

SAFETY DATA SHEET

PRODUCT: OLOPATADINE HYDROCHLORIDE OPHTHALMIC SOLUTION USP 0.1 %(5ML)

Section 1: PRODUCT AND COMPANY INFORMATION

54/1, Boodhihal village,
Nelamangala,
Bangalore, India-562123.

PRODUCT NAME: OLOPATADINE HCL OPHTHALMIC SOLUTION USP 0.1 %(5ML)

Section 2: HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW	
Appearance/Odor	A clear, colourless solution free from visible extraneous matter.
OSHA Hazards	Toxic by ingestion
GHS Classification	Acute toxicity: oral, category 3 Acute aquatic toxicity, category 1
GHS label elements, including precautionary elements	GHS signal word: Danger
GHS hazard statement(s)	H301: Toxic if swallowed H400: Very toxic to aquatic life
GHS precaution statement(S)	P273 : avoid release to the environment
GHS response phrases	P301+310: IF SWALLOWED: immediately call a poison centre or doctor/physician
GHS storage and disposal phrases	Please refer to section no. 7 for storage and section 13 for disposal information.
Potential Health Effects	Inhalation: May be harmful if inhaled, May cause respiratory tract irritation. Skin: May be harmful if absorbed through skin. May cause skin irritation. Eyes: May cause eye irritation. Ingestion: Toxic if swallowed
<i>Potential Health Effects: See Section 11 for more information</i>	
<i>Potential Environmental Effects: See Section 12 for more information</i>	

Section 3: COMPOSITION AND INFORMATION ON INGREDIENTS

Component	CAS Number	Qty/mL
Olopatadine Hydrochloride USP	140462-76-6	1.11 mg
Benzalkonium Chloride NF	8001-54-5	0.10 mg
Dibasic sodium phosphate USP anhydrous	7558-79-4	5.00 mg
Sodium Chloride	7647-14-5	6.50 mg
Sodium Hydroxide	1310-73-2	For pH adjustment
Hydrochloric Acid	7647-01-0	For pH adjustment
Water for Injection	7732-18-5	Quantity sufficient to 1 mL

Section 4: FIRST AID MEASURES

General advice	Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.
In case of inhalation	Remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Get immediate medical attention
In case of skin contact	Immediately wash skin with soap and plenty of water for at least 15 minutes. Remove contaminated clothing. Get medical attention if symptoms occur. Wash clothing before reuse.
In case of eye contact	Hold eyelids apart and flush eyes with plenty of water for at least 15 minutes. Have eyes examined and tested by medical personnel.
In case of ingestion	Wash out mouth with water provided person is conscious. Never give anything by mouth to an unconscious person. Get medical attention. Do not induce vomiting unless directed to do so by medical personnel.

Section 5: FIRE FIGHTING MEASURES

Suitable extinguishing media	Use alcohol – resistant foam, carbon dioxide, water or dry chemical spray. Use water spray to cool fire-exposed containers
Hazardous combustion products	Hazardous decomposition products formed under fire conditions. - Carbon oxides, nitrogen oxides (NOx), Hydrogen chloride gas
Protection for Firefighters:	Self-contained breathing apparatus (SCBA) demand (NOISH approved or

Section 6: ACCIDENTAL RELEASE MEASURES

Suitable precautions Protective equipment and emergency procedures.	Avoid raising and breathing and provide adequate ventilation. As conditions warrant, wear NOISH approved self-contained breathing apparatus or respirator and appropriate personal protection (rubber boots, safety goggles and heavy rubber gloves)
Methods and material for containment and cleaning up	Contain spill and collect as appropriate. Transfer to a chemical waste container of disposal in accordance with local regulations.
Environmental precautions	Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

Section 7: HANDLING AND STORAGE

Precautions for safe handling	Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed. Normal measures for preventive fire protection.
Conditions for safe storage	Keep container tightly closed in a dry and well-ventilated place.

Section 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

Contains no substances with occupational exposure limit values.

