

SAFETY DATA SHEETS

This SDS packet was issued with item:

078949209

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

078820271 078927512 078929556



Safety Data Sheet

Section 1: Identification

Product identifier

Product Name • **Neomycin and Polymyxin B Sulfates and Bacitracin Zinc Ophthalmic Ointment USP**

Product Code • AB03534; Core No. 035; NDC 24208--0780-55

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

Recommended use • Finished Pharmaceutical Product; Indicated for the topical treatment of superficial infections of the external eye and its adnexa caused by susceptible bacteria.

Restrictions on use • Refer to the product insert and/or prescribing information for restrictions on use and contraindications.

Details of the supplier of the safety data sheet

Manufacturer • Bausch & Lomb
1400 North Goodman Street
Rochester, NY 14609
United States
bausch.com

Telephone (General) • 1-800-553-5340

Emergency telephone number

Manufacturer • 1-800-535-5053

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to consumer use of the product.

Section 2: Hazard Identification

UN GHS

According to: UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Classification of the substance or mixture

UN GHS • Skin Sensitization 1B
Reproductive Toxicity 2

Label elements

UN GHS

WARNING



Hazard statements • May cause an allergic skin reaction
Suspected of damaging fertility or the unborn child.

Precautionary statements

Prevention ● Wash thoroughly after handling.

Response ● IF ON SKIN: Wash with plenty of soap and water.
If skin irritation or rash occurs: Get medical advice/attention.
Wash contaminated clothing before reuse.

Storage/Disposal ● Keep tightly closed. Store at room temperature 15-25°C (59-77°F), to maintain product integrity. Use before date marked on carton and/or container.

Other hazards

UN GHS ● No data available

Section 3 - Composition/Information on Ingredients**Substances**

- Material does not meet the criteria of a substance according to United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Mixtures

| Composition | | | |
|---------------------|-----------------------------------|------------|---|
| Chemical Name | Identifiers | % | Classifications According to Regulation/Directive |
| Bacitracin zinc | CAS:1405-89-6 EINECS:215-787-8 | < 5% | UN GHS: NDA |
| Neomycin sulfate | CAS:1405-10-3 EINECS:215-773-1 | 0.6% | UN GHS: Skin Irrit. 2; Eye Irrit. 2A |
| Polymyxin B sulfate | CAS:1405-20-5 EINECS:215-774-7 | < 1% | UN GHS: NDA |
| White mineral oil | CAS:8042-47-5 EINECS:232-455-8 | 10% TO 20% | UN GHS: Skin Irrit. 2; Eye Irrit. 2A |
| White petrolatum | CAS:8009-03-8 EINECS:232-373-2 | 85% | UN GHS: NDA |

The exact percentage of composition has been withheld as a trade secret.

Section 4: First-Aid Measures**Description of first aid measures****Inhalation**

- No inhalation exposure expected with this formulation under normal conditions of use. If signs/symptoms develop, get medical attention.

Skin

- Flush with fresh water if contact with skin or eyes. If skin irritation occurs: Get medical advice/attention.

Eye

- For accidental and non-therapeutic applications, flush eyes with copious amounts of water for at least 15 minutes. Get medical attention. If eye irritation persists: Get medical advice/attention.

Ingestion

- No specific treatment is necessary since this material is not likely to be hazardous by ingestion. If large quantities are accidentally ingested (greater than a tablespoon), get medical attention immediately.

Most important symptoms and effects, both acute and delayed

- No data available

Indication of any immediate medical attention and special treatment needed

Section 5: Fire-Fighting Measures

Extinguishing media

- Suitable Extinguishing Media**
- SMALL FIRES: Dry chemical, CO₂, water spray or regular foam.
 - LARGE FIRE: Water spray, fog or regular foam.

- Unsuitable Extinguishing Media**
- No data available

Special hazards arising from the substance or mixture

- Unusual Fire and Explosion Hazards**
- None known.

