



# SAFETY DATA SHEET

## 1. Identification

<b>Product identifier</b>	<b>Loratadine Related Compound A</b>	
<b>Other means of identification</b>		
<b>Catalog number</b>	1370280	
<b>Chemical name</b>	8-Chloro-6,11-dihydro-11-(4-piperidinylidene)-5H-benzo[5,6]cyclohepta[1,2-b]pyridine	
<b>Synonym(s)</b>	Desloratadine	
<b>Recommended use</b>	Specified quality tests and assay use only.	
<b>Recommended restrictions</b>	Not for use as a drug. Not for administration to humans or animals.	
<b>Manufacturer/Importer/Supplier/Distributor information</b>		
<b>Company name</b>	U. S. Pharmacopeia	
<b>Address</b>	12601 Twinbrook Parkway Rockville MD 20852-1790 US	
<b>Telephone</b>	RS Technical Services	301-816-8129
<b>Website</b>	www.usp.org	
<b>E-mail</b>	RSTECH@usp.org	
<b>Emergency phone number</b>	CHEMTREC within US & Canada	1-800-424-9300
	CHEMTREC outside US & Canada	+1 703-527-3887

## 2. Hazard(s) identification

<b>Physical hazards</b>	Not classified.	
<b>Health hazards</b>	Acute toxicity, oral	Category 4
	Serious eye damage/eye irritation	Category 2A
<b>OSHA hazard(s)</b>	Not classified.	
<b>Label elements</b>		



<b>Signal word</b>	Warning	
<b>Hazard statement</b>	Harmful if swallowed. Causes serious eye irritation.	
<b>Precautionary statement</b>		
<b>Prevention</b>	Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Wear eye/face protection.	
<b>Response</b>	Rinse mouth. If swallowed: Call a poison center/doctor/medical professional/ if you feel unwell. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.	
<b>Storage</b>	Not available.	
<b>Disposal</b>	Dispose of contents/container to an approved disposal site.	
<b>Hazard(s) not otherwise classified (HNOC)</b>	Not classified.	

## 3. Composition/information on ingredients

### Substance

### Hazardous components

<b>Chemical name</b>	<b>Common name and synonyms</b>	<b>CAS number</b>	<b>%</b>
Loratadine Related Compound A	Desloratadine	100643-71-8	100

## 4. First-aid measures

<b>Inhalation</b>	Move to fresh air. Call a physician if symptoms develop or persist.
<b>Skin contact</b>	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
<b>Eye contact</b>	Rinse cautiously with water for several minutes. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	Rinse mouth. Get medical attention if symptoms occur.
<b>Most important symptoms/effects, acute and delayed</b>	Irritation of eyes and mucous membranes.
<b>Indication of immediate medical attention and special treatment needed</b>	Provide general supportive measures and treat symptomatically. Do NOT induce vomiting. Administer activated charcoal as a slurry. Consider gastric lavage soon after ingestion (within 1 hour). Protect airway by placement in Trendelenburg and left lateral decubitus position or by endotracheal intubation. Control any seizures first. For anticholinergic delirium, treat with physostigmine. In agitated patients with tachycardia, sedate with benzodiazepines. For severe tachycardia in hemodynamic compromise or ischemia, a short-acting cardioselective drug, such as esmolol, should be used. For dysrhythmias, treat with intravenous lidocaine or sodium bicarbonate. For torsades de pointes in hemodynamically unstable patients, treat with electrical cardioversion. Treat stable patients with magnesium, isoproterenol, and/or atrial overdrive pacing. Correct electrolyte abnormalities. For seizures, administer diazepam or lorazepam. If seizures recur, treat with phenobarbital. Monitor for hypotension, dysrhythmias, respiratory depression, and need for endotracheal intubation. Evaluate for hypoglycemia, electrolyte imbalances, and hypoxia. For hypotension, administer isotonic fluid. If hypotension persists, treat with dopamine or norepinephrine. Administer for the following conditions: oral or intravenous diazepam for dystonia and intravenous benzodiazepines for agitation. For hyperthermia, sponge patient with tepid water and use fans. AVOID phenothiazines. If severe hyperthermia develops, neuromuscular paralysis may be necessary. [Meditext 2008]
<b>General information</b>	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

## 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	No unusual fire or explosion hazards noted.
<b>Special protective equipment and precautions for firefighters</b>	Wear suitable protective equipment.
<b>Fire-fighting equipment/instructions</b>	As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
<b>Specific methods</b>	Cool containers exposed to flames with water until well after the fire is out.

