

# SAFETY DATA SHEETS

**This SDS packet was issued with item:**

078830601

N/A

# **MATERIAL SAFETY DATA SHEET**

**PRODUCT NAME:**

**Mupirocin Ointment USP, 2%**

**AS SOLD BY PHOENIX PHARMACEUTICAL**

A Service of



## MATERIAL SAFETY DATA SHEET

### SECTION 1: PRODUCT IDENTIFICATION

<b>PRODUCT NAME:</b>	<b>Mupirocin Ointment USP, 2%</b>	<b>PRODUCT No.:</b>	<b>51672-1312</b>
<b>CAS #:</b>	<b>12650-69-0</b>	<b>FORMULA:</b>	<b>C<sub>26</sub>H<sub>44</sub>O<sub>9</sub></b>
<b>SUBSTANCE CLASS:</b>	<b>Topical Antibacterial</b>	<b>M.W.:</b>	<b>500.63</b>

### SECTION 2: PHYSICAL/CHEMICAL DATA

<b>BOILING POINT:</b>	N/A
<b>PHYSICAL STATE (liquid/solid/gas):</b>	Solid
<b>SPECIFIC GRAVITY (H<sub>2</sub>O=1):</b>	N/A
<b>EVAPORATION RATE (Butyl Acetate=1):</b>	N/A
<b>APPEARANCE:</b>	Smooth, white cream like ointment
<b>ODOR DESCRIPTION:</b>	No odor

### SECTION 3: FIRE AND EXPLOSION HAZARD DATA

<b>FLASH POINT:</b>	300°C
<b>EXTINGUISHING MEDIA:</b>	Water is recommended for fires involving packaging
<b>SPECIAL FIRE FIGHTING PROCEDURES:</b>	For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapors might be evolved from fires involving this product and associated packaging, self contained breathing apparatus and full protective equipment are recommended for firefighters. If possible, contain and collect firefighting water for later disposal.
<b>UNUSUAL FIRE AND EXPLOSION HAZARDS:</b>	Not expected for the product, although the packaging is combustible.
<b>HAZARDOUS COMBUSTION PRODUCTS:</b>	Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

### SECTION 4: STABILITY AND REACTIVITY DATA

<b>CHEMICAL STABILITY:</b>	This product is expected to be stable.
<b>CONDITIONS TO AVOID:</b>	None for normal handling of this product
<b>INCOMPATIBILITY WITH OTHER MATERIALS:</b>	None known
<b>HAZARDOUS DECOMPOSITION PRODUCTS:</b>	None known
<b>HAZARDOUS POLYMERIZATION:</b>	None known
<b>MATERIAL TO AVOID:</b>	None known

## SECTION 5: HEALTH HAZARD DATA

**EMERGENCY** Supplied in 22 g tubes.

### OVERVIEW

### POTENTIAL HEALTH HAZARDS

- Eye:** Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.
- Skin:** Using appropriate personal protective equipment, remove contaminated clothing and flush exposed area with large amounts of water. Obtain medical attention if skin reaction occurs, which may be immediate or delayed.
- Ingestion:** Never attempt to induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. If the exposed subject is fully conscious, give plenty of water to drink. Obtain medical attention.
- Inhalation:** Physical form suggests that risk of inhalation exposure is negligible.

## SECTION 6: SPILL OR LEAK PROCEDURES

### STEPS TO BE TAKEN IF MATERIAL IS RELEASED OR SPILLED:

Wear protective clothing and equipment consistent with the degree of hazard. For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.

### WASTE DISPOSAL METHOD:

Collect and place it in a suitable, properly labeled container for recovery or disposal. Dispose of in accordance with all Federal, State and Local laws.

## SECTION 7: HANDLING AND STORAGE

- HANDLING:** No special control measures required for the normal handling of this product. Normal room ventilation
- STORAGE:** Store at 20°-25°C (68°-77°F)[see USP Controlled Room Temperature]

## SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

- ENGINEERING CONTROLS:** Normal room ventilation is expected to be adequate for routine handling of this product.
- PERSONAL PROTECTION:**
- Respiratory: None required for normal handling.
  - Eye: None required for normal handling.
  - Clothing: None required for normal handling.
  - Gloves: None required for normal handling.
- WORK PRACTICES:** Wash hands and arms thoroughly after handling.

