

## 1 Identification

- **Product identifier**
- **Trade name:** Loratadine
- **Article number:** 101774
- **CAS Number:**  
79794-75-5
- **EC number:**  
935-907-9
- **Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture** Pharmaceutical intermediate
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Fagron Services B.V.  
Molenwerk 13, UITGEEEST, 1911DB  
Netherlands  
Phone: +31251361400  
  
Supplier  
Azelis Australia  
Suite 217  
117 Old Pittwater Road  
Brookvale  
NSW 2100  
Australia  
Phone: +61 0299392188  
Fax: +61 0299392799  
e-mail: info@azelis.com.au
- **Further information obtainable from:** info@fagron.com.au
- **Emergency telephone number:**  
In case of emergency, please call your local poisons:  
Emergency Australia: 13 11 26  
Emergency NZ: 0800 764 766 (0800 POISON)  
  
1800 127 406 (24 h, Australia) | +64 4 917 9888 (24 h, Worldwide) CareChem 24x7 : EUROPE:  
+44 1235 239670 | USA: +1 202 464 2554 | CANADA - +1 800 579 7421 (Toll Free)| ASIA - +65  
3158 1074 | MOROCCO - +44 1235 239671 | REST OF THE WORLD - +44 1865 407333  
(English only )

## 2 Hazard(s) Identification

- **Classification of the substance or mixture**

Acute Tox. 3	H301 Toxic if swallowed.
Skin Irrit. 2	H315 Causes skin irritation.
Eye Irritation 2A	H319 Causes serious eye irritation.
Skin Sens. 1	H317 May cause an allergic skin reaction.
Muta. 2	H341 Suspected of causing genetic defects.
Carc. 2	H351 Suspected of causing cancer.
STOT SE 3	H335 May cause respiratory irritation.

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- **Label elements**
- **GHS label elements**  
The substance is classified and labelled according to the Globally Harmonised System (GHS).
- **Hazard pictograms**



GHS06 GHS08

- **Signal word** Danger
- **Hazard statements**  
Toxic if swallowed.  
Causes skin irritation.  
Causes serious eye irritation.  
May cause an allergic skin reaction.  
Suspected of causing genetic defects.  
Suspected of causing cancer.  
May cause respiratory irritation.
- **Precautionary statements**  
IF SWALLOWED: Immediately call a POISON CENTER/ doctor.  
Specific treatment (see on this label).  
Rinse mouth.  
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
Take off contaminated clothing and wash it before reuse.  
Store locked up.  
Dispose of contents/container in accordance with local/regional/national/international regulations.
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

### \* 3 Composition and Information on Ingredients

- **Chemical characterisation: Substances**
- **CAS No. Description**  
CAS: 79794-75-5 Loratadine
- **Identification number(s)**
- **EC number:** 935-907-9

### \* 4 First Aid Measures

- **Description of first aid measures**
- **General information:**  
Immediately remove any clothing soiled by the product.  
In case of irregular breathing or respiratory arrest provide artificial respiration.
- **After inhalation:**  
Supply fresh air and to be sure call for a doctor.  
In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact:** Immediately wash with water and soap and rinse thoroughly.
- **After eye contact:**  
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- **After swallowing:** Do not induce vomiting; call for medical help immediately.

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- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed**  
No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

## 5 Fire Fighting Measures

- **Extinguishing media**
- **Suitable extinguishing agents:**  
Use fire extinguishing methods suitable to surrounding conditions.
- **Special hazards arising from the substance or mixture**  
No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** Wear self-contained respiratory protective device.

## 6 Accidental Release Measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**  
Dispose contaminated material as waste according to item 13.  
Ensure adequate ventilation.
- **Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

## 7 Handling and Storage

- **Handling:**
- **Precautions for safe handling** Thorough dedusting.
- **Information about fire - and explosion protection:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Keep container tightly sealed.
- **Specific end use(s)** No further relevant information available.

## 8 Exposure controls and personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:** Not required.
- **Additional information:** The lists valid during the making were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
Keep away from foodstuffs, beverages and feed.  
Immediately remove all soiled and contaminated clothing  
Wash hands before breaks and at the end of work.

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Avoid contact with the eyes and skin.

· **Respiratory protection:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

· **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

· **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **Eye protection:**



Tightly sealed goggles

· **Body protection:** Protective work clothing

**9 Physical and Chemical Properties**

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

Form: Crystalline powder

Colour: Whitish

· **Odour:** Characteristic

· **Odour threshold:** Not determined.

· **pH-value:** Not applicable.

· **Change in condition**

Melting point/freezing point: 131–136°C

Initial boiling point and boiling range: Undetermined.

· **Flash point:** Not applicable.

· **Flammability (solid, gas):** Product is not flammable.

· **Ignition temperature:** 630°C

· **Decomposition temperature:** Not determined.

· **Auto-ignition temperature:** Not determined.

· **Explosive properties:** Product does not present an explosion hazard.

