



Loratadine

SAFETY DATA SHEET

North America GHS

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations & the Hazardous Products Regulation (February 11, 2015) & NORMA Oficial Mexicana NOM-018-STPS-2015

1. IDENTIFICATION

Product identifier

Product Name: Loratadine

Synonyms: 1-Piperidinecarboxylic acid, 4-(8-chloro-5,6-dihydro-11H-benzo(5,6)cyclohepta(1,2-b)pyridin-11-ylidene)-, ethyl ester

Other means of identification

Formula: C₂₂H₂₃ClN₂O₂

CAS No.: 79794-75-5

Other Information: No other information

Recommended use of the chemical and restrictions on use

Recommended Use: Raw material for pharmaceuticals.

Uses advised against: Consumer use.

Details of the supplier of the safety data sheet

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Contact e-mail:

SDScontact@mylan.com

Emergency telephone number

Emergency Telephone:

For Hazardous Materials Incident
Spill, Leak, Fire, Exposure, or Accident
Call CHEMTREC (24 Hours)
Worldwide: +1 703-741-5970

2. HAZARDS IDENTIFICATION

Classification

Skin corrosion/irritation, Category 2

Serious eye damage/eye irritation, Category 2

Specific target organ toxicity (single exposure), Category 3 - (H335) [May cause respiratory irritation]

Chronic aquatic toxicity, Category 1

Label elements



Signal word:

Warning

Hazard statements:

H315 - Causes skin irritation

H319 - Causes serious eye irritation

H335 - May cause respiratory irritation

H410 - Very toxic to aquatic life with long lasting effects

Precautionary Statements - Prevention: Wash face, hands and any exposed skin thoroughly after handling

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

Use only outdoors or in a well-ventilated area

Wear protective gloves/eye protection/face protection

Avoid release to the environment

<u>Precautionary Statements - Response:</u>	Collect spillage Specific treatment (see supplemental first aid instructions on this label)
<u>Eyes:</u>	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
<u>Skin:</u>	IF ON SKIN: Wash with plenty of water and soap If skin irritation occurs: Get medical advice/attention Take off contaminated clothing and wash it before reuse
<u>Inhalation:</u>	IF INHALED: Remove person to fresh air and keep comfortable for breathing Call a POISON CENTER or doctor if you feel unwell
<u>Precautionary Statements - Storage:</u>	Store in a well-ventilated place. Keep container tightly closed Store locked up
<u>Precautionary Statements - Disposal:</u>	Dispose of contents/container to an approved waste disposal plant Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable

Other Hazards

No information available.

Unknown acute toxicity

No information available

3. COMPOSITION/INFORMATION ON INGREDIENTS**Substance**

Chemical name	CAS No.	Weight-%	Hazard statements
Loratadine	79794-75-5	> 98%	H315 - Causes skin irritation H319 - Causes serious eye irritation H335 - May cause respiratory irritation H410 - Very toxic to aquatic life with long lasting effects

4. FIRST AID MEASURES**Description of first aid measures****General advice:** Never give anything by mouth to an unconscious person, IF exposed or concerned: Get medical advice/attention, Show this safety data sheet to the doctor in attendance**Inhalation:** Remove to fresh air. IF exposed or concerned: Get medical advice/attention. Get medical attention immediately if symptoms occur.**Skin contact:** Wash off immediately with soap and plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.**Eye contact:** Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep eye wide open while rinsing. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists. Do not rub affected area.**Ingestion:** Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Call a physician.**Self-protection of the first aider:** Avoid contact with skin, eyes or clothing. Wear personal protective clothing (see section 8).**Most important symptoms and effects, both acute and delayed****Symptoms:** Irritating to eyes and skin. May cause respiratory irritation.**Indication of any immediate medical attention and special treatment needed**

Treat symptomatically. In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

5. FIRE-FIGHTING MEASURES**Extinguishing media****Suitable Extinguishing Media:** Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.**Unsuitable extinguishing media:** None known.**Specific hazards arising from the chemical****Fire hazard:** Not flammable.**Explosive hazard:** Not an explosive. Dust can form an explosive mixture with air.**Reactivity:** Hazardous reactions will not occur under normal conditions.**Hazardous combustion products:** Carbon oxides. Nitrogen oxides. Hydrogen chloride.**Advice for firefighters****Precautionary measures in case of fire:** Standard procedure for chemical fires.**Firefighting instructions:** Use water spray or fog; do not use straight streams.**Protection of Firefighters:** Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear**Other Information:** Refer to Section 9 for flammability properties.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal precautions: Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas. Avoid contact with skin, eyes or clothing.

For non-emergency personnel

Personal Protective Equipment: Use personal protective equipment as required.

Emergency procedures: Evacuate personnel to safe areas.

For emergency responders

Personal Protective Equipment: Use personal protective equipment as required.

Emergency procedures: Evacuate personnel to safe areas. Ventilate the area. Eliminate all ignition sources if safe to do so.

Other Information: Refer to protective measures listed in Sections 7 and 8.

Environmental precautions

Prevent further leakage or spillage if safe to do so.

Methods and material for containment and cleaning up

Methods for containment: Prevent further leakage or spillage if safe to do so.

Methods for cleaning up: Use appropriate personal protective equipment (PPE). Carefully shovel or sweep up spilled material and place in suitable container. Avoid generating dust. For spills: Soak up with inert absorbent material. Use clean non-sparking tools to collect absorbed material. Avoid breathing dust or spray mist.

Prevention of secondary hazards: Clean contaminated objects and areas thoroughly observing environmental regulations.

