# SAFETY DATA SHEET

| Section 1: Identification | |
|---|---|
| **Section 1, Identification** | |
| **Material** | Olopatadine Hydrochloride |
| **Product** | Olopatadine Hydrochloride Solution 0.1% |
| **Synonyms** | C21-H23-N-03.HCl; {(11Z)-11-[3-(dimethylamino)proplidene]-6, 11-dihydrobidenzo[b,e]oxepin-2-yl}acetic acid hydrochloride; Pataday; Patanol S; Opatanol; Patanese; antiallergic; antihistaminic; antihistamine; tricyclic |
| **Chemical Formula** | Not available |
| **Other Means of Identification** | Not Available |
| **CAS No.** | 140462-76-6 |
| **Relevant Identified Uses of the Substance or Mixture and Uses Advised Against**<br>Tricyclic antidepressants (TCAs) are a class of medications that are used primarily as antidepressants.<br>Although TCAs are sometimes prescribed for depressive disorders, they have been largely replaced in clinical use in most parts of the world by newer antidepressants such as selective serotonin reupdate inhibitors (SSRIs), serotonin-norepinephrine reuptake inhibitors (SNRIs) and norepinephrine reupdate inhibitors (NRIs). Adverse effects have been found to be of a similar leven between TCAs and SSRIs.<br>The TCAs are used primarily in the clinical treatment of mood disorders such as major depressive disorder (MDD), dysthymia, and treatment-resistant variants.<br>An antihistamine (as well as anticholinergic) and mast cell stabilizer, sold as a prescription eye drop. Used to treat itching associated with allergic conjunctivitis (eye allergies). Available as an eye drop, an oral tablet, or spray. A relatively selective H1-receptor antagonist. | |
| **Distributor** | SOLA Pharmaceuticals<br>655 Highlandia Drive, Ste B<br>Baton Rouge, LA. 70810<br>Tel: 866.747.7365<br>Fax: 800.754.9550<br>www.solameds.us<br>info@solameds.us |
| **NDC Number** | 70512-520-05 (5mL) |

## Section 2: Hazard(s) Identification

### Section 2, Hazard(s) Identification

Classification of the Substance or Mixture

**ChemWatch Hazard Ratings**

| | |
|---|---|
| Flammability | 1 |
| Toxicity | 1 |
| Body Contact | 0 |
| Reactivity | 1 |
| Chronic | 0 |

0 = Minimum
1 = Low
2 = Moderate
3 = High
4 = Extreme


Note: The hazard numbers found in GHS classification in Section 2 of this SDS are NOT to be used to fill in the NFPA 704 diamond. Blue = Health; Red = Fire; Yellow = Reactivity; White = Special (oxidizer or water-reactive substances)

**Classification**
Acute Toxicity (Oral) Category 5
**LIMITED EVIDENCE*

**Label Elements**

| | |
|---|---|
| **Hazard Pictogram(s)** | Not applicable |
| **Signal Word** | **Warning** |

**Hazard Statement(s)**

| | |
|---|---|
| **H303** | May be harmful if swallowed. |

| | |
|---|---|
| **Supplementary Statement(s)** | Not applicable |
| **CLP Classification (additional)** | Not applicable |
| **Precautionary Statement(s) Prevention** | Not Applicable |
| **Precautionary Statement(s) Response** | P301+P312 – IF SWALLOWED: Call a POISON CENTER/doctor/physician/first aider if you feel unwell. |
| **Precautionary Statement(s) Storage** | Not applicable |
| **Precautionary Statement(s) Disposal** | Not applicable |

## Section 3: Composition/Information on Ingredients

### Section 3, Composition/Information on Ingredients

**Substances**

| CAS No. | % weight | Name |
|---|---|---|
| 140462-76-6 | >98 | olopatadine hydrochloride |

**Mixtures**
See section above for composition of Substances.

## Section 4: First-Aid Measures

**Section 4, First-Aid Measures**

**Description of First Aid Measures**

**Eye Contact**

If this product comes in contact with the eyes:

- Wash out immediately with fresh running water.
- Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.
- Seek medical attention without delay; if pain persists or recurs, seek medical attention.
- Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

**Skin Contact**

If skin or hair contact occurs:

- Flush skin and hair with running water (and soap if available).
- Seek medical attention in event of irritation.

