

Section 1: Identification

Product Name Azelastine HCL USP
Commercial Name N/A
Product Use Active pharmaceutical ingredient
Restrictions On Use Uses other than those recommended

Product Code 30-5005

Company PCCA
9901 South Wilcrest
Houston, TX 77099
Phone: 1-800-331-2498
Fax: 1-800-874-5760

In case of emergency contact:
CHEMTREC (24hr) 1-800-424-9300

Section 2: Hazard(s) Identification

OSHA Haz Com: Acute Tox. 4 : Harmful in contact with skin. Acute Tox. 4 : Harmful if inhaled. Acute Tox. 4 : Harmful if swallowed. Aquatic Chronic 4 : May cause long lasting harmful effects to aquatic life. Carc. 2 : Suspected of causing cancer. Repr. 2 : Suspected of damaging fertility or the unborn child. Skin Irrit. 2 : Causes skin irritation. STOT SE 3 : May cause respiratory irritation.

Signal Word WARNING

Hazard Statement(s) HARMFUL IF SWALLOWED. HARMFUL IN CONTACT WITH SKIN. HARMFUL IF INHALED. CAUSES SKIN IRRITATION. MAY CAUSE RESPIRATORY IRRITATION.

Pictogram(s) or Symbol(s)



Precautionary Statement(s):

Prevention P201 Obtain special instructions before use. P261 Avoid breathing dust/fume/gas/mist/vapours/spray. P273 Avoid release to the environment. P280 Wear protective gloves/protective clothing/eye protection/face protection.
Response P321 Specific treatment (see ... on this label).
Storage P403+P233 Store in a well-ventilated place. Keep container tightly closed.
Disposal P501 Dispose of contents/container to hazardous wastes or to special waste collection point

Section 3: Composition/Information on Ingredients

Substance/Mixture Substance
Components 4-[(4-chlorophenyl)methyl]-2-(hexahydro-1-methyl-1H-azepin-4-yl)-, hydrochloride (9CI)
% By Weight 25-100%
CAS# 79307-93-0
Molecular Weight N/A
Chemical Formula N/A
Synonym(s) N/A

Mixtures

Name	CAS#	% by Weight	TLV/PEL	LC50/LD50
4-[(4-chlorophenyl)methyl]-2-(hexahydro-1-methyl-1H-azepin-4-yl)-, hydrochloride (9CI)	79307-93-0	25-100	Acute Tox. 4, H302 - STOT RE2, H373	N/A

Section 4: First-Aid Measures

Inhalation	Take the victim into open air; keep them warm and calm. If breathing is irregular or stops, perform artificial respiration. Do not administer anything orally. If unconscious, place them in a suitable position and seek medical assistance. The use of personal protective equipment is recommended for people providing first aid (see section 8).
Skin Contact	Remove contaminated clothing. Wash skin vigorously with water and soap or a suitable skin cleaner. NEVER use solvents or thinners. The use of personal protective equipment is recommended for people providing first aid (see section 8).
Eye Contact	Remove contact lenses, if present and if it is easy to do. Wash eyes with plenty of clean and cool water for at least 10 minutes while pulling eyelids up, and seek medical assistance.
Ingestion	If accidentally ingested, seek immediate medical attention. Keep calm. NEVER induce vomiting.
Symptoms/Effects	
Acute	Irritant Product, repeated or prolonged contact with skin or mucous membranes can cause redness, blisters or dermatitis, inhalation of spray mist or particles in suspension may cause irritation of the respiratory tract, some symptoms may not be immediate. Harmful Product, prolonged exposure due to inhalation may cause anaesthetic effects and the need for immediate medical assistance. Long-term chronic exposure may result in injury to certain organs or tissues.
Delayed	Irritant Product, repeated or prolonged contact with skin or mucous membranes can cause redness, blisters or dermatitis, inhalation of spray mist or particles in suspension may cause irritation of the respiratory tract, some symptoms may not be immediate. Harmful Product, prolonged exposure due to inhalation may cause anaesthetic effects and the need for immediate medical assistance. Long-term chronic exposure may result in injury to certain organs or tissues.

Immediate Medical Attention

In case of doubt or when symptoms of feeling unwell persist, get medical attention. Never administer anything orally to persons who are unconscious. Keep the person comfortable. Turn him/her over to the left side and stay there while waiting for medical care.

Section 5: Fire-Fighting Measures**Suitable Extinguishing Media**

Extinguisher powder or CO₂. In case of more serious fires, also alcohol-resistant foam and water spray.

Unsuitable Extinguishing Media

Do not use a direct stream of water to extinguish. In the presence of electrical voltage, you cannot use water or foam as extinguishing media.

