

SAFETY DATA SHEET

Bepotastine Besilate Ophthalmic Solution, 1.5%

Section 1: Identification

Product identifier

Product Name Bepotastine Besilate Ophthalmic Solution 1.5%

Product Code 5 mL – NDC 70069-711-01

10 mL – NDC 70069-712-01

Product Description Bepotastine Besilate Ophthalmic Solution 1.5% is a sterile, topically administered drug for ophthalmic use.

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

Recommended use Bepotastine besilate ophthalmic solution 1.5% is a histamine H1 receptor antagonist indicated for the treatment of itching associated with signs and symptoms of allergic conjunctivitis.

Restrictions on use Refer to product prescribing information. Refer to the product insert and/or prescribing information for restrictions on use and contraindications.

Details of the supplier of the safety data sheet

Manufactured for Somerset Therapeutics, LLC. Somerset, NJ 08873

Customer Care 1-800-417-9175

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 Acute Toxicity Oral 5
Eye Mild Irritation 2B

Label elements

UN GHS

WARNING

Hazard statements Causes eye irritation
May be harmful if swallowed

Precautionary statements

Prevention Use only in accordance with label instructions and supplied prescribing information.
Wash thoroughly after handling.

Response IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.
If eye irritation persists: Get medical advice/attention.
IF ON SKIN: Wash with plenty of soap and water.

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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.
 Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

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
Water for Injection	CAS:7732-18-5 EINECS:231-791-2	> 90%	UN GHS: NDA
Sodium chloride, USP	CAS:7647-14-5 EINECS:231-598-3	< 1%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 5
Sodium Hydroxide, NF	CAS: 1310-73-2	To adjust to pH	NA
Monobasic Sodium Phosphate USP Dihydrate	CAS:10049-21-5	1%	UN GHS: NDA
Benzalkonium chloride	CAS:63449-41-2 EINECS:264-151-6	0.005%	UN GHS: Skin Corr. 1B; Acute Tox. Oral 4; Acute Tox. Dermal 4; Aquatic Acute 1
Bepotastine Besilate	CAS:190786-44-8	1.5%	UN GHS: Acute Tox 5

The exact percentage of composition has been withheld as a trade secret.

Section 4: First-Aid Measures

Description of first aid measures

Inhalation No data available

Skin IF ON SKIN: Wash with plenty of soap and water. If skin irritation occurs: Get medical advice/attention.

Eye Flush eyes with water for at least 15 minutes. If eye irritation persists: Get medical advice/attention.

Ingestion If swallowed, rinse mouth with water (only if the person is conscious) Call a physician or poison control center immediately.

Most important symptoms and effects, both acute and delayed

Refer to the product insert and/or product prescribing information for comprehensive information regarding adverse reactions and other important symptoms and effects.

Indication of any immediate medical attention and special treatment needed other information

Refer to product prescribing information.

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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 Fire fighters should wear complete protective clothing including self-contained breathing apparatus.

Special hazards arising from the substance or mixture

Unusual Fire and Explosion Hazards None known.

Hazardous Combustion Products During a fire, thermal decomposition or combustion may generate irritating and highlytoxic gases.

Advice for firefighters
No data available

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. No special precautions expected to be necessary if material is used under ordinary conditions and as recommended. Avoid any skin contact.

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.
Use appropriate Personal Protective Equipment (PPE)
Avoid generating dust.
Wash away spilled liquid remainder with plenty of water.

Prohibited Materials None known.

Reference to other sections Refer to Section 8 - Exposure Controls/Personal Protection and Section 13 - Disposal Considerations.

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Section 7 - Handling and Storage

Precautions for safe handling

Handling	Use only in accordance with product literature. Wash thoroughly with warm water and soap after handling.
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.
Special Packaging Materials	Maintain product in original container only.
Other Information	Refer to product literature.

Section 8 - Exposure Controls/Personal Protection

Control parameters

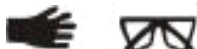
Exposure Limits/Guidelines Refer to the occupational exposure limits / guidelines for the individual product components.

Exposure controls

Engineering Measures/Controls Not required during normal clinical use. No special controls are required under conditions of intended use. Local exhaust ventilation should be provided when handling bulk product.

Personal Protective Equipment

Pictograms



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

Avoid contact with skin and eyes. 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.

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Section 9 - Physical and Chemical Properties

Information on Physical and Chemical Properties

Material Description			
Physical Form	Liquid		
General Properties			
Boiling Point	No data available	pH	6.8
Specific Gravity/Relative Density	1.007	Water Solubility	Dissolves readily in water.
Solvent Solubility	No data available	Viscosity	No data available
Flammability			
Flash Point	Not relevant		

Section 10: Stability and Reactivity

Reactivity Chemical

Stable under normal temperatures and pressures.