**Inhalation**

If fumes, aerosols or combustion products are inhaled, remove from contaminated area.
Other measures are usually unnecessary.

**Ingestion**

If swallowed, do NOT induce vomiting.
If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain an open airway and prevent aspiration
Observe the patient carefully.
Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e., becoming unconscious.
Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink.
Seek medical advice.

**Indication of any Immediate Medical Attention and Special Treatment Needed**

Treat symptomatically.

- Acute anticholinergic syndrome is reversible and subsides once all of the causative agent has been excreted. Reversible acetylcholinesterase inhibitor agents such as physostigmine can be used as an antidote in life-threatening cases.
- Wider use of hinhibitor agents is discouraged due to the significant side effects related to cholinergic excess including: seizures, muscle weakness, bradycardia, bronchoconstriction, lacrimation, salivation, bronchorrhea, vomiting, and diarrhea.
- Piracetam (and other racetams), L-alpha glycerylphosphorylcholine (alpha-GPC) and choline are known to activate the cholinergic system and alleviate cognitive symptoms caused by extended use of anticholinergic drugs.
- Physostigmine salicylate (1-2mg) subcutaneously or intravenously has been shown to reverse CNS symptoms of anticholinergic intoxication*.

**Mercke, Sharp and Dohme MSDS*

- Physostigmine is the only reversible acetylcholinesterase inhibitor capable of directly antagonizing the CNS manifestations of anticholinergic toxicity; it is an uncharged tertiary amine that efficiently crosses the blood brain barrier.
- Most patients can be treated safety without physostigmine, but it is recommended for use when at least one of the following aberrations are present: tachydysrhythmias with subsequent haemodynamic compromise,

intractable seizures, or severe agitation or psychosis (in which the patient is considered a threat to self or others).

- Although some recommend the use of benzodiazepines (such as diazepam) as first-line agents for the control of agitation associated with the anticholinergic syndrome, one study suggests that physostigmine is significantly more effective and no less safe for use in this setting. Physostigmine is contraindicated in patients with cardiac conduction disturbances (prolonged PR and QRS intervals) on ECG analysis.
- Even in documented cases of anticholinergic toxicity, seizures have been reported after the rapid administration of physostigmine. Asystole has occurred after physostigmine administration for tricyclic antidepressant overdose, so a conduction delay (QRS > 0.10 second) or suggestion of tricyclic antidepressant ingestion is generally considered a contraindication to physostigmine administration.

NOTE: Following overdosage, a curare-like action may occur, i.e., neuromuscular blockade leading to muscular weakness and possible paralysis. In the evet of a curare-like effect on respiratory muscles, artificial respiration should be instituted and maintained until effective respiratory action returns.

**Medical Regime for Atropine Intoxication(and for other anticholinergics):**

Hypersensitivity to material; glaucoma; liver or kidney disease; overactive thyroid; gastrointestinal tract obstructive disease; enlarged prostate gland, urinary obstruction, or urinary retention; intestinal atony; ulcerative colitis; myasthenia gravis; heart disease, including cardiac arrhythmias, congestive heart failure, coronary artery disease, and mitral stenosis; paralytic ileus; reflux oesophagitis (gastric reflux); hiatal hernia; pyloric obstruction; and tachycardia

Treatment regime for atropine intoxication (and for other anticholinergics):

- Empty the stomach by aspiration and lavage.
- The use of charcoal to prevent absorption, followed by lavage has been suggested.
- Give a purgative such as 30 gm sodium sulfate in 250 ml H2O.
- Excitement may be controlled by diazepam or other short acting barbiturates.
- Supportive therapy may require oxygen and assisted respiration, ice-bags or alcohol sponges for hyperpyrexia, especially in chdren, bladder catheterization and the administration of fluuids.