Products of Combustion

Fire can cause thick, black smoke. As a result of thermal decomposition, dangerous products can form: carbon monoxide, carbon dioxide. Exposure to combustion or decomposition products can be harmful to your health.

Firefighters Special Equipment and Precautions

Use water to cool tanks, cisterns, or containers close to the heat source or fire. Take wind direction into account. Prevent the products used to fight the fire from going into drains, sewers, or waterways. According to the size of the fire, it may be necessary to use protective suits against the heat, individual breathing equipment, gloves, protective goggles or facemasks, and boots.

Section 6: Accidental Release Measures

Personal precautions, protective equipment and emergency procedures. For exposure control and individual protection measures, see section 8. Environmental precautions. Prevent the contamination of drains, surface or subterranean waters, and the ground. Methods and material for containment and cleaning up. The contaminated area should be immediately cleaned with an appropriate de-contaminator. Pour the decontaminator on the remains in an opened container and let it act various days until no further reaction is produced.

Section 7: Handling and Storage

Precautions for safe handling. For personal protection, see section 8. Never use pressure to empty the containers. They are not pressure-resistant containers. In the application area, smoking, eating, and drinking must be prohibited. Follow legislation on occupational health and safety. Keep the product in containers made of a material identical to the original. Conditions for safe storage, including any incompatibilities. No special storage conditions in terms of maximum storage temperature need to be declared in the labelling since the product meets its corresponding stability specifications (as general storage measures, sources of heat, radiation, electricity and contact with food should be avoided). Keep away from oxidising agents and from highly acidic or alkaline materials. "Store according to local legislation. Observe indications on the label. Store the containers in a dry and well-ventilated place, far from sources of heat and direct solar light. Keep far away from ignition points. Prevent the entry of non-authorised persons. Once the containers are open, they must be carefully closed and placed vertically to prevent spills. The product is not affected by Directive 2012/18/EU (SEVESO III).

Section 8: Exposure Controls/Personal Protection**Exposure Limits**

The product does NOT contain substances with Professional Exposure Environmental Limit Values. The product does NOT contain substances with Biological Limit Values.

Engineering Controls

N/A

Personal Protection

Breathing Protection: PPE: Filter mask for protection against gases and particles. Characteristics: «CE» marking, category III. The mask must have a wide field of vision and an ;, anatomically designed form in order to be sealed and watertight. CEN standards: EN 136, EN 140, EN 405 Maintenance: Should not be stored in places exposed to high temperatures and damp environments before use. Special attention should be paid to the state of the inhalation and exhalation valves in the face adaptor. Read carefully the manufacturer's instructions regarding the equipment's use and maintenance. Attach Observations: the necessary filters to the equipment according to the specific nature of the risk (Particles and aerosols: P1- P2 -P3, Gases and vapours: A- B- E- K -AX), changing them as advised by the manufacturer. Filter Type needed: A2 Hand protection: PPE: Protective gloves. Characteristics: «CE» marking, category II. CEN standards: EN 374 -1, EN 374 -2, EN 374 -3, EN 420 Maintenance: Keep in a dry place, away from any sources of heat, and avoid exposure to sunlight as much as possible. Do not make any changes to the gloves that may alter their resistance, or apply paints, solvents or adhesives. Observations: Gloves should be of the appropriate size and fit the user's hand well, not being too loose or too tight. Always use with clean dry hands. Material: PVC (polyvinyl chloride) Breakthrough time: Min > 480 Material thickness: mm 0,35 Eye protection: PPE: Face shield. Characteristics: «CE» marking, category II. Face and eye protector against splashing liquid. CEN standards: EN 165, EN 166, EN 167, EN 168 Maintenance: Visibility through lenses should be ideal. Therefore, these parts should be cleaned daily. Protectors should be disinfected periodically following the manufacturer's instructions. Make sure that mobile parts move smoothly. Observations: Face shields should offer a field of vision with a dimension in the central line of, at least, 150 mm vertically once attached to the frame Skin protection: PPE: Protective clothing. Characteristics: «CE» marking, category II. Protective clothing should not be too tight or loose in order not to obstruct the user's movements. CEN standards: EN 340 Maintenance: In order to guarantee uniform protection, follow the washing and maintenance instructions provided by the manufacturer. Observations: The protective clothing should offer a level of comfort in line with the level of protection provided in terms of the hazard against which it protects, bearing in mind environmental conditions, the user's level of activity and the expected time of use. PPE: Work footwear. Characteristics: «CE» marking, category II. CEN standards: EN ISO 13287, EN 20347 Maintenance: This product adapts to the first user's foot shape. That is why, as well as for hygienic reasons, it should not be used by other people. Observations: Work footwear for professional use includes protection elements