Stability

No data available

Possibility of hazardous reactions

No data available

Conditions to avoid

Extreme heat or cold. Do not freeze.

Incompatible materials

Consult physician regarding potential drug interactions.

Hazardous decomposition products

During a fire, thermal decomposition or combustion may generate irritating and highlytoxic gases.

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Section 11 - Toxicological Information

Information on toxicological effects

Other Material Information Toxicological information refers to raw materials only. Concentrations and toxicological effects are substantially reduced in the product.

Components		
Water for Injection (> 90%)	7732-18-5	Acute Toxicity: Ingestion/Oral-Rat LD50 • >90 mL/kg
Sodium chloride (< 1%)	7647-14-5	Acute Toxicity: Ingestion/Oral-Rat LD50 • 3000 mg/kg; Irritation: Skin-Rabbit • 500 mg 24 Hour(s) • Mild irritation
Benzalkonium Chloride (0.005%)	63449-41-2	Acute Toxicity: Ingestion/Oral-Mouse LD50 • 150 mg/kg; <i>Behavioral:Somnolence (general depressed activity); Blood:Hemorrhage;</i> Skin-Rat LD50 • 1420 mg/kg; <i>Behavioral:Somnolence (general depressed activity); Blood:Hemorrhage;</i> Multi-dose Toxicity: Ingestion/Oral-Dog TDLo • 9100 mg/kg 52 Week(s)-Intermittent; <i>Lungs, Thorax, or Respiration:Chronic pulmonary edema; Gastrointestinal:Other changes; Related to Chronic Data:Death in the Other Multiple Dose data type field</i>
Bepotastine Besilate (1.5%)	190786-44-8	Multi-dose Toxicity: Ingestion/Oral-Rat TDLo • 8400 mg/kg 4 Week(s)-Intermittent; <i>Blood:Changes in serum composition (e.g., TP, bilirubin cholesterol); Nutritional and Gross Metabolic:Changes in Chemistry or Temperature:Ca; Biochemical:Enzyme inhibition, induction, or change in blood or tissue levels:Hepatic microsomal mixed oxidase (dealkylation, hydroxylation, etc.);</i> Ingestion/Oral-Rat TDLo • 10920 mg/kg 26 Week(s)-Intermittent; <i>Liver:Fatty liver degeneration; Liver:Changes in liver weight;</i> Reproductive: Ingestion/Oral-Rat TDLo • 84 g/kg (63D male/14D pre-7D preg); <i>Reproductive Effects:Effects on Fertility:Female fertility index; Reproductive Effects:Effects on Fertility:Male fertility index; Reproductive Effects:Effects on Fertility:Pre-implantation mortality;</i> Ingestion/Oral-Rat TDLo • 27 g/kg (17-22D preg/21D post); <i>Reproductive Effects:Effects on Newborn:Sex ratio; Reproductive Effects:Effects on Newborn:Viability index (e.g., # alive at day 4 per # born alive); Reproductive Effects: Effects on Newborn:Physical</i>

GHS Properties	Classification
Acute toxicity	UN GHS • Acute Toxicity - Oral 5
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 • Eye Mild Irritation 2B

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Potential Health Effects

Inhalation

Acute (Immediate)

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

Chronic (Delayed)

Refer to the product insert and/or product prescribing information for comprehensive information regarding adverse reactions and other important symptoms and effects.

Skin

Acute (Immediate)

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

Chronic (Delayed)

Refer to the product insert and/or product prescribing information for comprehensive information regarding adverse reactions and other important symptoms and effects.

Eye

Acute (Immediate)

May cause mild irritation.

Chronic (Delayed)

Refer to the product insert and/or product prescribing information for comprehensive information regarding adverse reactions and other important symptoms and effects.

Ingestion

Acute (Immediate)

May be harmful if swallowed.

Chronic (Delayed)

Refer to the product insert and/or product prescribing information for comprehensive information regarding adverse reactions and other important symptoms and effects.

Reproductive Effects

There are no adequate and well-controlled studies in humans.

Section 12 - Ecological Information

Toxicity

This material has not been tested for environmental effects.

Persistence and degradability

Substance is readily biodegradable.

Bioaccumulative potential

No data available

Mobility in Soil

No data available

Other adverse effects

Section 13 - Disposal Considerations

Waste treatment methods

Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.

Product waste

Packaging waste

Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

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Section 14 - Transport Information

	UN number	UN proper shipping name	Transport hazard class(es)	Packing group	Environmental hazards
DOT	NDA	Not Regulated	ND A	NDA	NDA
TDG	NDA	Not Regulated	ND A	NDA	NDA
IMO/IMDG	NDA	Not Regulated	ND A	NDA	NDA
IATA/ICAO	NDA	Not Regulated	ND A	NDA	NDA

Special precautions for user No special precautions.

