



Safety Data Sheet

Section 1: Identification

Product identifier

- Product Name** • **Muro 128®**, sodium chloride hypertonicity ophthalmic ointment 5%
- Product Code** • AB15834; AB15899; Core No. 158; NDC 24208-0385-55; NDC 24208-0385-56
- Relevant identified uses of the substance or mixture and uses advised against**
- Recommended use** • Finished Pharmaceutical Product; Temporary relief of corneal edema.
- 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

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 Mild Irritation 3
Eye Mild Irritation 2B

Label elements

UN GHS

WARNING

- Hazard statements** • Causes mild skin irritation
Causes eye irritation

Precautionary statements

- Prevention** • Wash thoroughly after handling.

- Response** • IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

If eye irritation persists: Get medical advice/attention.

If skin irritation occurs: Get medical advice/attention.

- 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	CAS:8006-54-0 EINECS:232-348-6	10% TO 20%	UN GHS: NDA
Mineral oil	CAS:8012-95-1 EINECS:232-384-2	10% TO 20%	UN GHS: NDA
Sodium chloride	CAS:7647-14-5 EINECS:231-598-3	5%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 5
Water	CAS:7732-18-5 EINECS:231-791-2	10% TO 20%	UN GHS: Not Classified
White Petrolatum	CAS:8009-03-8 EINECS:232-373-2	40% TO 60%	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

- Immediately flush skin with large amounts of water. Remove contaminated clothing. If irritation (redness, rash, blistering) develops, get medical 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 ● 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 15-25°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 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.

Eye/Face

- Avoid contact with the eye. No special controls or 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, protective rubber gloves should be worn.

Skin/Body

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

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	off-white to yellowish.
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	No data available	Water Solubility	Immiscible
Viscosity	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		
Sodium chloride (5%)	7647-14-5	Acute Toxicity: Ingestion/Oral-Rat LD50 • 3000 mg/kg; Irritation: Eye-Rabbit • 10 mg • Moderate irritation; Skin-Rabbit • 500 mg 24 Hour(s) • Mild irritation
Mineral oil (10% TO 20%)	8012-95-1	Acute Toxicity: Ingestion/Oral-Rat LD50 • >24 g/kg; <i>Gastrointestinal:Hypermotility, diarrhea;</i> Irritation: Eye-Rabbit • 100 mg 1 Hour(s) • Mild irritation; Skin-Rabbit • 100 mg 24 Hour(s) • Mild 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 • Skin Mild Irritation 3
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 • Eye Mild Irritation 2B

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)

- May cause mild irritation.

Chronic (Delayed)

- Causes mild skin irritation.

Eye

Acute (Immediate)

- May cause mild irritation.

Chronic (Delayed)

- Repeated and prolonged exposure may cause irritation.

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	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
Lanolin	8006-54-0	Yes	Yes	Yes
Mineral oil	8012-95-1	Yes	Yes	Yes
White Petrolatum	8009-03-8	Yes	Yes	Yes
Sodium chloride	7647-14-5	Yes	Yes	Yes
Water	7732-18-5	Yes	Yes	Yes

Canada

Labor

Canada - WHMIS - Classifications of Substances

• Lanolin	8006-54-0	Uncontrolled product according to WHMIS classification criteria (anhydrous)
• White Petrolatum	8009-03-8	Uncontrolled product according to WHMIS classification criteria
• Sodium chloride	7647-14-5	Uncontrolled product according to WHMIS classification criteria
• Water	7732-18-5	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	8006-54-0	Not Listed
• White Petrolatum	8009-03-8	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Water	7732-18-5	Not Listed
• Mineral oil	8012-95-1	1 %

Europe

Other

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

• Lanolin	8006-54-0	Not Listed
• White Petrolatum	8009-03-8	Carc.Cat.2; R45
• Sodium chloride	7647-14-5	Not Listed
• Water	7732-18-5	Not Listed
• Mineral oil	8012-95-1	Not Listed

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

• Lanolin	8006-54-0	Not Listed
• White Petrolatum	8009-03-8	T R:45 S:53-45
• Sodium chloride	7647-14-5	Not Listed
• Water	7732-18-5	Not Listed
• Mineral oil	8012-95-1	Not Listed

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

• Lanolin	8006-54-0	Not Listed
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• White Petrolatum	8009-03-8	N
• Sodium chloride	7647-14-5	Not Listed
• Water	7732-18-5	Not Listed
• Mineral oil	8012-95-1	Not Listed

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

• Lanolin	8006-54-0	Not Listed
• White Petrolatum	8009-03-8	S:53-45
• Sodium chloride	7647-14-5	Not Listed
• Water	7732-18-5	Not Listed
• Mineral oil	8012-95-1	Not Listed

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

• Lanolin	8006-54-0	Not Listed
• White Petrolatum	8009-03-8	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Water	7732-18-5	Not Listed
• Mineral oil	8012-95-1	Not Listed

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

• Lanolin	8006-54-0	Not Listed
• White Petrolatum	8009-03-8	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Water	7732-18-5	Not Listed
• Mineral oil	8012-95-1	Not Listed

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

• Lanolin	8006-54-0	Not Listed
• White Petrolatum	8009-03-8	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Water	7732-18-5	Not Listed
• Mineral oil	8012-95-1	Not Listed

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

• Lanolin	8006-54-0	Not Listed
• White Petrolatum	8009-03-8	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Water	7732-18-5	Not Listed
• Mineral oil	8012-95-1	Not Listed

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

• Lanolin	8006-54-0	Not Listed
• White Petrolatum	8009-03-8	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Water	7732-18-5	Not Listed
• Mineral oil	8012-95-1	Not Listed

Section 16 - Other Information

- Last Revision Date**
- 15/April/2015
- Preparation Date**
- 15/April/2015
- Disclaimer/Statement of Liability**
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