

1. Identification

Product identifier	Cyproheptadine Hydrochloride		
Other means of identification			
Catalog number	1161000		
Chemical name	Piperidine, 4-(5H-dibenzo[a,d]cyclohepten-5-ylidene)-1-methyl-, hydrochloride, sesquihydrate		
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			
Company name	U. S. Pharmacopeia		
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 US		
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	Acute toxicity, oral	Category 3	
	Serious eye damage/eye irritation	Category 2A	
OSHA hazard(s)	Not classified.		
Label elements			



Signal word	Danger		
Hazard statement	Toxic if swallowed. Causes serious eye irritation.		
Precautionary statement			
Prevention	Wash thoroughly after handling. Wear eye/face protection.		
Response	Rinse mouth. If swallowed: Immediately call a poison center/doctor. 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.		
Storage	Store locked up.		
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.		
Hazard(s) not otherwise classified (HNOC)	Not classified.		

3. Composition/information on ingredients

Substance

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
Cyproheptadine Hydrochloride		41354-29-4	100

4. First-aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
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Skin contact	Immediately flush skin with plenty of water. For minor skin contact, avoid spreading material on unaffected skin. Get medical attention if irritation develops and persists.
Eye contact	Immediately flush eyes with plenty of water for at least 15 minutes. 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. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. Rinse mouth thoroughly. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Do not use mouth-to-mouth method if victim ingested the substance. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Call a physician or poison control center immediately.
Most important symptoms/effects, acute and delayed	Irritation of eyes and mucous membranes.
Indication of immediate medical attention and special treatment needed	Treatment of antihistamine overdose should be symptomatic and supportive and may include the following: Do NOT induce vomiting. Administer activated charcoal as a slurry. For delirium, administer physostigmine. For tachycardia in agitated patients, sedate with benzodiazepines. If severe tachycardia results in hemodynamic compromise or ischemia, administer beta-blocking agents. A short-acting cardioselective agent, such as esmolol, is preferred. Administer intravenous lidocaine. For dysrhythmias, administer sodium bicarbonate. For torsades de pointes in hemodynamically unstable patients, treat with electrical cardioversion. In stable patients, treat with magnesium, isoproterenol, and/or atrial overdrive pacing. Correct electrolyte abnormalities. AVOID class Ia (quinidine, disopyramide, procainamide), class Ic (flecainide, ecainide, propafenone), and most class III antidysrhythmics (N-acetylprocainamide, sotalol). For seizures, administer intravenous diazepam or lorazepam. 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 isotonic fluid. If hypotension persists, administer dopamine or norepinephrine. Treat dystonia with oral or intravenous diazepam, agitation with benzodiazepines, hyperthermia with sponge application of tepid water and fanning (AVOID phenothiazines), and severe hyperthermia with neuromuscular paralysis. (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 spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	No unusual fire or explosion hazards noted.
Special protective equipment and precautions for firefighters	Wear suitable protective equipment.
Fire-fighting equipment/instructions	As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
Specific methods	Cool containers exposed to flames with water until well after the fire is out.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Wear appropriate personal protective equipment.
Methods and materials for containment and cleaning up	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Wash spill site.

7. Handling and storage

Precautions for safe handling	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. Use of a designated area is recommended for handling of potent materials.
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

Exposure limit values

Industrial Use

Material	Type	Value
Cyproheptadine Hydrochloride (CAS 41354-29-4)	TWA	0.2 mg/m3

Biological limit values

No biological exposure limits noted for the ingredient(s).

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.

Avoid any open handling of this material, particularly for grinding, crushing, weighing or other dust-generating or aerosol-generating procedures. Use a laboratory fume hood, vented enclosure, glovebox, or other effective containment.

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. This material is severely irritating. To reduce the risk of contamination of skin and surfaces, wear two pairs of gloves. Remove the outer gloves after handling and cleanup of the material, and remove the inner gloves only after removing other personal protective equipment.

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

Use a NIOSH-approved respirator, if it is determined to be necessary by an industrial hygiene survey involving air monitoring. In the event that a respirator is not required, an approved dust mask should be used. 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).

Thermal hazards

Not available.

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance

White to slightly yellow crystalline powder.

Physical state

Solid.

Form

Powder.

Odor

Odorless or practically odorless.

Odor threshold

Not available.

pH

Not available.

Melting point/freezing point

485.6 - 489.2 °F (252 - 254 °C) (decomposes)

Initial boiling point and boiling range

Not available.

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	Slightly soluble.
Partition coefficient (n-octanol/water)	4.682
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	Piperidine derivative.
Molecular formula	C21H21N . HCl . 3/2H2O
Molecular weight	350.88
Solubility (other)	Freely soluble in methanol; soluble in chloroform; sparingly soluble in alcohol; practically insoluble in ether.

