Safety Data Sheet

For Compliance with OSHA 29 CFR 1910.1200 and ANSI Z400.1-1998

Section 1: Identification

Product Name Amlodipine Besylate USP
Commercial Name Amlodipine Besilate
Product Use API used for antihypertensive
Restrictions On Use Not available.

Product Code 30-4261

Company
PCCA
9901 South Wilcrest
Houston, TX 77099
Phone: 1-800-331-2498
Fax: 1-800-874-5760

In case of emergency contact:
CHEMTREC (24hr) 1-800-424-9300

Section 2: Hazard(s) Identification

OSHA Haz Com: CFR 1910.1200 Acute Toxicity, Oral: Category 4 Skin corrosion/irritation: Category 2 Serious eye damage/eye irritation: Catergory 2A Specific target organ toxicity (Single exposure): Category 3

Signal Word WARNING

Hazard Statement(s) Harmful if swallowed. Causes serious eye irritation. Causes serious eye irritation. May cause respiratory irritation. May cause drowsiness or dizziness.

Pictogram(s) or Symbol(s)

Precautionary Statement(s):

Prevention P264: Wash face, hands and any exposed skin thoroghly after handling P270: Do not eat, drink or smoke when using this product P261: Avoid breathing dust P271: Use only outdoors or in well ventilated area P280: Wear protective gloves. Wear eye/face protection

Response P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lense if present and easy to do. Continue rinsing. P332+P313: IF ON SKIN: If skin irritation occurs: Get medical advice/attention, P362+P364: Take off contaminated clothing and wash it before reuse. P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P304+P312: Call a poison center or doctor/physician if you feel unwell. P301+P312: IF SWALLOWED: Immediately call a poison center/doctor, if you feel unwell

Storage P403+P225: Store in a well ventilated place. Keep container tighly closed P405: Store locked up

Disposal P501:Dispose contents and container to an approved waster disposal plant in accordance with local, regional, national, and international regulations as applicable

Section 3: Composition/Information on Ingredients

Substance/Mixture Substance
Components Amlodipine Besilate USP
% By Weight 100
CAS# 111470-99-6
Molecular Weight 567.1 g/mole
Chemical Formula C26H31CIN2O8S
Synonym(s) Amlodipine benzenesulfonate; Norvasc; 3,5-Pyridinecarboxylic acid; 2-((aminoethoxy)methyl)-4-(2-chlorophenyl)-1,4-dihyddro-6-methyl,3-ethyl-5-methyl ester; monobenzenesulfonate

Mixtures

Name	CAS#	% by Weight	TLV/PEL	LC50/LD50
Amlodipine Besilate USP	111470-99-6	100		

Section 4: First-Aid Measures

Inhalation Move to fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Obtain medical attention

Skin Contact Wash off immediately with sop and plenty of water while removing all contaminated clothes and shoes. Obtain medical attention. If skin irritation persists, call a physician.

Eye Contact Rinse immediately with plenty of water, also under the eyelids for at least 15 minutes. Obtain medical attention

Ingestion Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Obtain medical attention.

Symptoms/Effects

Acute Irritating to eyes and skin; irritation to respiratory system; Respiratory depression; Nausea; Vomiting; May cause diarrhea; Central Nervous system effects; Headache; Tremors; Drowsiness; fatigue; Insomnia; Weakness; May affect the cardiovascular system; Cardiac arrhythmias; Weak tachaycardia; Bradycardia; Peripheral neuropathy;Paresthesia; Muscle weakness; May affect the uninary system; It may the Kidneys

Delayed Not available.

Immediate Medical Attention

Treat sypmtomatically. At least half the does is excreted in the urine as metronidazole and its metabolites, including an acid oxidation product, a hydroxy derivative and a glucuronide.