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
Bepotastine Besilate	190786-44-8	No	No	No
Benzalkonium chloride	63449-41-2	Yes	Yes	Yes
Sodium chloride	7647-14-5	Yes	Yes	Yes
Sodium phosphate monobasic, monohydrate	10049-21-5	No	No	No
Water for Injection	7732-18-5	Yes	Yes	Yes

Canada

Labor

Canada - WHMIS - Classifications of Substances

• Benzalkonium chloride	63449-41-2	Not Listed
• Sodium chloride	7647-14-5	Uncontrolled product according to WHMIS classification criteria
• Sodium phosphate monobasic, monohydrate	10049-21-5	Not Listed
• Water	7732-18-5	Uncontrolled product according to WHMIS

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		classification criteria
• bepotastine besilate	190786-44-8	Not Listed
Canada - WHMIS - Ingredient Disclosure List		
• Benzalkonium chloride	63449-41-2	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Sodium phosphate monobasic, monohydrate	10049-21-5	Not Listed
• Water	7732-18-5	Not Listed
• bepotastine besilate	190786-44-8	Not Listed

Europe

Other

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

• Benzalkonium chloride	63449-41-2	Xn; R21/22 C; R34 N; R50
• Sodium chloride	7647-14-5	Not Listed
• Sodium phosphate monobasic, monohydrate	10049-21-5	Not Listed
• Water	7732-18-5	Not Listed
• bepotastine besilate	190786-44-8	Not Listed

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

• Benzalkonium chloride	63449-41-2	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Sodium phosphate monobasic, monohydrate	10049-21-5	Not Listed
• Water	7732-18-5	Not Listed
• bepotastine besilate	190786-44-8	Not Listed

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

• Sodium chloride	7647-14-5	36/37/39-45-61 Not Listed
• Sodium phosphate monobasic, monohydrate	10049-21-5	Not Listed
• Water	7732-18-5	Not Listed
• bepotastine besilate	190786-44-8	Not Listed

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

• Benzalkonium chloride	63449-41-2	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Sodium phosphate monobasic, monohydrate	10049-21-5	Not Listed
• Water	7732-18-5	Not Listed
• bepotastine besilate	190786-44-8	Not Listed

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

• Benzalkonium chloride	63449-41-2	S;(2)-36/37/39-45-61
• Sodium chloride	7647-14-5	Not Listed
• Sodium phosphate monobasic, monohydrate	10049-21-5	Not Listed
• Water	7732-18-5	Not Listed
• bepotastine besilate	190786-44-8	Not Listed

United States

Environment

U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities

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• Benzalkonium chloride	63449-41-2	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Sodium phosphate monobasic, monohydrate	10049-21-5	Not Listed
• Water	7732-18-5	Not Listed
• bepotastine besilate	190786-44-8	Not Listed

U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs

• Benzalkonium chloride	63449-41-2	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Sodium phosphate monobasic, monohydrate	10049-21-5	Not Listed
• Water	7732-18-5	Not Listed
• bepotastine besilate	190786-44-8	Not Listed

U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances TPQs

• Benzalkonium chloride	63449-41-2	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Sodium phosphate monobasic, monohydrate	10049-21-5	Not Listed
• Water	7732-18-5	Not Listed
• bepotastine besilate	190786-44-8	Not Listed

United States - California

Environment

U.S. - California - Proposition 65 - Carcinogens List

• Benzalkonium chloride	63449-41-2	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Sodium phosphate monobasic, monohydrate	10049-21-5	Not Listed
• Water	7732-18-5	Not Listed
• bepotastine besilate	190786-44-8	Not Listed

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

• Benzalkonium chloride	63449-41-2	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Sodium phosphate monobasic, monohydrate	10049-21-5	Not Listed
• Water	7732-18-5	Not Listed
• bepotastine besilate	190786-44-8	Not Listed

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

• Benzalkonium chloride	63449-41-2	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Sodium phosphate monobasic, monohydrate	10049-21-5	Not Listed
• Water	7732-18-5	Not Listed
• bepotastine besilate	190786-44-8	Not Listed

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

• Benzalkonium chloride	63449-41-2	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Sodium phosphate monobasic, monohydrate	10049-21-5	Not Listed
• Water	7732-18-5	Not Listed
• bepotastine besilate	190786-44-8	Not Listed



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Other Information

REACH: All components have been pre-registered. No component is a SIN or SVHC. NOTE: PR (Pre-registered), SVHC (Substance of Very High Concern), SIN (Substitute It Now)

Section 16 - Other Information

Preparation Date 06.09.2024

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