SAFETY DATA SHEETS

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Pharmaceutical Division

MATERIAL SAFETY DATA SHEET

 Issued:
 09/07/94

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 01

Prepared by: Gary Wong Manager EHS Core No. 158

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Generic Name: NDC No.	MURO 128 [®] Ointment 5% (OTC) Sodium Chloride Hypertonicity Ophthalmic Ointment 24208-385-55 (3.5 g) 24208-385-56 (2 X 3.5g)				
Legal Category:	Pharmaceutical preparation, filled inside tube suitable for dispensing, and overpacked inside a cardboard carton.				

Drug Composition: Inorganic salt (Draws water from the cornea)

BAUSCH & LOMB PHARMACEUTICALS, INC. 8500 Hidden River Parkway Tampa, FL 33637 Information: (800) 323-0000 (M-F) 8am-5pm EST Emergency: (800) 227-1427 24 hrs

2. COMPOSITION/INFORMATION ON INGREDIENTS

Description	CAS #	TLV (mg/m ³	³) PEL(mg/m ³)	% Content
Sodium Chloride	7647-14-5	NE	NE	5
Lanolin Anhydrous	8006-54-0	NE	NE	≥1
Mineral Oil	8042-47-5	5(mist)	5	≥1
White Petrolatum	8009-03-8	NE	NE	≥1

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3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Tube packed in a cardboard box. Off-white to yellow, smooth, unctuous mass with a characteristic odor.

POTENTIAL HEALTH HAZARDS

Carcinogenicity: (NTP) No (IARC) No (OSHA) No

Eye: May cause irritation, temporary burning sensation and hypersensitivity (anaphylactic) in some individuals.

Skin: May cause irritation and hypersensitivity in some individuals.

Ingestion: May cause irritation and hypersensitivity in some individuals. Ingestion of large quantities can induce gastric disturbances.

Inhalation: May cause irritation and hypersensitivity some individuals.

Chronic Effects: May cause irritation and hyper-sensitivity. Prolonged application can induce changes in vision.

Target Organs: Eyes and digestive tract.

Medical Conditions Aggravated by Long Term Exposure: Hypersensitivity to any of the components of the product.

4. FIRST AID MEASURES

Eyes: Rinse immediately with copious amounts of water for at least 20 minutes. Contact a physician.

Skin: Remove all contaminated clothing and wash skin with copious amounts of water for at least 20 minutes. Contact physician if skin becomes irritated.

Ingestion: Wash out mouth. Give plenty of water and bland fluids. Do not give anything to an unconscious person. Contact physician.

Inhalation: Remove person to fresh air, and if breathing stops, use artificial respiration. Contact physician.

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Note to Physicians: None

5. FIRE FIGHTING MEASURES

Flammable Properties: Flash point: NE Method: NE

Hazardous Products: Toxic Fumes.

Extinguishing Media: Dry chemical, carbon dioxide, halon, water spray or fog, and foam on surrounding materials.

Fire Fighting Instructions: Wear self-contained breathing apparatus and protective clothing. Use water spray to keep fire-exposed containers cool. Do not spray water into the burning material.

6. ACCIDENTAL RELEASE MEASURES

Large/Small Spills: Use personal protective equipment. Contain the spill to prevent drainage into sewers, drains or streams. Use absorbent material to solidify the spill. Shovel or scoop up solidified waste. Dispose of material according to Federal, State and Local regulations.

7. HANDLING AND STORAGE

Handling: Avoid contact with product and use caution to prevent puncturing containers. No special protective equipment or procedures are required in the clinical or home environment.

Storage: Store product upright in original containers with the cap tightly closed at a controlled room temperature $15^{0}-30^{0}$ C ($59^{0}-86^{0}$ F). **KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.**

8. EXPOSURE CONTROL/PERSONAL PROTECTION

Engineering Controls: In the manufacturing plant, provide adequate ventilation for the raw material handling and compounding process which will maintain the dust and vapor levels below the TLV, STEL, and PEL values for the ingredients. Ventilation fans should be explosion proof. Use adequate personal protective equipment e.g. NIOSH-approved respirators, goggles or safety glasses, gloves and protective clothing. Ensure training in the handling of chemical material and use current Material Safety Data Sheets.

Eye Protection: (29 CFR 1910.133) Recommend goggles or chemical safety glasses.

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Skin Protection: Thick impermeable gloves and protective clothing.

Respiratory Protection: (29 CFR 1910.134) NIOSH approved respirator, with organic vapor, acid gas and HEPA filter recommended for handling raw materials. **Warning: Do not use air purifying respirators in oxygen depleted environments**. No respiratory protection is required in the clinical or home environment.

Other: None

Ventilation: Recommended

Contaminated Equipment: Wash contaminated clothing separately. Wash equipment with soap and water. Release rinse water into an approved wastewater system or according to Federal, State and Local regulations.

9. CHEMICAL & PHYSICAL PROPERTIES

Appearance & Odor:	Off-white to yellow, smooth, unctuous mass with a characteristic odor.		
Boiling Point:	NE	Evaporation Rate:	NE
Specific Gravity:	NE	Vapor Density:	NE
Vapor Pressure:	NE	Viscosity:	NE
Water Solubility:	Immiscible	Percent Volatile by Volume:	<1

10. STABILITY AND REACTIVITY

Chemical Stability: Stable

Conditions to avoid: Extreme heat or cold.

Incompatibility: This product has the incompatibilities of water e.g. strong acids, bases, alkali metals, alkali hydrides and silver preparations.

Hazardous Decomposition Products: Emits toxic fumes.