Section 5: Fire-Fighting Measures

Suitable Extinguishing Media

Extinguishing media: foam, dry chemical powder, cardon dioxide Alert Fire Brigade and tell them location and nature of hazard. Wear breathing apparatus plus protective gloves. Prevent, by any means available, spillage from entering drains or water courses, Use water delivered as a fine spray to control fire and cool adjacent area. When any large container (including road and rail tankers) is involved in a fire, consider evacuation by 100 meters in all directions.

Unsuitable Extinguishing Media

N/A

Products of Combustion

Avoid contamination with oxidizing agents i.e. nitrates, oxidizing acids, chlorine bleaches, pool chlorine etc. as igition may result.

Firefighters Special Equipment and Precautions

N/A

Section 6: Accidental Release Measures

Minor spills: Clena up waste regularly and abnormal spills immediately. Avoid breathing dust and contact with skin and eyes. Wear protective clothing, gloves, safety glasses and dust respirator. Use dry clean up procendures and avoid generating dust. Environmental hazard- contain spillage. Major spills: Clear area or personnel and move upwind. Alert Fire Brigade and tell them location and nature of hazard. Wear full body protective clothing with breathing appapartus. Environmental hazard- contain spillage.

Section 7: Handling and Storage

Avoid all personal contact, including inhalation. Wear protective clothing when rish of exposure occurs. Use in a well-ventilated area. Prevent concentration in hollows and sumps. Empty containers may contain residual dust which has the potentnial to accumulate following settling. Such dusts may explode in the presence of an appropriate ignition source. Do not cut, drill, grind or weld such containers. In addition ensure such activity is not performed near full, partially empty or empty containers without appropriate workplace safety authorization or permit. Polyethylene or polypropylene or fiber body container. Check all containers are clearly labeled and free from leaks. Avoid reaction with oxidizing agents/ Store in original containers. Keep containers securely sealed. Store in a cool, dry area protected from environmental extremes. Store away from incompatible materials and foodstuff containers. Store in dark.

Section 8: Exposure Controls/Personal Protection

Exposure Limits	Employees exposed to confirmes human carcinogens should be authorized to do so by the employer, and work in a regulated area. Work should be undertaken in an isolated system such as a "glove-box'. Employees should wash their hands and arms upon completion of the assigned task and before engaging in other activities not associated with the isolated system. Within regulated areas, the carcinogen should be stored in sealed containers, or enclosed in a closed system, including piping systems, with any sample ports or openings closed while the carcinogens are contained within. Open-vessel systems are prohibited.
Engineering Controls	Employees working with confirmed human cnarcinogens should be provided with, and be required to wear, clean, full body protective clothing (smocks, coveralls, or long-sleeved shirt and pants), shoe covers and gloves prior to entering the regulated area. Employees engaged in handling operations involving carcinogens should be provided with, nad required to wear and se half-face filter-type respirators with filters for dusts, mists and fumes, or air purifying canisters or cartidges. A respirator affording higher levels or protection may be substituted. Emergency deluge and eyewash fountains, supplied with potable water, should be located near, within sight of, and on the same level with locations where direct exposure is likely. Prior to each exit from an area containing confirmed human carcinogens, employees should be required to remove and leave protective clothing and equipment at the point of exit and at the last exit of the day, to place used clothing and equipment in impervious containers at the point of exit for purposes of decontamination or disposal. The contents of such impervious containers must be identified with suitable labels. For maintenance and decontamination activities, authorized employess entering the area should be provided with and required to wear clean, impervious garments, including gloves, boots and continuous -air supplied hood. prior to removing protective garments the employee should undergo decontamination and be required to shower upon removal of the garments and hood. Overalls, pVC apron, barrier cream, skin cleansing cream.
Personal Protection	Respirator. Safety glasses with side shields. Chemical goggles. Check for and remove contact lenses may pose a special hazard. Suitability and durability of glove type iis dependent on usage. Important factors in the selection of gloves incluse: frequency and duration of contact, chemical resistances of glove material, glove thickness and dexterity. Experience indicates that the following polymers are suitable as glove materials for portection against undisclosed, dry solids, where abrasive particles are not present: polychloroprene nitrile rubber, butyl rubber, fluorocaoutchouc.