## 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.
<b>Methods and materials for containment and cleaning up</b>	Sweep up or vacuum up spillage and collect in suitable container for disposal. For waste disposal, see section 13 of the SDS. Wash spill site.

## 7. Handling and storage

<b>Precautions for safe handling</b>	As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Use of a designated area is recommended for handling of potent materials.
<b>Conditions for safe storage, including any incompatibilities</b>	Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

## 8. Exposure controls/personal protection

### Exposure limit values

#### Industrial Use

Material	Type	Value
Loratadine Related Compound A (CAS 100643-71-8)	TWA	125 micrograms/m3

### Biological limit values

No biological exposure limits noted for the ingredient(s).

### Appropriate engineering controls

Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials.

Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.

### Individual protection measures, such as personal protective equipment

#### Eye/face protection

Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

#### Skin protection

##### Hand protection

Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

##### Other

For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.

#### Respiratory protection

Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

#### Thermal hazards

Not available.

### General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

## 9. Physical and chemical properties

### Appearance

White to off-white powder.

#### Physical state

Solid.

#### Form

Powder.

### Odor

Odorless.

### Odor threshold

Not available.

### pH

Not available.

### Melting point/freezing point

302 - 303.8 °F (150 - 151 °C)

### Initial boiling point and boiling range

Not available.

### Flash point

Not available.

### Evaporation rate

Not available.

### Flammability (solid, gas)

Not applicable.

### Upper/lower flammability or explosive limits

#### Flammability limit - lower (%)

Not available.

#### Flammability limit - upper (%)

Not available.

#### Explosive limit - lower (%)

Not available.

#### Explosive limit - upper (%)

Not available.

### Vapor pressure

Not available.

### Vapor density

Not available.

### Relative density

Not available.

### Solubility in water

Slightly soluble.

<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Other information</b>	
<b>Chemical family</b>	Piperidine derivative.
<b>Molecular formula</b>	C19H19CIN2
<b>Molecular weight</b>	310.83
<b>Solubility (other)</b>	Very soluble in ethanol and in propylene glycol; freely soluble in methanol, in methylene chloride, and in octanol; soluble in 0.1N hydrochloric acid and in dimethyl sulfoxide; slightly soluble in pH 7.4 phosphate buffer.

## 10. Stability and reactivity

<b>Reactivity</b>	No reactivity hazards known.
<b>Chemical stability</b>	Stable at normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	None known.
<b>Incompatible materials</b>	Acids. Strong oxidizers. Reducing agents.
<b>Hazardous decomposition products</b>	NOx. Cl-. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Ingestion</b>	Harmful if swallowed.
<b>Inhalation</b>	Due to lack of data the classification is not possible.
<b>Skin contact</b>	Due to lack of data the classification is not possible.
<b>Eye contact</b>	Causes serious eye irritation.
<b>Symptoms related to the physical, chemical, and toxicological characteristics</b>	Dry mouth. Fatigue. Headache. Dizziness. Drowsiness. Fast heartbeat. Irregular heartbeat. Shortness of breath. Swelling. Itching. Skin rash. Hives. Nausea. Heartburn. Muscle pain. Joint pain. Cough. Sore throat. Fever. Hoarseness. Runny nose. Swollen glands.
<b>Cross sensitivity</b>	Persons sensitive to loratadine may also be sensitive to this material.
<b>Medical conditions aggravated by exposure</b>	Bladder neck obstruction. Kidney impairment. Liver impairment. Urinary retention. Glaucoma.
<b>Acute toxicity</b>	Harmful if swallowed.

