

1 Identification

- **Product identifier**
- **Trade name:** Loratadine
- **Article number:** 101774
- **CAS Number:**
79794-75-5
- **EC number:**
935-907-9
- **Application of the substance / the mixture** Pharmaceutical intermediate
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Fagron Inc
2400 Pilot Knob Road
St. Paul, MN 55120
www.fagron.us
QA@fagron.us
- **Information department:**
Tel.: 800-423-6967
Fax: 800-339-1596
- **Emergency telephone number:**
Emergency Telephone:
US: 1-800-535-5053
International: 1-352-323-3500

2 Hazard(s) identification

- **Classification of the substance or mixture**

| | |
|--|--|
| Acute Toxicity - Oral 3 | H301 Toxic if swallowed. |
| Skin Irritation 2 | H315 Causes skin irritation. |
| Eye Irritation 2A | H319 Causes serious eye irritation. |
| Sensitization - Skin 1 | H317 May cause an allergic skin reaction. |
| Germ Cell Mutagenicity 2 | H341 Suspected of causing genetic defects. |
| Carcinogenicity 2 | H351 Suspected of causing cancer. |
| Specific Target Organ Toxicity - Single Exposure 3 | H335 May cause respiratory irritation. |

- **Label elements**

- **GHS label elements**

The substance is classified and labeled according to the Globally Harmonized System (GHS).

- **Hazard pictograms**



GHS06 GHS07 GHS08

- **Signal word** Danger

- **Hazard statements**

Toxic if swallowed.
Causes skin irritation.
Causes serious eye irritation.
May cause an allergic skin reaction.

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Suspected of causing genetic defects.

Suspected of causing cancer.

May cause respiratory irritation.

· **Precautionary statements**

Obtain special instructions before use.

Do not handle until all safety precautions have been read and understood.

Avoid breathing dust/fume/gas/mist/vapors/spray

Wash thoroughly after handling.

Do not eat, drink or smoke when using this product.

Use only outdoors or in a well-ventilated area.

Contaminated work clothing must not be allowed out of the workplace.

Wear protective gloves/protective clothing/eye protection/face protection.

If swallowed: Immediately call a poison center/doctor.

Specific treatment (see on this label).

Rinse mouth.

If on skin: Wash with plenty of water.

IF INHALED: Remove person to fresh air and keep comfortable for breathing.

If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

IF exposed or concerned: Get medical advice/attention.

Call a poison center/doctor if you feel unwell.

Take off contaminated clothing and wash it before reuse.

If skin irritation or rash occurs: Get medical advice/attention.

If eye irritation persists: Get medical advice/attention.

Wash contaminated clothing before reuse.

Store in a well-ventilated place. Keep container tightly closed.

Store locked up.

Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Classification system:**

· **NFPA ratings (scale 0 - 4)**



Health = 2
Fire = 0
Reactivity = 0

· **HMS-ratings (scale 0 - 4)**



Health = 2
Fire = 0
Reactivity = 0

· **Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

3 Composition/information on ingredients

· **Chemical characterization: Substances**

· **CAS No. Description**

CAS: 79794-75-5 Loratadine

· **Identification number(s)**

· **EC number:** 935-907-9

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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; immediately call for medical help.
- **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 fighting measures that suit the environment.
- **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.
- **Protective Action Criteria for Chemicals**
- **PAC-1:** Substance is not listed.
- **PAC-2:** Substance is not listed.
- **PAC-3:** Substance is not listed.

7 Handling and storage

- **Handling:**
- **Precautions for safe handling** Thorough dedusting.
- **Information about protection against explosions and fires:** 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 receptacle tightly sealed.

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- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**
- **Components with limit values that require monitoring at the workplace:** Not required.
- **Additional information:** The lists that were valid during the creation 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.
Avoid contact with the eyes and skin.
- **Breathing equipment:**
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.
- **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

Color:

Whitish

- **Odor:**

Characteristic

- **Odor threshold:**

Not determined.

