




# SAFETY DATA SHEET

## 1. Identification

Product identifier	Amitriptyline Hydrochloride	
Other means of identification		
Catalog number	1029002	
CAS number	549-18-8	
Chemical name	10,11-Dihydro-N,N-dimethyl-5H-dibenzo[a,d]cycloheptene-Δ5,γ-propylamine hydrochloride)	
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

<b>Physical hazards</b>	Not classified.	
<b>Health hazards</b>	Acute toxicity, oral	Category 3
	Serious eye damage/eye irritation	Category 1
	Specific target organ toxicity, single exposure	Category 1 (nervous system)
<b>Environmental hazards</b>	Not classified.	
<b>OSHA defined hazards</b>	Not classified.	
<b>Label elements</b>		
<b>Signal word</b>	Danger	
<b>Hazard statement</b>	Toxic if swallowed. Causes serious eye damage. Causes damage to organs (nervous system).	
<b>Precautionary statement</b>		
<b>Prevention</b>	Do not breathe dust/fume/gas/mist/vapors/spray. Wash thoroughly after handling. Wear eye protection/face protection.	
<b>Response</b>	If swallowed: Immediately call a poison center/doctor. Rinse mouth. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a poison center/doctor. If exposed: Call a poison center/doctor.	
<b>Storage</b>	Store locked up.	
<b>Disposal</b>	Dispose of contents/container in accordance with local/regional/national/international regulations.	
<b>Hazard(s) not otherwise classified (HNOC)</b>	None known.	
<b>Supplemental information</b>	Pharmacologically active material.	

### 3. Composition/information on ingredients

#### Substance

Chemical name	Common name and synonyms	CAS number	%
Amitriptyline Hydrochloride		549-18-8	100

### 4. First-aid measures

<b>Inhalation</b>	Move to fresh air. Call a physician if symptoms develop or persist.
<b>Skin contact</b>	Wash off with soap and water. Get medical attention if irritation develops and persists.
<b>Eye contact</b>	Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Get medical attention immediately. Continue rinsing.
<b>Ingestion</b>	Call a physician or poison control center immediately. Rinse mouth. 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 substance is ingested. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.
<b>Most important symptoms/effects, acute and delayed</b>	Pharmacologically active material. Occupational exposure may cause physiological effects. Central nervous system depression. Gastrointestinal disturbances. Cardiovascular effects.
<b>Indication of immediate medical attention and special treatment needed</b>	Provide general supportive measures and treat symptomatically. Treatment of overdose may include the following: Perform gastric lavage. Administer activated charcoal slurry repeatedly, followed by a stimulant cathartic. Maintain respiratory and cardiac function and body temperature. Monitor cardiovascular function (ECG) for not less than 5 days. Digitalize cautiously for congestive heart failure. Control cardiac arrhythmias with lidocaine or by alkalinizing blood to pH 7.4 to 7.5 with intravenous sodium bicarbonate. Arrhythmias refractory to sodium bicarbonate may be managed with slow intravenous infusion of phenytoin while monitoring ECG. Propranolol is also effective but should be used with caution because of its negative inotropic and hypotensive effects. Quinidine and procainamide should be avoided. Administer physostigmine salicylate, 1 to 3 mg (adults) by slow intravenous infusion over 2 to 3 minutes, to help reverse severe anticholinergic effects (myoclonic seizures, severe hallucinations, hypertension, and ventricular arrhythmias). Because of the short duration of action of physostigmine, dosage may need to be repeated at 30 to 60 minute intervals, especially if life-threatening symptoms occur. However, routine administration of physostigmine is not recommended because of its toxicity. Physostigmine should be reserved for patients in coma with respiratory depression, uncontrollable seizures, severe hypertension, or serious cardiac arrhythmias. Use standard measures to manage circulatory shock and metabolic acidosis. Administer anticonvulsants such as diazepam, paraldehyde, phenytoin, and an inhalation anesthetic to control convulsions. Dialysis of tricyclic antidepressants has not been successful because of their high-protein binding.
<b>General information</b>	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

<b>Suitable extinguishing media</b>	Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials.
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	No unusual fire or explosion hazards noted.
<b>Special protective equipment and precautions for firefighters</b>	Wear suitable protective equipment.
<b>Fire fighting equipment/instructions</b>	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.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	No unusual fire or explosion hazards noted.

