



SAFETY DATA SHEET

1. Identification

Product identifier	Clomipramine Hydrochloride	
Other means of identification		
Catalog number	1140247	
CAS number	17321-77-6	
Chemical name	5H-Dibenz[b,f]azepine-5-propanamine, 3-chloro-10,11-dihydro-N,N-dimethyl-, monohydrochloride	
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	Acute toxicity, oral	Category 4
	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	Harmful if swallowed. May cause drowsiness or dizziness.	
Precautionary statement		
Prevention	Avoid breathing dust/fume/gas/mist/vapors/spray. Wash thoroughly after handling. Use only outdoors or in a well-ventilated area.	
Response	If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth. 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)	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.	
Supplemental information	Pharmacologically active material.	

3. Composition/information on ingredients

Substance

Chemical name	Common name and synonyms	CAS number	%
Clomipramine Hydrochloride		17321-77-6	100

4. First-aid measures

Inhalation	If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.
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 SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs.
Most important symptoms/effects, acute and delayed	Narcotic effects. Pharmacologically active material. Occupational exposure may cause physiological effects.
Indication of immediate medical attention and special treatment needed	Treat symptomatically. Treatment of tricyclic antidepressant overdose may include the following: Administer activated charcoal as a slurry within two hours of ingestion. For severe toxicity or CNS depression, manage with intubation and ventilator support. For seizures, administer intravenous diazepam or lorazepam. If seizures recur, consider phenobarbital followed by propofol and/or rapid sequence intubation, general anesthesia, and continuous EEG monitoring. For QRS widening, treat with serum alkalization and sodium bicarbonate and/or hyperventilation. For severe QRS widening not responsive to alkalization, treat with hypertonic saline. Consider infusion of lipid emulsion for dysrhythmias or hypotension. For ventricular dysrhythmias, treat with alkalization. For dysrhythmias unresponsive to alkalization, administer antiarrhythmics. For ventricular tachycardia and fibrillation, treat with lidocaine, amiodarone, and/or D/C shock. For torsades de pointes, treat with magnesium, overdrive pacing, and D/C shock. For significant cardiovascular toxicity, administer intravenous lipids. For hypotension, treat with positioning, fluid expansion, and pressors if needed. Dopamine may be ineffective. Hemodialysis may not be effective.
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 CO2. 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	Cool containers exposed to flames with water until well after the fire is out.
General fire hazards	No unusual fire or explosion hazards noted.

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. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. For personal protection, see section 8 of the SDS. Wear appropriate protective equipment and clothing during clean-up.
Methods and materials for containment and cleaning up	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. For waste disposal, see section 13 of the SDS.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

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). Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

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

Occupational exposure limits

Exposure limit values

Industrial Use Material	Type	Value
-------------------------	------	-------

Clomipramine Hydrochloride (CAS 17321-77-6)	TWA	0.2 mg/m ³
---	-----	-----------------------

Biological limit values

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

Appropriate engineering controls

For laboratory operations, use local exhaust ventilation or a ventilated enclosure for high energy operations such as particle sizing. Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

Individual protection measures, such as personal protective equipment

Eye/face protection

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

Skin protection

Hand protection

Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

Other

Train employees in proper gowning and degowning practices. Wear lab coat. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

Respiratory protection

Respirators are generally not required for laboratory operations. Use a tight-fitting full-face respirator with HEPA filters for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment.

9. Physical and chemical properties

Appearance

Appearance descriptions are general information and not specific to any USP lot.

Physical state

Solid.

Form

Powder.

Color

White. Yellow.

Odor

Odorless.

Odor threshold

Not available.

pH

Not available.

Melting point/freezing point

372.2 - 377.6 °F (189 - 192 °C)

Initial boiling point and boiling range

Not available.

Flash point

Not available.

Evaporation rate

Not available.

Flammability (solid, gas)

Not available.

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	< 0.0000001 kPa at 25 °C
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Very soluble.
Solubility (other)	Methanol: Freely soluble. Methylene chloride: Freely soluble. Ethyl ether: Insoluble.
Auto-ignition temperature	662 °F (350 °C) (BAM)
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	Dibenzazepine derivative.
Dust explosion properties	
Minimum ignition energy (MIE) - dust cloud	3 - 10 mJ
Molecular formula	C19H23ClN2 . HCl
Molecular weight	351.31
pH in aqueous solution	3.5 - 5 Solution: 10%

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	None known.
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

Inhalation	May cause drowsiness and dizziness.
Skin contact	Knowledge about health hazard is incomplete.
Eye contact	Knowledge about health hazard is incomplete.
Ingestion	Harmful if swallowed. Based on information from therapeutic use, this material may cause: Central nervous system effects.
Symptoms related to the physical, chemical, and toxicological characteristics	Tricyclic antidepressants: Dizziness. Drowsiness. Stupor. Restlessness. Vomiting. Troubled breathing. Tiredness. Enlarged pupils. Fever. Headache. Dry mouth. Weakness. Increased appetite. Diarrhea. Excessive sweating. Heartburn. Blurred vision. Eye pain. Confusion. Hallucinations. Difficult urination. Difficulty speaking or swallowing. Nervousness. Loss of balance. Convulsions.