MARTINDALE: The Extra Pharmacopoeia: 29th Edition

Olopatadine is an inhibitor of the release of histamine from the mast cell and a relatively selective histamine H1-antagonist that inhibits the in vivo and in vitro type 1 immediate hypersensitivity reaction including inhibition of histamine induced effects on human conjunctival epithelial cells. Olopatadine is devoid of effects on alpha-adrenergic, dopamine and muscarinic type 1 and 2 receptors. Following topical ocular administration in man, olopatadine was shown to have low systemic exposure. Two studies in normal volunteers (totaling 24 subjects) dosed bilaterally with olopatadine 0.15% ophthalmic solution once every 12 hours for 2 weeks demonstrated plasma concentrations to be generally below the quantitation limit of the assay ( lt;0.5 ng/mL). Samples in which olopatadine was quantifiable were typically found within 2 hours of dosing and ranged from 0.5 to 1.3 ng/mL. The half-life in plasma was approximately 3 hours, and elimination was predominantly through renal excretion. Approximately 60-70% of the dose was recovered in the urine as parent drug. Two metabolites, the mono-desmethyl and the N-oxide, were detected at low concentrations in the urine.

## Section 5: Fire-Fighting Measures

**Section 5, Fire-Fighting Measures**

**Extinguishing Media**

- Water spray or fog
- Foam
- Dry chemical powder
- BCF (where regulations permit)

**Special Hazards Arising From the Substrate or Mixture**

**Fire Incompatibility** Avoid contamination with oxidizing agents, i.e., nitrates, oxidizing acids, chlorine bleaches, pool chlorine, etc., as ignition may result.

**Advice for Firefighters**

**Fire Fighting** Alert Fire Brigade and tell them location and nature of hazard.
Wear breathing apparatus plus protective gloves.
Prevent, by any means available, spillage from entering drains or water courses.
Use Water delivered as a fine spray to control fire and cool adjacent area.

**Fire/Explosion Hazard** Combustible solid which burns but propagates flame with difficulty; it is estimated that most organic dusts are combustible (circa 70%) – according to the circumstances under which the combustion process occurs, such materials may cause fires and/or dust explosions.
Organic powders when finely divided over a range of concentrations regardless of particulate size or shape and suspended in air or some other oxidizing medium may form explosive dust-air mixtures and result in a fire or dust explosion (including secondary explosions).
Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e., flame or spark, will cause fire or explosion. Dust clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust (420 micron or less) may burn rapidly and fiercely if ignited – particles exceeding this limit will generally not form flammable dust clouds; once initiated, however, larger particles up to 1400 microns diameter will contribute to the propagation of an explosion.

**Combustion products include:**
Carbon monoxide (CO)
Carbon dioxide ($CO_2$)
Hydrogen chloride
Phosgene
Nitrogen oxides (NOx)
Other pyrolysis products typical of burning organic material
May emit poisonous fumes

## Section 6: Accidental Release Measures

**Section 6, Accidental Release Measures**

**Personal Precautions, Protective Equipment and Emergency Procedures**
See Section 8

**Environmental Precautions**
See Section 12

**Methods and Material for Containment and Cleaning Up**

| | |
|---|---|
| **Minor Spills** | Clean up waste regularly and abnormal spills immediately.<br>Avoid breathing dust and contact with skin and eyes.<br>Wear protective clothing, gloves, safety glasses and dust respirator.<br>Use dry clean up procedures and avoid generating dust. |
| **Major Spills** | Moderate harard.<br>**CAUTION**: Advise personnel in area.<br>Alert Emergency Services and tell them location and nature of hazard.<br>Control personal contact by wearing protective clothing. |

Personal Protective Equipment advise is contained in Section 8.