- Hazardous Combustion Products**
- None known.

Advice for firefighters

- Structural firefighters' protective clothing will only provide limited protection. Wear positive pressure self-contained breathing apparatus (SCBA).

Section 6 - Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

- Personal Precautions**
- No special controls or personal protection required under conditions of intended use. In the event of bulk spills, wear suitable protective eyewear, clothing, protective boots and protective gloves. Evacuate immediate area. Ensure adequate ventilation. Refer to Section 8.

- Emergency Procedures**
- Keep unauthorized personnel away. Ventilate closed spaces before entering. Stop leak if you can do it without risk.

Environmental precautions

- Prevent spilled material from entering storm sewers or drains, waterways, and contact with soil.

Methods and material for containment and cleaning up

- Containment/Clean-up Measures**
- Contain spilled product. For small spills, add suitable absorbent material. Scoop up and place in an appropriate liquid-tight container equipped with a tight cover for disposal. For large spills, dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate, liquid-tight container equipped with a tight cover for disposal. Dispose of in accordance with Section 13.

Section 7 - Handling and Storage

Precautions for safe handling

- Handling**
- No special handling is required. Refer to Section 8. Use only in accordance with product literature. Use only in accordance with product literature.

Conditions for safe storage, including any incompatibilities

- Storage**
- Keep tightly closed. Store at room temperature 15-25°C (59-77°F), to maintain product integrity. Use before date marked on carton and/or container.

- Incompatible Materials or Ignition Sources**
- None specified.

Section 8 - Exposure Controls/Personal Protection

Control parameters

- Exposure Limits/Guidelines**
- Refer to the occupational exposure limits / guidelines for the individual product components.

Exposure controls

Engineering Measures/Controls

- Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protective Equipment

Respiratory

- In the event of a bulk spill, and where risk assessment shows that air-purifying respirators are appropriate, a NIOSH (US) or CEN (EU) -certified air-purifying respirator equipped with HEPA cartridges may be permissible under certain circumstances where airborne concentrations are expected to exceed exposure limits, when adequate oxygen is present and as a backup to engineering controls. Use a positive pressure air-supplied respirator if there is any potential for an uncontrolled release or any other circumstances where air purifying respirators may not provide adequate protection.

Eye/Face

- Wear protective eyewear (goggles, face shield, or safety glasses) when handling bulk product before closed in final packaging. In the event of a spill, appropriate eye protection should be worn.

Hands

- No special personal protection required under conditions of intended use. In the event of a bulk spill, wear rubber or nitrile gloves.

Skin/Body

- No special personal protection required under conditions of intended use. In the event of a bulk spill, wear appropriate protective clothing.

General Industrial Hygiene Considerations

- Wash thoroughly after handling.

Environmental Exposure Controls

- No data available

Section 9 - Physical and Chemical Properties

Information on Physical and Chemical Properties

| Material Description | | | |
|---------------------------------------|-------------------------|-------------------------------------|---|
| Physical Form | Liquid ointment | Appearance/Description | Translucent, off white to yellowish ointment. |
| Color | off-white to yellowish. | Particulate Size | Not relevant |
| General Properties | | | |
| Boiling Point | Not relevant | Melting Point | Not relevant |
| Decomposition Temperature | Not relevant | Heat of Decomposition | Not relevant |
| pH | Not relevant | Specific Gravity/Relative Density | Not relevant |
| Density | Not relevant | Water Solubility | Not relevant |
| Viscosity | Not relevant | | |
| Flammability | | | |
| Flash Point | Not relevant | Heat of Combustion (ΔH_c) | Not relevant |
| Flammability (solid, gas) | Not relevant | | |
| Environmental | | | |
| Half-Life | Not relevant | Octanol/Water Partition coefficient | Not relevant |
| Coefficient of water/oil distribution | Not relevant | Bioaccumulation Factor | Not relevant |
| Bioconcentration Factor | Not relevant | Biochemical Oxygen Demand BOD/BOD5 | Not relevant |
| Chemical Oxygen Demand | Not relevant | Persistence | Not relevant |

Degradation

Not relevant

Section 10: Stability and Reactivity

Reactivity

- No dangerous reaction known under conditions of normal use.