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| | |
|--|---|
| · pH-value: | Not applicable. |
| · Change in condition | |
| Melting point/Melting range: | 131–136°C (267.8–276.8°F) |
| Boiling point/Boiling range: | Undetermined. |
| · Flash point: | Not applicable. |
| · Flammability (solid, gaseous): | Product is not flammable. |
| · Ignition temperature: | 630°C (1166°F) |
| · Decomposition temperature: | Not determined. |
| · Auto igniting: | Not determined. |
| · Danger of explosion: | Product does not present an explosion hazard. |
| · Explosion limits: | |
| Lower: | Not determined. |
| Upper: | Not determined. |
| · Vapor pressure: | Not applicable. |
| · Density: | Not determined. |
| · Relative density | Not determined. |
| · Vapor density | Not applicable. |
| · Evaporation rate | Not applicable. |
| · Solubility in / Miscibility with Water: | Not determined. |
| · Partition coefficient (n-octanol/water): | Not determined. |
| · Viscosity: | |
| Dynamic: | Not applicable. |
| Kinematic: | Not applicable. |
| · Other information | 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 that are relevant for classification:

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

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- **Primary irritant effect:**
- **on the skin:** Irritant to skin and mucous membranes.
- **on the eye:** Irritating effect.
- **Sensitization:** Sensitization possible through skin contact.
- **Additional toxicological information:**
- **Carcinogenic categories**
- **IARC (International Agency for Research on Cancer)** Substance is not listed.
- **NTP (National Toxicology Program)** Substance is not listed.
- **OSHA-Ca (Occupational Safety & Health Administration)** Substance is not listed.

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior 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 (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 of together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

| | |
|----------------------------------|--|
| · UN-Number | |
| · DOT, IMDG, IATA | UN2811 |
| · UN proper shipping name | |
| · DOT | Toxic solids, organic, n.o.s. (Loratadine) |
| · IMDG | TOXIC SOLID, ORGANIC, N.O.S. (Loratadine) |
| · IATA | Toxic solid, organic, n.o.s. (Loratadine) |

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acc. to OSHA HCS

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· **Transport hazard class(es)**

· **DOT**



· **Class** 6.1 Toxic substances
· **Label** 6.1

· **IMDG, IATA**



· **Class** 6.1 Toxic substances
· **Label** 6.1

· **Packing group**
· **DOT, IMDG, IATA** III

· **Environmental hazards:** Environmentally hazardous substance, solid

· **Special precautions for user** Warning: Toxic substances

· **Hazard identification number (Kemler code):** 60

· **EMS Number:** F-A,S-A

· **Stowage Category** A

· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.

· **Transport/Additional information:**

· **DOT**

· **Quantity limitations** On passenger aircraft/rail: 100 kg
On cargo aircraft only: 200 kg

· **IMDG**

· **Limited quantities (LQ)** 5 kg
· **Excepted quantities (EQ)** Code: E1
Maximum net quantity per inner packaging: 30 g
Maximum net quantity per outer packaging: 1000 g

· **UN "Model Regulation":** 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**

No further relevant information available.

· **Sara**

· **Section 355 (extremely hazardous substances):** Substance is not listed.

· **Section 313 (Specific toxic chemical listings):** Substance is not listed.

· **TSCA (Toxic Substances Control Act):** Substance is not listed.

· **Hazardous Air Pollutants** Substance is not listed.

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- **Proposition 65**
- **Chemicals known to cause cancer:** Substance is not listed.
- **Chemicals known to cause reproductive toxicity for females:** Substance is not listed.
- **Chemicals known to cause reproductive toxicity for males:** Substance is not listed.
- **Chemicals known to cause developmental toxicity:** Substance is not listed.
- **Carcinogenic categories**
- **EPA (Environmental Protection Agency)** Substance is not listed.
- **TLV (Threshold Limit Value)** Substance is not listed.
- **NIOSH-Ca (National Institute for Occupational Safety and Health)** Substance is not listed.
- **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.

- **Department issuing SDS:**

Fagron US

Quality Assurance

- **Contact:** QA@fagron.us

- **Date of preparation / last revision** 12/06/2022

- **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

DOT: US Department of Transportation

IATA: International Air Transport Association

EINECS: European Inventory of Existing Commercial Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

Acute Toxicity - Oral 3: Acute toxicity – Category 3

Skin Irritation 2: Skin corrosion/irritation – Category 2

Eye Irritation 2A: Serious eye damage/eye irritation – Category 2A

Sensitization - Skin 1: Skin sensitisation – Category 1

Germ Cell Mutagenicity 2: Germ cell mutagenicity – Category 2

Carcinogenicity 2: Carcinogenicity – Category 2

Specific Target Organ Toxicity - Single Exposure 3: Specific target organ toxicity (single exposure) – Category 3

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