## Section 7: Handling and Storage

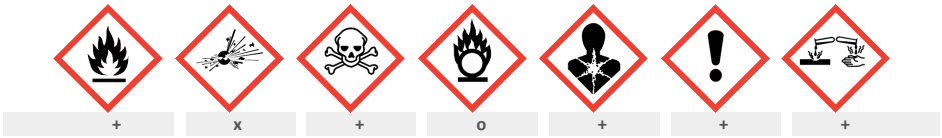
**Section 7, Handling and Storage**

**Precautions for Safe Handling**

| | |
|---|---|
| **Safe Handling** | Avoid all personal contact, including inhalation.<br>Wear protective clothing when risk of exposure occurs.<br>Use in a well-ventilated area.<br>Prevent contentration in hollows and sumps.<br>Organic powders when finely divided over a range of concentrations regardless of particulate size or shape and suspended in air or some other oxiding medium may form explosive dust-air mixtures and result in a fire or dust explosion (including secondary explosions).<br>Minimize airborne dust and eliminate all ignition sources. Keep away from heat, hot surfaces, sparks, and flame.<br>Establish good housekeeping practices.<br>Remove dust accumulations on a regular basis by vacuuming or gentle sweeping to avoid creating dust clouds. |
| **Other Information** | Store in original containers.<br>Keep containers securely sealed<br>Store in a cool, dry area protected from environmental extremes.<br>Store away from incompatible materials and foodstuff containers. |

**Conditions for Safe Storage, Including Any Incompatibilities**

| | |
|---|---|
| **Suitable Container** | Glass container is suitable for laboratory quantities.<br>Polyethylene or polypropylene container.<br>Check all containers are clearly labeled and free from leaks. |
| **Storage Incompatibility** | Avoid reaction with oxidizing agents. |




*X -* *Must not be stored together*
*0 -* *May be stored together with specific preventions*
*+ -* *May be stored together*

*Note: Depending on other risk factors, compatibility assessment based on the table above may not be relevant to storage situations, particularly where large volumes of dangerous goods are stored and handled. Reference should be made to the Safety Data Sheets for each substance or article and risks assessed accordingly.*

## Section 8: Exposure Controls / Personal Protection

**Section 8, Exposure Controls / Personal Protection**

**Control Parameters**

**Occupational Exposure Limit (OEL)**
**INGREDIENT DATA**
Not available

**Emergency Limits**

| Ingredient | TEEL-1 | TEEL-2 | TEEL-3 |
|---|---|---|---|
| Olopatadine Hydrochloride | Not available | Not available | Not available |

| Ingredient | Original IDLH | Revised IDLH |
|---|---|---|
| Olopatadine Hydrochloride | Not available | Not available |

**MATERIAL DATA**
Airborne particulate or vapour must be kept to levels as low as is practicably achievable given access to modern engineering controls and monitoring hardware. Biologically active compounds may produce idiosyncratic effects which are entirely unpredictable on the basis of literature searches and prior clinical experience (both recent and past).

**Exposure Controls**

**Appropriate Engineering Controls**
Enclosed local exhaust ventilation is required at points of dusy, fume, or vapour generation.

**Personal Protection**

**Eye and Face Protection**
When handling very small quantities of the material, eye protection may not be required.
For laboratory, larger scale, or bulk handling or where regular exposure in an occupational setting occurs:

- Chemical goggles
- Face shield. Full face shield may be required for supplementary but never for primary protection of eyes.

**Skin Protection**

See Hand Protection below.

**Hands/Feet Protection**

The selection of suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer. Where the chemical is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
The exact breakthrough time for substances has to be obtained from the manufacturer of the protective gloves and has to be observed when making a final choice.
Personal hygiene is a key element of effective hand care.

- Rubber gloves (nitrile or low-protein, powder-free latex, latex/nitrile). Employees allergic to latex gloves should use nitrile gloves in preference.
- Double-gloving should be considered.
- PVC gloves.

Experience indicates that the following polymers are suitable as glove materials for protection against undissolved, dry solids, where abrasive particles are not present.

- Polychloroprene
- Nitrile rubber
- Butyl rubber

**Body Protection**

See Other Protection below.

**Other Protection**

For quantities up to 500 grams, a laboratory coat may be suitable.
For quantities up to 1 kilogram, a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs.
For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers.

