

OLOPATADINE HYDROCHLORIDE SOLUTION

SOLA Pharmaceuticals, LLC

Version No: 2.1
Safety Data Sheet

Issue Date: 8/15/2022
Print Date: 8/15/2022

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

Product Identifier

Product name	OLOPATADINE HYDROCHLORIDE SOLUTION
Chemical Name	olopatadine hydrochloride
Synonyms	C21-H23-N-O3.HCl; ((11Z)-11-[3-(dimethylamino)propylidene]-6,11-dihydrodibenzo[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 number	140462-76-6

Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses	<p>Tricyclic antidepressants (TCAs) are a class of medications that are used primarily as antidepressants. 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 reuptake inhibitors (SSRIs), serotonin-norepinephrine reuptake inhibitors (SNRIs) and norepinephrine reuptake inhibitors (NRIs). Adverse effects have been found to be of a similar level between TCAs and SSRIs. The TCAs are used primarily in the clinical treatment of mood disorders such as major depressive disorder (MDD), dysthymia, and treatment-resistant variants.</p> <p>An antihistamine (as well as anticholinergic) and mast cell stabiliser, sold as a prescription eye drop. Used to treat itching associated with allergic conjunctivitis (eye allergies) Available as an eye drop, an oral table or spray. A relatively selective H1-receptor antagonist</p>
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Details of the supplier of the safety data sheet

Registered company name	SOLA Pharmaceuticals, LLC
Address	655 Highlandia Dr Ste A
Telephone	1-866-747-7365
Fax	1-800-753-9550
Website	www.solameds.us
Email	info@solameds.us

Emergency telephone number

Association / Organisation	SOLA Pharmaceuticals, LLC
Emergency telephone numbers	1-866-747-7365
Other emergency telephone numbers	Not Available

SECTION 2 Hazards identification

Classification of the substance or mixture

ChemWatch Hazard Ratings

	Min	Max
Flammability	1	1
Toxicity	1	1
Body Contact	0	0
Reactivity	1	1
Chronic	0	0

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

NFPA 704 diamond



Note: The hazard category numbers found in GHS classification in section 2 of this SDSs 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 <i>*LIMITED EVIDENCE</i>
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Label elements

OLOPATADINE HYDROCHLORIDE SOLUTION

Hazard pictogram(s)	Not Applicable
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Signal word	Warning
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Hazard statement(s)

H303	May be harmful if swallowed.
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*LIMITED EVIDENCE

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.
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Precautionary statement(s) Storage

Not Applicable

Precautionary statement(s) Disposal

Not Applicable

SECTION 3 Composition / information on ingredients**Substances**

CAS No	%[weight]	Name
140462-76-6	>98	<u>olopatadine hydrochloride</u>

Mixtures

See section above for composition of Substances

SECTION 4 First aid measures**Description of first aid measures**

Eye Contact	<p>If this product comes in contact with the eyes:</p> <ul style="list-style-type: none"> ▶ 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	<p>If skin or hair contact occurs:</p> <ul style="list-style-type: none"> ▶ Flush skin and hair with running water (and soap if available). ▶ Seek medical attention in event of irritation.
Inhalation	<ul style="list-style-type: none"> ▶ If fumes, aerosols or combustion products are inhaled remove from contaminated area. ▶ Other measures are usually unnecessary.
Ingestion	<ul style="list-style-type: none"> ▶ If swallowed do NOT induce vomiting. ▶ If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain 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 inhibitor 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 (1-2 mg) 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 antagonising the CNS manifestations of anticholinergic toxicity; it is an uncharged tertiary amine that efficiently crosses the blood brain barrier
- ▶ Most patients can be treated safely 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

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OLOPATADINE HYDROCHLORIDE SOLUTION

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

Medical Conditions Aggravated by Exposure: 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 children, bladder catheterisation and the administration of fluids.

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 (I_t :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 Firefighting 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 oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result
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Advice for firefighters

Fire Fighting	<ul style="list-style-type: none"> ▶ 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	<ul style="list-style-type: none"> ▶ 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. <p>Combustion products include: carbon monoxide (CO) carbon dioxide (CO₂) hydrogen chloride phosgene nitrogen oxides (NO_x) other pyrolysis products typical of burning organic material. May emit poisonous fumes.</p>

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	<ul style="list-style-type: none"> ▶ Clean up waste regularly and abnormal spills immediately. ▶ Avoid breathing dust and contact with skin and eyes. ▶ Wear protective clothing, gloves, safety glasses and dust respirator. ▶ Use dry clean up procedures and avoid generating dust.
Major Spills	<p>Moderate hazard.</p> <ul style="list-style-type: none"> ▶ CAUTION: Advise personnel in area. ▶ Alert Emergency Services and tell them location and nature of hazard. ▶ Control personal contact by wearing protective clothing.

Personal Protective Equipment advice is contained in Section 8 of the SDS.