Hazardous Polymerization: Should not occur.

11. TOXICOLOGY INFORMATION

Summary of Risks: Toxicological information refers to the raw materials of the product. Concentrations and toxicological effects are substantially reduced in the product. For more detailed information see MSDS on chemical material.

CAS #

8042-47-5 Mineral Oil

May cause mild irritation to the eyes or skin. Can cause irritation if mist is inhaled and act as a laxative if ingested in large quantities causing abdominal cramps and diarrhea. Inhalation control for oil mists 5 mg/M^3 .

8006-54-0 Lanolin, Anhydrous

May cause skin and digestive tract irritation. Can cause hypersensitivity (anaphylactic) in some individuals. Oral-rat LD₅₀ >46.5 cc/kg.

7647-14-5Sodium Chloride

May cause irritation to eyes, skin, nerves, respiratory and digestive tract. Eyes and respiratory tract can be irritated by solid or dust. Prolonged skin contact can cause irritation. Ingestion of large amounts can cause high blood pressure (hypertension) and congestion of the internal organs (esp. the meninges and brain), cramps, vomiting, prostration, coma and death. Skin-rabbit 500 mg/24 hrs mild irritation. Eyerabbit 100 mg/24 hrs severe irritation. Oral-rat LD₅₀ 3000 mg/kg. Intravenous-mouse LD₅₀ 645 mg/kg.

8009-03-8 White Petrolatum

May cause irritation to the eyes. Inhalation can cause irritation. Mist levels regulated as an oil mist at TLV 5 mg/M3.

12. ECOLOGICAL INFORMATION

Chemical Fate Information: Product administered to patients presents a negligible impact on the environment.

13. DISPOSAL INFORMATION

Dispose of material according to Federal, State, and Local regulations. The method typically used is incineration.

EPA Designations: RCRA Hazardous Waste: Not Listed

SARA Title III: Not Listed

14. TRANSPORTATION INFORMATION

Transportation Data: Not classified as hazardous by DOT regulations.

15. REGULATORY INFORMATION

DOT Designations: Not classified as hazardous by DOT regulations.

EPA Designations:	RCRA Hazardous Waste (40 CFR 261.33) Not Listed			
FDA Designations:	OTC NDC No. 24208-385-55 (3.5 g) NDC No. 24208-385-56 (2 X 3.5 g)			
OSHA Designations:	(29 CFR 1910.1000, Table Z) Not Listed			
SARA Title III:	Not listed under Section 313 of Toxic Release Reporting.			
CALIFORNIA PROPOSITION 65: Not Listed				

16. OTHER INFORMATION

None

The information contained herein is furnished without warranty of any kind. The above information is believed to be correct but does not purport to be all-inclusive and should be used only as a guide. Users should make independent determinations of the suitability and completeness of information from all sources to assure proper use and disposal of these materials and the safety and health of employees and customers.

NA – Not Applicable NE - Not Established < - Less Than > - Greater Than

Safety Data Sheet

BAUSCH + LOMB

See better. Live better.

Section 1: Identification Product identifier Muro 128[®], sodium chloride hypertonicity ophthalmic ointment **Product Name** 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. 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.
Еуе	 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 sympto	oms 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	a .	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

Hazards **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

cy procedures are expected to be necessary when used in accordance emergend with product literature.

Environmental precautions

No data available

Methods and material for containment and cleaning up

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Containment/Clean-up
Measures
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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						
R	lesult	ACGIH	Canada Quebec	NIOSH	OSHA	
I I	I					

1	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 Equipme	ent
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	рН	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%)		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; Gastrointestinal:Hypermotility, diarrhea; 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
Chronic (Delayed)	 Under normal conditions of use, no health effects are
Skin	
Acute (Immediate)	 May cause mild irritation.
Chronic (Delayed)	 Causes mild skin irritation.
Eye	

Acute (Immediate)

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e expected.

- e expected.
- May cause mild irritation.

Chronic (Delayed) Ingestion	 Repeated and prolonged exposure may cause irritation.
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	I	
	•	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

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		Inve	ntory	
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

		Uncontrolled product
Lanolin	8006-54-0	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

8006-54-0	Not Listed
	Carc.Cat.2; R45
	Not Listed
7732-18-5	Not Listed
8012-95-1	Not Listed
8006-54-0	Not Listed
8009-03-8	T R:45 S:53-45
7647-14-5	Not Listed
7732-18-5	Not Listed
8012-95-1	Not Listed
onarations	
8006-54-0	Not Listed
	8012-95-1 8006-54-0 8009-03-8 7647-14-5 7732-18-5 8012-95-1 reparations

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 Phra	ISES	
EU - CLP (1272/2008) - Annex VI - Table 3.2 - Safety Phra • Lanolin		Not Listed
	8006-54-0	Not Listed S:53-45
• Lanolin	8006-54-0 8009-03-8	
Lanolin White Petrolatum	8006-54-0 8009-03-8 7647-14-5	S:53-45

United States

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Environment U.S CERCLA/SARA - Hazardous Substances and th	eir 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

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• 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	8006-54-0	Not Listed
U.S California - Proposition 65 - Reproductive Toxicity - Male • Lanolin	8006-54-0 8009-03-8	Not Listed Not Listed
 U.S California - Proposition 65 - Reproductive Toxicity - Male Lanolin White Petrolatum 		
 U.S California - Proposition 65 - Reproductive Toxicity - Male Lanolin White Petrolatum Sodium chloride Water 	8009-03-8	Not Listed

Section 16 - Other Information		
Last Revision Date	• 15/April/2015	
Preparation Date	• 15/April/2015	
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