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: $C_{26}H_{44}O_9$

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

Boiling Point:	N/A
Physical State (liquid/solid/gas):	Solid
Specific Gravity (H_2O = 1):	N/A
Evaporation Rate (Butyl Acetate = 1):	N/A
Appearance:	A smooth, white, cream-like ointment
Odor Description:	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.

Product	Species	Test Results
Mupirocin (CAS 12650-69-0)		
Oral		
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 unsceduled 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

D I S C L A I M E R

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