

MATERIAL SAFETY DATA SHEET

SECTION 1: IDENTIFICATION

PRODUCT NAME: Antibiotic Cream Plus Pain Relief **PRODUCT No.:** 51672-2076
(Neomycin Sulfate, Polymyxin B Sulfate, Pramoxine)

Distributor: Taro Pharmaceuticals U.S.A., Inc.
3 Skyline Drive, Hawthorne, New York 10532
Telephone: 1-888-TARO-USA

Recommended Use: First aid to help prevent infection and for the temporary relief of pain or discomfort in minor cuts, scrapes, burns.

Restrictions on Use: For external use only

Do not use in the eyes, over large areas of the body, if you are allergic to any of the ingredients, longer than 1 week.

Ask a doctor before use on deep or puncture wounds, animal bites, or serious burns.

Stop use and ask a doctor if condition gets worse, condition persists for more than 7 days, condition clears up and occurs again within a few days, a rash or other allergic reaction develops.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

SUBSTANCE CLASS: Not applicable.

FORMULA: Not applicable.

M.W.: Not applicable.

SECTION 2: HAZARD(S) IDENTIFICATION

Primary Routes of Exposure: Skin contact, eye contact

Signs of Overexposure: Itching, skin rash, redness, swelling or other signs of irritation not present before use of this medicine.

Medical Conditions Aggravated By Exposure: Hypersensitivity to the materials in the preparation; pramoxine hydrochloride, neomycin sulfate or polymyxin B sulfate. Persons hypersensitive to any of the ingredients should avoid contact.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient: Neomycin Sulfate, Polymyxin B Sulfate, Pramoxine Hydrochloride

Inactive Ingredients: Emulsifying wax, methylparaben, mineral oil, propylene glycol, purified water, white petrolatum

CAS#: Neomycin Sulfate: 1405-10-3

Polymyxin B Sulfate: 1405-20-5

Pramoxine Hydrochloride: 637-58-1

SECTION 4: FIRST-AID MEASURES

Eye: Possibly Eye Irritant. Eye contact may cause mild to moderate irritation. In case of contact, immediately flush eyes with water. Hold eyelids open to ensure adequate flushing. Get medical assistance if persistent irritation or other adverse symptoms develop.

Skin: Skin contact may cause mild irritation or rash in sensitive individuals. In case of accidental contact, promptly wash exposed areas with soap and water. Get medical assistance if persistent irritation or other adverse symptoms develop.

Ingestion: Ingestion may cause gastrointestinal irritation. Administer 1-2 glasses of milk or water to dilute ingested material. Get medical assistance if persistent irritation or other adverse symptoms develop.

Inhalation: This material is not an inhalation hazard under normal conditions of use.

SECTION 5: FIRE-FIGHTING MEASURES

FLASH POINT: Not applicable.

EXTINGUISHING MEDIA: Fires involving this material may be extinguished with water spray, carbon dioxide (CO₂), dry chemical, or foam.

SPECIAL FIRE FIGHTING PROCEDURES: All fire fighting activities must be done by trained personnel and include the use of appropriate protective clothing.

UNUSUAL FIRE AND EXPLOSION HAZARDS: See HAZARDOUS COMBUSTION PRODUCTS.

HAZARDOUS COMBUSTION PRODUCTS: Hazardous combustion products may include hydrogen cyanide (HCN), carbon monoxide, and other oxidized and reduced forms of this material and its constituent elements. Combustion products are irritating and toxic. Avoid inhalation.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Avoid contact with combustible materials. Move container away from spill if conditions are safe. Collect spilled material and place in an appropriate container for disposal.

SECTION 7: HANDLING AND STORAGE

HANDLING: Have emergency equipment (for fires, spills, etc.) readily available.

STORAGE: Store in a cool, dry, well ventilated area away from ignition sources and heat. Store in suitable labeled containers kept closed and protected from damage.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

ENGINEERING CONTROLS: None required under normal conditions of use. If unusual exposures are expected, an industrial hygiene review of work practices and engineering controls is recommended.

PERSONAL PROTECTION:

Respiratory: No respiratory protection required under normal conditions of use.

Eye: No eye protection required under normal conditions of use.

Skin: No skin protection required under normal conditions of use.

