



SAFETY DATA SHEET

1. Identification

Product identifier	Nicardipine Hydrochloride	
Other means of identification		
Catalog number	1463224	
CAS number	54527-84-3	
Chemical name	2-[Methyl(phenylmethyl)amino]ethyl methyl 1,4-dihydro-2,6-dimethyl-4-(3-nitrophenyl)-3,5-pyridine dicarboxylate hydrochloride	
Recommended use	For analytical laboratory 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	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
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	

Label elements



Signal word	Danger
Hazard statement	Toxic if swallowed.
Precautionary statement	
Prevention	Wash thoroughly after handling.
Response	If swallowed: Immediately call a poison center/doctor. Rinse mouth.
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	%
Nicardipine Hydrochloride		54527-84-3	100

Information provided in the SDS is not specific to the lot provided. Refer to the label and USP Certificate/Product Information Sheet for the assigned value of a particular lot.

4. First-aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact	Wash off with soap and water. Get medical attention if irritation develops and persists.
Eye contact	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	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.
Most important symptoms/effects, acute and delayed	Pharmacologically active material. Occupational exposure may cause physiological effects. Cardiovascular effects. Hypotension. Gastrointestinal disturbances.
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. 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 materials, 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. 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

Nicardipine Hydrochloride
(CAS 54527-84-3)

TWA

0.6 mg/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 USP materials.

9. Physical and chemical properties

Appearance

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

Physical state

Solid.

Form

Powder.

Color

Pale green. Yellow green.

Odor

Odorless.

Odor threshold

Not available.

pH

Not available.

Melting point/freezing point

329 - 339.8 °F (165 - 171 °C) (beta form)

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 Not available.

Vapor density Not available.

Relative density Not available.

Solubility(ies)

Solubility (water) Slightly soluble.

Solubility (other) Hexane: Insoluble.
Acetic acid: Soluble.
Acetone: Slightly soluble.
Anhydrous ethanol: Partially soluble.
Benzene: Insoluble.
Chloroform: Soluble.
Dioxane: Slightly soluble.
Ether: Insoluble.
Ethyl acetate: Slightly soluble.
Methanol: Soluble.
n-Butanol: Slightly soluble.

Auto-ignition temperature Not available.

Decomposition temperature Not available.

Viscosity Not available.

Other information

Chemical family Dihydropyridine derivative.

Molecular formula C₂₆H₂₉N₃O₆ · HCl

Molecular weight 515.99

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 NO_x. HCl. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

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

Inhalation Knowledge about health hazard is incomplete.

Skin contact Knowledge about health hazard is incomplete.

Eye contact Knowledge about health hazard is incomplete.

Ingestion Toxic if swallowed.

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 if swallowed.

Product	Species	Test Results
Nicardipine Hydrochloride (CAS 54527-84-3)		
<u>Acute</u>		
Oral		
LD50	Mouse	322 mg/kg
	Rat	184 mg/kg
Skin corrosion/irritation	Knowledge about health hazard is incomplete.	
Serious eye damage/eye irritation	Knowledge about health hazard is incomplete.	
Respiratory or skin sensitization		
Respiratory sensitization	Knowledge about health hazard is incomplete.	
Skin sensitization	Knowledge about health hazard is incomplete.	
	Skin sensitization study	
	Result: Non-sensitizing.	
	Species: Guinea pig	
Germ cell mutagenicity	Knowledge about mutagenicity is incomplete.	
Mutagenicity		
	Micronucleus tests in mice and hamsters	
	Result: Negative.	
	Mutagenicity tests in microbial indicator organisms	
	Result: Negative.	
	Sister chromatid exchange test in hamsters	
	Result: Negative.	
Carcinogenicity	Based on available data, the classification criteria are not met.	
	100 mg/kg/day Long-term carcinogenicity study, administered in diet. (Nicardipine)	
	Result: No evidence of neoplasia of any tissue and no evidence of thyroid changes.	
	Species: Mouse	
	Test Duration: 18 months	
	45 mg/kg/day Long-term carcinogenicity study, administered in diet. (Nicardipine)	
	Result: Dose-dependent increase in thyroid hyperplasia and neoplasia.	
	Species: Rat	
	Test Duration: 2 years	
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	Based on available data, the classification criteria are not met.	
	In animals, many of the processes of embryogenesis appear to be calcium-dependent, and there are theoretical concerns about use of calcium channel blockers by humans in early pregnancy. However, epidemiological studies have not shown an association between therapeutic use of calcium channel blocking agents during pregnancy and an increased incidence of birth defects.	
Reproductivity		
	1 mg/kg/day Reproductivity and development, administered intravenously (Nicardipine)	
	Result: Embryo-lethal, but not teratogenic.	
	Species: Rabbit	
	10 mg/kg/day Reproductivity and development, administered intravenously (Nicardipine)	
	Result: Embryo-lethal, but not teratogenic.	
	Species: Rat	
	100 mg/kg/day Reproductivity and development, administered orally during organogenesis (Nicardipine)	
	Result: No adverse effects on the fetus.	
	Species: New Zealand rabbit	

Reproductivity

100 mg/kg/day Reproductivity and development, administered orally during pregnancy (Nicardipine)
Result: Fetotoxicity, but no evidence of embryolethality or teratogenicity.

Species: Rat

50 - 150 mg/kg/day Reproductivity and development, administered orally during organogenesis (Nicardipine)

Result: Embryocidal at high dose but not at low dose.

Species: New Zealand white rabbit

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

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

UN number UN2811
UN proper shipping name Toxic solid, organic, n.o.s. (Nicardipine 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. (Nicardipine 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.

**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)

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.

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)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No

Country(s) or region	Inventory name	On inventory (yes/no)*
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	No
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	10-18-2011
Revision date	08-20-2021
Version #	04
Disclaimer	<p>USP materials are sold for analytical laboratory use only, and NOT for human consumption. The information contained herein is applicable solely to the chemical substance when used for analytical laboratory use 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 materials 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.</p>