Personal Protective Equipment	Description
Eye protection	Face shield and safety glasses Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).
Hand protection	Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.
Skin and body protection	Complete suit protecting against chemicals, The type of protective equipment must be selected

Respiratory Protection	Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N99 (US) or type P2 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).
Hygiene measures	Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance	A clear, colorless solution free from visible extraneous matter.
pH	Between 5.0 to 8.0
Density	0.96 to 1.06 g/mL
Assay	Not less than 90.0% and not more than 110.0% w/v of label claim or amount of Olopatadine (C ₂₁ H ₂₃ NO ₃)
Melting/freezing point	No data available
Boiling point	No data available
Flash point	No data available
Ignition temperature	No data available
Lower explosion limit	No data available
Upper explosion limit	No data available

Section 10: STABILITY AND REACTIVITY

Chemical Stability	Stable under recommended storage conditions.
Possibility of hazardous reactions	No data available
Conditions to Avoid	No data available
Incompatibility – materials to avoid	Reactive with strong oxidising agents
Hazardous Decomposition by-products	Hazardous decomposition products formed under fire conditions. - Carbon oxides, nitrogen oxides (NO _x), Hydrogen chloride gas
Other decomposition products	No data available

Section 11: TOXICOLOGY INFORMATION

Acute toxicity

Oral LD50	<p>TDLo Oral – rat – 20 mg/kg TDLo Oral - rat - 50 mg/kg Remarks: Brain and Coverings: Other degenerative changes. Behavioural: Altered sleep time (including change in righting reflex). TDLo Oral - mouse - 0.1 mg/kg Remarks: Biochemical: Metabolism (intermediary): Effect on inflammation or mediation of inflammation.</p>
Inhalation LC50	No data available
Dermal LD50	No data available
Other information on acute toxicity	No data available
Skin corrosion/irritation	No data available
Serious eye damage/eye irritation	No data available
Respiratory or skin sensitization	No data available
Germ cell mutagenicity	No data available
Carcinogenicity	<p>IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC. ACGIH: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH. NTP: No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP. OSHA: No component of this product present at levels greater than or equal to 0.1% is identified as a Carcinogen or potential carcinogen by OSHA.</p>
Reproductive toxicity	No data available
Teratogenicity	No data available
Specific target organ toxicity - single exposure (Globally Harmonized System)	No data available
Aspiration hazard	No data available

Potential health effects	Inhalation May be harmful if inhaled. May cause respiratory tract irritation. Ingestion Toxic if swallowed. Skin May be harmful if absorbed through skin. May cause skin irritation. Eyes May cause eye irritation.
Signs and Symptoms of Exposure	To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.
Synergistic effects	No data available
Additional Information	RTECS: Not available

Section 12: ECOLOGICAL INFORMATION

Toxicity	Avoid release into the environment Runoff from fire control or dilution water may cause pollution
Persistence and degradability	No data available
Bio accumulative potential	No data available
Mobility in soil	No data available
Results of PBT and vPvB assessment	No data available
Other adverse effects	No data available An environmental hazard cannot be excluded in the event of unprofessional handling or disposal. Very toxic to aquatic life.

Section 13: DISPOSAL CONDITIONS

Disposal do not mix with other substances. Dispose of in accordance with Federal, state and local regulations. Contact your state or local government environmental and / or sanitation department for guidance on disposal.

Contaminated packaging: Dispose of as unused product.

Section 14: TRANSPORTATION INFORMATION

DOT (US)	Non-hazardous for transportation.
IATA	Non-hazardous for transportation.
IMDG	Non-hazardous for transportation.

Section 15: REGULATORY INFORMATION

Regulatory information statement	This safety data sheet (SDS) prepared in accordance with 29 CFR 1910.1200 and regulation (EC) No. 1272/2008
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Section 16: OTHER INFORMATION

This information is believed to be accurate and represents the best information currently available to us. However, we make no warranty or merchantability or any other warranty, express or implied, with respect to such information and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes.