



MATERIAL SAFETY DATA SHEET

While we believe the information provided herein is accurate and current, Monarch Pharmaceuticals makes no representations or warranties, either expressed or implied, and assumes no responsibility for any damage or injuries of any kind, which may result from use or reliance upon this information.

SECTION I	MATERIAL IDENTIFICATION
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PRODUCT NAME: Cortisporin® Cream

DATE OF ISSUE: 05/27/03

REVISIONS: 05/15/07

FORMULA: Polymyxin B is the sulfate salt of polymyxin B₁ and B₂, which are produced by the growth of *Bacillus polymyxa* (Prazmowski) Migula (Fam. Bacillaceae); Neomycin is the sulfate salt of neomycin B and C, which are produced by the growth of *Streptomyces fradiae* Waksman (Fam. Streptomycetaceae); and Hydrocortisone acetate is 21-(acetyloxy)-11β, 17-dihydroxypregn-4-ene3,20-dione

NDC#: 61570-032-75 (7.5gm tube)

SYNONYMS: Neomycin and Polymyxin B Sulfates and Hydrocortisone Acetate Cream, USP

MANUFACTURING DIVISION:	ADDRESS	PERSON TO CONTACT	PHONE #
	501 Fifth Street Bristol, TN 37620	Bill Smith	423-989-8042

SECTION II	INGREDIENT (S)
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EXPOSURE LIMITS/GUIDELINES

CAS#	INGREDIENT NAME	OSHA PEL	ACGIH TLV	OTHER	LISTED AS CARCINOGEN
1405-10-3	Neomycin Sulfate	N/D	N/D	N/D	No
1405-20-5	Polymyxin B Sulfate	N/D	N/D	N/D	No
50-03-3	Hydrocortisone Acetate	N/D	N/D	N/D	No
N/D	Liquid Petrolatum	N/D	N/D	N/D	N/D
N/D	White Petrolatum	N/D	N/D	N/D	N/D
N/D	Propylene glycol	N/D	N/D	N/D	N/D
N/D	Polyoxyethylene polyoxypropylene compound	N/D	N/D	N/D	N/D
N/D	Emulsifying wax	N/D	N/D	N/D	N/D
N/D	Purified water	N/D	N/D	N/D	N/D
N/D	Methylparaben	N/D	N/D	N/D	N/D
N/D	Sodium hydroxide	N/D	N/D	N/D	N/D
N/D	Sulfuric acid	N/D	N/D	N/D	N/D

SECTION III	PHYSICAL AND CHEMICAL DATA
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PHYSICAL STATE: Semi-solid

APPEARANCE: White cream

CHARACTERISTIC ODOR: N/D

SPECIFIC GRAVITY: N/D

SOLUBILITY IN WATER: N/D

pH: Approx. 5.0

SECTION IV**FIRE AND EXPLOSION DATA**

FLASH POINT AND METHOD: N/D

EXTINGUISHING MEDIUM: Use agent appropriate to the nature of the fire and other materials involved.

SPECIAL FIRE FIGHTING PROCEDURES: Self-contained breathing apparatus.

HAZARDOUS DECOMPOSITION OR COMBUSTION PRODUCTS: None known.

SECTION V**CHEMICAL REACTIVITY DATA**

STABILITY: Stable

INCOMPATIBILITY: None known

HAZARDOUS POLYMERIZATION: None known

HAZARDOUS DECOMPOSITION OF BYPRODUCTS: None known

CONDITIONS TO AVOID: None known

SECTION VI**HEALTH HAZARD INFORMATION**

ROUTE OF ENTRY: Ocular, Inhalation, Ingestion, Skin

HEALTH HAZARD: See Toxicity Information

TOXICITY INFORMATION: This information pertains to the following ingredients individually. Emphasis should be placed on the potential effects that may occur with the occupational handling (by inhalation, dermal or ocular contact) of this product.

Neomycin Sulfate: Hypersensitivity reactions (primarily skin rashes) have occurred in persons treated with neomycin sulfate. May cause severe renal (kidney) toxicity and neurotoxicity including ototoxicity (hearing loss and diminished balance) when administered parenterally (IV). Neuromuscular blockade and respiratory paralysis have also occurred in rare cases. Oral-Rat LD50=>4325 mg/kg; IV-Mouse LD50=17.4-150 mg/kg.

Polymyxin B Sulfate: Neurotoxicity, nephrotoxicity and neuromuscular blockade are the characteristic results of systemic polymyxin poisoning. Fever has also been reported. Repeated or prolonged exposure by ingestion may cause kidney damage. In view of the nonabsorbability of this antibiotic, it does not present an oral hazard unless the gut is diseased. Hygienic precautions should anticipate possibility of sensitization. IV-Mouse LD50=5.4 mg/kg; IV-Dog LD50=8 mg/kg; Oral-Mouse LD50=790 mg/kg; IP-Mouse LD50=20.5 mg/kg; Dermal Subcutaneous-Mouse LD50=59.5 mg/kg.

Hydrocortisone Acetate: Hydrocortisone acetate belongs to the corticosteroid class of steroids. Overexposure may affect carbohydrate, protein and fat metabolism; electrolyte and water balance; functions of the cardiovascular system, kidney, skeletal, muscle, nervous system and other organs and tissues; and may modify the body's immune responses to diverse stimuli. Corticosteroids are generally teratogenic in laboratory animals when administered systemically, but there are not well-controlled studies in women.

(For further information see current package insert)

SECTION VII**FIRST AID INFORMATION**

EYES: Rinse immediately with plenty of water. Contact physician.

SKIN: Remove all contaminated clothing. Wash off skin with plenty of water. Consult physician if contact produces irritation.

INHALATION: Remove person to fresh air, rest and keep warm. Use artificial respiration if breathing stops. Contact physician.

INGESTION: Wash out mouth. Give plenty of water or bland fluids. Contact physician. Unless vomiting is copious, lavage should be carried out.

REGULATED EXPOSURE LIMITS: N/D

SECTION VIII

SPECIAL PROTECTION INFORMATION

RESPIRATORY PROTECTION: None necessary

PROTECTIVE GLOVES: Latex

VENTILATION: None necessary

EYE PROTECTION: Avoid contact with eyes.

OTHER PROTECTIVE CLOTHING OR EQUIPMENT: N/A

SECTION IX

SPILL, LEAK, AND DISPOSAL PROCEDURES

ACTION TO BE TAKEN IF MATERIAL IS RELEASED OR SPILLED: Prevent exposure. Wipe or mop up spilled material. Wash all contaminated surfaces with soap and water. Place waste in appropriately labeled, sealed container(s) for future disposal.

WASTE DISPOSAL METHOD: Dispose of as a medical waste in accordance with local, state and federal regulations or the authority having jurisdiction.

SECTION X

SPECIAL PRECAUTIONS

STORE AS STATED IN PRODUCT LABELING: Store in original container, tightly closed. Store at 15 to 25 degrees C (59 to 77 degrees F).

OTHER PRECAUTIONS: Avoid skin and eye contact. Should such contact occur, wash exposed area promptly.

N/D=Not determined

N/A=Not applicable

The information provided in this Material Safety Data Sheet has been compiled from our experience and the data presented in various technical publications. It is the user's responsibility to determine the suitability of this information for the adoption of safety precautions as may be necessary. We reserve the right to revise the Material Safety Data Sheets from time to time as new information becomes available. The user has the responsibility to contact the company to make sure the sheet is the latest one issued.