Reference to other sections

See section 8 for more information. See section 13 for more information.

7. HANDLING AND STORAGE

Precautions for safe handling

Advice on safe handling: Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash before reuse. Ensure adequate ventilation. Avoid breathing vapors or mists. In case of insufficient ventilation, wear suitable respiratory equipment.

Conditions for safe storage, including any incompatibilities

Storage Conditions: Keep containers tightly closed in a dry, cool and well-ventilated place. Keep away from heat. Protect from light.

Specific end use(s): Raw material for pharmaceuticals.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Limits: No information available

Exposure controls

Appropriate engineering controls: Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

Individual protection measures, such as personal protective equipment

Hand protection: Wear suitable gloves. Impervious gloves.

Eye/face protection: If splashes are likely to occur, wear safety glasses with side-shields.

Skin and body protection: Wear suitable protective clothing. Long sleeved clothing.

Respiratory protection: Use appropriate respiratory protection.

General hygiene considerations: Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this product. Avoid contact with skin, eyes or clothing.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state:	Solid
Appearance:	Powder
Color:	White to off-white
Odor:	No data available
Odor threshold:	No data available
pH:	No data available
Melting point / freezing point:	No data available
Boiling point / boiling range:	No data available
Flash point:	No data available
Evaporation rate:	No data available
Flammability (solid, gas):	No data available
Upper flammability limit:	No data available
Lower flammability limit:	No data available

Vapor pressure:	No data available
Vapor density:	No data available
Relative density:	No data available
Water solubility:	No data available
Solubility in other solvents:	No data available
Partition coefficient:	No data available
Autoignition temperature:	No data available
Decomposition temperature:	No data available
Kinematic viscosity:	No data available
Dynamic viscosity:	No data available
Explosive properties:	No data available
Oxidizing properties:	No data available
<u>Other Information</u>	
Molecular weight:	382.89
VOC Content (%):	No data available

10. STABILITY AND REACTIVITY

Reactivity

Hazardous reactions will not occur under normal conditions.

Chemical stability

Stable under normal conditions.

Possibility of hazardous reactions

None under normal processing.

Conditions to avoid

Extremes of temperature and direct sunlight.

Incompatible materials

Strong acids. Strong bases. Strong oxidizing agents.

Hazardous decomposition products

Decomposition will not occur under normal conditions.

11. TOXICOLOGICAL INFORMATION

Information on toxicological effects

Information on likely routes of exposure

Inhalation: May cause irritation of respiratory tract.

Ingestion: Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.

Eye contact: Irritating to eyes. Causes serious eye irritation.

Skin contact: Causes skin irritation.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms: Irritating to eyes and skin, May cause respiratory irritation

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation: Irritating to skin.

Serious eye damage/eye irritation: Irritating to eyes.

Respiratory or skin sensitization: Based on available data, the classification criteria are not met.

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

Carcinogenicity: Based on available data, the classification criteria are not met.

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.

Numerical measures of toxicity

Acute toxicity:

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Loratadine (CAS #: 79794-75-5)	> 5000 mg/kg (Rat)	Not available	Not available

12. ECOLOGICAL INFORMATION

Ecotoxicity

Very toxic to aquatic life with long lasting effects.

Chemical name	Algae/aquatic plants	Fish	Crustacea
Loratadine (CAS #: 79794-75-5)	-	LC50 (<i>Lepomis macrochirus</i>): 0.382 mg/l, 96 h	EC50 (<i>Daphnia magna</i>): 0.83 mg/l, 48 h

Persistence and degradability

Not readily biodegradable.

Bioaccumulation

No information available.

Mobility

No information available.

Other adverse effects

No information available.

13. DISPOSAL CONSIDERATIONS**Waste treatment methods**

Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable. Dispose of waste in accordance with environmental legislation. Do not flush into surface water or sanitary sewer system.

14. TRANSPORT INFORMATION

Transportation requirements can vary based on numerous factors such as regional regulations and shipment volume. It is the responsibility of the transporting organization to ensure compliance with all applicable laws and regulations regarding the transportation of this product.

In accordance with DOT / ICAO / IATA / TDG**UN Number**

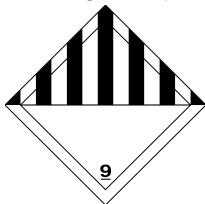
UN 3077

UN proper shipping name

Environmentally hazardous substances, solid, n.o.s. (Loratadine)

Transport hazard class(es)

Hazard Class: Not regulated 9

**Packing group**

III

Environmental hazards

Yes

Special precautions for user

No information available

Transport in bulk according to Annex II of MARPOL and the IBC Code

Not applicable

15. REGULATORY INFORMATION**Safety, health and environmental regulations/legislation specific for the substance or mixture****International Regulations**

Ozone-depleting substances (ODS): Not applicable

Persistent Organic Pollutants: Not applicable

The Rotterdam Convention: Not applicable

US Federal Regulations

SARA 313: Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

US State Regulations

California Proposition 65: This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

US State Regulations: This product does not contain any substances regulated by state right-to-know regulations

Canada

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the SDS contains all

the information required by the CPR.

16. OTHER INFORMATION

Revision Date: 24-October-2017

Other Information: This document has been prepared in accordance with standards for workplace safety. The precautionary statements and warning included might not apply in all cases. Your needs may vary depending on the potential for exposure in your workplace.

Key or legend to abbreviations and acronyms used in the safety data sheet:

Legend, Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA: TWA (time-weighted average)

STEL: STEL (Short Term Exposure Limit)

Party responsible for the preparation of this document:

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To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for completeness of the information herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

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