



Section 1. Product and Company Identification

Product Name Loratadine
CAS Number 79794-75-5

Parchem - fine & specialty chemicals
415 Huguenot Street
New Rochelle, NY 10801
☎ (914) 654-6800 ☎ (914) 654-6899
🌐 parchem.com ✉ info@parchem.com

EMERGENCY RESPONSE NUMBER
CHEMTEL
Toll Free US & Canada: 1 (800) 255-3924
All other Origins: 1 (813) 248-0585
Collect Calls Accepted

Section 2. Hazards Identification

Classification of the substance or mixture
Not classified as a hazardous substance or mixture

GHS Label Elements
Pictograms: N/A
Signal word: N/A

Hazard and precautionary statements
None

Emergency Overview: WARNING! May be harmful if swallowed or inhaled. May cause irritation to skin, eyes, and respiratory tract.

Potential Health Effects

Inhalation: May cause irritation to the respiratory tract. Symptoms may include coughing, sore throat, labored breathing, and chest pain.

Ingestion: Symptoms from overexposure include: headache, insomnia, dry mouth, somnolence, nervousness, dizziness, fatigue, dyspepsia, nausea, pharyngitis, anorexia, and thirst.

Skin Contact: May cause irritation with redness and pain.

Eye Contact: May cause irritation, redness and pain.

Chronic Exposure: No information found.

Aggravation of Pre-existing Conditions: No information found.

Section 3. Composition / Information on Ingredients

Common Name Loratadine
Synonym(s) 4-(8-Chloro-5,6-dihydro-11-H-benzo-(5,6)cyclohepta (1,2-b)Pyridine-11-ylidene-1-piperidine carboxylic acid ethyl ester; 11-[N-(ethoxycarbonyl)-4-piperidylidene] - 8-chloro-6,11-dihydro-5H-benzo [5,6] cyclohepta[1,2-b] pyridine
Formula $C_{22}H_{23}N_2O_2Cl$



CAS Number 79794-75-5

COMPONENT	CAS NUMBER	CONCENTRATION
Loratadine	79794-75-5	100%

Section 4. First Aid Measures

Inhalation: Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Ingestion: Give large amounts of water to drink. Never give anything by mouth to an unconscious person. Get medical attention.

Skin Contact: Immediately flush skin with plenty of water for at least 15 minutes. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse.

Eye Contact: Immediately flush eyes with plenty of water for at least 15 minutes, lifting lower and upper eyelids occasionally. Get medical attention immediately.

Section 5. Firefighting Measures

Fire: As with most organic solids, fire is possible at elevated temperatures or by contact with an ignition source.

Explosion: Fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Maximum Explosion Pressure (P_{max}, bar-g): 8.3 Maximum Rate of Pressure Rise (R_{max}, bar/s): 929 Maximum Scaled Rate of Pressure Rise (K_{st}, bar-m/s): 252 Minimum Explosible Concentration, (MEC, g/m³): 53 Minimum Spark Ignition Energy, (MIE, mJ): <9 Minimum Ignition Temperature of a Dust Clouds, (T_c): 370C Hot Surface Ignition Temperature of Dust Layers, (T_s): Loratadine melted Dust Class: St-2.

Fire Extinguishing Media: Water spray, dry chemical, alcohol foam, or carbon dioxide.

Special Information: In the event of a fire, wear full protective clothing and NIOSH-approved self-contained breathing apparatus with full face piece operated in the pressure demand or other positive pressure mode. Follow handling guidance appropriate for OEB-2 potent compounds, (see Section 7).

Section 6. Accidental Release Measures

Remove all sources of ignition. Ventilate area of leak or spill. Wear appropriate personal protective equipment as specified in Section 8, and follow handling guidance appropriate for OEB-2 potent compounds, (see Section 7). Isolate hazard area. Keep unnecessary and unprotected personnel from entering. Spills: Carefully sweep up material into an appropriate container and save for reclamation or disposal. Do not flush to sewer!

Section 7. Handling and Storage

Keep in a tightly closed container, stored in a cool, dry, ventilated area. Protect against physical damage. Containers of this material may be hazardous when empty since they retain product residues (dust, solids); observe all warnings and precautions listed for the product.



Loratadine has potent pharmacological activity and is classified as an OEB-2* material. Handling practices for OEB-2 substances are described below:

Laboratory

- *Wear appropriate gloves, lab coat, and safety glasses. Use good lab practices.
- *No local exhaust ventilation required for transfer/handling of quantities of powder less than 100 g (total weight transferred or handled). However, if the source container contains 2 kg or more, pilot plant practices apply.
- *No local exhaust ventilation required for solutions of these compounds.
- *Quantities of solid above 100 g require use of a powders weighing hood or other approved containment/ventilation system.
- *High-energy operations such as milling, particle-sizing, spraying or fluidizing should be done within an approved emission control or containment system.
- *Develop cleaning procedures and techniques that limit potential exposure.