**Respiratory Protection**

Particulate. (AS/NZS 1716 & 1715, EN 143:2000 & 149:001, ANSI Z88, or national equivalent).

| Required Minimum Protection Factor | Half-Face Respirator | Full-Face Respirator | Powered Air Respirator |
|---|---|---|---|
| Up to 10 x ES | P1<br>Air-line* | --- | PAPR-P1<br>--- |
| Up to 50 x ES | Air-line** | P2 | PAPR-P2 |
| Up to 100 x ES | --- | P3 | --- |
| | --- | Air-line* | --- |
| 100+ x ES | --- | Air-line** | PAPR-P3 |

* Negative pressure demand
** Continuous flow

A (all classes) = Organic vapours, B AUS or B1= Acid gasses, B2 = Acid gas or hydrogen cyanide (HCN), B3 = Acid gas or hydrogen cyanide (HCN), E = Sulfur dioxide (S)2), G = Agricultural chemicals, K = Ammonia (HN3), Hg = Mercury, NO = Oxides of nitrogen, MB = Methyl bromide, AX = Low boiling point organic compounds (below 65°C)

- Respirators may be necessary when engineering and administrative controls do not adequately prevent exposures.
- The decision to use respiratory protection should be based on professional judgment that takes into account toxicity information, exposure measurement data, and frequency and likelihood of the worker's exposure – ensure users are not subject to high thermal loads which may result in heat stress or distress due to personal protective equipment (powered, positive flow, full face apparatus may be an option).
- Published occupational exposure limits, where they exist, will assist in determining the adequacy of the selected respiratory protection. These may be government mandated or vendor recommended.
- Certified respirators will be useful for protecting works from inhalation of particulates when properly selected and fit tested as part of a complete respiratory protection program.
- Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1 (EN 143) dust masks. Use respirators and components tested and approved under appropriate government standards such as HIOSH (US) or CEN (EU).
- Use approved positive flow mask if significant quantities of dust becomes airborne.
- Try to avoid creating dust conditions.

## Section 9: Physical and Chemical Properties

**Section 9, Physical and Chemical Properties**

Information on Basic Physical and Chemical Properties

| | | | |
|---|---|---|---|
| **Appearance** | Clear colorless solution | | |
| **Physical state** | Solution | **Relative density (Water = 1)** | Not available |
| **Odor** | Not available | **Partition coefficient n-octanol/water** | Not available |
| **Odor threshold** | Not available | **Auto-ignition temperature (°C)** | Not available |
| **pH (as supplied)** | Not applicable | **Decomposition temperature** | Not available |
| **Melting point/freezing point (°C)** | 248 (decomposes) | **Viscosity (cSt)** | Not applicable |
| **Initial boiling point and boiling range (°C)** | Not applicable | **Molecular weight (g/mol)** | 373.87 |
| **Flash point (°C)** | Not available | **Taste** | Not available |
| **Evaporation rate** | Not applicable | **Explosive properties** | Not available |
| **Flammability** | Not available | **Oxidising properties** | Not available |
| **Upper Explosive Limit (%)** | Not available | **Surface Tension (dyn/cm or mN/m)** | Not applicable |
| **Lower Explosive Limit(%)** | Not available | **Volatile Component (%vol)** | Negligible |
| **Vapor pressure (kPa)** | Negligible | **Gas group** | Not available |
| **Solubility in water** | Miscible | **pH as a solution (Not Available %)** | Not available |
| **Vapor density (Air = 1)** | Not applicable | **VOC g/L** | Not available |

## Section 10: Stability and Reactivity

**Section 10, Stability and Reactivity**

| | |
|---|---|
| **Reactivity** | See Section 7 |
| **Chemical stability** | Unstable in the presence of incompatible materials.<br>Product is considered stable.<br>Hazardous polymerization will not occur. |
| **Possibility of hazardous Reactions** | See Section 7 |
| **Conditions to avoid** | See Section 7 |
| **Incompatible materials** | See Section 7 |
| **Hazardous decomposition Products** | See Section 5 |

## Section 11: Toxicological Information

**Section 11, Toxicological Information**

**Inhaled**

The material is not thought to produce either adverse health effects or irritation of the respiratory tract following inhalation (as classified by EC Directives using animal models). Neverthless, adverse systemic effects have been produced following exposure of animals by at least one other route and good hygiene practice requires that exposure be kept to a minimum and that suitable controls measures be used in an occupational setting.
Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive contcentrations of particulate are inhaled.
If prior damage to the circulatory or nervous systems has occurred or if kidney damage has been sustained, proper screenings should be conducted on individuals who may be exposed to further risk if handling and use of the material result in excessive exposures.

