showed that the decrease in blood pressure observed after single-dose or long-term oral treatment with guanfacine was accompanied by a significant decrease in peripheral resistance and a slight reduction in heart rate (5 beats/min). Cardiac output under conditions of rest or exercise was not altered by guanfacine.

Tenex (guanfacine hydrochloride) lowered elevated plasma renin activity and plasma catecholamine levels in hypertensive patients, but this does not correlate with individual blood-pressure responses.

Growth hormone secretion was stimulated with single oral doses of 2 and 4 mg of guanfacine. Long-term use of Tenex had no effect on growth hormone levels.

Guanfacine had no effect on plasma aldosterone. A slight but insignificant decrease in plasma volume occurred after one month of guanfacine therapy. There were no changes in mean body weight or electrolytes.

Pharmacokinetics: Relative to an intravenous dose of 3 mg, the absolute oral bioavailability of guanfacine is about 80%. Peak plasma concentrations occur from 1 to 4 hours with an average of 2.6 hours after single oral doses or at steady state.

The area under the concentration-time curve (AUC) increases linearly with the dose.

In individuals with normal renal function, the average elimination half-life is approximately 17 hr (range 10–30 hr). Younger patients tend to have shorter elimination half-lives (13–14 hr) while older patients tend to have half-lives at the upper end of the range. Steady state blood levels were attained within 4 days in most subjects.

In individuals with normal renal function, guanfacine and its metabolites are excreted primarily in the urine. Approximately 50% (40–75%) of the dose is eliminated in the urine as unchanged drug, the remainder is eliminated mostly as conjugates of metabolites produced by oxidative metabolism of the aromatic ring.

The guanfacine-to-creatinine clearance ratio is greater than 1.0, which would suggest that tubular secretion of drug occurs.

The drug is approximately 70% bound to plasma proteins, independent of drug concentration.

The whole body volume of distribution is high (a mean of 6.3 L/kg), which suggests a high distribution of drug to the tissues.

The clearance of guanfacine in patients with varying degrees of renal insufficiency is reduced, but plasma levels of drug are only slightly increased compared to patients with normal renal function. When prescribing for patients with renal impairment, the low end of the dosing range should be used. Patients on dialysis also can be given usual doses of guanfacine hydrochloride as the drug is poorly dialyzed.

Indications and Usage: Tenex (guanfacine hydrochloride) is indicated in the management of hypertension. Since dosing information (see Dosage and Administration) has been established in the presence of a thiazide-type diuretic; Tenex should, therefore, be used in patients who are already receiving a thiazide-type diuretic.

Contraindications: Tenex is contraindicated in patients with known hypersensitivity to guanfacine hydrochloride.

Precautions: ***General.*** Like other antihypertensive agents, Tenex (guanfacine hydrochloride) should be used with caution in patients with severe coronary insufficiency, recent myocardial infarction, cerebrovascular disease or chronic renal or hepatic failure.

Sedation. Tenex, like other orally active central alpha-2 adrenergic agonists, causes sedation or drowsiness, especially when beginning therapy. These symptoms are dose-related (see Adverse Reactions). When Tenex is used with other centrally active depressants (such as phenothiazines, barbiturates, or benzodiazepines), the potential for additive sedative effects should be considered.

Rebound. Abrupt cessation of therapy with orally active central alpha-2 adrenergic agonists may be associated with increases (from depressed on-therapy levels) in plasma and urinary catecholamines, symptoms of "nervousness and anxiety" and, less commonly, increases in blood pressure to levels significantly greater than those prior to therapy.

Information for Patients. Patients who receive Tenex should be advised to exercise caution when operating dangerous machinery or driving motor vehicles until it is determined that they do not become drowsy or dizzy from the medication. Patients should be warned that their tolerance for alcohol and other CNS depressants may be diminished. Patients should be advised not to discontinue therapy abruptly.

Laboratory Tests. In clinical trials, no clinically relevant laboratory test abnormalities

were identified as causally related to drug during short-term treatment with Tenex (guanfacine hydrochloride).

Drug Interactions. No specific adverse drug interactions have been identified, but the potential for increased sedation when Tenex is given with other CNS-depressant drugs should be appreciated.

Anticoagulants. Ten patients who were stabilized on oral anticoagulants were given guanfacine, 1–2 mg/day, for 4 weeks. No changes were observed in the degree of anticoagulation.

In several well-controlled studies, guanfacine was administered together with diuretics with no drug interactions reported. In the long-term safety studies, Tenex was given concomitantly with many drugs without evidence of any interactions. The principal drugs given (number of patients in parentheses) were: cardiac glycosides (115), sedatives and hypnotics (103), coronary vasodilators (52), oral hypoglycemics (45), cough and cold preparations (45), NSAIDs (38), antihyperlipidemics (29), antigout drugs (24), oral contraceptives (18), bronchodilators (13), insulin (10), and beta blockers (10).

Drug/Laboratory Test Interactions. No laboratory test abnormalities related to the use of Tenex (guanfacine hydrochloride) have been identified.

Carcinogenesis, Mutagenesis, Impairment of Fertility. No carcinogenic effect was observed in studies of 78 weeks in mice at doses more than 150 times the maximum recommended human dose and 102 weeks in rats at doses more than 100 times the maximum recommended human dose. In a variety of test models guanfacine was not mutagenic.

No adverse effects were observed in fertility studies in male and female rats.

Pregnancy Category B. Administration of guanfacine to rats at 70 times the maximum recommended human dose and rabbits at 20 times the maximum recommended human dose resulted in no evidence of impaired fertility or harm to the fetus. Higher doses (100 and 200 times the maximum recommended human dose in rabbits and rats respectively) were associated with reduced fetal survival and maternal toxicity. Rat experiments have shown that guanfacine crosses the placenta.

There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Labor and Delivery. Tenex (guanfacine hydrochloride) is not recommended in the treatment of acute hypertension associated with toxemia of pregnancy. There is no information available on the effects of guanfacine on the course of labor and delivery.

Nursing Mothers. It is not known whether Tenex (guanfacine hydrochloride) is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Tenex is administered to a nursing woman. Experiments with rats have shown that guanfacine is excreted in the milk.

Pediatric Use. Safety and effectiveness in children under 12 years of age have not been demonstrated. Therefore, the use of Tenex in this age group is not recommended.

Adverse Reactions: Adverse reactions noted with Tenex (guanfacine hydrochloride) are similar to those of other drugs of the central α-2 adrenoreceptor agonist class: dry mouth, sedation (somnolence), weakness (asthenia), dizziness, constipation, and impotence. While the reactions are common, most are mild and tend to disappear on continued dosing.

In a 12-week placebo-controlled, dose-response study the frequency of the most commonly observed adverse reactions showed a clear dose relationship from 0.5 to 3 mg, as follows:

Adverse Reaction	Placebo	0.5 mg	1.0 mg	2.0 mg	3.0 mg
n=	73	72	73	72	72
Dry Mouth	5 (7%)	4 (6%)	6 (8%)	8 (11%)	20 (28%)
Somnolence	1 (1%)	3 (4%)	0 (0%)	1 (1%)	10 (14%)
Asthenia	0 (0%)	2 (3%)	0 (0%)	2 (3%)	7 (10%)
Dizziness	2 (3%)	1 (1%)	3 (4%)	6 (8%)	3 (4%)
Headache	3 (4%)	4 (6%)	3 (4%)	1 (1%)	2 (3%)
Impotence	1 (1%)	1 (1%)	0 (0%)	1 (1%)	3 (4%)
Constipation	0 (0%)	0 (0%)	0 (0%)	1 (1%)	1 (1%)
Fatigue	3 (3%)	2 (3%)	2 (3%)	5 (6%)	3 (4%)

There were 41 premature terminations because of adverse reactions in this study. The percent of patients who terminated and the dose at which they terminated were as follows:

Dose:	Placebo	0.5 mg	1 mg	2 mg	3 mg
Terminated	6.9%	4.2%	3.2%	6.9%	8.3%

Reasons for dropouts among patients who received guanfacine were: somnolence, headache, weakness, dry mouth, dizziness, impotence, insomnia, constipation, syncope, urinary incontinence, conjunctivitis, paresthesia, and dermatitis.

In a second placebo-controlled study in which the dose could be adjusted upward to 3 mg per day in 1-mg increments at 3-week intervals, i.e., a setting more similar to ordinary clinical use, the most commonly recorded reactions were: dry mouth 47%, constipation 16%, fatigue 12%, somnolence 10%, asthenia 6%, dizziness 6%, headache 4%, and insomnia 4%.

Reasons for dropouts among patients who received guanfacine were: somnolence, dry mouth, dizziness, impotence, constipation, confusion, depression, and palpitations.

In the clonidine/guanfacine comparison described in Clinical Pharmacology, the most common adverse reactions noted were:

	Guanfacine (n = 279)	Clonidine (n = 278)
Dry mouth	30%	37%
Somnolence	21%	35%
Dizziness	11%	6%
Constipation	10%	5%
Fatigue	9%	6%
Headache	4%	4%
Insomnia	4%	3%

Adverse reactions occurring in 3% or less of patients in the three controlled trials were:

Cardiovascular—	bradycardia palpitations substernal pain
Gastrointestinal—	abdominal pain diarrhea dyspepsia dysphagia nausea
CNS—	amnesia confusion depression insomnia libido decrease
ENT disorders—	rhinitis taste perversion tinnitus
Eye disorders—	conjunctivitis, reduced vision disturbance
Musculoskeletal—	leg cramps hypokinesia
Respiratory—	dyspnea
Dermatologic—	dermatitis pruritus purpura sweating
Urogenital—	testicular disorder urinary incontinence
Other—	malaise paresthesia paresis

Adverse reaction reports tend to decrease over time. In an open-label trial of one year's duration, 580 hypertensive subjects were given guanfacine, titrated to achieve goal blood pressure, alone (51%), with diuretic (38%), with beta blocker (3%), with diuretic plus beta blocker (6%), or with diuretic plus vasodilator (2%). The mean daily dose of guanfacine reached was 4.7 mg.

Adverse Reaction	Incidence of adverse reactions at any time during the study n = 580	Incidence of adverse reactions at end of one year n = 580
Dry mouth	60%	15%
Drowsiness	33%	6%
Dizziness	15%	1%
Constipation	14%	3%
Weakness	5%	1%
Headache	4%	0.2%
Insomnia	5%	0%

There were 52 (8.9%) dropouts due to adverse effects in this 1-year trial. The causes were: dry mouth (n = 20), weakness (n = 12), constipation (n = 7), somnolence (n = 3), nausea (n = 3), orthostatic hypotension (n = 2), insomnia (n = 1), rash (n = 1), nightmares (n = 1), headache (n = 1), and depression (n = 1).

Drug Abuse and Dependence: No reported abuse or dependence has been associated with the administration of Tenex (guanfacine hydrochloride).

Overdosage: ***Signs and Symptoms.*** One case of guanfacine overdose has been reported. A 25-year-old female intentionally ingested 60 mg. She presented with severe drowsiness and bradycardia of 45 beats/minute. Gastric lavage was performed and an infusion of isoproterenol (0.8 mg in 12 hours) was administered. She recovered quickly and without sequelae.

Treatment of Overdosage. Gastric lavage and infusion of isoproterenol, as appropriate.

Guanfacine is not dialyzable in clinically significant amounts (2.4%).

Dosage and Administration: The recommended dose of Tenex (guanfacine hydrochloride) is 1 mg daily given at bedtime to minimize somnolence. Patients should already be receiving a thiazide type diuretic.

If after 3 to 4 weeks of therapy, 1 mg does not give a satisfactory result, doses of 2 and then subsequently 3 mg may be given, although most of the effect of Tenex is seen at 1 mg (see Clinical Pharmacology). Some patients may show a rise in pressure toward the end of the dosing interval; in this event a divided dose may be utilized.

Higher daily doses (rarely up to 40 mg/day, in divided doses) have been used, but adverse reactions increase significantly with doses above 3 mg/day and there is no evidence of increased efficacy. No studies have established an appropriate dose or dosing interval when Tenex (guanfacine hydrochloride) is given as the sole antihypertensive agent.

The frequency of rebound hypertension is low, but rebound can occur. When rebound occurs, it does so after 2–4 days, which is delayed compared with clonidine hydrochloride. This is consistent with the longer half-life of guanfacine. In most cases, after abrupt withdrawal of guanfacine, blood pressure returns to pretreatment levels slowly (within 2–4 days) without ill effects.

How Supplied: Tenex tablets containing 1 mg guanfacine (as the hydrochloride salt) are available in bottles of 100 (NDC 0031-8901-63) and 500 (NDC 0031-8901-70) and in Dis-Co® Unit Dose Packs of 100 (NDC 0031-8901-64).

Store at controlled room temperature, between 15°C and 30°C (59°F and 86°F). Dispense in tight, light-resistant container.

October 1986

Rev. March 1986

Viokase®
(Pancrelipase, USP)
Tablets and Powder

Description: Viokase (Pancrelipase, USP) is a pancreatic enzyme concentrate of porcine origin containing standardized lipase, protease, and amylase as well as other pancreatic enzymes. Viokase is available in tablet and powder dosage form for oral administration.

The enzyme potencies of the tablets and powder are:

	Each Tablet	Each 0.7 g powder (¼ teaspoonful)
Lipase, USP Units	8,000	16,800
Protease, USP Units	30,000	70,000
Amylase, USP Units	30,000	70,000

Inactive Ingredients:
Tablets: Lactose, Magnesium Stearate, Sodium Chloride, Stearic Acid.
Powder: Lactose, Sodium Chloride.

Clinical Pharmacology: The natural digestive enzymes in Viokase hydrolyze fats into fatty acids and glycerol, split protein into amino acids, and convert carbohydrates to dextrins and short chain sugars.

Under conditions of the USP test method (in vitro) Viokase has the following total digestive capacity:

	Each Tablet	Each 0.7 g powder
Dietary Fat, grams	28	59
Dietary Protein grams	30	70
Dietary Starch, grams	30	70

Viokase Tablets are not enteric coated.

The digestive capacity of a pancreatic enzyme concentrate depends on the amount that passes through the stomach unchanged and is available at the site of action in the small intestine.

Indications: Viokase (Pancrelipase, USP) is indicated as a digestive aid in the treatment of exocrine pancreatic insufficiency as associated with but not limited to cystic fibrosis, chronic pancreatitis, pancreatectomy, or obstruction of the pancreas ducts.

Contraindications: Do not use in patients hypersensitive to pork protein.

Precautions: ***General:*** Individuals previously sensitized to trypsin, pancreatin or pancrelipase may have allergic manifestations.

Information for patients: Viokase should not be held in the mouth as the proteolytic action may cause irritation of the mucosa.

Avoid inhalation of the powder when administering Viokase.

Carcinogenesis, Mutagenesis, Impairment of fertility: Long-term studies in animals have not been performed to evaluate carcinogenic potential.

Pregnancy Category C. Animal reproduction studies have not been conducted with Viokase. It is also not known whether Viokase can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Viokase should be given to a pregnant woman only if clearly needed.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Viokase is administered to a nursing mother.

Adverse Reactions: The dust or finely powdered pancreatic enzyme concentrate is irritating to the nasal mucosa and the respiratory tract. It has been documented that inhalation of the airborne powder can precipitate an asthma attack. The literature also contains several references to asthma due to inhalation in patients sensitized to pancreatic enzyme concentrates. Extremely high doses of exogenous pancreatic enzymes have been associated with hyperuricemia and hyperuricosuria. Overdosage of pancreatic enzyme concentrate may cause diarrhea or transient intestinal upset.

Overdosage: Acute toxicity determinations in animals have not been possible since the maximum dose that could be given orally produced no toxic reaction. In chronic feeding tests, rats developed swollen salivary glands. This is believed due to the proteolytic activity and the mucosal irritation caused by tissue digestion.*

No acute toxic reactions have been reported.

Dosage and Administration: ***Powder:*** Dosage for patients with cystic fibrosis–¼ teaspoonful (0.7 grams) with meals.
Tablets: Dosage for patients with cystic fibrosis or chronic pancreatitis–1 to 3 tablets with meals or as directed by physician. As a digestive aid in patients with pancreatectomy or obstruction of pancreatic ducts–1 to 2 tablets taken at 2-hour intervals or as directed by physician.

How Supplied: ***Tablets***—Tan, round, compressed tablets engraved Viokase/AHR on one side and 9111 on the other side in bottles of 100 (NDC 0031-9111-63) and 500 (NDC 0031-9111-70). ***Powder***—Tan powder in bottles of 4 oz. (113.5 grams) (NDC 0031-9115-12) and 8 oz. (227 grams) (NDC 0031-9115-25).

Store in tightly closed container in a dry place at a temperature not exceeding 25°C (77°F).

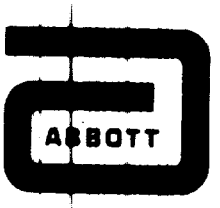
Dispense tablets and powder in tight container, preferably with a desiccant.

Clinical Studies: The effectiveness of Viokase as a digestive aid in the treatment of patients with exocrine pancreatic insufficiency has been documented in the literature as follows:

1. Regan, PT, Malagelada J-R, DiMagno EP, Glanzman SL., Go VLW: Comparative effects of antacids, cimetidine and enteric coating on the therapeutic response to oral enzymes in severe pancreatic insufficiency. N. Engl. J. Med. 297:854-8, 1977.
2. Graham DY: Enzyme replacement therapy of exocrine pancreatic insufficiency in man. N. Engl. J. Med. 296:1314-7, 1977.

Rev. March 1986

MATERIAL SAFETY DATA SHEETS



ABBOTT LABORATORIES

PHARMACEUTICAL PRODUCTS DIVISION

CUSTOMER RELATIONS DEPARTMENT

NORTH CHICAGO, IL 60064

Quelidrine® Cough Syrup, Non-Narcotic, Antihistimine Cough Suppressant
Selsun® Selenium Sulfide Lotion, USP
Tral® Hexocyclium Methylsulfate Filmtab® Tablets
Tranxene® Clorazepate Dipotassium Capsules Tablet; Tranxene-SD and Tranxene-SD Half Strength Clorazepate Dipotassium Tablets
Tridione® Trimethadione Tablets, Capsules and Oral Solutions
Tronothane® Hydrochloride Pramoxine Hydrochloride Cream
Vercyte® Pipobroman Tablets, USP

Material Safety Data Sheet

IDENTITY *(As Used on Label and List)*
ABBOKINASE® Urokinase for Injection

Note: Blank spaces are not permitted. If any item is not applicable or no information is available, the space must be marked to indicate that.

Section I List No. 6109

Manufacturer's Name **Abbott Laboratories**	Emergency Telephone Number **(312) 937-6100**
Address *(Number, Street, City, State, and ZIP Code)* **Pharmaceutical Products Division**	Telephone Number for Information **(312) 937-7350**
1400 Sheridan Road	Date Prepared July 20, 1987
North Chicago, Illinois 60064	Signature of Preparer *(optional)* Jim Mooney

Section II — Hazardous Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity; Common Name(s))	OSHA PEL	ACGIH TLV	Other Limits Recommended	% *(optional)*
None	NA	NA	NA	

Section III — Physical/Chemical Characteristics

Boiling Point	NA	Specific Gravity (H_2O = 1)	NA
Vapor Pressure (mm Hg.)	NA	Melting Point	ND
Vapor Density (AIR = 1)	NA	Evaporation Rate (Butyl Acetate = 1)	NA

Solubility in Water
Soluble

Appearance and Odor
Sterile lyophilized white powder preparation in a vial

Section IV — Fire and Explosion Hazard Data

Flash Point (Method Used)	Flammable Limits	LEL	UEL
NA		NA	NA

Extinguishing Media
Use media appropriate for primary cause of fire

Special Fire Fighting Procedures
None known

Unusual Fire and Explosion Hazards
None known

Section V — Reactivity Data

Stability	Unstable		Conditions to Avoid: None under normal use.
	Stable	X	

Incompatibility (*Materials to Avoid*)
None under normal use.

Hazardous Decomposition or Byproducts
oxide of nitrogen

Hazardous Polymerization	May Occur		Conditions to Avoid: None under normal use.
	Will Not Occur	X	

Section VI — Health Hazard Data

Route(s) of Entry: Inhalation? Unlikely | Skin? Unlikely | Ingestion? Unlikely

Health Hazards (*Acute and Chronic*)
No known occupational hazards. Consult the Physicians Desk Reference (PDR) for clinical health effects.

Carcinogenicity: NTP? No | IARC Monographs? No | OSHA Regulated? No

Signs and Symptoms of Exposure
None expected for occupational exposure. Refer to the PDR for clinical symptoms.

Medical Conditions Generally Aggravated by Exposure: None known for occupational exposure. Refer to the PDR for clinical information.

Emergency and First Aid Procedures
Remove from source of exposure. If skin or eye contact, flush with copious amounts of water. If irritation develops or symptoms of toxicity occur, seek medical attention.

Section VII — Precautions for Safe Handling and Use

Steps to Be Taken in Case Material Is Released or Spilled
No special procedures required

Waste Disposal Method
Dispose of in accordance with local, state and federal regulations

Precautions to Be Taken in Handling and Storing
No special precautions required under normal use.

Other Precautions
None required under normal use.

Section VIII — Control Measures

Respiratory Protection (*Specify Type*): NA

Ventilation	Local Exhaust: NA		Special: NA	
	Mechanical (*General*): NA		Other: NA	
Protective Gloves: NA		Eye Protection: NA		

Other Protective Clothing or Equipment: NA

Work/Hygienic Practices: Use good clinical and hygienic practices.

NA = Not Applicable
ND = No Data

Material Safety Data Sheet

IDENTITY (As Used on Label and List)	Note: Blank spaces are not permitted. If any item is not applicable or no information is available, the space must be marked to indicate that
Butesin® Picrate Ointment (Butamben Picrate)	

Section I List No. 4392

Manufacturer's Name **Abbott Laboratories**	Emergency Telephone Number **(312) 937-6100**
Address (Number, Street, City, State, and ZIP Code) **Pharmaceutical Products Division**	Telephone Number for Information **(312) 937-7350**
1400 Sheridan Road	Date Prepared July 20, 1987
North Chicago, Illinois 60064	Signature of Preparer (optional) Jim Mooney

Section II — Hazardous Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity, Common Name(s))	OSHA PEL	ACGIH TLV	Other Limits Recommended	% (optional)
Butamben Picrate	NA	NA	*	1%

* Internal employee exposure limit = 100 mcg/m^3 (8 hr TWA)

Section III — Physical/Chemical Characteristics

Boiling Point	NA	Specific Gravity (H_2O = 1)	NA
Vapor Pressure (mm Hg.)	NA	Melting Point	ND
Vapor Density (AIR = 1)	NA	Evaporation Rate (Butyl Acetate = 1)	NA

Solubility in Water
Soluble

Appearance and Odor
Ointment that can permanently stain animal fibers, silk, wool and hair

Section IV — Fire and Explosion Hazard Data

Flash Point (Method Used)	Flammable Limits	LEL	UEL
NA		NA	NA

Extinguishing Media
Use media appropriate for primary cause of fire.

Special Fire Fighting Procedures
None known

Unusual Fire and Explosion Hazards
None known

Section V — Reactivity Data

Stability	Unstable		Conditions to Avoid: None under normal use
	Stable	X	

Incompatibility (*Materials to Avoid*): None under normal use.

Hazardous Decomposition or Byproducts: ND

Hazardous Polymerization	May Occur		Conditions to Avoid: None under normal use.
	Will Not Occur	X	

Section VI — Health Hazard Data

Route(s) of Entry: Inhalation? Unlikely; Skin? Clinical route; Ingestion? Unlikely

Health Hazards (*Acute and Chronic*)

Oral LD50 = 500 mg/kg in rats for butamben picrate.

Butamben picrate is an eye irritant producing severe redness and some swelling.

Carcinogenicity: NTP? No; IARC Monographs? No; OSHA Regulated? No

Signs and Symptoms of Exposure
Numbing of the skin or exposed area can occur

Medical Conditions Generally Aggravated by Exposure: None known for occupational exposure. Refer to the Physicians Desk Reference for clinical information.

Emergency and First Aid Procedures
Remove from source of expsoure. If skin or eye contact, flush with copious amounts of water. If irritation develops or symptoms of toxicity occur, seek medical attention.

Section VII — Precautions for Safe Handling and Use

Steps to Be Taken in Case Material Is Released or Spilled
No special procedures required

Waste Disposal Method
Dispose of in accordance with local, state, and federal regulations

Precautions to Be Taken in Handling and Storing: No special precautions required under normal use.

Other Precautions: None required under normal use.

Section VIII — Control Measures

Respiratory Protection (*Specify Type*): NA

Ventilation	Local Exhaust	NA	Special	NA
	Mechanical (General)	NA	Other	NA

Protective Gloves: NA

Eye Protection: NA

Other Protective Clothing or Equipment: NA

Work/Hygienic Practices: Use good clinical and hygienic practices.

NA = Not Applicable
ND = No Data

Material Safety Data Sheet

IDENTITY (As Used on Label and List)	Note: Blank spaces are not permitted. If any item is not applicable or no information is available, the space must be marked to indicate that
Bueyn® Butacaine Anesthetic Dental Ointment	

Section I List No. 7388

Manufacturer's Name **Abbott Laboratories**	Emergency Telephone Number **(312) 937-6100**
Address (Number, Street, City, State, and ZIP Code) **Pharmaceutical Products Division**	Telephone Number for Information **(312) 937-7350**
1400 Sheridan Road	Date Prepared June 30, 1987
North Chicago, Illinois 60064	Signature of Preparer (optional) Jm Mooney

Section II — Hazardous Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity; Common Name(s))	OSHA PEL	ACGIH TLV	Other Limits Recommended	% (optional)
Butacaine (CAS No. 149-16-6, RTECS No. UB0875000)	NA	NA	NA	4%
Benzyl Alcohol (CAS No. 100-51-6, RTECS No. DN3150000)	NA	NA	NA	1%

Section III — Physical/Chemical Characteristics

Boiling Point	NA	Specific Gravity (H_2O = 1)	NA
Vapor Pressure (mm Hg.)	NA	Melting Point	ND
Vapor Density (AIR = 1)	NA	Evaporation Rate (Butyl Acetate = 1)	NA

Solubility in Water
ND

Appearance and Odor
Anesthetic dental ointment

Section IV — Fire and Explosion Hazard Data

Flash Point (Method Used)	Flammable Limits	LEL	UEL
NA		NA	NA

Extinguishing Media
Use appropriate media for primary cause of fire.

Special Fire Fighting Procedures
None known

Unusual Fire and Explosion Hazards
None known

Section V — Reactivity Data

Stability			Conditions to Avoid
	Unstable		None under normal use
	Stable	X	

Incompatibility (*Materials to Avoid*)
None under normal use

Hazardous Decomposition or Byproducts
Oxides of nitrogen

Hazardous Polymerization			Conditions to Avoid
	May Occur		None under normal use
	Will Not Occur	X	

Section VI — Health Hazard Data

Route(s) of Entry: Inhalation? Unlikely | Skin? Clinical route (dental surface) | Ingestion? Unlikely

Health Hazards (*Acute and Chronic*)
Oral LD50 = 1040-1230 mg/kg in rats, rabbits and mice for benzyl alcohol. Inhalation LCLo = 1000 ppm/8 hr in rats for benzyl alcohol. Butacaine sulfate can cause numbing of exposed areas. Benzyl alcohol is a severe eye irritant in rabbits.

Carcinogenicity: NTP? No | IARC Monographs? No | OSHA Regulated? No

Signs and Symptoms of Exposure
Butacaine sulfate can cause numbing of exposed areas through skin contact or inhalation. Benzyl alcohol can produce irritation, headache, nausea, and vomiting.

Medical Conditions Generally Aggravated by Exposure: None known for occupational exposure. Refer to the Physicians Desk Reference for clinical information.

Emergency and First Aid Procedures
Remove from source of exposure. If skin or eye contact, flush with copious amounts of water. If irritation persists or symptoms of toxicity occur, seek medical attention.

Section VII — Precautions for Safe Handling and Use

Steps to Be Taken in Case Material Is Released or Spilled
No special precautions required

Waste Disposal Method
Dispose of in accordance with local, state, and federal regulations.

Precautions to Be Taken in Handling and Storing
No special precautions required under normal use.

Other Precautions
None required under normal use.

Section VIII — Control Measures

Respiratory Protection (*Specify Type*)
NA

Ventilation		
	Local Exhaust: NA	Special: NA
	Mechanical (*General*): NA	Other: NA

Protective Gloves: NA | Eye Protection: NA

Other Protective Clothing or Equipment
NA

Work/Hygienic Practices
Use good clinical and hygienic practices.

NA = Not Applicable
ND = No Data

Material Safety Data Sheet

IDENTITY (As Used on Label and List)	Note: Blank spaces are not permitted. If any item is not applicable or no information is available, the space must be marked to indicate that
Calcidrine® Syrup	

Section I List No. 5763

Manufacturer's Name **Abbott Laboratories**	Emergency Telephone Number **(312) 937-6100**
Address (Number, Street, City, State, and ZIP Code) **Pharmaceutical Products Division**	Telephone Number for Information **(312) 937-7350**
1400 Sheridan Road	Date Prepared July 20, 1987
North Chicago, Illinois 60064	Signature of Preparer (optional) Jim Mooney

Section II — Hazardous Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity; Common Name(s))	OSHA PEL	ACGIH TLV	Other Limits Recommended	% (optional)
Codeine (CAS No. 76-57-3, RTECS No. QD0893000)	NA	NA	NA	1%
Calcium Iodide (CAS No. 10102-68-8)	NA	NA	NA	3%
Ethyl Alcohol (CAS No. 64-17-5, RTECS No. KQ6300000)	1000ppm (1900mg/m^3)	1000ppm (1900mg/m^3)	NA	6%

Section III — Physical/Chemical Characteristics

Boiling Point	ND	Specific Gravity (H_2O = 1)	ND
Vapor Pressure (mm Hg.)	ND	Melting Point	NA
Vapor Density (AIR = 1)	ND	Evaporation Rate (Butyl Acetate = 1)	ND

Solubility in Water: Soluble

Appearance and Odor: orange colored syrup

Section IV — Fire and Explosion Hazard Data

Flash Point (Method Used)	Flammable Limits	LEL	UEL
ND		ND	ND

Extinguishing Media: Use media appropriate for primary cause of fire.

Special Fire Fighting Procedures: None known

Unusual Fire and Explosion Hazards: None known.

Section V — Reactivity Data

Stability	Unstable		Conditions to Avoid: None under normal use.
	Stable	X	

Incompatibility (*Materials to Avoid*): None under normal use.

Hazardous Decomposition or Byproducts: oxides of calcium

Hazardous Polymerization	May Occur		Conditions to Avoid: None under normal use.
	Will Not Occur	X	

Section VI — Health Hazard Data

Route(s) of Entry: Inhalation? Unlikely; Skin? Unlikely; Ingestion? Clinical route

Health Hazards (*Acute and Chronic*): Oral LD50 = 250-427 mg/kg in rats and mice with codeine. LD50 = 5560-7060 mg/kg in rats, mice, rabbits, and guinea pigs for ethyl alcohol. Ethyl alcohol is an eye and skin irritant

Carcinogenicity: NTP? No; IARC Monographs? No; OSHA Regulated? No

Signs and Symptoms of Exposure: None expected for occupational exposure. Refer to the Physicians Desk Reference (PDR) for clinical symptoms.

Medical Conditions Generally Aggravated by Exposure: None known for occupational exposure. Refer to the PDR for clinical information.

Emergency and First Aid Procedures: Remove from source of exposure. If skin or eye contact, flush with copious amounts of water. If irritation persists or symptoms of toxicity occur, seek medical attention.

Section VII — Precautions for Safe Handling and Use

Steps to Be Taken in Case Material Is Released or Spilled: No special procedures required

Waste Disposal Method: Dispose of in accordance with local, state, and federal regulations. Controlled Substance.

Precautions to Be Taken in Handling and Storing: No special precautions required under normal use.

Other Precautions: None required under normal use.

Section VIII — Control Measures

Respiratory Protection (*Specify Type*): NA

Ventilation	Local Exhaust	NA	Special	NA
	Mechanical (*General*)	NA	Other	NA

Protective Gloves: NA; Eye Protection:

Other Protective Clothing or Equipment: NA

Work/Hygienic Practices: Use good clinical and hygienic practices.

NA = Not Applicable
ND = No Data

Material Safety Data Sheet

IDENTITY *(As Used on Label and List)* Chlorthalidone Tablets USP, Oral Antihypertensive - Diuretic

Note: Blank spaces are not permitted. If any item is not applicable, or no information is available, the space must be marked to indicate that.

Section I List No. 4325, 4338

Manufacturer's Name **Abbott Laboratories**	Emergency Telephone Number **(312) 937-6100**
Address *(Number, Street, City, State, and ZIP Code)* **Pharmaceutical Products Division**	Telephone Number for Information **(312) 937-7350**
1400 Sheridan Road	Date Prepared July 20, 1987
North Chicago, Illinois 60064	Signature of Preparer *(optional)* Jan Mooney

Section II — Hazardous Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity; Common Name(s))	OSHA PEL	ACGIH TLV	Other Limits Recommended	% (optional)
Chlorthalidone (CAS No. 77-36-1, RTECS No. DB1556000)	NA	NA	NA	17-35%*

*percentage varies with dosage form

Section III — Physical/Chemical Characteristics

Boiling Point	NA	Specific Gravity (H_2O = 1)	NA
Vapor Pressure (mm Hg.)	NA	Melting Point	ND
Vapor Density (AIR = 1)	NA	Evaporation Rate (Butyl Acetate = 1)	NA

Solubility in Water: Soluble

Appearance and Odor: peach or lavender colored tablets

Section IV — Fire and Explosion Hazard Data

Flash Point (Method Used)	Flammable Limits	LEL	UEL
NA		NA	NA

Extinguishing Media: Use media appropriate for primary cause of fire.

Special Fire Fighting Procedures: none known

Unusual Fire and Explosion Hazards: none known

Section V — Reactivity Data

Stability	Unstable		Conditions to Avoid: none under normal use
	Stable	X	

Incompatibility (*Materials to Avoid*): none under normal use

Hazardous Decomposition or Byproducts: ND

Hazardous Polymerization	May Occur		Conditions to Avoid: none under normal use
	Will Not Occur	X	

Section VI — Health Hazard Data

Route(s) of Entry — Inhalation? Unlikely; Skin? Unlikely; Ingestion? Clinical route

Health Hazards (*Acute and Chronic*): Oral TD50 = 25,000 mg/kg in mice and rats for chlorthalidone. Chlorthalidone is reported to produce skin, eye and respiratory irritation.

Carcinogenicity — NTP? No; IARC Monographs? No; OSHA Regulated? No

Signs and Symptoms of Exposure: None expected for occupational exposure. Refer to the Physicians Desk Reference (PDR) for clinical symptoms.

Medical Conditions Generally Aggravated by Exposure: None known for occupational exposure. Refer to the PDR for clinical information.

Emergency and First Aid Procedures: Remove from source of exposure. If skin or eye contact, flush with copious amounts of water. If irritation persists or symptoms of toxicity occur, seek medical attention.

Section VII — Precautions for Safe Handling and Use

Steps to Be Taken in Case Material Is Released or Spilled: no special precautions required

Waste Disposal Method: Dispose of in accordance with local, state and federal regulations

Precautions to Be Taken in Handling and Storing: no special precautions required under normal use

Other Precautions: none required under normal use

Section VIII — Control Measures

Respiratory Protection (*Specify Type*): NA

Ventilation	Local Exhaust	NA	Special	NA
	Mechanical (*General*)	NA	Other	NA

Protective Gloves: NA — Eye Protection: NA

Other Protective Clothing or Equipment: NA

Work/Hygienic Practices: Use good clinical and hygienic practices.

NA = Not Applicable
ND = No Data

Material Safety Data Sheet

IDENTITY *(As Used on Label and List)*
Colchine Tablets, USP

Note: Blank spaces are not permitted. If any item is not applicable or no information is available, the space must be marked to indicate that

Section I List No. 0074, 3781

Manufacturer's Name **Abbott Laboratories**	Emergency Telephone Number **(312) 937-6100**
Address *(Number, Street, City, State, and ZIP Code)* **Pharmaceutical Products Division**	Telephone Number for Information **(312) 937-7350**
1400 Sheridan Road	Date Prepared July 20, 1987
North Chicago, Illinois 60064	Signature of Preparer *(optional)* Jim Mooney

Section II — Hazardous Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity, Common Name(s))	OSHA PEL	ACGIH TLV	Other Limits Recommended	% (optional)
Colchicine (CAS No. 64-86-8, RTECS No. GH0700000)	NA	NA	NA	0.5-1.3%*

*percentage varies with dosage form

Section III — Physical/Chemical Characteristics

Boiling Point	NA	Specific Gravity (H_2O = 1)	NA
Vapor Pressure (mm Hg.)	NA	Melting Point	ND
Vapor Density (AIR = 1)	NA	Evaporation Rate (Butyl Acetate = 1)	NA

Solubility in Water
Soluble

Appearance and Odor
yellow granules or yellow tablets

Section IV — Fire and Explosion Hazard Data

Flash Point (Method Used)	Flammable Limits	LEL	UEL
NA		NA	NA

Extinguishing Media
Use media appropriate for primary cause of fire.

Special Fire Fighting Procedures
none known

Unusual Fire and Explosion Hazards
none known

Section V — Reactivity Data

Stability			Conditions to Avoid
	Unstable		none under normal use
	Stable	X	

Incompatibility (*Materials to Avoid*): none under normal use

Hazardous Decomposition or Byproducts: ND

Hazardous Polymerization			Conditions to Avoid
	May Occur		none under normal use
	Will Not Occur	X	

Section VI — Health Hazard Data

Route(s) of Entry: Inhalation? Unlikely; Skin? Possible; Ingestion? Clinical route

Health Hazards (*Acute and Chronic*)

Fatal dose for colchicine in adults is 20 mg. Oral LDLo = 12.5-125 mcg/kg in dogs, cats, rabbits, and guinea pigs for colchicine. Colchicine can be absorbed through the skin, is extremely toxic by inhalation, and is irritating to skin and severely irritating to eyes.

Carcinogenicity: NTP? No; IARC Monographs? No; OSHA Regulated? No

Signs and Symptoms of Exposure

Colchicine is an experimental mutagen. It arrests cell division in animals, adversely affects spermatogenesis in humans and has been shown to be teratogenic in mice.

Medical Conditions Generally Aggravated by Exposure: None known for occupational exposure. Refer to the Physicians Desk Reference for clinical information.

Emergency and First Aid Procedures

Remove from source of exposure. If skin or eye contact, flush with copious amounts of water. If irritation develops or symptoms of toxicity occur, seek medical attention.

Section VII — Precautions for Safe Handling and Use

Steps to Be Taken in Case Material Is Released or Spilled

Surgical gloves and respirators should be used when cleaning spills.

Waste Disposal Method

Dispose of in accordance with local, state and federal regulations

Precautions to Be Taken in Handling and Storing: avoid direct contact

Other Precautions

Surgical gloves and respirators should be used when handling granules and uncoated tablets.

Section VIII — Control Measures

Respiratory Protection (*Specify Type*): NA

Ventilation			
	Local Exhaust: NA	Special: NA	
	Mechanical (*General*): NA	Other: NA	

Protective Gloves: Surgical gloves should be used to avoid | Eye Protection: NA

Other Protective Clothing or Equipment: excessive skin contact.

Work/Hygienic Practices

Use good clinical and hygienic practices.

