



SAFETY DATA SHEET

1. Identification

Product identifier	Amlodipine Besylate	
Other means of identification		
Catalog number	1029501	
CAS number	111470-99-6	
Synonyms	Amlodipine benzenesulfonate	
Chemical name	3,5-Pyridinedicarboxylic acid, 2-[(2-aminoethoxy)methyl]-4-(2-chlorophenyl)-1,4-dihydro-6-methyl-, 3-ethyl 5-methyl ester, (+/-)-, monobenzenesulfonate	
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
	Serious eye damage/eye irritation	Category 2A
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	
Label elements		



Signal word	Warning	
Hazard statement	Harmful if swallowed. Causes serious eye irritation.	
Precautionary statement		
Prevention	Wash thoroughly after handling. Wear eye protection/face protection.	
Response	If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth. 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	Not available.	
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	Potent pharmacologically active material.	

3. Composition/information on ingredients

Substance

Chemical name	Common name and synonyms	CAS number	%
Amlodipine Besylate	Amlodipine benzenesulfonate	111470-99-6	100

4. First-aid measures

Inhalation	Move to fresh air. 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. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately. 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.
Most important symptoms/effects, acute and delayed	Heart rhythm abnormalities. Hypotension. Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.
Indication of immediate medical attention and special treatment needed	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 CO ₂ . 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	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. 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. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	For waste disposal, see section 13 of the SDS. 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.

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.
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

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	Form
Amlodipine Besylate (CAS 111470-99-6)	TWA	0.1 mg/m3	(base)

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

Appropriate engineering controls No open handling. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). 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 Consider double gloves. 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 disposable lab coat, disposable sleeve covers and two pair of gloves as appropriate for the task. 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 Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head cover 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 Pharmacological effects may be seen with occupational exposure. 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. Light yellow.

Odor Not available.

Odor threshold Not available.

pH Not available.

Melting point/freezing point 390.2 - 397.4 °F (199 - 203 °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 Not available.

Vapor density Not available.

Relative density Not available.

Solubility(ies)

Solubility (water) Slightly soluble.

Solubility (other) Dimethylsulfoxide: Freely soluble.
Methanol: Freely soluble.
Dimethylformamide: Freely soluble.
Ethanol: Sparingly soluble.
Isopropanol: Slightly soluble.
Acetone: Slightly soluble.
Methylene chloride: Slightly soluble.

Partition coefficient (n-octanol/water) 2.759 at 20 °C, pH 7

Auto-ignition temperature Not available.

Decomposition temperature Not available.

Viscosity Not available.

Other information

Chemical family Dihydropyridine calcium channel blocker.

Dust explosion properties

Kst 233 bar.m/s

St class 2 Strong explosion.

Minimum ignition energy (MIE) - dust cloud 9 - 18 mJ

Molecular formula C20-H25-Cl-N2-O5.C6-H6-S-O3

Molecular weight 567.06 g/mol

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 SOx, 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 Knowledge about health hazard is incomplete.

Skin contact Knowledge about health hazard is incomplete.

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 Harmful if swallowed.

Product	Species	Test Results
Amlodipine Besylate (CAS 111470-99-6)		
Acute		
Oral		
LD50	Mouse	37 mg/kg
	Rat	393 mg/kg

Skin corrosion/irritation Knowledge about health hazard is incomplete.

Serious eye damage/eye irritation Causes serious eye irritation.

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.
Mutagenicity: In vitro and in vivo bone marrow cytogenetics assays
Result: Negative.
Species: Mouse
Mutagenicity: In vitro chromosomal aberration assay in lymphocytes
Result: Negative.
Species: Human

Carcinogenicity Based on available data, the classification criteria are not met. Several case-control studies have shown that use of calcium antagonists is not associated with a statistically significant increased risk of developing cancer as compared with non-users of calcium antagonists.

0.5 mg/kg/day Carcinogenicity
Result: No evidence of carcinogenicity.
Species: Mouse
2.5 mg/kg/day Carcinogenicity
Result: No evidence of carcinogenicity.
Species: Rat

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. 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

25 mg/kg/day Reproductivity / Developmental, administered orally.

Result: Maternal toxicity, but no fetotoxicity, embryotoxicity, or teratogenicity noted.

Species: Rat

25 mg/kg/day Reproductivity / Developmental, administered orally.

Result: No embryotoxicity, fetotoxicity, or teratogenicity noted.

Species: 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	Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

12. Ecological information

Ecotoxicity

Product	Species	Test Results
Amlodipine Besylate (CAS 111470-99-6)		
Aquatic		
<i>Acute</i>		
Algae	EC50	0.28 mg/l, 72 hours
Crustacea	EC50	9.9 mg/l, 48 hours
Fish	LC50	14 mg/l, 96 hours

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

Bioaccumulative potential

Octanol/water partition coefficient log Kow

2.759, at 20 °C, pH 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	UN3077
UN proper shipping name	Environmentally hazardous substance, solid, n.o.s. (Amlodipine besylate)
Transport hazard class(es)	
Class	9
Subsidiary risk	-
Packing group	III

IATA

UN number	UN3077
------------------	--------

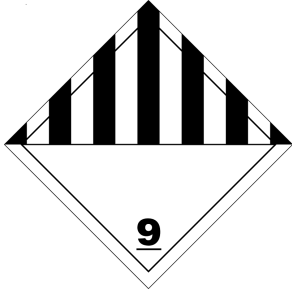
UN proper shipping name Environmentally hazardous substance, solid, n.o.s. (Amlodipine besylate)
Transport hazard class(es)
Class 9
Subsidiary risk -
Packing group III
Other information

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 Combustible dust
 Acute toxicity (any route of exposure)
 Serious eye damage or eye irritation

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 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)	No
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
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	03-16-2006
Revision date	02-14-2019
Version #	03
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.