



Safety Data Sheet

Section 1: Identification

Product identifier

- Product Name** • **White Petrolatum, Mineral Oil Lanolin Ophthalmic Ointment**
- Product Code** • Core No. 068
- Product Description** • Dry eye therapy.

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

- Recommended use** • Relieves dryness of the eye
- Restrictions on use** • Use in accordance with product literature.

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

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** • Classification criteria not met

Label elements

UN GHS

Precautionary statements

- 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
Lanolin Oil	CAS:8006-54-0 EINECS:232-348-6	< 5%	UN GHS: NDA
Mineral oil	CAS:8012-95-1 EINECS:232-384-2	15%	UN GHS: NDA
White Petrolatum	CAS:8009-03-8 EINECS:232-373-2	83%	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 specific treatment is necessary since this material is not likely to be hazardous by inhalation. If exposed to excessive levels of mists, remove to fresh air and get medical attention.

Skin

- No specific treatment is necessary since this material is not likely to be hazardous by contact with the skin or mucous membranes.

Eye

- No specific treatment is necessary since this material is not irritating to the eye.

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 • Water spray, carbon dioxide, dry chemical powder or appropriate foam for surrounding fire.

Unsuitable Extinguishing Media • No data available

Special hazards arising from the substance or mixture

Unusual Fire and Explosion Hazards • None known - product is not flammable or combustible.

Hazardous Combustion Products • No data available

Advice for firefighters

- As in any fire, wear self-contained breathing apparatus and full protective gear to

prevent contact with skin and eyes.

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. Refer to Section 8.
- Emergency Procedures**
- No emergency procedures are expected to be necessary when used in accordance with product literature.

Environmental precautions

- No data available

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.

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 15-30°C (59-86°F), to maintain product integrity. use before expiration date marked on carton and/or container.

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 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**
- No respiratory protection required during normal handling.
- Eye/Face**
- No eye protection is required during normal handling.
- Hands**
- Gloves are not required under normal handling conditions.

- Skin/Body**
- Not required during normal 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	Color	No data available
Odor	No data available	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	= 0.86	Water Solubility	Highly soluble in water
Viscosity	No data available	Oxidizing Properties:	No data available
Volatility			
Vapor Pressure	No data available	Vapor Density	No data available
Evaporation Rate	No data available		
Flammability			
Flash Point	No data available	UEL	No data available
LEL	No data available	Autoignition	No data available
Flammability (solid, gas)	No data available		
Environmental			
Octanol/Water Partition coefficient	No data available		

Section 10: Stability and Reactivity

Reactivity

- No dangerous reactions known.

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

- None.

Hazardous decomposition products

- None expected.

Section 11 - Toxicological Information

Information on toxicological effects

Components		
White Petrolatum (83%)	8009-03-8	Acute Toxicity: Intraperitoneal-Mouse LD50 • >50 g/kg
Mineral oil (15%)	8012-95-1	Acute Toxicity: Ingestion/Oral-Rat LD50 • >24 g/kg; <i>Gastrointestinal:Hypermotility, diarrhea</i>

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 • Classification criteria not met
STOT-RE	UN GHS • Classification criteria not met
STOT-SE	UN GHS • Classification criteria not met
Toxicity for Reproduction	UN GHS • Classification criteria not met
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)**
 - Under normal conditions of use, no health effects are expected.

Skin

- Acute (Immediate)**
 - Under normal conditions of use, no health effects are expected.
- Chronic (Delayed)**
 - Under normal conditions of use, no health effects are expected.

Eye

- Acute (Immediate)**
 - Under normal conditions of use, no health effects are expected.
- Chronic (Delayed)**
 - Under normal conditions of use, no health effects are expected.

Ingestion

- Acute (Immediate)**
 - Small amounts (a tablespoonful) swallowed are not likely to cause injury: swallowing amounts larger than that may cause gastrointestinal irritation.
- Chronic (Delayed)**
 - No data available

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	NDA	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	EU EINECS	TSCA
Lanolin Oil	8006-54-0	Yes	Yes	Yes
Mineral oil	8012-95-1	Yes	Yes	Yes
White Petrolatum	8009-03-8	Yes	Yes	Yes

Canada

Labor

Canada - WHMIS - Classifications of Substances

• Lanolin Oil	8006-54-0	Uncontrolled product according to WHMIS classification criteria (anhydrous)
• White Petrolatum	8009-03-8	Uncontrolled product according to WHMIS classification criteria
• Mineral oil	8012-95-1	Uncontrolled product according to WHMIS classification criteria

Canada - WHMIS - Ingredient Disclosure List

• Lanolin Oil	8006-54-0	Not Listed
• White Petrolatum	8009-03-8	Not Listed
• Mineral oil	8012-95-1	1 %

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

• Lanolin Oil	8006-54-0	Not Listed
• White Petrolatum	8009-03-8	Carc.Cat.2; R45
• Mineral oil	8012-95-1	Not Listed

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

• Lanolin Oil	8006-54-0	Not Listed
• White Petrolatum	8009-03-8	T R:45 S:53-45
• Mineral oil	8012-95-1	Not Listed

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

• Lanolin Oil	8006-54-0	Not Listed
• White Petrolatum	8009-03-8	N
• Mineral oil	8012-95-1	Not Listed

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

• Lanolin Oil	8006-54-0	Not Listed
• White Petrolatum	8009-03-8	S:53-45
• Mineral oil	8012-95-1	Not Listed

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

• Lanolin Oil	8006-54-0	Not Listed
• White Petrolatum	8009-03-8	Not Listed
• Mineral oil	8012-95-1	Not Listed

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

• Lanolin Oil	8006-54-0	Not Listed
• White Petrolatum	8009-03-8	Not Listed
• Mineral oil	8012-95-1	Not Listed

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

• Lanolin Oil	8006-54-0	Not Listed
• White Petrolatum	8009-03-8	Not Listed
• Mineral oil	8012-95-1	Not Listed

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

• Lanolin Oil	8006-54-0	Not Listed
• White Petrolatum	8009-03-8	Not Listed
• Mineral oil	8012-95-1	Not Listed

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

• Lanolin Oil	8006-54-0	Not Listed
• White Petrolatum	8009-03-8	Not Listed
• Mineral oil	8012-95-1	Not Listed

Section 16 - Other Information

Last Revision Date

- 15/April/2015

Preparation Date

- 15/April/2015

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