SECTION-1: Identification of the substance / mixture and the company / undertaking

Catalogue Number	CS-MM-12714
Product Name	Azelastine
CAS No.	58581-89-8
Category	API
Synonyms	.
Brand	Clearsynth Labs Ltd.
Identified uses	Laboratory Chemicals
Uses advised against	Not available
Company	Clearsynth Labs Ltd. Mumbai, India
Emergency Phone #	+91-22-245045900
REACH No.	Not available

SECTION 2: Hazards identification

Disclaimer: This is sample MSDS. Please email **sales@clearsynth.com** for more details.

2.1 Classification of the substance or mixture-Regulation (EC) No 1272/2008:

Skin irritation (Category 2)
Acute toxicity (Category 4)

2.2 Label Elements

Signal Word: Warning

Hazard Statement(s)

Code	Statement
H302	Harmful if swallowed.
H312	Harmful in contact with skin.
H315	Causes skin irritation.

H332	Harmful if inhaled.
H335	Not available
H351	Not available
H413	Not available

Precautionary Statement(s)

Code	Statement
P203	Not available
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P264	Wash hands thoroughly after handling.
P270	Not available
P271	Use only outdoors or in a well-ventilated area.
P273	Not available
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301+P317	Not available
P302+P352	IF ON SKIN: Wash with plenty of water and soap.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P317	Not available
P318	Not available
P319	Get medical help if you feel unwell.
P321	Specific treatment (see … on this label).
P330	Not available
P332+P317	If skin irritation occurs: Get medical help.
P362+P364	Take off contaminated clothing and wash it before reuse.
P403+P233	Store in a well-ventilated place. Keep container tightly closed.
P405	Store locked up.
P501	Dispose of contents/container in accordance with local/regional/national/international regulatio

SECTION 3: Composition / information on ingredients

3.1 Substance

Component : Azelastine

CAS Number : 58581-89-8
Molecular Formula : C■■H■■Cl■N■■O
Molecular Weight : 418.37
Parent Chemical : Azelastine
Synonyms : .
Concentration : Not available

SECTION 4: First aid measures

Not available

SECTION 5: Firefighting measures

Not available

SECTION 6: Accidental release measures

Not available

SECTION-7: Handling and storage

Not available

SECTION 8: Exposure controls / personal protection

Not available

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Test	Result
Appearance	No data available
IR spectrum	No data available
pH	No data available
Solubility	No data available

Property	Value
a) Physical State	No data available
b) Color	No data available

Property	Value
c) Odor	No data available
d) pH	No data available
e) Vapour Pressure	No data available
f) Viscosity	No data available
g) Initial Boiling Point and boiling range	No data available
h) Melting Point / Freezing Point	No data available
i) Auto Ignition Temperature	No data available
j) Flash Point	No data available
k) Explosion Limit, Lower	No data available
l) Explosion Limit, Upper	No data available
m) Decomposition Temperature	No data available
n) Loss on Drying	No data available
o) Relative Density	No data available
p) Solubility (in DMSO)	No data available
q) Oxidizing Properties	No data available

SECTION 10: Stability and reactivity

Not available

SECTION 11: Toxicological information

11.1 Information on toxicological effects
- Acute toxicity: /SIGNS AND SYMPTOMS/ There have been no reported overdosages with Astelin Nasal Spray. Acute overdosage by adults with this dosage form is unlikely to result in clinically significant adverse events, other than increased somnolence, since one bottle of Astelin Nasal Spray contains 30 mg of azelastine hydrochloride. Clinical studies in adults with single doses of the oral formulation of azelastine hydrochloride (up to 16 mg) have not resulted in increased incidence of serious adverse events. /LABORATORY ANIMALS: Acute Exposure/ Oral doses of 120 mg/kg and greater (approximately 460 times the maximum recommended daily intranasal dose in adults and children on a mg/sq m basis) were lethal in mice. Responses seen prior to death were tremor, convulsions, decreased muscle tone, and salivation.
- Skin corrosion/irritation: No data available.
- Serious eye damage/eye irritation: No data available.
- Respiratory or skin sensitization: No data available.
- Germ cell mutagenicity: No data available.