Information on toxicological effects

Acute toxicity	Harmful if swallowed.
-----------------------	-----------------------

Product	Species	Test Results
Clomipramine Hydrochloride (CAS 17321-77-6)		
Oral		
LD50	Mouse	470 mg/kg
	Rat	914 mg/kg

Skin corrosion/irritation Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation Knowledge about health hazard is incomplete.

Local effects
 Skin irritation
 Result: Non-irritant.
 Species: Rabbit

Respiratory or skin sensitization

Respiratory sensitization Knowledge about health hazard is incomplete.

Skin sensitization Knowledge about health hazard is incomplete.

Germ cell mutagenicity Knowledge about mutagenicity is incomplete.

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

100 mg/kg Carcinogenicity
 Result: Negative.
 Species: Rat
 Test Duration: 2 years

80 mg/kg Carcinogenicity
 Result: Negative.
 Species: Mouse
 Test Duration: 2 years

IARC Monographs. Overall Evaluation of Carcinogenicity
 Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)
 Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens
 Not listed.

Reproductive toxicity Based on available data, the classification criteria are not met. For tricyclic antidepressants: Withdrawal symptoms such as colic, cyanosis, rapid breathing, and irritability have been observed in infants whose mothers received tricyclic antidepressants prior to delivery.

Reproductivity

100 mg/kg Reproductivity
 Result: No evidence of increased incidence of birth defects, but slight non-specific embryo/fetotoxic effects occurred in offspring at 100 mg/kg.
 Species: Mouse

100 mg/kg Reproductivity
 Result: No evidence of increased incidence of birth defects, but slight non-specific embryo/fetotoxic effects occurred in offspring at 50 mg/kg.
 Species: Rat

24 mg/kg Reproductivity
 Result: No effects on fertility.
 Species: Rat

Specific target organ toxicity - single exposure Narcotic effects.

Specific target organ toxicity - repeated exposure Knowledge about health hazard is incomplete.

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

Further information Pharmacologically active material. Occupational exposure may cause physiological effects.

12. Ecological information

Ecotoxicity

Product	Species	Test Results
Clomipramine Hydrochloride (CAS 17321-77-6)		
Aquatic		
Fish	LC50 Danio rerio	0.43 mg/l, 96 hours

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential No data available.

Mobility in soil No data available.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

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

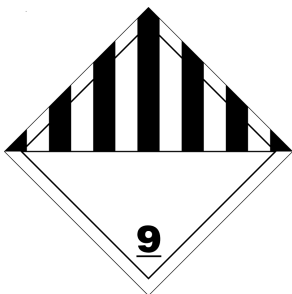
Other information

Passenger and cargo aircraft Allowed with restrictions.

Cargo aircraft only Allowed with restrictions.

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

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.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)**SARA 302 Extremely hazardous substance**

Not listed.

SARA 311/312 Hazardous chemical Yes**Classified hazard categories** Acute toxicity (any route of exposure)
Specific target organ toxicity (single or repeated exposure)**SARA 313 (TRI reporting)**

Not regulated.

Other federal regulations**Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.**US state regulations****California Proposition 65****US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd. (a))**

Clomipramine Hydrochloride (CAS 17321-77-6)

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)	Yes
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)	Yes
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes
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** 12-20-2006**Revision date** 03-26-2019**Version #** 04**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.

Disclaimer

USP Reference Standards are sold for chemical test and assay purposes only, and NOT for human consumption. The information contained herein is applicable solely to the chemical substance when used as a USP Reference Standard and does not necessarily relate to any other use of the substance described, (i.e. at different concentrations, in drug dosage forms, or in bulk quantities). USP Reference Standards are intended for use by persons having technical skill and at their own discretion and risk. This information has been developed by USP staff from sources considered reliable but has not been independently verified by the USP. Therefore, the USP Convention cannot guarantee the accuracy of the information in these sources nor should the statements contained herein be considered an official expression. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE is made with respect to the information contained herein.