Pilot Plant and Production

- *Wear appropriate gloves; lab coat, nylon coveralls or disposable Tyvek suit; safety glasses and safety shoes. Use good manufacturing practices (i.e., cGMPs).
- *Use local exhaust and/or enclosure at dust-generating points. Emphasis is to be placed on closed material transfer systems and process containment, with limited open handling of powders.
- *Where open handling of powders occurs, use a powered, air-purifying respirator (PAPR) with HEPA cartridges or a supplied-air respirator (SAR), unless air-monitoring data has shown that a lower level of respiratory protection is adequate.
- *Protective garments (coveralls, Tyveks, lab coat) are not to be worn in common areas (e.g., cafeterias) or out-of-doors.
- *High-energy operations such as milling, particle-sizing, spraying or fluidizing should be done within an approved emission control or containment system.
- *Develop cleaning procedures and techniques that limit potential exposure.
- *OEB - Mallinckrodt's Occupational Exposure Band: The classification of a compound or pharmaceutical ingredient into one of four ordinal categories of increasing potency and toxicity. This rating assigns a set of pre-determined handling and containment practices to a compound until a quantitative OEL is established.

Section 8. Exposure Controls / Personal Protection

Airborne Exposure Limits: None established.

Ventilation System: A system of local and/or general exhaust is recommended to keep employee exposures as low as possible. Local exhaust ventilation is generally preferred because it can control the emissions of the contaminant at its source, preventing dispersion of it into the general work area. Please refer to the ACGIH document, Industrial Ventilation, A Manual of Recommended Practices, most recent edition, for details.

Personal Respirators (NIOSH Approved): Where open handling of powders occurs, use a powered, air-purifying respirator (PAPR) with HEPA cartridges or a supplied-air respirator (SAR), unless air-monitoring data has shown that a lower level of respiratory protection is adequate.



Skin Protection: Wear impervious protective clothing, including boots, gloves, lab coat, apron or coveralls, as appropriate, to prevent skin contact.

Eye Protection: Use chemical safety goggles and/or a full face shield where splashing is possible. Maintain eye wash fountain and quick-drench facilities in work area.

Other Control Measures: See Section 7 for additional information on occupational control measures appropriate for OEB-2 potent compounds.

Section 9. Physical and Chemical Properties

Appearance: White powder.

Odor: No information found.

Solubility: Insoluble in water.

Specific Gravity: No information found.

pH: No information found.

% Volatiles by volume @ 21°C (70°F): 0

Boiling Point: No information found.

Melting Point: 131 - 135°C (268 - 275°F)

Vapor Density (Air=1): No information found.

Vapor Pressure (mmHg): No information found.

Evaporation Rate (BuAc=1): No information found.

Section 10. Stability and Reactivity

Stability: Stable under ordinary conditions of use and storage.

Hazardous Decomposition Products: May produce carbon monoxide, carbon dioxide, nitrogen oxides and hydrogen chloride when heated to decomposition.

Hazardous Polymerization: Will not occur.

Incompatibilities: Strong oxidizing agents, strong acids, strong bases.

Conditions to Avoid: Incompatibles.

Section 11. Toxicological Information

Cancer Lists

Ingredient	NTP Carcinogen		IARC Category
	Known	Anticipated	
Loratadine (79794-75-5)	No	No	None

Section 12. Ecological Information

Environmental Fate: No information found.

Environmental Toxicity: No information found.

Section 13. Disposal Considerations

Waste Treatment Methods: Dispose of product and contaminated packaging in accordance with all local, state, and federal environmental control regulations.

Section 14. Transport Information

Not regulated

Section 15. Regulatory Information

Chemical Inventory Status

TSCA: Exempt

EC: No

Japan: No

Australia: No

Korea: No

Canada - DSL: No

Canada - NDSL: No

Philippines: No

Federal, State & International Regulations

SARA 302 - RQ: No

SARA 302 - TPQ: No

SARA 313 - List: No

SARA 313 - Chemical Catg.: No

CERCLA: No

RCRA 261.33: No

TSCA 8(d): No

Chemical Weapons Convention: No

TSCA 12(b): No

CDTA: No

SARA 311/312

Acute: Yes

Chronic: No

Fire: No

Pressure: No

Reactivity: No (Pure / Solid)

Australian Hazchem Code: None allocated.

Poison Schedule: S4



WHMIS: This MSDS has been prepared according to the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by the CPR.

Section 16. Other Information

Disclaimer: The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product.

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