

Safety Data Sheet

Section 1: Identification

Product identifier

Product Name

- **Neomycin and Polymyxin B Sulfates and Dexamethasone Ophthalmic Ointment**

Product Code

- AB04034; Core No. 040; NDC 24208-0795-35

Relevant identified uses of the substance or mixture and uses advised against**Recommended use**

- Finished Pharmaceutical Product; For steroid-responsive inflammatory ocular conditions for which a corticosteroid is indicated and where bacterial infection or a risk of bacterial ocular infection exists.

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 - Infotrac

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.
Store protected from light and heat.

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
Dexamethasone	CAS:50-02-2 EINECS:200-003-9	<= 0.1%	UN GHS: NDA
Lanolin	CAS:8006-54-0 EINECS:232-348-6	1% TO 5%	UN GHS: NDA
Methyparaben	CAS:99-76-3 EINECS:202-785-7	0.05%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A
Mineral oil	CAS:8012-95-1 EINECS:232-384-2	10% TO 15%	UN GHS: NDA
Neomycin, sulfate (salt)	CAS:1405-10-3 EINECS:215-773-1	<= 1%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A
Polymyxin B sulfate	CAS:1405-20-5 EINECS:215-774-7	<= 1%	UN GHS: NDA
Propylparaben	CAS:94-13-3 EINECS:202-307-7	0.01%	UN GHS: NDA
White Petrolatum	CAS:8009-03-8 EINECS:232-373-2	>= 80%	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.

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. Protect from light.
- 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 Limits/Guidelines					
	Result	ACGIH	Canada Quebec	NIOSH	OSHA
Mineral oil (8012-95-1)	STELs	Not established	10 mg/m3 STEV (mist)	10 mg/m3 STEL	Not established
	TWAs	5 mg/m3 TWA (excluding metal working fluids, highly & severely refined, inhalable fraction)	5 mg/m3 TWAEV (mist)	5 mg/m3 TWA	5 mg/m3 TWA

Exposure Control Notations

ACGIH

•Mineral oil (8012-95-1): **Carcinogens:** (A4 - Not Classifiable as a Human Carcinogen (highly and severely refined); A2 - Suspected Human Carcinogen (poorly and mildly refined))

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	smooth, cloudy white ointment.
Color	White	Odor	No odor.
Odor Threshold	No data available		
General Properties			
Boiling Point	No data available	Melting Point	No data available
Decomposition Temperature	No data available	pH	No data available
Specific Gravity/Relative Density	No data available	Water Solubility	Immiscible
Viscosity	Not relevant		
Volatility			
Vapor Pressure	Not relevant	Vapor Density	Not relevant
Evaporation Rate	Not relevant		
Flammability			
Flash Point	Not relevant	UEL	Not relevant
LEL	Not relevant	Autoignition	Not relevant
Flame Height	Not relevant	Flammability (solid, gas)	Not relevant
Environmental			
Octanol/Water Partition coefficient	No data available		

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. Protect from light and heat.

Incompatible materials

- No data available

Hazardous decomposition products

- No data available

Section 11 - Toxicological Information

Information on toxicological effects

Components		
Dexamethasone (<= 0.1%)	50-02-2	Acute Toxicity: Ingestion/Oral-Rat LD50 • >3 g/kg
Neomycin, sulfate (salt) (<= 1%)	1405-10-3	Acute Toxicity: Ingestion/Oral-Mouse LD50 • >8 g/kg
Polymyxin B sulfate (<= 1%)	1405-20-5	Acute Toxicity: Ingestion/Oral-Mouse LD50 • 790 mg/kg
Mineral oil (10% TO 15%)	8012-95-1	Acute Toxicity: Ingestion/Oral-Rat LD50 • >24 g/kg; <i>Gastrointestinal:Hypermotility, diarrhea</i>
White Petrolatum (>= 80%)	8009-03-8	Acute Toxicity: Intraperitoneal-Mouse LD50 • >50 g/kg

Methylparaben (0.05%)	99-76-3	Acute Toxicity: Ingestion/Oral-Rat LD50 • 2100 mg/kg
Propylparaben (0.01%)	94-13-3	Acute Toxicity: Ingestion/Oral-Mouse LD50 • 6332 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 irritation.

Eye

- Acute (Immediate)**
 - May cause irritation.
- 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

- There are no adequate and well-controlled studies in humans. 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	Not regulated	NDA	NDA	NDA
TDG	NDA	Not regulated	NDA	NDA	NDA
IMO/IMDG	NDA	Not regulated	NDA	NDA	NDA
IATA/ICAO	NDA	Not regulated	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
Methylparaben	99-76-3	Yes	No	Yes	Yes
Propylparaben	94-13-3	Yes	No	Yes	Yes
Lanolin	8006-54-0	Yes	No	Yes	Yes
Mineral oil	8012-95-1	Yes	No	Yes	Yes
Neomycin, sulfate (salt)	1405-10-3	Yes	No	Yes	Yes
White Petrolatum	8009-03-8	Yes	No	Yes	Yes
Polymyxin B sulfate	1405-20-5	Yes	No	Yes	No
Dexamethasone	50-02-2	No	Yes	Yes	Yes

Canada

Labor

Canada - WHMIS - Classifications of Substances

• Methyparaben	99-76-3	Not Listed
• Propylparaben	94-13-3	Not Listed
• Neomycin, sulfate (salt)	1405-10-3	D2B
• Polymyxin B sulfate	1405-20-5	Not Listed
		Uncontrolled product according to WHMIS classification criteria (anhydrous)
• Lanolin	8006-54-0	
		Uncontrolled product according to WHMIS classification criteria
• White Petrolatum	8009-03-8	
		Not Listed
• Dexamethasone	50-02-2	
		Uncontrolled product according to WHMIS classification criteria
• Mineral oil	8012-95-1	