SECTION 7 Handling and storage

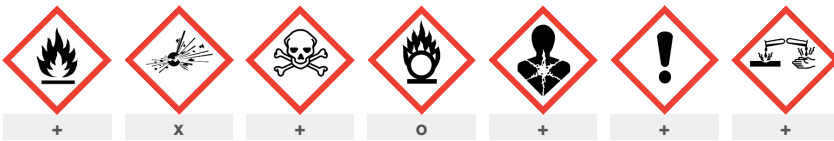
OLOPATADINE HYDROCHLORIDE SOLUTION

Precautions for safe handling

Safe handling	<ul style="list-style-type: none"> ▶ Avoid all personal contact, including inhalation. ▶ Wear protective clothing when risk of exposure occurs. ▶ Use in a well-ventilated area. ▶ Prevent concentration in hollows and sumps. ▶ 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) ▶ Minimise airborne dust and eliminate all ignition sources. Keep away from heat, hot surfaces, sparks, and flame. ▶ Establish good housekeeping practices. ▶ Remove dust accumulations on a regular basis by vacuuming or gentle sweeping to avoid creating dust clouds.
Other information	<ul style="list-style-type: none"> ▶ Store in original containers. ▶ Keep containers securely sealed. ▶ Store in a cool, dry area protected from environmental extremes. ▶ Store away from incompatible materials and foodstuff containers.

Conditions for safe storage, including any incompatibilities

Suitable container	<ul style="list-style-type: none"> ▶ Glass container is suitable for laboratory quantities ▶ Polyethylene or polypropylene container. ▶ Check all containers are clearly labelled and free from leaks.
Storage incompatibility	<ul style="list-style-type: none"> ▶ Avoid reaction with oxidising agents



X — Must not be stored together

O — May be stored together with specific precautions

+ — 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

Control parameters

Occupational Exposure Limits (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	<p>Enclosed local exhaust ventilation is required at points of dust, fume or vapour generation. HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapours. Barrier protection or laminar flow cabinets should be considered for laboratory scale handling. A fume hood or vented balance enclosure is recommended for weighing/ transferring quantities exceeding 500 mg.</p>
Personal protection	
Eye and face protection	<p>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:</p> <ul style="list-style-type: none"> ▶ 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	<p>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 break through 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.</p> <ul style="list-style-type: none"> ▶ 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.

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OLOPATADINE HYDROCHLORIDE SOLUTION

	<ul style="list-style-type: none"> ▶ PVC gloves. <p>Experience indicates that the following polymers are suitable as glove materials for protection against undissolved, dry solids, where abrasive particles are not present.</p> <ul style="list-style-type: none"> ▶ polychloroprene. ▶ nitrile rubber. ▶ butyl rubber.
Body protection	See Other protection below
Other protection	<ul style="list-style-type: none"> ▶ 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 Air-line*	- -	PAPR-P1 -
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(SO₂), G = Agricultural chemicals, K = Ammonia(NH₃), Hg = Mercury, NO = Oxides of nitrogen, MB = Methyl bromide, AX = Low boiling point organic compounds(below 65 degC)

- 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 workers 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 (EN143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (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**Information on basic physical and chemical properties**

Appearance	Clear Colorless Solution		
Physical state	Solution	Relative density (Water = 1)	Not Available
Odour	Not Available	Partition coefficient n-octanol / water	Not Available
Odour 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
Vapour pressure (kPa)	Negligible	Gas group	Not Available
Solubility in water	Miscible	pH as a solution (Not Available%)	Not Available
Vapour density (Air = 1)	Not Applicable	VOC g/L	Not Available

SECTION 10 Stability and reactivity

Reactivity	See section 7
Chemical stability	<ul style="list-style-type: none"> ▶ Unstable in the presence of incompatible materials. ▶ Product is considered stable. ▶ Hazardous polymerisation will not occur.
Possibility of hazardous reactions	See section 7

OLOPATADINE HYDROCHLORIDE SOLUTION

Conditions to avoid	See section 7
Incompatible materials	See section 7
Hazardous decomposition products	See section 5

SECTION 11 Toxicological information

Information on toxicological effects

Inhaled	<p>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). Nevertheless, 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 control measures be used in an occupational setting.</p> <p>Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled.</p> <p>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.</p>
Ingestion	<p>Accidental ingestion of the material may be damaging to the health of the individual.</p> <p>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, epileptiform seizures, occasional extrapyramidal symptoms (including speech difficulties) may also occur. Allergic skin reactions and photosensitisation have been reported.</p> <p>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.</p> <p>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.</p> <p>The most common side-effect of antihistamines include sedation, gastro-intestinal disturbances (nausea, vomiting, diarrhoea or constipation) and epigastric pain. Antihistamines may also produce blurred vision, tinnitus (ringing in the ears), elation or depression, irritability, nightmares, anorexia, difficulty 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 crises (disturbed rotation of the eyeballs), facial dyskinesia, paraesthesia, palpitations, faintness, tachycardia and infrequently other cardiac arrhythmias, 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, thick 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.</p> <p>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.</p> <p>The most common adverse events reported by patients receiving anticholinergics are dry mouth, headache, constipation, vertigo/dizziness, and abdominal pain. Xerostomia (dry mouth), constipation, abnormal vision (accommodation abnormalities, blurred vision, photophobia) due to dilation of the pupils (mydriasis), urinary retention, 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.</p>
Skin Contact	<p>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.</p> <p>Open cuts, abraded or irritated skin should not be exposed to this material</p> <p>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 suitably protected.</p>
Eye	<p>Although the material is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may cause transient discomfort characterised by tearing or conjunctival redness (as with windburn). Slight abrasive damage may also result. The material may produce foreign body irritation in certain individuals.</p>
Chronic	<p>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 minimised as a matter of course.</p> <p>Long term exposure to high dust concentrations may cause changes in lung function (i.e. pneumoconiosis) caused by particles less than 0.5 micron penetrating and remaining in the lung. A prime symptom is breathlessness. Lung shadows show on X-ray.</p>

