

1. Identification

Product identifier	Clemastine Fumarate		
Other means of identification			
Catalog number	1134506		
Chemical name	Pyrrolidine, 2-[2-[1-(4-chlorophenyl)-1-phenylethoxy]ethyl]-1-methyl-, [R-(R*,R*)]-, (E)-2-butenedioate (1:1)		
Synonym(s)	Clemastine hydrogen fumarate		
Recommended use	Specified quality tests and assay use only.		
Recommended restrictions	Not for use as a drug. Not for administration to humans or animals.		
Manufacturer/Importer/Supplier/Distributor information			
Manufacturer			
Company name	U. S. Pharmacopeia		
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 United States		
Telephone	RS Technical Services	301-816-8129	
Website	www.usp.org		
E-mail	RSTECH@usp.org		
Emergency phone number	CHEMTREC within US & Canada	1-800-424-9300	
	CHEMTREC outside US & Canada	+1 703-527-3887	

2. Hazard(s) identification

Physical hazards	Not classified.
Health hazards	Specific target organ toxicity, single exposure Category 3 narcotic effects
Environmental hazards	Not classified.
OSHA defined hazards	Not classified.

Label elements



Signal word	Warning
Hazard statement	May cause drowsiness or dizziness.
Precautionary statement	
Prevention	Avoid breathing dust/fume/gas/mist/vapors/spray. Use only outdoors or in a well-ventilated area.
Response	If inhaled: Remove person to fresh air and keep comfortable for breathing. Call a poison center/doctor if you feel unwell.
Storage	Store in a well-ventilated place. Keep container tightly closed. Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	Not classified.
Other hazards which do not result in classification	This product is supplied in a small quantity which does not constitute a combustible dust hazard. The physical properties of this material indicate that in large quantities accumulated dust may be hazardous.

3. Composition/information on ingredients

Substance

Chemical name	Common name and synonyms	CAS number	%
Clemastine Fumarate	Clemastine hydrogen fumarate	14976-57-9	100

4. First-aid measures

Inhalation	Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor/physician if you feel unwell.
Skin contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
Eye contact	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.
Most important symptoms/effects, acute and delayed	Sedation.
Indication of immediate medical attention and special treatment needed	Treatment of antihistamine overdose should be symptomatic and supportive and may include the following: Administer activated charcoal as a slurry. For severe tachycardia, use beta blocking agents such as esmolol as a temporizing measure. For Torsades de Pointes: Administer magnesium, isoproterenol, and/or atrial overdrive pacing to stable patients. Hemodynamically unstable patients may require electrical cardioversion. Correct electrolyte abnormalities. For seizures, administer intravenous benzodiazepines. If seizures recur, consider phenobarbital. Monitor for hypotension, dysrhythmias, respiratory depression, and need for endotracheal intubation. Evaluate for hypoglycemia, electrolyte disturbances, and hypoxia. For hypotension: Infuse 10 to 20 mL/kg isotonic fluid. If hypotension persists, administer dopamine or norepinephrine. For agitation or dystonia, administer oral or intravenous benzodiazepines. Hemodialysis, hemoperfusion, peritoneal dialysis, and repeat-dose activated charcoal are not effective in removing antihistamines. (Meditext)
General information	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

Suitable extinguishing media	Water. Foam. Dry chemical or CO ₂ . Use fire-extinguishing media appropriate for surrounding materials.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard.
Special protective equipment and precautions for firefighters	Wear suitable protective equipment.
Fire-fighting equipment/instructions	Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	For waste disposal, see section 13 of the SDS. Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination.

7. Handling and storage

Precautions for safe handling	Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. Combustible dust clouds may be created where operations produce fine material (dust). As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices.
Conditions for safe storage, including any incompatibilities	Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

Biological limit values	No biological exposure limits noted for the ingredient(s).
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Exposure guidelines	No exposure standards allocated.
Appropriate engineering controls	Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.
Individual protection measures, such as personal protective equipment	
Eye/face protection	Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.
Skin protection	
Hand protection	Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.
Other	For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.
Respiratory protection	Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance	White to faint yellow crystalline powder.
Physical state	Solid.
Form	Powder.
Odor	Odorless.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	347 - 352.4 °F (175 - 178 °C)
Initial boiling point and boiling range	309.2 °F (154 °C) 0.002666 kPa
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility in water	Very slightly soluble.
Partition coefficient (n-octanol/water)	2.4 = log Pow (at 22 °C)
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	Ethanolamine derivative.

Dust explosion properties

Minimum ignition energy (MIE) - dust cloud 1 - 3 mJ

Molecular formula C₂₁H₂₆ClNO . C₄H₄O₄

Molecular weight 460.01 g/mol

pH in aqueous solution 3.2 - 4.2 (10% suspension)

Solubility (other) Slightly soluble in chloroform and in methanol; sparingly soluble in ethanol.

