Safety Data Sheet

BAUSCH+LOMB

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Section 1: Identification

Product identifier

• White Petrolatum, Mineral Oil Lanolin Ophthalmic Ointment -

Private Label

Synonyms • Artificial Tears Ophthalmic Ointment; Lubrifresh P.M. Ophthalmic Ointment

Product CodeCore No. 068Product DescriptionDry 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

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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

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

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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 confainer.

Section 8 - Exposure Controls/Personal Protection

Control parameters

Exposure Limits/Guidelines

Refer to the occupational exposure limits / quidelines for the individual product components.

	Exposure Limits/Guidelines				
	Result	ACGIH	Canada Quebec	NIOSH	OSHA
	STELs	Not established	10 mg/m3 STEV (mist)	10 mg/m3 STEL	Not established
Mineral oil (8012-95-1)	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.

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Eye/Face

Hands

Skin/Body

Environmental Exposure Controls

- No eye protection is required during normal handling.
- Gloves are not required under normal handling conditions.
- Not required during normal handling.
- 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

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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; Gastrointestinal:Hypermotility, diarrhea

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)

Chronic (Delayed)

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

Skin

Acute (Immediate)

Chronic (Delayed)

Eye Acute (Immediate)

Chronic (Delayed)

Ingestion

Acute (Immediate)

Chronic (Delayed)

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

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 Small amounts (a tablespoonful) swallowed are not likely to cause injury: swallowing amounts larger than that may cause gastrointestinal irritation.

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

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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

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		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 Reporta	ble 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

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

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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 Preparation Date Disclaimer/Statement of Liability

- 15/April/2015
- 15/April/2015
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