

APOTEX
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patient affordability
Safety Data Sheet

Section 1. Identification

Common/Trade name : **Olopatadine Hydrochloride Ophthalmic Solution USP, 0.1% and 0.2%**

Recommended use : Pharmaceutical industry: Dosage form
Therapeutic category: Anti-allergy Agent

This Safety Data Sheet has been provided to inform workers of the safety, health and environmental information associated with this product. It is to be used by people handling the material within the workplace only. It is not meant for patients taking the medication. Patients should consult with their physician, pharmacist or the information provided on the label or on the insert.

Recommended restrictions : No other uses are advised.

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Emergency phone : United States/Canada (Chemtrec) 1-800-424-9300 or
+1 703-527-3887 (24 hours)
For general information call:
1-(416)-749-9300 ext. 8483 (8 AM-4 PM)

Section 2. Hazards Identification

Classification of the substance or mixture : As per 29 CFR 1910.1200 (b)(6) and according to Article 1, item 5 a) of CLP Regulation (EC) 1272/2008, medicinal products (drugs) when it is in the solid, final form for direct administration to the patient or are packaged by the manufacturer for sale to consumers in a retail establishment are exempt from the requirements of classification, labels and SDS's.

GHS label elements : Exempt from requirements.

Hazards not otherwise classified : Exempt from requirements.

Section 3. Composition/Information on Ingredients

Name	CAS #	% (w/w)
Olopatadine hydrochloride	140462-76-6	0.1-1
Benzalkonium chloride	8001-54-5	<0.1
Sodium chloride	7647-14-5	N/A
Sodium phosphate dibasic	7558-79-4	N/A

Specific chemical identity and/or percentage of composition has been withheld as a trade secret.

Chemical name : Not applicable.

Synonyms : Not available.

Chemical family : Dibenzoxepin

Molecular weight : Not applicable.

Chemical formula : Not applicable.

Section 4. First Aid Measures

- Eye contact** : Flush with copious quantities of water. If irritation persists, obtain medical advice.
- Skin contact** : No additional information.
- Inhalation** : Remove from exposure. Persons developing serious hypersensitivity reactions must receive immediate medical attention. If not breathing give artificial respiration. If breathing is difficult give oxygen.
- Ingestion** : Never give anything by mouth if victim is losing consciousness, or is unconscious or convulsing. Rinse mouth thoroughly with water. If breathing is difficult, give oxygen. If breathing has stopped, trained personnel should begin artificial respiration, or if the heart has stopped, cardiopulmonary resuscitation (CPR) immediately. Seek medical attention.
- Potential acute and delayed health effects** : Refer to Sec. 11

Section 5. Fire Fighting Measures

- Specific hazard arising from the chemical** : Not applicable.
- Suitable extinguishing media and special protective equipment for firefighters** : Extinguisher media: Use extinguishing media suitable for surrounding materials.
Special fire fighting procedures: As with all fires, evacuate personnel to safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Section 6. Accidental Release Measures

- Methods and materials for containment and cleaning up** : Assess hazard levels. Contain and clean up spillage and place into an appropriate labeled waste disposal container. Avoid generating dust or aerosols. Wash spill surface using appropriate cleaning solutions. Should clothing be contaminated, wash before reuse.
- Protective equipment and personal precautions** : Keep unnecessary personnel away. Wear appropriate personal protective equipment.

Section 7. Handling and Storage

- Precautions for safe handling** : Avoid contact with eyes.
- Conditions for safe storage** : Store as directed by product packaging.

Section 8. Exposure Controls/Personal Protection

- Engineering Controls** : The engineering control measures appropriate for a particular worksite depend on how this material is handled and on the extent of exposure. Ensure that control measures are designed to comply with occupational, environmental, fire and other applicable regulations. Control measures can include mechanical ventilation (local or general) and process enclosure. Administrative controls and personal protective equipment may also be required.

