

*SAFETY DATA SHEET***Azelastine Hydrochloride Ophthalmic Solution 0.05%****1. Product and Company Information**

Product Identifier: Azelastine Hydrochloride Ophthalmic Solution 0.05%
Synonyms: None
National Drug Code: 70069-091-01 (6 ml)
Recommended Use: Pharmaceutical Eye Drop
Company: Somerset Therapeutics LLC
Somerset, NJ 08873
Contact Telephone: 1800-417-9175
E-Mail: customerservice@somersetpharma.com
Emergency Phone Number: 732-554-1100

2. Hazardous(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: Although this material is classifiable as non-hazardous under the OSHA standard, this SDS contains valuable information critical to safe handling and proper use of the product.

3. Composition and Information on Ingredients

Chemical Name	CAS Number
Azelastine Hydrochloride	79307-93-0
Benzalkonium Chloride NF	63449-41-2
Edetate Disodium USP	6381-92-6
Hypromellose USP	9004-65-3
Sorbitol Solution USP 70 %	50-70-4
Sodium Hydrochloride NF	1310-73-2
Water for Injection USP	7732-18-5

The exact percentage (concentration) of the composition is being withheld as a trade secret is required.

4. First Aid Measures

- Eye Contact** Azelastine hydrochloride ophthalmic solution, 0.05% is a sterile ophthalmic solution containing azelastine hydrochloride, for topical administration to the eyes.
If irritation occurs or persists, discontinue use and get medical attention.
- Skin Contact:** Possible irritant, obtain medical assistance if irritation occurs.
- Inhalation:** Harmful if inhaled, contact a physician.
- Ingestion:** Wash out mouth and drink plenty of water and bland fluids. Do not give anything to an unconscious person. Contact physician.

5. Fire-Fighting Measures

- Extinguishing Media:** Not Flammable. Select extinguishing agent appropriate to other materials involved.
- Hazardous Combustion Products:** Low Density Polyethylene, High density polyethylene
- Fire Fighting Procedures:** Wear self-contained breathing apparatus and protective clothing.
- Fire / Explosion Hazards:** Not applicable

6. Accidental Release Measures

- Health and Safety Precautions:** Use personal protective equipment
- Measures for Cleaning / Collecting:** Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.
- Measures for Environmental Protections:** Contain the spill to prevent drainage into sewers, drains or streams. Use absorbent material to solidify the spill. Shovel or scoop up solidified waste

7. Handling and Storage:

Handling: Avoid contact with product and use caution to prevent puncturing containers. No special protective equipment or procedures are required in the clinical or home environment.

Storage: Store product upright in original containers with the cap tightly closed at a controlled room temperature 2°-25°C (36°- 77° F).

8. Exposure Controls / Personal Protection

Exposure Limits None assigned

Hands: Wear protective gloves

Eyes: Recommend goggles or chemical safety glasses.

Skin: Thick impermeable gloves and protective clothing

Respiratory protection: NIOSH approved respirator, with organic vapor, acid gas and HEPA filter recommended for handling raw materials.

Warning: Do not use air-purifying respirators in oxygen-depleted environments.

No respiratory protection is required in the clinical or home environment.

9. Physical and Chemical Properties

Appearance	Clear, greenish yellow solution,
Decomposition Temperature (°C):	No data available.
Evaporation Rate (Gram/s):	No data available
Vapour Pressure (kPa):	No data available
Vapour Density (g/ml):	No data available
Specific Gravity:	1.010 – 1.020
Viscosity:	1.7 – 2.7 mPas
Flammability:	Not flammable
Flash Point (Liquid) (°C):	Not flammable
Upper Explosive Limits (Liquid) (% by Vol.):	No data available
Lower Explosive Limits (Liquid) (% by Vol.):	No data available

10. Stability and Reactivity

Reactivity:	No data available
Chemical Stability:	Stable under normal ambient temperatures
Incompatible Materials:	No data available
Hazardous Decomposition Products	Oxides of carbon, oxides of nitrogen, ammonia, hydrocarbons
Hazardous Polymerization	No data available

11. Toxicological Information

Information on the Likely Routes of Exposure:

Inhalation:	Product has no effect.
Ingestion:	May cause stomach discomfort if ingested.
Skin Contact:	Product has no effect.
Eye Contact:	Product is intended for use in the ocular area.
Delayed and Immediate Effects of Exposure:	No data available.
Acute Toxicity – Oral:	No data available.
Acute Toxicity – Dermal:	No data available
Acute Toxicity – Inhalation:	No data available
Toxicokinetics /Metabolism:	No data available
Target Organ Effects:	No data available
Reproductive Effects:	No data available
Carcinogenicity:	No data available.
National Toxicology Program:	Not considered to be a carcinogen.
International Agency for Research on Cancer:	Not considered to be a carcinogen.
Occupational Safety and Health Administration:	Not considered to be a carcinogen.
Mutagenicity:	No data available.
Aspiration Hazard:	No data available.
Chronic Effects:	This product is not expected to cause long term adverse health effects. No evidence of carcinogenicity was seen in rat or mice

12. Ecological Information

Aquatic:	No data available
Terrestrial:	No data available
Persistence and Degradability:	No data available
Bio-accumulative Potential:	No data available
Mobility in Soil:	No data available
Mobility in Environment:	No data available
Other Adverse Effects:	No data available

13. Disposal Conditions

Dispose of material according to Federal, State, and Local regulations.

14. Transportation Information

UN Number:	None
UN Proper Shipping Name:	None
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable.
Department of Transportation:	Not regulated as a hazardous material.
International Air Transport Association (IATA):	Not regulated as a dangerous good.
International Maritime Dangerous Good (IMDG):	Not regulated as a dangerous good.

15. Regulatory Information

DOT Designations:	Non-hazardous
RCRA Hazardous Waste:	Not Listed
FDA Designations:	Prescription only medication. NDC No. 70069-091-01 (6 ml)
OSHA Designations: (29 CFR 1910.1000, Table Z):	Not Listed
SARA Title III:	Not listed under Section 313 of Toxic Release Reporting.
California Proposition 65:	Not Listed

16. Other Information

NFPA Rating:	
Health:	1
Flammability:	0
Reactivity:	0

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Disclaimer: As of the date of issuance, we are providing available information relevant to the handling of this material. All information contained herein is offered with the good faith belief that it is accurate. In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.