NA = Not Applicable

ND = No Data

Material Safety Data Sheet

IDENTITY (As Used on Label and List)	Note: Blank spaces are not permitted. If any item is not applicable or no information is available, the space must be marked to indicate that.
Covicone Cream	

Section I List No. 6413

Manufacturer's Name **Abbott Laboratories**	Emergency Telephone Number **(312) 937-6100**
Address (Number, Street, City, State, and ZIP Code) **Pharmaceutical Products Division**	Telephone Number for Information **(312) 937-7350**
1400 Sheridan Road	Date Prepared July 20, 1987
North Chicago, Illinois 60064	Signature of Preparer (optional) Jm Mooney

Section II — Hazardous Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity; Common Name(s))	OSHA PEL	ACGIH TLV	Other Limits Recommended	% (optional)
Nitrocellulose (CAS No. 9004-70-0, RTECS No. QW 0970000)	NA	NA	NA	2%

Section III — Physical/Chemical Characteristics

Boiling Point	NA	Specific Gravity (H_2O = 1)	NA
Vapor Pressure (mm Hg.)	NA	Melting Point	ND
Vapor Density (AIR = 1)	NA	Evaporation Rate (Butyl Acetate = 1)	NA

Solubility in Water: ND

Appearance and Odor: protective skin cream

Section IV — Fire and Explosion Hazard Data

Flash Point (Method Used)	Flammable Limits	LEL	UEL
NA		NA	NA

Extinguishing Media: use appropriate media for primary cause of fire

Special Fire Fighting Procedures: none known

Unusual Fire and Explosion Hazards: none known

Section V — Reactivity Data

Stability	Unstable		Conditions to Avoid: none under normal use
	Stable	X	

Incompatibility (*Materials to Avoid*): none under normal use

Hazardous Decomposition or Byproducts: ND

Hazardous Polymerization	May Occur		Conditions to Avoid: none under normal use
	Will Not Occur	X	

Section VI — Health Hazard Data

Route(s) of Entry: Inhalation? Unlikely | Skin? Clinical route | Ingestion? Unlikely

Health Hazards (*Acute and Chronic*)

Covicone cream has been used for years without adverse effects. Refer to the Physicians Desk Reference (PDR) for clinical health effects.

Carcinogenicity: No | NTP? | IARC Monographs? No | OSHA Regulated? No

Signs and Symptoms of Exposure

None expected for occupational exposure. Refer to the PDR for clinical symptoms.

Medical Conditions Generally Aggravated by Exposure: None known for occupational exposure. Refer to the PDR for clinical information.

Emergency and First Aid Procedures

Remove from source of exposure. If skin or eye contact, flush with copious amounts of water. If irritation develops or symptoms of toxicity occur, seek medical attention.

Section VII — Precautions for Safe Handling and Use

Steps to Be Taken in Case Material Is Released or Spilled: no special precautions required

Waste Disposal Method

Dispose of in accordance with local, state and federal regulations.

Precautions to Be Taken in Handling and Storing: no special precautions required under normal use

Other Precautions: none required under normal use

Section VIII — Control Measures

Respiratory Protection (*Specify Type*): NA

Ventilation	Local Exhaust	NA	Special	NA
	Mechanical (*General*)	NA	Other	NA

Protective Gloves: NA | Eye Protection: NA

Other Protective Clothing or Equipment: NA

Work/Hygienic Practices

Use good clinical and hygienic practices.

NA = Not Applicable

ND = No Data

Material Safety Data Sheet

IDENTITY (As Used on Label and List)	Note: Blank spaces are not permitted. If any item is not applicable or no information is available, the space must be marked to indicate that.
Cylert® Pemoline	

Section I List No. 6025, 6057, 6073

Manufacturer's Name **Abbott Laboratories**	Emergency Telephone Number **(312) 937-6100**
Address (Number, Street, City, State, and ZIP Code) **Pharmaceutical Products Division**	Telephone Number for Information **(312) 937-7350**
1400 Sheridan Road	Date Prepared July 20, 1987
North Chicago, Illinois 60064	Signature of Preparer (optional) Jim Mooney

Section II — Hazardous Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity, Common Name(s))	OSHA PEL	ACGIH TLV	Other Limits Recommended	% (optional)
Pemoline (CAS No. 2152-34-3, RTECS No. RQ2975000)	NA	NA	**	13-19%*

* percentage varies with dosage form

** internal employee exposure limit = 0.3 mg/m^3 (8 hr TWA)

Section III — Physical/Chemical Characteristics

Boiling Point	NA	Specific Gravity (H_2O = 1)	NA
Vapor Pressure (mm Hg.)	NA	Melting Point	ND
Vapor Density (AIR = 1)	NA	Evaporation Rate (Butyl Acetate = 1)	NA

Solubility in Water: Soluble

Appearance and Odor: white, orange or tan colored tablets

Section IV — Fire and Explosion Hazard Data

Flash Point (Method Used)	Flammable Limits	LEL	UEL
NA		NA	NA

Extinguishing Media: Use media appropriate for primary cause of fire.

Special Fire Fighting Procedures: none known

Unusual Fire and Explosion Hazards: none known

Section V — Reactivity Data

Stability	Unstable		Conditions to Avoid: None under normal use
	Stable	X	

Incompatibility (*Materials to Avoid*): None under normal use

Hazardous Decomposition or Byproducts: oxides of nitrogen

Hazardous Polymerization	May Occur		Conditions to Avoid: None under normal use
	Will Not Occur	X	

Section VI — Health Hazard Data

Route(s) of Entry: Inhalation? Unlikely; Skin? Unlikely; Ingestion? Clinical route

Health Hazards (*Acute and Chronic*): Oral LD50 = 500 mg/kg in rats and mice with pemoline. No known occupational exposure hazard. Consult the Physicians Desk Reference (PDR) for clinical health hazards.

Carcinogenicity: NTP? No; IARC Monographs? No; OSHA Regulated? No

Signs and Symptoms of Exposure: None expected for occupational exposure. Refer to the PDR for clinical symptoms.

Medical Conditions Generally Aggravated by Exposure: None known for occupational exposure. Refer to the PDR for clinical information.

Emergency and First Aid Procedures: Remove from source of exposure. If skin or eye contact, flush with copious amounts of water. If irritation develops or symptoms of toxicity occur, seek medical attention.

Section VII — Precautions for Safe Handling and Use

Steps to Be Taken in Case Material Is Released or Spilled: No special precautions required.

Waste Disposal Method: Dispose of in accordance with local, state and federal regulations.

Precautions to Be Taken in Handling and Storing: No special precautions required under normal use.

Other Precautions: None required under normal use.

Section VIII — Control Measures

Respiratory Protection (*Specify Type*): NA

Ventilation	Local Exhaust	NA	Special	NA
	Mechanical (*General*)	NA	Other	NA

Protective Gloves: NA; Eye Protection: NA

Other Protective Clothing or Equipment: NA

Work/Hygienic Practices: Use good clinical and hygienic practices.

NA = Not Applicable
ND = No Data

Material Safety Data Sheet

IDENTITY (As Used on Label and List)	Note: Blank spaces are not permitted. If any item is not applicable or no information is available, the space must be marked to indicate that.
Depakene® Valproic Acid Capsules and Syrup	

Section I List No. 5681, 5682

Manufacturer's Name **Abbott Laboratories**	Emergency Telephone Number **(312) 937-6100**
Address (Number, Street, City, State, and ZIP Code) **Pharmaceutical Products Division**	Telephone Number for Information **(312) 937-7350**
1400 Sheridan Road	Date Prepared July 20, 1987
North Chicago, Illinois 60064	Signature of Preparer (optional) Jim Mooney

Section II — Hazardous Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity; Common Name(s))	OSHA PEL	ACGIH TLV	Other Limits Recommended	% (optional)
Valproic Acid (CAS No. 99-66-1, RTECS No. YV7875000)	NA	NA	*	54%

* Internal employee exposure limit = 750 mcg/m^3 - valproic acid (8 hr TWA)

Section III — Physical/Chemical Characteristics

Boiling Point	ND	Specific Gravity (H_2O = 1)	ND
Vapor Pressure (mm Hg.)	ND	Melting Point	NA
Vapor Density (AIR = 1)	ND	Evaporation Rate (Butyl Acetate = 1)	ND

Solubility in Water: Soluble

Appearance and Odor: Orange colored soft gelatin capsules or red syrup

Section IV — Fire and Explosion Hazard Data

Flash Point (Method Used)	Flammable Limits	LEL	UEL
NA		NA	NA

Extinguishing Media: Use media appropriate for primary cause of fire

Special Fire Fighting Procedures: none known

Unusual Fire and Explosion Hazards: none known

Section V — Reactivity Data

Stability			Conditions to Avoid
	Unstable		None under normal use
	Stable	X	

Incompatibility (*Materials to Avoid*): None under normal use.

Hazardous Decomposition or Byproducts: oxides of nitrogen

Hazardous Polymerization			Conditions to Avoid
	May Occur		None under normal use.
	Will Not Occur	X	

Section VI — Health Hazard Data

Route(s) of Entry: Inhalation? Unlikely | Skin? Possible | Ingestion? Clinical route

Health Hazards (*Acute and Chronic*): Oral LD50 = 670-2307 mg/kg in rats and mice with valproic acid. Valproic acid can cause moderate skin irritation and severe conjunctival irritation. Animal studies have reported reproductive and teratagenic effects.

Carcinogenicity	NTP?	IARC Monographs?	OSHA Regulated?
	No	No	No

Signs and Symptoms of Exposure: None expected for occupational exposure. Refer to the Physicians Desk Reference (PDR) for clinical symptoms.

Medical Conditions Generally Aggravated by Exposure: None known for occupational exposure. Refer to the PDR for clinical information.

Emergency and First Aid Procedures: Remove from source of exposure. If skin or eye contact, flush with copious amounts of water. If irritation develops or symptoms of toxicity occur, seek medical attention.

Section VII — Precautions for Safe Handling and Use

Steps to Be Taken in Case Material Is Released or Spilled: No special procedures required

Waste Disposal Method: Dispose of in accordance with local, state and federal regulations.

Precautions to Be Taken in Handling and Storing: None required under normal use.

Other Precautions: None required under normal use.

Section VIII — Control Measures

Respiratory Protection (*Specify Type*): NA

Ventilation				
	Local Exhaust	NA	Special	NA
	Mechanical (*General*)	NA	Other	NA

Protective Gloves		Eye Protection	
	NA		NA

Other Protective Clothing or Equipment: NA

Work/Hygienic Practices: Use good clinical and hygienic practices.

NA = Not Applicable
ND = No Data

Material Safety Data Sheet

IDENTITY (As Used on Label and List) Depakote® Divalproex Sodium Enteric-coated Tablets	Note. Blank spaces are not permitted. If any item is not applicable, or no information is available, the space must be marked to indicate that.

Section I List No. 6214, 6215

Manufacturer's Name	Emergency Telephone Number
Abbott Laboratories	**(312) 937-6100**
Address (Number, Street, City, State, and ZIP Code)	Telephone Number for Information
Pharmaceutical Products Division	**(312) 937-7350**
1400 Sheridan Road	Date Prepared: July 20, 1987
North Chicago, Illinois 60064	Signature of Preparer (optional): Jim Mooney

Section II — Hazardous Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity, Common Name(s))	OSHA PEL	ACGIH TLV	Other Limits Recommended	% (optional)
Divalproex (CAS No. 99-66-1, RTECS No. YV7875000 for Valproic Acid)	NA	NA	*	58%

* Internal employee exposure limit = 750 mcg/m^3 - valproic acid (8 hr TWA)

Section III — Physical/Chemical Characteristics

Boiling Point	NA	Specific Gravity (H_2O = 1)	NA
Vapor Pressure (mm Hg.)	NA	Melting Point	ND
Vapor Density (AIR = 1)	NA	Evaporation Rate (Butyl Acetate = 1)	NA

Solubility in Water: Soluble

Appearance and Odor: salmon-pink, peach or lavender colored tablets

Section IV — Fire and Explosion Hazard Data

Flash Point (Method Used)	Flammable Limits	LEL	UEL
NA		NA	NA

Extinguishing Media: Use media appropriate for primary cause of fire.

Special Fire Fighting Procedures: none known

Unusual Fire and Explosion Hazards: none known

Section V — Reactivity Data

Stability	Unstable		Conditions to Avoid: None under normal use
	Stable	X	

Incompatibility (*Materials to Avoid*): None under normal use.

Hazardous Decomposition or Byproducts: oxides of nitrogen

Hazardous Polymerization	May Occur		Conditions to Avoid: None under normal use.
	Will Not Occur	X	

Section VI — Health Hazard Data

Route(s) of Entry: Inhalation? Unlikely; Skin? Unlikely; Ingestion? Clinical route

Health Hazards (*Acute and Chronic*)

Oral LD50 = 2060-2710 mg/kg in rats and mice with divalproex sodium. Valproic acid is a moderate skin irritant and severe conjunctival irritant. Animal studies have reported reproductive and teratagenic effects.

Carcinogenicity: NTP? No; IARC Monographs? No; OSHA Regulated? No

Signs and Symptoms of Exposure

None expected for occupational exposure. Refer to the Physicians Desk Reference (PDR) for clinical symptoms.

Medical Conditions Generally Aggravated by Exposure

None known for occupational exposure. Refer to PDR for clinical information.

Emergency and First Aid Procedures

Remove from source of exposure. If skin or eye contact, flush with copious amounts of water. If irritation develops or symptoms of toxicity occur, seek medical attention.

Section VII — Precautions for Safe Handling and Use

Steps to Be Taken in Case Material is Released or Spilled

No special procedures required

Waste Disposal Method

Dispose of in accordance with local, state and federal regulations.

Precautions to Be Taken in Handling and Storing

No special precautions required under normal use.

Other Precautions: None required under normal use.

Section VIII — Control Measures

Respiratory Protection (*Specify Type*): NA

Ventilation	Local Exhaust	NA	Special	NA
	Mechanical (*General*)	NA	Other	NA

Protective Gloves: NA

Eye Protection: NA

Other Protective Clothing or Equipment: NA

Work/Hygienic Practices

Use good clinical and hygienic practices.

NA = Not Applicable

ND = No Data

Material Safety Data Sheet

IDENTITY *(As Used on Label and List)* Desoxyn® Methamphetamine Hydrochloride Tablets-Gradumet® Tablets

Note: *Blank spaces are not permitted. If any item is not applicable or no information is available, the space must be marked to indicate that.*

Section I List No. 6941, 6948, 6959, 3377

Manufacturer's Name **Abbott Laboratories**	Emergency Telephone Number **(312) 937-6100**
Address *(Number, Street, City, State, and ZIP Code)* **Pharmaceutical Products Division**	Telephone Number for Information **(312) 937-7350**
1400 Sheridan Road	Date Prepared July 20, 1987
North Chicago, Illinois 60064	Signature of Preparer *(optional)* Jim Mooney

Section II — Hazardous Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity, Common Name(s))	OSHA PEL	ACGIH TLV	Other Limits Recommended	% (optional)
Methamphetamine Hydrochloride	NA	NA	NA	4-13%*
(CAS No. 300-42-5; RTECS No. SH5075000)				

* Percentage varies with dosage forms

Section III — Physical/Chemical Characteristics

Boiling Point	NA	Specific Gravity (H_2O = 1)	NA
Vapor Pressure (mm Hg.)	NA	Melting Point	ND
Vapor Density (AIR = 1)	NA	Evaporation Rate (Butyl Acetate = 1)	NA

Solubility in Water: Soluble

Appearance and Odor: White, orange, or yellow tablets with no apparent odor.

Section IV — Fire and Explosion Hazard Data

Flash Point (Method Used)	Flammable Limits	LEL	UEL
NA		NA	NA

Extinguishing Media: Use media appropriate for primary cause of fire.

Special Fire Fighting Procedures: None known

Unusual Fire and Explosion Hazards: None known

Section V — Reactivity Data

Stability			Conditions to Avoid
	Unstable		None under normal use.
	Stable	X	

Incompatibility (*Materials to Avoid*) None under normal use.

Hazardous Decomposition or Byproducts
Hydrogen chloride and oxides of nitrogen

Hazardous Polymerization			Conditions to Avoid
	May Occur		None under normal use.
	Will Not Occur	X	

Section VI — Health Hazard Data

Route(s) of Entry — Inhalation? Unlikely; Skin? Unlikely; Ingestion? Clinical route

Health Hazards (*Acute and Chronic*)
Oral TDLo=17 mg/kg in humans, LD50=109-247 mg/kg in rats and mice with methamphetamine hydrochloride. May cause mild eye irritation. Methamphetamine has been shown to have teratogenic and embroycidal effects in animals at very high doses.

Carcinogenicity — NTP? No; IARC Monographs? No; OSHA Regulated? No

Signs and Symptoms of Exposure
None expected for occupational exposure. Refer to the PDR for clinical symptoms.

Medical Conditions
Generally Aggravated by Exposure
None known for occupational exposure. Refer to the PDR for clinical information.

Emergency and First Aid Procedures
Remove from source of exposure. If skin or eye contact, flush with copious amounts of water. If irritation develops or symptoms of toxicity occur, seek medical attention.

Section VII — Precautions for Safe Handling and Use

Steps to Be Taken in Case Material Is Released or Spilled
No special procedures required

Waste Disposal Method
Controlled Substance. Dispose of in accordance with local, state and federal regulations.

Precautions to Be Taken in Handling and Storing
No special precautions required under normal use.

Other Precautions
None required under normal use.

Section VIII — Control Measures

Respiratory Protection (*Specify Type*)
NA

Ventilation				
	Local Exhaust	NA	Special	NA
	Mechanical (*General*)	NA	Other	NA

Protective Gloves: NA — Eye Protection: NA

Other Protective Clothing or Equipment
N/A

Work/Hygienic Practices
Use good clinical and hygenic practices.

NA = Not Applicable
ND = No Data

Material Safety Data Sheet

IDENTITY (As Used on Label and List)	Note: Blank spaces are not permitted. If any item is not applicable or no information is available, the space must be marked to indicate that
Dicumarol Tablets, USP	

Section I List No. 3794, 3773, 3775

Manufacturer's Name **Abbott Laboratories**	Emergency Telephone Number **(312) 937-6100**
Address (Number, Street, City, State, and ZIP Code) **Pharmaceutical Products Division**	Telephone Number for Information **(312) 937-7350**
1400 Sheridan Road	Date Prepared July 20, 1987
North Chicago, Illinois 60064	Signature of Preparer (optional) Jim Mooney

Section II — Hazardous Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity; Common Name(s))	OSHA PEL	ACGIH TLV	Other Limits Recommended	% (optional)
Dicumarol (CAS No. 66-76-2; RTECS No. GN7875000)	NA	NA	NA	32.13-32.*

*percentage varies with dosage form

Section III — Physical/Chemical Characteristics

Boiling Point	NA	Specific Gravity (H_2O = 1)	NA
Vapor Pressure (mm Hg.)	NA	Melting Point	ND
Vapor Density (AIR = 1)	NA	Evaporation Rate (Butyl Acetate = 1)	NA

Solubility in Water: Soluble

Appearance and Odor: White or red colored tablets

Section IV — Fire and Explosion Hazard Data

Flash Point (Method Used)	Flammable Limits	LEL	UEL
NA		NA	NA

Extinguishing Media: Use media appropriate for primary cause of fire.

Special Fire Fighting Procedures: None known

Unusual Fire and Explosion Hazards: None known

Section V — Reactivity Data

Stability	Unstable		Conditions to Avoid: None under normal use.
	Stable	X	

Incompatibility (*Materials to Avoid*): None under normal use.

Hazardous Decomposition or Byproducts: ND

Hazardous Polymerization	May Occur		Conditions to Avoid: None under normal use.
	Will Not Occur	X	

Section VI — Health Hazard Data

Route(s) of Entry: Inhalation? Unlikely; Skin? Unlikely; Ingestion? Clinical Route

Health Hazards (*Acute and Chronic*): Oral LD50 = 233-750 mg/kg in rats and mice with Dicumarol. No known occupational exposure hazards. Consult the Physicians Desk Reference (PDR) for clinical health effects.

Carcinogenicity: NTP? No; IARC Monographs? No; OSHA Regulated? No

Signs and Symptoms of Exposure: None expected for occupational exposure. Refer to the PDR clinical symptoms.

Medical Conditions Generally Aggravated by Exposure: None known for occupational exposure. Refer to the PDR for clinical information.

Emergency and First Aid Procedures: Remove from source of exposure: If skin or eye contact, flush with copious amounts of water. If irritation develops or symptoms of toxicity occur, seek medical attention.

Section VII — Precautions for Safe Handling and Use

Steps to Be Taken in Case Material Is Released or Spilled: No special procedures required

Waste Disposal Method: Dispose of in accordance with local, state and federal regulations.

Precautions to Be Taken in Handling and Storing: No special precautions required under normal use.

Other Precautions: None required under normal use.

Section VIII — Control Measures

Respiratory Protection (*Specify Type*): NA

Ventilation	Local Exhaust: NA	Special: NA
	Mechanical (General): NA	Other: NA

Protective Gloves: NA

Eye Protection: NA

Other Protective Clothing or Equipment: NA

Work/Hygienic Practices: Use good clinical and hygienic practices.

NA = Not Applicable

ND = No Data

Material Safety Data Sheet

IDENTITY (As Used on Label and List)	Note: Blank spaces are not permitted. If any item is not applicable or no information is available, the space must be marked to indicate that
Enduron® Methyclothiazide Tablets	

Section I List No. 6827, 6812

Manufacturer's Name	Emergency Telephone Number
Abbott Laboratories	**(312) 937-6100**
Address (Number, Street, City, State, and ZIP Code)	Telephone Number for Information
Pharmaceutical Products Division	**(312) 937-7350**
1400 Sheridan Road	Date Prepared: July 20, 1987
North Chicago, Illinois 60064	Signature of Preparer (optional): Jim Mooney

Section II — Hazardous Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity; Common Name(s))	OSHA PEL	ACGIH TLV	Other Limits Recommended	% (optional)
Methyclothiazide (CAS No. 135-07-9; RTECS No. DK8575000)	NA	NA	*	1.28 - 2.**

* internal employee exposure limit = 25 mcg/m^3 (8 hr TWA)

** percentage varies with dosage form

Section III — Physical/Chemical Characteristics

Boiling Point	NA	Specific Gravity (H_2O = 1)	NA
Vapor Pressure (mm Hg.)	NA	Melting Point	ND
Vapor Density (AIR = 1)	NA	Evaporation Rate (Butyl Acetate = 1)	NA

Solubility in Water: Soluble

Appearance and Odor: Orange or salmon colored, monogrammed, grooved, square-shaped tablets.

Section IV — Fire and Explosion Hazard Data

Flash Point (Method Used)	Flammable Limits	LEL	UEL
NA		NA	NA

Extinguishing Media: Use media appropriate for primary cause of fire.

Special Fire Fighting Procedures: None known

Unusual Fire and Explosion Hazards: None known

Section V — Reactivity Data

Stability			Conditions to Avoid
	Unstable		None under normal use.
	Stable	X	

Incompatibility (*Materials to Avoid*): None under normal use.

Hazardous Decomposition or Byproducts: ND

Hazardous Polymerization			Conditions to Avoid
	May Occur		None under normal use.
	Will Not Occur	X	

Section VI — Health Hazard Data

Route(s) of Entry	Inhalation?	Skin?	Ingestion?
	Unlikely	Unlikely	Clinical route

Health Hazards (*Acute and Chronic*)

Oral LD50 = 1000-10,000 mg/kg in rats, mice and dogs with methyclothiazide. No known occupational exposure hazard. Consult the Physicians Desk Reference (PDR) for clinical health effects.

Carcinogenicity:	NTP?	IARC Monographs?	OSHA Regulated?
	No	No	No

Signs and Symptoms of Exposure

No known occupational exposure hazard. Consult PDR for clinical health effects and symptoms.

Medical Conditions Generally Aggravated by Exposure

None known for occupational exposure. Refer to the PDR for clinical information.

Emergency and First Aid Procedures

If skin or eye contact, flush with copious amounts of water. If irritation develops or signs of toxicity occur, seek medical attention.

Section VII — Precautions for Safe Handling and Use

Steps to Be Taken in Case Material Is Released or Spilled

No special procedures required.

Waste Disposal Method

Dispose of in accordance with local, state and federal regulations.

Precautions to Be Taken in Handling and Storing: No special precautions required under normal use.

Other Precautions

None required under normal use.

Section VIII — Control Measures

Respiratory Protection (*Specify Type*): NA

Ventilation				
	Local Exhaust	NA	Special	NA
	Mechanical (*General*)	NA	Other	NA

Protective Gloves	Eye Protection
NA	NA

Other Protective Clothing or Equipment: NA

Work/Hygienic Practices

Use good clinical and hygienic practices.

NA = Not Applicable

ND = No Data

Material Safety Data Sheet

IDENTITY *(As Used on Label and List)* Endronyl®
Methyclothiazide and Deserpidine Tablets

Note: Blank spaces are not permitted. If any item is not applicable or no information is available, the space must be marked to indicate that

Section I List No. 6838

Manufacturer's Name **Abbott Laboratories**	Emergency Telephone Number **(312) 937-6100**
Address *(Number, Street, City, State, and ZIP Code)* **Pharmaceutical Products Division**	Telephone Number for Information **(312) 937-7350**
1400 Sheridan Road	Date Prepared July 20, 1987
North Chicago, Illinois 60064	Signature of Preparer *(optional)* Jim Mooney

Section II — Hazardous Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity; Common Name(s))	OSHA PEL	ACGIH TLV	Other Limits Recommended	% (optional)
Deserpidine (CAS No. 131-01-1; RTECS No. ZG0875000)	NA	NA	**	1%
Methyclothiazide (CAS No. 135-07-9; RTECS No. DK8575000)	NA	NA	*	2.55%

* Internal employee exposure limit = 25 mcg/m^3 (8 hr TWA)

** Internal employee exposure limit = 0.25 mcg/m^3 (8 hr TWA)

Section III — Physical/Chemical Characteristics

Boiling Point	NA	Specific Gravity (H_2O = 1)	NA
Vapor Pressure (mm Hg)	NA	Melting Point	ND
Vapor Density (AIR = 1)	NA	Evaporation Rate (Butyl Acetate = 1)	NA

Solubility in Water: Soluble

Appearance and Odor: yellow or gray tablets

Section IV — Fire and Explosion Hazard Data

Flash Point (Method Used)	Flammable Limits	LEL	UEL
NA		NA	NA

Extinguishing Media: Use media appropriate for primary cause of fire.

Special Fire Fighting Procedures: None known

Unusual Fire and Explosion Hazards: None known

Section V — Reactivity Data

Stability	Unstable		Conditions to Avoid: None under normal use.
	Stable	X	

Incompatibility (*Materials to Avoid*): None under normal use.

Hazardous Decomposition or Byproducts: Chlorine, Hydrogen Chloride and oxides of sulfur and nitrogen.

Hazardous Polymerization	May Occur		Conditions to Avoid: None under normal use.
	Will Not Occur	X	

Section VI — Health Hazard Data

Route(s) of Entry: Inhalation? Unlikely | Skin? Unlikely | Ingestion? Clinical route

Health Hazards (*Acute and Chronic*)

Oral LB50 = 1000 - 10,000 mg/kg in rats, mice, and dogs with methylclothiazide. LD50=500 mg/k in mice for deserpidine. No known occupational exposure hazards. Consult the Physicians Desk Reference (PDR) for clinical health effects.

Carcinogenicity: NTP? No | IARC Monographs? No | OSHA Regulated? No

Signs and Symptoms of Exposure

None expected for occupational exposure. Refer to the PDR clinical symptoms.

Medical Conditions Generally Aggravated by Exposure

None known for occupational exposure. Refer to the PDR for clinical information.

Emergency and First Aid Procedures

Remove from source of exposure. If skin or eye contact, flush with copious amounts of water. If irritation develops or symptoms of toxicity occur, seek medical attention.

Section VII — Precautions for Safe Handling and Use

Steps to Be Taken in Case Material Is Released or Spilled: No special precautions required.

Waste Disposal Method

Dispose of in accordance with local, state and federal regulations.

Precautions to Be Taken in Handling and Storing: No special precautions required under normal use.

Other Precautions: None required under normal use.

Section VIII — Control Measures

Respiratory Protection (*Specify Type*): NA

Ventilation	Local Exhaust: NA		Special: NA	
	Mechanical (*General*): NA		Other: NA	

Protective Gloves: NA | Eye Protection: NA

Other Protective Clothing or Equipment: NA

Work/Hygienic Practices: Use good clinical and hygienic practices.

NA = Not Applicable

ND = No Data

Material Safety Data Sheet

IDENTITY (As Used on Label and List) Eutonyl® Pargyline Hydrochloride Tablets, USP Filmtab®	Note: Blank spaces are not permitted. If any item is not applicable or no information is available, the space must be marked to indicate that

Section I Lst No. 6876, 6878

Manufacturer's Name **Abbott Laboratories**	Emergency Telephone Number **(312) 937-6100**
Address (Number, Street, City, State, and ZIP Code) **Pharmaceutical Products Division**	Telephone Number for Information **(312) 937-7350**
1400 Sheridan Road	Date Prepared July 20, 1987
North Chicago, Illinois 60064	Signature of Preparer (optional) Jim Mooney

Section II — Hazardous Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity; Common Name(s))	OSHA PEL	ACGIH TLV	Other Limits Recommended	% (optional)
Pargyline Hydrochloride	NA	NA	NA	7-17%*
(CAS No. 306-07-0; RTECS No. DP6650000)				

* percentage varies with dosage form

Section III — Physical/Chemical Characteristics

Boiling Point	NA	Specific Gravity (H_2O = 1)	NA
Vapor Pressure (mm Hg)	NA	Melting Point	ND
Vapor Density (AIR = 1)	NA	Evaporation Rate (Butyl Acetate = 1)	NA

Solubility in Water: Soluble

Appearance and Odor: pink or apricot colored tablets

Section IV — Fire and Explosion Hazard Data

Flash Point (Method Used)	Flammable Limits	LEL	UEL
NA		NA	NA

Extinguishing Media: Use media appropriate for primary cause of fire.

Special Fire Fighting Procedures: None known

Unusual Fire and Explosion Hazards: None known

Section V — Reactivity Data

Stability	Unstable		Conditions to Avoid: None under normal use.
	Stable	X	

Incompatibility (*Materials to Avoid*): None under normal use.

Hazardous Decomposition or Byproducts: Hydrogen Chloride and oxides of nitrogen

Hazardous Polymerization	May Occur		Conditions to Avoid: None under normal use.
	Will Not Occur	X	

Section VI — Health Hazard Data

Route(s) of Entry: Inhalation? Unlikely; Skin? Unlikely; Ingestion? Clinical route

Health Hazards (*Acute and Chronic*)
Oral TDLo=1.5 mg/kg in humans, LD50 = 175-680 mg/kg in rats, mice, and dogs with pargyline hydrochloride. No known occupational exposure hazards. Consult the Physicians Desk Reference (PDR) for clinical health hazards.

Carcinogenicity: NTP? No; IARC Monographs? No; OSHA Regulated? No

Signs and Symptoms of Exposure
None expected for occupational exposure. Refer to the PDR for clinical symptoms.

Medical Conditions
Generally Aggravated by Exposure
None known for occupational exposure. Refer to the PDR for clinical information.

Emergency and First Aid Procedures
Remove from source of exposure. If skin or eye contact, flush with copious amounts of water. If irritation develops or symptoms of toxicity occur, seek medical attention.

Section VII — Precautions for Safe Handling and Use

Steps to Be Taken in Case Material Is Released or Spilled: No special procedures required.

Waste Disposal Method
Dispose of in accordance with local, state and federal regulations.

Precautions to Be Taken in Handling and Storing: No special precautions required under normal use.

Other Precautions: None required under normal use.

Section VIII — Control Measures

Respiratory Protection (*Specify Type*): NA

Ventilation	Local Exhaust: NA		Special: NA	
	Mechanical (*General*): NA		Other: NA	

Protective Gloves: NA; Eye Protection: NA

Other Protective Clothing or Equipment: NA

Work/Hygienic Practices: Use good clinical and hygienic practices.

NA = Not Applicable
ND = No Data

Material Safety Data Sheet

IDENTITY *(As Used on Label and List)* Eutron® Pargyline Hydrochloride and Methyclothiazide Filmtab®

Note: Blank spaces are not permitted. If any item is not applicable or no information is available, the space must be marked to indicate that.

Section I List No. 7240

Manufacturer's Name **Abbott Laboratories**	Emergency Telephone Number **(312) 937-6100**
Address *(Number, Street, City, State, and ZIP Code)* **Pharmaceutical Products Division**	Telephone Number for Information **(312) 937-7350**
1400 Sheridan Road	Date Prepared July 20, 1987
North Chicago, Illinois 60064	Signature of Preparer *(optional)* Jim Mooney

Section II — Hazardous Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity; Common Name(s))	OSHA PEL	ACGIH TLV	Other Limits Recommended	% (optional)
Pargyline Hydrochloride (CAS No. 306-07-0; RTECS No. DP6650000)	NA	NA	NA	6%
Methyclothiazide (CAS No. 135-07-9; RTECS No. DK8575000)	NA	NA	*	1.12%

* Internal employee exposure limit = 25 mcg/m^3 (8 hr TWA)

Section III — Physical/Chemical Characteristics

Boiling Point	NA	Specific Gravity (H_2O = 1)	NA
Vapor Pressure (mm Hg.)	NA	Melting Point	ND
Vapor Density (AIR = 1)	NA	Evaporation Rate (Butyl Acetate = 1)	NA

Solubility in Water: Soluble

Appearance and Odor: light purple tablets

Section IV — Fire and Explosion Hazard Data

Flash Point (Method Used)	Flammable Limits	LEL	UEL
NA		NA	NA

Extinguishing Media: Use media appropriate for primary cause of fire

Special Fire Fighting Procedures: None known

Unusual Fire and Explosion Hazards: None known

Section V — Reactivity Data

Stability	Unstable		Conditions to Avoid: None under normal use.
	Stable	X	

Incompatibility (*Materials to Avoid*): None under normal use.

Hazardous Decomposition or Byproducts: Hydrogen Chloride and oxides of sulfur and nitrogen.

Hazardous Polymerization	May Occur		Conditions to Avoid: None under normal use.
	Will Not Occur	X	

Section VI — Health Hazard Data

Route(s) of Entry: Inhalation? Unlikely | Skin? Unlikely | Ingestion? Clinical Route

Health Hazards (*Acute and Chronic*)

Oral TDLo=1.5 mg/kg in humans, LD50=175-680 mg/kg in rats, mice, and dogs for pargyline hydrochloride. LD50 ≥ 1000-10,000 mg/kg in rats, mice, and dogs for methyclothiazide. No known occupational exposure hazards. Consult the PDR for clinical health effects.

Carcinogenicity: NTP? No | IARC Monographs? No | OSHA Regulated? No

Signs and Symptoms of Exposure: None expected for occupational exposure. Refer to the PDR clinical symptoms.

Medical Conditions Generally Aggravated by Exposure: None known for occupational exposure. Refer to the PDR for clinical information.

Emergency and First Aid Procedures: Remove from source of exposure. If skin or eye contact, flush with copious amounts of water. If irritation develops or symptoms of toxicity occur, seek medical attention.

Section VII — Precautions for Safe Handling and Use

Steps to Be Taken in Case Material Is Released or Spilled: No special precautions required.

Waste Disposal Method: Dispose of in accordance with local, state and federal regulations.

Precautions to Be Taken in Handling and Storing: No special precautions required under normal use.

Other Precautions: None required under normal use.

Section VIII — Control Measures

Respiratory Protection (*Specify Type*): NA

Ventilation	Local Exhaust: NA	Special: NA	
	Mechanical (*General*): NA	Other: NA	

Protective Gloves: NA | Eye Protection: NA

Other Protective Clothing or Equipment: NA

Work/Hygienic Practices: Use good clinical and hygienic practices.

NA = Not Applicable
ND = No Data

Material Safety Data Sheet

IDENTITY (As Used on Label and List)	Note: Blank spaces are not permitted. If any item is not applicable or no information is available, the space must be marked to indicate that.
Gemonil® Metharbital Tablets, USP	

Section I List No. 6401

Manufacturer's Name **Abbott Laboratories**	Emergency Telephone Number **(312) 937-6100**
Address (Number, Street, City, State, and ZIP Code) **Pharmaceutical Products Division**	Telephone Number for Information **(312) 937-7350**
1400 Sheridan Road	Date Prepared July 20, 1987
North Chicago, Illinois 60064	Signature of Preparer (optional) Jim Mooney

Section II — Hazardous Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity, Common Name(s))	OSHA PEL	ACGIH TLV	Other Limits Recommended	% (optional)
Metharbital (CAS No. 50-11-3)	NA	NA	NA	58%

Section III — Physical/Chemical Characteristics

Boiling Point	NA	Specific Gravity (H_2O = 1)	NA
Vapor Pressure (mm Hg.)	NA	Melting Point	ND
Vapor Density (AIR = 1)	NA	Evaporation Rate (Butyl Acetate = 1)	NA

Solubility in Water: Soluble

Appearance and Odor: Tablets

Section IV — Fire and Explosion Hazard Data

Flash Point (Method Used)	Flammable Limits	LEL	UEL
NA		NA	NA

Extinguishing Media: Use media appropriate for primary cause of fire.

Special Fire Fighting Procedures: None known

Unusual Fire and Explosion Hazards: None known

Section V — Reactivity Data

Stability	Unstable		Conditions to Avoid: None under normal use.
	Stable	X	

Incompatibility (*Materials to Avoid*): None under normal use.

Hazardous Decomposition or Byproducts: ND

Hazardous Polymerization	May Occur		Conditions to Avoid: None under normal use.
	Will Not Occur	X	

Section VI — Health Hazard Data

Route(s) of Entry: Inhalation? Unlikely; Skin? Unlikely; Ingestion? Clinical Route

Health Hazards (*Acute and Chronic*):
Estimated fatal dose of metharbital in humans = 2 g. LD50 = 500 mg/kg in mice for metharbital. No known occupational exposure hazards. Consult the Physicians' Desk Reference for clinical health hazards.

Carcinogenicity: NTP? No; IARC Monographs? No; OSHA Regulated? No

Signs and Symptoms of Exposure:
None expected for occupational exposure. Refer to the PDR clinical symptoms.

Medical Conditions Generally Aggravated by Exposure:
None known for occupational exposure. Refer to the PDR for clinical information.

Emergency and First Aid Procedures:
Remove from source of exposure. If skin or eye contact, flush with copious amounts of water. If irritation develops or symptoms of toxicity occur, seek medical attention.

Section VII — Precautions for Safe Handling and Use

Steps to Be Taken in Case Material Is Released or Spilled: No special procedures required.

Waste Disposal Method:
Dispose of in accordance with local, state and federal regulations.

Precautions to Be Taken in Handling and Storing: No special precautions required under normal use.

Other Precautions: None required under normal use.

Section VIII — Control Measures

Respiratory Protection (*Specify Type*): NA

Ventilation	Local Exhaust	NA	Special	NA
	Mechanical (*General*)	NA	Other	NA

Protective Gloves: NA

Eye Protection: NA

Other Protective Clothing or Equipment: NA

Work/Hygienic Practices: Use good clinical and hygienic practices.