Section 9: Physical and Chemical Properties

Appearance	Solid powder, white		
Odor	N/A		
Odor Threshold	N/A		
Melting Point	225-229C at 760mmHg degi	pH	N/A
Freezing Point	N/A	Vapor Pressure	N/A
Boiling Point/Range	N/A	Vapor Density	N/A
Decomposition temperature	N/A	Viscosity	N/A
Partition Coefficient: n-octanol/water	N/A	Evaporation Rate	N/A
Flash Point	N/A	Autoignition temperature	N/A
Flammability	N/A	Flammability or Explosive Limits:	
		Lower	N/A
		Upper	N/A
Solubility(ies)	N/A		
Other	N/A		

Section 10: Stability and Reactivity

Reactivity	The product does not present hazards by their reactivity.
Chemical Stability	Stable under the recommended handling and storage conditions (see section 7).
Hazardous Polymerization	The product does not present possibility of hazardous reactions.
Conditions to Avoid	Avoid any improper handling.
Incompatible Materials	Keep away from oxidising agents and from highly alkaline or acidic materials in order to prevent exothermic reactions.
Hazardous Decomposition Products	No decomposition if used for the intended uses.

Section 11: Toxicological Information
RTECS N/A

Acute Toxicity

Acute toxicity (Dermal), Category 4: Harmful in contact with skin. Acute toxicity (Inhalation), Category 4: Harmful if inhaled. Acute toxicity (Oral), Category 4: Harmful if swallowed.

Skin Corrosion/Irritation

Skin irritant, Category 2: Causes skin irritation.

Serious Eye Damage/Irritation

Not conclusive data for classification.

Respiratory or Skin Sensitization

Not conclusive data for classification.

Germ Cell Mutagenicity

Not conclusive data for classification.

Carcinogenicity

Carcinogen, Category 2: Suspected of causing cancer.

Reproductive Toxicity

Reproductive toxicant, Category 2: Suspected of damaging fertility or the unborn child.

Routes of Entry

N/A

Symptoms Related to Exposure

Not conclusive data for classification.

Potential Health Effects

Not conclusive data for classification.

Target Organ(s) Specific target organ toxicity following a single exposure, Category 3:

Section 12: Ecological Information**Ecotoxicity**

No information is available regarding the ecotoxicity of the substances present.

Persistence and Degradability

There is no information available on the degradability of the substances present. No information is available regarding the degradability. No information is available about persistence and degradability of the product.

Bioaccumulative Potential

No information is available regarding the bioaccumulation of the substances present.

Mobility in Soil

No information is available about the mobility in soil. The product must not be allowed to go into sewers or waterways. Prevent penetration into the ground.

Other Adverse Effects

Results of PBT and vPvB assessment. No information is available about the results of PBT and vPvB assessment of the product.

Section 13: Disposal Considerations**Waste Disposal**

Do not dump into sewers or waterways. Waste and empty containers must be handled and eliminated according to current, local /national legislation. Follow the provisions of Directive 2008/98/EC regarding waste management.

Disposal of Container

N/A

Other Considerations

N/A

Section 14: Transport Information**DOT Classification**

Transportation is not dangerous. In case of road accident causing the product's spillage, proceed in accordance with point 6. UN number. Transportation is not dangerous. UN proper shipping name: Transportation is not dangerous. Transport hazard class(es): Transportation is not dangerous. Packing group.: Transportation is not dangerous. Environmental hazards. :Transportation is not dangerous. Special precautions for user: Transportation is not dangerous. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code.: Transportation is not dangerous.

Section 15: Regulatory Information**Regulations**

Safety, health and environmental regulations/ legislation specific for the mixture. The product is not affected by the Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer. See annex I of the Directive 96/82/EC of 9 December 1996 on the control of major- accident hazards involving dangerous substances and the Regulation (EC) No 689/2008 of the European Parliament and of the Council of 17 June 2008 concerning the export and import of dangerous chemicals and its subsequent updates. The product is not affected by Directive 2012/18/EU (SEVESO III). The product is not affected by Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products. The product is not affected by the procedure established Regulation (EU) No 649/2012, concerning the export and import of dangerous chemicals.

Other

Chemical safety assessment: There has been no evaluation a chemical safety assessment of the product.

Section 16: Other Information



Safety Data Sheet

For Compliance with OSHA 29 CFR 1910.1200 and ANSI Z400.1-1998

Azelastine HCL USP

30-5005

N/A