## SECTION 9: TOXICOLOGICAL INFORMATION

<b>Oral Toxicity:</b>	Not expected to be toxic following ingestion
<b>Skin Effects:</b>	Irritation is not expected following direct contact
<b>Eye Effects:</b>	Minor irritation might occur following direct contact with eyes
<b>Sensitization:</b>	Sensitization (allergic skin reaction) is not expected
<b>Carcinogenicity:</b>	Not expected to produce cancer in humans under occupational exposure conditions
<b>Genetic Toxicity:</b>	Not expected to be genotoxic under occupational exposure conditions.
<b>Reproductive Effects:</b>	No adverse effects have been reported following extensive use or exposure in humans
<b>Pharmacological Effects:</b>	This preparations contains ingredient(s) with the following activity: an antibiotic
<b>Other Adverse Effects:</b>	None known for occupational exposure

## SECTION 10: OTHER INFORMATION

No information is available about the potential of this product to produce adverse environmental effects. Local regulations and procedures should be consulted prior to environmental release.

## SECTION 11: TRANSPORTATION INFORMATION

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

## SECTION 12: REGULATORY INFORMATION

Taro Pharmaceuticals U.S.A., Inc.  
Attn: Regulatory Affairs Department  
3 Skyline Drive  
Hawthorne, NY 10532  
(914) 345-9001  
(914) 593-0078 fax

## DISCLAIMER

The above information has been obtained from a number of sources and its accuracy cannot be guaranteed. It is the user's responsibility to evaluate the information and use it in a prudent manner for its particular purpose. Taro Pharmaceuticals assumes no responsibility for the use of this information.

## SAFETY DATA SHEET

### SECTION 1: IDENTIFICATION

**Product Name:** Mupirocin Ointment USP, 2%                      **Product No.:** 51672-1312

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

**Recommended Use:** Mupirocin Ointment USP, 2% is indicated for the topical treatment of impetigo due to: *S. aureus* and *S. pyogenes*.

**Restrictions on Use:** This drug is contraindicated in patients with known hypersensitivity to any of the constituents of the product.

**Substance Class:** Topical Antibacterial

**Formula:** C<sub>26</sub>H<sub>44</sub>O<sub>9</sub>

**M.W.:** 500.63

### SECTION 2: HAZARD(S) IDENTIFICATION

**Physical Hazards:** Not classified.

**Health Hazards:** Sensitization, skin Category 1B

**OSHA Hazard(s):** Not classified.

#### Label Elements

**Signal Word:** Warning

**Hazard Statement:** May cause an allergic skin reaction.

#### Precautionary Statement

**Prevention:** Contaminated work clothing must not be allowed out of the workplace.  
Wear protective gloves.

**Response:** Wash contaminated clothing before reuse. If on skin: Wash with plenty of water/soap. If skin irritation or rash occurs: Get medical advice/attention.

**Disposal:** Dispose of contents/container to an approved disposal site.

**Hazard(s) Not Otherwise Classified (HNOC):** Not classified.

### SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient: Mupirocin CAS#: 12650-69-0  
Inactive Ingredients: Polyethylene glycol 400 NF and polyethylene glycol 3350 NF.

### SECTION 4: FIRST-AID MEASURES

**Inhalation:** If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.

**Skin Contact:** Rinse skin with water/shower. Get medical attention if irritation develops and persists.

**Eye Contact:** Rinse with water. Get medical attention if irritation develops and persists.

**Ingestion:** Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.

**Most Important Symptoms/Effects, Acute and Delayed:** May cause allergic skin reaction.

**Indication of Immediate Medical Attention and Special Treatment Needed:** Provide general supportive measures and treat symptomatically.

**General Information:** Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

### SECTION 5: FIRE-FIGHTING MEASURES

**Suitable Extinguishing Media:** Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.

**Unsuitable Extinguishing Media:** None known.

**Specific Hazards Arising from the Chemical:** No unusual fire or explosion hazards noted.

**Special Protective Equipment and Precautions for Firefighters:** Wear suitable protective equipment.

**Fire-Fighting Equipment/Instructions:** As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

**Specific Methods:** Cool containers exposed to flames with water until well after the fire is out.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

**Personal Precautions, Protective Equipment and Emergency Procedures:** Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.

**Methods and Materials for Containment and Cleaning Up:** Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Wash spill site.

## SECTION 7: HANDLING AND STORAGE

**Precautions for Safe Handling:** As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly.

**Conditions for Safe Storage, Including Any Incompatibilities:** Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

**Store at 20°-25°C (68°-77°F)** [see USP Controlled Room Temperature].

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

**Biological Limit Values:** No biological exposure limits noted for the ingredient(s).

**Exposure Guidelines:** No exposure standards allocated.

**Appropriate Engineering Controls:** Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials.

### Individual Protection Measures, Such As Personal Protective Equipment

**Eye/Face Protection:** Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.



### Skin Protection

**Hand Protection:** Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

**Other:** For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.

**Respiratory Protection:** Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

**Thermal Hazards:** Not available.

**General Hygiene Considerations:** Handle in accordance with good industrial hygiene and safety practice.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