NA = Not Applicable
ND = No Data

Material Safety Data Sheet

IDENTITY (As Used on Label and List)	Note: Blank spaces are not permitted. If any item is not applicable or no information is available, the space must be marked to indicate that
Halazone	

Section I List No. 1157

Manufacturer's Name	Emergency Telephone Number
Abbott Laboratories	**(312) 937-6100**
Address (Number, Street, City, State, and ZIP Code)	Telephone Number for Information
Pharmaceutical Products Division	**(312) 937-7350**
1400 Sheridan Road	Date Prepared: July 20, 1987
North Chicago, Illinois 60064	Signature of Preparer (optional): Jim Mooney

Section II — Hazardous Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity; Common Name(s))	OSHA PEL	ACGIH TLV	Other Limits Recommended	% (optional)
p-dichlorosulfamoyl benzoic acid (CAS No. 80-13-7; RTECS No. DG8100000)	NA	NA	NA	3%

Section III — Physical/Chemical Characteristics

Boiling Point	NA	Specific Gravity (H_2O = 1)	NA
Vapor Pressure (mm Hg.)	NA	Melting Point	ND
Vapor Density (AIR = 1)	NA	Evaporation Rate (Butyl Acetate = 1)	NA

Solubility in Water: Soluble

Appearance and Odor: Tablets

Section IV — Fire and Explosion Hazard Data

Flash Point (Method Used)	Flammable Limits	LEL	UEL
NA		NA	NA

Extinguishing Media: Use media appropriate for primary cause of fire.

Special Fire Fighting Procedures: None known

Unusual Fire and Explosion Hazards: None known

Section V — Reactivity Data

Stability	Unstable		Conditions to Avoid: None under normal use.
	Stable	X	

Incompatibility (*Materials to Avoid*): None under normal use.

Hazardous Decomposition or Byproducts: Chlorine , Hydrogen chloride and oxides of nitrogen and sulfur.

Hazardous Polymerization	May Occur		Conditions to Avoid: None under normal use.
	Will Not Occur	X	

Section VI — Health Hazard Data

Route(s) of Entry: Inhalation? Unlikely Skin? Unlikely Ingestion? Unlikely

Health Hazards (*Acute and Chronic*)

Oral LDLo = 3500 mg/kg in rats for halazone. Possible skin and respiratory irritant. Dichlorosulfamoyl benzoic acid is a severe eye irritant in rabbits but only a mild irritant after rinsing.

Carcinogenicity: No NTP? No IARC Monographs? No OSHA Regulated? No

Signs and Symptoms of Exposure: Eye redness

Medical Conditions Generally Aggravated by Exposure: None known but halazone would be likely to aggravate skin or ocular lens or respiratory diseas

Emergency and First Aid Procedures: Remove from source of exposure. If skin or eye contact, flush with copious amounts of water. If irritation develops or symptoms of toxicity occur, seek medical attention.

Section VII — Precautions for Safe Handling and Use

Steps to Be Taken in Case Material Is Released or Spilled: No special procedures required.

Waste Disposal Method: Dispose of in accordance with local, state and federal regulations.

Precautions to Be Taken in Handling and Storing: No special precautions required under normal use.

Other Precautions: None required under normal use.

Section VIII — Control Measures

Respiratory Protection (*Specify Type*): NA

Ventilation	Local Exhaust	NA	Special	NA
	Mechanical (*General*)	NA	Other	NA

Protective Gloves: NA Eye Protection: NA

Other Protective Clothing or Equipment: NA

Work/Hygienic Practices: Use good clinical and hygienic practices.

NA = Not Applicable
ND = No Data

Material Safety Data Sheet

IDENTITY *(As Used on Label and List)* Harmonyl® Deserpidine Tablets Antihypertensive Agents

Note: Blank spaces are not permitted. If any item is not applicable or no information is available, the space must be marked to indicate that.

Section I List No. 6901, 6906

Manufacturer's Name **Abbott Laboratories**	Emergency Telephone Number **(312) 937-6100**
Address *(Number, Street, City, State, and ZIP Code)* **Pharmaceutical Products Division**	Telephone Number for Information **(312) 937-7350**
1400 Sheridan Road	Date Prepared July 20, 1987
North Chicago, Illinois 60064	Signature of Preparer *(optional)* Jim Mooney

Section II — Hazardous Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity, Common Name(s))	OSHA PEL	ACGIH TLV	Other Limits Recommended	% *(optional)*
Deserpidine	NA	NA	*	0.2%
(CAS No. 131-01-0; RTECS No. ZG0875000)				

* Internal employee exposure limit = 0.25 mcg/m^3 (8 hr TWA)

Section III — Physical/Chemical Characteristics

Boiling Point	NA	Specific Gravity (H_2O = 1)	NA
Vapor Pressure (mm Hg.)	NA	Melting Point	ND
Vapor Density (AIR = 1)	NA	Evaporation Rate (Butyl Acetate = 1)	NA

Solubility in Water: Soluble

Appearance and Odor: salmon-pink tablets

Section IV — Fire and Explosion Hazard Data

Flash Point (Method Used) NA	Flammable Limits	LEL NA	UEL NA

Extinguishing Media: Use media appropriate for primary cause of fire.

Special Fire Fighting Procedures: None known

Unusual Fire and Explosion Hazards: None known

Section V — Reactivity Data

Stability	Unstable		Conditions to Avoid: None under normal use.
	Stable	X	

Incompatibility (*Materials to Avoid*): None under normal use.

Hazardous Decomposition or Byproducts: oxides of nitrogen

Hazardous Polymerization	May Occur		Conditions to Avoid: None under normal use.
	Will Not Occur	X	

Section VI — Health Hazard Data

Route(s) of Entry — Inhalation? Unlikely; Skin? Unlikely; Ingestion? Clinical Route

Health Hazards (*Acute and Chronic*): Oral LD50 = 500 mg/kg in mice for deserpidine. No known occupational exposure hazards.

Consult the Physicians' Desk Reference (PDR) for clinical health effects.

Carcinogenicity — NTP? No; IARC Monographs? No; OSHA Regulated? No

Signs and Symptoms of Exposure: None expected for occupational exposure. Refer to the PDR clinical symptoms.

Medical Conditions Generally Aggravated by Exposure: None known for occupational exposure. Refer to the PDR for clinical information.

Emergency and First Aid Procedures: Remove from source of exposure. If skin or eye contact, flush with copious amounts of water. If irritation develops or symptoms of toxicity occur, seek medical attention.

Section VII — Precautions for Safe Handling and Use

Steps to Be Taken in Case Material Is Released or Spilled: No special procedures required.

Waste Disposal Method: Dispose of in accordance with local, state, and federal regulations

Precautions to Be Taken in Handling and Storing: No special precautions required under normal use.

Other Precautions: None required under normal use.

Section VIII — Control Measures

Respiratory Protection (*Specify Type*): NA

Ventilation	Local Exhaust	NA	Special	NA
	Mechanical (*General*)	NA	Other	NA

Protective Gloves: NA — Eye Protection: NA

Other Protective Clothing or Equipment: NA

Work/Hygienic Practices: Use good clinical and hygienic practices.

NA = Not Applicable
ND = No Data

Material Safety Data Sheet

IDENTITY *(As Used on Label and List)* Janimine® Imipramine Hydrochloride Tablets, USP Filmrab® Tablets

Note: Blank spaces are not permitted. If any item is not applicable or no information is available, the space must be marked to indicate that.

Section I List No. 1897, 1898, 1899

Manufacturer's Name **Abbott Laboratories**	Emergency Telephone Number **(312) 937-6100**
Address *(Number, Street, City, State, and ZIP Code)* **Pharmaceutical Products Division**	Telephone Number for Information **(312) 937-7350**
1400 Sheridan Road	Date Prepared July 20, 1987
North Chicago, Illinois 60064	Signature of Preparer *(optional)* Jim Mooney

Section II — Hazardous Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity, Common Name(s))	OSHA PEL	ACGIH TLV	Other Limits Recommended	% (optional)
Imipramine Hydrochloride	NA	NA	NA	12.5-2(
(CAS No. 113-52-0; RTECS No. 1925000)				

* percentage varies with dosage form

Section III — Physical/Chemical Characteristics

Boiling Point	NA	Specific Gravity (H_2O = 1)	NA
Vapor Pressure (mm Hg.)	NA	Melting Point	ND
Vapor Density (AIR = 1)	NA	Evaporation Rate (Butyl Acetate = 1)	NA

Solubility in Water: Soluble

Appearance and Odor: orange, yellow or peach colored tablets

Section IV — Fire and Explosion Hazard Data

Flash Point (Method Used) NA	Flammable Limits	LEL NA	UEL NA

Extinguishing Media: Use media appropriate for primary cause of fire.

Special Fire Fighting Procedures: None known

Unusual Fire and Explosion Hazards: None known

Section V — Reactivity Data

Stability			Conditions to Avoid
	Unstable		None under normal use.
	Stable	X	

Incompatibility (*Materials to Avoid*): None under normal use.

Hazardous Decomposition or Byproducts

Hazardous Polymerization			Conditions to Avoid
	May Occur		None under normal use.
	Will Not Occur	X	

Section VI — Health Hazard Data

Route(s) of Entry: Inhalation? Unlikely | Skin? Unlikely | Ingestion? Clinical route

Health Hazards (*Acute and Chronic*)

Death has occurred from a dose of imipramine of 5g in adults, oral LD50 = 175-682 mg/kg in rats, mice, and dogs for imipramine hydrochloride. Imipramine hydrochloride is reported to cause eye, skin, and respiratory tract irritation.

Carcinogenicity: NTP? No | IARC Monographs? No | OSHA Regulated? No

Signs and Symptoms of Exposure

None expected for occupational exposure. Refer to the PDR for clinical symptoms.

Medical Conditions Generally Aggravated by Exposure

None known for occupational exposure. Refer to the PDR for clinical information.

Emergency and First Aid Procedures

Remove from source of exposure. If skin or eye contact, flush with copious amounts of water. If irritation develops or symtpoms of toxicity occur, seek medical attention.

Section VII — Precautions for Safe Handling and Use

Steps to Be Taken in Case Material is Released or Spilled

No special procedures required.

Waste Disposal Method

Dispose of in accordance with local, state and federal regulations.

Precautions to Be Taken in Handling and Storing

No special precautions required under normal use.

Other Precautions

None required under normal use.

Section VIII — Control Measures

Respiratory Protection (*Specify Type*): NA

Ventilation				
	Local Exhaust	NA	Special	NA
	Mechanical (*General*)	NA	Other	NA

Protective Gloves	Eye Protection
NA	NA

Other Protective Clothing or Equipment: NA

Work/Hygienic Practices: Use good clinical and hygienic practices.

NA = Not Applicable
ND = No Data

Material Safety Data Sheet

IDENTITY (As Used on Label and List) K-Lor® Potassium Chloride for Oral Solution, USP Powder	Note: Blank spaces are not permitted. If any item is not applicable or no information is available, the space must be marked to indicate that

Section I List No. 3611, 3633

Manufacturer's Name	Emergency Telephone Number
Abbott Laboratories	**(312) 937-6100**
Address (Number, Street, City, State, and ZIP Code)	Telephone Number for Information
Pharmaceutical Products Division	**(312) 937-7350**
1400 Sheridan Road	Date Prepared: July 20, 1987
North Chicago, Illinois 60064	Signature of Preparer (optional): Jim Mooney

Section II — Hazardous Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity; Common Name(s))	OSHA PEL	ACGIH TLV	Other Limits Recommended	% (optional)
Potassium Chloride (CAS No. 7447-40-7; RTECS No. TS8050000)	NA	NA	NA	56-58%*

* percentage varies with dosage form

Section III — Physical/Chemical Characteristics

Boiling Point	NA	Specific Gravity (H_2O = 1)	NA
Vapor Pressure (mm Hg.)	NA	Melting Point	ND
Vapor Density (AIR = 1)	NA	Evaporation Rate (Butyl Acetate = 1)	NA

Solubility in Water: Soluble

Appearance and Odor: packets of powder

Section IV — Fire and Explosion Hazard Data

Flash Point (Method Used)	Flammable Limits	LEL	UEL
NA		NA	NA

Extinguishing Media: Use media appropriate for primary cause of fire.

Special Fire Fighting Procedures: None known

Unusual Fire and Explosion Hazards: None known

Section V — Reactivity Data

Stability			Conditions to Avoid
	Unstable		None under normal use.
	Stable	X	

Incompatibility (*Materials to Avoid*)
Incompatible with BrF_3 (H_2SO_4 + $kMnO_4$)

Hazardous Decomposition or Byproducts
Chlorine

Hazardous Polymerization			Conditions to Avoid
	May Occur		None under normal use
	Will Not Occur	X	

Section VI — Health Hazard Data

Route(s) of Entry — Inhalation? Unlikely — Skin? Unlikely — Ingestion? Clinical Route

Health Hazards (*Acute and Chronic*)
Oral LDLo = 20 mg/kg in man, TDLo = 60 mg/kg/D in women, LD50 = 2500-3314 mg/kg in rats, mice, and guinea pigs with potassium chloride. Potassium chloride is a severe eye irritant in rabbits.

Carcinogenicity — NTP? No — IARC Monographs? No — OSHA Regulated? No

Signs and Symptoms of Exposure
None expected for occupational exposure. Refer to the PDR for clinical symptoms.

Medical Conditions Generally Aggravated by Exposure
None known for occupational exposure. Refer to the PDR for clinical information.

Emergency and First Aid Procedures
Remove from source of exposure. If skin or eye contact, flush with copious amounts of water. If irritation develops or symptoms of toxicity occur, seek medical attention.

Section VII — Precautions for Safe Handling and Use

Steps to Be Taken in Case Material Is Released or Spilled
No special procedures required.

Waste Disposal Method
Dispose of in accordance with local, state and federal regulations.

Precautions to Be Taken in Handling and Storing
No special precautions required under normal use.

Other Precautions
None required under normal use.

Section VIII — Control Measures

Respiratory Protection (*Specify Type*)
NA

Ventilation			
	Local Exhaust: NA	Special: NA	
	Mechanical (*General*): NA	Other: NA	

Protective Gloves: NA — Eye Protection: NA

Other Protective Clothing or Equipment
NA

Work/Hygienic Practices
Use good clinical and hygienic practices.

NA = Not Applicable
ND = No Data

Material Safety Data Sheet

IDENTITY (As Used on Label and List) K-Tab® Potassium Chloride Extended-Release Tablets, USP	Note: Blank spaces are not permitted. If any item is not applicable or no information is available, the space must be marked to indicate that

Section I List No. 7804

Manufacturer's Name	Emergency Telephone Number
Abbott Laboratories	**(312) 937-6100**
Address (Number, Street, City, State, and ZIP Code)	Telephone Number for Information
Pharmaceutical Products Division	**(312) 937-7350**
1400 Sheridan Road	Date Prepared: July 20, 1987
North Chicago, Illinois 60064	Signature of Preparer (optional): Jim Mooney

Section II — Hazardous Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity, Common Name(s))	OSHA PEL	ACGIH TLV	Other Limits Recommended	% (optional)
Potassium Chloride	NA	NA	NA	56-58% *
(CAS No. 7447-40-7; RTECS No. TS805000)				

* percentage varies with dosage form

Section III — Physical/Chemical Characteristics

Boiling Point	NA	Specific Gravity (H_2O = 1)	NA
Vapor Pressure (mm Hg.)	NA	Melting Point	ND
Vapor Density (AIR = 1)	NA	Evaporation Rate (Butyl Acetate = 1)	NA

Solubility in Water: Soluble

Appearance and Odor: Yellow Oval Tablets

Section IV — Fire and Explosion Hazard Data

Flash Point (Method Used)	Flammable Limits	LEL	UEL
NA		NA	NA

Extinguishing Media: Use media appropriate for primary cause of fire.

Special Fire Fighting Procedures: None known

Unusual Fire and Explosion Hazards: None known

Section V — Reactivity Data

Stability			Conditions to Avoid
	Unstable		None under normal use.
	Stable	X	

Incompatibility (*Materials to Avoid*)
Incompatible with BrF_3 (H_2SO_4 + $kMnO_4$)

Hazardous Decomposition or Byproducts
Chlorine

Hazardous Polymerization			Conditions to Avoid
	May Occur		None under normal use.
	Will Not Occur	X	

Section VI — Health Hazard Data

Route(s) of Entry — Inhalation? Unlikely — Skin? Unlikely — Ingestion? Clinical Route

Health Hazards (*Acute and Chronic*)
Oral LDLo = 20 mg/kg in man, TDLo = 60 mg/kg/D in women, LD50 = 2500-3314 mg/kg in rats, mice, and guinea pigs with potassium chloride. Potassium chloride is a severe eye irritant in rabbits.

Carcinogenicity — NTP? No — IARC Monographs? No — OSHA Regulated? No

Signs and Symptoms of Exposure
None expected for occupational exposure. Refer to the PDR for clinical symptoms.

Medical Conditions
Generally Aggravated by Exposure
None known for occupational exposure. Refer to the PDR for clinical information.

Emergency and First Aid Procedures
Remove from source of exposure. If skin or eye contact, flush with copious amounts of water. If irritation develops or symptoms of toxicity occur, seek medical attention.

Section VII — Precautions for Safe Handling and Use

Steps to Be Taken in Case Material Is Released or Spilled
No special procedures required.

Waste Disposal Method
Dispose of in accordance with local, state and federal regulations.

Precautions to Be Taken in Handling and Storing
No special precautions required under normal use.

Other Precautions
None required under normal use.

Section VIII — Control Measures

Respiratory Protection (*Specify Type*) NA

Ventilation		
	Local Exhaust: NA	Special: NA
	Mechanical (*General*): NA	Other: NA

Protective Gloves: NA — Eye Protection: NA

Other Protective Clothing or Equipment: NA

Work/Hygienic Practices
Use good clinical and hygienic practices.

NA = Not Applicable
ND = No Data

Material Safety Data Sheet

IDENTITY (As Used on Label and List)	Note: Blank spaces are not permitted. If any item is not applicable, or no information is available, the space must be marked to indicate that
Pentobarbital Elixir, USP Nembutal® Elixir	

Section I List No. 3142

Manufacturer's Name **Abbott Laboratories**	Emergency Telephone Number **(312) 937-6100**
Address (Number, Street, City, State, and ZIP Code) **Pharmaceutical Products Division**	Telephone Number for Information **(312) 937-7350**
1400 Sheridan Road	Date Prepared July 20, 1987
North Chicago, Illinois 60064	Signature of Preparer (optional) Jim Mooney

Section II — Hazardous Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity, Common Name(s))	OSHA PEL	ACGIH TLV	Other Limits Recommended	% (optional)
Pentobarbital Sodium (CAS No. 57-33-0; CQ6125000)	NA	NA	NA	0.37%
Sodium Saccharin (CAS No. 128-44-9; RTECS No. DE45550000)	NA	NA	NA	0.3%
Ethyl Alcohol (CAS No. 64-17-5; RTECS KQ6300000)	1000ppm ($1900mg/m^3$)	1000ppm ($1900mg/m^3$)	NA	18%

Section III — Physical/Chemical Characteristics

Boiling Point	ND	Specific Gravity (H_2O = 1)	ND
Vapor Pressure (mm Hg.)	ND	Melting Point	NA
Vapor Density (AIR = 1)	NA	Evaporation Rate (Butyl Acetate = 1)	ND

Solubility in Water NA

Appearance and Odor
Orange colored liquid

Section IV — Fire and Explosion Hazard Data

Flash Point (Method Used)	Flammable Limits	LEL	UEL
ND		ND	ND

Extinguishing Media
Water, CO_2, dry chemical

Special Fire Fighting Procedures
None known

Unusual Fire and Explosion Hazards
Product contains ethyl alcohol which is flammable

Section V — Reactivity Data

Stability			Conditions to Avoid
	Unstable		None under normal use.
	Stable	X	

Incompatibility (*Materials to Avoid*)
None under normal use.

Hazardous Decomposition or Byproducts
Oxides of sulfur and nitrogen

Hazardous Polymerization			Conditions to Avoid
	May Occur		None under normal use.
	Will Not Occur	X	

Section VI — Health Hazard Data

Route(s) of Entry: Inhalation? Unlikely | Skin? Unlikely | Ingestion? Clinical Route

Health Hazards (*Acute and Chronic*)
Oral TDLo = 60 mg/kg women, TDLo = 6.4 mg/kg men, LD50 = 60-239 mg/kg in guinea pigs, mice, rabbits, and rats with pentobarbitual sodium. About 2-10g of barbiturates (ingested) are lethal in humans. Ethyl alcohol is a skin and eye irritant and is known to produce liver injury

Carcinogenicity: NTP? Yes | IARC Monographs? No | OSHA Regulated? No

Saccharin produced bladder tumors in animal bioassays.

Signs and Symptoms of Exposure
None expected for occupational exposure. Refer to the PDR for clinical symptoms.

Medical Conditions Generally Aggravated by Exposure
None known for occupational exposure. Refer to the PDR for clinical information.

Emergency and First Aid Procedures
Remove from source of exposure. If skin or eye contact, flush with copious amounts of water. If irritation develops or symptoms of toxicity occur, seek medical attention.

Section VII — Precautions for Safe Handling and Use

Steps to Be Taken in Case Material Is Released or Spilled
No special procedures required.

Waste Disposal Method
Controlled substance. Dispose of in accordance with local, state, and federal regulations.

Precautions to Be Taken in Handling and Storing
Protect from freezing.

Other Precautions
None required under normal use.

Section VIII — Control Measures

Respiratory Protection (*Specify Type*)
NA

Ventilation			
	Local Exhaust: NA	Special: NA	
	Mechanical (*General*): NA	Other: NA	

Protective Gloves: NA | Eye Protection: NA

Other Protective Clothing or Equipment
NA

Work/Hygienic Practices
Use good clinical and hygienic practices.

NA = Not Applicable
ND = No Data

Material Safety Data Sheet

IDENTITY (As Used on Label and List) Nembutal® Sodium Solution Pentobarbital Sodium Injection, USP	Note: Blank spaces are not permitted. If any item is not applicable or no information is available, the space must be marked to indicate that

Section I List No. 6899, 3778

Manufacturer's Name	Emergency Telephone Number
Abbott Laboratories	**(312) 937-6100**
Address (Number, Street, City, State, and ZIP Code)	Telephone Number for Information
Pharmaceutical Products Division	**(312) 937-7350**
1400 Sheridan Road	Date Prepared: June 30, 1987
North Chicago, Illinois 60064	Signature of Preparer (optional): Jim Mooney

Section II — Hazardous Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity, Common Name(s))	OSHA PEL	ACGIH TLV	Other Limits Recommended	% (optional)
Pentobarbital Sodium	NA	NA	NA	5%
(CAS No. 57-33-0; RTECS No. CQ6125000)				
Propylene Glycol	NA	NA	*	40%
(CAS No. 57-55-6; RTECS No. TY2000000)				
Ethyl Alcohol	1000ppm (1900mg/m^3)	1000ppm (1900mg/m^3)	NA	10%
(CAS No. 64-17-5; RTECS No. KQ6300000)				

* AIHA -weel® = 50 ppm total; 10 mg/m^3 aerosol alone (8 hr TWA)

Section III — Physical/Chemical Characteristics

Boiling Point	ND	Specific Gravity (H_2O = 1)	ND
Vapor Pressure (mm Hg.)	ND	Melting Point	NA
Vapor Density (AIR = 1)	ND	Evaporation Rate (Butyl Acetate = 1)	ND

Solubility in Water: ND

Appearance and Odor: Injectible liquid

Section IV — Fire and Explosion Hazard Data

Flash Point (Method Used)	Flammable Limits	LEL	UEL
ND		ND	ND

Extinguishing Media: Water, CO_2, dry chemical

Special Fire Fighting Procedures: None known

Unusual Fire and Explosion Hazards: None known

Section V — Reactivity Data

Stability	Unstable		Conditions to Avoid: None under normal use.
	Stable	X	

Incompatibility (*Materials to Avoid*)
None under normal use

Hazardous Decomposition or Byproducts
Oxides of nitrogen

Hazardous Polymerization	May Occur		Conditions to Avoid: None under normal use
	Will Not Occur	X	

Section VI — Health Hazard Data

Route(s) of Entry — Inhalation? Unlikely — Skin? Unlikely — Ingestion? Unlikely

Health Hazards (*Acute and Chronic*)
Oral TDLo = 60 mg/kg women, TDLo = 6.4 mg/kg men, LD50 = 60-239 mg/kg in guinea pigs, mice, rabbits, and rats with pentobarbital sodium. About 2-10g of barbiturates (ingested) are lethal. Ethyl alcohol is a skin and eye irritant, and is known to produce liver injury.

Carcinogenicity — NTP? No — IARC Monographs? No — OSHA Regulated? No

Signs and Symptoms of Exposure
None expected for occupational exposure. Refer to the PDR for clinical symptoms.

Medical Conditions Generally Aggravated by Exposure
None known for occupational exposure. Refer to the PDR for clinical information.

Emergency and First Aid Procedures
Remove from source of exposure. If skin or eye contact, flush with copious amounts of water. If irritation develops or symptoms of toxicity occur, seek medical attention.

Section VII — Precautions for Safe Handling and Use

Steps to Be Taken in Case Material Is Released or Spilled
No special procedures required.

Waste Disposal Method
Controlled substance. Dispose of in accordance with local, state, and federal regulations.

Precautions to Be Taken in Handling and Storing
Protect from freezing.

Other Precautions
None required under normal use.

Section VIII — Control Measures

Respiratory Protection (*Specify Type*)
NA

Ventilation	Local Exhaust: NA	Special: NA
	Mechanical (*General*): NA	Other: NA

Protective Gloves: NA — Eye Protection: NA

Other Protective Clothing or Equipment
NA

Work/Hygienic Practices
Use good clinical and hygienic practices.

NA = Not Applicable
ND = No Data

Material Safety Data Sheet

IDENTITY (As Used on Label and List) Nembutal® Sodium Capsules Pentobarbital Sodium Capsules, USP	Note: Blank spaces are not permitted. If any item is not applicable or no information is available, the space must be marked to indicate that

Section I List No. 3120, 3150, 3114

Manufacturer's Name	Emergency Telephone Number
Abbott Laboratories	**(312) 937-6100**
Address (Number, Street, City, State, and ZIP Code)	Telephone Number for Information
Pharmaceutical Products Division	**(312) 937-7350**
1400 Sheridan Road	Date Prepared July 20, 1987
North Chicago, Illinois 60064	Signature of Preparer (optional) Jim Mooney

Section II — Hazardous Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity; Common Name(s))	OSHA PEL	ACGIH TLV	Other Limits Recommended	% (optional)
Pentobarbital Sodium	NA	NA	NA	22-65%*
(CAS No. 57-33-0; RTECS No. CQ6125000)				

* percentage varies with dosage form

Section III — Physical/Chemical Characteristics

Boiling Point	NA	Specific Gravity (H_2O = 1)	NA
Vapor Pressure (mm Hg.)	NA	Melting Point	ND
Vapor Density (AIR = 1)	NA	Evaporation Rate (Butyl Acetate = 1)	NA

Solubility in Water: Soluble

Appearance and Odor: orange or yellow colored capsules.

Section IV — Fire and Explosion Hazard Data

Flash Point (Method Used)	Flammable Limits	LEL	UEL
NA		NA	NA

Extinguishing Media: Use media appropriate for primary cause of fire.

Special Fire Fighting Procedures: None known

Unusual Fire and Explosion Hazards: None known

Section V — Reactivity Data

Stability	Unstable		Conditions to Avoid: None under normal use.
	Stable	X	

Incompatibility (*Materials to Avoid*): None under normal use.

Hazardous Decomposition or Byproducts: oxides of nitrogen

Hazardous Polymerization	May Occur		Conditions to Avoid: None under normal use.
	Will Not Occur	X	

Section VI — Health Hazard Data

Route(s) of Entry: Inhalation? Unlikely; Skin? Unlikely; Ingestion? Clinical Route

Health Hazards (*Acute and Chronic*): Oral TDLo= 60 mg/kg in women, TDLo = 6.4 mg/kg men, LD50 = 60-239 mg/kg in guinea pigs, mice, rabbits, and rats with pentobarbital sodium. About 2-10g of barbiturates (ingested) are lethal in humans.

Carcinogenicity: NTP? No; IARC Monographs? No; OSHA Regulated? No

Signs and Symptoms of Exposure: None expected for occupational exposure. Refer to the PDR for clinical symptoms.

Medical Conditions Generally Aggravated by Exposure: None known for occupational exposure. Refer to the PDR for clinical information.

Emergency and First Aid Procedures: Remove from source of exposure. If skin or eye contact, flush with copious amounts of water. If irritation develops or symptoms of toxicity occur, seek medical attention.

Section VII — Precautions for Safe Handling and Use

Steps to Be Taken in Case Material Is Released or Spilled: No special procedures required

Waste Disposal Method: Controlled Substance. Dispose of in accordance with local, state and federal regulations.

Precautions to Be Taken in Handling and Storing: No special precautions required under normal use.

Other Precautions: None required under normal use.

Section VIII — Control Measures

Respiratory Protection (*Specify Type*): NA

Ventilation	Local Exhaust	NA	Special	NA
	Mechanical (*General*)	NA	Other	NA

Protective Gloves: NA; Eye Protection: NA

Other Protective Clothing or Equipment: NA

Work/Hygienic Practices: Use good clinical and hygienic practices.

NA = Not Applicable
ND = No Data

Material Safety Data Sheet

IDENTITY *(As Used on Label and List)* Nembutal® Sodium Suppositories Pentobarbital Sodium Suppositories

Note: Blank spaces are not permitted. If any item is not applicable or no information is available, the space must be marked to indicate that

Section I List No. 3272, 3148, 3145, 3164

Manufacturer's Name **Abbott Laboratories**	Emergency Telephone Number **(312) 937-6100**
Address *(Number, Street, City, State, and ZIP Code)* **Pharmaceutical Products Division**	Telephone Number for Information **(312) 937-7350**
1400 Sheridan Road	Date Prepared July 20, 1987
North Chicago, Illinois 60064	Signature of Preparer *(optional)* Jim Mooney

Section II — Hazardous Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity, Common Name(s))	OSHA PEL	ACGIH TLV	Other Limits Recommended	% (optional)
Pentobarbital Sodium	NA	NA	NA	22-65%*
(CAS No. 57-33-0; RTECS No. CQ6125000)				

* percentage varies with dosage form

Section III — Physical/Chemical Characteristics

Boiling Point	NA	Specific Gravity (H_2O = 1)	NA
Vapor Pressure (mm Hg.)	NA	Melting Point	ND
Vapor Density (AIR = 1)	NA	Evaporation Rate (Butyl Acetate = 1)	NA

Solubility in Water: Soluble

Appearance and Odor: suppositories

Section IV — Fire and Explosion Hazard Data

Flash Point (Method Used)	Flammable Limits	LEL	UEL
NA		NA	NA

Extinguishing Media: Use media appropriate for primary csuse of fire.

Special Fire Fighting Procedures: None known

Unusual Fire and Explosion Hazards: None known

Section V — Reactivity Data

Stability	Unstable		Conditions to Avoid: None under normal use.
	Stable	X	

Incompatibility (*Materials to Avoid*): None under normal use.

Hazardous Decomposition or Byproducts: oxides of nitrogen

Hazardous Polymerization	May Occur		Conditions to Avoid: None under normal use.
	Will Not Occur	X	

Section VI — Health Hazard Data

Route(s) of Entry: Inhalation? Unlikely; Skin? Unlikely; Ingestion? Unlikely

Health Hazards (*Acute and Chronic*): Oral TDLo = 60 mg/kg women, TDLo = 6.4 mg/kg men, LD50 = 60-239 mg/kg in rats, mice, guinea pigs, and rabbits with pentobarbital sodium. About 2-10g of barbiturates (ingested) are lethal in humans.

Carcinogenicity: NTP? No; IARC Monographs? No; OSHA Regulated? No

Signs and Symptoms of Exposure: None expected for occupational exposure. Refer to the PDR for clinical symptoms.

Medical Conditions Generally Aggravated by Exposure: None known for occupational exposure. Refer to the PDR for clinical information.

Emergency and First Aid Procedures: Remove from source of exposure. If skin or eye contact, flush with copious amounts of water. If irritation develops or symptoms of toxicity occur, seek medical attention.

Section VII — Precautions for Safe Handling and Use

Steps to Be Taken in Case Material Is Released or Spilled: No special procedures required.

Waste Disposal Method: Controlled substance. Dispose of in accordance with local, state, and federal regulations.

Precautions to Be Taken in Handling and Storing: Store suppositories in refrigerator (36-46 degrees F)

Other Precautions: None required under normal use.

Section VIII — Control Measures

Respiratory Protection (*Specify Type*): NA

Ventilation	Local Exhaust	NA	Special	NA
	Mechanical (*General*)	NA	Other	NA

Protective Gloves: NA

Eye Protection: NA

Other Protective Clothing or Equipment: NA

Work/Hygienic Practices: Use good clinical and hygienic practices.

NA = Not Applicable

ND = No Data

Material Safety Data Sheet

IDENTITY (As Used on Label and List) Norisodrine® Aerotrol® (Isoproterenol Hydrochloride Inhalation Aerosol, USP)	Note: Blank spaces are not permitted. If any item is not applicable or no information is available, the space must be marked to indicate that

Section I List 6869

Manufacturer's Name	Emergency Telephone Number
Abbott Laboratories	**(312) 937-6100**
Address (Number, Street, City, State, and ZIP Code)	Telephone Number for Information
Pharmaceutical Products Division	**(312) 937-7350**
1400 Sheridan Road	Date Prepared June 30, 1987
North Chicago, Illinois 60064	Signature of Preparer (optional) Jim Mooney

Section II — Hazardous Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity; Common Name(s))	OSHA PEL	ACGIH TLV	Other Limits Recommended	% (optional)
Isoproterenol Hydrochloride	NA	NA	NA	0.25%
(CAS No. 51-30-9; RTECS No. DO1925000)				
Ethyl Alcohol	1000ppm	1000ppm	NA	33%
(CAS No. 64-17-5; RTECS No. KQ6300000)	(1900mg/m^3)	(1900mg/m^3)		

Section III — Physical/Chemical Characteristics

Boiling Point	ND	Specific Gravity (H_2O = 1)	ND
Vapor Pressure (mm Hg.)	ND	Melting Point	NA
Vapor Density (AIR = 1)	ND	Evaporation Rate (Butyl Acetate = 1)	NA

Solubility in Water
Soluble

Appearance and Odor
Bronchodilating aerosol

Section IV — Fire and Explosion Hazard Data

Flash Point (Method Used)	Flammable Limits	LEL	UEL
ND		ND	ND

Extinguishing Media
Water, CO_2, dry chemical

Special Fire Fighting Procedures
None known

Unusual Fire and Explosion Hazards
Product contains ethyl alcohol which is flammable. Do not puncture or incinerate containe

Do not expose to heat or store at temperatures above 120°F.

Section V — Reactivity Data

Stability			Conditions to Avoid
	Unstable		None under normal use.
	Stable	x	

Incompatibility (*Materials to Avoid*)
None under normal use

Hazardous Decomposition or Byproducts
Oxides of nitrogen

Hazardous Polymerization			Conditions to Avoid
	May Occur		None under normal use.
	Will Not Occur	x	

Section VI — Health Hazard Data

Route(s) of Entry — Inhalation? Clinical route — Skin? Unlikely — Ingestion? Unlikely

Health Hazards (*Acute and Chronic*)
Oral LD50 = 1645-2220 mg/kg in rats, mice, guinea pigs, and rabbits for isoproterenal hydrochloride. LD50 = 5560-7060 mg/kg in rats, mice, rabbits, and guinea pigs for ethyl alcohol. Ethyl alcohol is a skin and eye irritant and is known to produce liver injury.

Carcinogenicity — NTP? No — IARC Monographs? No — OSHA Regulated? No

Signs and Symptoms of Exposure
None expected for occupational exposure. Refer to the PDR for clinical symptoms.

Medical Conditions
Generally Aggravated by Exposure
None known for occupational exposure. Refer to the PDR for clinical information.

Emergency and First Aid Procedures
Remove from source of exposure. If skin or eye contact, flush with copious amounts of water. If irritation develops or symptoms of toxicity occur, seek medical attention.

Section VII — Precautions for Safe Handling and Use

Steps to Be Taken in Case Material Is Released or Spilled
No special procedures required.

Waste Disposal Method
Dispose of in accordance with local, state and federal regulations.

Precautions to Be Taken in Handling and Storing
Do not puncture or incinerate container. Do not expose to heat or store at temperatures above 120°F.

Other Precautions
None required under normal use.

Section VIII — Control Measures

Respiratory Protection (*Specify Type*)
NA

Ventilation		
Local Exhaust: NA	Special: NA	
Mechanical (*General*): NA	Other: NA	

Protective Gloves: NA — Eye Protection: NA

Other Protective Clothing or Equipment
NA

Work/Hygienic Practices
Use good clinical and hygienic practices.

NA = Not Applicable
ND = No Data

Material Safety Data Sheet

IDENTITY (As Used on Label and List)	Note: Blank spaces are not permitted. If any item is not applicable or no information is available, the space must be marked to indicate that
Norisodrine® with Calcium Iodide Syrup	

Section I

Manufacturer's Name **Abbott Laboratories**	Emergency Telephone Number **(312) 937-6100**
Address (Number, Street, City, State, and ZIP Code) **Pharmaceutical Products Division**	Telephone Number for Information **(312) 937-7350**
1400 Sheridan Road	Date Prepared June 30, 1987
North Chicago, Illinois 60064	Signature of Preparer (optional) Jim Mooney

Section II — Hazardous Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity; Common Name(s))	OSHA PEL	ACGIH TLV	Other Limits Recommended	% (optional)
Isoproterenol Sulfate (CAS No. 114-45-4; RTECS No. DO2100000)	NA	NA	NA	0.06%
Calcium Iodide (CAS No. 10102-68-8)	NA	NA	NA	3%
Ethyl Alcohol (CAS NO. 64-17-5; RTECS No. KQ6300000)	1000ppm ($1900 mg/m^3$)	1000 ppm ($1900 mg/m^3$)	NA	6%

Section III — Physical/Chemical Characteristics

Boiling Point	ND	Specific Gravity (H_2O = 1)	ND
Vapor Pressure (mm Hg.)	ND	Melting Point	NA
Vapor Density (AIR = 1)	ND	Evaporation Rate (Butyl Acetate = 1)	ND

Solubility in Water
Soluble

Appearance and Odor
Palatable, aromatic syrup

Section IV — Fire and Explosion Hazard Data

Flash Point (Method Used)	Flammable Limits	LEL	UEL
ND		ND	ND

Extinguishing Media
Use media appropriate for primary cause of fire.

Special Fire Fighting Procedures
None known

Unusual Fire and Explosion Hazards
NA

Section V — Reactivity Data

Stability			Conditions to Avoid
	Unstable		None under normal use.
	Stable	x	

Incompatibility (*Materials to Avoid*)
None under normal use

Hazardous Decomposition or Byproducts
Oxides of nitrogen and sulfur, iodine and iodine compounds

Hazardous Polymerization			Conditions to Avoid
	May Occur		None under normal use.
	Will Not Occur	x	

Section VI — Health Hazard Data

Route(s) of Entry: Inhalation? Unlikely | Skin? Unlikely | Ingestion? Clinical route

Health Hazards (*Acute and Chronic*)
Oral LD50 = 282-3602 mg/kg in rats, mice, rabbits, dogs, and guinea pigs for isoproterenal sulfate, LD50 = 5560-7060 mg/kg in rats, mice, rabbits, and guinea pigs for ethyl alcohol.

