SAFETY DATA SHEET

SECTION 1: IDENTIFICATION

PRODUCT NAME: **Double Antibiotic Ointment (Bacitracin Zinc and Polymyxin B Sulfate)** **PRODUCT No.:** 51672-2044

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

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) 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

FLAMMABLE LIMITS in Air by Volume:	
Upper Explosion Limit (UEL%):	Not Determined.
Lower Explosion Limit (LEL%):	Not Determined.
AUTO-IGNITION TEMPERATURE (^{o}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

pH:	N/A
Refractive Index at 20^{o}C:	Not indicated.
Viscosity CPS @ 25^{o}C:	Not indicated.
Congealing Point ^{o}F:	Not indicated.
Solubility in Water:	Insoluble.
Solubility in Alcohol:	Practically insoluble.
Solubility in Oil:	Soluble.
% Volatile by Volume	0
Evaporation Rate:	0.00 (ether reference).
Vapor pressure (mmHg @ 20^{o} C)	<1 mm.
Vapor density (Air=1)	Not indicated.

SECTION 10: STABILITY AND REACTIVITY

CHEMICAL STABILITY:	Stable.
HAZARDOUS POLYMERIZATION:	Should not occur.
CONDITIONS TO AVOID:	Not found.
INCOMPATILITY (Material to Avoid):	Extreme heat, sparks, open flame, oxidizers, strong acids and alkalis.
HAZARDOUS POLYMERIZATION:	Should not occur.
HAZARDOUS DECOMPOSITION PRODUCTS:	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

DOT: Not regulated as dangerous goods.
IATA: Not regulated as dangerous goods.
IMDG: Not regulated as dangerous goods.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: 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: December 2015

D I S C L A I M E R

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