WORK PRACTICES: Use good work practices. Avoid skin and eye contact. Wash hands before eating, drinking, smoking or using toilet facilities.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

BOILING POINT: Not Applicable

PHYSICAL STATE (liquid/solid/gas): Semi-Solid

SPECIFIC GRAVITY (H₂O=1): 0.958 - 0.984

EVAPORATION RATE (Butyl Acetate=1): Not available

SOLUBILITY: Water: Not Determined

Other: Not Determined

APPEARANCE: A smooth white cream

ODOR DESCRIPTION: Characteristic odor

SECTION 10: STABILITY AND REACTIVITY

CHEMICAL STABILITY: This material is stable under normal conditions of use.

CONDITIONS TO AVOID: Keep away from ignition sources and heat

INCOMPATIBILITY WITH OTHER MATERIALS: Not Determined.

HAZARDOUS DECOMPOSITION PRODUCTS: CO, CO₂, HF (small amounts) and HCl (small amounts)

HAZARDOUS POLYMERIZATION: Hazardous polymerization will not occur under normal conditions of use.

SECTION 11: TOXICOLOGICAL INFORMATION

Neomycin Sulfate:

Acute Health Effects

Human/Clinical Toxicity:

Neomycin sulfate is an aminoglycoside antibiotic administered topically or orally at doses ranging from 3-12 grams. It is not absorbed through intact skin, but is readily absorbed through broken skin. Neomycin sulfate is a contact sensitizer causing conjunctivitis, rash, redness, itching, and burning in about 5-15% of patients. A retrospective study found no evidence that use of neomycin during pregnancy adversely affects offspring.

Other Toxicological Information:

No drug-induced birth defects have been seen in mice or rabbits following administration of this material. The mutagenic and carcinogenic potentials of this compound are unknown.

Polymyxin B Sulfate:

Acute Health Effects:

Human/Clinical Toxicity:

Polymyxin is antibiotic administered parenterally or topically for the treatment of various types of infections. In humans, it has a low order of toxicity when taken by mouth or when applied to skin or mucous membranes, since it is not well absorbed by these routes. However, polymyxin may cause bronchial irritation and bronchospasm after inhalation. A retrospective study of seven exposed human pregnancies did not find any adverse effects related to the use of polymyxin.

Ingestion Effects:

Acute/Subacute Toxicity: Rat Oral LD₅₀: 750 mg/kg

Other Toxicological Information:

No drug-induced birth defects have been seen in rats or rabbits following administration of this material. The mutagenic and carcinogenic potentials of this compound are unknown.

Pramoxine Hydrochloride:

Acute Health Effects:

Human/Clinical Toxicity:

Pramoxine Hydrochloride is a local anesthetic used to relieve pain and discomfort associated with skin irritation, minor cuts and abrasions and hemorrhoids. It is used topically in creams, ointments, gels, lotions, and sprays, as well as rectally in suppositories. Adverse effects associated with the therapeutic use of Pramoxine HCl are mild and are usually limited to burning

or stinging following application. Pramoxine HCl is irritating when used in the eyes and nose. It is not believed to be a sensitizer, although mild allergic reactions have occasionally been reported with repeated therapeutic use.

Ingestion Effects:

Acute/Subacute Toxicity: Rat Oral LD50: 1050 mg/kg

Other Toxicological Information:

The mutagenicity and carcinogenicity of this compound, as well as its potential to cause reproductive toxicity, are unknown.

Note: The above information pertains to the ingredients of this material and not to the product as marketed.

SECTION 12: ECOLOGICAL INFORMATION

Ecological Paragraph: No data are available on the adverse environmental effects of this material.

SECTION 13: DISPOSAL CONSIDERATIONS

This material is not regulated for transportation.

SECTION 14: TRANSPORT INFORMATION

Transportation and shipping of this product is not restricted. It has no known, significant hazards requiring special packaging or labeling for air, maritime, US or European ground transport purposes

SECTION 15: REGULATORY INFORMATION

Applies to all ingredients:

European Community Chemical Inventory Status:

Hazard Symbols: None Required

Risk Phrases:

None Required

Safety Phrase:

None Required

United States Regulations:

Hazard Communication Labels: Possible Eye Irritant

SECTION 16: OTHER INFORMATION

Contact: Taro Pharmaceuticals U.S.A., Inc., Regulatory Affairs Department
3 Skyline Drive, Hawthorne, NY 10532

Preparation and/or Revision Date: October 2014

DISCLAIMER

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