<b>Boiling Point:</b>	N/A
<b>Physical State (liquid/solid/gas):</b>	Solid
<b>Specific Gravity (H<sub>2</sub>O = 1):</b>	N/A
<b>Evaporation Rate (Butyl Acetate = 1):</b>	N/A
<b>Appearance:</b>	A smooth, white, cream-like ointment
<b>Odor Description:</b>	No odor

## SECTION 10: STABILITY AND REACTIVITY

**Reactivity:** No reactivity hazards known.

**Chemical Stability:** Material is stable under normal conditions.

**Possibility of Hazardous Reactions:** No dangerous reaction known under conditions of normal use.

**Conditions to Avoid:** None known.

**Incompatible Materials:** Strong oxidizing agents.

**Hazardous Decomposition Products:** Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

## SECTION 11: TOXICOLOGICAL INFORMATION

### Information on Likely Routes of Exposure

**Ingestion:** Based on available data, the classification criteria are not met.

**Inhalation:** Due to lack of data the classification is not possible.

**Skin Contact:** May cause an allergic skin reaction.

**Eye Contact:** Due to lack of data the classification is not possible.

**Symptoms Related to the Physical, Chemical, and Toxicological Characteristics:** Dry skin, burning skin, itching, stinging skin, headache, nausea, cough, sore throat, stuffy nose, taste changes.

**Acute Toxicity:** Based on available data, the classification criteria are not met.

<u>Product</u>	<u>Species</u>	<u>Test Results</u>
Mupirocin (CAS 12650-69-0)		
<i>Oral</i>		
LD50	Mouse	5 g/kg
	Rat	5 g/kg

**Skin Corrosion/Irritation:** Due to lack of data the classification is not possible.

**Serious Eye Damage/Eye Irritation:** Due to lack of data the classification is not possible.

**Respiratory Sensitization:** Due to lack of data the classification is not possible.

**Skin Sensitization:** May cause an allergic skin reaction. Contact dermatitis has been reported in the literature.

#### Sensitization

Modified Draize test

Result: Sensitizing potential.

Species: Guinea pig

Organ: Skin.

**Germ Cell Mutagenicity:** Based on available data, the classification criteria are not met.

#### Mutagenicity

Ames test

Result: Negative.

Bone marrow micronuclei assay

Result: Negative.

Species: Mouse

E. coli mutation assay

Result: Negative.

Human lymphocyte metaphase test  
Result: Negative.  
Lymphoma assay  
Result: Negative.  
Species: Mouse  
Primary hepatocyte unscdeduled DNA synthesis test  
Result: Negative.  
Species: Rat  
Sediment analysis for DNA strand breaks  
Result: Negative.

**Carcinogenicity:** Due to lack of data the classification is not possible. This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

## SECTION 12: ECOLOGICAL INFORMATION

**Ecotoxicity:** No ecotoxicity data noted for the ingredient(s).  
**Persistence and Degradability:** No data is available on the degradability of this product.  
**Bioaccumulative Potential:** Not available.  
**Mobility in Soil:** Not available.  
**Other Adverse Effects:** Not available.

## SECTION 13: DISPOSAL CONSIDERATIONS

**Disposal Instructions:** This product, in its present state, when discarded or disposed of, is not a hazardous waste according to Federal regulations (40 CFR 261.4 (b)(4)). Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste. Dispose in accordance with all applicable regulations.

**Local Disposal Regulations:** Not available.

**Hazardous Waste Code:** Not regulated.

**Waste from Residues / Unused Products:** Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

**Contaminated Packaging:** Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

## SECTION 14: TRANSPORT INFORMATION

**DOT:** Not regulated as a hazardous material by DOT.

**IATA:** Not regulated as a dangerous good.

**Transport in Bulk According to Annex II of MARPOL 73/78 and the IBC Code:** No information available.

## SECTION 15: REGULATORY INFORMATION

**U.S. Federal Regulations:** CERCLA/SARA Hazardous Substances - Not applicable. One or more components are not listed on TSCA.

### Superfund Amendments and Reauthorization Act of 1986 (SARA)

#### Hazard Categories:

Immediate Hazard - No

Delayed Hazard - No

Fire Hazard - No

Pressure Hazard - No

Reactivity Hazard - No

**SARA 302 Extremely Hazardous Substance:** No

**SARA 311/312 Hazardous Chemical:** No

### Other Federal Regulations

**Safe Drinking Water Act (SDWA):** Not regulated.

**Food and Drug Administration (FDA):** Not regulated.

**U.S. State Regulations:** This product does not contain a chemical known to the State of California to cause cancer, birth defects or other reproductive harm.

## 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: January 2016

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