

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

- **1.1 Product identifier**
- **Trade name:** Loratadine
- **Article number:** 101774
- **CAS Number:**  
79794-75-5
- **EC number:**  
935-907-9
- **1.2 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
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
FAGRON a.s.  
Holická 1098/31m  
779 00 Olomouc  
Česká republika
- **Further information obtainable from:**  
Tel.: +420 585 222 590  
info@fagron.cz
- **1.4 Emergency telephone number:**  
Toxikologické informační středisko,  
Na Bojišti 1,  
128 08 Praha 2  
tel.: +420 224 919 293, +420 224 915 402 (nepřetržitá lékařská služba),  
e-mail:tis.cuni@cesnet.cz

## SECTION 2: Hazards identification

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

|                   |  |
|-------------------|--|
| Acute Tox. 3      | H301 Toxic if swallowed.                                   |
| Skin Irrit. 2     | H315 Causes skin irritation.                               |
| Eye Irrit. 2      | 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.                     |
| Aquatic Acute 1   | H400 Very toxic to aquatic life.                           |
| Aquatic Chronic 1 | H410 Very toxic to aquatic life with long lasting effects. |
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**  
The substance is classified and labelled according to the CLP regulation.

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· **Hazard pictograms**



GHS06 GHS08 GHS09

· **Signal word** Danger

· **Hazard statements**

- H301 Toxic if swallowed.
- H315 Causes skin irritation.
- H319 Causes serious eye irritation.
- H317 May cause an allergic skin reaction.
- H341 Suspected of causing genetic defects.
- H351 Suspected of causing cancer.
- H335 May cause respiratory irritation.
- H410 Very toxic to aquatic life with long lasting effects.

· **Precautionary statements**

- P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/ doctor.
- P321 Specific treatment (see on this label).
- P330 Rinse mouth.
- P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P362+P364 Take off contaminated clothing and wash it before reuse.
- P405 Store locked up.
- P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· **2.3 Other hazards**

· **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.
- **vPvB:** Not applicable.

## SECTION 3: Composition/information on ingredients

· **3.1 Substances**

· **CAS No. Description**

CAS: 79794-75-5 Loratadine

· **Identification number(s)**

· **EC number:** 935-907-9

## SECTION 4: First aid measures

· **4.1 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.

· **4.2 Most important symptoms and effects, both acute and delayed**

No further relevant information available.

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- **4.3 Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

## SECTION 5: Firefighting measures

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

## SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **6.2 Environmental precautions:**  
Inform respective authorities in case of seepage into water course or sewage system.  
Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**  
Dispose contaminated material as waste according to item 13.  
Ensure adequate ventilation.
- **6.4 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.

## SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** Thorough dedusting.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 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.
- **7.3 Specific end use(s)** No further relevant information available.

## SECTION 8: Exposure controls/personal protection

- **8.1 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.
- **8.2 Exposure controls**
- **Appropriate engineering controls** No further data; see item 7.
- **Individual protection measures, such as 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.  
Avoid contact with the eyes and skin.

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· **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.

· **Hand protection**



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/face protection**



Tightly sealed goggles

· **Body protection:** Protective work clothing

## SECTION 9: Physical and chemical properties

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

· **General Information**

· **Physical state**

Solid

· **Colour:**

Whitish

· **Odour:**

Characteristic

· **Odour threshold:**

Not determined.

· **Melting point/freezing point:**

131–136°C

· **Boiling point or initial boiling point and boiling range**

Undetermined.

· **Flammability**

Product is not flammable.

· **Lower and upper explosion limit**

· **Lower:**

Not determined.

· **Upper:**

Not determined.

· **Flash point:**

Not applicable.

· **Ignition temperature:**

630°C

· **Decomposition temperature:**

Not determined.

· **pH**

Not applicable.

· **Viscosity:**

· **Kinematic viscosity**

Not applicable.

· **Dynamic:**

Not applicable.

· **Solubility**

· **water:**

Not determined.

· **Partition coefficient n-octanol/water (log value)**

Not determined.

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|   |   |
|---|---|
| · Vapour pressure:  | Not applicable.                               |
| · Density and/or relative density   |   |
| · Density:  | Not determined.                               |
| · Relative density  | Not determined.                               |
| · Vapour density  | Not applicable.                               |
| · Particle characteristics  | See item 3.                                   |
| <b>9.2 Other information</b>  |   |
| · Appearance:   |   |
| · Form:   | Crystalline powder                            |
| · Important information on protection of health and environment, and on safety. |   |
| · Auto-ignition temperature:  | Not determined.                               |
| · Explosive properties:   | Product does not present an explosion hazard. |
| · Molecular weight  | 382,9 g/mol                                   |
| · Change in condition   |   |
| · Evaporation rate  | Not applicable.                               |
| <b>Information with regard to physical hazard classes</b>                       |   |
| · Explosives  | Void  |
| · Flammable gases   | Void  |
| · Aerosols  | Void  |
| · Oxidising gases   | Void  |
| · Gases under pressure  | Void  |
| · Flammable liquids   | Void  |
| · Flammable solids  | Void  |
| · Self-reactive substances and mixtures   | Void  |
| · Pyrophoric liquids  | Void  |
| · Pyrophoric solids   | Void  |
| · Self-heating substances and mixtures  | Void  |
| · Substances and mixtures, which emit flammable gases in contact with water     | Void  |
| · Oxidising liquids   | Void  |
| · Oxidising solids  | Void  |
| · Organic peroxides   | Void  |
| · Corrosive to metals   | Void  |
| · Desensitised explosives   | Void  |