olopatadine hydrochloride	TOXICITY	IRRITATION
	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	<p>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 studied. Carcinogenesis, Mutagenesis, Impairment of Fertility: Olopatadine administered orally was not carcinogenic in mice and rats in doses up to 500 mg/kg/day and 200 mg/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 reproductive 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 600 mg/kg/day, or 93,750 times the MROHD and rabbits treated at 400 mg/kg/day, or 62,500 times the MROHD, during organogenesis showed a decrease in live fetuses</p>
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OLOPATADINE HYDROCHLORIDE SOLUTION

Acute Toxicity	✓	Carcinogenicity	✗
Skin Irritation/Corrosion	✗	Reproductivity	✗
Serious Eye Damage/Irritation	✗	STOT - Single Exposure	✗
Respiratory or Skin sensitisation	✗	STOT - Repeated Exposure	✗
Mutagenicity	✗	Aspiration Hazard	✗

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

SECTION 12 Ecological information

Toxicity

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

Ingredient	Persistence: Water/Soil	Persistence: Air
	No Data available for all ingredients	No Data available for all ingredients

Bioaccumulative potential

Ingredient	Bioaccumulation
	No Data available for all ingredients

Mobility in soil

Ingredient	Mobility
	No Data available for all ingredients

SECTION 13 Disposal considerations

Waste treatment methods

Product / Packaging disposal	<p>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.</p> <p>A Hierarchy of Controls seems to be common - the user should investigate:</p> <ul style="list-style-type: none"> ▶ Reduction ▶ Reuse ▶ Recycling ▶ Disposal (if all else fails) <p>This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use.</p> <ul style="list-style-type: none"> ▶ 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 wastes 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.
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SECTION 14 Transport information

Labels Required

Marine Pollutant	NO
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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

Product name	Group
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Continued...

OLOPATADINE HYDROCHLORIDE SOLUTION

Product name	Group
olopatadine hydrochloride solution	Not Available

Transport in bulk in accordance with the ICG Code

Product name	Ship Type
olopatadine hydrochloride solution	Not Available

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

ECHA SUMMARY

Ingredient	CAS number	Index No	ECHA Dossier
olopatadine hydrochloride	140462-76-6	Not Available	Not Available

Harmonisation (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

Harmonisation Code 1 = The most prevalent classification. Harmonisation Code 2 = The most severe classification.

National Inventory Status

National Inventory	Status
Australia - AIIIC / 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

Revision Date	27/06/2017
Initial Date	Not Available

Other information

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

Definitions and abbreviations

PC—TWA: Permissible Concentration-Time Weighted Average
 PC—STEL: Permissible Concentration-Short Term Exposure Limit
 IARC: International Agency for Research on Cancer
 ACGIH: American Conference of Governmental Industrial Hygienists
 STEL: Short Term Exposure Limit
 TEEL: Temporary Emergency Exposure Limit.
 IDLH: Immediately Dangerous to Life or Health Concentrations
 ES: Exposure Standard
 OSF: Odour Safety Factor
 NOAEL :No Observed Adverse Effect Level
 LOAEL: Lowest Observed Adverse Effect Level
 TLV: Threshold Limit Value

Continued...

OLOPATADINE HYDROCHLORIDE SOLUTION

LOD: Limit Of Detection
OTV: Odour Threshold Value
BCF: BioConcentration Factors
BEI: Biological Exposure Index
AIIIC: Australian Inventory of Industrial Chemicals
DSL: Domestic Substances List
NDSL: Non-Domestic Substances List
IECSC: Inventory of Existing Chemical Substance in China
EINECS: European INventory of Existing Commercial chemical Substances
ELINCS: European List of Notified Chemical Substances
NLP: No-Longer Polymers
ENCS: Existing and New Chemical Substances Inventory
KECI: Korea Existing Chemicals Inventory
NZIoC: New Zealand Inventory of Chemicals
PICCS: Philippine Inventory of Chemicals and Chemical Substances
TSCA: Toxic Substances Control Act
TCSI: Taiwan Chemical Substance Inventory
INSQ: Inventario Nacional de Sustancias Químicas
NCI: National Chemical Inventory
FBEPH: Russian Register of Potentially Hazardous Chemical and Biological Substances

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