Ethyl Alcohol is a skin and eye irritant and is known to produce liver injury.

Carcinogenicity: NTP? No | IARC Monographs? No | OSHA Regulated? No

Signs and Symptoms of Exposure
None expected for occupational exposure. Refer to the PDR for clinical symptoms.

Medical Conditions
Generally Aggravated by Exposure

None known for occupational exposure. Refer to the PDR for clinical information.

Emergency and First Aid Procedures
Remove from source of exposure. If skin or eye contact, flush with copious amounts of water. If irritation develops or symptoms of toxicity occur, seek medical attention.

Section VII — Precautions for Safe Handling and Use

Steps to Be Taken in Case Material Is Released or Spilled
No special procedures required.

Waste Disposal Method
Dispose of in accordance with local, state and federal regulations.

Precautions to Be Taken in Handling and Storing
Store at temperatures below 77°F (25°C)

Other Precautions
None required under normal use

Section VIII — Control Measures

Respiratory Protection (*Specify Type*)
NA

Ventilation		
	Local Exhaust: NA	Special: NA
	Mechanical (*General*): NA	Other: NA

Protective Gloves: NA | Eye Protection: NA

Other Protective Clothing or Equipment
NA

Work/Hygienic Practices
Use good clinical and hygienic practices.

NA = Not Applicable
ND = No Data

Material Safety Data Sheet

IDENTITY (As Used on Label and List)	Note: Blank spaces are not permitted. If any item is not applicable or no information is available, the space must be marked to indicate that
Ogen® Estropipate Tablets, USP	

Section I List No. 3943, 3946, 3951, 3958

Manufacturer's Name	Emergency Telephone Number
Abbott Laboratories	**(312) 937-6100**
Address (Number, Street, City, State, and ZIP Code)	Telephone Number for Information
Pharmaceutical Products Division	**(312) 937-7350**
1400 Sheridan Road	Date Prepared July 20, 1987
North Chicago, Illinois 60064	Signature of Preparer (optional) Jim Mooney

Section II — Hazardous Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity; Common Name(s))	OSHA PEL	ACGIH TLV	Other Limits Recommended	% (optional)
Estropipate- piperazine estrone sulfate (CAS No. 7280-37-7)	NA	NA	*	0.3 - 2.3%

* Internal employee exposure limit = 1.0 mcg/m^3 (8 hr TWA)

** Percentage varies with dosage form

Section III — Physical/Chemical Characteristics

Boiling Point	NA	Specific Gravity (H_2O = 1)	NA
Vapor Pressure (mm Hg.)	NA	Melting Point	ND
Vapor Density (AIR = 1)	NA	Evaporation Rate (Butyl Acetate = 1)	NA

Solubility in Water
Slightly soluble

Appearance and Odor
Lavender, orange, peach or yellow tablets

Section IV — Fire and Explosion Hazard Data

Flash Point (Method Used)	Flammable Limits	LEL	UEL
NA		NA	NA

Extinguishing Media
Use media appropriate for primary cause of fire

Special Fire Fighting Procedures
None known

Unusual Fire and Explosion Hazards
None known

Section V — Reactivity Data

Stability			Conditions to Avoid
	Unstable		None under normal use
	Stable	X	

Incompatibility (*Materials to Avoid*)
None under normal use

Hazardous Decomposition or Byproducts
acrid smoke and fumes

Hazardous Polymerization			Conditions to Avoid
	May Occur		None under normal use
	Will Not Occur	X	

Section VI — Health Hazard Data

Route(s) of Entry — Inhalation? Unlikely — Skin? Possible — Ingestion? Clinical Route

Health Hazards (*Acute and Chronic*)
Estropipate has produced estrogenic changes in animal studies including testicular changes, vulvar swelling, cornification and mamary gland development.

Carcinogenicity — NTP? No — IARC Monographs? No — OSHA Regulated? No

Conjugated estrogens have been casually associated with cancer in humans.

Signs and Symptoms of Exposure
None expected for occupational exposure. Refer to the PDR clinical symptoms.

Medical Conditions
Generally Aggravated by Exposure

None known for occupational exposure. Refer to the PDR for clinical information.

Emergency and First Aid Procedures
Remove from source of exposure. If skin or eye contact, flush with copious amounts of water. If irritation develops or symptoms of toxicity occur, seek medical attention.

Section VII — Precautions for Safe Handling and Use

Steps to Be Taken in Case Material Is Released or Spilled
No special procedures required.

Waste Disposal Method
Dispose of in accordance with local, state, and federal regulations.

Precautions to Be Taken in Handling and Storing
Avoid excessive contact.

Other Precautions
None required under normal use.

Section VIII — Control Measures

Respiratory Protection (*Specify Type*)
NA

Ventilation			
	Local Exhaust NA	Special	NA
	Mechanical (*General*) NA	Other	NA

Protective Gloves
May be used to prevent excessive skin contact

Eye Protection
NA

Other Protective Clothing or Equipment
NA

Work/Hygienic Practices
Use good clinical and hygienic practices

NA = Not Applicable
ND = No Data

Material Safety Data Sheet

IDENTITY *(As Used on Label and List)* Ogen® Vaginal Cream
Estropipate Vaginal Cream, USP

Note: Blank spaces are not permitted. If any item is not applicable, or no information is available, the space must be marked to indicate that

Section I

List No. 2467

Manufacturer's Name **Abbott Laboratories**	Emergency Telephone Number **(312) 937-6100**
Address *(Number, Street, City, State, and ZIP Code)* **Pharmaceutical Products Division**	Telephone Number for Information **(312) 937-7350**
1400 Sheridan Road	Date Prepared July 20, 1987
North Chicago, Illinois 60064	Signature of Preparer *(optional)* Jim Mooney

Section II — Hazardous Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity; Common Name(s))	OSHA PEL	ACGIH TLV	Other Limits Recommended	% *(optional)*
Estropipate - piperazine estrone sulfate	NA	NA	*	0.15%
(CAS No. 7280-37-7)				

* Internal employee exposure limit = 1.0 mcg/m^3 (8 hr TWA)

Section III — Physical/Chemical Characteristics

Boiling Point	NA	Specific Gravity (H_2O = 1)	NA
Vapor Pressure (mm Hg.)	NA	Melting Point	ND
Vapor Density (AIR = 1)	NA	Evaporation Rate (Butyl Acetate = 1)	NA

Solubility in Water
Soluble

Appearance and Odor
Vaginal cream with almost no odor

Section IV — Fire and Explosion Hazard Data

Flash Point (Method Used)	Flammable Limits	LEL	UEL
NA		NA	NA

Extinguishing Media
Use media appropriate for primary cause of fire.

Special Fire Fighting Procedures
None known

Unusual Fire and Explosion Hazards
None known

Section V — Reactivity Data

Stability			Conditions to Avoid
	Unstable		None under normal use
	Stable	X	

Incompatibility (*Materials to Avoid*)
None under normal use

Hazardous Decomposition or Byproducts
Acrid smoke and fumes

Hazardous Polymerization			Conditions to Avoid
	May Occur		None under normal use
	Will Not Occur	X	

Section VI — Health Hazard Data

Route(s) of Entry — Inhalation? Unlikely — Skin? Clinical Route — Ingestion? Unlikely

Health Hazards (*Acute and Chronic*)
Estropipate has produced estrogenic changes in animal studies including testicular changes, vulvar swelling, cornification and mamary gland development.

Carcinogenicity: NTP? No — IARC Monographs? No — OSHA Regulated? No

Conjugated estrogens have been casually associated with cancer in humans.

Signs and Symptoms of Exposure
None expected for occupational exposure. Refer to the PDR for clinical symptoms.

Medical Conditions
Generally Aggravated by Exposure

None known for occupational exposure. Refer to the PDR for clinical information.

Emergency and First Aid Procedures
Remove from source of exposure. If skin or eye contact flush with copious amounts of water. If irritation develops or symptoms of toxicity occur, seek medical attention.

Section VII — Precautions for Safe Handling and Use

Steps to Be Taken in Case Material Is Released or Spilled
No special procedures required

Waste Disposal Method
Dispose of in accordance with local, state, and federal regulations

Precautions to Be Taken in Handling and Storing
Avoid excessive contact

Other Precautions
None required under normal use

Section VIII — Control Measures

Respiratory Protection (*Specify Type*)
NA

Ventilation		
	Local Exhaust: NA	Special: NA
	Mechanical (*General*): NA	Other: NA

Protective Gloves: May be used to prevent excessive skin contact
Eye Protection: NA

Other Protective Clothing or Equipment
NA

Work/Hygienic Practices
Use good clinical and hygienic practices

NA = Not Applicable
ND = No Data

Material Safety Data Sheet

IDENTITY (As Used on Label and List)	Note: Blank spaces are not permitted. If any item is not applicable or no information is available, the space must be marked to indicate that
Oretic® Hydrochlorothiazide Tablets, USP	

Section I List No. 6978, 6985

Manufacturer's Name **Abbott Laboratories**	Emergency Telephone Number **(312) 937-6100**
Address (Number, Street, City, State, and ZIP Code) **Pharmaceutical Products Division**	Telephone Number for Information **(312) 937-7350**
1400 Sheridan Road	Date Prepared July 20, 1987
North Chicago, Illinois 60064	Signature of Preparer (optional) Jim Mooney

Section II — Hazardous Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity, Common Name(s))	OSHA PEL	ACGIH TLV	Other Limits Recommended	% (optional)
Hydrochlorothiazide (CAS No. 58-93-5; RTECS No. DK9100000)	NA	NA	NA	14.5-29%*

* percentage varies with dosage form.

Section III — Physical/Chemical Characteristics

Boiling Point	NA	Specific Gravity (H_2O = 1)	NA
Vapor Pressure (mm Hg.)	NA	Melting Point	ND
Vapor Density (AIR = 1)	NA	Evaporation Rate (Butyl Acetate = 1)	NA

Solubility in Water
Soluble

Appearance and Odor
White tablets

Section IV — Fire and Explosion Hazard Data

Flash Point (Method Used)	Flammable Limits	LEL	UEL
NA		NA	NA

Extinguishing Media
Use media appropriate for primary cause of fire

Special Fire Fighting Procedures
None known

Unusual Fire and Explosion Hazards
None known

Section V — Reactivity Data

Stability	Unstable		Conditions to Avoid: None under normal use
	Stable	X	

Incompatibility (*Materials to Avoid*)
None under normal use

Hazardous Decomposition or Byproducts
ND

Hazardous Polymerization	May Occur		Conditions to Avoid: None under normal use
	Will Not Occur	X	

Section VI — Health Hazard Data

Route(s) of Entry — Inhalation? Unlikely; Skin? Unlikely; Ingestion? Clinical Route

Health Hazards (*Acute and Chronic*)
Oral LD50 = 3080 mg/kg in mice with hydrochlorothiazide. No known occupational hazards.

Consult the Physicians Desk Reference (PDR) for clinical health effects.

Carcinogenicity: NTP? No; IARC Monographs? No; OSHA Regulated? No

Signs and Symptoms of Exposure
None expected for occupational exposure. Refer to the PDR clinical symptoms.

Medical Conditions
Generally Aggravated by Exposure

None known for occupational exposure. Refer to the PDR for clinical information.

Emergency and First Aid Procedures
Remove from source of exposure. If skin or eye contact, flush with copious amounts of water. If irritation develops or sumptoms of toxicity occur, seek medical attention.

Section VII — Precautions for Safe Handling and Use

Steps to Be Taken in Case Material Is Released or Spilled
No special procedures required

Waste Disposal Method
Dispose of in accordance with local, state, and federal regulations.

Precautions to Be Taken in Handling and Storing
No special precautions required under normal use.

Other Precautions
None required under normal use.

Section VIII — Control Measures

Respiratory Protection (*Specify Type*)
NA

Ventilation	Local Exhaust: NA	Special: NA
	Mechanical (General): NA	Other: NA

Protective Gloves: NA
Eye Protection: NA

Other Protective Clothing or Equipment
NA

Work/Hygienic Practices
Use good clinical and hygienic practices

NA = Not Applicable
ND = No Data

Material Safety Data Sheet

IDENTITY *(As Used on Label and List)* Oreticyl® Hydro-Chlorothiazide and Deserpidine Tablets

Note: *Blank spaces are not permitted. If any item is not applicable or no information is available, the space must be marked to indicate that*

Section I List No. 6922, 6931

Manufacturer's Name **Abbott Laboratories**	Emergency Telephone Number **(312) 937-6100**
Address *(Number, Street, City, State, and ZIP Code)* **Pharmaceutical Products Division**	Telephone Number for Information **(312) 937-7350**
1400 Sheridan Road	Date Prepared July 20, 1987
North Chicago, Illinois 60064	Signature of Preparer *(optional)* Jim Mooney

Section II — Hazardous Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity; Common Name(s))	OSHA PEL	ACGIH TLV	Other Limits Recommended	% *(optional)*
Deserpidine	NA	NA	**	0.09-0.2
(CAS No. 131-01-1; RTECS No. ZG0875000)				
Hycrochlorothiazide	NA	NA	NA	24.22-35.
(CAS No. 58-93-5; RTECS No. DK91000000)				

* percentage varies with dosage form

** internal employee explosure limit = 0.25 mcg/m^3 (8 hr TWA)

Section III — Physical/Chemical Characteristics

Boiling Point	NA	Specific Gravity (H_2O = 1)	NA
Vapor Pressure (mm Hg.)	NA	Melting Point	ND
Vapor Density (AIR = 1)	NA	Evaporation Rate (Butyl Acetate = 1)	NA

Solubility in Water
Soluble

Appearance and Odor
Rose or gray colored, grooved tablets

Section IV — Fire and Explosion Hazard Data

Flash Point (Method Used)	Flammable Limits	LEL	UEL
NA		NA	NA

Extinguishing Media
Use media appropriate for primary cause of fire

Special Fire Fighting Procedures
None known

Unusual Fire and Explosion Hazards
None known

Section V — Reactivity Data

Stability			Conditions to Avoid
	Unstable		None under normal use
	Stable	X	

Incompatibility (*Materials to Avoid*)
None under normal use

Hazardous Decomposition or Byproducts
Oxides of nitrogen

Hazardous Polymerization			Conditions to Avoid
	May Occur		None under normal use
	Will Not Occur	X	

Section VI — Health Hazard Data

Route(s) of Entry — Inhalation? Unlikely — Skin? Unlikely — Ingestion? Clinical Route

Health Hazards (*Acute and Chronic*)
Oral LD50 = 3080 mg/kg in mice for hydrochlorothiazide, LD50 = 500 mg/kg in mice for deserpidine. No known occupational hazards. Consult the Physician's Desk Reference (PDR) for clinical health effects.

Carcinogenicity — NTP? No — IARC Monographs? No — OSHA Regulated? No

Signs and Symptoms of Exposure
None expected for occupational exposure. Refer to the PDR for clinical symptoms.

Medical Conditions Generally Aggravated by Exposure
None known for occupational exposure. Refer to the PDR for clinical information.

Emergency and First Aid Procedures
Remove from source of exposure. If skin or eye contact, flush with copious amounts of water. If irritation develops or sumptoms of toxicity occur, seek medical attention.

Section VII — Precautions for Safe Handling and Use

Steps to Be Taken in Case Material Is Released or Spilled
No special procedures required

Waste Disposal Method
Dispose of in accordance with local, state, and federal regulations

Precautions to Be Taken in Handling and Storing
No special precautions required under normal use.

Other Precautions
None required under normal use.

Section VIII — Control Measures

Respiratory Protection (*Specify Type*)
NA

Ventilation		
	Local Exhaust: NA	Special: NA
	Mechanical (*General*): NA	Other: NA

Protective Gloves: NA — Eye Protection: NA

Other Protective Clothing or Equipment
NA

Work/Hygienic Practices
Use good clinical and hygienic practices

NA = Not Applicable
ND = No Data

Material Safety Data Sheet

IDENTITY (As Used on Label and List) Panhematin® Hemin for Injection for IV Use Only	Note: Blank spaces are not permitted. If any item is not applicable or no information is available, the space must be marked to indicate that

Section I

List No. 2000

Manufacturer's Name	Emergency Telephone Number
Abbott Laboratories	**(312) 937-6100**
Address (Number, Street, City, State, and ZIP Code)	Telephone Number for Information
Pharmaceutical Products Division	**(312) 937-7350**
1400 Sheridan Road	Date Prepared: July 20, 1987
North Chicago, Illinois 60064	Signature of Preparer (optional): Jm Mooney

Section II — Hazardous Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity; Common Name(s))	OSHA PEL	ACGIH TLV	Other Limits Recommended	% (optional)
None				

Section III — Physical/Chemical Characteristics

Boiling Point	NA	Specific Gravity (H_2O = 1)	NA
Vapor Pressure (mm Hg.)	NA	Melting Point	ND
Vapor Density (AIR = 1)	NA	Evaporation Rate (Butyl Acetate = 1)	NA

Solubility in Water: Soluble

Appearance and Odor: Sterile, lyophilized black powder in single dose dispensing vials

Section IV — Fire and Explosion Hazard Data

Flash Point (Method Used)	Flammable Limits	LEL	UEL
NA		NA	NA

Extinguishing Media: Use media appropriate for primary cause of fire

Special Fire Fighting Procedures: None known

Unusual Fire and Explosion Hazards: None known

Section V — Reactivity Data

Stability			Conditions to Avoid
	Unstable		None under normal use
	Stable	X	

Incompatibility (*Materials to Avoid*)
None under normal use

Hazardous Decomposition or Byproducts
ND

Hazardous Polymerization			Conditions to Avoid
	May Occur		None under normal use
	Will Not Occur	X	

Section VI — Health Hazard Data

Route(s) of Entry	Inhalation?	Skin?	Ingestion?
	Unlikely	Unlikely	Unlikely

Health Hazards (*Acute and Chronic*)
No known occupational hazards. Consult the Physicians' Desk Reference (PDR) for clinical health effects.

Carcinogenicity	NTP?	IARC Monographs?	OSHA Regulated?
	No	No	No

Signs and Symptoms of Exposure
None expected for occupational exposure. Refer to the PDR for clinical symptoms.

Medical Conditions
Generally Aggravated by Exposure
None known for occupational exposure. Refer to the PDR for clinical information.

Emergency and First Aid Procedures
Remove from source of exposure. If skin or eye contact, flush with copious amounts of water. If irritation develops or symptoms of toxicity occur, seek medical attention.

Section VII — Precautions for Safe Handling and Use

Steps to Be Taken in Case Material Is Released or Spilled
No special procedures required

Waste Disposal Method
Dispose of in accordance with local, state, and federal regulations.

Precautions to Be Taken in Handling and Storing
No special precautions required under normal use.

Other Precautions
None required under normal use.

Section VIII — Control Measures

Respiratory Protection (*Specify Type*)
NA

Ventilation		
	Local Exhaust: NA	Special: NA
	Mechanical (*General*): NA	Other: NA

Protective Gloves	Eye Protection
NA	NA

Other Protective Clothing or Equipment
NA

Work/Hygienic Practices
Use good clinical and hygienic practices

NA = Not Applicable
ND = No Data

Material Safety Data Sheet

IDENTITY *(As Used on Label and List)* Panwarfin® Warfarin Sodium Tablets, USP Oral Anticoagulant

Note: Blank spaces are not permitted. If any item is not applicable or no information is available, the space must be marked to indicate that.

Section I

List No. 6626, 7202, 7210, 6638, 7218

Manufacturer's Name	Emergency Telephone Number
Abbott Laboratories	**(312) 937-6100**
Address *(Number, Street, City, State, and ZIP Code)*	Telephone Number for Information
Pharmaceutical Products Division	**(312) 937-7350**
1400 Sheridan Road	Date Prepared: July 20, 1987
North Chicago, Illinois 60064	Signature of Preparer *(optional)*: Jm Mooney

Section II — Hazardous Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity; Common Name(s))	OSHA PEL	ACGIH TLV	Other Limits Recommended	% (optional)
Warfarin Sodium (CAS No. 129-06-6; RTECS No. GN47525000)	0.1 mg/m^3 Warfarin	0.1 mg/m^3 Warfarin	NA	1.1-5.4%*

* percentage varies with dosage form

Section III — Physical/Chemical Characteristics

Boiling Point	NA	Specific Gravity (H_2O = 1)	NA
Vapor Pressure (mm Hg.)	NA	Melting Point	ND
Vapor Density (AIR = 1)	NA	Evaporation Rate (Butyl Acetate = 1)	NA

Solubility in Water: Soluble

Appearance and Odor: Lavender, orange, yellow or white colored tablets

Section IV — Fire and Explosion Hazard Data

Flash Point (Method Used)	Flammable Limits	LEL	UEL
NA		NA	NA

Extinguishing Media: Use appropriate media to fight primary cause of fire

Special Fire Fighting Procedures: None known

Unusual Fire and Explosion Hazards: None known

Section V — Reactivity Data

Stability			Conditions to Avoid
	Unstable		None under normal use
	Stable	X	

Incompatibility (*Materials to Avoid*): None under normal use

Hazardous Decomposition or Byproducts: Na_2O

Hazardous Polymerization			Conditions to Avoid
	May Occur		None under normal use
	Will Not Occur	x	

Section VI — Health Hazard Data

Route(s) of Entry — Inhalation? Unlikely; Skin? Unlikely; Ingestion? Clinical Route

Health Hazards (*Acute and Chronic*): Oral LDLo = 15 mg/kg in humans, TDLo = 0.3 mg/kg/2 day in women, LD50 = 8.?-700 mg/kg in rats and mice with warfarin sodium. No known occupational hazards. Consult the Physicians Desk Reference (PDR) for clinical health effects.

Carcinogenicity — NTP? No; IARC Monographs? No; OSHA Regulated? No

Signs and Symptoms of Exposure: None expected for occupational exposure. Refer to the PDR for clinical symptoms.

Medical Conditions Generally Aggravated by Exposure: None known for occupational exposure. Refer to the PDR for clinical information.

Emergency and First Aid Procedures: Remove from source of exposure. If skin or eye contact, flush with copious amounts of water. If irritation develops or sumptoms of toxicity occur, seek medical attention.

Section VII — Precautions for Safe Handling and Use

Steps to Be Taken in Case Material Is Released or Spilled: No special procedures required.

Waste Disposal Method: Dispose of in accordance with local, state, and federal regulations

Precautions to Be Taken in Handling and Storing: No special precautions required under normal use

Other Precautions: None required under normal use.

Section VIII — Control Measures

Respiratory Protection (*Specify Type*): NA

Ventilation		
	Local Exhaust: NA	Special: NA
	Mechanical (*General*): NA	Other: NA

Protective Gloves: NA — Eye Protection:

Other Protective Clothing or Equipment: NA

Work/Hygienic Practices: Use good clinical and hygienic practices

NA = Not Applicable
ND = No Data

Material Safety Data Sheet

IDENTITY (As Used on Label and List)	Note: Blank spaces are not permitted. If any item is not applicable or no information is available, the space must be marked to indicate that
Paradione® (Paramethadione) Oral Solution	

Section I

List No. 3860

Manufacturer's Name **Abbott Laboratories**	Emergency Telephone Number **(312) 937-6100**
Address (Number, Street, City, State, and ZIP Code) **Pharmaceutical Products Division**	Telephone Number for Information **(312) 937-7350**
1400 Sheridan Road	Date Prepared June 30, 1987
North Chicago, Illinois 60064	Signature of Preparer (optional) Jim Mooney

Section II — Hazardous Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity; Common Name(s))	OSHA PEL	ACGIH TLV	Other Limits Recommended	% (optional)
Paramethadione	NA	NA	NA	30%
(CAS No. 115-67-3; RTECS No. RP9800000)				
Ethyl Alcohol	1000 ppm	1000 ppm	NA	65%
(CAS No. 64-17-5; RTECS No. KQ6300000)	(1900mg/m^3)	(1900mg/m^3)		

Section III — Physical/Chemical Characteristics

Boiling Point	ND	Specific Gravity (H_2O = 1)	ND
Vapor Pressure (mm Hg.)	ND	Melting Point	NA
Vapor Density (AIR = 1)	ND	Evaporation Rate (Butyl Acetate = 1)	ND

Solubility in Water
Slightly soluble

Appearance and Odor
Clear, oily liquid

Section IV — Fire and Explosion Hazard Data

Flash Point (Method Used)	Flammable Limits	LEL	UEL
ND		ND	ND

Extinguishing Media
Water, CO_2, dry chemical

Special Fire Fighting Procedures
none known

Unusual Fire and Explosion Hazards
Product contains ethyl alcohol which is flammable

Section V — Reactivity Data

Stability			Conditions to Avoid
	Unstable		None under normal use.
	Stable	X	

Incompatibility (*Materials to Avoid*)
None under normal use

Hazardous Decomposition or Byproducts
Oxides of nitrogen

Hazardous Polymerization			Conditions to Avoid
	May Occur		None under normal use.
	Will Not Occur	X	

Section VI — Health Hazard Data

Route(s) of Entry — Inhalation? Unlikely — Skin? Unlikely — Ingestion? Clinical Route

Health Hazards (*Acute and Chronic*)
Oral LD50 = 1000 mg/kg for paramethadione. LD50 = 5560-7060 mg/kg in rats, mice, rabbits, and guinea pigs for ethyl alcohol. Ethyl alcohol is a skin and eye irritant and is known to produce liver injury.

Carcinogenicity — NTP? No — IARC Monographs? No — OSHA Regulated? No

Signs and Symptoms of Exposure
None expected for occupational exposure. Refer to the PDR for clinical symptoms.

Medical Conditions
Generally Aggravated by Exposure
None known for occupational exposure. Refer to the PDR for clinical information.

Emergency and First Aid Procedures
Remove from source of exposure. If skin or eye contact, flush with copious amounts of water. If irritation develops or symptoms of toxicity occur, seek medical attention.

Section VII — Precautions for Safe Handling and Use

Steps to Be Taken in Case Material Is Released or Spilled
No special procedures required.

Waste Disposal Method
Dispose of in accordance with local, state, and federal regulations.

Precautions to Be Taken in Handling and Storing
No special precautions required under normal use.

Other Precautions
None required under normal use.

Section VIII — Control Measures

Respiratory Protection (*Specify Type*)
NA

Ventilation			
	Local Exhaust	Special	
	NA		NA
	Mechanical (General)	Other	
	NA		NA

Protective Gloves
NA

Eye Protection
NA

Other Protective Clothing or Equipment
NA

Work/Hygienic Practices
Use good clinical and hygienic practices.

NA = Not Applicable
ND = No Data

Material Safety Data Sheet

IDENTITY (As Used on Label and List)	Note: Blank spaces are not permitted. If any item is not applicable or no information is available, the space must be marked to indicate that.
Peganone® Ethotoin Tablets	

Section I List No. 6902, 6905

Manufacturer's Name **Abbott Laboratories**	Emergency Telephone Number **(312) 937-6100**
Address (Number, Street, City, State, and ZIP Code) **Pharmaceutical Products Division**	Telephone Number for Information **(312) 937-7350**
1400 Sheridan Road	Date Prepared July 20, 1987
North Chicago, Illinois 60064	Signature of Preparer (optional) Jim Mooney

Section II — Hazardous Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity; Common Name(s))	OSHA PEL	ACGIH TLV	Other Limits Recommended	% (optional)
Ethotoin	NA	NA	NA	71-74%
(CAS No. 86-35-1; RTECS No. MU2450000)				

* percentage varies with dosage form

Section III — Physical/Chemical Characteristics

Boiling Point	NA	Specific Gravity (H_2O = 1)	NA
Vapor Pressure (mm Hg.)	NA	Melting Point	ND
Vapor Density (AIR = 1)	NA	Evaporation Rate (Butyl Acetate = 1)	NA

Solubility in Water
Soluble

Appearance and Odor
Grooved, white tablets

Section IV — Fire and Explosion Hazard Data

Flash Point (Method Used)	Flammable Limits	LEL	UEL
NA		NA	NA

Extinguishing Media
Use media appropriate for primary cause of fire

Special Fire Fighting Procedures
None known

Unusual Fire and Explosion Hazards
None known

Section V — Reactivity Data

Stability	Unstable		Conditions to Avoid: None under normal use
	Stable	X	

Incompatibility (*Materials to Avoid*): None under normal use

Hazardous Decomposition or Byproducts: ND

Hazardous Polymerization	May Occur		Conditions to Avoid: None under normal use
	Will Not Occur	X	

Section VI — Health Hazard Data

Route(s) of Entry: Inhalation? Unlikely; Skin? Unlikely; Ingestion? Clinical Route

Health Hazards (*Acute and Chronic*): Oral LD50 = 1500-1750 mg/kg in rats and mice for ethotoin. No known occupational hazards. Consult the Physicians' Desk Reference (PDR) for clinical health effects.

Carcinogenicity: NTP? No; IARC Monographs? No; OSHA Regulated? No

Signs and Symptoms of Exposure: None expected for occupational exposure. Refer to the PDR for clinical symptoms.

Medical Conditions Generally Aggravated by Exposure: None known for occupational exposure. Refer to the PDR for clinical information.

Emergency and First Aid Procedures: Remove from source of exposure. If skin or eye contact, flush with copious amounts of water. If irritation develops or symptoms of toxicity occur, seek medical attention.

Section VII — Precautions for Safe Handling and Use

Steps to Be Taken in Case Material Is Released or Spilled: No special procedures required

Waste Disposal Method: Dispose of in accordance with local, state, and federal regultions

Precautions to Be Taken in Handling and Storing: No special precautions required under normal use.

Other Precautions: None required under normal use.

Section VIII — Control Measures

Respiratory Protection (*Specify Type*): NA

Ventilation	Local Exhaust: NA	Special: NA	
	Mechanical (*General*): NA	Other: NA	
Protective Gloves: NA		Eye Protection: NA	

Other Protective Clothing or Equipment: NA

Work/Hygienic Practices: Use good clinical and hygienic practices

NA = Not Applicable
ND = No Data

Material Safety Data Sheet

IDENTITY (As Used on Label and List)	Note: Blank spaces are not permitted. If any item is not applicable or no information is available, the space must be marked to indicate that
Phenurone® Phenacemide Tablets, USP	

Section I

Manufacturer's Name **Abbott Laboratories**	Emergency Telephone Number **(312) 937-6100**
Address (Number, Street, City, State, and ZIP Code) **Pharmaceutical Products Division**	Telephone Number for Information **(312) 937-7350**
1400 Sheridan Road	Date Prepared June 30, 1987
North Chicago, Illinois 60064	Signature of Preparer (optional) Jim Mooney

Section II — Hazardous Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity, Common Name(s))	OSHA PEL	ACGIH TLV	Other Limits Recommended	% (optional)
Phenacemide	NA	NA	NA	67.1%
(CAS No. 63-98-9; RTECS No. YU0875000)				

Section III — Physical/Chemical Characteristics

Boiling Point	NA	Specific Gravity (H_2O = 1)	NA
Vapor Pressure (mm Hg.)	NA	Melting Point	NA
Vapor Density (AIR = 1)	NA	Evaporation Rate (Butyl Acetate = 1)	NA

Solubility in Water

Soluble

Appearance and Odor

Grooved White tablets

Section IV — Fire and Explosion Hazard Data

Flash Point (Method Used)	Flammable Limits	LEL	UEL
NA		NA	NA

Extinguishing Media

Use media appropriate for primary cause of fire.

Special Fire Fighting Procedures

None

Unusual Fire and Explosion Hazards

None known

Section V — Reactivity Data

Stability			Conditions to Avoid
	Unstable		None under normal use
	Stable	X	

Incompatibility (*Materials to Avoid*)
None under normal use

Hazardous Decomposition or Byproducts
ND

Hazardous Polymerization			Conditions to Avoid
	May Occur		
	Will Not Occur	X	

Section VI — Health Hazard Data

Route(s) of Entry: Inhalation? Unlikely | Skin? Unlikely | Ingestion? Clinical Route

Health Hazards (*Acute and Chronic*)
Oral LD50 = 882-500 mg/kg in rats, mice, rabbits, and guinea pigs for phenacemide. No known occupational hazards. Consult the Physicians' Desk Reference (PDR) for clinical health effects.

Carcinogenicity: NTP? No | IARC Monographs? No | OSHA Regulated? No

Signs and Symptoms of Exposure
None expected for occupational exposure. Refer to the PDR for clinical symptoms.

Medical Conditions
Generally Aggravated by Exposure

None known for occupational exposure. Refer to the PDR for clinical information.

Emergency and First Aid Procedures
Remove from source of exposure. If skin or eye contact, flush with copious amounts of water. If irritation develops or symptoms of toxicity occur, seek medical attention.

Section VII — Precautions for Safe Handling and Use

Steps to Be Taken in Case Material Is Released or Spilled
No special procedures required.

Waste Disposal Method
Dispose of in accordance with local, state, and federal regulations.

Precautions to Be Taken in Handling and Storing
No special procedures required under normal use.

Other Precautions
None required under normal use.

Section VIII — Control Measures

Respiratory Protection (*Specify Type*)
NA

Ventilation		
	Local Exhaust: NA	Special: NA
	Mechanical (*General*): NA	Other: NA

Protective Gloves: NA | Eye Protection: NA

Other Protective Clothing or Equipment
NA

Work/Hygienic Practices
Use good clinical and hygienic practices

NA = Not Applicable
ND = No Data

Material Safety Data Sheet

IDENTITY *(As Used on Label and List)* Placidyl® Ethchlorvynol Capsules, USP Oral Hypnotic

Note: Blank spaces are not permitted. If any item is not applicable or no information is available, the space must be marked to indicate that

Section I

List No. 6649, 6661, 6685, 6630

Manufacturer's Name **Abbott Laboratories**	Emergency Telephone Number **(312) 937-6100**
Address *(Number, Street, City, State, and ZIP Code)* **Pharmaceutical Products Division**	Telephone Number for Information **(312) 937-7350**
1400 Sheridan Road	Date Prepared July 20, 1987
North Chicago, Illinois 60064	Signature of Preparer *(optional)* Jim Mooney

Section II — Hazardous Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity, Common Name(s))	OSHA PEL	ACGIH TLV	Other Limits Recommended	% (optional)
Ethclorvynol (CAS No. 113-18-8; RTECS No. SB4725000)	NA	NA	NA	56-75%*

* percentage varies with dosage form

Section III — Physical/Chemical Characteristics

Boiling Point	NA	Specific Gravity (H_2O = 1)	NA
Vapor Pressure (mm Hg.)	NA	Melting Point	ND
Vapor Density (AIR = 1)	NA	Evaporation Rate (Butyl Acetate = 1)	NA

Solubility in Water
Soluble

Appearance and Odor
Red or green colored capsules

Section IV — Fire and Explosion Hazard Data

Flash Point (Method Used)	Flammable Limits	LEL	UEL
NA		NA	NA

Extinguishing Media
Use media appropriate for primary cause of fire

Special Fire Fighting Procedures
None known

Unusual Fire and Explosion Hazards
None known

Section V — Reactivity Data

Stability			Conditions to Avoid
	Unstable		None under normal use
	Stable	X	

Incompatibility (*Materials to Avoid*)
None under normal use

Hazardous Decomposition or Byproducts
ND

Hazardous Polymerization			Conditions to Avoid
	May Occur		None under normal use
	Will Not Occur	X	

Section VI — Health Hazard Data

Route(s) of Entry: Inhalation? Unlikely; Skin? Possible; Ingestion? Clinical Route

Health Hazards (*Acute and Chronic*)
Death has resulted from an oral dose as low as 6g of Placidyl while patients have survived overdoses of 50 g or more. Oral TDLo = 10 mg/kg to 15 mg/kg/2 days in women for ethchlorvynal. Ethchlorvynol is corrosive to skin and eyes.

Carcinogenicity: NTP? No; IARC Monographs? No; OSHA Regulated? No

Signs and Symptoms of Exposure
Liquid from leaking capsules may cause skin irritation.

Medical Conditions Generally Aggravated by Exposure
None known for occupational exposure. Refer to the PDR for clinical information.

Emergency and First Aid Procedures
Remove from source of exposure. If skin or eye contact, flush with copious amounts of water. If irritation develops or symptoms of toxicity occur, seek medical attention.

Section VII — Precautions for Safe Handling and Use

Steps to Be Taken in Case Material Is Released or Spilled
Protective gloves should be used to prevent contact with liquid from leaking capsules.

Waste Disposal Method
Controlled substance. Dispose of in accordance with local, state, and federal regulations.

Precautions to Be Taken in Handling and Storing
Avoid direct contact.

Other Precautions
None required under normal use

Section VIII — Control Measures

Respiratory Protection (*Specify Type*)
NA

Ventilation		
	Local Exhaust: NA	Special: NA
	Mechanical (*General*): NA	Other: NA

Protective Gloves: Should be used to prevent excessive skin contact.
Eye Protection: NA
Other Protective Clothing or Equipment: NA
Work/Hygienic Practices: Use good clinical and hygienic practices

NA = Not Applicable
ND = No Data

Material Safety Data Sheet

IDENTITY (As Used on Label and List) Quelidrine® Cough Syrup Non-Narcotic, Antihistamine Cough Suppressant	Note: Blank spaces are not permitted. If any item is not applicable or no information is available, the space must be marked to indicate that

Section I List No. 6883

Manufacturer's Name	Emergency Telephone Number
Abbott Laboratories	**(312) 937-6100**
Address (Number, Street, City, State, and ZIP Code)	Telephone Number for Information
Pharmaceutical Products Division	**(312) 937-7350**
1400 Sheridan Road	Date Prepared June 30, 1987
North Chicago, Illinois 60064	Signature of Preparer (optional) Jim Mooney

Section II — Hazardous Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity, Common Name(s))	OSHA PEL	ACGIH TLV	Other Limits Recommended	% (optional)
Ethyl Alcohol	1000 ppm	1000 ppm	NA	2%
(CAS No. 64-17-5; RTECS No. KQ6300000)	(1900 mg/m^3)	(1900 mg/m^3)		

Section III — Physical/Chemical Characteristics

Boiling Point	ND	Specific Gravity (H_2O = 1)	ND
Vapor Pressure (mm Hg.)	ND	Melting Point	NA
Vapor Density (AIR = 1)	ND	Evaporation Rate (Butyl Acetate = 1)	ND

Solubility in Water
Soluble

Appearance and Odor
Palatable, aromatic syrup

Section IV — Fire and Explosion Hazard Data

Flash Point (Method Used)	Flammable Limits	LEL	UEL
ND		ND	ND

Extinguishing Media
Use media appropriate for primary cause of fire

Special Fire Fighting Procedures
None known

Unusual Fire and Explosion Hazards
None known

Section V — Reactivity Data

Stability	Unstable		Conditions to Avoid: None under normal use.
	Stable	X	

Incompatibility (*Materials to Avoid*)
None under normal use.

Hazardous Decomposition or Byproducts
Oxides of nitrogen, hydrogen bromide, hydrogen chloride, ammonia

Hazardous Polymerization	May Occur		Conditions to Avoid: None under normal use.
	Will Not Occur	X	

Section VI — Health Hazard Data

Route(s) of Entry: Inhalation? Unlikely; Skin? Unlikely; Ingestion? Clinical Route

Health Hazards (*Acute and Chronic*)
Oral LD50 = 5560-7060 mg/kg in rats, mice, guinea pigs, and rabbits for ethyl alcohol.

Ethyl alcohol is a skin and eye irritant and is known to produce liver injury.

Carcinogenicity: NTP? No; IARC Monographs? No; OSHA Regulated? No

Signs and Symptoms of Exposure
None expected for occupational exposure. Refer to the PDR for clinical symptoms.