Chemical stability

- Stable under normal temperatures and pressures.

Possibility of hazardous reactions

- No data available

Conditions to avoid

- Extreme heat or cold. Do not freeze.

Incompatible materials

- No data available

Hazardous decomposition products

- No data available

Section 11 - Toxicological Information

Information on toxicological effects

| Components | | |
|----------------------------|-----------|--|
| Polymyxin B sulfate (< 1%) | 1405-20-5 | Acute Toxicity: Ingestion/Oral-Mouse LD50 • 790 mg/kg |

| GHS Properties | Classification |
|-------------------------------|--|
| Acute toxicity | UN GHS • Classification criteria not met |
| Aspiration Hazard | UN GHS • Classification criteria not met |
| Carcinogenicity | UN GHS • Classification criteria not met |
| Germ Cell Mutagenicity | UN GHS • Classification criteria not met |
| Skin corrosion/Irritation | UN GHS • Classification criteria not met |
| Skin sensitization | UN GHS • Skin Sensitizer 1B |
| STOT-RE | UN GHS • Classification criteria not met |
| STOT-SE | UN GHS • Classification criteria not met |
| Toxicity for Reproduction | UN GHS • Toxic to Reproduction 2 |
| Respiratory sensitization | UN GHS • Classification criteria not met |
| Serious eye damage/Irritation | UN GHS • Classification criteria not met |

Potential Health Effects

Inhalation

Acute (Immediate)

- Under normal conditions of use, no health effects are expected.

Chronic (Delayed)

- No data available.

Skin

- Acute (Immediate)**
- Not expected to cause skin irritation.
- Chronic (Delayed)**
- Repeated and prolonged exposure may cause sensitization.
- Eye**
- Acute (Immediate)**
- Non-irritating to the eyes when used as directed.
- Chronic (Delayed)**
- Refer to the product insert and/or product prescribing information for comprehensive information regarding adverse reactions and other important symptoms and effects. Under normal conditions of use, no health effects are expected.
- Ingestion**
- Acute (Immediate)**
- Not expected to be an exposure route. However, may cause gastric and intestinal irritation if ingested.
- Chronic (Delayed)**
- No data available.
- Reproductive Effects**
- Pregnancy Category C. Corticosteroids have been found to be teratogenic in rabbits when applied topically at concentrations of 0.5% on days 6 to 18 of gestation and in mice when applied topically at a concentration of 15% on days 10 to 13 of gestation. There are no adequate and well-controlled studies in pregnant women. Polymyxin B has been reported to impair the motility of equine sperm, but its effects on male or female fertility are unknown.

Section 12 - Ecological Information

Toxicity

- This material has not been tested for environmental effects.

Persistence and degradability

- No data available.

Bioaccumulative potential

- No data available

Mobility in Soil

- No data available

Other adverse effects

Section 13 - Disposal Considerations

Waste treatment methods

- Product waste**
- Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.
- Packaging waste**
- Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Section 14 - Transport Information

| | UN number | UN proper shipping name | Transport hazard class (es) | Packing group | Environmental hazards |
|----------|-----------|-------------------------|-----------------------------|---------------|-----------------------|
| DOT | NDA | NDA | NDA | NDA | NDA |
| TDG | NDA | NDA | NDA | NDA | NDA |
| IMO/IMDG | NDA | NDA | NDA | NDA | NDA |
| ADN | NDA | NDA | NDA | NDA | NDA |

| | | | | | |
|-----------|-----|-----|-----|-----|-----|
| ADR/RID | NDA | NDA | NDA | NDA | NDA |
| IATA/ICAO | NDA | NDA | NDA | NDA | NDA |

