



SAFETY DATA SHEET

Trade Name: Triple Antibiotic Ointment

Prepared Date: 6/16/2022

1. Product and Company Identification

Product Name: Triple Antibiotic Ointment
Recommended Use: External use medicinal product
Synonyms: Triple Antibiotic Ointment

Manufacturer/Supplier

Natureplex, LLC
11085 Airport Road
Olive Branch, MS 38654-0221
662-874-1370 (Monday – Friday, 8:00 a.m. – 5:00 p.m. CST)

Emergency Telephone Number: 1-866-323-0107

CHEMTREC: 1-800-424-9300 (Transportation Spill Response 24 hours)

2. Hazard Identification

Classified hazards

Respiratory sensitization: Category 1
Skin sensitization: Category 1
Acute toxicity, Oral: Category 4

GHS Label elements including precautionary statements

Signal word: Danger, Warning

Hazard Statements

H317 May cause an allergic skin reaction
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H302 Harmful if swallowed



Precautionary Statements – Prevention

P264 Wash skin thoroughly after handling
P270 Do not eat, drink or smoke when using this product
P301 + P312 If swallowed call a poison center or doctor/physician if you feel unwell.
P330 Rinse mouth
P201 Wash skin thoroughly after handling
P501 Dispose of contents/container to an approved waste disposal plant
P261 Avoid breathing dust, fume/gas/mist vapor spray
P272 Contaminated work clothing should not be allowed out of the workplace
P280 Wear protective gloves



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P285 In case of inadequate ventilation wear respiratory protection
P302 + P352 If on skin wash with plenty of soap and water
P304 + P341 If inhaled: if breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing
P333 + P313 If skin irritation or rash occurs, get medical advised attention
P342 + P311 If experiencing respiratory symptoms, call poison center or doctor
P363 Wash contaminated clothing before reuse
P501 Dispose of contents container to an approved waste disposal plant

Patients/Consumers: Please refer to the product label for appropriate consumer-specific information about this product when used according to the directions. Pharmaceutical Agent – Handling of this product in its final form presents minimal occupational exposure risk.

This product is a drug as defined by the U.S. Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.). It is in final form for direct use by consumers. Therefore it is exempt from the U.S. 2012 Hazard Communication Standard, as defined in the 29 CFR 1910.1200(b)(5)(iii)

3. Composition/Information on Ingredients

Chemical Name	CAS Number	Percent
Petrolatum*	8009-03-8	Trade Secret
Neomycin Sulfate USP*	1405-10-3	Trade Secret
Bacitracin Zinc USP*	1405-89-6	Trade Secret
Polymyxin B Sulfate*	1405-20-5	Trade Secret

*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

4. First Aid Measures

Skin contact

Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.

Eye contact

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

Ingestion

If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center.



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Most important symptoms/effects, acute and delayed

Accidental exposure or contact might produce symptoms of hypersensitivity (such as skin rash, hives, itching).

Indication of immediate medical attention and special treatment needed

No specific antidotes are recommended. Treat per locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center.

5. Fire Fighting Measures

Suitable extinguishing agents:

Use carbon dioxide, dry chemical, foam.

Fire and/or Explosion Hazards:

No data available.

Special Fire Fighting Procedures:

Water may be ineffective but can be used to cool containers exposed to heat or flame. Caution should be exercised when using water or foam as frothing may occur, especially if sprayed into containers of hot, burning liquid.

UNUSUAL FIRE AND EXPLOSIVE HAZARDS:

Dense smoke may be generated while burning. Carbon monoxide, carbon dioxide, and other oxides may be generated as products of combustion.

6. Accidental Release Measures

Steps to Take in Case Product Is Released or Spilled:

Small spills: Absorb with appropriate inert material such as sand, clay, etc. and dispose of into a suitable container.

Large Spills: May be picked up using vacuum pumps, shovels, buckets, or other means and placed in drums or other suitable containers. **Do not allow spill to enter sewer or waterways**

7. Handling and Storage

Precautions for safe handling: Avoid breathing fume/mist/vapors/spray.

Handling: No special technical protective measures required.

Storage: Store according to labeled instructions.

No special restrictions on storage with other products.



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8. Exposure Controls/Personal Protection

Exposure Limits:

Engineering controls: Not Required.

Recommended personal protective measures (PPE): Use personal protective equipment as required.