Medical Conditions Generally Aggravated by Exposure
None known for occupational exposure. Refer to the PDR for clinical information.

Emergency and First Aid Procedures
Remove from source of exposure. If skin or eye contact, flush with copious amounts of water. If irritation develops or symptoms of toxicity occur, seek medical attention.

Section VII — Precautions for Safe Handling and Use

Steps to Be Taken in Case Material Is Released or Spilled
No special procedures required.

Waste Disposal Method
Dispose of in accordance with local, state, and federal regulations.

Precautions to Be Taken in Handling and Storing
No special precuations required under normal use.

Other Precautions
None required under normal use.

Section VIII — Control Measures

Respiratory Protection (*Specify Type*)
NA

Ventilation	Local Exhaust: NA	Special: NA
	Mechanical (*General*): NA	Other: NA

Protective Gloves: NA
Eye Protection: NA

Other Protective Clothing or Equipment
NA

Work/Hygienic Practices
Use good clinical and hygienic practices

NA = Not Applicable
ND = No Data

Material Safety Data Sheet

IDENTITY (As Used on Label and List)	Note: Blank spaces are not permitted. If any item is not applicable or no information is available, the space must be marked to indicate that
Selsun® Selenium Sulfide Lotion, USP	

Section I

List No. 2660

Manufacturer's Name **Abbott Laboratories**	Emergency Telephone Number **(312) 937-6100**
Address (Number, Street, City, State, and ZIP Code) **Pharmaceutical Products Division**	Telephone Number for Information **(312) 937-7350**
1400 Sheridan Road	Date Prepared 3/2/87
North Chicago, Illinois 60064	Signature of Preparer (optional) Jm Mooney

Section II — Hazardous Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity; Common Name(s))	OSHA PEL	ACGIH TLV	Other Limits Recommended	% (optional)
Selenium Sulfide (CAS No. 7446-34-6; RTECS No. VT0525000)	0.2mg/m^3 as Se	0.2mg/m^3 as Se	NA	2.5%

Section III — Physical/Chemical Characteristics

Boiling Point	NA	Specific Gravity (H_2O = 1)	NA
Vapor Pressure (mm Hg.)	NA	Melting Point	ND
Vapor Density (AIR = 1)	NA	Evaporation Rate (Butyl Acetate = 1)	NA

Solubility in Water
Soluble

Appearance and Odor
Lotion

Section IV — Fire and Explosion Hazard Data

Flash Point (Method Used)	Flammable Limits	LEL	UEL
NA		NA	NA

Extinguishing Media
Use media appropriate for primary cause of fire

Special Fire Fighting Procedures
None known

Unusual Fire and Explosion Hazards
None known

Section V — Reactivity Data

Stability			Conditions to Avoid
	Unstable		None under normal use
	Stable	X	

Incompatibility (*Materials to Avoid*)
Silver oxide

Hazardous Decomposition or Byproducts
Selenium and oxides of sulfur

Hazardous Polymerization			Conditions to Avoid
	May Occur		None under normal use
	Will Not Occur	X	

Section VI — Health Hazard Data

Route(s) of Entry: Inhalation? Unlikely | Skin? Clinical Route | Ingestion? Unlikely

Health Hazards (*Acute and Chronic*)
Oral LD50 = 370 mg/kg in mice for selenium sulfide. Selenium compounds have produced eye, nose, throat and respiratory irritation. Can produce skin irritation and a sensitization response.

Carcinogenicity: NTP? No | IARC Monographs? No | OSHA Regulated? No

Selenium sulfide has produced tumors in animals treated by oral administration.

Signs and Symptoms of Exposure
None expected for occupational exposure. Refer to the PDR for clinical symptoms.

Medical Conditions
Generally Aggravated by Exposure

None known for occupational exposure. Refer to the PDR for clinical information.

Emergency and First Aid Procedures
Remove from source of exposure. If skin or eye contact, flush with copious amounts of water. If irritation develops or symptoms of toxicity occur, seek medical attention.

Section VII — Precautions for Safe Handling and Use

Steps to Be Taken in Case Material Is Released or Spilled
No special procedures required.

Waste Disposal Method
Dispose of in accordance with local, state, and federal regulations.

Precautions to Be Taken in Handling and Storing
No special procedures required under normal use.

Other Precautions
None required under normal use.

Section VIII — Control Measures

Respiratory Protection (*Specify Type*)
NA

Ventilation		
	Local Exhaust: NA	Special: NA
	Mechanical (*General*): NA	Other: NA

Protective Gloves: NA | Eye Protection: NA

Other Protective Clothing or Equipment
NA

Work/Hygienic Practices
Use good clinical and hygienic practices

NA = Not Applicable
ND = No Data

Material Safety Data Sheet

IDENTITY (As Used on Label and List)	Note: Blank spaces are not permitted. If any item is not applicable or no information is available, the space must be marked to indicate that
Trai® Hexocyclium Methylsulfate Filmtab® Tablets	

Section I List No. 6698

Manufacturer's Name **Abbott Laboratories**	Emergency Telephone Number **(312) 937-6100**
Address (Number, Street, City, State, and ZIP Code) **Pharmaceutical Products Division**	Telephone Number for Information **(312) 937-7350**
1400 Sheridan Road	Date Prepared July 20, 1987
North Chicago, Illinois 60064	Signature of Preparer (optional) Jim Mooney

Section II — Hazardous Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity; Common Name(s))	OSHA PEL	ACGIH TLV	Other Limits Recommended	% (optional)
Hexocyclium Methylsulfate	NA	NA	NA	13.62%
(CAS No. 6004-98-4; RTECS No. TM3150000)				

Section III — Physical/Chemical Characteristics

Boiling Point	NA	Specific Gravity (H_2O = 1)	NA
Vapor Pressure (mm Hg.)	NA	Melting Point	ND
Vapor Density (AIR = 1)	NA	Evaporation Rate (Butyl Acetate = 1)	NA

Solubility in Water
Soluble

Appearance and Odor
Green tablets

Section IV — Fire and Explosion Hazard Data

Flash Point (Method Used)	Flammable Limits	LEL	UEL
NA		NA	NA

Extinguishing Media
Use media appropriate for primary cause of fire

Special Fire Fighting Procedures
None known

Unusual Fire and Explosion Hazards
None known

Section V — Reactivity Data

Stability	Unstable		Conditions to Avoid: None under normal use
	Stable	X	

Incompatibility (*Materials to Avoid*)
None under normal use

Hazardous Decomposition or Byproducts
Oxides of sulfur and nitrogen

Hazardous Polymerization	May Occur		Conditions to Avoid: None under normal use
	Will Not Occur	X	

Section VI — Health Hazard Data

Route(s) of Entry: Inhalation? Unlikely | Skin? Unlikely | Ingestion? Clinical Route

Health Hazards (*Acute and Chronic*)
Oral LD50 = 600 mg/kg in mice for hexocyclium methysulfate. No known occupational hazards. Consult the Physicians' Desk Reference (PDR) for clinical health hazards.

Carcinogenicity: NTP? No | IARC Monographs? No | OSHA Regulated? No

Signs and Symptoms of Exposure
None expected for occupational exposure. Refer to the PDR for clinical symptoms.

Medical Conditions
Generally Aggravated by Exposure
None known for occupational exposure. Refer to the PDR for clinical information.

Emergency and First Aid Procedures
Remove from source of exposure. If skin or eye contact, flush with copious amounts of water. If irritation develops or symptoms of toxicity occur, seek medical attention.

Section VII — Precautions for Safe Handling and Use

Steps to Be Taken in Case Material Is Released or Spilled
No special procedures required

Waste Disposal Method
Dispose of in accordance with local, state, and federal regulations.

Precautions to Be Taken in Handling and Storing
No special precautions required under normal use

Other Precautions
None required under normal use

Section VIII — Control Measures

Respiratory Protection (*Specify Type*)
NA

Ventilation	Local Exhaust: NA	Special: NA	
	Mechanical (*General*): NA	Other: NA	

Protective Gloves: NA | Eye Protection: NA

Other Protective Clothing or Equipment
NA

Work/Hygienic Practices
Use good clinical and hygienic practice

NA = Not Applicable
ND = No Data

Material Safety Data Sheet

IDENTITY (As Used on Label and List)	Note: Blank spaces are not permitted. If any item is not applicable or no information is available, the space must be marked to indicate that
Tranxene® Clorazepate Dipotassium Capsules, Tablets; Tranxene SD & Tranxene - SD Half Strength Chlorazepate Dipotassium Tablets List No. 3417, 3418, 3419, 4389, 4390, 4391, 2997, 2699	
Section I	
Manufacturer's Name: **Abbott Laboratories**	Emergency Telephone Number: **(312) 937-6100**
Address (Number, Street, City, State, and ZIP Code): **Pharmaceutical Products Division**	Telephone Number for Information: **(312) 937-7350**
1400 Sheridan Road	Date Prepared: July 20, 1987
North Chicago, Illinois 60064	Signature of Preparer (optional): Jm Mooney

Section II — Hazardous Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity; Common Name(s))	OSHA PEL	ACGIH TLV	Other Limits Recommended	% (optional)
Chlorazepate Dipotassium (CAS No. 57019-90-7; RTECS No. DE8750000)	NA	NA	NA	3-11%*

* Percentage varies with dosage form

Section III — Physical/Chemical Characteristics

Boiling Point	NA	Specific Gravity (H_2O = 1)	NA
Vapor Pressure (mm Hg.)	NA	Melting Point	ND
Vapor Density (AIR = 1)	NA	Evaporation Rate (Butyl Acetate = 1)	NA

Solubility in Water: Soluble

Appearance and Odor: Gray and white, gray and maroon or gray capsules. Blue, peath, lavender or tan colored ta

Section IV — Fire and Explosion Hazard Data

Flash Point (Method Used)	Flammable Limits	LEL	UEL
NA		NA	NA

Extinguishing Media: Use media appropriate for primary cause of fire

Special Fire Fighting Procedures: None known

Unusual Fire and Explosion Hazards: None known

Section V — Reactivity Data

Stability			Conditions to Avoid
	Unstable		None under normal use
	Stable	X	

Incompatibility (*Materials to Avoid*)
None under normal use

Hazardous Decomposition or Byproducts
Chlorine, oxides of nitrogen, K_2O

Hazardous Polymerization			Conditions to Avoid
	May Occur		None under normal use
	Will Not Occur	X	

Section VI — Health Hazard Data

Route(s) of Entry: Inhalation? Unlikely; Skin? Unlikely; Ingestion? Clinical Route

Health Hazards (*Acute and Chronic*)
Oral LD50 = 70-1600 mg/kg in rats, mice, and monkeys for chlorazepate dipotassium. No known occupational hazards. Consult the Physicians' Desk Reference (PDR) for clinical health effects.

Carcinogenicity: NTP? No; IARC Monographs? No; OSHA Regulated? No

Signs and Symptoms of Exposure
None expected for occupational exposure. Refer to the PDR for clinical symptoms.

Medical Conditions Generally Aggravated by Exposure
None known for occupational exposure. Refer to the PDR for clinical information.

Emergency and First Aid Procedures
Remove from source of exposure. If skin or eye contact, flush with copious amounts of water. If irritation develops or symptoms of toxicity occur, seek medical attention.

Section VII — Precautions for Safe Handling and Use

Steps to Be Taken in Case Material Is Released or Spilled
No special procedures required

Waste Disposal Method
Controlled drug. Dispose of in accordance with local, state, and federal regulations.

Precautions to Be Taken in Handling and Storing
No special precautions required under normal use

Other Precautions
None required under normal use

Section VIII — Control Measures

Respiratory Protection (*Specify Type*)
NA

Ventilation		
	Local Exhaust: NA	Special: NA
	Mechanical (*General*): NA	Other: NA

Protective Gloves: NA
Eye Protection: NA

Other Protective Clothing or Equipment
NA

Work/Hygienic Practices
Use good clinical and hygienic practice

NA = Not Applicable
ND = No Data

Material Safety Data Sheet

IDENTITY *(As Used on Label and List)* Tridione® Trimethadione Tablets, Capsules, and Oral Solution

Note: Blank spaces are not permitted. If any item is not applicable or no information is available, the space must be marked to indicate that

Section I List No. 3709, 3753, 3721

Manufacturer's Name **Abbott Laboratories**	Emergency Telephone Number **(312) 937-6100**
Address *(Number, Street, City, State, and ZIP Code)* **Pharmaceutical Products Division**	Telephone Number for Information **(312) 937-7350**
1400 Sheridan Road	Date Prepared July 20, 1987
North Chicago, Illinois 60064	Signature of Preparer *(optional)* Jm Mooney

Section II — Hazardous Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity; Common Names)	OSHA PEL	ACGIH TLV	Other Limits Recommended	% *(optional)*
Trimethadione	NA	NA	NA	19-67% *
(CAS No. 127-48-0; RTECS No. RQ2100000)				

* Percentage varies with dosage form

Section III — Physical/Chemical Characteristics

Boiling Point	NA	Specific Gravity (H_2O = 1)	NA
Vapor Pressure (mm Hg.)	NA	Melting Point	ND
Vapor Density (AIR = 1)	NA	Evaporation Rate (Butyl Acetate = 1)	NA

Solubility in Water
Soluble

Appearance and Odor
White capsules or tablets. Also available in solution.

Section IV — Fire and Explosion Hazard Data

Flash Point (Method Used) NA	Flammable Limits	LEL NA	UEL NA

Extinguishing Media
Use media appropriate for primary cause of fire

Special Fire Fighting Procedures
None known

Unusual Fire and Explosion Hazards
None known

Section V — Reactivity Data

Stability			Conditions to Avoid
	Unstable		None under normal use
	Stable	X	

Incompatibility (*Materials to Avoid*)
None under normal use

Hazardous Decomposition or Byproducts
Oxides of nitrogen

Hazardous Polymerization			Conditions to Avoid
	May Occur		None under normal use
	Will Not Occur	X	

Section VI — Health Hazard Data

Route(s) of Entry: Inhalation? Unlikely | Skin? Unlikely | Ingestion? Clinical Route

Health Hazards (*Acute and Chronic*)
Oral LD50 = 2290-2500 mg/kg in rats and mice for trimethadione. No known occupational hazards. Consult the Physicians' Desk Reference (PDR) for clinical health effects.

Carcinogenicity: NTP? No | IARC Monographs? No | OSHA Regulated? No

Signs and Symptoms of Exposure
None expected for occupational exposure. Refer to the PDR for clinical symptoms.

Medical Conditions Generally Aggravated by Exposure
None known for occupational exposure. Refer to the PDR for clinical information.

Emergency and First Aid Procedures
Remove from source of exposure. If skin or eye contact, flush with copious amounts of water. If irritation develops or symptoms of toxicity occur, seek medical attention.

Section VII — Precautions for Safe Handling and Use

Steps to Be Taken in Case Material Is Released or Spilled
No special procedures required.

Waste Disposal Method
Dispose of in accordance with local, state, and federal regulations.

Precautions to Be Taken in Handling and Storing
No special precautions required under normal use

Other Precautions
None required under normal use

Section VIII — Control Measures

Respiratory Protection (*Specify Type*)
NA

Ventilation		
	Local Exhaust: NA	Special: NA
	Mechanical (*General*): NA	Other: NA

Protective Gloves: NA | Eye Protection: NA

Other Protective Clothing or Equipment
NA

Work/Hygienic Practices
Use good clinical and hygienic practices.

NA = Not Applicable
ND = No Data

Material Safety Data Sheet

IDENTITY (As Used on Label and List) Tronothane® Hydro-Chloride Pramoxine Hydrochloride Cream	Note: Blank spaces are not permitted. If any item is not applicable or no information is available, the space must be marked to indicate that

Section I List No. 6645, 6650

Manufacturer's Name	Emergency Telephone Number
Abbott Laboratories	**(312) 937-6100**
Address (Number, Street, City, State, and ZIP Code)	Telephone Number for Information
Pharmaceutical Products Division	**(312) 937-7350**
1400 Sheridan Road	Date Prepared: July 20, 1987
North Chicago, Illinois 60064	Signature of Preparer (optional): Jim Mooney

Section II — Hazardous Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity, Common Name(s))	OSHA PEL	ACGIH TLV	Other Limits Recommended	% (optional)
Pramoxine Hydrochloride	NA	NA	NA	1%
(CAS No. 637-58-1; RTECS No. QD8750000)				
Sodium Laurylsulfate	NA	NA	NA	2%
(CAS No. 151-21-3; RTECS No. WT1050000)				

Section III — Physical/Chemical Characteristics

Boiling Point	NA	Specific Gravity (H_2O = 1)	NA
Vapor Pressure (mm Hg.)	NA	Melting Point	ND
Vapor Density (AIR = 1)	NA	Evaporation Rate (Butyl Acetate = 1)	NA

Solubility in Water
Soluble

Appearance and Odor
Cream

Section IV — Fire and Explosion Hazard Data

Flash Point (Method Used)	Flammable Limits	LEL	UEL
NA		NA	NA

Extinguishing Media
Use media appropriate for primary cause of fire

Special Fire Fighting Procedures
None known

Unusual Fire and Explosion Hazards
None known

Section V — Reactivity Data

Stability			Conditions to Avoid
	Unstable		None under normal use
	Stable	x	

Incompatibility (*Materials to Avoid*)
None under normal use

Hazardous Decomposition or Byproducts
ND

Hazardous Polymerization			Conditions to Avoid
	May Occur		None under normal use
	Will Not Occur	X	

Section VI — Health Hazard Data

Route(s) of Entry — Inhalation? Unlikely — Skin? Clinical Route — Ingestion? Unlikely

Health Hazards (*Acute and Chronic*)
Oral LD50 = 1050 mg/kg in mice for pramoxine hydrochloride, LD50 = 1288 mg/kg for sodium lauryl sulfate in rats. Sodium lauryl sulfate is a mild eye irritant.

Carcinogenicity — NTP? No — IARC Monographs? No — OSHA Regulated? No

Signs and Symptoms of Exposure
Can produce an irritation response in exposed area for sensitive individuals.

Medical Conditions
Generally Aggravated by Exposure
None known for occupational exposure. Refer to the PDR for clinical information.

Emergency and First Aid Procedures
Remove from source of exposure. If skin or eye contact, flush with copious amounts of water. If irritation develops or sumptoms of toxicity occur, seek medical attention.

Section VII — Precautions for Safe Handling and Use

Steps to Be Taken in Case Material Is Released or Spilled
No special procedures required

Waste Disposal Method
Dispose of in accordance with local, state, and federal regulations

Precautions to Be Taken in Handling and Storing
No special precautions required under normal use

Other Precautions
None required under normal use

Section VIII — Control Measures

Respiratory Protection (*Specify Type*)
NA

Ventilation		
	Local Exhaust: NA	Special: NA
	Mechanical (*General*): NA	Other: NA

Protective Gloves: NA — Eye Protection: NA

Other Protective Clothing or Equipment
NA

Work/Hygienic Practices
Use good clinical and hygienic practices

NA = Not Applicable
ND = No Data

Material Safety Data Sheet

IDENTITY (As Used on Label and List)	Note: Blank spaces are not permitted. If any item is not applicable or no information is available, the space must be marked to indicate that
Vercyte® Pipobroman Tablets, USP	

Section I

List No. 7363

Manufacturer's Name **Abbott Laboratories**	Emergency Telephone Number **(312) 937-6100**
Address (Number, Street, City, State, and ZIP Code) **Pharmaceutical Products Division**	Telephone Number for Information **(312) 937-7350**
1400 Sheridan Road	Date Prepared July 20, 1987
North Chicago, Illinois 60064	Signature of Preparer (optional) Jim Mooney

Section II — Hazardous Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity, Common Name(s))	OSHA PEL	ACGIH TLV	Other Limits Recommended	% (optional)
Pipobroman	NA	NA	NA	19%
(CAS No. 54-9-1)				

Section III — Physical/Chemical Characteristics

Boiling Point	NA	Specific Gravity (H_2O = 1)	NA
Vapor Pressure (mm Hg.)	NA	Melting Point	ND
Vapor Density (AIR = 1)	NA	Evaporation Rate (Butyl Acetate = 1)	NA

Solubility in Water
Soluble

Appearance and Odor
Grooved tablets

Section IV — Fire and Explosion Hazard Data

Flash Point (Method Used)	Flammable Limits	LEL	UEL
NA		NA	NA

Extinguishing Media
Use media appropriate for primary cause of fire

Special Fire Fighting Procedures
None known

Unusual Fire and Explosion Hazards
None known

Section V — Reactivity Data

Stability			Conditions to Avoid
	Unstable		None under normal use
	Stable	X	

Incompatibility (*Materials to Avoid*)
None under normal use

Hazardous Decomposition or Byproducts
Bromine and oxides of nitrogen

Hazardous Polymerization			Conditions to Avoid
	May Occur		None under normal use
	Will Not Occur	X	

Section VI — Health Hazard Data

Route(s) of Entry — Inhalation? Unlikely — Skin? Unlikely — Ingestion? Clinical Route

Health Hazards (*Acute and Chronic*)
Oral LD50 = 215-510 mg/kg in rats and mice with pipobroman. No known occupational hazards. Consult the Physicians' Desk Reference (PDR) for clinical health effects.

Carcinogenicity — NTP? No — IARC Monographs? No — OSHA Regulated? No

Signs and Symptoms of Exposure
None expected for occupational exposure. Refer to the PDR for clinical symptoms.

Medical Conditions
Generally Aggravated by Exposure
None known for occupational exposure. Refer to the PDR for clinical information.

Emergency and First Aid Procedures
Remove from source of exposure. If skin or eye contact, flush with copious amounts of water. If irritation develops or symptoms of toxicity occur, seek medical attention.

Section VII — Precautions for Safe Handling and Use

Steps to Be Taken in Case Material Is Released or Spilled
No special procedures required.

Waste Disposal Method
Dispose of in accordance with local, state, and federal regulations.

Precautions to Be Taken in Handling and Storing
No special precautions required under normal use

Other Precautions
None required under normal use

Section VIII — Control Measures

Respiratory Protection (*Specify Type*)
NA

Ventilation		
	Local Exhaust: NA	Special: NA
	Mechanical (*General*): NA	Other: NA

Protective Gloves: NA — Eye Protection: NA

Other Protective Clothing or Equipment
NA

Work/Hygienic Practices
Use good clinical and hygienic practices

NA = Not Applicable
ND = No Data

FoxMeyer Corporation

CERTIFICATE OF NON-HAZARDOUS CHEMICALS

ACACIA INC
P.O. BOX 1799
OJAI, CA 93023

I, JAMES J SULLIVAN, certify that all products manufactured by ACACIA INC and distributed by FoxMeyer Drug Co contain no hazardous chemicals. In the event this changes, the appropriate documentation (M.S.D.S) will be forwarded to FoxMeyer upon date of initial manufacture.

Name: JAMES J SULLIVAN

Title: President

Signature: James J Sullivan Date: 11-20-87

FoxMeyer Corporation

CERTIFICATE OF NON-HAZARDOUS CHEMICALS

ACME/CHASTON
P.O. BOX 419
DAYVILLE, CT. 06241

I, Neal Izaks, certify that all products manufactured by ACME/CHASTON and distributed by FoxMeyer Drug Co contain no hazardous chemicals. In the event this changes, the appropriate documentation (M.S.D.S) will be forwarded to FoxMeyer upon date of initial manufacture.

Name: Neal Izaks

Title: Consumer Division Director

Signature: _____ Date: 11/20/87

FoxMeyer Corporation

CERTIFICATE OF NON-HAZARDOUS CHEMICALS

ACTION LABS INC
P.O. BOX 1090
PLACENTA, CA 92670

I, James R. Bailey, certify that all products manufactured by ACTION LABS INC and distributed by FoxMeyer Drug Co contain no hazardous chemicals. In the event this changes, the appropriate documentation (M.S.D.S) will be forwarded to FoxMeyer upon date of initial manufacture.

Name: James R. Bailey

Title: President

Signature: James R Bailey Date: 12/4/87

FoxMeyer Corporation

CERTIFICATE OF NON-HAZARDOUS CHEMICALS

ADAMS LABS
10800 S. PIPELINE RD
HURST, TX 76053

I, John Q. Adams, certify that all products manufactured by ADAMS LABS and distributed by FoxMeyer Drug Co contain no hazardous chemicals. In the event this changes, the appropriate documentation (M.S.D.S) will be forwarded to FoxMeyer upon date of initial manufacture.

Name: John Q. Adams

Title: President

Signature: John Q. Adams Date: November 18, 1987

MATERIAL SAFETY DATA SHEET

SECTION 1 - IDENTITY

COMMON NAME: FOLEX PFS INJECTION			HAZARD DETERMINATION UNDER OSHA HAZCOM STD. Hazardous
CHEMICAL NAME	Methotrexate Sodium	CHEMICAL FAMILY Pteridine	USE: Prescription Medicine - Antineoplastic/Antimetabolite
FORMULA	$C_{20}H_{22}N_8O_5$ m.w. = 454.44		
MANUFACTURER'S NAME	Taylor Pharmacal; Distributor; Adria Labs. Div. of Erbamont Inc.		EMERGENCY TELEPHONE NO. 614/764-8100
ADDRESS	P.O. Box 16529, Columbus, OH 43216	OTHER INFORMATION CALLS	614/761-6284
SIGNATURE OF PERSON RESPONSIBLE FOR PREPARATION	Albert S Bauman	DATE PREPARED	June 26, 1987

SECTION 2 - HAZARDOUS INGREDIENTS

PRINCIPAL HAZARDOUS COMPONENT(S) (CHEMICAL & COMMON NAME(S))	CAS NO.	%	THRESHOLD LIMIT VALUE (UNITS)
Methotrexate	59-05-2	2.5	Undetermined

SECTION 3 - PHYSICAL & CHEMICAL CHARACTERISTICS (FIRE & EXPLOSION DATA)

BOILING POINT	100°C (aqueous solution)	SPECIFIC GRAVITY (H_2O=1)	1.00	VAPOR PRESSURE (mmHg)	Undetermined
PERCENT VOLATILE BY VOLUME (%)	97%	VAPOR DENSITY (AIR=1)	Undetermined	EVAPORATION RATE (=1)	Undetermined
SOLUBILITY IN WATER	N/A			REACTIVITY IN WATER	None
APPEARANCE AND ODOR	Bright yellow-orange odorless solution.				
FLASH POINT	N/A	FLAMMABLE LIMITS IN AIR & BY VOLUME	LOWER N/A, UPPER N/A	EXTINGUISHER MEDIA	N/A
AUTO-IGNITION TEMPERATURE	N/A				
SPECIAL FIRE FIGHTING PROCEDURES	N/A				
UNUSUAL FIRE AND EXPLOSION HAZARDS	N/A				

SECTION 4 - PHYSICAL HAZARDS

STABILITY	UNSTABLE | |		CONDITIONS TO AVOID	None
	STABLE | X |			

INCOMPATIBILITY (MATERIALS TO AVOID) Unknown

HAZARDOUS DECOMPOSITION PRODUCTS Unknown

HAZARDOUS POLYMERIZATION	MAY OCCUR | |	CONDITIONS TO AVOID	N/A
	WILL NOT OCCUR | X |		

SECTION 5 - HEALTH HAZARDS

THRESHOLD LIMIT VALUE Undetermined

SIGNS AND SYMPTOMS OF EXPOSURE	1. ACUTE OVEREXPOSURE	By injection - Nausea, Vomiting, Myelosuppression, Mucositis, skin rash, renal failure, pneumonitis
	2. CHRONIC OVEREXPOSURE	Myelosuppression, Liver failure

MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE Undetermined

CHEMICAL LISTED AS CARCINOGEN OR POTENTIAL CARCINOGEN	NATIONAL TOXICOLOGY PROGRAM	YES | |	I.A.R.C. MONOGRAPHS	YES | |	
		NO | X |		NO | X |	
OSHA YES | | NO | X |	OSHA PERMISSIBLE EXPOSURE LIMIT	Undetermined	ACGIH THRESHOLD LIMIT VALUE	Undetermined	

OTHER EXPOSURE LIMIT USED N/A

EMERGENCY AND FIRST AID PROCEDURES

1. INHALATION: Seek medical attention
2. INGESTION: Calcium leucovorin at a dose equal to amount ingested in milligram given IV, followed by Calcium leucovorin IV or IM, 6 to 12 mg every 6 hours for 4 or more doses.
3. EYES: Flush with copious amounts of water or physiological saline
4. SKIN: Wash thoroughly with soap and water

SECTION 6 - SPECIAL PROTECTION INFORMATION

RESPIRATORY PROTECTION (SPECIFY TYPE) Approved aerosal respirator

VENTILATION	LOCAL EXHAUST	MECHANICAL
YES	Vertical laminar flow hood	(GENERAL)

OTHER Chemical carcinogen glove box with HEPA filter to outside

SPECIAL HEPA Filter vented to outside

PROTECTIVE GLOVES - Powder-free surgical latex gloves

EYE PROTECTION - Recommend splash goggles

OTHER PROTECTIVE CLOTHING OR EQUIPMENT - Long sleeved, impermeable disposable gown with elastic cuffs.

SECTION 7 - SPECIAL PRECAUTIONS AND SPILL/LEAK PROCEDURES

PRECAUTIONS TO BE TAKEN IN HANDLING AND STORAGE - Store in light-proof tightly closed containers

OTHER PRECAUTIONS Pregnant women should avoid contact with Methotrexate. The danger of fetal death or deformation exists.

STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED OR SPILLED - Wear gloves; soak up liquid with paper towels. Clean contaminated area with dilute bleach solution. CAUTION: DO NOT GET BLEACH ON SKIN OR IN EYES.

WASTE DISPOSAL METHODS - Deactivate with dilute bleach solution. Dispose of in accordance with your procedure for hazardous waste disposal to meet local, state and federal regulations.

MATERIAL SAFETY DATA SHEET

SECTION 1 - IDENTITY

COMMON NAME:	VINCASAR PFS INJECTION	HAZARD DETERMINATION UNDER OSHA HAZCOM STD.	Hazardous
CHEMICAL NAME	Vincristine Sulfate	CHEMICAL FAMILY: Vincaleukoblastine USE: Prescription medicine (Antineoplastic)	
FORMULA	$C_{46}H_{56}N_4O_{10}.H_2SO_4$ m.w. = 923.04		
MANUFACTURER'S NAME	Quad Pharmaceuticals; Distributor: Adria Labs., Div. of Erbamont Inc.	EMERGENCY TELEPHONE NO.	614/764-8100
ADDRESS	P.O. Box 16529, Columbus, OH 43216	OTHER INFORMATION CALLS	614/761-6284
SIGNATURE OF PERSON RESPONSIBLE FOR PREPARATION	Albert N Bauman	DATE PREPARED	June 26, 1987

SECTION 2 - HAZARDOUS INGREDIENTS

PRINCIPAL HAZARDOUS COMPONENT(S) (CHEMICAL & COMMON NAME(S))	CAS NO.	%	THRESHOLD LIMIT VALUE (UNITS)
Vincristine Sulfate	2068-78-2	0.1	Not Established

SECTION 3 - PHYSICAL & CHEMICAL CHARACTERISTICS (FIRE & EXPLOSION DATA)

BOILING POINT	100°C (aqueous solution)	SPECIFIC GRAVITY (H_2O=1)	1.03	VAPOR PRESSURE (mmHg)	N/A
PERCENT VOLATILE BY VOLUME (%)	89.7	VAPOR DENSITY (AIR=1)	N/A	EVAPORATION RATE (=1)	N/A
SOLUBILITY IN WATER	10 g/100 g	REACTIVITY IN WATER	None		
APPEARANCE AND ODOR	Clear colorless aqueous liquid.				
FLASH POINT	N/A	FLAMMABLE LIMITS IN AIR & BY VOLUME	N/A	LOWER	UPPER
EXTINGUISHER MEDIA	Foam CO_2	AUTO IGNITION TEMPERATURE	N/A		
SPECIAL FIRE FIGHTING PROCEDURES	- Wear self-contained breathing apparatus.				
UNUSUAL FIRE AND EXPLOSION HAZARDS	- May emit toxic fumes or smoke.				

SECTION 4 - PHYSICAL HAZARDS

STABILITY	UNSTABLE		CONDITIONS	
	STABLE	X	TO AVOID	N/A

INCOMPATIBILITY (MATERIALS TO AVOID) N/A

HAZARDOUS DECOMPOSITION PRODUCTS - May emit toxic fumes when heated to decomposition.

HAZARDOUS POLYMERIZATION	MAY OCCUR		CONDITIONS TO AVOID	N/A
	WILL NOT OCCUR	X		

SECTION 5 - HEALTH HAZARDS

THRESHOLD LIMIT VALUE - Not Established

SIGNS AND SYMPTOMS OF EXPOSURE
1. ACUTE OVEREXPOSURE - Nausea and vomiting.
2. CHRONIC OVEREXPOSURE - Paresthesias, constipation, alopecia, leukopenia, muscle wasting.

MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE Hypersensitivity to material

CHEMICAL LISTED AS CARCINOGEN OR POTENTIAL CARCINOGEN	No	NATIONAL TOXICOLOGY PROGRAM	YES		I.A.R.C. MONOGRAPHS	YES	
			NO	X		NO	X
OSHA	YES		OSHA PERMISSIBLE EXPOSURE LIMIT Not Established		ACGIH THRESHOLD LIMIT VALUE Not Established		
	NO	X					

OTHER EXPOSURE LIMIT USED Not Established

EMERGENCY AND FIRST AID PROCEDURES

1. INHALATION: Seek medical attention.
2. EYES: Flush with copious amounts of water or physiological saline.
3. SKIN: Wash thoroughly with soap and water. If injected in or under the skin, seek medical attention.
4. INGESTION: Seek medical attention.

SECTION 6 - SPECIAL PROTECTION INFORMATION

RESPIRATORY PROTECTION (SPECIFY TYPE) - Approved toxic aerosol respirator.

VENTILATION LOCAL EXHAUST MECHANICAL (GENERAL)

Recommended - Vertical laminar flow hood vented to outside.

OTHER - Chemical Carcinogen glove box with HEPA filter to outside. SPECIAL N/A

PROTECTIVE GLOVES - Surgical latex gloves, powder-free. EYE PROTECTION - Splash goggles

OTHER PROTECTIVE CLOTHING OR EQUIPMENT - Long sleeve, impermeable disposable gown with elastic cuffs.

SECTION 7 - SPECIAL PRECAUTIONS AND SPILL/LEAK PROCEDURES

PRECAUTIONS TO BE TAKEN IN HANDLING AND STORING - Store in tight containers. Protect from damage or spilling. Handle with great care. DANGER - POISON, TERATOGEN, IRRITANT.

OTHER PRECAUTIONS - Avoid contact with eyes, skin or clothing. Wash thoroughly after handling.

STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED OR SPILLED - Wear approved aerosol respirator, and powder-free surgical latex gloves. Absorb spillage and place in appropriate container for waste disposal.

WASTE DISPOSAL METHODS - Dispose of in accordance with your procedure for hazardous waste disposal to meet local, state and federal regulations.

MATERIAL SAFETY DATA SHEET

SECTION 1 - IDENTITY

COMMON NAME:	NEOSAR FOR INJECTION	HAZARD DETERMINATION UNDER OSHA HAZCOM STD.	Hazardous
CHEMICAL NAME	Cyclophosphamide, USP	CHEMICAL FAMILY: Nitrogen Mustards (Phosphoramide) USE: Prescription medicine - Antineoplastic	
FORMULA	$C_7H_{15}Cl_2N_2O_2P \cdot H_2O$		
MANUFACTURER'S NAME	Aste Werke-Bielefeld, Germany, Distributor: Adria Laboratories, Division of Erbamont Inc.	EMERGENCY TELEPHONE NO.	614/764-8100
ADDRESS	P.O. Box 16529 Columbus, OH 43216	OTHER INFORMATION CALLS	614/761-6284
SIGNATURE OF PERSON RESPONSIBLE FOR PREPARATION	Albert S Baumann	DATE PREPARED	June 26, 1987

SECTION 2 - HAZARDOUS INGREDIENTS

PRINCIPAL HAZARDOUS COMPONENT(S) (CHEMICAL & COMMON NAME(S))	CAS NO.	%	THRESHOLD LIMIT VALUE (UNITS)
Cyclophosphamide, USP	50-18-0	69	Undetermined

SECTION 3 - PHYSICAL & CHEMICAL CHARACTERISTICS (FIRE & EXPLOSION DATA)

BOILING POINT	N/A	SPECIFIC GRAVITY (H_2O=1)	N/A	VAPOR PRESSURE (mmHg)	N/A
PERCENT VOLATILE BY VOLUME (%)	N/A	VAPOR DENSITY (AIR=1)	N/A	EVAPORATION RATE (=1)	N/A
SOLUBILITY IN WATER	40 g/L	REACTIVITY IN WATER	None		
APPEARANCE AND ODOR	White powder				
FLASH POINT	N/A	FLAMMABLE LIMITS IN AIR & BY VOLUME	LOWER non-flammable	UPPER	
EXTINGUISHER MEDIA	N/A	AUTO IGNITION TEMPERATURE	N/A		
SPECIAL FIRE FIGHTING PROCEDURES	N/A				
UNUSUAL FIRE AND EXPLOSION HAZARDS	When heated to decomposition, it emits highly toxic fumes of oxides of Phosphorous and Nitrogen. ref.: SAX - "Dangerous Properties of Industrial Materials".				

SECTION 4 - PHYSICAL HAZARDS

STABILITY	UNSTABLE	| |	CONDITIONS TO AVOID	None
	STABLE	| X |		
INCOMPATIBILITY (MATERIALS TO AVOID)	Benzyl Alcohol Preserved Diluents			
HAZARDOUS DECOMPOSITION PRODUCTS	Oxides of Phosphorous and Nitrogen			
HAZARDOUS POLYMERIZATION	MAY OCCUR | |		CONDITIONS TO AVOID	None
	WILL NOT OCCUR | X |			

SECTION 5 - HEALTH HAZARDS

THRESHOLD LIMIT VALUE Undetermined

SIGNS AND SYMPTOMS OF EXPOSURE

1. ACUTE OVEREXPOSURE Nausea, vomiting, Leukopenia, hair loss
2. CHRONIC OVEREXPOSURE Leukopenia, hair loss, cystitis

MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE Undetermined

CHEMICAL LISTED AS CARCINOGEN OR POTENTIAL CARCINOGEN	NATIONAL TOXICOLOGY PROGRAM YES | X | NO | |		I.A.R.C. MONOGRAPHS YES | X | NO | |	
OSHA YES | | NO | X |	OSHA PERMISSIBLE EXPOSURE LIMIT	Undetermined	ACGIH THRESHOLD LIMIT VALUE	Undetermined	

OTHER EXPOSURE LIMIT USED Undetermined

EMERGENCY AND FIRST AID PROCEDURES

1. INHALATION: Seek medical attention
2. EYES: Irrigate with copious amounts of physiological saline or water
3. SKIN: Wash with soap and water
4. INGESTION: Seek medical attention

SECTION 6 - SPECIAL PROTECTION INFORMATION

RESPIRATORY PROTECTION (SPECIFY TYPE) Approved toxic dust mask or aerosol mask

VENTILATION LOCAL EXHAUST MECHANICAL (GENERAL)

vertical laminar flow hood

OTHER SPECIAL HEPA filter vented to otuside

PROTECTIVE GLOVES Synthetic or Rubber Gloves EYE PROTECTION Recommend splash goggles

OTHER PROTECTIVE CLOTHING OR EQUIPMENT Long sleeved, impermeable disposable gown with elastic cuffs

SECTION 7 - SPECIAL PRECAUTIONS AND SPILL/LEAK PROCEDURES

PRECAUTIONS TO BE TAKEN IN HANDLING AND STORING - Neosar is a potent anti-cancer drug. Caution in the handling and use must be exercised. If Neosar powder or solution contacts skin or mucosae, immediately wash thoroughly with soap and water.