10. Stability and reactivity

Reactivity None known.

Chemical stability Material is stable under normal conditions.

Possibility of hazardous reactions No dangerous reaction known under conditions of normal use.

Conditions to avoid Avoid dust close to ignition sources.
Contact with incompatible materials.

Incompatible materials Strong oxidizing agents.

Hazardous decomposition products Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. NO_x, Cl-

11. Toxicological information**Information on likely routes of exposure**

Ingestion Not classified.

Inhalation May cause drowsiness and dizziness.

Skin contact Classification not possible.

Eye contact Classification not possible.

Symptoms related to the physical, chemical, and toxicological characteristics Drowsiness. Dry mouth. Gastrointestinal disturbances. Urinary retention. Irregular heartbeat. Changes in vision. Agitation. Seizures.

Delayed and immediate effects of exposure For antihistamines: Coma. Death.

Cross sensitivity Persons sensitive to one antihistamine may be sensitive to this material also.

Medical conditions aggravated by exposure For antihistamines: Active alcoholism. Bronchial asthma. Hyperthyroidism. Heart disease. Hypertension. Urinary retention. Bladder neck obstruction. Prostate enlargement. Glaucoma. Peptic ulcer. Pyloric obstruction. Concurrent use of monoamine oxidase inhibitors (MAOIs). Porphyria.

Acute toxicity

Product	Species	Test Results
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Clemastine Fumarate (CAS 14976-57-9)

Acute**Oral**

LD50	Mouse	730 mg/kg
	Rat	3550 mg/kg

Skin corrosion/irritation Classification not possible.

Serious eye damage/eye irritation Classification not possible.

Respiratory or skin sensitization

Respiratory sensitization Classification not possible.

Skin sensitization Classification not possible.

Germ cell mutagenicity Classification not possible.

Carcinogenicity Not classified.
This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

206 mg/kg Carcinogenicity study, administered orally.

Result: No evidence of carcinogenicity.

Species: Mouse

Test Duration: 85 weeks

84 mg/kg Carcinogenicity study, administered orally.

Result: No evidence of carcinogenicity.

Species: Rat

Test Duration: 2 years

Reproductive toxicity Not classified.

Reproductivity

Epidemiological studies, therapeutic usage in early pregnancy.

Result: No evidence of an association with congenital anomalies observed.

Species: Human

Reproductivity and development studies in rats and rabbits, 312 times the human dose (rat) and 188 times the human dose (rabbits) administered orally.

Result: No harm to fetuses observed.

Reproductivity and development study, 156 times the human dose.

Result: No adverse effects on mating observed.

Species: Rat

Specific target organ toxicity - single exposure May cause drowsiness and dizziness.

Specific target organ toxicity - repeated exposure Classification not possible.

Aspiration hazard Not classified.

12. Ecological information

Ecotoxicity

Product	Species	Test Results
Clemastine Fumarate (CAS 14976-57-9)		
Aquatic		
<i>Acute</i>		
Algae	EC50	Algae 0.04 mg/l, 72 hours
Crustacea	EC50	Daphnia magna 2.4 mg/l, 48 hours
Fish	LC50	Oncorhynchus mykiss 0.6 - 0.75 mg/l, 96 hours

Persistence and degradability Partially biodegradable.

Bioaccumulative potential Not available.

Mobility in soil Not available.

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport information

DOT

UN number	UN3077
UN proper shipping name	Environmentally hazardous substance, solid, n.o.s. (Clemastine Fumarate)
Transport hazard class(es)	
Class	9
Subsidiary risk	-
Packing group	III

IATA

UN number	UN3077
UN proper shipping name	Environmentally hazardous substance, solid, n.o.s. (Clemastine Fumarate)
Transport hazard class(es)	
Class	9
Subsidiary risk	-

Packing group III

Other information

Passenger and cargo aircraft Allowed.

Cargo aircraft only Allowed.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not available.

DOT; IATA



General information It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.
One or more components are not listed on TSCA.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - Yes
Delayed Hazard - No
Fire Hazard - Yes
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance
Not listed.

SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)
Not regulated.

Other federal regulations

Safe Drinking Water Act (SDWA) Not regulated.

Food and Drug Administration (FDA) Not regulated.

US state regulations

US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No

Country(s) or region	Inventory name	On inventory (yes/no)*
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date	08-06-2003
Revision date	03-29-2016
Version #	02
Further information	Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling.
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Revision Information	This document has undergone significant changes and should be reviewed in its entirety.