Personal Protection	: Skin: Lab coat
	Respiratory: Under normal work conditions, the use of respiratory protective equipment is not expected to be required. If the physical state of the finished product is altered by crushing, grinding or breakage or for spill cleaning, an approved NIOSH respirator may be required.
	Hand: Nitrile gloves
	Eye: Safety glasses
Occupational exposure limits	: Not established.

Section 9. Physical and Chemical Properties

Physical state and appearance	: Solution.		
pH	: Not available.	Odor	: Not available.
Melting point/Freezing point	: Not available.	Odor threshold	: Not available.
Boiling point	: Not available.	Conditions of instability	: Not available.
Volatility	: Not available.	Decomposition temperature	: Not available.
Specific gravity	: Not available.	Partition Coefficient:	: Not available.
Evaporation rate	: Not applicable.	Viscosity	: Not available.
Vapor density	: Not available.	Flash points	: Not applicable.
Relative density	: Not available.	Flammable limits	: Not applicable.
Vapor pressure	: Not available.	Autoignition temperature	: Not applicable.
Flammability	: Not flammable.		
Solubility	: Not available.		

Section 10. Stability and Reactivity

Reactivity	: Not available.
Chemical Stability	: Normally stable.
Possibility of hazardous reactions	: Not available.
Hazardous decomp. products	: When heated to decomposition material emits toxic fumes.
Incompatible materials/Conditions to avoid	: Not available.

Section 11. Toxicological Information

Information on the likely routes of exposure : Eye contact. Skin contact.

Toxicity data : Olopatadine hydrochloride:
RTECS#: HQ4135060
LD50: 3870 mg/kg (oral-rat)
LD50: 1490 mg/kg (oral-mouse)
Irritancy data: Eye rabbit (0.6% and 1.5%): not irritant
Sensitization data: Guinea pig maximization test: negative

Delayed and immediate effects and also chronic effects from short and long term exposure : Carcinogenicity: Not listed by IARC, NTP, ACGIH, or OSHA. Olopatadine administered orally was not carcinogenic in mice and rats in doses up to 500 mg/kg/day and 200 mg/kg/day, respectively.

Reproductive Toxicity: Olopatadine administered to male and female rats at oral doses of 62,500 times MROHD level resulted in a slight decrease in the fertility index and reduced implantation rate; no effects on reproductive function were observed at doses of 7,800 times the maximum recommended ocular human use level.

Teratogenicity: Pregnancy Category C. Olopatadine hydrochloride was negative in the Ames test, the in vitro mammalian chromosome aberration assay, and the in vivo mouse micronucleus test.

Mutagenicity: Olopatadine hydrochloride was negative in the Ames test, the in vitro mammalian chromosome aberration assay, and the in vivo mouse micronucleus test.

Remark

Not available.

Symptoms related to the physical, chemical and toxicological characteristics : Adverse effects may include headaches, asthenia, blurred vision, burning or stinging, cold syndrome, dry eye, foreign body sensation, hyperemia, hypersensitivity, keratitis, lid edema, nausea, pharyngitis, pruritis, rhinitis, sinusitis, and taste perversion.

Section 12. Ecological Information

Ecotoxicity : Not available.

Persistence and degradability : Not available.

Bioaccumulative potential : Not available.

Mobility in soil : Not available.

Other adverse effects : Not available.

Section 13. Disposal Considerations

Waste Disposal : Follow all appropriate safe work procedures and local regulations for disposal. Use only licensed disposal and waste hauling companies.

Section 14. Transport information

Regulatory information	UN number	Proper shipping name	Class	Packing group	Additional information
TDG- road Canada/U.S.			Not regulated.		
ICAO/IATA			Not regulated.		
IMDG Class			Not regulated.		

Section 15. Regulatory Information

Canada Regulations : Not regulated under WHMIS: Covered by Food & Drug Act.

Not on the DSL list.

Other Regulations : Not available.

Section 16. Other Information

References : RTECS Database
RxList Monographs
Apotex Product Monograph
U. S. Pharmacopeia

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Notice to Reader

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