OTHER PRECAUTIONS See product insert for further information.

STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED OR SPILLED Wash area with copious amounts of water.

WASTE DISPOSAL METHODS Mix with Sodium hypochlorite, dispose in accordance with your procedure for hazardous waste disposal to meet local, state, and federal regulations.

MATERIAL SAFETY DATA SHEET

SECTION 1 - IDENTITY

COMMON NAME:	Adriamycin RDF	HAZARD DETERMINATION UNDER OSHA HAZCOM STD.	Hazardous RTECS CAS #23214-92-8
CHEMICAL NAME	Doxorubicin hydrochloride	CHEMICAL FAMILY	Tetracycline
		USE:	Prescription medicine
FORMULA	$C_{27}H_{29}NO_{11}.HCl$ M.W. = 579.99		
MANUFACTURER'S NAME	Farmitalia Carlo Erba, Adria Laboratories Distributor; Adria Labs. Div. of Erbamont Inc.	EMERGENCY TELEPHONE NO.	614/764-8100
ADDRESS	P.O. Box 16529, Columbus, OH 43216	OTHER INFORMATION CALLS	614/761-6284
SIGNATURE OF PERSON RESPONSIBLE FOR PREPARATION	Albert S Bauman	DATE PREPARED	Feb 12, 1987

SECTION 2 - HAZARDOUS INGREDIENTS

PRINCIPAL HAZARDOUS COMPONENT(S) (CHEMICAL & COMMON NAME(S))	CAS NO.	%	THRESHOLD LIMIT VALUE (UNITS)
Doxorubicin hydrochloride	25316-40-9	16	Undetermined

SECTION 3 - PHYSICAL & CHEMICAL CHARACTERISTICS (FIRE & EXPLOSION DATA)

BOILING POINT	N/A	SPECIFIC GRAVITY (H_2O=1)	0.060 gm/cm^3
VAPOR PRESSURE (mmHg)	N/A		
PERCENT VOLATILE BY VOLUME (%)	N/A	VAPOR DENSITY (AIR=1)	N/A
EVAPORATION RATE (=1)	N/A		
SOLUBILITY IN WATER	Soluble	REACTIVITY IN WATER	None
APPEARANCE AND ODOR	Red crystals - odorless		

FLASH POINT	FLAMMABLE LIMITS IN AIR & BY VOLUME	LOWER	UPPER
N/A	Unknown	Unknown	Unknown

AUTO-IGNITION TEMPERATURE	EXTINGUISHER MEDIA
Unknown	Dry chemical foam or carbon dioxide.

SPECIAL FIRE FIGHTING PROCEDURES	Evacuate personnel to safe area. Firefighters should use self contained breathing equipment and protective clothing - use water spray, dry chemical foam or carbon dioxide.
UNUSUAL FIRE AND EXPLOSION HAZARDS	Unknown

SECTION 4 - PHYSICAL HAZARDS

STABILITY	UNSTABLE | |	CONDITIONS TO AVOID	Material is stable from safety point of view. Store at 15°-30°C (59°-86°F).
	STABLE | X |		
INCOMPATIBILITY (MATERIALS TO AVOID)	Unknown		
HAZARDOUS DECOMPOSITION PRODUCTS	When heated to decomposition, > 204°C, it emits very toxic fumes of NO_X and HCl.		
HAZARDOUS POLYMERIZATION	MAY OCCUR | |	CONDITIONS TO AVOID	
	WILL NOT OCCUR | X |		Not applicable

SECTION 5 - HEALTH HAZARDS

THRESHOLD LIMIT VALUE	Unknown					
SIGNS AND SYMPTOMS OF EXPOSURE	1. ACUTE OVEREXPOSURE Undetermined		2. CHRONIC OVEREXPOSURE Undetermined			
MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE	Cardiovascular, Hepatic, Renal, Bone Marrow Impairment					
CHEMICAL LISTED AS CARCINOGEN OR POTENTIAL CARCINOGEN	NATIONAL TOXICOLOGY PROGRAM	YES | X |	I.A.R.C. MONOGRAPHS	YES | X |		
		NO | |		NO | |		
OSHA YES | | NO | X |	OSHA PERMISSIBLE EXPOSURE LIMIT	Undetermined	ACGIH THRESHOLD LIMIT VALUE	Undetermined		
OTHER EXPOSURE LIMIT USED	Unknown					

EMERGENCY AND FIRST AID PROCEDURES

1. INHALATION: Seek medical attention
2. INGESTION: Seek medical attention
3. SKIN: Wash with soap and water immediately
4. EYES: Irrigate immediately with saline or water

SECTION 6 - SPECIAL PROTECTION INFORMATION

RESPIRATORY PROTECTION (SPECIFY TYPE)	Approved toxic dust respirator mask.		
VENTILATION	LOCAL EXHAUST Vertical laminar flow hood	MECHANICAL (GENERAL)	
OTHER	SPECIAL - HEPA filter vented to outside area		
PROTECTIVE GLOVES - Synthetic or rubber gloves	EYE PROTECTION - Recommend splash goggle		
OTHER PROTECTIVE CLOTHING OR EQUIPMENT	Long sleeved impermeable, disposable gown with elastic cuffs - glove box.		

SECTION 7 - SPECIAL PRECAUTIONS AND SPILL/LEAK PROCEDURES

PRECAUTIONS TO BE TAKEN IN HANDLING AND STORAGE	Adriamycin RDF is a potent anti-cancer drug. Caution in the handling and preparation of the powder and solution must be exercised. If Adriamycin powder or solution contacts skin or mucosa, immediately wash thoroughly with soap and water.
OTHER PRECAUTIONS	See product insert for further information.
STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED OR SPILLED	Deactivate with dilute bleach solution. Rinse well with water.
WASTE DISPOSAL METHODS	Deactivate with dilute bleach solution. Dispose of the waste in accordance with your procedure for hazardous waste disposal to meet local, state and federal regulations.

MATERIAL SAFETY DATA SHEET

SECTION 1 - IDENTITY

COMMON NAME:	ADRUCIL INJECTION	HAZARD DETERMINATION UNDER OSHA HAZCOM STD.	Hazardous
CHEMICAL NAME	Fluorouracil, USP	CHEMICAL FAMILY: Pyrimidine USE: Prescription Medicine - Antineoplastic	
FORMULA	$C_4H_3FN_2O_2$ m.w. = 130.08		
MANUFACTURER'S NAME	Taylor Pharmacal; Distributor; Adria Laboratories, Division of Erbamont Inc.	EMERGENCY TELEPHONE NO.	614/764-8100
ADDRESS	Adria Laboratories: P.O. Box 16529 Columbus, OH 43216	OTHER INFORMATION CALLS	614/761-6284
SIGNATURE OF PERSON RESPONSIBLE FOR PREPARATION	Albert W Bauman	DATE PREPARED	June 26, 1987

SECTION 2 - HAZARDOUS INGREDIENTS

PRINCIPAL HAZARDOUS COMPONENT(S) (CHEMICAL & COMMON NAME(S))	CAS NO.	%	THRESHOLD LIMIT VALUE (UNITS)
Fluorouracil, USP	51-21-8	5	Undetermined

SECTION 3 - PHYSICAL & CHEMICAL CHARACTERISTICS (FIRE & EXPLOSION DATA)

BOILING POINT	similar to water	SPECIFIC GRAVITY (H_2O=1)	1.0297	VAPOR PRESSURE (mmHg)	unknown
PERCENT VOLATILE BY VOLUME (%)	Undetermined	VAPOR DENSITY (AIR=1)	unknown	EVAPORATION RATE (=1)	Undeterimined
SOLUBILITY IN WATER	Is an aqueous solution	REACTIVITY IN WATER	None		
APPEARANCE AND ODOR	Clear aqueous solution; no odor				
FLASH POINT	N/A	FLAMMABLE LIMITS IN AIR & BY VOLUME	LOWER non-flammable	UPPER	
EXTINGUISHER MEDIA	N/A	AUTO-IGNITION TEMPERATURE	N/A		
SPECIAL FIRE FIGHTING PROCEDURES	N/A				
UNUSUAL FIRE AND EXPLOSION HAZARDS	N/A				

SECTION 4 - PHYSICAL HAZARDS

STABILITY	UNSTABLE		CONDITIONS	
	STABLE	X	TO AVOID	Undetermined
INCOMPATIBILITY (MATERIALS TO AVOID)	Undetermined			
HAZARDOUS DECOMPOSITION PRODUCTS	Undetermined			
HAZARDOUS POLYMERIZATION	MAY OCCUR		CONDITIONS TO AVOID	
	WILL NOT OCCUR	X		N/A

SECTION 5 - HEALTH HAZARDS

THRESHOLD LIMIT VALUE	Undetermined						
SIGNS AND SYMPTOMS OF EXPOSURE	The effects of overexposure have not been established but it is likely that an exaggeration of known toxic effects may occur, the most prominent of which are myelosuppressive and mucous membrane toxicity.						
1. ACUTE OVEREXPOSURE	By injection - Nausea, Vomiting, myelosuppressive						
2. CHRONIC OVEREXPOSURE	Undetermined						
MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE	Undetermined						
CHEMICAL LISTED AS CARCINOGEN OR POTENTIAL CARCINOGEN			NATIONAL TOXICOLOGY PROGRAM	YES		I.A.R.C. MONOGRAPHS	YES
				NO	X		NO X
OSHA	YES		OSHA PERMISSIBLE EXPOSURE LIMIT	Undetermined		ACGIH THRESHOLD LIMIT VALUE	Undetermined
	NO	X					
OTHER EXPOSURE LIMIT USED	Undetermined						

EMERGENCY AND FIRST AID PROCEDURES

1. INHALATION: Seek medical attention
2. EYES: Rinse with copious amounts of water. Irrigate immediately with water or saline
3. SKIN: Wash thoroughly with soap and water and rinse with copious amounts of water
4. INGESTION: Seek medical attention

SECTION 6 - SPECIAL PROTECTION INFORMATION

RESPIRATORY PROTECTION (SPECIFY TYPE)	Approved respirator for toxic mists or aersols		
VENTILATION	LOCAL EXHAUST	MECHANICAL (GENERAL)	
	Vertical laminar flow hood	Same	
OTHER	SPECIAL	HEPA filter vented to outside air	
PROTECTIVE GLOVES	Synthetic or rubber gloves	EYE PROTECTION	Splash goggles
OTHER PROTECTIVE CLOTHING OR EQUIPMENT	Long sleeved impermeable, disposable gown with elastic cuffs		

SECTION 7 - SPECIAL PRECAUTIONS AND SPILL/LEAK PROCEDURES

PRECAUTIONS TO BE TAKEN IN HANDLING AND STORAGE	Adrucil is a potent anti-cancer drug. Caution in the handling and use must be exercised. If Adrucil solution contacts skin or mucosae, immediately wash thoroughly with soap and water.
OTHER PRECAUTIONS	See product insert for further information.
STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED OR SPILLED	Deactivate with dilute bleach solution. Rinse well with water.
WASTE DISPOSAL METHODS	Deactivate with dilute bleach solution. Dispose of in accordance with your procedure for hazardous waste disposal to meet local, state and federal regulations.

MATERIAL SAFETY DATA SHEET

SECTION 1 - IDENTITY

COMMON NAME:	FOLEX FOR INJECTION	HAZARD DETERMINATION UNDER OSHA HAZCOM STD.	Hazardous
CHEMICAL NAME	Methotrexate Sodium	CHEMICAL FAMILY: Pteridine USE: Prescription medicine (Antineoplastic/Antimetabolite)	
FORMULA	$C_{20}H_{22}N_8O_5$ m.w. = 454.44		
MANUFACTURER'S NAME	Ben Venue Laboratories, Inc.; Distributor; Adria Labs. Div. of Erbamont Inc.	EMERGENCY TELEPHONE NO.	614/764-8100
ADDRESS	P.O. Box 16529, Columbus, OH 43216	OTHER INFORMATION CALLS	614/761-6284
SIGNATURE OF PERSON RESPONSIBLE FOR PREPARATION	Albert S Banaman	DATE PREPARED	June 26, 1987

SECTION 2 - HAZARDOUS INGREDIENTS

PRINCIPAL HAZARDOUS COMPONENT(S) (CHEMICAL & COMMON NAME(S))	CAS NO.	%	THRESHOLD LIMIT VALUE (UNITS)
Methotrexate	59-05-2	95	Undetermined

SECTION 3 - PHYSICAL & CHEMICAL CHARACTERISTICS (FIRE & EXPLOSION DATA)

BOILING POINT	Melting Point at 185°-204° with decomposition	SPECIFIC GRAVITY (H_2O=1)	N/A
VAPOR PRESSURE (mmHg)	Undetermined		
PERCENT VOLATILE BY VOLUME (%)	Undetermined	VAPOR DENSITY (AIR=1)	Undetermined
EVAPORATION RATE (=1)	Undetermined		
SOLUBILITY IN WATER	Methotrexate Sodium is soluble in water ADS* - Practically insoluble in water	REACTIVITY IN WATER	None
APPEARANCE AND ODOR	Bright yellow-orange odorless powder.		

FLASH POINT	N/A	FLAMMABLE LIMITS IN AIR & BY VOLUME	LOWER N/A	UPPER N/A	EXTINGUISHER MEDIA	N/A	AUTO-IGNITION TEMPERATURE N/A

SPECIAL FIRE FIGHTING PROCEDURES	N/A
UNUSUAL FIRE AND EXPLOSION HAZARDS	N/A

SECTION 4 - PHYSICAL HAZARDS

STABILITY	UNSTABLE [ ]	CONDITIONS TO AVOID	None
	STABLE [X]		
INCOMPATIBILITY (MATERIALS TO AVOID)	Unknown		
HAZARDOUS DECOMPOSITION PRODUCTS	None		
HAZARDOUS POLYMERIZATION	MAY OCCUR [ ]	CONDITIONS TO AVOID	N/A
	WILL NOT OCCUR [X]		

SECTION 5 - HEALTH HAZARDS

THRESHOLD LIMIT VALUE Undetermined

SIGNS AND SYMPTOMS OF EXPOSURE
1. ACUTE OVEREXPOSURE By injection - Nausea, Vomiting, Myelosuppression, Mucositis, skin rash, renal failure, pneumonitis
2. CHRONIC OVEREXPOSURE Myelosuppression, Liver failure

MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE Undetermined

CHEMICAL LISTED AS CARCINOGEN OR POTENTIAL CARCINOGEN	NATIONAL TOXICOLOGY PROGRAM YES [ ]	NO [X]	I.A.R.C. MONOGRAPHS YES [ ]	NO [X]	
OSHA YES [ ] NO [X]	OSHA PERMISSIBLE EXPOSURE LIMIT	Undetermined	ACGIH THRESHOLD LIMIT VALUE	Undetermined	

OTHER EXPOSURE LIMIT USED N/A

EMERGENCY AND FIRST AID PROCEDURES
1. INHALATION: Seek medical attention
2. INGESTION: Calcium leucovorin at a dose equal to amount ingested in milligram given IV, followed by Calcium leucovorin IV or IM, 6 to 12 mg every 6 hours for 4 or more doses.
3. EYES: Flush with copious amounts of water or physiological saline.
4. SKIN: Wash thoroughly with soap and water.

SECTION 6 - SPECIAL PROTECTION INFORMATION

RESPIRATORY PROTECTION (SPECIFY TYPE) Approved toxic dust mask

VENTILATION	LOCAL EXHAUST	MECHANICAL
YES	Vertical laminar flow hood	(GENERAL)

OTHER Bacterial Glove Box with HEPA filter to outside

SPECIAL HEPA Filter vented to outside

PROTECTIVE GLOVES - Synthetic or rubber gloves

EYE PROTECTION - Recommend splash goggles

OTHER PROTECTIVE CLOTHING OR EQUIPMENT - Long sleeved, impermeable disposable gown with elastic cuffs.

SECTION 7 - SPECIAL PRECAUTIONS AND SPILL/LEAK PROCEDURES

PRECAUTIONS TO BE TAKEN IN HANDLING AND STORAGE - Store in light-proof tightly closed containers

OTHER PRECAUTIONS Pregnant women should avoid contact with Methotrexate. The danger of fetal death or deformation exists.

STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED OR SPILLED If dry powder, wear toxic dust mask and gloves. If liquid, wear gloves. Carefully collect powder with disposable means. Soak up liquid with paper towels. Clean contaminated area with dilute bleach solution. CAUTION: Do not get bleach on skin or in eyes.

WASTE DISPOSAL METHODS - Deactivate with dilute bleach solution. Dispose of in accordance with your procedure for hazardous waste disposal to meet local, state and federal regulations.

MATERIAL SAFETY DATA SHEET

SECTION 1 - IDENTITY

COMMON NAME: Velsar	HAZARD DETERMINATION UNDER OSHA HAZCOM STD. Hazardous RTECS #YY8400000
CHEMICAL NAME Sterile Vinblastine Sulfate, USP	CHEMICAL FAMILY: Vincaleukoblastine USE: Antineoplastic (Prescription only)
FORMULA $C_{46}H_{58}N_4O_9.H_2SO_4$ m.w. = 909.06	
MANUFACTURER'S NAME David Bull Laboratories, Mulgrave Australia Distributor: Adria Labs., Div. of Erbamont Inc.	EMERGENCY TELEPHONE NO. 614/764-8100
ADDRESS 7001 Post Road, Dublin, OH 43017	OTHER INFORMATION CALLS 614/761-6284
SIGNATURE OF PERSON RESPONSIBLE FOR PREPARATION Albert S Barman	DATE PREPARED December 15, 1987

SECTION 2 - HAZARDOUS INGREDIENTS

PRINCIPAL HAZARDOUS COMPONENT(S) (CHEMICAL & COMMON NAME(S))		CAS NO.	%	THRESHOLD LIMIT VALUE (UNITS)
Vinblastine SO_4	$C_{46}H_{58}N_4O_9.H_2SO_4$	143-67-9	100	Not Established

SECTION 3 - PHYSICAL & CHEMICAL CHARACTERISTICS (FIRE & EXPLOSION DATA)

BOILING POINT	N/A	SPECIFIC GRAVITY (H_2O=1)	N/A	VAPOR PRESSURE (mmHg)	N/A
PERCENT VOLATILE BY VOLUME (%)	N/A	VAPOR DENSITY (AIR=1)	N/A	EVAPORATION RATE (-1)	N/A
SOLUBILITY IN WATER	Freely soluble	REACTIVITY IN WATER	None		
APPEARANCE AND ODOR	Yellowish white odorless amorphous solid, having the characteristic appearance of products prepared by freeze-drying.				
FLASH POINT	N/A	FLAMMABLE LIMITS IN AIR & BY VOLUME		LOWER N/A	UPPER N/A
EXTINGUISHER MEDIA	Water, foam, carbon dioxide, dry chemical, halon 1211.			AUTO IGNITION TEMPERATURE	N/A
SPECIAL FIRE FIGHTING PROCEDURES	Use self-contained breathing apparatus with full face piece.				
UNUSUAL FIRE AND EXPLOSION HAZARDS	Assume this material to be combustible. When heated to decomposition the material emits toxic fumes.				

SECTION 4 - PHYSICAL HAZARDS

STABILITY	UNSTABLE | |	CONDITIONS TO AVOID	Material is stable from a safety view point. Light may decompose it.
	STABLE | X |		
INCOMPATIBILITY (MATERIALS TO AVOID)	Strong oxidizing agents.		
HAZARDOUS DECOMPOSITION PRODUCTS	Emits toxic fumes when heated to decomposition.		
HAZARDOUS POLYMERIZATION	MAY OCCUR | | WILL NOT OCCUR | X |	CONDITIONS TO AVOID	N/A

SECTION 5 - HEALTH HAZARDS

THRESHOLD LIMIT VALUE Not Established

SIGNS AND SYMPTOMS OF EXPOSURE

1. ACUTE OVEREXPOSURE - Eye, skin and respiratory tract irritation. Possible allergic reaction to dust inhaled, ingested or in contact with skin. Nausea, vomiting, constipation, central nervous system damage, mental depression, leukopenia, bone marrow, depression, vocal chord and/or laryngeal paralysis.

2. CHRONIC OVEREXPOSURE - Possible hypersensitivity.

MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE Hypersensitivity to material

CHEMICAL LISTED AS CARCINOGEN OR POTENTIAL CARCINOGEN	No	NATIONAL TOXICOLOGY PROGRAM	YES | | NO | X |	I.A.R.C. MONOGRAPHS	YES | | NO | X |
OSHA	YES | | NO | X |	OSHA PERMISSIBLE EXPOSURE LIMIT	Not Established	ACGIH THRESHOLD LIMIT VALUE	Not Established

OTHER EXPOSURE LIMIT USED LD_{50} 4300 mcg/kg intraperitoneal (hamster); 12 mg/kg i.p. (mouse); 2.2 mg/kg i.p. (rat); LD_{50} 15 mg/kg intravenous (mouse)

EMERGENCY AND FIRST AID PROCEDURES

1. INHALATION: May cause irritation of respiratory tract. Remove to fresh air. Seek medical attention.
2. EYES: May cause irritation. Flush with copious amounts of water or physiological saline.
3. SKIN: May cause irritation. Flush out with copious amounts of water.
4. INGESTION: May cause irritation. Flush mouth with water. Seek medical attention.

SECTION 6 - SPECIAL PROTECTION INFORMATION

RESPIRATORY PROTECTION (SPECIFY TYPE) Use OSHA-NIOSH approved respirator for toxic particles with TLV less than 0.005 mg/m^3.

VENTILATION LOCAL EXHAUST MECHANICAL (GENERAL)
Recommend vertical laminar flow vented to outside.

OTHER Chemical carcinogen glove box with HEPA filter. SPECIAL N/A

PROTECTIVE GLOVES PVC or latex, powder-free. EYE PROTECTION Splash goggles

OTHER PROTECTIVE CLOTHING OR EQUIPMENT Gauze mask, apron or lab coat. Work clothes should be laundered daily. Long sleeve, impermeable disposable gown with elastic cuffs.

SECTION 7 - SPECIAL PRECAUTIONS AND SPILL/LEAK PROCEDURES

PRECAUTIONS TO BE TAKEN IN HANDLING AND STORING Poison, teratogen, irritant. Handle Velsar with great care since it is a potent cytotoxic agent. Store in a refrigerator (2°-3°C). Avoid contact with eyes, skin and clothing.

OTHER PRECAUTIONS Avoid contact with eyes, skin, clothing, wash thoroughly after handling.

STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED OR SPILLED Wear approved aerosol respirator, and powder-free surgical latex gloves. Absorb spillage and place in appropriate container for waste disposal.

WASTE DISPOSAL METHODS - Dispose of in accordance with your procedure for hazardous waste disposal to meet local, state and federal regulation.

MATERIAL SAFETY DATA SHEET

Nitrol® Ointment
(2% nitroglycerin ointment, U.S.P.)

SECTION 1 - IDENTITY

COMMON NAME:	Nitrol Ointment, 2%	HAZARD DETERMINATION UNDER OSHA HAZCOM STD.	Not Hazardous
CHEMICAL NAME	2% Nitroglycerin Ointment, USP	CHEMICAL FAMILY: N/A USE: Coronary Vasodilator	
FORMULA CONTAINS	$C_3H_5N_3O_9$ m.w. = 227.09		
MANUFACTURER'S NAME	Paco Pharmaceuticals - Puerto Rico Distributor: Adria Labs., Div. of Erbamont, Inc.	EMERGENCY TELEPHONE NO.	614/764-8100
ADDRESS	P.O. Box 16529, Columbus, OH 43216	OTHER INFORMATION CALLS	614/761-6284
SIGNATURE OF PERSON RESPONSIBLE FOR PREPARATION	Albert D Bauman	DATE PREPARED	November 20, 1987

SECTION 2 - HAZARDOUS INGREDIENTS

PRINCIPAL HAZARDOUS COMPONENT(S) (CHEMICAL & COMMON NAME(S))	CAS NO.	%	THRESHOLD LIMIT VALUE (UNITS)
Nitroglycerin	55-63-0	2	0.05 ppm (skin)

SECTION 3 - PHYSICAL & CHEMICAL CHARACTERISTICS (FIRE & EXPLOSION DATA)

BOILING POINT	N/A	SPECIFIC GRAVITY (H_2O=1)	0.90 (approx.)	VAPOR PRESSURE (mmHg)	N/A
PERCENT VOLATILE BY VOLUME (%)	N/A	VAPOR DENSITY (AIR=1)	N/A	EVAPORATION RATE (=1)	N/A
SOLUBILITY IN WATER	Slight	REACTIVITY IN WATER	Not Determined		
APPEARANCE AND ODOR	White ointment with oleaginous odor.				
FLASH POINT	N/A	FLAMMABLE LIMITS IN AIR & BY VOLUME	LOWER N/A	UPPER	
EXTINGUISHER MEDIA	Water, carbon dioxide, monoammonium phosphate dry powder, Halon 12M.	AUTO IGNITION TEMPERATURE	Not Determined		
SPECIAL FIRE FIGHTING PROCEDURES	Self-contained breathing apparatus, barricade.				
UNUSUAL FIRE AND EXPLOSION HAZARDS	This product will burn, but is not explosive and will not detonate. Nitroglycerin is a powerful explosive and separation of it from the ointment is extremely hazardous. If the fire is intense, product will be entirely consumed. Less intense smouldering type fires can cause nitroglycerin to migrate and collect, leading to an explosion if sufficient heat is present.				

SECTION 4 - PHYSICAL HAZARDS

STABILITY	UNSTABLE | |	CONDITIONS TO AVOID	High temperature in storage, any water contact.	
	STABLE | X |			

INCOMPATIBILITY (MATERIALS TO AVOID) Water, acid, base, oxidizing materials.

HAZARDOUS DECOMPOSITION PRODUCTS Nitrogen oxides

HAZARDOUS POLYMERIZATION	MAY OCCUR | |	CONDITIONS TO AVOID	
	WILL NOT OCCUR | X |		N/A

SECTION 5 - HEALTH HAZARDS

THRESHOLD LIMIT VALUE Not determined

SIGNS AND SYMPTOMS OF EXPOSURE

1. ACUTE OVEREXPOSURE - Nausea, dizziness, vomiting, headache, reduced blood pressure, cyanosis.
2. CHRONIC OVEREXPOSURE - Severe headache, hallucinations, skin rashes.

MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE Hypotensive

CHEMICAL LISTED AS CARCINOGEN OR POTENTIAL CARCINOGEN		NATIONAL TOXICOLOGY PROGRAM	YES | |	I.A.R.C. MONOGRAPHS	YES | |		
			NO | X |		NO | X |		
OSHA	YES | |	OSHA PERMISSIBLE EXPOSURE LIMIT	N/A	ACGIH THRESHOLD LIMIT VALUE	0.05 ppm (skin)		
	NO | X |						

OTHER EXPOSURE LIMIT USED None

EMERGENCY AND FIRST AID PROCEDURES

1. INHALATION: N/A in this product
2. EYES: Flush immediately with water for at least 15 minutes, get medical attention.
3. SKIN: Wash with soap and water immediately. If redness, itching or burning sensation develops or person feels sick or dizzy, get medical attention. Wash contaminated clothing before reuse.
4. INGESTION: Contact physician immediately.

SECTION 6 - SPECIAL PROTECTION INFORMATION

RESPIRATORY PROTECTION (SPECIFY TYPE) Not required under normal conditions.

VENTILATION	LOCAL EXHAUST	MECHANICAL (GENERAL)
Normal ventilation is adequate	N/A	N/A

OTHER	N/A	SPECIAL	N/A
PROTECTIVE GLOVES	Latex or rubber	EYE PROTECTION	Safety glasses with side shields or safety goggles.

OTHER PROTECTIVE CLOTHING OR EQUIPMENT N/A

SECTION 7 - SPECIAL PRECAUTIONS AND SPILL/LEAK PROCEDURES

PRECAUTIONS TO BE TAKEN IN HANDLING AND STORING - Product should be stored in cool, dry place away from sources of heat and flammable materials. Facility should be equipped with adequate fire protection system. Avoid high temperatures. Store at controlled room temperatare 59°-86°F (15°-30°C).

OTHER PRECAUTIONS None

STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED OR SPILLED DO NOT flush with water, shovel into plastic lined fiber containers immediately.

WASTE DISPOSAL METHODS Disposal of waste or neutralized materials should be handled as per the appropriate federal, state, and local regulations.

MATERIAL SAFETY DATA SHEET

SECTION 1 - IDENTITY

COMMON NAME:	ADRIAMYCIN	HAZARD DETERMINATION UNDER OSHA HAZCOM STD.	Hazardous
CHEMICAL NAME	Doxorubicin hydrochloride	CHEMICAL FAMILY: Anthracycline USE: Prescription medicine - Antineoplastic	
FORMULA	$C_{27}H_{29}NO_{11}$. HCl m.w. = 579.99		
MANUFACTURER'S NAME	Farmitalia Carlo Erba, Adria Laboratories Distributor; Adria Labs. Div. of Erbamont Inc.	EMERGENCY TELEPHONE NO.	614/764-8100
ADDRESS	P.O. Box 16529, Columbus, OH 43216	OTHER INFORMATION CALLS	614/761-6284
SIGNATURE OF PERSON RESPONSIBLE FOR PREPARATION	Albert S Bauman	DATE PREPARED	June 26, 1987

SECTION 2 - HAZARDOUS INGREDIENTS

PRINCIPAL HAZARDOUS COMPONENT(S) (CHEMICAL & COMMON NAME(S))	CAS NO.	%	THRESHOLD LIMIT VALUE (UNITS)
Doxorubicin hydrochloride, USP	25316-40-9	17	Undetermined

SECTION 3 - PHYSICAL & CHEMICAL CHARACTERISTICS (FIRE & EXPLOSION DATA)

BOILING POINT	Melting Point-205° With disposition	SPECIFIC GRAVITY (H_2O=1)	N/A	VAPOR PRESSURE (mmHg)	N/A
PERCENT VOLATILE BY VOLUME (%)	N/A	VAPOR DENSITY (AIR=1)	N/A	EVAPORATION RATE (=1)	N/A
SOLUBILITY IN WATER	Freely soluble	REACTIVITY IN WATER	None		
APPEARANCE AND ODOR	Red cake, no odor				
FLASH POINT	N/A	FLAMMABLE LIMITS IN AIR & BY VOLUME	N/A	LOWER UPPER	non-flammable
EXTINGUISHER MEDIA	N/A	AUTO-IGNITION TEMPERATURE	N/A		
SPECIAL FIRE FIGHTING PROCEDURES	N/A				
UNUSUAL FIRE AND EXPLOSION HAZARDS	N/A				

SECTION 4 - PHYSICAL HAZARDS

STABILITY	UNSTABLE		CONDITIONS	
	STABLE	X	TO AVOID	N/A
INCOMPATIBILITY (MATERIALS TO AVOID)	N/A			
HAZARDOUS DECOMPOSITION PRODUCTS	N/A			
HAZARDOUS POLYMERIZATION	MAY OCCUR		CONDITIONS	
	WILL NOT OCCUR	X	TO AVOID	

SECTION 5 - HEALTH HAZARDS

THRESHOLD LIMIT VALUE Undetermined

SIGNS AND SYMPTOMS OF EXPOSURE: 1. ACUTE OVEREXPOSURE none known; 2. CHRONIC OVEREXPOSURE pigmentation of skin

MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE: None known

CHEMICAL LISTED AS CARCINOGEN OR POTENTIAL CARCINOGEN	NATIONAL TOXICOLOGY PROGRAM YES		I.A.R.C. MONOGRAPHS YES	X
	NO	X	NO	
OSHA YES		OSHA PERMISSIBLE EXPOSURE LIMIT	Undetermined	ACGIH THRESHOLD LIMIT VALUE	Undetermined
OSHA NO	X				

OTHER EXPOSURE LIMIT USED: Undetermined

EMERGENCY AND FIRST AID PROCEDURES

1. INHALATION: Seek medical attention
2. INGESTION: Seek medical attention
3. SKIN: Wash with soap and water immediately
4. EYES: Irrigate with saline or water

SECTION 6 - SPECIAL PROTECTION INFORMATION

RESPIRATORY PROTECTION (SPECIFY TYPE): Approved toxic dust respirator mask.

VENTILATION: LOCAL EXHAUST: Vertical laminar flow hood; MECHANICAL (GENERAL)

OTHER: SPECIAL - HEPA filter vented to outside area

PROTECTIVE GLOVES - Synthetic or Rubber gloves EYE PROTECTION - Recommend splash goggle

OTHER PROTECTIVE CLOTHING OR EQUIPMENT - Long sleeved impermeable, disposable gown with elastic cuffs.

SECTION 7 - SPECIAL PRECAUTIONS AND SPILL/LEAK PROCEDURES

PRECAUTIONS TO BE TAKEN IN HANDLING AND STORAGE - Adriamycin is a potent anti-cancer drug. Caution in the handling and preparation of the powder and solution must be exercised. If Adriamycin powder or solution contacts skin or mucosae, immediately wash thoroughly with soap and water.

OTHER PRECAUTIONS: See product insert for further information.

STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED OR SPILLED: Deactivate with dilute bleach solution. Rinse well with water.

WASTE DISPOSAL METHODS - Deactivate with dilute bleach solution. Dispose of in accordance with your procedure for hazardous waste disposal to meet local, state and federal regulations.

FoxMeyer Corporation

CERTIFICATE OF NON-HAZARDOUS CHEMICALS

ADVANCED NUTRITIONAL TECH.
BOX 3225
ELIZABETH, N.J. 07207

I, I.R. Berry, certify that all products manufactured by ADVANCED NUTRITIONAL TECH. and distributed by FoxMeyer Drug Co contain no hazardous chemicals. In the event this changes, the appropriate documentation (M.S.D.S) will be forwarded to FoxMeyer upon date of initial manufacture.

Name: I.R. Berry

Title: Vice President - Technical Services

Signature: IRBerry Date: 11-20-87

SECTION I

Product Name: AEROZOIN (Tincture of Benzoin) Size: 3.5 Weight Ounc

Chemical Name:

Formula:

Manufacturer: ATI, INC.

Address: 5 Taft Road, Totowa, New Jersey 07512 (CHEM-SPRAY DIVISION)

For Information on Health Hazards Call: Henry Els(R & D Center-203-877-4591)

Aeroceuticals Health Care Prod.
For Other Information Call: 355-7255

Signature and Date: Henry Els 12/2/82

SECTION II HAZARDOUS INGREDIENTS OF MIXTURES

Principal Hazardous Component (s)	%	TLV (Units)
Propane/Isobutane 57/43%	25 35%	
Propellant Mixture - Extremely Flammable		

SECTION III PHYSICAL DATA

Boiling Point (°F.)		Specific Gravity (H_2O=1)	
@ 70°F. Vapor Pressure (mm Hg.)	30-40 psig	Percent Volatile By Volume (%)	
Vapor Density (Air=1)		Evaporation Rate (=1)	
Solubility in Water			
Appearance and Odor	Medium to fine spray-characteristic odor of Benzoin		

SECTION IV FIRE AND EXPLOSION HAZARD DATA

Flash Point Concentrate Only (Method Used) Tag Open Cup @ 70°F.	Flammable Limits in Air % by Vol. Propel-lant only	Lower 1.80% v/v	Upper 8.44% v/v
Extinguisher Media Water, fog, CO_2 or Dry Chemical Extinguisher	Autoignition Temperature		

Special Fire Fighting Procedures: Keep container cool. Use equipment or shielding required to protect personnel against bursting, rupturing or venting container.

Unusual Fire and Explosion Hazards: At elevated temperatures (over 130°F. or 54.4°C.), container may vent, rupture or burst.

* A standard form (Form OSHA-20) used by many manufacturers to describe the health and safety hazards of their products.

SECTION V HEALTH HAZARD DATA

Threshold Limit Value	Not Applicable
Effects of Over exposure	
Acute Overexposure:	
Chronic Overexposure:	Not Applicable

Emergency and First Aid Procedures

Inhalation: See label precautions.
Eyes: Flush immediately with large amounts of water.
Skin: Wipe off and wash with soap and water.
Ingestion:

SECTION VI REACTIVITY DATA

Stability	unstable		Conditions to Avoid
	stable	X	Fire/Flame - Temperatures in excess of 120°F

Incompatibility (Materials to Avoid): Acids

Hazardous Decomposition Products: Multi-Component Product - None Known

Hazardous Polymerization		Conditions to Avoid
May Occur	Will not Occur	
	X	Not applicable to common aerosol products

SECTION VII SPILL OR LEAK PROCEDURES

Steps to Be Taken In Case Material is Released Or Spilled: Avoid fire/flame; avoid getting product in eyes. Give to proper disposal service.

Waste Disposal Method: Do not puncture or incinerate containers. Give to proper disposal service equipped to safely handle and dispose of pressurized containers.

SECTION VIII SPECIAL PROTECTION INFORMATION

Respiratory Protection (Specify Type): None Needed

Ventilation	Local Exhaust	X	Special
	Mechanical (general)	X	Other

Protective Gloves Rubber Gloves	Eye Protection Standard Safety Glasses/Goggles

Other Protective Clothing or Equipment

SECTION IX SPECIAL PRECAUTIONS

Precautions To Be Taken In Handling And Storing: Please read and follow the precautions on the product label.

Other Precautions: Avoid contamination of food and food utensils.

FoxMeyer Corporation

CERTIFICATE OF NON-HAZARDOUS CHEMICALS

AKORN INC
100 AKORN DR.
ABITTA SPRINGS, LA 70420

I, GARY CANNIZARO, certify that all products manufactured by AKORN INC and distributed by FoxMeyer Drug Co contain no hazardous chemicals. In the event this changes, the appropriate documentation (M.S.D.S) will be forwarded to FoxMeyer upon date of initial manufacture.

Name: GARY CANNIZARO

Title: OPERATIONS MANG.

Signature: Gary Cannizaro Date: Nov. 19, 87

ALBERTO CULVER

December 11, 1987

Mr. William R. Stratton
FoxMeyer Drug Co.
1220 Senlac
Carrollton, TX 75006

Dear Mr. Stratton:

Please find enclosed the Material Safety Data Sheets for the following products:

VO5 Hairspray (Aerosol and Non-Aerosol)
VO5 Mousse (For Men and Women)
Alberto Mousse
Alberto Hairspray (Aerosol and Non-Aerosol)
FDS
Get Set Lotion
Command Hairspray
New Dawn Hair Color

The MSDS Sheet for For Brunettes Only will follow at a later date.

If there are any further questions, please contact us.

Sincerely,

August E. Fiebig/dt

August E. Fiebig, PhD
Director Applied Research

AEF:dt
Enclosures

cc: P. Morrison
MSDS File

Section I

Product Name
VO5 Hairspray

Emergency Telephone No.
(312)-450-3175

Manufacturers Name
ALBERTO-CULVER COMPANY

Address (Number, Street, City, State and Zip Code)
2525 ARMITAGE AVENUE, MELROSE PARK, ILLINOIS 60160

Hazardous Materials Description and Proper Shipping Name — Hazard Class
Consumer Commodity — ORM-D

Section II - Ingredients

) Alcohol 40 (CAS #977021-81-0), Isobutane (CAS #75-28-5), Butyl Ester of PVM/MA Copolymer CAS #54018-18-7, #54578-91-5), Aminomethyl Propanol (CAS #124-68-5), Fragrance, D&C Violet o. 2 (CAS #81-48-1) and Other Ingredients

Section III - Physical Data

Solubility: Water — pH 6.5-7.5

Material Is: Alcohol based aerosol hairspray

Section IV - Fire and Explosion Hazard Data

Extinguishing Media
Water mist, CO_2 or dry chemical

Unusual Fire and Explosion Hazards
Flammable. Avoid fire, flame or smoking during application and until hair is fully dry. Do not incinerate cans - exploding cans.