## SECTION 10: Stability and reactivity

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

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## SECTION 11: Toxicological information

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Toxic if swallowed.

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

|      |      |                                      |
|------|------|--------------------------------------|
| Oral | LD50 | 293 mg/kg (mouse)<br>189 mg/kg (rat) |
|------|------|--------------------------------------|

- **Skin corrosion/irritation** Causes skin irritation.
- **Serious eye damage/irritation** Causes serious eye irritation.
- **Respiratory or skin sensitisation** May cause an allergic skin reaction.
- **Germ cell mutagenicity** Suspected of causing genetic defects.
- **Carcinogenicity** Suspected of causing cancer.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** May cause respiratory irritation.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.
- **11.2 Information on other hazards**
- **Endocrine disrupting properties** Substance is not listed.

## SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties**  
The product does not contain substances with endocrine disrupting properties.
- **12.7 Other adverse effects**
- **Remark:** Very toxic for fish
- **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.  
Also poisonous for fish and plankton in water bodies.  
Very toxic for aquatic organisms

## SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**  
Must not be disposed together with household garbage. Do not allow product to reach sewage system.

- **European waste catalogue**

|     |   |
|-----|---|
| HP4 | Irritant - skin irritation and eye damage                 |
| HP5 | Specific Target Organ Toxicity (STOT)/Aspiration Toxicity |
| HP6 | Acute Toxicity  |

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|      |              |
|------|--------------|
| HP7  | Carcinogenic |
| HP11 | Mutagenic    |
| HP13 | Sensitising  |
| HP14 | Ecotoxic     |

- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

## SECTION 14: Transport information

|   |  |
|---|--|
| · 14.1 UN number or ID number<br>· ADR, IMDG, IATA  | UN2811   |
| · 14.2 UN proper shipping name<br>· ADR, IMDG<br>· IATA   | TOXIC SOLID, ORGANIC, N.O.S. (Loratadine)<br>Toxic solid, organic, n.o.s. (Loratadine)                                 |
| · 14.3 Transport hazard class(es)<br>· ADR  |  |
| · Class<br>· Label  | 6.1 Toxic substances.<br>6.1   |
| · IMDG, IATA  |  |
| · Class<br>· Label  | 6.1 Toxic substances.<br>6.1   |
| · 14.4 Packing group<br>· ADR, IMDG, IATA   | III  |
| · 14.5 Environmental hazards:<br>· Special marking (ADR):   | Environmentally hazardous substance, solid<br>Symbol (fish and tree)   |
| · 14.6 Special precautions for user<br>· Hazard identification number (Kemler code):<br>· EmS Number:<br>· Stowage Category | Warning: Toxic substances.<br>60<br>F-A,S-A<br>A   |
| · 14.7 Maritime transport in bulk according to IMO instruments  | Not applicable.  |
| · Transport/Additional information:   |  |
| · ADR<br>· Limited quantities (LQ)<br>· Excepted quantities (EQ)  | 5 kg<br>Code: E1<br>Maximum net quantity per inner packaging: 30 g<br>Maximum net quantity per outer packaging: 1000 g |

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|                                   |  |
|-----------------------------------|--|
| · <b>Transport category</b>       | 2  |
| · <b>Tunnel restriction code</b>  | E  |
| -----                             |  |
| · <b>IMDG</b>                     |  |
| · <b>Limited quantities (LQ)</b>  | 5 kg   |
| · <b>Excepted quantities (EQ)</b> | Code: E1<br>Maximum net quantity per inner packaging: 30 g<br>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                         |

## SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **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
- **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**  
Substance is not listed.
- **REGULATION (EU) 2019/1148**
- **Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**  
Substance is not listed.
- **Annex II - REPORTABLE EXPLOSIVES PRECURSORS** Substance is not listed.
- **Regulation (EC) No 273/2004 on drug precursors** Substance is not listed.
- **Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**  
Substance is not listed.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

## SECTION 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.

- **Department issuing SDS:** Fagron Česká republika
- **Contact:** msds@fagron.cz
- **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  
GHS: Globally Harmonised System of Classification and Labelling of Chemicals  
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

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# Safety data sheet

according to 1907/2006/EC, Article 31

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**Trade name: Loratadine**

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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 Irrit. 2: Serious eye damage/eye irritation – Category 2  
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  
Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1  
Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

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