

## SAFETY DATA SHEET

**PRODUCT:** Azelastine Hydrochloride Ophthalmic solution, 0.05%

### Section 1: PRODUCT AND COMPANY INFORMATION

Wintac Limited 54/1, Boodhihal village, Nelamangala, Bangalore, India-562123. PRODUCT NAME: Azelastine Hydrochloride Ophthalmic solution, 0.05% National Drug Code: 70069-091-01
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### Section 2: HAZARD(S) IDENTIFICATION

<b>Main Hazards</b>	Not classified as hazardous
<b>Routes of Entry</b>	Inhalation – Ingestion – skin contact – Absorption – Eye contact
<b>Carcinogenic status</b>	Not considered carcinogenic by NTP, IARC and OSHA
<b>Target Organs</b>	Eye- skin- Respiratory system
<b>Health effects – Eyes</b>	No adverse effects are expected. Contact may cause slight transient irritation
<b>Health effects – Skin</b>	Material may cause slight irritation on prolonged or repeated contact
<b>Health effects - Ingestion</b>	A large dose may have the following effects: Irritation of mouth, throat and digestive tract
<b>Health effects - Inhalation</b>	Prolonged or repeated exposure will have the following effects: Irritation of nose, throat and respiratory.

### Section 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

#### Section 4: FIRST AID MEASURES

<b>Ingestion</b>	Do not induce vomiting- Have victim drink 1-3 glasses of water to dilute stomach contents. Never administer anything by mouth if a victim is losing consciousness, is unconscious or is convulsing. Obtain medical attention immediately
<b>Eye Contact</b>	If eye irritation develops, or others symptoms occur, discontinue use. obtain medical attention if soreness or redness persists
<b>Skin Contact:</b>	If skin irritation develops, or others symptoms occur, discontinue use, seek medical attention if symptoms persist
<b>Inhalation:</b>	If there is difficulty in breathing, give oxygen. Seek medical attention if symptoms persist
<b>Advice to Physicians</b>	Treat symptomatically

#### Section 5: FIRE FIGHTING MEASURES

<b>Extinguishing Media:</b>	Not Flammable. Select extinguishing agent appropriate to other material involved
<b>Hazardous Combustion Products:</b>	Low Density Polyethylene, High density polyethylene
<b>Protective equipment for Fire Fighting Procedures:</b>	Wear full protective clothing and self – contained breathing apparatus
<b>Unusual Fire / Explosion Hazards:</b>	None Known

#### Section 6: ACCIDENTAL RELEASE MEASURES

<b>Measures for Cleaning / Collecting:</b>	This product may be collected by carefully scooping into a pan, paper towel or other absorbent material. Transfer into suitable containers for recovery or disposal. Wear appropriate protective clothing.
<b>Health and Safety Precautions:</b>	Use personal protective equipment
<b>Measures for Environmental Protections:</b>	Contain the spill to prevent drainage into sewers, drains or streams. Use absorbent material to solidify the spill. Shovel or scoop up solidified waste

## Section 7: HANDLING AND STORAGE

<b>Handling</b>	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
<b>Storage</b>	Store product upright in original containers with the cap tightly closed at a controlled room temperature 15°-30°C (59°- 86° F).

## Section 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

<b>Exposure Limits</b>	None assigned
<b>Engineering control measures</b>	Good general room ventilation is expected to be adequate to control airborne level
<b>Respiratory Protection:</b>	NIOSH approved respirator, with organic vapor, acid gas and HEPA filter recommended for handling raw materials. <b>Warning: Do not use air-purifying respirators in oxygen-depleted environments.</b> No respiratory protection is required in the clinical or home environment
<b>Hand Protection:</b>	Chemical resistant gloves
<b>Eye Protection</b>	Eye protection not normally required. However, care should be taken to avoid accidental exposure. The use of safety glasses with side shields is recommended in situations where repeated contact with the eyes may occur.
<b>Body Protection</b>	Normal work wear

## Section 9: PHYSICAL AND CHEMICAL PROPERTIES

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

## Section 10: STABILITY AND REACTIVITY

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

## Section 11: TOXICOLOGY 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  
 Toxicokinetic /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.  
 Effects: This product is not expected to cause long term adverse health effects. No evidence of carcinogenicity was seen in rat or mice

## Section 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

### Section 13: Disposal Conditions

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

### Section 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.

### Section 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

### Section 16: OTHER INFORMATION

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose. Wintac shall not be held liable for any damage resulting from handling or from contact with the above product. Wintac reserves the right to revise this MSDS.