Skin Protection: Chemical resistant gloves, footwear and protective clothing appropriate for the risk of exposure.

Face Protection: Wear goggles/face shield. Wear a full-face respirator, if needed. Wear safety glasses with side shields and a face shield.

9. Physical and Chemical Properties

Appearance

Physical state: Semi-Solid Liquid

Form: Ointment

Color: Cloudy and Translucent

Odor: Characteristic scent

Odor threshold: NDA

Specific gravity: 0.8 to 1.0

Viscosity: $\geq 100,000$ cps

pH: 5.5-7.5

Melting point/freezing point: NDA

Initial boiling point and boiling range: NDA

Flash point: NDA

Evaporation rate: NDA

Flammability (solid, gas): NDA

Upper/lower flammability or explosive limits

Flammability limit - lower (%): NDA

Flammability limit - upper (%): NDA

Explosive limit - lower (%): NDA

Explosive limit - upper (%): NDA

Vapor pressure: NDA

Vapor density: NDA

Relative density: NDA

Solubility (water): NDA

Partition coefficient (n-octanol/water): NDA

Auto-ignition temperature: NDA

Decomposition temperature: NDA



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10. Stability and Reactivity

Reactivity: The product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability: Material is stable under normal conditions. Possibility of hazardous reactions No dangerous reaction known under conditions of normal use.

Conditions to avoid: Keep away from heat, sparks and open flame. Contact with incompatible materials.

Incompatible materials: Strong oxidizing agents.

Hazardous decomposition products: Hazardous decomposition products formed under fire conditions – carbon oxides, nitrogen oxides, Sulphur oxides

11. Toxicological Information

Information on Toxicological Effects:

Information on likely routes of exposure

Inhalation: Specific test data for the substance or mixture is not available. May cause irritation.

Eye Contact: Specific test data for the substance or mixture is not available. May cause eye irritation with susceptible persons.

Skin Contact: Specific test data for the substance or mixture is not available. May be harmful in contact with skin. Causes mild skin irritation.

Ingestion: Specific test data for the substance or mixture is not available. May cause gastrointestinal discomfort if consumed in large amounts.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms: May cause skin irritation in susceptible persons. May cause redness and tearing of the eyes.

Acute toxicity

Numerical measures of toxicity

The following values are calculated based on chapter 3.1 of the GHS document

ATEmix (dermal) 3,640.80 mg/kg



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Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Petrolatum		=3600 mg/kg (rabbit)	

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation:	May cause mild to moderate irritation.
Serious eye damage/eye irritation:	May cause mild to moderate irritation.
Respiratory or skin sensitization:	Not expected to be sensitizer.
Germ on cell mutagenicity:	Based available data, the classification criteria are not met.
Carcinogenicity:	No information available.
Reproductive toxicity:	Based on available data, the classification criteria are not met. No information available.
STOT - single exposure:	No information available.
STOT - repeated exposure	No information available
Aspiration hazard:	No information available.

12. Ecological Information

Toxicity: NDA

The environmental impact of this product has not been fully investigated.

Aquatic toxicity effects: Substance possibly harmful for the aquatic environment, due to antibiotic properties

Bioaccumulative potential: NDA

13. Disposal Considerations

Waste Treatment Methods

Disposal instructions: Waste disposal must be in accordance with appropriate local, Federal, State, and international regulations.

14. Transport Information

US DOT Information : Not regulated as hazardous material.

UN Number : NDA

UN proper shipping name: NDA

Transport hazard class(es): NDA

Packing Group: NDA

Environmental hazards: NDA

Special precautions for users: none specified

Transport in bulk: NDA



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15. Regulatory Information

U.S. Federal Regulations: None

TOSCA : None

CERLA Hazardous Substance List : None

Superfund Amendments and Reauthorization Act of 1986 (SARA): This product is FDA regulated and is not subject to SARA.

OSHA Specifically Regulated Substances: None present or none present in regulated quantities.

16. Other Information

Last Revision: 16 June 2022

Disclaimer: The information herein is based on data considered to be accurate as of the date of preparation of this safety data sheet. However, no warranty or representation, expressed or implied, is made as to the accuracy or completeness of the foregoing data and safety information. The user assumes all liability for any damage or injury resulting from abnormal use, from any failure to adhere to recommended practices or from any hazards inherent in the nature of the product.

Key to abbreviations

NDA = no data available

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