**Ingestion**

Accidental ingestion of the material may be damaging to the health of the individual.
Many side effects produced by the tricyclic (TCA) and tetracyclic (TeCA) antidepressants are caused by their anticholinergic actions. These include dry mouth, sour or metallic taste, constipation (leading occasionally to paralytic ileum), urinary retention, blurred vision and changes in accommodation, palpitations and tachycardia.
Gastrointestinal disturbances (including nausea and vomiting), drowsiness, tremor, orthostatic hypotension (or occasional hypertension), dizziness, sweating, weakness and fatigue, ataxia, epilptiform seizures, occasional extrapyramidal symptoms (including speech difficulties) may also occur. Allergic skin reactions and photosensitization have been reported.
Common side-effects of antidepressants include dry mouth, weight gain, dizziness, headaches, sexual dysfunction and emotional blunting. There is a slight increased risk of suicidal thinking and behavior when taken by children, adolescents, and young adults. A discontinuation syndrome can occur after stopping any antidepressant which resembles recurrent depression. Antidepressants can cause various adverse effects, depending on the individual and the drug in question.
Almost any medication involved with serotonin regulation has the potential to cause serotonin toxicity (also known as serotonin syndrome) – an excess of serotonin that can induce mania, restlessness, agitation, emotional lability, insomnia and confusion as its primary symptoms. Although the condition is serious, it is not particularly common, generally only appearing at high doses or while on other medications.

The most common side-effect of antihistamines include sedation, gastro-intestinal disturbances (nausea, vomiting, diarrhea, or constipation) and epigastric pain. Antihistamines may also produce blurred vision, tinnitus (ringing in the ears), elation or depression, irritability, nightmares, anorexia, difficulting in passing water, dryness of the mouth, tightness of the chest, and tingling, heaviness and weakness of the hands, headache, nervousness, restlessness, irritability, euphoria, oculogyric crisis (disturbed rotation of the eyeballs), facial dyskinesia, paraesthesia, palpitations, faintness, tachycardia and infrequently other cardiac arrhytimias, pulmonary oedema, insomnia and disturbed dreams. Side-effects of the treatment may occur within 15 minutes and include dryness of the mouth and tracheobronchial tissues, nasal stuffiness, wheezing, thich bronchial secretions, fever, sweating, disturbances in sense of smell, flushing of the skin, diplopia, and mydriasis. Central nervous system depression may produce drowsiness, dizziness, lethargy, fatigue, loss of mental alertness and concentration, ataxia, apnea, stupor and coma. So-called anticholinergic (parasympatholytic) agents (such as atropine, belladonna alkaloids) block cholinergic effects produced by activation of both muscarinic and nicotinic receptors. Clinical effects of these agents include elevated blood pressure and temperature, erythema, delirium and mydriasis (all of which are also produced by sympathomimetic agents) and in addition, silent bowel sounds and dry skin.
The most common adverse events reported by patients receiving anticholinergics are dry mouth, headache, constipation, vertigo/dizziness, and abdominal pain. Xerostomia (dry mouth), contstipation, abnormal vision (accommodation abnormalities, blurred vision, photophobia) due to dilation of the pupils (mydriasis), urinary retetention, cystoplegia (paralysis of the urinary bladder), increased ocular tension, tachycardia; palpitation, decreased sweating, loss of taste, nervousness, drowsiness, weakness, dizziness, insomnia, vomiting, impotence, suppression of lactation, constipation, bloated feeling, a degree of mental confusion or excitement (especially in the elderly) and xerophthalmia (dry eye syndrome) are expected side effects of anticholinergic agents.

**Skin Contact**
The material is not thought to produce adverse health effects or skin irritation following contact (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting.
Open cuts, abraded or irritated skin should not be exposed to this material.
Entry into the blood-stream through, for example, cuts, abrasions, puncture wounds or lesions, may produce systemic injury with harmful effects.
Examine the skin prior to the use of the material and ensure that any external damage is suitable protected.