Product	Species	Test Results
Loratadine Related Compound A (CAS 100643-71-8)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	500 - 2000 mg/kg
<b>Skin corrosion/irritation</b>	Based on available data, the classification criteria are not met.	
<b>Serious eye damage/eye irritation</b>	Causes serious eye irritation.	
<b>Local effects</b>		
Irritancy test		
Result: Irritant.		
Species: Rabbit		
Organ: Eye.		
Severity: Severe.		
Irritancy test		
Result: Non-irritant.		
Species: Rabbit		
Organ: Skin.		
<b>Respiratory sensitization</b>	Due to lack of data the classification is not possible.	
<b>Skin sensitization</b>	Based on available data, the classification criteria are not met.	

**Sensitization**

Sensitization test  
Result: Non-sensitizing.  
Species: Guinea pig  
Organ: Skin.

**Germ cell mutagenicity** Based on available data, the classification criteria are not met.

**Mutagenicity**

Ames assay  
Result: Negative (with and without activation).  
Bone marrow micronucleus assay  
Result: Negative.  
Species: Mouse  
Chromosomal aberration assay in human lymphocytes  
Result: Negative.

**Carcinogenicity** Based on available data, the classification criteria are not met. This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

16 mg/kg/day Carcinogenicity test  
Result: No increase in tumors in males.  
Species: Mouse  
Test Duration: 2 years  
32 mg/kg/day Carcinogenicity test  
Result: No increase in tumors in females.  
Species: Mouse  
Test Duration: 2 years

**Reproductive toxicity** Based on available data, the classification criteria are not met.

**Reproductivity**

24 mg/kg Reproductivity test  
Result: Increase in pre-implantation loss and a decreased number of implantations and fetuses.  
Species: Rat  
48 mg/kg/day Reproductivity test  
Result: No increase in birth defects or malformations.  
Species: Rat  
60 mg/kg/day Reproductivity test  
Result: No increase in birth defects or malformations.  
Species: Rabbit

**Specific target organ toxicity - single exposure** Based on available data, the classification criteria are not met.

**Specific target organ toxicity - repeated exposure** Based on available data, the classification criteria are not met.

**Aspiration hazard** Based on available data, the classification criteria are not met.

**12. Ecological information**

**Ecotoxicity** No ecotoxicity data noted for the ingredient(s).

**Persistence and degradability** No data is available on the degradability of this product.

**Bioaccumulative potential** Not available.

**Mobility in soil** Not available.

**Other adverse effects** Not available.

**13. Disposal considerations**

**Disposal instructions** This product, in its present state, when discarded or disposed of, is not a hazardous waste according to Federal regulations (40 CFR 261.4 (b)(4)). Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste. Dispose in accordance with all applicable regulations.

**Local disposal regulations** Not available.

**Hazardous waste code** Not regulated.

**Waste from residues / unused products** Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

**Contaminated packaging** Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

**14. Transport information****DOT**

Not regulated as a hazardous material by DOT.

**IATA**

Not regulated as a dangerous good.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** No information available.

**15. Regulatory information**

**US federal regulations** CERCLA/SARA Hazardous Substances - Not applicable.

One or more components are not listed on TSCA.

**Superfund Amendments and Reauthorization Act of 1986 (SARA)**

**Hazard categories** Immediate Hazard - Yes  
Delayed Hazard - No  
Fire Hazard - No  
Pressure Hazard - No  
Reactivity Hazard - No

**SARA 302 Extremely hazardous substance** No

**SARA 311/312 Hazardous chemical** No

**Other federal regulations**

**Safe Drinking Water Act (SDWA)** Not regulated.

**Food and Drug Administration (FDA)** Not regulated.

**US state regulations**

This product does not contain a chemical known to the State of California to cause cancer, birth defects or other reproductive harm.

**International Inventories**

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

**16. Other information, including date of preparation or last revision**

**Issue date** 07-15-2008

**Revision date** 03-08-2013

**Version #** 02

**Further information** Not available.

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**Revision Information**

This document has undergone significant changes and should be reviewed in its entirety.