10. Stability and reactivity

Reactivity	No reactivity hazards known.
Chemical stability	Stable at normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	None known.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	NOx. Cl-. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure

Ingestion	Toxic if swallowed.
Inhalation	Due to lack of data the classification is not possible.
Skin contact	Due to lack of data the classification is not possible.
Eye contact	Causes serious eye irritation.
Symptoms related to the physical, chemical, and toxicological characteristics	For antihistamines: Nausea. Diarrhea. Stomach pain. Change in appetite. Change in weight. Difficult or painful urination. Headache. Drowsiness. Dizziness. Tiredness. Weakness. Trouble sleeping. Clumsiness. Unsteadiness. Blurred vision. Changes in vision. Ringing or buzzing in ears. Confusion. Fainting. Hallucinations. Seizures. Sore throat. Fever. Chills. Bleeding or bruising. Thickening of mucus. Dry mouth, nose, or throat. Sweating. Sensitivity to sunlight. Skin rash. Clay-colored stools. Dark urine. Burning, prickly sensations. Tingling. Flushing. Trouble breathing. Fast heartbeat. Irregular heartbeat. Fixed or dilated pupils.
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).

Acute toxicity	Toxic if swallowed.
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Product	Species	Test Results
Cyproheptadine Hydrochloride (CAS 41354-29-4)		
Oral LD50	Mouse	69 mg/kg, anhydrous
	Rat	295 mg/kg, anhydrous

Skin corrosion/irritation	Based on available data, the classification criteria are not met.
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Serious eye damage/eye irritation	Causes serious eye irritation.
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Local effects
Irritancy test (anhydrous)
Result: Irritant.
Species: Rabbit
Organ: Eye
Test Duration: 24 hours
Severity: Severe.

Local effects

Irritancy test (anhydrous)
Result: Non-irritant.
Species: Rabbit
Organ: Skin
Test Duration: 14 days

Respiratory sensitization

Due to lack of data the classification is not possible.

Skin sensitization

Due to lack of data the classification is not possible.

Germ cell mutagenicity

Based on available data, the classification criteria are not met.
A related material tested negative in in vitro assays.

Carcinogenicity

Due to lack of data the classification is not possible.
This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

Reproductive toxicity

Based on available data, the classification criteria are not met.
A related material did not impair fertility in animal studies. Reproductivity studies in animals administered a related material have yielded mixed results.

Specific target organ toxicity - single exposure

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

Specific target organ toxicity - repeated exposure

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

Aspiration hazard

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

12. Ecological information

Ecotoxicity

No ecotoxicity data noted for the ingredient(s).

Persistence and degradability

No data is available on the degradability of this product.

Bioaccumulative potential

Not available.

Mobility in soil

Not available.

Other adverse effects

Not available.

13. Disposal considerations

Disposal instructions

This product, in its present state, when discarded or disposed of, is not a hazardous waste according to Federal regulations (40 CFR 261.4 (b)(4)). 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

Not available.

Hazardous waste code

Not available.

Waste from residues / unused products

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

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

14. Transport information

DOT

UN number

UN2811

UN proper shipping name

Toxic solid, organic, n.o.s. (Cyproheptadine Hydrochloride)

Transport hazard class(es)

6.1

Subsidiary class(es)

Not available.

Packing group

III

IATA

UN number

UN2811

UN proper shipping name

Toxic solid, organic, n.o.s. (Cyproheptadine Hydrochloride)

Transport hazard class(es)

6.1

Subsidiary class(es)

-

Packaging group

III

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

No information available.



15. Regulatory information

US federal regulations CERCLA/SARA Hazardous Substances - Not applicable.

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 - No
 Pressure Hazard - No
 Reactivity Hazard - No

SARA 302 Extremely hazardous substance No

SARA 311/312 Hazardous chemical No

Other federal regulations

Safe Drinking Water Act (SDWA) Not regulated.

Food and Drug Administration (FDA) Not regulated.

US state regulations

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)	Yes
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)	No
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	Yes
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)

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

Issue date 02-18-2008
Revision date 07-09-2015
Version # 03
Further information Not available.

Disclaimer

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Revision Information

Hazard(s) identification: <INDENT>Response
First-aid measures: Indication of immediate medical attention and special treatment needed
First-aid measures: General information
Physical & Chemical Properties: Multiple Properties
Toxicological information: Medical conditions aggravated by exposure
Toxicological information: Reproductive toxicity
Toxicological information: Symptoms related to the physical, chemical, and toxicological characteristics
Toxicological information: Delayed and immediate effects of exposure