**Eye**
Although the material is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may cuase transient discomfort characterized by tearing of conjunctival redness (as with windburn). Slight abrasive damage may also result. The material may produce foreign body irritation in certain individuals.

**Chronic**
Long-term exposure to the product is not thought to produce chronic effects adverse to health (as classified by EC Directives using animal models), nevertheless, exposure by all routes should be minimized as a matter of course.
Long-term exposure to high dust concentrations may cause changes in lung function (i.e., pneumoconioisis) caused by particules less than 0.5 micron penetrating and remaining in the lung. A prime symptom is breathlessness. Lung shadows show on X-ray.

| | **Toxicity** | **Irritation** |
|---|---|---|
| Olopatadine Hydrochloride | Not available | Not available |

*Legend: 1. Value obtained from Europe ECHA Registered Substances – Acute toxicity; 2.* Value obtained from manufacturer's SDS. Unless otherwise specified, data extracted from RTECS – Register of Toxic Effect of Chemical Substances*

**Olopatadine Hydrochloride**

No significant acute toxicological data identified in literature search. Headaches have been reported at an incidence of 7%. The following adverse experiences have been reported in less than 5% of patients: asthenia, blurred vision, burning or stinging, cold syndrome, dry eye, foreign body sensation, hyperemia, hypersensitivity, keratitis, lid edema, nausea, pharyngitis, pruritis, rhinitis, sinusitis, and taste perversion. Some of these events were similar to the underlying disease being studies. Carcinogenesis, mutagenesis, impairment of fertility: olopatadine administered orally was not carcinogenic in mice and rats in doses up to 500mg/kg/day and 200mg/kg/day, respectively. Based on a 40 uL drop size, these doses were 78,125 and 31, 250 times higher than the maximum recommended ocular human dose (MROHD). No mutagenic potential was observed when olopatadine was tested in an *in vitro* bacterial reverse mutation (Ames) test, an *in vitro* mammalian chromosome aberration assay or an *in vivo* mouse micronucleus test. Olopatadine administered to male and female rats at oral doses of 62,500 times MROHD level resulted in a slight decrease in the fertility index and reduced implantation rate, no effects on reproduction function were observed at doses of 7,800 times the maximum recommended ocular human use level. Olopatadine was found not to be teratogenic in rats and rabbits. However, rats treated at 600mg/kg/day or 93,750 times the MROHD and rabbits treated at 400mg/kg/day or 62,500 times the MROHD, during organogenesis showed a decrease in live fetuses.

| | | | |
|---|---|---|---|
| **Acute Toxicity** | √ | **Carcinogenicity** | X |
| **Skin Irritation/Corrosion** | X | **Reproductivity** | X |
| **Serious Eye Damage/Irritation** | X | **STOT – Single Exposure** | X |
| **Respiratory or Skin Sensitisation** | X | **STOT – Repeated Exposure** | X |
| **Mutagenicity** | X | **Aspiration Hazard** | X |

*Legend:* *X – Data either not available or does not fill the criteria for classification*
*✓ - Data available to make classification*

## Section 12: Ecological Information

**Section 12, Ecological Information**

| **Olopatadine Hydrochloride** | **Endpoint** | **Test Duration (hr)** | **Species** | **Value** | **Source** |
|---|---|---|---|---|---|
| | Not available | Not available | Not available | Not available | Not available |

*Legend:* *Extracted from 1. IUCLID Toxicity Data; 2. Europe ECHA Registered Substances – Ecotoxicological Information – Aquatic Toxicity; 4. US EPA, Ecotox database – Aquatic Toxicity Data; 5. ECETOC Aquatic Hazard Assessment Data; 6. NITE (Japan) – Bioconcentration Data; 7. METI (Japan) – Bioconcentration Data; 8. Vendor Data*

**DO NOT** discharge into sewer or waterways.

**Persistence and Degradability**

**Persistence: Water/Soil**
No data available for all ingredients
**Persistence: Air**
No data available for all ingredients

**Bioaccumulative Potential**
No data available for all ingredients

**Mobility in Soil**
No data available for all ingredients

## Section 13: Disposal Considerations

**Section 13, Disposal Considerations**

**Waste Treatment Methods**

**Product/Packaging Disposal**
Legislation addressing waste disposal requirements may differ by country, state and/or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.
A Hierarchy of Controls seems to be common – the user should investigate:

- Reduction
- Reuse
- Recycling
- Disposal (if all else fails)

This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use.