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· <b>Explosion limits:</b>	
Lower:	Not determined.
Upper:	Not determined.
· <b>Vapour pressure:</b>	Not applicable.
· <b>Density:</b>	Not determined.
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not applicable.
· <b>Evaporation rate</b>	Not applicable.
· <b>Solubility in / Miscibility with water:</b>	Not determined.
· <b>Partition coefficient: n-octanol/water:</b>	Not determined.
· <b>Viscosity:</b>	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
· <b>Other information</b>	No further relevant information available.

## 10 Stability and Reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:**  
No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

## 11 Toxicological Information

- **Information on toxicological effects**
- **Acute toxicity**

- **LD/LC50 values relevant for classification:**

Oral	LD50	293 mg/kg (mouse)
		189 mg/kg (rat)

- **Primary irritant effect:**
- **Skin corrosion/irritation** Irritant to skin and mucous membranes.
- **Serious eye damage/irritation** Irritating effect.
- **Respiratory or skin sensitisation** Sensitisation possible through skin contact.
- **Additional toxicological information:**
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**  
Muta. 2, Carc. 2

## 12 Ecological Information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.

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- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**  
Water hazard class 3 (German Regulation) (Self-assessment): extremely hazardous for water  
Do not allow product to reach ground water, water course or sewage system, even in small quantities.  
Danger to drinking water if even extremely small quantities leak into the ground.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

### 13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**  
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

### 14 Transport information

· <b>UN-Number</b> · <b>ADG, IMDG, IATA</b>	UN2811
· <b>UN proper shipping name</b> · <b>ADG, IMDG</b> · <b>IATA</b>	TOXIC SOLID, ORGANIC, N.O.S. (Loratadine) Toxic solid, organic, n.o.s. (Loratadine)
· <b>Transport hazard class(es)</b> · <b>ADG</b>	
 	
· <b>Class</b> · <b>Label</b>	6.1 Toxic substances. 6.1
· <b>IMDG, IATA</b>	
	
· <b>Class</b> · <b>Label</b>	6.1 Toxic substances. 6.1
· <b>Packing group</b> · <b>ADG, IMDG, IATA</b>	III
· <b>Environmental hazards:</b>	Environmentally hazardous substance, solid

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· <b>Special marking (ADG):</b>	Symbol (fish and tree)
· <b>Special precautions for user</b>	Warning: Toxic substances.
· <b>Hazard identification number (Kemler code):</b>	60
· <b>EmS Number:</b>	F-A,S-A
· <b>Stowage Category</b>	A
· <b>Transport in bulk according to Annex II of Marpol and the IBC Code</b>	Not applicable.
· <b>Transport/Additional information:</b>	
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· <b>ADG</b>	
· <b>Limited quantities (LQ)</b>	5 kg
· <b>Excepted quantities (EQ)</b>	Code: E1 Maximum net quantity per inner packaging: 30 g Maximum net quantity per outer packaging: 1000 g
· <b>Transport category</b>	2
· <b>Tunnel restriction code</b>	E
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· <b>IMDG</b>	
· <b>Limited quantities (LQ)</b>	5 kg
· <b>Excepted quantities (EQ)</b>	Code: E1 Maximum net quantity per inner packaging: 30 g Maximum net quantity per outer packaging: 1000 g
· <b>UN "Model Regulation":</b>	UN 2811 TOXIC SOLID, ORGANIC, N.O.S. (LORATADINE), 6.1, III, ENVIRONMENTALLY HAZARDOUS

## 15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Australian Inventory of Industrial Chemicals** Substance is not listed.
- **Standard for the Uniform Scheduling of Medicines and Poisons S2 ,S4**
- **Australia: Priority Existing Chemicals** Substance is not listed.
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** Substance is not listed.
- **Seveso category**  
H2 ACUTE TOXIC  
E1 Hazardous to the Aquatic Environment
- **Qualifying quantity (tonnes) for the application of lower-tier requirements** 50 t
- **Qualifying quantity (tonnes) for the application of upper-tier requirements** 200 t
- **National regulations:**
- **Other regulations, limitations and prohibitive regulations**  
Therapeutic goods are listed on the Australian Register of Therapeutic Goods(ARTG)
- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

## 16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

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- **Department issuing SDS:** Product Safety Department
- **Contact:**
- **Abbreviations and acronyms:**
  - ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)
  - IMDG: International Maritime Code for Dangerous Goods
  - IATA: International Air Transport Association
  - EINECS: European Inventory of Existing Commercial Chemical Substances
  - CAS: Chemical Abstracts Service (division of the American Chemical Society)
  - LC50: Lethal concentration, 50 percent
  - LD50: Lethal dose, 50 percent
  - PBT: Persistent, Bioaccumulative and Toxic
  - vPvB: very Persistent and very Bioaccumulative
  - Acute Tox. 3: Acute toxicity – Category 3
  - Skin Irrit. 2: Skin corrosion/irritation – Category 2
  - Eye Irritation 2A: Serious eye damage/eye irritation – Category 2A
  - Skin Sens. 1: Skin sensitisation – Category 1
  - Muta. 2: Germ cell mutagenicity – Category 2
  - Carc. 2: Carcinogenicity – Category 2
  - STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
- **\* Data compared to the previous version altered.**

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