



SAFETY DATA SHEET

1. Identification

Product identifier	Diltiazem Hydrochloride	
Other means of identification		
Catalog number	1205003	
CAS number	33286-22-5	
Chemical name	1,5-Benzothiazepin-4(5H)-one, 3-(acetyloxy)-5-[2-dimethylamino)ethyl]-2,3-dihydro-2-(4-methoxyphenyl)-, monohydrochloride, (+)-cis-	
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
	Acute toxicity, dermal	Category 3
	Skin corrosion/irritation	Category 2
	Serious eye damage/eye irritation	Category 2A
	Sensitization, skin	Category 1
	Specific target organ toxicity, single exposure	Category 2 (cardiovascular system)
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	
Label elements		



Signal word	Danger
Hazard statement	Harmful if swallowed. Toxic in contact with skin. Causes skin irritation. May cause an allergic skin reaction. Causes serious eye irritation. May cause damage to organs (cardiovascular system).
Precautionary statement	
Prevention	Do not breathe dust/fume/gas/mist/vapors/spray. Wash thoroughly after handling. Contaminated work clothing must not be allowed out of the workplace. Wear eye protection/face protection. Wear protective gloves/protective clothing.

Response	If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth. If on skin: Wash with plenty of water. Take off immediately all contaminated clothing and wash it before reuse. If skin irritation or rash occurs: Get medical advice/attention. 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. If exposed or concerned: Call a poison center/doctor.
Storage	Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	Pharmacologically active material.

3. Composition/information on ingredients

Substance

Chemical name	Common name and synonyms	CAS number	%
Diltiazem Hydrochloride		33286-22-5	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	Remove contaminated clothing immediately and wash skin with soap and water. Get medical advice/attention if you feel unwell. In case of eczema or other skin disorders: Seek medical attention and take along these instructions. Wash contaminated clothing before reuse.
Eye contact	Immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Get medical advice/attention if you feel unwell.
Most important symptoms/effects, acute and delayed	Cardiovascular effects. Pharmacologically active material. Occupational exposure may cause physiological effects.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Treatment of calcium-channel blocker overdose may include the following: Administer activated charcoal and consider gastric lavage. Hypotension secondary to reduced systemic resistance and lowered cardiac output may require fluid replacement, Trendelenburg positioning, and vasoconstriction with norepinephrine or high-dose dopamine. Calcium may also help, especially when depressed cardiac contractility is contributory. Glucagon may improve perfusion pressure by stimulating cardiac output. Pacing may be required. Conduction deficits and bradydysrhythmias do not need specific treatment if they are not felt to be contributing to continuing hypotension. Antidotal therapy should include calcium (as the chloride) and/or atropine initially, followed by isoproterenol and/or pacing for resistant or nonresponsive cases. Seizures should be treated with diazepam initially, progressing to phenobarbital for nonresponsive cases. Correct underlying metabolic acidosis, hypoxia, and hypotension. Pulmonary edema is a potential complication, especially with rapid return to normalized vascular tone in combination with aggressive fluid therapy. Due to protein binding, dialysis and hemoperfusion are not effective. Monitor ECG and vital signs frequently.
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	No unusual fire or explosion hazards noted.
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.
General fire hazards	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. 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
Diltiazem Hydrochloride (CAS 33286-22-5)	TWA	500 micrograms/m3

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. Off-white.
Odor	Odorless.

Odor threshold	Not available.
pH	4.3 - 5.3 Solution: 1%
Melting point/freezing point	> 410 °F (> 210 °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)	Freely soluble.
Solubility (other)	Benzene: Practically insoluble. Chloroform: Freely soluble. Ethanol: Slightly soluble. Ether: Insoluble. Formic acid: Freely soluble. Methyl alcohol: Freely soluble.
Partition coefficient (n-octanol/water)	2.7
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	Benzothiazepine.
Molecular formula	C ₂₂ H ₂₆ N ₂ O ₄ S . HCl
Molecular weight	450.98

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	Strong oxidizing agents.
Hazardous decomposition products	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. NOx. SOx. Cl-.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Knowledge about health hazard is incomplete.
Skin contact	Toxic in contact with skin. Causes skin irritation. May cause an allergic skin reaction.
Eye contact	Causes serious eye irritation.
Ingestion	Harmful if swallowed. Based on information from therapeutic use, this material may cause: Cardiovascular effects.

Symptoms related to the physical, chemical, and toxicological characteristics

Calcium channel blocking agents: Cardiovascular effects. Dizziness. Fatigue. Hyperglycemia. Gastrointestinal effects. Flushing. Confusion. Seizures. Peripheral edema.

Information on toxicological effects

Acute toxicity Toxic in contact with skin. Harmful if swallowed.

Product	Species	Test Results
Diltiazem Hydrochloride (CAS 33286-22-5)		
Dermal		
LD50	Rat	271 mg/kg
Oral		
LD50	Mouse	508 mg/kg
	Rat	560 mg/kg

Skin corrosion/irritation Causes skin irritation.

Serious eye damage/eye irritation Causes serious eye irritation.

Local effects

Eye irritation
Result: Moderate.
Species: Human
Skin irritation
Result: Moderate.
Species: Human

Respiratory or skin sensitization

Respiratory sensitization Knowledge about health hazard is incomplete.

Skin sensitization May cause an allergic skin reaction.
Dermal hypersensitivity reactions with therapeutic use have been reported.

Germ cell mutagenicity Knowledge about mutagenicity is incomplete.

Mutagenicity

Ames test
Result: Negative.
Chromosome aberration
Result: Negative.
Micronucleus test
Result: Negative.

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

100 mg/kg/day Carcinogenicity, oral doses
Result: Negative.
Species: Rat
Test Duration: 24 months
30 mg/kg/day Carcinogenicity, oral doses
Result: Negative.
Species: Mouse
Test Duration: 21 months

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 Knowledge about health hazard is incomplete.
Epidemiological studies are not sufficient to determine an association between therapeutic use of this material during pregnancy and an increased incidence of birth defects. This material has been administered during pregnancy in humans to stop preterm labor.
Reproductivity studies in animals administered the base of this material have yielded mixed results.

Reproductivity

100 mg/kg/day Fertility study

Result: Negative.

Species: Rat

Specific target organ toxicity - single exposure May cause damage to organs (cardiovascular 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

Octanol/water partition coefficient log Kow

2.7

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

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

IATA

UN number	UN2811
UN proper shipping name	Toxic solid, organic, n.o.s. (Diltiazem Hydrochloride)
Transport hazard class(es)	
Class	6.1
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)
Skin corrosion or irritation
Serious eye damage or eye irritation
Respiratory or skin sensitization
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



WARNING: This product can expose you to Diltiazem Hydrochloride, which is known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

California Proposition 65 - CRT: Listed date/Developmental toxin

Diltiazem Hydrochloride (CAS 33286-22-5)

Listed: February 27, 2001

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

Country(s) or region	Inventory name	On inventory (yes/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	05-04-2006
Revision date	02-13-2019
Version #	04
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