

SAFETY DATA SHEET

Azelastine Hydrochloride Ophthalmic Solution, 0.05%

1. IDENTIFICATION

Product Identifier: Azelastine Hydrochloride Ophthalmic Solution, 0.05%

Synonyms: (±)-1-(2H)-phthalazinone, 4-[(4-chlorophenyl) methyl]-2-(hexahydro-1-methyl-1H-azepin-4-yl), monohydrochloride

National Drug Code (NDC): 17478-718-10

Recommended Use: Pharmaceutical. Azelastine Hydrochloride Ophthalmic Solution is indicated for the treatment of itching of the eye associated with 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
Azelastine Hydrochloride	(±)-1-(2H)-phthalazinone, 4-[(4-chlorophenyl) methyl]-2-(hexahydro-1-methyl-1H-azepin-4-yl)-, monohydrochloride	79307-93-0	$C_{22}H_{24}ClN_3O \cdot HCl$	418.37	0.05%

The formula also contains Benzalkonium Chloride, 0.125 mg as a preservative, Disodium Edeate Dihydrate, Hypromellose, Sorbitol Solution, Sodium Hydroxide and Water for Injection.

SAFETY DATA SHEET

Azelastine Hydrochloride Ophthalmic Solution, 0.05%

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:	Solution is intended for human consumption under guidance of a physician. Solution is not considered hazardous under normal conditions.
Medical Conditions Aggravated by Exposure:	Material is a liquid drug dosage form intended for human use. Always follow prudent laboratory practices. Consult the package insert for further information.
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.

SAFETY DATA SHEET

Azelastine Hydrochloride Ophthalmic Solution, 0.05%

Specific Hazards Arising from the Chemical

Hazardous Combustion Products: Not determined.

Other Specific Hazards: Not determined.

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 2° to 25°C (36° to 77°F). Store upright.

Specific End Use: Pharmaceutical drug product.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Occupational Exposure Guidelines:

Ingredient	Type	Value
Azelastine Hydrochloride	Not established	Not established

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

SAFETY DATA SHEET

Azelastine Hydrochloride Ophthalmic Solution, 0.05%

Respiratory Protection:	None required for normal use. 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:	None required for normal use. 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:	None required for normal use. Chemically compatible gloves are recommended for bulk handling. 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 liquid.
Odor:	Odorless.
Odor Threshold:	No data available.
pH:	5.0 to 6.5.
Melting Point:	225°C.
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):	Sparingly 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.

SAFETY DATA SHEET

Azelastine Hydrochloride Ophthalmic Solution, 0.05%

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:	No data available.
Conditions to Avoid (e.g., static discharge, shock, or vibration):	No data available.
Incompatible Materials:	Avoid oxidizing agents.
Hazardous Decomposition Products:	No data available.

11. TOXICOLOGICAL INFORMATION

Information on the Likely Routes of Exposure

Inhalation:	May cause irritation of nose, throat and respiratory tract.
Ingestion:	May be harmful if swallowed.
Skin Contact:	May cause slight irritation on prolonged or repeated contact.
Eye Contact:	May cause slight eye irritation.
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
Azelastine Hydrochloride	Rat	Oral	LD ₅₀	410 mg/kg
Azelastine Hydrochloride	Mouse	Oral	LD ₅₀	143 mg/kg
Azelastine Hydrochloride	Guinea Pig	Oral	LD ₅₀	126 mg/kg
Azelastine Hydrochloride	Dog	Oral	LD ₅₀	107 mg/kg

SAFETY DATA SHEET

Azelastine Hydrochloride Ophthalmic Solution, 0.05%

Irritation / Sensitization

Ingredient	Study Type	Species	Severity
Azelastine Hydrochloride	0.2% Sensitization test (skin)	Guinea pig	Non-sensitizing

Repeated Dose 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)
No data available	No data available	No data available	No data available	No data available	No data available	No data available

Genetic Toxicity

Ingredient	Study Type	Result
No data available	No data available	No data available

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. Azelastine Hydrochloride has been shown to be embryotoxic, fetotoxic and teratogenic (external and skeletal abnormalities) in mice at an oral dose of 68.6 mg/kg/day. This is 57,000 times the recommended ocular human dose level. Reproductive and fertility studies in rats showed no effects on male or female fertility at oral doses up to 25,000 times the maximum recommended ocular human use level.

Carcinogenicity: Azelastine Hydrochloride administered orally for 24 months was not carcinogenic in rats and mice at doses up to 30 mg/kg/day and 25 mg/kg/day, respectively.

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.

SAFETY DATA SHEET

Azelastine Hydrochloride Ophthalmic Solution, 0.05%

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

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

15. REGULATORY INFORMATION

US FEDERAL REGULATIONS

Toxic Substance Control Act (TSCA):

Ingredient	Inventory
Azelastine Hydrochloride	No

SAFETY DATA SHEET

Azelastine Hydrochloride Ophthalmic Solution, 0.05%

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
Azelastine Hydrochloride	Not listed	Not 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.

Disclaimer: This document is generated to distribute health, safety and environmental data. It is not a specification sheet and none of the displayed data should be construed as a specification. Information on this SDS sheet was obtained from sources which we believe are reliable, and we believe that the information is complete and accurate. However, the information is provided without any warranty, express or implied, regarding its correctness. Some of the information presented and conclusions drawn are from sources other than direct test data of the substance. The conditions or methods of handling, storage, use and disposal of the product are beyond our control and may also be beyond our knowledge. It is the user's responsibility to determine the suitability of any material for a specific purpose and to adopt such safety precautions as may be necessary. If the product is used as a component in another product, this SDS information may not be applicable. For these reasons, we do not assume any responsibility and expressly disclaim liability for any loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of this product.