Section V - Health Hazard Data

Effects of Overexposure
Drowsiness. Move victim to fresh air.

Precautions
Do not spray into eyes. Do not ingest.

Emergency and First Aid Procedures
Rinse eyes with large quantities of water. Seek medical attention if irritation persists. Seek medical attention if ingested.

Section VI - Reactivity Data

Stability
Stable

Hazardous Polymerization
Will not occur

Section VII - Spill or Leak Procedures

Steps To Be Taken In Case Material Is Released Or Spilled

Flush with large quantities of water. Beware of sparks, flames or other ignition sources. Flammable propellant and solvent.

Waste Disposal Method

Do not incinerate cans - exploding cans.

Section VIII - Special Protection Information

Respiratory Protection

Adequate ventilation

Protective Gloves

Rubber or plastic

Other Protective Equipment

None necessary

Eye Protection

Goggles

Section IX - Special Precautions

Precautions To Be Taken In Handling And Storing

Do not store at temperatures above 120°F. Keep out of reach of children.

Section I

Product Name
VO5 Non-Aerosol Hairspray (Ultra Hold, Unscented Regular, Blonde & Gray and Permed/Color Treated)

Emergency Telephone No.
(312)-450-3175

Manufacturers Name
ALBERTO-CULVER COMPANY

Address (Number, Street, City, State and Zip Code)
2525 ARMITAGE AVENUE, MELROSE PARK, ILLINOIS 60160

Hazardous Materials Description and Proper Shipping Name — Hazard Class
Consumer Commodity — ORM-D

Section II - Ingredients

SD Alcohol 40 (CAS #977021-81-0), Ethyl Ester of PVM/MA Copolymer (CAS #50935-57-4; #54578-90-4), Aminomethyl Propanol (CAS #124-68-5), Fragrance, D&C Violet No. 2 (CAS #81-48-1) and Other Ingredients. May also contain: Jojoba Oil (No Number)

Section III - Physical Data

Solubility: Water — pH 5.0-5.6

Material Is: Non-Aerosol Hairspray

Section IV - Fire and Explosion Hazard Data

Extinguishing Media
Water or CO_2

Unusual Fire and Explosion Hazards
Flammable Liquid. Avoid fire, flame or smoking during application and until hair is fully dry.

Section V - Health Hazard Data

Effects of Overexposure
Drowsiness due to solvent vapor. Remove victim to a well ventilated area.

Precautions
Do not spray into eyes. Do Not Ingest.

Emergency and First Aid Procedures
If sprayed into eyes rinse well with water. Seek medical attention if irritation persists. If ingested contact a Poison Control Center.

Section VI - Reactivity Data

Stability
Stable

Hazardous Polymerization
Will not occur

Section VII - Spill or Leak Procedures

Steps To Be Taken In Case Material Is Released Or Spilled

Flush with large quantities of water. Beware of sparks, flames or other ignition sources. Flammable solvent.

Waste Disposal Method

Usual trash disposal for empty containers.

Section VIII - Special Protection Information

Respiratory Protection
None necessary

Protective Gloves

Rubber or plastic

Other Protective Equipment
None necessary

Eye Protection

Goggles

Section IX - Special Precautions

Precautions To Be Taken In Handling And Storing

Do not store at temperatures above 120°F. Keep out of reach of children.

MATERIAL SAFETY DATA SHEET

Section I

Product Name
Alberto Mousse

Emergency Telephone No.
(312)-450-3175

Manufacturers Name
ALBERTO-CULVER COMPANY

Address (Number, Street, City, State and Zip Code)
2525 ARMITAGE AVENUE, MELROSE PARK, ILLINOIS 60160

Hazardous Materials Description and Proper Shipping Name
Consumer Commodity

Hazard Class
ORM-D

Section II - Ingredients

SEE ATTACHED LISTING

Section III - Physical Data

Solubility: Water

pH

Material Is: Aerosol Foam

Section IV - Fire and Explosion Hazard Data

Extinguishing Media
Water or CO_2

Unusual Fire and Explosion Hazards

Exploding cans

Section V - Health Hazard Data

Effects of Overexposure
Drowsiness from propellant inhalation

Precautions
Avoid eye contact. Do not ingest.

Emergency and First Aid Procedures
Remove individual to a well ventilated area. In case of eye contact rinse well with water. Seek medical attention if irritation persists. If ingested contact a Poison Control Center.

Section VI - Reactivity Data

Stability
Stable

Hazardous Polymerization
Will not occur

INGREDIENT LISTING

Water (CAS #7732-18-5)

Isobutane (CAS #75-28-5)

SD Alcohol 40 (CAS #977021-81-0)

Propane (CAS #74-98-6)

PVP/VA Copolymer (CAS #25086-89-9)

Polyquaternium-11 (CAS #37348-62-2, #37348-63-3)

PVP (CAS #9003-39-8)

Polyquaternium-4

Butoxyethanol (CAS #111-76-2)

Polysorbate 20 (CAS #9005-64-5 generic)

Cocamide DEA (CAS #61791-31-9, #68603-42-9)

Fragrance

PPG-12-PEG-50 Lanolin (CAS #68458-58-8 generic)

Olealkonium Chloride (CAS #37139-99-4)

Benzyl Alcohol (CAS #100-51-6)

Cyclomethicone (CAS #69430-24-6)

Sodium Benzoate (CAS #532-32-1)

Quaternium-15 (CAS #4080-31-3)

Polyquaternium-7 (CAS #26590-05-6)

PEG-2 Oleamonium Chloride (RD #977066-73-1)

Cocamidopropyl Betaine (CAS 61789-40-0)

Lactic Acid (CAS #50-21-5)

Isopropyl Alcohol (CAS #67-63-0)

Ditallowdimonium Chloride (CAS #68783-78-8)

Octyl Hydroxystearate (CAS #29383-26-4, #29710-25-6, RD #977057-45-6)

Dimethicone (CAS #9006-65-9, #9016-00-6, #63148-62-9)

Dimethicone Copolyol (CAS #64365-23-7, RD #977058-72-2)

Polyglyceryl-4 Oleate (CAS #9007-48-1 generic)

Glycerin (CAS #56-81-5)

Sodium PCA (CAS #28874-51-3, #54571-67-

Sorbitol (CAS #50-70-4)

Soyamide

Ribonucleic Acid (CAS #63231-63-0)

Lecithin (CAS #8002-43-5)

Hydrolyzed Elastin

FD&C Red No. 40 (CAS #25956-17-6)

Section VII - Spill or Leak Procedures

Steps To Be Taken In Case Material Is Released Or Spilled

Flush area with large amounts of water.

Waste Disposal Method

Cans should not be incineated as they will explode.

Section VIII - Special Protection Information

Respiratory Protection

None necessary

Protective Gloves

None necessary

Other Protective Equipment

None necessary

Eye Protection

Keep out of eyes. Flush with large amounts of water if sprayed into eyes. Seek medical attention if irritation persists.

Section IX - Special Precautions

Precautions To Be Taken In Handling And Storing

Keep from extremes of heat (130°F and above). Protect from freezing.

MATERIAL SAFETY DATA SHEET

Section I

Product Name
VO5 Mousse For Men - Natural Control

Emergency Telephone No.
(312)-450-3175

Manufacturers Name
ALBERTO-CULVER COMPANY

Address (Number, Street, City, State and Zip Code)
2525 ARMITAGE AVENUE, MELROSE PARK, ILLINOIS 60160

Hazardous Materials Description and Proper Shipping Name
Consumer Commodity

Hazard Class
ORM-D

Section II - Ingredients

SEE ATTACHED LISTING

Section III - Physical Data

Solubility: Water

pH

Material Is: Aerosol Foam

Section IV - Fire and Explosion Hazard Data

Extinguishing Media
Water or CO_2

Unusual Fire and Explosion Hazards
Exploding cans

Section V - Health Hazard Data

Effects of Overexposure
Drowsiness from propellant inhalation

Precautions
Avoid eye contact. Do Not Ingest.

Emergency and First Aid Procedures
Remove individual to a well ventilated area. In case of eye contact rinse well with water. Seek medical attention if irritation persists. If ingested contact a Poison Control Center.

Section VI - Reactivity Data

Stability
Stable

Hazardous Polymerization
Will not occur

ATTACHED LISTING

/ater (CAS #7732-18-5)

:sobutane (CAS #75-28-5)

;D Alcohol 40 (CAS #977021-82-1)

'VP/VA Copolymer (CAS #25086-89-9)

'ropane (CAS #74-98-6)

'olyquaternium-11 (CAS #37348-62-2; #37348-63-3)

'VP (CAS #9003-39-8)

'olyquaternium-4 (No Number)

;utoxyethanol (CAS #111-76-2)

PG-12-PEG-50 Lanolin (CAS #68458-58-8 generic, RD #977062-71-7)

olysorbate 20 (CAS #9005-64-5 generic)

lealkonium Chloride (CAS #37139-99-4)

ocamide DEA (CAS #61791-31-9; #680603-42-9)

ragrance

enzyl Alcohol (CAS #100-51-6)

odium Benzoate (CAS #532-32-1)

yclomethicone (CAS #69430-24-6)

uaternium-15 (CAS #4080-31-3)

olyquaternium-7 (CAS #26590-05-6)

PEG-2 Oleamonium Chloride (CAS #977066-73-1)

Cocamidopropyl Betaine (CAS #61789-40-0)

Lactic Acid (CAS #50-21-5)

Isopropyl Alcohol (CAS #67-63-0)

Ditallowdimonium Chloride (CAS #68783-78-8)

Octyl Hydroxystearate (CAS #29383-26-4, #29710-25-6; RD #977057-45-6)

Dimethicone (CAS #9006-65-9; #9016-00-6; #63148-62-9)

Dimethicone Copolyol (CAS #64365-23-7; RD #977058-72-2)

Polyglyceryl-4 Oleate (CAS #9007-48-1; RD #977057-95-6)

Polysorbate 80 (CAS #9005-65-6 generic)

Glycerine (CAS #56-81-5)

Sodium PCA (CAS #28874-51-3; #54571-67-4_

Sorbitol (CAS #50-70-4)

Soyamide DEA (CAS #68425-47-8)

Ribonucleic Acid (CAS #63231-63-0)

Lecithin (CAS #8002-43-5)

Hydrolyzed Elastin (No Number)

FD&C Red No. 40 (CAS #25956-17-6)

Section VII - Spill or Leak Procedures

Steps To Be Taken In Case Material Is Released Or Spilled

Flush area with large amounts of water.

Waste Disposal Method

Cans should not be incinerated as they will explode.

Section VIII - Special Protection Information

Respiratory Protection

None necessary

Protective Gloves

None necessary

Other Protective Equipment

None necessary

Eye Protection

Keep out of eyes. Flush with large amounts of water if sprayed into eyes. Seek medical attention if irritation persists.

Section IX - Special Precautions

Precautions To Be Taken In Handling And Storing

Keep from extremes of heat (130°F and above). Protect from freezing.

MATERIAL SAFETY DATA SHEET

Section I

Product Name
705 Mousse For Men - Thickening Formula

Emergency Telephone No.
(312)-450-3175

Manufacturers Name
ALBERTO-CULVER COMPANY

Address (Number, Street, City, State and Zip Code)
2525 ARMITAGE AVENUE, MELROSE PARK, ILLINOIS 60160

Hazardous Materials Description and Proper Shipping Name
Consumer Commodity

Hazard Class
ORM-D

Section II - Ingredients

SEE ATTACHED LISTING

Section III - Physical Data

Solubility: Water

pH

Material Is: Aerosol Foam

Section IV - Fire and Explosion Hazard Data

Extinguishing Media
Water or CO_2

Unusual Fire and Explosion Hazards
Exploding cans

Section V - Health Hazard Data

Effects of Overexposure
Drowsiness from propellant inhalation

Precautions
Avoid eye contact. Do Not Ingest.

Emergency and First Aid Procedures
Remove individual to a well ventilated area. In case of eye contact rinse well with water. Seek medical attention if irritation persists. If ingested contact a Poison Control Center.

Section VI - Reactivity Data

Stability
Stable

Hazardous Polymerization
Will not occur

ATTACHED LISTING

Water (CAS #7732-18-5)

SD Alcohol 40 (CAS #977021-81-1)

Isobutane (CAS #75-28-5)

PVP/VA Copolymer (CAS #25086-89-8)

Butyl Ester of PVM/MA Copolymer (CAS #54018-18-7; #54578-91-5)

Propane (CAS #74-98-6)

Polyquaternium-11 (CAS #37348-62-2; #37348-63-3)

Panthenol (CAS #81-13-0 D-Form; #16485-10-2 DL-Form)

Isostearamidopropyl Betaine (No Number)

PVP (CAS #9003-39-8)

Polyquaternium-4 (No Number)

Ammonia (CAS #7664-41-7)

PPG-12-PEG-50 Lanolin (CAS #68458-58-8 generic, RD #977062-71-7)

Cocamide DEA (CAS #61791-31-9; #68603-42-9)

Cyclomethicone (CAS #69430-24-6)

Fragrance

Quaternium-15 (CAS #4080-31-3)

Sodium Benzoate (CAS #532-32-1)

Benzyl Alcohol (CAS #100-51-6)

Cocamidopropyl Betaine (CAS #61789-40-0)

Stearamidopropyl Cetearyl Dimonium Tosylate (No Number)

Propylene Glycol (CAS #57-55-6)

PPG-5-Ceteth-20 (CAS #9087-53-0 generic; RD #977061-66-7)

Nonoxynol-10 (CAS #9016-45-9 generic; #26027-38-3 generic; #27177-08-8; #37205-87 generic; RD #977057-35-4)

Polysorbate 20 (CAS #9005-64-5 generic)

Triethanolamine (CAS #102-71-6)

Octyl Hydroxystearate (CAS #29383-26-4; #29710-25-6; RD #977057-45-6)

Dimethicone (CAS #9006-65-9; #9016-00-6; #63148-62-9)

Dimethicone Copolyol (CAS #64365-23-7; RD #977058-72-2)

Polysorbate 80 (CAS #9005-65-6 generic)

Polyglyceryl-4 Oleate (CAS #9007-48-1 generi RD #977057-95-6)

Section VII - Spill or Leak Procedures

tops To Be Taken In Case Material Is Released Or Spilled

lush with large amount of water.

aste Disposal Method

ans should not be incinerated as they will explode.

Section VIII - Special Protection Information

espiratory Protection

one necessary

rotective Gloves

one necessary

ther Protective Equipment

one necessary

ye Protection

eep out of eyes. Flush with large amounts of water if sprayed into eyes. Seek medical ttention if irritation persists.

Section IX - Special Precautions

Precautions To Be Taken In Handling And Storing

eep from extremes of heat (130°F and above). Protect from freezing.

MATERIAL SAFETY DATA SHEET

Product Name
VO5 Mousse For Women (Extra Hold and Extra Body)

Emergency Telephone No.
(312) 450-3175

Manufacturer's Name
ALBERTO-CULVER COMPANY

Address (Number, Street, City, State and Zip Code)
2525 Armitage Avenue, Melrose Park, Illinois 60160

Hazardous Materials Description and Proper Shipping Name
Consumer Commodity

Hazard Class
ORM-D

SECTION II - INGREDIENTS

Water (CAS #7732-18-5), Isobutane (CAS #75-28-5), Polyquaternium-11 (CAS #37348-62-2), PVP/VA Copolymer (CAS #25086-89-9), Propane (CAS #74-98-6), Hydrolyzed Elastin (No Number), Polyquaternium-4 (No Number), Polyquaternium-7 (CAS #26590-05-6), Quaternium-15 (CAS #4080-31-3), Ribonucleic Acid (CAS #63231-63-0), Lecithin (CAS #8002-43-5), PVP (CAS #9003-39-8), Glycerin (CAS #56-81-5), Sodium PCA (CAS #28874-51-3), PPG-12-PEG-50 Lanolin (CAS #68458-58-8), PEG-15 Cocomonium Chloride (RD #977066-75-3), Olealkonium Chloride (CAS #37139-99-4), Isostearamidopropyl Morpholine Lactate (No Number), Cyclomethicone (CAS #69430-24-6), Dimethicone Copolyol (CAS #64365-23-7), Distearayldimonium Chloride (CAS #107-64-2), Cocamidopropyl Betaine (CAS #61789-40-0), Dimethicone (CAS #9006-65-9), Polysorbate 20 (CAS #9005-64-5), Sorbitol (CAS #50-70-4), Sodium Benzoate (CAS #532-32-1), Butoxyethanol (CAS #111-76-2), Octyl Hydroxystearate (CAS #29383-26-4), Polyglyceryl-4 Oleate (CAS #9007-48-1), Sodium Hydroxide (CAS #1310-73-2), Polysorbate 80 (CAS #9005-65-6), Fragrance, Soyamide (CAS #68425-47-8), FD&C Red No. 40 (CAS #25956-17-6).
May also contain: Methacrylamidopropyltrimethyl Ammonium Chloride (No Number).

SECTION III - PHYSICAL DATA

Solubility: Water Dispersible

pH: N/A

Material Is: Aerosol Foam

SECTION IV - FIRE AND EXPLOSION HAZARD DATA

Extinguishing Media
Water Mist, Co_2 or Dry Powder

Unusual Fire and Explosion Hazards
Containers exposed to intense heat from fires should be cooled with water to prevent vapor pressure build-up which could result in container explosion and rocketing. Container areas exposed to direct flame contact should be cooled with large quantities of water as needed to prevent weakening of container structure.

Special Fire Fighting Procedures
Warning. Flammable. Clear fire area of unprotected personnel. Do not enter confined fire space without full bunker gear (helmet with face shield, bunker coats, gloves and rubber boots), including a positive pressure NIOSH approved self-contained breathing apparatus. Cool fire exposed containers with water.

SECTION V - HEALTH HAZARD DATA

Effects of Overexposure
Drowsiness from propellant inhalation

Precautions
Avoid eye contact. Do Not Ingest.

SECTION V - HEALTH HAZARD DATA (Cont.)

Emergency and First Aid Procedures
Remove individual to a well ventilated area. In case of eye contact rinse well with water. Seek medical attention if irritation persists. If ingested contact a Poison Control Center.

SECTION VI - REACTIVITY DATA

Stability
Stable

Hazardous Polymerization
Will not occur

SECTION VII - SPILL OR LEAK PROCEDURES

Steps To Be Taken In Case Material Is Released Or Spilled
Flush with large amounts of water. CAUTION: Flammable propellant. Protect from ignition sources.

Waste Disposal Method
Cans should not be incinerate as they will explode.

SECTION VIII - SPECIAL PROTECTION INFORMATION

Respiratory Protection
None necessary

Protective Gloves
None necessary

Other Protective Equipment
None necessary

Eye Protection
Keep out of eyes. Flush with large amounts of water if sprayed into eyes. Seek medical attention if irritation persists.

SECTION IX - SPECIAL PRECAUTIONS

Precautions To Be Taken In Handling And Storing
Keep from extremes of heat (130°F). Protect from freezing. Keep Out Of Reach Of Children.

MATERIAL SAFETY DATA SHEET

Section I

Product Name

Alberto Hairspray (Normal, Ultimate Hold and Extra Hold Unscented)

Emergency Telephone No.
(312)-450-3175

Manufacturers Name
ALBERTO-CULVER COMPANY

Address (Number, Street, City, State and Zip Code)
2525 ARMITAGE AVENUE, MELROSE PARK, ILLINOIS 60160

Hazardous Materials Description and Proper Shipping Name
Consumer Commodity

Hazard Class
ORM-D

Section II - Ingredients

SD Alcohol 40 (CAS #977021-82-1), Isobutane (CAS #75-28-5), Butyl Ester of PVM/MA Copolymer (CAS #54578-91-5), Aminomethyl Propanol (CAS #124-68-5), Jojoba Oil (No Number) Fragrance, D&C Violet No. 2 (CAS #81-48-1) and Other Ingredients.

Section III - Physical Data

Solubility: Water

pH

Material Is: Aerosol Hairspray

Section IV - Fire and Explosion Hazard Data

Extinguishing Media
Water or CO_2

Unusual Fire and Explosion Hazards
Flammable. Avoid fire, flame or smoking during application and until hair is fully dry. Do not incinerate cans - exploding cans.

Section V - Health Hazard Data

Effects of Overexposure
Drowsiness from propellant. Remove victim to a well ventilated area.

Precautions
Do not spray into eyes. Do Not Ingest.

Emergency and First Aid Procedures
If sprayed into eyes rinse well with water. Seek medical attention if irritation persis
If ingested contact a Poison Control Center.

Section VI - Reactivity Data

Stability
Stable

Hazardous Polymerization
Will not occur

Section VII - Spill or Leak Procedures

Steps To Be Taken In Case Material Is Released Or Spilled

Flush with large quantities of water. Beware of sparks, flames or other ignition sources. Flammable propellant and solvent.

Waste Disposal Method

Do not incinerate cans.

Section VIII - Special Protection Information

Respiratory Protection
None necessary

Protective Gloves
Rubber or plastic

Other Protective Equipment
None necessary

Eye Protection
Goggles

Section IX - Special Precautions

Precautions To Be Taken In Handling And Storing

Do not store at temperatures above 120°F. Keep out of reach of children.

MATERIAL SAFETY DATA SHEET

Section I

Product Name
Alberto Non-Aerosol Hairspray (Normal Hold, Extra Hold and Extra Hold Unscented)

Emergency Telephone No.
(312)-450-3175

Manufacturers Name
ALBERTO-CULVER COMPANY

Address (Number, Street, City, State and Zip Code)
2525 ARMITAGE AVENUE, MELROSE PARK, ILLINOIS 60160

Hazardous Materials Description and Proper Shipping Name
Consumer Commodity

Hazard Class
ORM-D

Section II - Ingredients

SD Alcohol 40 (CAS #977021-81-5), Butyl Ester of PVM/MA Copolymer (CAS #54018-18-7), Aminomethyl Propanol (CAS #124-68-5), Fragrance, D&C Violet No. 2 (CAS #81-48-1) and Other Ingredients. May also contain Jojoba Oil (No Number).

Section III - Physical Data

Solubility: Water

pH 6.5-7.5

Material Is: Non-Aerosol Hairspray

Section IV - Fire and Explosion Hazard Data

Extinguishing Media
Water or CO_2

Unusual Fire and Explosion Hazards
Flammable Liquid. Avoid fire, flame or smoking during application and until hair is fully dry.

Section V - Health Hazard Data

Effects of Overexposure
Drowsiness due to solvent vapor. Remove victim to a well ventilated area.

Precautions
Do not spray into eyes. Do Not Ingest.

Emergency and First Aid Procedures
If sprayed into eyes rinse well with water. Seek medical attention if irritation persists
If ingested contact a Poison Control Center.

Section VI - Reactivity Data

Stability
Stable

Hazardous Polymerization
Will not occur

Section VII - Spill or Leak Procedures

Steps To Be Taken In Case Material Is Released Or Spilled

Flush with large quantities of water. Beware of sparks, flames and other ignition sources Flammable solvent.

Waste Disposal Method

Usual trash disposal of empty containers.

Section VIII - Special Protection Information

Respiratory Protection
None necessary

Protective Gloves
Rubber or plastic

Other Protective Equipment
None necessary

Eye Protection
Goggles

Section IX - Special Precautions

Precautions To Be Taken In Handling And Storing
Do not store at temperatures above 120°F. Keep out of reach of children.

MATERIAL SAFETY DATA SHEET

Product Name
FDS

Emergency Telephone No.
(312)-450-3175

Manufacturers Name
ALBERTO-CULVER COMPANY

Address (Number, Street, City, State and Zip Code)
2525 ARMITAGE AVENUE, MELROSE PARK, ILLINOIS 60160

Hazardous Materials Description and Proper Shipping Name
Consumer Commodity

Hazard Class
ORM-D

Section II - Ingredients -Typical

Isobutane (CAS #75-28-5), Isopropyl Myristate (CAS #110-27-0), Mineral Oil (CAS #8012-95-1), Fragrance, Silica (CAS #7631-86-9), Magnesium Stearate (CAS #557-04-0), Lanolin Alcohol (CAS #8027-04-0) Benzyl Alcohol (CAS #100-51-6)

Section III - Physical Data

Solubility: Water Dispersible

pH

Material Is: Oil based aerosol spray

Section IV - Fire and Explosion Hazard Data

Extinguishing Media
Water mist, CO_2 or dry chemical

Unusual Fire and Explosion Hazards
Flammable. Avoid fire, Flame or smoking during application. Do not incinerate cans - explodi cans.

Section V - Health Hazard Data

Effects of Overexposure
Drowsiness. Move victim to fresh air.

Precautions
Do not spray into eyes. Do not ingest.

Emergency and First Aid Procedures
Rinse eyes with large quantities of water. Seek medical attention if irritation persists. Seek medical attention if ingested.

Section VI - Reactivity Data

Stability
Stable

Hazardous Polymerization
Will not occur

Section VII - Spill or Leak Procedures

Steps To Be Taken In Case Material Is Released Or Spilled

Flush with large quantities of water. Beware of sparks, flames or other ignition sources. Flammable propellant and solvent.

Waste Disposal Method

Do not incinerate cans - exploding cans.

Section VIII - Special Protection Information

Respiratory Protection

Adequate ventilation

Protective Gloves

Rubber or plastic

Other Protective Equipment

None necessary

Eye Protection

Goggles

Section IX - Special Precautions

Precautions To Be Taken In Handling And Storing

Do not store at temperatures above 120°F. Keep out of reach of children.

MATERIAL SAFETY DATA SHEET

Product Name
Get Set Hair Setting Lotion
(Natural and Extra Hold)

Emergency Telephone No.
(312)-450-3175

Manufacturers Name
ALBERTO-CULVER COMPANY

Address (Number, Street, City, State and Zip Code)
2525 ARMITAGE AVENUE, MELROSE PARK, ILLINOIS 60160

Hazardous Materials Description and Proper Shipping Name
Consumer Commodity

Hazard Class
None

Section II - Ingredients

Water (CAS #7732-18-5), SD Alcohol 40 (CAS #977021-82-1), PVP (CAS #9003-39-8), Octoxynol-9 (No Number), Polysorbate 20 (CAS #9005-64-5 generic), Fragrance, Formaldehyde (CAS #50-00-0)

Section III - Physical Data

Solubility: Water

pH 3.5-3.9

Material Is: Hair Setting Product

Section IV - Fire and Explosion Hazard Data

Extinguishing Media
None

Unusual Fire and Explosion Hazards
None

Section V - Health Hazard Data

Precautions
Keep out of eyes. Do Not Ingest.

Emergency and First Aid Procedures
Rinse eyes with large quantities of running water. Seek medical attention if irritation persists. Seek medical attention if ingested.

Section VI - Reactivity Data

Stability
Stable

Hazardous Polymerization
Will not occur

Section VII - Spill or Leak Procedures

eps To Be Taken In Case Material Is Released Or Spilled
'lush with water to drain sump or pick-up with solid absorbent.

aste Disposal Method
sual trash disposal

Section VIII - Special Protection Information

espiratory Protection
one necessary

rotective Gloves
ubber or plastic

ther Protective Equipment
one necessary

ye Protection
oggles

Section IX - Special Precautions

recautions To Be Taken In Handling And Storing
rotect from extreme heat and freezing. Keep out of reach of children.

MATERIAL SAFETY DATA SHEET

Section I

Product Name
Command Hairspray (Regular, Extra Hold, and Conditioning)

Emergency Telephone No.
(312)-450-3175

Manufacturers Name
ALBERTO-CULVER COMPANY

Address (Number, Street, City, State and Zip Code)
2525 ARMITAGE AVENUE, MELROSE PARK, ILLINOIS 60160

Hazardous Materials Description and Proper Shipping Name	Hazard Class
Consumer Commodity	ORM-D

Section II - Ingredients

SD Alcohol 40 (CAS #977021-82-1), Isobutane (CAS #75-28-5), Butyl Ester of PVM/MA Copolymer (CAS #54018-18-7; #54578-91-5), Aminomethyl Propanol (CAS #124-68-5), Dimethyl Phthalate (CAS #131-11-3), Fragrance, May also contain Propane (CAS #74-98-6)

Section III - Physical Data

Solubility: Water

pH

Material Is: Aerosol Hairspray

Section IV - Fire and Explosion Hazard Data

Extinguishing Media

Water or CO_2

Unusual Fire and Explosion Hazards

Flammable. Avoid fire, flame or smoking during application and until hair is fully dry. Do not incinerate cans - exploding cans.

Section V - Health Hazard Data

Effects of Overexposure

Drowsiness from propellant. Remove victim to a well ventilated area.

Precautions

Do not spray into eyes. Do Not Ingest.

Emergency and First Aid Procedures

If sprayed into eyes rinse well with water. Seek medical attention if irritation persists. If ingested contact a Poison Control Center.

Section VI - Reactivity Data

Stability

Stable

Hazardous Polymerization

Will not occur

Section VII - Spill or Leak Procedures

teps To Be Taken In Case Material Is Released Or Spilled
lush with large quantities of water. Beware of sparks, flames or other ignition sources.
lammable propellant and solvent.

aste Disposal Method
o not incinerate cans.

Section VIII - Special Protection Information

espiratory Protection
one necessary

rotective Gloves
/A

ther Protective Equipment
one necessary

ye Protection
o not spray into eyes.

Section IX - Special Precautions

Precautions To Be Taken In Handling And Storing
o not store at temperatures above 120°F. Keep out of reach of children.

Date Prepared: October 9, 1987

MATERIAL SAFETY DATA SHEET

Product Name
NEW DAWN HAIR COLOR
(1D, 2D, 3D, 4D, 6D, 7D, 8D, 9D, 10D, 11D, 12D)

Emergency Telephone No.
(312) 450-3175

Manufacturer's Name
ALBERTO-CULVER COMPANY

Address (Number, Street, City, State and Zip Code)
2525 Armitage Avenue, Melrose Park, Illinois 60160

Hazardous Materials Description and Proper Shipping Name
Consumer Commodity

Hazard Class
ORM-D

SECTION II - INGREDIENTS

SEE ATTACHED LISTING

SECTION III - PHYSICAL DATA

Solubility: Water

pH: N/A

Material Is: Hair Coloring Product

SECTION IV - FIRE AND EXPLOSION HAZARD DATA

Extinguishing Media
Water Mist, CO_2, Dry Chemical

Unusual Fire and Explosion Hazards
None

Special Fire Fighting Procedures
Clear fire area of unprotected personnel. Do not enter confined fire space without full bunker gear (helmet with face shield, bunker coats, gloves and rubber boots), including a positive pressure NIOSH approved self-contained breathing apparatus. Cool fire exposed containers with water.

SECTION V - HEALTH HAZARD DATA

Effects of Overexposure
Skin irritation from excessive exposure. Eye and mucous membrane irritation from product vapors.

Precautions
Keep out of eyes. Do not ingest.

Emergency and First Aid Procedures
In case of eye contact rinse well with water. Seek medical attention. Wash with soap and water after skin contact. If ingested seek medical attention.

SECTION VI - REACTIVITY DATA

Stability
Stable

Hazardous Polymerization
Creme Lotion Developer and Hair Color react to produce oxygen which may cause a tightly sealed bottle to explode. Mix only immediately before use. Follow Directions Carefully.

SECTION VII - SPILL OR LEAK PROCEDURES

Steps To Be Taken In Case Material Is Released Or Spilled
Flush with water or pick-up with absorbent material.

Waste Disposal Method
Usual trash disposal.

SECTION VIII - SPECIAL PROTECTION INFORMATION

Respiratory Protection
None necessary. Use with adequate ventilation.

Protective Gloves
Rubber or plastic

Other Protective Equipment
None necessary

Eye Protection
Keep out of eyes.

SECTION IX - SPECIAL PRECAUTIONS

Precautions To Be Taken In Handling And Storing
Keep from extremes of heat and freezing. Keep Out Of Reach Of Children.

ATTACHED LISTING

CREME DEVELOPER:

Water (CAS #7732-18-5), Hydrogen Peroxide (CAS #7722-84-1), PEG-6 Stearate (CAS #9004-99-3), Polysorbate 60 (CAS #9005-67-8), Phenacetin (CAS #62-44-2), Phosphoric Acid (CAS #7664-38-2).

CONDITIONER:

Water (CAS #7732-18-5), Emulsifying Wax NF (No Number), Acetylated Lanolin (CAS #61788-48-5), Glycol Stearate (CAS #111-60-4), Quaternium-33 (No Number), Ethyl Hexanediol (CAS #94-96-2), Glyceryl Stearate (CAS #123-94-4), PEG-100 Stearate (CAS #9004-99-3), PPG-2 Lanolin Ether (CAS #68439-53-2), Hydrolyzed Animal Protein (CAS #9015-54-7), Isopropyl Myristate (CAS #110-27-0), Quaternium-31 (No Number), Mineral Oil (CAS #8012-95-1), Lanolin Alcohol (CAS #8027-33-6), Lauryl Alcohol (CAS #112-53-8), Fragrance, Stearalkonium Chloride (CAS #122-19-0), Butylparaben (CAS #94-26-8), Methylparaben (CAS #99-76-3), Disodium EDTA (CAS #139-33-3), Formaldehyde (CAS #50-00-0), Citric Acid (CAS #77-92-9), FD&C Yellow No. 5 (CAS #1934-21-0), FD&C Yellow No. 6 (CAS #2783-94-0) and Other Ingredients.

HAIR COLOR (1D, 2D, 3D, 4D, 6D, 7D, 8D, 9D, 10D, 11D, 12D):

Water (CAS #7732-18-5), Oleic Acid (CAS #112-80-1), Isopropyl Alcohol (CAS #67-63-0), Lauryl Alcohol (CAS #112-53-8), Propylene Glycol (CAS #57-55-6), Octoxynol-5 (CAS #9002-93-1), Glycerin (CAS #56-81-5), PEG-3 Lauramide (CAS #26635-75-6), Ammonia (CAS #7664-41-7), PEG-5 Tallow Amine (CAS #61791-26-2), Ammonium Lauryl Sulfate (CAS #2235-54-3), Ethoxydiglycol (CAS #111-90-0), Sodium Sulfite (CAS #7757-83-7), Fragrance, Sodium Lauriminodipropionate (CAS #14960-06-6), Trisodium EDTA (CAS #150-38-9), Hydroquinone (CAS #123-31-9).

1D - BLACK Also Contains:

Resorcinol (CAS #108-46-3), 4-Ethoxy-m-Phenylenediamine Sulfate (CAS #68015-98-5), o-Aminophenol (CAS #95-55-6), Ammonium Chloride (CAS #12125-02-9), 2-Methoxy-p-Phenylenediamine Sulfate (CAS #42909-29-5), 4-Nitro-o-Phenylenediamine (CAS #99-56-9).

2D - DARK BROWN Also Contains:

Resorcinol (CAS #108-46-3), 4-Ethoxy-m-Phenylenediamine Sulfate (CAS #68015-98-5), p-Phenylenediamine (CAS #106-50-3), Ammonium Chloride (CAS #12125-02-9), 2-Methoxy-p-Phenylenediamine Sulfate (CAS #42909-29-5).

3D - MEDIUM BROWN Also Contains:

Resorcinol (CAS #108-46-3), 4-Ethoxy-m-Phenylenediamine Sulfate (CAS #68015-98-5), p-Phenylenediamine (CAS #106-50-3), Ammonium Chloride (CAS #12125-02-9), 2-Methoxy-p-Phenylenediamine Sulfate (CAS #42909-29-5).

4D - LIGHT BROWN Also Contains:

Resorcinol (CAS #108-46-3), 4-Ethoxy-m-Phenylenediamine Sulfate (CAS #68015-98-5), p-Phenylenediamine (CAS #106-50-3), Ammonium Chloride (CAS #12125-02-9), 2-Methoxy-p-Phenylenediamine Sulfate (CAS #42909-29-5).

6D - MEDIUM ASH BROWN Also Contains:

Resorcinol (CAS #108-46-3), 4-Ethoxy-m-Phenylenediamine Sulfate (CAS #68015-98-5), p-Phenylenediamine (CAS #106-50-3), 2-Methoxy-p-Phenylenediamine Sulfate (CAS #42909-29-5), 4-Nitro-o-Phenylenediamine (CAS #99-56-9).

7D - LIGHT AUBURN Also Contains:

p-Aminophenol (CAS #123-30-8), p-Phenylenediamine (CAS #106-50-3), 4-Nitro-o-Phenylenediamine (CAS #99-56-9), 2-Nitro-p-Phenylenediamine (CAS #5307-14-2), 1-Naphthol (CAS #90-15-3), o-Aminophenol (CAS #95-55-6).

8D - DARK AUBURN Also Contains:

p-Aminophenol (CAS #123-30-8), p-Phenylenediamine (CAS #106-50-3), 4-Nitro-o-Phenylenediamine (CAS #99-56-9), 2-Nitro-p-Phenylenediamine (CAS #5307-14-2), o-Aminophenol (CAS #95-55-6), Resorcinol (CAS #108-46-3), 4-Ethoxy-m-Phenylenediamine Sulfate (CAS #68015-98-5).

9D - DARK ASH BLONDE Also Contains:

p-Aminophenol (CAS #123-30-8), p-Phenylenediamine (CAS #106-50-3), 4-Nitro-o-Phenylenediamine (CAS #99-56-9), 2-Methoxy-p-Phenylenediamine Sulfate (CAS #42909-29-5), BHA (CAS #25013-16-5), Resorcinol (CAS #108-46-3), 4-Ethoxy-m-Phenylenediamine Sulfate (CAS #68015-98-5).

10D - MEDIUM BLONDE Also Contains:

p-Aminophenol (CAS #123-30-8), p-Phenylenediamine (CAS #106-50-3), 4-Nitro-o-Phenylenediamine (CAS #99-56-9), 4-Ethoxy-m-Phenylenediamine Sulfate (CAS #68015-98-5), BHA (CAS #25013-16-5), Resorcinol (CAS #108-46-3), 2-Methoxy-p-Phenylenediamine Sulfate (CAS #42909-29-5).

11D - LIGHT ASH BLONDE Also Contains:

p-Aminophenol (CAS #123-30-8), p-Phenylenediamine (CAS #106-50-3), 4-Nitro-o-Phenylenediamine (CAS #99-56-9), 4-Ethoxy-m-Phenylenediamine Sulfate (CAS #68015-98-5), BHA (CAS #25013-16-5), Resorcinol (CAS #108-46-3), 2-Methoxy-p-Phenylenediamine Sulfate (CAS #42909-29-5).

12D - PALE BLONDE Also Contains:

p-Aminophenol (CAS #123-30-8), 4-Ethoxy-m-Phenylenediamine Sulfate (CAS #68015-98-5), Resorcinol (CAS #108-46-3), 2-Methoxy-p-Phenylenediamine Sulfate (CAS #42909-29-5), 1-Naphthol (CAS #90-15-3).

