

Safety Data Sheet

Section 1: Identification

Product identifier

- Product Name** • **SOOTHE® Night Time Ointment**
- Product Code** • 3-10119-02013-5; AB31334; Core No. 313
- Product Description** • Ophthalmic ointment.

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

- Recommended use** • Lubricate and moisturize eyes

Details of the supplier of the safety data sheet

- Manufacturer** • Bausch & Lomb Incorporated
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** • Classification criteria not met

Label elements

UN GHS

Classification criteria not met

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
Mineral oil	CAS:8012-95-1 EINECS:232-384-2	20%	UN GHS: NDA
White Petrolatum	CAS:8027-32-5	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 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 if cough or other symptoms develop.

Skin

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

Eye

- For accidental and non-therapeutic applications, flush eyes with copious amounts of water for at least 15 minutes. Get medical attention.

Ingestion

- If swallowed, get medical help or contact a Poison Control Center immediately.

Most important symptoms and effects, both acute and delayed

- No data available

Indication of any immediate medical attention and special treatment needed

Other information

- Additional details are provided on the product packaging and/or the product insert.

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.

Firefighting Procedures • As in any fire, wear self-contained breathing apparatus and full protective gear.

Special hazards arising from the substance or mixture

Unusual Fire and Explosion Hazards • None known.

Hazardous Combustion Products • None known.

Advice for firefighters

- Refer to Section 5 Firefighting Procedures.

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

- No emergency procedures are expected to be necessary when used in accordance with product literature.

Environmental precautions

- No data available on the environmental impact of this product.

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

- When using this product: do not touch tip of container to any surface to avoid contamination, remove contact lenses before using, and always replace the cap after use. 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.

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 British Columbia	Canada Nova Scotia	Canada Ontario	Canada Quebec
Mineral oil (8012-95-1)	TWAs	5 mg/m3 TWA (excluding metal working fluids, highly & severely refined, inhalable fraction)	0.2 mg/m3 TWA (mildly refined); 1 mg/m3 TWA (severely refined)	5 mg/m3 TWA (excluding metal working fluids, highly & severely refined, inhalable fraction)	Not established	5 mg/m3 TWAEV (mist)
	STELs	Not established	Not established	Not established	10 mg/m3 STEV (mist)	10 mg/m3 STEV (mist)
Exposure Limits/Guidelines (Con't.)						
	Result	NIOSH		OSHA		
Mineral oil (8012-95-1)	TWAs	5 mg/m3 TWA		5 mg/m3 TWA		
	STELs	10 mg/m3 STEL		Not established		

Exposure Control Notations

ACGIH

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

Carcinogen (poorly & mildly refined))

Exposure Limits Supplemental ACGIH

•Mineral oil (8012-95-1): **TLV Basis - Critical Effects:** (upper respiratory tract irritation (excluding metal working fluids)) | **No Adopted Value:** (Exposure by all routes should be carefully controlled to levels as low as possible (excluding metal working fluids, poorly & mildly refined))

Exposure controls

Engineering Measures/Controls

- No special controls are required under conditions of intended use. Local exhaust ventilation should be provided when handling bulk product.

Personal Protective Equipment

Respiratory

- No special controls or personal protection required under conditions of intended use. In the event of a bulk spill, a NIOSH-certified air-purifying respirator equipped with HEPA -organic vapor cartridges may be permissible under certain circumstances where airborne concentrations are expected to exceed exposure limits and when adequate oxygen is present. 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

- No special personal protection required under conditions of intended use. In the event of a bulk 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.

Thermal hazards

- None known.

General Industrial Hygiene Considerations

- Wash thoroughly with soap and water after handling.

Environmental Exposure Controls

- No special controls are required under conditions of intended use. In the event of a bulk spill, prevent spilled material from entering storm sewers or drains, waterways, and contact with the soil.

Section 9 - Physical and Chemical Properties

Information on Physical and Chemical Properties

Material Description			
Physical Form	Liquid	Appearance/Description	Gel
Color	Clear to opaque.	Odor	No odor.
Odor Threshold	Not relevant		
General Properties			
Boiling Point	No data available	Melting Point	Not relevant
Decomposition Temperature	No data available	pH	Not relevant
Specific Gravity/Relative Density	= 0.86	Water Solubility	Soluble
Viscosity	No data available		
Volatility			
Vapor Pressure	No data available	Vapor Density	No data available
Evaporation Rate	No data available	VOC (Wt.)	Not relevant
Flammability			
Flash Point	Not relevant	UEL	Not relevant
LEL	Not relevant	Autoignition	Not relevant
Environmental			
Octanol/Water Partition coefficient	No data available		

Section 10: Stability and Reactivity

Reactivity

- Stable under normal temperatures and pressures.

Chemical stability

- Stable when stored at room temperature 15-25°C (59-77°F). Use before expiration date marked on carton and/or container.

Possibility of hazardous reactions

- Will not occur.

Conditions to avoid

- Extreme heat or cold. Do not freeze.

Incompatible materials

- None known.

Hazardous decomposition products

- None known.

Section 11 - Toxicological Information

Information on toxicological effects

Components		
Mineral oil (20%)	8012-95-1	Acute Toxicity: Ingestion/Oral-Mouse LD50 • 22 g/kg; Irritation: Eye-Rabbit • 500 mg • Moderate irritation

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)

- No data available.

Skin

Acute (Immediate)

- Not expected to cause skin irritation.

- Chronic (Delayed)**
- Allergic contact dermatitis with drying and fissuring of the fingertips has been reported.
- 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)**
- Under normal conditions of use, no health effects are expected.
- 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**
- Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.
- Packaging waste**
- Recycle

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	EU EINECS	TSCA
Mineral oil	8012-95-1	Yes	Yes	Yes
White Petrolatum	8027-32-5	No	No	No

Canada**Labor****Canada - WHMIS - Classifications of Substances**

• Mineral oil	8012-95-1	Uncontrolled product according to WHMIS classification criteria
• White Petrolatum	8027-32-5	Not Listed

Canada - WHMIS - Ingredient Disclosure List

• Mineral oil	8012-95-1	1 %
• White Petrolatum	8027-32-5	Not Listed

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

• Mineral oil	8012-95-1	Not Listed
• White Petrolatum	8027-32-5	Not Listed

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

• Mineral oil	8012-95-1	Not Listed
• White Petrolatum	8027-32-5	Not Listed

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

• Mineral oil	8012-95-1	Not Listed
• White Petrolatum	8027-32-5	Not Listed

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

• Mineral oil	8012-95-1	Not Listed
• White Petrolatum	8027-32-5	Not Listed

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

• Mineral oil	8012-95-1	Not Listed
• White Petrolatum	8027-32-5	Not Listed

Section 16 - Other Information

Last Revision Date	• 08/May/2015
Preparation Date	• 08/May/2015
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