

## **SAFETY DATA SHEETS**

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

078939936

**The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).**

078933865

## SAFETY DATA SHEET

### SECTION 1: IDENTIFICATION

**PRODUCT NAME:** Triple Antibiotic Ointment (Bacitracin Zinc, Neomycin Sulfate and Polymyxin B Sulfate) **PRODUCT No.:** 51672-2016

**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 in  
• minor cuts • scrapes • burns

**Restrictions on Use:** **Warnings** 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 persists or gets worse
- 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:** Antibiotic

**FORMULA:**

Bacitracin:	$C_{66}H_{103}N_{17}O_{16}S$	M.W. 1422.69
Neomycin:	$C_{23}H_{46}N_6O_{13}$	M.W. 614.65
Polymyxin B:	$C_{56}H_{100}N_{16}O_{17}S$	M.W. 1301.56

### SECTION 2: HAZARD(S) IDENTIFICATION

#### Signs and Symptoms of Exposure:

**Overexposure Effects:** Allergy, kidney and liver impairment, dizziness, incoordination, sensory loss, deafness, nausea, vomiting and diarrhea.

**Chronic effects:** May cause allergic reactions in susceptible.

**Inhalation:** Not likely due to the physical state of the product.

**Eyes:** Use only specified ophthalmic ointment in eyes. Topical ointment will cause eye irritation.

**Skin:** Non-toxic under standard application

**Ingestion:** May cause kidney, liver and gastrointestinal impairment; may induce dizziness, incoordination, sensory loss and deafness.

### SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient: Bacitracin (CAS# 1405-87-4)  
Neomycin Sulfate (CAS#1405-10-3)  
Polymyxin B (CAS#1405-20-5)

Inactive Ingredients: White petrolatum

### SECTION 4: FIRST-AID MEASURES

Inhalation N/A

Ingestion Induce vomiting. Do not give anything to an unconscious person.

Skin Contact Wash with soap and water.

Eye Contact Flush eyes with copious amounts of water for at least 15 minutes (non-ophthalmic form only).

General Precautions N/A

### SECTION 5: FIRE-FIGHTING MEASURES

**FLASH POINT (Closed Cup):** 390°F, 199°C (97% Petroleum Concentration).

**FLAMMABLE LIMITS in Air by Volume:**

**Upper Explosion Limit (UEL%):** Not Determined.

**Lower Explosion Limit (LEL%):** Not Determined.

**AUTO-IGNITION TEMPERATURE (°F):** Not Determined.

**EXTINGUISHING MEDIA:** Alcohol foam, dry chemical and carbon dioxide.

**SPECIAL FIRE FIGHTING PROCEDURES:** Wear full protective clothing.

**UNUSUAL FIRE AND EXPLOSION HAZARDS:** May emit toxic fumes.

### SECTION 6: ACCIDENTAL RELEASE MEASURES

Assure slippery conditions are nullified. Add sand or dirt. Scoop up and remove. Dispose in accordance with Federal, State and local regulations.

## SECTION 7: HANDLING AND STORAGE

Keep containers closed when not in use. Do not handle or store near heat, flame or oxidizers.

Wash thoroughly after handling. Use normal hygiene to protect hands, eyes and skin. Use general ventilation to protect your lungs. Do not wear contaminated clothing until thoroughly laundered.

Store at room temperature.

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

ENGINEERING CONTROLS: N/A

PERSONAL PROTECTION:

Respiratory: General ventilation

Eye: Normal hygiene

Clothing: Normal hygiene

Gloves: Normal hygiene

Other Protective Clothing or Equipment: As needed to protect repeated/prolonged contact.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

<b>BOILING POINT:</b>	200°C (392°F)
<b>FREEZING/ MELTING POINT:</b>	58°C (136°F.)
<b>pH:</b>	N/A
<b>Refractive Index at 20°C:</b>	Not indicated.
<b>Viscosity CPS @ 25°C:</b>	Not indicated.
<b>Congealing Point °F:</b>	Not indicated.
<b>Solubility in Water:</b>	Insoluble.
<b>Solubility in Alcohol:</b>	Practically insoluble.
<b>Solubility in Oil:</b>	Soluble.
<b>Solubility in Other</b>	Most polar solvents.
<b>Specific Gravity (H<sub>2</sub>O =1)</b>	0.85 @ 60°C.
<b>% Volatile by Volume</b>	0
<b>Appearance and odor:</b>	A pale, yellow ointment that is odorless.
<b>Evaporation Rate:</b>	0.00 (ether reference).
<b>Vapor pressure (mmHg @ 20° C)</b>	<1 mm.
<b>Vapor density (Air=1)</b>	Not indicated.

## SECTION 10: STABILITY AND REACTIVITY

<b>CHEMICAL STABILITY:</b>	Stable.
<b>HAZARDOUS POLYMERIZATION:</b>	Should not occur.
<b>CONDITIONS TO AVOID:</b>	Not found.
<b>INCOMPATILITY (Material to Avoid):</b>	Extreme heat, sparks, open flame, oxidizers, strong acids and alkalis.
<b>HAZARDOUS POLYMERIZATION:</b>	Should not occur.
<b>HAZARDOUS DECOMPOSITION PRODUCTS:</b>	May give off fumes of carbon monoxide and carbon dioxide.

## SECTION 11: TOXICOLOGICAL INFORMATION

Listed as a Carcinogen:

NTP:	No
IARC:	No
OSHA:	No
Other:	N/A

## SECTION 12: ECOLOGICAL INFORMATION

**Ecotoxicity:** Not expected to be harmful to aquatic organisms.

**Persistence and degradability:** Not available.

**Bioaccumulative Potential:** Not available.

**Mobility in Soil:** Not available.

**Other Adverse Effects:** No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

## SECTION 13: DISPOSAL CONSIDERATIONS

Assure conformity with appliance disposal regulations. Dispose of absorbed material at approved incineration or chemical landfill waste disposal site.

## SECTION 14: TRANSPORT INFORMATION

<b>DOT:</b>	Not regulated as dangerous goods.
<b>IATA:</b>	Not regulated as dangerous goods.
<b>IMDG:</b>	Not regulated as dangerous goods.
<b>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code:</b> Not available.	

## SECTION 15: REGULATORY INFORMATION

**US Federal Regulations:** All components are on the U.S. EPA TSCA Inventory List.  
**TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D):** Not regulated.  
**SARA 304 Emergency release notification:** Not regulated.  
**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050):** Not listed.

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

**Hazard categories:** Delayed Hazard - No  
Fire Hazard - No  
Pressure Hazard - No  
Reactivity Hazard - No

**SARA 302 Extremely Hazardous Substance:** Not listed.

### Other Federal Regulations

**Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List:** Not regulated.  
**Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130):** Not regulated.  
**Safe Drinking Water Act (SDWA):** Not regulated.

### US State Regulations

**US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100):** Not listed.

**US. California Proposition 65:** Not applicable.

## 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:** May 2015

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