Canada - WHMIS - Ingredient Disclosure List

• Methyparaben	99-76-3	Not Listed
• Propylparaben	94-13-3	Not Listed
• Neomycin, sulfate (salt)	1405-10-3	Not Listed
• Polymyxin B sulfate	1405-20-5	Not Listed
• Lanolin	8006-54-0	Not Listed
• White Petrolatum	8009-03-8	Not Listed
• Dexamethasone	50-02-2	Not Listed
• Mineral oil	8012-95-1	1 %

Europe

Other

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

• Methyparaben	99-76-3	Not Listed
• Propylparaben	94-13-3	Not Listed
• Neomycin, sulfate (salt)	1405-10-3	Not Listed
• Polymyxin B sulfate	1405-20-5	Not Listed
• Lanolin	8006-54-0	Not Listed
• White Petrolatum	8009-03-8	Carc.Cat.2; R45
• Dexamethasone	50-02-2	Not Listed
• Mineral oil	8012-95-1	Not Listed

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

• Methyparaben	99-76-3	Not Listed
• Propylparaben	94-13-3	Not Listed
• Neomycin, sulfate (salt)	1405-10-3	Not Listed
• Polymyxin B sulfate	1405-20-5	Not Listed
• Lanolin	8006-54-0	Not Listed
• White Petrolatum	8009-03-8	T R:45 S:53-45
• Dexamethasone	50-02-2	Not Listed
• Mineral oil	8012-95-1	Not Listed

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

• Methyparaben	99-76-3	Not Listed
• Propylparaben	94-13-3	Not Listed

• Neomycin, sulfate (salt)	1405-10-3	Not Listed
• Polymyxin B sulfate	1405-20-5	Not Listed
• Lanolin	8006-54-0	Not Listed
• White Petrolatum	8009-03-8	N
• Dexamethasone	50-02-2	Not Listed
• Mineral oil	8012-95-1	Not Listed

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

• Methyparaben	99-76-3	Not Listed
• Propylparaben	94-13-3	Not Listed
• Neomycin, sulfate (salt)	1405-10-3	Not Listed
• Polymyxin B sulfate	1405-20-5	Not Listed
• Lanolin	8006-54-0	Not Listed
• White Petrolatum	8009-03-8	S:53-45
• Dexamethasone	50-02-2	Not Listed
• Mineral oil	8012-95-1	Not Listed

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

• Methyparaben	99-76-3	Not Listed
• Propylparaben	94-13-3	Not Listed
• Neomycin, sulfate (salt)	1405-10-3	Not Listed
• Polymyxin B sulfate	1405-20-5	Not Listed
• Lanolin	8006-54-0	Not Listed
• White Petrolatum	8009-03-8	Not Listed
• Dexamethasone	50-02-2	Not Listed
• Mineral oil	8012-95-1	Not Listed

U.S. - EPA - Designated Generic Categories - Polychlorinated Alkanes

• Methyparaben	99-76-3	Not Listed
• Propylparaben	94-13-3	Not Listed
• Neomycin, sulfate (salt)	1405-10-3	Not Listed
• Polymyxin B sulfate	1405-20-5	Not Listed
• Lanolin	8006-54-0	Not Listed
• White Petrolatum	8009-03-8	Not Listed
• Dexamethasone	50-02-2	Not Listed
• Mineral oil	8012-95-1	Not Listed

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

• Methyparaben	99-76-3	Not Listed
• Propylparaben	94-13-3	Not Listed
• Neomycin, sulfate (salt)	1405-10-3	Not Listed
• Polymyxin B sulfate	1405-20-5	Not Listed
• Lanolin	8006-54-0	Not Listed
• White Petrolatum	8009-03-8	Not Listed
• Dexamethasone	50-02-2	Not Listed
• Mineral oil	8012-95-1	Not Listed

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

• Methyparaben	99-76-3	Not Listed
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• Propylparaben	94-13-3	Not Listed
• Neomycin, sulfate (salt)	1405-10-3	developmental toxicity, initial date 10/1/92 (internal use)
• Polymyxin B sulfate	1405-20-5	Not Listed
• Lanolin	8006-54-0	Not Listed
• White Petrolatum	8009-03-8	Not Listed
• Dexamethasone	50-02-2	Not Listed
• Mineral oil	8012-95-1	Not Listed

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

• Methyparaben	99-76-3	Not Listed
• Propylparaben	94-13-3	Not Listed
• Neomycin, sulfate (salt)	1405-10-3	Not Listed
• Polymyxin B sulfate	1405-20-5	Not Listed
• Lanolin	8006-54-0	Not Listed
• White Petrolatum	8009-03-8	Not Listed
• Dexamethasone	50-02-2	Not Listed
• Mineral oil	8012-95-1	Not Listed

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

• Methyparaben	99-76-3	Not Listed
• Propylparaben	94-13-3	Not Listed
• Neomycin, sulfate (salt)	1405-10-3	Not Listed
• Polymyxin B sulfate	1405-20-5	Not Listed
• Lanolin	8006-54-0	Not Listed
• White Petrolatum	8009-03-8	Not Listed
• Dexamethasone	50-02-2	Not Listed
• Mineral oil	8012-95-1	Not Listed

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

- 29/April/2015

Preparation Date

- 23/April/2015

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