

SAFETY DATA SHEET

Olopatadine Hydrochloride Ophthalmic Solution, USP 0.1%

1. IDENTIFICATION

Product Identifier: Olopatadine Hydrochloride Ophthalmic Solution, USP 0.1%

Synonyms: Dibenz[b,e]oxepin-2-acetic acid, 11-[3-(dimethylamino) propylidene]-6,11-dihydro-, hydrochloride, (Z)-

National Drug Code (NDC): 17478-105-05

Recommended Use: Pharmaceutical. Olopatadine Hydrochloride Ophthalmic Solution, USP 0.1% is indicated for the treatment of the signs and symptoms of allergic conjunctivitis.

Company: Akorn, Inc.
1925 West Field Court, Suite 300
Lake Forest, Illinois 60045

Contact Telephone: 1-800-932-5676

E mail: customer.service@akorn.com

Emergency Phone Number: CHEMTREC 1-800-424-9300 (U.S. and Canada)

2. HAZARD(S) IDENTIFICATION

Physical Hazards: Not classifiable.
Health Hazards: Not classifiable.
Symbol(s): None.
Signal Word: None.
Hazard Statement(s): None.
Precautionary Statement(s): None.
Hazards Not Otherwise Classified: None.

Supplementary Information: While this material is not classifiable as hazardous under the OSHA standard, this SDS contains valuable information critical to safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	Synonyms	CAS Number	Chemical Formula	Molecular Weight	Percentage
Olopatadine Hydrochloride	Dibenz[b,e]oxepin-2-acetic acid, 11-[3-(dimethylamino) propylidene] -6,11-dihydro-hydrochloride, (Z)-	140462-76-6	C ₂₁ H ₂₃ NO ₃ •HCl	373.88	0.1%

The formula also contains Benzalkonium Chloride, 0.01% as preservative, Dibasic Sodium Phosphate, Sodium Chloride, Hydrochloric Acid/Sodium Hydroxide used to adjust pH and Water for Injection.

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4. FIRST AID MEASURES

Ingestion:	If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.
Eye Contact:	Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Skin Contact:	Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Inhalation:	Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Protection of First-Aiders:	Use personal protective equipment (see section 8).
Signs and Symptoms:	No data available.
Medical Conditions Aggravated by Exposure:	No data available.
Notes to Physician:	Treat supportively and symptomatically.

5. FIREFIGHTING MEASURES

Suitable Extinguishing Media:	Use water, carbon dioxide, dry chemical or water spray.
Unsuitable Extinguishing Media:	Not determined.

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Specific Hazards Arising from the Chemical

Hazardous Combustion Products: No data available.

Other Specific Hazards: Closed containers may explode from the heat of fire.

Special Protective Equipment and Precautions for Firefighters: Wear self-contained breathing apparatus and full and protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions: Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.

Personal Protective Equipment: For personal protection see section 8.

Methods for Cleaning Up: Absorb with inert material. Recover product and place in an appropriate container for disposal in accordance with local, state and federal regulations. Wipe working area surfaces to dryness, and then wash with soap and water.

Environmental Precautions: Contain material and prevent release to basements, confined spaces, waterways or soil.

Reference to Other Sections: Refer to Sections 8, 12 and 13 for further information.

7. HANDLING AND STORAGE

Precautions for Safe Handling: Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

Conditions for Safe Storage, Including Any Incompatibilities: Store at 4° to 25°C (39° to 77°F).

Specific End Use: Pharmaceutical drug product.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Occupational Exposure Guidelines:

Ingredient	Type	Value
Olopatadine Hydrochloride	No data available	No data available

Engineering Controls: Engineering controls should be used as the primary means to control exposures.

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Respiratory Protection:	Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).
Eyes Protection:	Avoid contact with eyes. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.
Hand Protection:	Wear chemically compatible gloves for handling solutions and ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.
Skin Protection:	Wear protective laboratory coat, apron, or disposable garment when working with large quantities.
General Hygiene Considerations:	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State/Color:	Clear colorless solution.
Odor:	Odorless.
Odor Threshold:	No data available.
pH:	Approximately 7.0.
Melting Point:	No data available.
Freezing Point:	No data available.
Boiling Point:	No data available.
Flash Point:	No data available.
Evaporation Rate:	No data available.
Flammability (solid, gas):	No data available.
Flammability Limit - Lower:	No data available.
Flammability Limit - Upper:	No data available.
Vapor Pressure:	No data available.
Vapor Density:	No data available.
Relative Density:	No data available.
Solubility(ies):	Soluble in water.
Partition Coefficient (n-octanol/water):	No data available.
Auto-Ignition Temperature:	No data available.
Decomposition Temperature:	No data available.
Viscosity:	No data available.

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10. STABILITY AND REACTIVITY

Reactivity:	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical Stability:	Stable under recommended storage conditions.
Possibility of Hazardous Reactions:	Not determined.
Conditions to Avoid (e.g., static discharge, shock, or vibration):	Not determined.
Incompatible Materials:	None known.
Hazardous Decomposition Products:	Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), nitrogen oxides (NOx).

