

# SAFETY DATA SHEET

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

### 1.1 Product identifiers

Product name : Antibiotic Ointment

### 1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified uses : Pharmaceutical

### 1.3 Details of the supplier of the safety data sheet

Company : Trifecta Pharmaceuticals USA, LLC.  
2701 NW 27<sup>th</sup> Ave. Ste. 2923  
Pompano Beach, FL. 33069  
USA

Telephone : (888) 296-9067

Fax : (888) 878-3609

### 1.4 Emergency telephone number

Emergency Phone # : (888) 296-9067

## SECTION 2: Hazards identification

### 2.1 Classification of the substance or mixture

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

### 2.2 Label elements

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

### 2.3 Other hazards - none

## SECTION 3: Composition/information on ingredients

### 3.1 Substances

Chemical Name	CAS Number	Formula	Molecular Weight
Neomycin sulfate	1405-10-3	$C_{23}H_{46}N_6O_{13} \cdot 3H_2SO_4 \cdot xH_2O$	908.88
Mineral oil	8042-47-5	N/A	N/A
White petrolatum	8009-03-8	C <sub>15</sub> H <sub>15</sub> N	209.2863

## SECTION 4: First aid measures

**Ingestion:** If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

**Eye Contact:** Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

**Skin Contact:** Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as

necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

**Inhalation:** Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

**Protection of First-Aiders:** Use personal protective equipment (see section 8).

**Signs and Symptoms:** Ointment is intended for topical use only under guidance of a physician. Ointment is not considered hazardous under normal conditions.

**Medical Conditions Aggravated by Exposure:** See package insert for detailed information.

**Other Health Warnings:** For external use only. Avoid contact with eyes or lips.

**Notes to Physician:** Not available.

## **SECTION 5: Firefighting measures**

### **5.1 Extinguishing media**

#### **Suitable extinguishing media**

Use water spray, dry chemical or carbon dioxide.

### **5.2 Special hazards arising from the substance or mixture**

Carbon oxides, carbon dioxide, Nitrogen oxides (NO<sub>x</sub>), and Hydrogen chloride.

### **5.3 Advice for firefighters**

Wear self-contained breathing apparatus for firefighting if necessary.

### **5.4 Further information**

No data available

## **SECTION 6: Accidental release measures**

### **6.1 Personal precautions, protective equipment and emergency procedures**

Use personal protective equipment. Ensure adequate ventilation.

For personal protection see section 8.

### **6.2 Environmental precautions**

Do not let product enter drains.

### **6.3 Methods and materials for containment and cleaning up**

Soak up with inert absorbent material and dispose of as hazardous waste. Keep in suitable, closed containers for disposal.

### **6.4 Reference to other sections**

For disposal see section 13.

## **SECTION 7: Handling and storage**

### **7.1 Precautions for safe handling**

Normal measures for preventive fire protection.

For precautions see section 2.2.

### **7.2 Conditions for safe storage, including any incompatibilities**

Keep container tightly closed in a dry and well-ventilated place. Containers which are opened must be carefully resealed and kept upright to prevent leakage.

### **7.3 Specific end use(s)**

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

## **SECTION 8: Exposure controls/personal protection**

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## 8.1 Control parameters

## 8.2 Exposure controls

### Appropriate engineering controls

General industrial hygiene practice.

### Personal protective equipment

#### Eye/face protection

Safety glasses with side-shields conforming to EN166 Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

#### Skin protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product.

Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices.

Wash and dry hands.

The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

#### Body Protection

Impervious clothing, The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

#### Respiratory protection

Respiratory protection not required. For nuisance exposures use type OV/AG (US) or type ABEK (EU EN 14387) respirator cartridges. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

#### Control of environmental exposure

Do not let product enter drains.

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

a) Appearance	White ointment
b) Odor	Odor aromatic
c) Odor Threshold	No data available
d) pH	No data available
e) Melting point/freezing point	No data available
f) Initial boiling point and boiling range	No data available
g) Flash point	No data available
h) Evaporation rate	No data available
i) Flammability (solid, gas)	No data available
j) Upper/lower flammability or explosive limits	No data available
k) Vapour pressure	No data available
l) Vapour density	No data available
m) Relative density	No data available
n) Water solubility	No data available
o) Partition coefficient: octanol/water	No data available
p) Auto-ignition temperature	No data available
q) Decomposition temperature	No data available

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r) Viscosity	No data available
s) Explosive properties	No data available
t) Oxidizing properties	No data available

## 9.2 Other safety information

No data available

## SECTION 10: Stability and reactivity

### 10.1 Reactivity

No data available

### 10.2 Chemical stability

Stable under recommended storage conditions.

### 10.3 Possibility of hazardous reactions

No data available

### 10.4 Conditions to avoid

No data available

### 10.5 Incompatible materials

Strong oxidizing agents

### 10.6 Hazardous decomposition products

Hazardous decomposition products formed under fire conditions. - Carbon oxides, Sodium oxides

Other decomposition products - No data available

In the event of fire: see section 5

## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

#### Acute toxicity

No data available

#### Skin corrosion/irritation

No data available

#### Serious eye damage/eye irritation

No data available

#### Respiratory or skin sensitisation

No data available

#### Germ cell mutagenicity

No data available

#### Carcinogenicity

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

#### Reproductive toxicity

No data available

#### Specific target organ toxicity - single exposure

No data available

#### Specific target organ toxicity - repeated exposure

No data available

#### Aspiration hazard

No data available

#### Additional Information

RTECS: Not available

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

## **SECTION 12: Ecological information**

### **12.1 Toxicity**

No data available

### **12.2 Persistence and degradability**

No data available

### **12.3 Bioaccumulative potential**

No data available

### **12.4 Mobility in soil**

No data available

### **12.5 Results of PBT and vPvB assessment**

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted

### **12.6 Other adverse effects**

No data available

## **SECTION 13: Disposal considerations**

### **13.1 Waste treatment methods**

#### **Product**

Offer surplus and non-recyclable solutions to a licensed disposal company.

#### **Contaminated packaging**

Dispose of as unused product.

## **SECTION 14: Transport information**

### **14.1 UN number**

ADR/RID: -      IMDG: -      IATA: -

### **14.2 UN proper shipping name**

ADR/RID: Not dangerous goods

IMDG: Not dangerous goods

IATA: Not dangerous goods

### **14.3 Transport hazard class(es)**

ADR/RID: -      IMDG: -      IATA: -

### **14.4 Packaging group**

ADR/RID: -      IMDG: -      IATA: -

### **14.5 Environmental hazards**

ADR/RID: no      IMDG Marine pollutant: no      IATA: no

### **14.6 Special precautions for user**

No data available

## **SECTION 15: Regulatory information**

### **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

### **15.2 Chemical safety assessment**

For this product a chemical safety assessment was not carried out

## **SECTION 16: Other information**

**Further information**

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product.