- Carcinogenicity: /LABORATORY ANIMALS: Chronic Exposure or Carcinogenicity/ In 2 year carcinogenicity studies in rats and mice azelastine hydrochloride did not show evidence of carcinogenicity at oral doses up to 30 mg/kg and 25 mg/kg, respectively (approximately 240 and 100 times the maximum recommended daily intranasal dose in adults and children on a mg/sq m basis).
- Reproductive toxicity: /LABORATORY ANIMALS: Developmental or Reproductive Toxicity/ In rabbits, oral doses of 30 mg/kg and greater (approximately 500 times the maximum recommended daily intranasal dose in adults on a mg/sq m basis) caused abortion, delayed ossification and decreased fetal weight; however, these doses also resulted in severe maternal toxicity. Neither fetal nor maternal effects occurred at a dose of 0.3 mg/kg (approximately 5 times the maximum recommended daily intranasal dose in adults on a mg/sq m basis).
- STOT-single exposure: No data available.
- STOT-repeated exposure: /LABORATORY ANIMALS: Chronic Exposure or Carcinogenicity/ In 2 year carcinogenicity studies in rats and mice azelastine hydrochloride did not show evidence of carcinogenicity at oral doses up to 30 mg/kg and 25 mg/kg, respectively (approximately 240 and 100 times the maximum recommended daily intranasal dose in adults and children on a mg/sq m basis).
- Aspiration hazard: No data available.

Likely routes of exposure
- /HUMAN EXPOSURE STUDIES/ ... With three different doses of oral azelastine, /investigators/ have performed a dose-response study to determine its protective effect on the airways against histamine-induced bronchoconstriction in 12 patients with mild, atopic asthma. On 4 separate days, patients undertook standardized inhalation-challenge tests with increasing concentrations of histamine (0.03 to 32 mg/mL) 4 hours after placebo or azelastine, 4.4, 8.8, and 17.6 mg, administered double blind and in random order. On 2 additional days, patients underwent methacholine challenge tests after placebo or azelastine, 17.6 mg. Baseline FEV1 between treatment days and 4 hours after placebo and azelastine did not change significantly. The three doses of azelastine, 4.4, 8.8, and 17.6 mg, increased the concentration of histamine required to cause a 20% fall in FEV1 (PC20) from 0.16 mg/mL geometric mean (GM) after placebo to 1.98 (p less than 0.01), 8.8 (p less than 0.01), and 8.1 (p less than 0.01) mg/mL, respectively. GM potency ratios derived from the PC20 values obtained for each patient indicated that the three increasing doses of azelastine displaced the histamine dose-response curve to the right by factors of 12.8, 54.4, and 50.2. Azelastine had no effect on the airway response to methacholine with GM PC20 values of 0.16 and 0.19 after placebo and azelastine, 17.6 mg. Azelastine is a potent H1histamine-receptor antagonist on human airways in vivo without demonstrable anticholinergic effect.

Symptoms related to the physical, chemical and toxicological characteristics
- /SIGNS AND SYMPTOMS/ There have been no reported overdosages with Astelin Nasal Spray. Acute overdosage by adults with this dosage form is unlikely to result in clinically significant adverse events, other than increased somnolence, since one bottle of Astelin Nasal Spray contains 30 mg of azelastine hydrochloride. Clinical studies in adults with single doses of the oral formulation of azelastine hydrochloride (up to 16 mg) have not resulted in increased incidence of serious adverse events.

SECTION 12: Ecological information

Not available

SECTION 13: Disposal considerations

Not available

SECTION 14: Transport information

Not available

SECTION 15: Regulatory information

Not available

SECTION 16: Other information

Not available

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