## 6. Accidental release measures

### Personal precautions, protective equipment and emergency procedures

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

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

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. 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

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

### Exposure limit values

#### Industrial Use Material

#### Type

#### Value

Amitriptyline Hydrochloride  
(CAS 549-18-8)

TWA

0.1 mg/m<sup>3</sup>

### 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

Crystalline powder.

#### Color

White. Off-white.

### Odor

Odorless. Practically odorless.

### Odor threshold

Not available.

<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	384.8 - 386.6 °F (196 - 197 °C)
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	< 1 mm Hg @ 20 ° C
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Freely soluble.
<b>Solubility (other)</b>	Chloroform: Freely soluble. Dichloromethane: Freely soluble. Alcohol: Freely soluble.
<b>Auto-ignition temperature</b>	701.6 °F (372 °C)
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Other information</b>	
<b>Chemical family</b>	Dibenzocycloheptadiene derivative.
<b>Molecular formula</b>	C20H23N . HCl
<b>Molecular weight</b>	313.9
<b>pH in aqueous solution</b>	5 - 6 (1% aqueous solution)

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Contact with incompatible materials.
<b>Incompatible materials</b>	Oxidizing agents. Acids. Bases.
<b>Hazardous decomposition products</b>	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. NOx. HCl.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Inhalation</b>	Knowledge about health hazard is incomplete.
<b>Skin contact</b>	Knowledge about health hazard is incomplete.
<b>Eye contact</b>	Causes serious eye damage.
<b>Ingestion</b>	Toxic if swallowed.

<b>Symptoms related to the physical, chemical and toxicological characteristics</b>	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.
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### Information on toxicological effects

<b>Acute toxicity</b>	Toxic if swallowed.
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Product	Species	Test Results
Amitriptyline Hydrochloride (CAS 549-18-8)		
Oral		
LD50	Mouse	140 mg/kg
	Rat	240 mg/kg
Skin corrosion/irritation	Based on available data, the classification criteria are not met.	
Serious eye damage/eye irritation	Causes serious eye damage.	
Local effects		
0.1 ml Eye irritation		
Result: Severe irritation; severe corneal capacity and ulceration observed.		
Species: Rabbit		
500 mg 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.	
Mutagenicity		
Ames test		
Result: Negative.		
Carcinogenicity	Knowledge about carcinogenicity is incomplete.	
IARC Monographs. Overall Evaluation of Carcinogenicity		
Not listed.		
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)		
Not listed.		
US. National Toxicology Program (NTP) Report on Carcinogens		
Not listed.		
Reproductive toxicity	Knowledge about health hazard is incomplete. 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.	
Specific target organ toxicity - single exposure	Causes damage to organs (nervous system).	
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	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.	
Persistence and degradability	No data is available on the degradability of this substance.	
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**

Since emptied containers may retain product residue, follow label warnings even after container is emptied.

## 14. Transport information

### DOT

<b>UN number</b>	UN2811
<b>UN proper shipping name</b>	Toxic solid, organic, n.o.s. (Amitriptyline Hydrochloride)
<b>Transport hazard class(es)</b>	
<b>Class</b>	6.1
<b>Subsidiary risk</b>	-
<b>Packing group</b>	III

### IATA

<b>UN number</b>	UN2811
<b>UN proper shipping name</b>	Toxic solid, organic, n.o.s. (Amitriptyline Hydrochloride)
<b>Transport hazard class(es)</b>	
<b>Class</b>	6.1
<b>Subsidiary risk</b>	-
<b>Packing group</b>	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.

#### Toxic Substances Control Act (TSCA)

##### 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 1910.1001-1053)

Not listed.

### 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)  
Serious eye damage or eye irritation  
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**

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. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).

**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)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
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** 10-24-2006

**Revision date** 12-17-2020

**Version #** 06

**Disclaimer**

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