FoxMeyer Corporation

CERTIFICATE OF NON-HAZARDOUS CHEMICALS

ALIVIO PROD INC
1675 BROADWAY STE 2410
DENVER, CO 80202

I, Beverly D. Cain, certify that all products manufactured by ALIVIO PROD INC and distributed by FoxMeyer Drug Co contain no hazardous chemicals. In the event this changes, the appropriate documentation (M.S.D.S) will be forwarded to FoxMeyer upon date of initial manufacture.

Name: Beverly D. Cain

Title: Controller

Signature: Beverly D. Cain Date: 11/19/89

ALLERGAN

2525 DUPONT DRIVE IRVINE CALIFORNIA 92715 (714) 752-4500

12/8 To. Bill Stratton

December 14, 1987

FoxMeyer Corporation
1220 Senlac Drive
Carrollton, TX 75006

ATTN: ROBERT W. WILKINS

Dear Mr. Wilkins:

In response to your and others' requests for MSDSs for our products, Allergan, Inc. has decided to initiate a company-wide effort to develop Material Safety Data Sheets for our products which qualify as hazardous material according the the OSHA definition. As you may well imagine, this will be a significant task. This effort, however, will result in a quality MSDS reflective of our commitment to the spirit of the Hazard Communication Standard and service to our customers.

As we develop Allergan Material Safety Data Sheets we will forward those which match your request list. We expect to have your request fulfilled within six to twelve months.

Sincerely,

James Messelbeck

James Messelbeck
Director
Environmental Health and Safety

r1021j

FoxMeyer Corporation

CERTIFICATE OF NON-HAZARDOUS CHEMICALS

ALPINE WATER
2301 PULASKI ST
LITTLE ROCK, AR 72206

I, GARY GHAN, certify that all products manufactured by ALPINE WATER and distributed by FoxMeyer Drug Co contain no hazardous chemicals. In the event this changes, the appropriate documentation (M.S.D.S) will be forwarded to FoxMeyer upon date of initial manufacture.

Name: GARY GHAN

Title: Safety Director

Signature: Gary Ghan Date: 11-24-97

Alva-Amco Pharmacal Companies, Inc.

Fine Pharmaceuticals Since 1904

November 23, 1987

FoxMeyer Drug Company
Attn: William R. Stratton
1220 Senlac
Carrollton, TX 75006

Re: M.S.D.S.

Dear Mr. Stratton:

In response to your letter relative to the above captioned subject, please be advised, to our best knowledge, no product which we market contains hazardous chemicals. No change in this status is anticipated.

Sincerely,

Dilip V. Desai

Dilip V. Desai
Director of Technical Affairs

DVD:dm

6625 Avondale Avenue Chicago, Illinois 60631 312/RX2-0200

AMERICAL
PHARMACEUTICALS, INC.
20510 Earlgate Street • Walnut, California 91789
(714) 598-6504 Telex 350558 Telefax (714) 595-4376

January 6, 1988

FoxMeyer Corporation
1220 Senlac Drive
Carrollton, TX 75006

Attn: Mr. William R. Stratton

Dear Mr. Stratton,

Attached please find Material Safety Data Sheets, as requested by Mr. Robert W. Wilkins (Sr. Vice President, Inventory Management/FoxMeyer Corporation), for the following products:

1. 5-Fluorouracil (20 copies)

2. Methotrexate (20 copies)

Of the products you acquire from us, only the two above mentioned contain hazardous chemicals.

Should there be any questions regarding this matter, please do not hesitate to call.

Sincerely yours,

Sunita Kakar

Sunita Kakar
Manager, Regulatory Compliance

cc: Gary Dolana, Ph.D.
V.P. Scientific Affairs

MATERIAL SAFETY DATA SHEET

Effective Date: June 1, 1986

I. IDENTIFICATION

PRODUCT NAME: Fluorouracil Injection USP, 50 mg/mL; 5 mL, 10 mL in Ampuls
CHEMICAL NAME: Fluorouracil
CHEMICAL FAMILY: Antineoplastic MOLECULAR WEIGHT: 130.08

FORMULA: $C_4 H_3 FN_2 O_2$

DEPARTMENT OF TRANSPORTATION	HAZARD CLASSIFICATION	None
	SHIPPING NAME	None
CAS#	CAS NAME	None

II. PHYSICAL DATA

BOILING POINT	Ca 100°C	FREEZING POINT	Ca 0°C
MELTING POINT	n/a	VAPOR PRESSURE at 20°C	n/a
PER CENT VOLATILES BY VOLUME	Ca 95% (water)	SOLUBILITY IN WATER % by wt. at 20°C	Complete
APPEARANCE AND ODOR	Clear, colorless to faint yellow solution, essentially odorless.		

III. INGREDIENTS

MATERIAL	%	TLV (Units)	HAZARD
5-Fluorouracil	5% w/v	n/a	Toxic; inhibits DNA synthesis; irritant.

IV. FIRE AND EXPLOSION HAZARD DATA

FLASH POINT: n/a

FLAMMABLE LIMITS IN AIR, % by volume | LOWER | | UPPER |

EXTINGUISHING MEDIA	If water is boiled off, the residual material may burn. Use water-spray, carbon dioxide, dry chemical powder, alcohol-type or universal type foams applied by manufacturers recommended technique.
SPECIAL FIRE FIGHTING PROCEDURES	Self-contained breathing apparatus should be available to fire-fighters. Vapors may be irritating and/or toxic.
UNUSUAL FIRE AND EXPLOSION HAZARDS	No information available.

International Pharmaceutical Products, Inc., 3001 Red Hill Ave., Costa Mesa, CA 9262
Telephone (714) 549-3591.

MATERIAL SAFETY DATA SHEET

V. HEALTH HAZARD DATA

TLV AND SOURCE:	unknown
THE EFFECTS OF OVEREXPOSURE:	
SWALLOWING	High toxicity potential, usually dose-related. Consult physician.
SKIN ABSORPTION	Irritant.
INHALATION	Irritant to mucous membrane. Consult physician.
SKIN CONTACT	Irritant.
EYE CONTACT	Irritant.
CHRONIC EFFECTS OF OVEREXPOSURE	Anorexia, nausea, vomiting, allergic reactions, local irritant effects.
OTHER HEALTH HAZARDS	Delayed, long term adverse effect is probably bone-marrow depression with leukopenia, anaemia, and thrombocytopenia and bleeding, see attached package insert.
EMERGENCY AND FIRST AID PROCEDURES:	
SWALLOWING	Consult physician.
SKIN	Remove contaminated clothing and flush skin with water. Wash clothing before reuse.
INHALATION	Consult physician.
EYES	Immediately flush eyes with plenty of water for at least 15 min. Promptly get medical care, preferrably an eye specialist.

NOTES TO PHYSICIAN: Please read attached package insert for Fluorouracil Injection USP.

MATERIAL SAFETY DATA SHEET

VI. REACTIVITY DATA

STABILITY			
UNSTABLE	STABLE	CONDITIONS TO AVOID	Light and heat exposure.

INCOMPATIBILITY	Methotrexate
HAZARDOUS COMBUSTION OR DECOMPOSITION PRODUCTS	n/a

HAZARDOUS POLYMERIZATION			
May Occur	Will not Occur	CONDITIONS TO AVOID	unknown

VII. SPILL OR LEAK PROCEDURES

STEPS TO BE TAKEN IF MATERIAL IS RELEASED OR SPILLED	Wear protective gloves and mask. Absorb spillage immediately, using sufficient cloth or tork-type absorbi water with cloth. Repeat this step twice. Place cloth in double polyethylene bag for chemical destruction.
WASTE DISPOSAL METHOD	After collection of the remnants containing 5-fluorourac into a disposal vessel, add an adequate amount of sodium hypochlorite (bleach) containing 2.5 - 3.0% W/V available chlorine, to obtain a 1:5 solution in the rinse water (m thoroughly). Let stand 4-6 hours; then pour the solutio off into the sewerage after determination of the surplus chlorine (Cl_2) according to the following method: Determination of Available Chlorine Take about 50 mL of the solution. Add 2 g of KI, 10 mL glacial acetic acid, and 1.3 mL of TS starch solution. blue color of iodine must be obtained, indicating the presence of free Cl_2.

VIII. SPECIAL PROTECTION INFORMATION

RESPIRATORY PROTECTION (specify type)	Drager colloidal dust filter. Grade 11B, Type 855 sc.
VENTILATION	Mechanical exhaust required.
PROTECTIVE GLOVES	Wear latex gloves.
EYE PROTECTION	Wear safety goggles.
OTHER PROTECTIVE EQUIPMENT	Lab coat or cover-alls with cap & shoes.

IX. SPECIAL PRECAUTIONS

PRECAUTIONS TO BE TAKEN IN HANDLING AND STORING:

Observe special protection information outlined in Item VIII.
Avoid inhalation and contact with skin and clothing.
Have safety shower and eye bath.
Store in a cool dry place; protect container form physical damage.

MATERIAL SAFETY DATA SHEET

Effective Date: June 1, 1986

I. IDENTIFICATION

PRODUCT NAME: Methotrexate Sodium Injection; 25 mg/mL in Vials
CHEMICAL NAME: Methotrexate Sodium
CHEMICAL FAMILY: Antineoplastic MOLECULAR WEIGHT: 454.46

FORMULA: $C_{20}H_{22}N_8O_5$

DEPARTMENT OF TRANSPORTATION	HAZARD CLASSIFICATION	None
	SHIPPING NAME	None
CAS# None	CAS NAME	None

II. PHYSICAL DATA

BOILING POINT	Ca 100°C	FREEZING POINT	Ca 0°C
MELTING POINT	n/a	VAPOR PRESSURE at 20°C	n/a
PER CENT VOLATILES BY VOLUME	Ca 97% (water)	SOLUBILITY IN WATER % by wt. at 20°C	Complete
APPEARANCE AND ODOR	Clear, yellow - brown solution, essentially odorless.		

III. INGREDIENTS

MATERIAL	%	TLV (Units)	HAZARD
Methotrexate Sodium	~2.6	n/a	Carcinogen, irritant

IV. FIRE AND EXPLOSION HAZARD DATA

FLASH POINT	n/a
FLAMMABLE LIMITS IN AIR, % by volume	LOWER / UPPER
EXTINGUISHING MEDIA	If water is boiled off, the residual material can burn. Use water-spray, carbon dioxide, dry chemical powder, alcohol-type or universal type foams applied by manufacturers recommended technique.
SPECIAL FIRE FIGHTING PROCEDURES	Self-contained breathing apparatus should be available to fire fighters. Vapors can be irritating.
UNUSUAL FIRE AND EXPLOSION HAZARDS	No information available.

International Pharmaceutical Products, Inc., 3001 Red Hill Ave., Costa Mesa, CA 92
Telephone (714) 549-3591.

V. HEALTH HAZARD DATA

TLV AND SOURCE:	unknown
THE EFFECTS OF OVEREXPOSURE:	
SWALLOWING	High toxicity potential, usually dose-related. Consult physician.
SKIN ABSORPTION	Irritant.
INHALATION	Irritant to mucous membrane. Consult physician.
SKIN CONTACT	Irritant.
EYE CONTACT	Irritant.
CHRONIC EFFECTS OF OVEREXPOSURE	Anorexia, nausea, vomiting, allergic reactions, local irritant effects.
OTHER HEALTH HAZARDS	Delayed, long term adverse effect is probably bone-marrow depression with leukopenia, anaemia, and thrombocytopenia and bleeding, see attached package insert.
EMERGENCY AND FIRST AID PROCEDURES:	
SWALLOWING	Folinic acid rescue (Leucovorin Calcium). Consult physician.
SKIN	Remove contaminated clothing and flush skin with water. Wash clothing before reuse.
INHALATION	Consult physician.
EYES	Immediately flush eyes with plenty of water for at least 15 min. Promptly get medical care, preferrably an eye specialist.

NOTES TO PHYSICIAN: Please read attached package insert for Abitrexate™ (Methotrex Sodium) Injection.

MATERIAL SAFETY DATA SHEET

VI. REACTIVITY DATA

STABILITY			
UNSTABLE	STABLE	CONDITIONS TO AVOID	Light and heat exposure.

INCOMPATIBILITY	5-Fluorouracil, strong alkalies
HAZARDOUS COMBUSTION OR DECOMPOSITION PRODUCTS	

HAZARDOUS POLYMERIZATION			
May Occur	Will not Occur	CONDITIONS TO AVOID	unknown

VII. SPILL OR LEAK PROCEDURES

STEPS TO BE TAKEN IF MATERIAL IS RELEASED OR SPILLED	Wear protective gloves and mask. Absorb spillage immediately, using sufficient cloth or tork-type absorb water with cloth. Repeat this step twice. Place cloth in double polyethylene bag for chemical destruction.
WASTE DISPOSAL METHOD	1. Adjust pH to 2.5 - 3.0 with conc. HCl. Allow to sta for 6 hrs. 2. Filter, allowing all liquid to pass thru filter pape 3. Add activated charcoal to the filtrate, mix for 5 mi 4. Filter through filter paper from (2) & pour into the sewerage 5. Return contaminated filter to the original bottle & 100 mL sulfochromic acid for cleaning purposes, mix gently wetting all material, allow to stand for 24 h 6. Add enough ice and neutralize with Sodium Hydroxide. 7. Dispose neutralized cold solution per Federal, State and local laws concerning health and pollution.

VIII. SPECIAL PROTECTION INFORMATION

RESPIRATORY PROTECTION (specify type)	Drager colloidal dust filter. Grade 11B, Type 855 sc.
VENTILATION	Mechanical exhaust required.
PROTECTIVE GLOVES	Wear latex gloves.
EYE PROTECTION	Wear safety goggles.
OTHER PROTECTIVE EQUIPMENT	Lab coat or cover-alls with cap & shoes.

IX. SPECIAL PRECAUTIONS

PRECAUTIONS TO BE TAKEN IN HANDLING AND STORING:

Observe special protection information outlined in Item VIII.
Avoid inhalation and contact with skin and clothing.
Have safety shower and eye bath.
Store in a cool dry place; protect container form physical damage.

AMERICAN
DERMAL
CORPORATION

12-L WORLDS FAIR DRIVE, P.O. BOX 6727, SOMERSET, NEW JERSEY 08873 (201) 356-5544 (800) 526-0199

CERTIFICATE OF NON-HAZARDOUS CHEMICALS

AMERICAN DERMAL CORP
P.O. BOX 427
SOMERSET, NJ 08873

I, Donald B. DeVogel, certify that all products manufactured by American Dermal Corporation and distributed by FoxMeyer Drug Co. contain no hazardous chemicals. In the event this changes, the appropriate documentation (M.S.D.S.) will be forwarded to FoxMeyer upon date of initial manufacture.

NAME: Donald B. DeVogel

TITLE: Vice President

SIGNATURE: Donald B DeVogel DATE: February 25, 1988

FoxMeyer Corporation
Corporate Office
1220 Senlac Drive
Carrollton, TX 75006
(214) 446-9090

AMERICAN SCIENTIFIC Prod.

MONOJECT SCIENTIFIC
DIVISION OF SHERWOOD MEDICAL

11311 Hammack Dr.
Bridgeton, MO 63044

ADDITIONAL INFORMATION PHONE NO.
(800) 325-8668

MATERIAL SAFETY DATA SHEET

DATE OF ISSUE: 4/16/86
REPLACES ISSUE DATE: -
APPROVED BY:

SECTION I: PRODUCT IDENTIFICATION

B 5395 All Flavors

PRODUCT LABEL NAME: Glucose Tolerance Test Beverage

SECTION II: HAZARDOUS INGREDIENTS

CHEMICAL NAME	COMMON NAMES	% IN PRODUCT	CAS #

THE ABOVE PRODUCT HAS BEEN EVALUATED IN ACCORDANCE WITH THE OCCUPATIONAL SAFETY AND HEALTH HAZARD COMMUNICATION STANDARD (CFR, TITLE 29, § 1910.1200) AND IS NOT CONSIDERED HAZARDOUS.

SECTION III: PRECAUTIONS FOR HANDLING AND USE OF THE PRODUCT

A. SPILL OR LEAK PROCEDURES

Steps to be taken in case material is released or spilled:

Waste Disposal Method:

Dispose of in accordance with Federal, State and Local Regulations.

B. SPECIAL PROTECTION INFORMATION

Respiratory Protection: (Specify type)

Ventilation: Local Exhaust ____ Mechanical ____

Other Protective Equipment: Gloves ____ Eyes ____ Other ____

C. SPECIAL PRECAUTIONS

Recommended Storage Conditions:

FoxMeyer Corporation

CERTIFICATE OF NON-HAZARDOUS CHEMICALS

AMERICAN THERMOMETER CO
DEPARTMENT 00143
CINCINNATI, OH 45263

I, Sandra Haney, certify that all products manufactured by AMERICAN THERMOMETER CO and distributed by FoxMeyer Drug Co contain no hazardous chemicals. In the event this changes, the appropriate documentation (M.S.D.S) will be forwarded to FoxMeyer upon date of initial manufacture.

Name: American Thermometer Co

Title: Vice President & Gen. Manager

Signature: Sandra Haney Date: 11-24-87

FoxMeyer Corporation

CERTIFICATE OF NON-HAZARDOUS CHEMICALS

AMERICAN UROLOGICAL
7881 PINES BLVE-SUITE 4
PEMBROKE PINES, FL 33024

I, HAWIN LUND, certify that all products manufactured by AMERICAN UROLOGICAL and distributed by FoxMeyer Drug Co contain no hazardous chemicals. In the event this changes, the appropriate documentation (M.S.D.S) will be forwarded to FoxMeyer upon date of initial manufacture.

Name: HAWIN LUND

Title: PRESIDENT

Signature: _____ Date: 11/10/87

FoxMeyer Corporation

CERTIFICATE OF NON-HAZARDOUS CHEMICALS

AMIDE PHARM
101 E. MAIN
LITTLE FALLS, N.J. 07424

I, J. K. Shah, certify that all products manufactured by AMIDE PHARM and distributed by FoxMeyer Drug Co contain no hazardous chemicals. In the event this changes, the appropriate documentation (M.S.D.S) will be forwarded to FoxMeyer upon date of initial manufacture.

Name: J. K. Shah

Title: President

Signature: J. K Shah Date: 11/23/87

FoxMeyer Corporation

CERTIFICATE OF NON-HAZARDOUS CHEMICALS

AMITY LEATHER PROD
DRAWER 222
MILWAUKEE, WI 53278

I, Thomas D. Wolley, certify that all products manufactured by AMITY LEATHER PROD and distributed by FoxMeyer Drug Co contain no hazardous chemicals. In the event this changes, the appropriate documentation (M.S.D.S) will be forwarded to FoxMeyer upon date of initial manufacture.

Name: Thomas D. Wolley

Title: Tax & Risk Manager

Signature: Thomas D. Wolley Date: 11-24-87

FoxMeyer Corporation

CERTIFICATE OF NON-HAZARDOUS CHEMICALS

AMTEC MEDICAL INC
2201 DENTON DR-STE#105
AUSTIN, TX 78758

I, Richard A Jones, certify that all products manufactured by AMTEC MEDICAL INC and distributed by FoxMeyer Drug Co contain no hazardous chemicals. In the event this changes, the appropriate documentation (M.S.D.S) will be forwarded to FoxMeyer upon date of initial manufacture.

Name: Richard A Jones

Title: President

Signature: [signature] Date: 11/25/87

Anaquest

Product Safety Information Sheet

Manufacturer	Anaquest A Division of BOC Inc 2005 West Beltline Highway Madison Wisconsin 53713 2318	**Telephone**	608 273-0019

Trade/Common Names	Ethrane® (enflurane)
Chemical Name	2-chloro-1,1,2-trifluoroethyl difluoromethyl ether
Chemical Family	Halogenated Ether
Formula	CHF_2OCF_2CHClF
CAS Number	13838-16-9

Hazard Summary

Product can enter the body through ingestion or inhalation.
Exposure can cause irritation of the eyes, nose, mouth and throat.
Overexposure can cause headaches, drowsiness, unconsciousness, death.
Contact may irritate the skin, cause itching or rashes, drying or cracking.
Product is a potent respiratory depressant and can impair cardiac performance.

Identification

Product is a colorless liquid with a mild ethereal odor.

Work Place Exposure Limits

ACGIH: The proposed recommended airborne exposure limit is 75 ppm averaged over an 8 hour work day. (1985-86)

NIOSH: The recommended permissible level of exposure to halogenated anesthetic agents in general is 2 ppm. (1978)

Exposure Indicators

The odor threshold only serves as a warning of exposure.
Not smelling it does not mean you are not being exposed.

Exposure Reduction Techniques

Wear protective clothing.
Where possible, enclose operations and use local exhaust ventilation at site of the chemical release.
If local exhaust ventilation or enclosure is not used, respirators should be worn.

Fire Hazards

Use foam, dry chemical or liquified gas extinguishers.
Toxic gases such as phosgene, hydrogen chloride and hydrogen fluoride may be released in a fire involving the product.

Spills and Emergencies

Restrict persons not wearing protective equipment from areas of spills or leaks until cleanup is complete.
Ventilate area of spill or leak.
It may be necessary to contain and dispose of the product as a hazardous waste.
Contact your regional office of the United States Environmental Protection Agency (USEPA) for specific regulations.
For large spills and fires immediately call your local fire department.

First Aid

Eye Contact	Immediately flush with large amounts of tepid potable water for at least 15 minutes ensuring inner surfaces of upper and lower lids are being rinsed. Seek medical attention.
Skin Contact	Remove contaminated clothing. If redness or irritation results, seek medical attention.
Breathing	Remove person from exposure. Begin artificial respiration if breathing has stopped and CPR if heart action has stopped. Transfer promptly to a medical facility.
Ingestion	If product has been swallowed and person is conscious, immediately administer large amounts of water and induce vomiting. Begin artificial respiration if breathing has stopped and CPR if heart action has stopped. Seek medical attention immediately.
Handling and Storage	Product must be stored to avoid contact with peroxides. Store in tightly closed containers in cool well ventilated area away from heat. Protect product from freezing.

Physical Data

Boiling Point: 133.7 °F.

Solubility in Water: Slight

Flash Point: Greater than 200 °F. **Method Used:** PMCC

Date Issued: March 1986

Date Revised:

Anaquest

Product Safety Information Sheet

Manufacturer	Anaquest A Division of BOC Inc 2005 West Beltline Highway Madison Wisconsin 53713 2318	**Telephone**	608 273-0019

Trade/Common Names	Forane® (isoflurane)
Chemical Name	1-chloro-2,2,2-trifluoroethyl difluoromethyl ether
Chemical Family	Halogenated Ether
Formula	$CF_3CHClOCHF_2$
CAS Number	26675-46-7

Hazard Summary	Product can enter the body through ingestion or inhalation. Exposure can cause irritation of the eyes, nose, mouth and throat. Overexposure can cause headaches, drowsiness, unconsciousness, death. Contact may irritate the skin, cause itching or rashes, drying or cracking. Product is a potent respiratory depressant and can impair cardiac performance.
Identification	Product is a colorless liquid with a mild ethereal odor.
Work Place Exposure Limits	**NIOSH:** The recommended permissible level of exposure to halogenated anesthetic agents in general is 2 ppm. (1978)
Exposure Indicators	The odor threshold only serves as a warning of exposure. Not smelling it does not mean you are not being exposed.
Exposure Reduction Techniques	Wear protective clothing. Where possible, enclose operations and use local exhaust ventilation at site of the chemical release. If local exhaust ventilation or enclosure is not used, respirators should be worn.
Fire Hazards	Use foam, dry chemical or liquified gas extinguishers. Toxic gases such as phosgene, hydrogen chloride and hydrogen fluoride may be released in a fire involving the product.
Spills and Emergencies	Restrict persons not wearing protective equipment from areas of spills or leaks until cleanup is complete. Ventilate area of spill or leak. It may be necessary to contain and dispose of the product as a hazardous waste. Contact your regional office of the United States Environmental Protection Agency (USEPA) for specific regulations. For large spills and fires immediately call your local fire department.

Continued on Reverse Side

First Aid

Eye Contact	Immediately flush with large amounts of tepid potable water for at least 15 minutes ensuring inner surfaces of upper and lower lids are being rinsed. Seek medical attention.
Skin Contact	Remove contaminated clothing. If redness or irritation results, seek medical attention.
Breathing	Remove person from exposure. Begin artificial respiration if breathing has stopped and CPR if heart action has stopped. Transfer promptly to a medical facility.
Ingestion	If product has been swallowed and person is conscious, immediately administer large amounts of water and induce vomiting. Begin artificial respiration if breathing has stopped and CPR if heart action has stopped. Seek medical attention immediately.
Handling and Storage	Product must be stored to avoid contact with peroxides. Store in tightly closed containers in cool well ventilated area away from heat. Protect product from freezing.

Physical Data

Boiling Point: 119.3 °F.

Solubility in Water: Slight

Flash Point: Greater than 200 °F. **Method Used:** PMCC

Date Issued: March 1986

Date Revised:

Jergens

THE ANDREW JERGENS COMPANY · P. O. BOX 145444 · CINCINNATI, OHIO 45214

December 18, 1987

William R. Stratton
FoxMeyer Corporation
1220 Senlac Drive
Carrollton, TX 75006

Dear Mr. Stratton,

In response to your company's recent request for Material Safety Data Sheets in order to comply with the Final Rule by OSHA,(52 FR 31852), we would like to reply as follows.

The Andrew Jergens Company is a cosmetic establishment and as such is registered with the U.S. Food & Drug Administration. All Andrew Jergens Company cosmetic products comply with the Federal Food, Drug, & Cosmetic Act and regulations pertaining to the Act. One applicable regulation under the Food and Drug Administration (Title 21 CFR Part 740.1) states that

> "The label of a cosmetic product shall bear a warning statement whenever necessary or appropriate to prevent a health hazard that may be associated with the product."

Therefore, the safety of all products for their intended purpose must be substantiated before the products are marketed.

Additionally, the OSHA Final Rule relative to the Hazard Communication Standard (52 FR 31878) Title 29 CFR Part 1910.1200 (b)(6)(v) and (vii) states that,

> "This section does not apply to:..."
>
> "...Food, drugs, cosmetics, or alcoholic beverages in a retail establishment which are packaged for sale to consumers;..."

2535 SPRING GROVE AVENUE · TELEPHONE (513) 421-1400 · TELEX 21-4474 · CABLE ADDRESS JERGWOOD

and

> "...Any consumer product or hazardous substance, as those terms are defined in the Consumer Product Safety Act (15 U.S.C. 2051 et seq.) and Federal Hazardous Substances Act (15 U.S.C. 1261 et seq.) respectively, where the employer can demonstrate it is used in the workplace in the same manner as normal consumer use, and which use results in a duration and frequency of exposure which is not greater than exposures experienced by consumers;...".

Also, the preamble to this regulation, which has the force of law, includes the following,

> "The expansion of the HCS into the non-manufacturing sector will result in many of these types of products being present in workplaces (e.g., liquor stores) where they are not intended for employee consumption, and where they normally would not result in employee exposure because they are packaged for sale to consumers. Although some of these products may meet the definition of a 'hazardous chemical' (e.g., vinegar is acetic acid), when packaged for retail sale they do not pose a hazard to workers that is any different than the hazards of such products in their homes. The label information required by other Federal agencies for foods, drugs, cosmetics, and alcoholic beverages should thus provide sufficient protection for workers, and OSHA has exempted these products from coverage under the rule. It should be noted that this is not an exemption for facilities of any particular industry, as all facilities may have other chemicals in use that would be covered by the HCS. In addition, since these products are exempted, employers which package them for retail sale would not have to furnish material safety data sheets to distributors receiving the products."

As a final comment, the Office of Management and Budget published a critique of OSHA's existing Hazard Communication Standard (November 23, 1983) and the revision (August 24, 1987) (52 FR 46075) stating in effect that:

> no recognition is given (by OSHA) to a sealed container placed on a shelf (such as a stock boy in a supermarket) as opposed to a 55 gallon drum in a warehouse for which Material Safety Data Sheets and hazard training for potential spillage is required.

OSHA has been given a very short period of time in which to review and revise or intend to revise their Hazard Communication Standard (March 1, 1988).

We have included copies of the regulations cited above and believe at the present time they should provide an acceptable response to your request. If we may be of further assistance please let me know.

Sincerely,

L. A. Denton

L. A. Denton
Director Regulatory Compliance

Enclosure

cc: Robert W. Wilkins

Title 21 CFR Part 740.1

(a) The label of a cosmetic product shall bear a warning statement whenever necessary or appropriate to prevent a health hazard that may be associated with the product.

Title 29 CFR Part 1910.1200 (b)(6)(v) and (vii)

(6) This section does not apply to:

(v) Food, drugs, cosmetics, or alcoholic beverages in a retail establishment which are packaged for sale to consumers;

(vii) Any consumer product or hazardous substance, as those terms are defined in the Consumer Product Safety Act (15 U.S.C. 2051 *et seq.*) and Federal Hazardous Substances Act (15 U.S.C. 1281 *et seq.*) respectively, where the employer can demonstrate it is used in the workplace in the same manner as normal consumer use, and which use results in a duration and frequency of exposure which is not greater than exposures experienced by consumers;

Preamble

The expansion of the HCS into the non-manufacturing sector will result in many of these types of products being present in workplaces (*e.g.*, liquor stores) where they are not intended for employee consumption, and where they normally would not result in employee exposure because they are packaged for sale to consumers. Although some of these products may meet the definition of a "hazardous chemical" (*e.g.*, vinegar is acetic acid), when packaged for retail sale they do not pose a hazard to workers that is any different than the hazards of such products in their homes. The label information required by other Federal agencies for foods, drugs, cosmetics, and alcoholic beverages should thus provide sufficient protection for workers, and OSHA has exempted these products from coverage under the rule. It should be noted that this is not an exemption for facilities of any particular industry, as all facilities may have other chemicals in use that would be covered by the HCS. In addition, since these products are exempted, employers which package them for retail sale would not have to furnish material safety data sheets to distributors receiving the products

employers of any precautionary measures that need to be taken to protect employees, and therefore ensures that workers are protected from unusual hazards at a multi-employer worksite, as well as the normal hazards that would be included in a generalized training program.

Consumer Products

OSHA exempts from this final rule any consumer product where "the employer can demonstrate it is used in the workplace in the same manner as normal consumer use, and which use results in a duration and frequency of exposure which is not greater than exposures experienced by consumers" (1910.1200(b)(6)(vii)). This is a new exemption not contained in the existing rule, and is appropriately intended to exclude the large numbers of consumer products found in non-manufacturing workplaces. Nonetheless, this exemption is limited to consumer products that are used under certain circumstances, and hence the HCS would continue to apply to numerous consumer products present in workplaces.

The record indicates that this exemption would continue to place under the HCS large numbers of consumer products for which MSDSs would have little practical utility, and for which the burden of compliance would be substantial. We have four major concerns:

- Consumer product labeling already provides information to identify significant hazards that may result from use of the product and to enable users to avoid those hazards. For the overwhelming majority of consumer products that would remain subject to the standard, there is no evidence in the record that the MSDS would have practical utility beyond the information already included on the label.
- The exemption imposes a burden on the employer to "demonstrate" that exposures for each substance are the same as "normal consumer use," a burden that may be difficult to meet (2-44). More importantly, such a trigger would not exclude many situations where risks are very low. For example, is an employee who cleans and waxes floors once a week using a supermarket product exposed at the same duration and frequency as consumers? If not, should the employee be trained in the hazards of floor wax? Under OSHA's language, the employee may well be treated exactly like a worker on a chemical production line. In addition, the HCS requires that even consumer products that are not opened under normal workplace use, such as those a stock boy places on a supermarket shelf, be treated as "sealed containers," for which MSDSs and hazard training for potential spillage are required. This would result in treating a can of floor wax in a grocery store exactly the same as a 55-gallon drum of industrial chemical in a warehouse. In this regard, the National Retail Merchants Association stated, "It would be exceptionally difficult for retailers to adequately assess whether the hundreds of products they regularly sell could potentially become workplace hazards in the event of spillage" (Ex. 1-24, see also comments by the National Restaurant Association, 2-31).
- The exemption does not allow upstream suppliers to determine which products are exempted, because they do not know how downstream empoyers will use them. Moreover, OSHA's explanation that downstream distributors who do not "generally" sell to employers would not be covered offers no relief to wholesalers and other consumer product distributors who have some accounts that are subject to the standard and others that are not. In fact upstream suppliers who want to ensure compliance will have no practical alternative but to assume that downstream employers are covered, and will therefore ship MSDSs and labels along with all consumer products. Thus, upstream suppliers will continue to bear all of the costs and the distribution/retail sector will continue to receive all of the hazard information for all consumer product. This is exactly what the consumer product exemption should be designed to avoid.
- The number of MSDSs involved is very large. Although OSHA estimated that the typical food store contained 11 chemical hazards and the largest 58, the Food Marketing Institute estimated that the typica supermarket would sell at least 1,200 nonfood consumer products that may be convered by the HCS (Ex. 2-32). The National Paint and Coatings Association calculated that paint manufacturers would be required to supply 7,000,000 MSDSs initially to retail establishments (Ex. 2-38).

We have therefore disapproved, effective May 23, 1988, coverage under the HCS of any consumer product excluded by Congress from the definition of "hazardous chemical" under Section 311(e) (3) of the Superfund Amendments and Reauthorization Act of 1986 (SARA): "Any substance to the extent it is used for personal, family or household purposes, or is present in the same form and concentration as a product packaged for distribution and use by the general public." This language would exempt any substance packaged in the same form and concentration as a consumer product whether or not it is used for the same purpose as the consumer product. EPA concluded in its final rule on Sections 311 and 312 of SARA (52 FR 38344) that this exemption is appropriate for household or consumer products in commercial and industrial as well as household use because "the public is generally familiar with such substances, their hazards and their likely locations (hence), the disclosure of such substances is unnecessary for right-to-know purposes." This alternative consumer products exemption would address the concern that the current HCS imposes unnecessary paperwork in many situations in which exposures and risks are trivial, and would reduce and simplify the paperwork requirements:

- It makes the OSHA and EPA right-to-know paperwork requirements, which are closely linked, mutually consistent. Using the same exemption in both rules avoids the situation in which employers must separate the paperwork for their "consumer products" into two groups: an OSHA "consumer product" and an EPA "consumer product."
- It establishes objective criteria that enable upstream and downstream employers to determine what is exempted and what is included. Upstream suppliers would not be forced to speculate as to the identity of the final user (consumer or employer?) in determining whether the product is subject to the HCS. The flow of MSDSs and labels would be restricted to unpackaged substances or substances packaged for industrial or commercial use, for which detailed hazard information would be expected to have practical utility.

Drugs Regulated by FDA

The standard exempts drugs in "solid, final form for direct administration to the patient (i.e., tablets or pills)." This exemption in part avoids duplication of paperwork. Drugs for human consumption are heavily regulated by the Food and Drug Administration, which requires the transmittal of detailed information downstream from the manufacturer through professional package inserts and labels. The exemption also limits the odd situation in which a drugstore owner would be responsible for training professional pharmacists about the hazards of the drugs they dispense.

Outside the manufacturing sector, however, both rationales are equally relevant to liquid drugs not in final form. OSHA does not explain why all drugs regulated by the FDA are not exempted, except to say that North Carolina has adopted a similar exemption. Yet the paperwork burdens of covering such drugs appear to be very high. The National Wholesale Druggists Association has estimated that *each* drug wholesaler, with 400 pharmacy customers and 12,000 individual products covered by the HCS, would initially be required to distribute 4.8 million MSDSs (Ex. 2-24). If capsules containing solids or liquids are covered by the HCS, another 5,520 products would be added. A similar concern was raised by the Department of Agriculture (Ex. 2-50) and the Animal Health Institute (Ex. 2-40) concerning potential duplication of paperwork for veterinary biological products. Since coverage of any FDA-regulated drug would result in duplicative paperwork and is unlikely to provide additional information of any practical utility, we have disapproved coverage of FDA-regulated drugs outside the manufacturing sector, effective May 23, 1988.

Definition of "Article"

The HCS exemption of "articles" from the scope of the standard is conditionally approved through May 23, 1988. Although the record supports the need for an article exemption, the record does not support the existing definition of "article," particularly with regard to the lack of a *de minimis* exemption and the agency's interpretation of "normal conditions of use."

"Article" is defined as "a manufactured item: (i) which is formed to a specific shape or design during the manufacture; (ii) which has end use function(s) dependent in whole or in part upon its shape or design during end use; and (iii) which does not release, or otherwise result, in exposure to a hazardous chemical under normal conditions of use." OSHA explains in the preamble to the final expanded rule that "exposure" does not mean releases of "very small quantities," a "trace amount," or "a few molecules" of the hazard.

The issue raised in the record is whether an objective "de minimis" exemption should

FoxMeyer Corporation

CERTIFICATE OF NON-HAZARDOUS CHEMICALS

ANSELL PERSONAL PRODUCTS
P.O. BOX 2153
BIRINGHAM, AL 35201

I, BRADLEY PUGH, certify that all products manufactured by ANSELL PERSONAL PRODUCTS and distributed by FoxMeyer Drug Co contain no hazardous chemicals. In the event this changes, the appropriate documentation (M.S.D.S) will be forwarded to FoxMeyer upon date of initial manufacture.

Name: BRADLEY PUGH

Title: V.P. RESEARCH/DEVELOPMENT & REGULATOR AFFA

Signature: Bradley Pugh/RH Date: 12/2/87

ANTIGEN SUPPLY HOUSE

Antigens International
19201-B Parthenia St., Northridge Executive Center
Northridge, California 91324

U.S.	(800) 423-5783
CANADA	(800) 237-6391
CALIF.	(800) 331-4700
	(818) 701-5997
TELEX	#910-3212305

February 22, 1988

FoxMeyer Corporation
1220 Senlac Drive
Carrollton, TX 75006

Attention: Mr. William R. Stratton

Dear Mr. Stratton:

Thank you for your request for a Material Safety Data Sheet (MSDS) on an Antigen Supply House product. As you are aware, our products are covered by the Federal Food, Drug and Cosmetic Act (21 U.S.C. 30/et seq.) and are subject to the testing and labeling requirements of that Act and of the Food and Drug Administration.

The OSHA Hazard Communication Standard CFR, 1910.1200 specifically exempts these products in Section B (4) (ii). Therefore, an MSDS is not required for these products. If we can be of service in any other way, please do not hesitate to ask.

Sincerely yours,

Michele Yulfo
for ANTIGEN SUPPLY HOUSE

MYY/mar

FoxMeyer Corporation

CERTIFICATE OF NON-HAZARDOUS CHEMICALS

APEX MEDICAL SUPPLY INC
P.O. BOX 88008
SIOUX FALLS, SD 57105

I, D. R. Beaton, certify that all products manufactured by APEX MEDICAL SUPPLY INC and distributed by FoxMeyer Drug Co contain no hazardous chemicals. In the event this changes, the appropriate documentation (M.S.D.S) will be forwarded to FoxMeyer upon date of initial manufacture.

Apex Medical Corp.

Name: D. R. Beaton

Title: President

Signature: D R Beaton Date: 12-8-87

FoxMeyer Corporation

CERTIFICATE OF NON-HAZARDOUS CHEMICALS

APLOQ OF COLORADO
5657 GRAY ST
ARVADA, CO 80002

I, Scott Robinson, certify that all products manufactured by APLOQ OF COLORADO and distributed by FoxMeyer Drug Co contain no hazardous chemicals. In the event this changes, the appropriate documentation (M.S.D.S) will be forwarded to FoxMeyer upon date of initial manufacture.

Name: Scott Robinson

Title: Manager/Sales & Marketing

Signature: Scott Robinson Date: Nov 19, 1987