11. TOXICOLOGICAL INFORMATION

Information on the Likely Routes of Exposure

Inhalation:	No data available.
Ingestion:	No data available.
Skin Contact:	No data available.
Eye Contact:	No data available.

Symptoms Related to the Physical, Chemical and Toxicological Characteristics:

See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

Delayed and Immediate Effects of Exposure:

No data available.

Acute Toxicity

Not fully established. This product is a mixture that has not been fully tested as a whole. Information provided herein is derived from the approved product insert and/or supplier SDS for active ingredients.

Ingredient	Species	Route	Test Type	Dosage
Olopatadine Hydrochloride	Rat	Oral	LD ₅₀	3,870 mg/kg
Olopatadine Hydrochloride	Mouse	Oral	LD ₅₀	1,490 mg/kg

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Irritation / Sensitization

Ingredient	Study Type	Species	Severity
Olopatadine Hydrochloride	Antigenic potential test	Guinea Pig	Negative
Olopatadine Hydrochloride	Antigenic potential test	Mouse	Negative
Olopatadine Hydrochloride	Maximization test	Guinea Pig	Non-sensitizing

Repeated Does Toxicity

Ingredient	Duration	Species	Route	Dosage	Test Type	Target Organ
No data available	No data available	No data available	No data available	No data available	No data available	No data available

Reproduction and Developmental Toxicity

Ingredient	Study Type	Species	Route	Dosage	Test Type	Effect(s)
Olopatadine Hydrochloride	Reproductivity Study	Rabbit	Not specified	25 mg/kg maternal dose	Not specified	Decreased numbers of live fetuses
Olopatadine Hydrochloride	Reproductivity Study	Rabbit	Not specified	400 mg/kg/day	Not specified	No birth defects
Olopatadine Hydrochloride	Reproductivity Study	Rat	Not specified	60 mg/kg maternal dose	Not specified	Decreased numbers of live fetuses, reduced viability and body weight of live pups
Olopatadine Hydrochloride	Reproductivity Study	Rat	Not specified	600 mg/kg/day	Not specified	Reduced fetal weight; no birth defects

Genetic Toxicity

Ingredient	Study Type	Cell Type / Organism	Result
Olopatadine Hydrochloride	Ames test	Not specified	Negative
Olopatadine Hydrochloride	In Vitro	Mammalian chromosome aberration assay	Negative
Olopatadine Hydrochloride	In Vivo	Mouse micronucleus test	Negative

Aspiration Hazard:

No data available.

Toxicokinetics/Metabolism:

No data available.

Target Organ Effects:

No data available.

Systemic Effects:

No data available.

Reproductive Effects:

Pregnancy Category C. Olopatadine was found not to be teratogenic in rats and rabbits.

Carcinogenicity:

Olopatadine administered orally was not carcinogenic in mice and rats in doses up to 500 mg/kg/day and 200 mg/kg/day.

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National Toxicology Program (NTP): Not considered to be a carcinogen.

International Agency for Research on Cancer (IARC): Not considered to be a carcinogen.

Occupational Safety and Health Administration (OSHA): Not considered to be a carcinogen.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity

Ingredient	Species	Test Type	Dosage	Duration
No data available	No data available	No data available	No data available	No data available

Terrestrial Toxicity: No data available.
Persistence and Degradability: No data available.
Bioaccumulative Potential: No data available.
Mobility in Soil: No data available.
Mobility in Environment: No data available.
Other Adverse Effects: No data available.

13. DISPOSAL CONSIDERATIONS

Do not empty into drains; dispose of this material and its container in a safe way. Dispose of all waste in accordance with Federal, State and Local regulations.

14. TRANSPORT INFORMATION

Department of Transportation (DOT): Not regulated as a hazardous material.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Not applicable	Not applicable	Not applicable	Not applicable

International Air Transport Association (IATA): Not regulated as a dangerous good.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Not applicable	Not applicable	Not applicable	Not applicable

International Maritime Dangerous Good (IMDG): Not regulated as a dangerous good.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Not applicable	Not applicable	Not applicable	Not applicable

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15. REGULATORY INFORMATION

US FEDERAL REGULATIONS

Toxic Substance Control Act (TSCA):

Ingredient	Inventory
Olopatadine Hydrochloride	No

CERCLA Hazardous Substance:

Ingredient	Reportable Quantity
Not applicable	Not applicable

EPCRA Extremely Hazardous Substances and Toxic Chemicals:

Ingredient	Section 302	Section 313
Not applicable	Not applicable	Not applicable

U.S. STATE RIGHT-TO-KNOW REGULATIONS

Ingredient	New Jersey	Pennsylvania	Massachusetts
Olopatadine Hydrochloride	Listed	Listed	Not Listed

California Proposition 65:

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

16. OTHER INFORMATION

See footer of this document for Revision Date and Revision Number.

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