Special precautions for user • No data available

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code • No data available

Section 15 - Regulatory Information

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

SARA Hazard Classifications • No data available

| Inventory | | | | | |
|---------------------|-----------|------------|-------------|-----------|------|
| Component | CAS | Canada DSL | Canada NDSL | EU EINECS | TSCA |
| White petrolatum | 8009-03-8 | Yes | No | Yes | Yes |
| Polymyxin B sulfate | 1405-20-5 | Yes | No | Yes | No |
| Bacitracin zinc | 1405-89-6 | No | Yes | Yes | Yes |

Canada

Labor

Canada - WHMIS - Classifications of Substances

| | | |
|-----------------------|-----------|---|
| • Polymyxin B sulfate | 1405-20-5 | Not Listed |
| • White petrolatum | 8009-03-8 | Uncontrolled product according to WHMIS classification criteria |
| • Bacitracin zinc | 1405-89-6 | Not Listed |

Europe

Other

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Classification

| | | |
|-----------------------|-----------|-----------------|
| • Polymyxin B sulfate | 1405-20-5 | Not Listed |
| • White petrolatum | 8009-03-8 | Carc.Cat.2; R45 |
| • Bacitracin zinc | 1405-89-6 | Not Listed |

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Labelling

| | | |
|-----------------------|-----------|----------------|
| • Polymyxin B sulfate | 1405-20-5 | Not Listed |
| • White petrolatum | 8009-03-8 | T R:45 S:53-45 |
| • Bacitracin zinc | 1405-89-6 | Not Listed |

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Notes - Substances and Preparations

| | | |
|-----------------------|-----------|------------|
| • Polymyxin B sulfate | 1405-20-5 | Not Listed |
| • White petrolatum | 8009-03-8 | N |
| • Bacitracin zinc | 1405-89-6 | Not Listed |

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Safety Phrases

| | | |
|-----------------------|-----------|------------|
| • Polymyxin B sulfate | 1405-20-5 | Not Listed |
| • White petrolatum | 8009-03-8 | S:53-45 |
| • Bacitracin zinc | 1405-89-6 | Not Listed |

United States

Environment**U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities**

| | | |
|-----------------------|-----------|------------|
| • Polymyxin B sulfate | 1405-20-5 | Not Listed |
| • White petrolatum | 8009-03-8 | Not Listed |
| • Bacitracin zinc | 1405-89-6 | Not Listed |

United States - California**Environment****U.S. - California - Proposition 65 - Carcinogens List**

| | | |
|-----------------------|-----------|------------|
| • Polymyxin B sulfate | 1405-20-5 | Not Listed |
| • White petrolatum | 8009-03-8 | Not Listed |
| • Bacitracin zinc | 1405-89-6 | Not Listed |

U.S. - California - Proposition 65 - Developmental Toxicity

| | | |
|-----------------------|-----------|------------|
| • Polymyxin B sulfate | 1405-20-5 | Not Listed |
| • White petrolatum | 8009-03-8 | Not Listed |
| • Bacitracin zinc | 1405-89-6 | Not Listed |

U.S. - California - Proposition 65 - Reproductive Toxicity - Female

| | | |
|-----------------------|-----------|------------|
| • Polymyxin B sulfate | 1405-20-5 | Not Listed |
| • White petrolatum | 8009-03-8 | Not Listed |
| • Bacitracin zinc | 1405-89-6 | Not Listed |

U.S. - California - Proposition 65 - Reproductive Toxicity - Male

| | | |
|-----------------------|-----------|------------|
| • Polymyxin B sulfate | 1405-20-5 | Not Listed |
| • White petrolatum | 8009-03-8 | Not Listed |
| • Bacitracin zinc | 1405-89-6 | Not Listed |

Section 16 - Other Information**Last Revision Date**

- 14/May/2015

Preparation Date

- 14/May/2015

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