- **DO NOT** allow wash water from cleaning or process equipment to enter drains.
- It may be necessary to collect all wash water for treatment before disposal.
- In all cases, disposal to sewer may be subject to local laws and regulations and these should be considered first.
- Where in doubt, contact the responsible authority.
- Recycle wherever possible.
- Consult manufacturer for recycling options or consult local or regional waste management authority for disposal if no suitable treatment or disposal facility can be identified.
- Dispose of by: burial in a land-fill specifically licensed to accept chemical and/or pharmaceutical wasts or incineration in a licensed apparatus (after admixture with suitable combustible material).
- Decontaminate empty containers. Observe all label safeguards until containers are cleaned and destroyed.

## Section 14: Transport Information

**Section 14, Transport Information**

| | |
|---|---|
| Land transport (UN) | Not regulated for transport of dangerous goods |
| Air transport (ICAO-IATA/DGR) | Not regulated for transport of dangerous goods |
| Sea transport (IMDG-Code/GGVSee) | Not regulated for transport of dangerous goods |
| Transport in bulk according to Annex II of MARPOL and the IBC Code | Not applicable |
| Transport in bulk in accordance with MARPOL Annex V and the IMSBC Code | Not available |
| Transport in bulk in accordance with the ICG Code | Not available |

## Section 15: Regulatory Information

**Section 15, Regulatory Information**

**Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture**

**Olopatadine Hydrochloride is found on the following regulatory lists:** Not applicable

| Ingredient | CAS No. | Index No. | ECHA Dossier |
|---|---|---|---|
| Olopatadine Hydrochloride | 140462-76-6 | Not available | Not available |

| Harmonization (C&L Inventory) | Hazard Class and Category Code(s) | Pictograms Signal Word Code(s) | Hazard Statement Code(s) |
|---|---|---|---|
| 1 | Acute Tox 3; Aquatic Acute 1 | GHS09; GHS06; Dgr | H301; H400 |
| 2 | Acute Tox 3; Aquatic Acute 1; Skin Irrit 2; Repr 2; Acute Tox 4; Repr 2; Lact; Acute Tox 4; Eye Irrit 2; Muta 2 | GHS09; GHS06; Dgr; GHS08 | H301; H400; H315, H361; H332; H362; H312; H319; H341 |

*Harmonization Code 1 = The most prevalent classification. Harmonization Code 2 = The most severe classification.*

**National Inventory Status**

| National Inventory | Status |
|---|---|
| Australia – AIIC / Australia Non-Industrial Use | No (olopatadine hydrochloride) |
| Canada – DSL | No (olopatadine hydrochloride) |
| Canada – NDSL | No (olopatadine hydrochloride) |
| China – IECSC | No (olopatadine hydrochloride) |
| Europe – EINEC/ELINCS/NLP | No (olopatadine hydrochloride) |
| Japan – ENCS | No (olopatadine hydrochloride) |
| Korea – KECI | No (olopatadine hydrochloride) |
| New Zealand – NZIoC | No (olopatadine hydrochloride) |
| Philippines – PICCS | No (olopatadine hydrochloride) |
| USA – TSCA | No (olopatadine hydrochloride) |
| Taiwan – TCSI | Yes |
| Mexico – INSQ | No (olopatadine hydrochloride) |
| Vietnam – NCI | No (olopatadine hydrochloride) |
| Russia – FBEPH | No (olopatadine hydrochloride) |

*Legend:* *Yes = All CAS declared ingredients are on the inventory*
*No = One or more of the CAS listed ingredients are not on the inventory. These ingredients may be exempt or will require registration.*

## Section 16: Other Information

**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.

**SOLA** shall not be held liable for any damage resulting from handling or from contact with the above product. SOLA reserves the right to revise this Safety Data Sheet.