Section 9: Physical and Chemical Properties

Appearance	White to pale-yellow crystalline powder or crystals
Odor	odorless or with slight odor
Odor Threshold	Not available.

Melting Point	195 - 250°C	**pH**	Not available.
Freezing Point	Not available.	**Vapor Pressure**	N/A
Boiling Point/Range	Not determined	**Vapor Density**	N/A
Decomposition temperature	Not available.	**Viscosity**	N/A
Partition Coefficient: n-octanol/water	Not available.	**Evaporation Rate**	Not available.
Flash Point	Not determined.	**Autoignition temperature**	Not available.
Flammability	Not available.	**Flammability or Explosive Limits:**	
		Lower	Not available.
		Upper	Not available.

Solubility(ies)	slightly soluble in water, freely soluble in chloroform and methanol, sparingly soluble in alcohol (96%), acetone and methylene chloride
Other	bitter slightly saline taste; does not mix well with water. Darkens on exposure to light.

Section 10: Stability and Reactivity

Reactivity	Not available.
Chemical Stability	This product is stable.
Hazardous Polymerization	Polymerization will not occur.
Conditions to Avoid	Excess heat.
Incompatible Materials	Not available.
Hazardous Decomposition Products	Not available.

Section 11: Toxicological Information

RTECS N/A

Acute Toxicity
Maybe harmful if swallwed, Causes skin irritation. May cause damamge to organs through prolonged or repated exposure. Causes serious eye damage. Toxicity to animals: Acute oral toxicity (LD50): 37 37 mg/kg [mouse] Chronic effects on humans: not available

Skin Corrosion/Irritation
Not available.

Serious Eye Damage/Irritation
Not available.

Respiratory or Skin Sensitization
Not available.

Germ Cell Mutagenicity
Not available.

Carcinogenicity
Not available.

Reproductive Toxicity
Not available.

Routes of Entry
Inhalation. Ingestion.

Symptoms Related to Exposure
Not available.

Potential Health Effects
Not available.

Target Organ(s) Not available.

Section 12: Ecological Information

Ecotoxicity
Possibly hazardous short-term degredation products are not likely. However, long-term degredation products may arise. Toxicity of the products of biodegredation: The procust of degredation are as toxic as the product itself.

Persistance and Degradability
Not available.

Bioaccumulative Potential
Not available.

Mobility in Soil
Not available.

Other Adverse Effects
Not available.

Section 13: Disposal Considerations

Waste Disposal
Containers may still present a chemical hazard/danger when empty. Return to supplier for reuse/recycling if possible. If container can not be cleaned sufficiently well to ensure that residuals do not remain or if the container cannot be used to store the same product, then puncture containers, to prevent re-use, and bury at an authorized landfill. Where possible retain label warnings and MSDS and observes all noties pertaining to the product. Legislation addressing waste disposal requirements may differ by country, state and/or territory. Each user must refer to laws operating in ther area. A hierarchy of controls seems to be common-the user should investigate: reduction, do not allow wash water from cleaning or process equipment to enter drains. It may be necessary to collect all wash water for treatment before disposal. In allcases disposal to sewer may be subject to local laws and regulations and these should be considered first. Where in doubt contact the responsible authority. Recycle whereever possible. Consult maufacturer for recycling options or consult local or regional waste mamagement authority for diposal if no suitable treatment or disposal facility can be identified. Dispose of by: burial in a landd-fill specifically licensed to accept chemical and/or pharmamceutical wastes or incineration in a licensed apparatus (after admixture with suitable combustible material). Decontaminate empty containers. Observe all labels safeguards until containers are cleaned and destroyed.

Disposal of Container
Not available.

Other Considerations
Not available.

Section 14: Transport Information

DOT Classification
Not a DOT controlled material. This material is not classified dangerous good according to international transportation regulations (ADR/RID-IMDG-ICAO/IATA)

Section 15: Regulatory Information

Regulations
Federal and State Regulations: No products were found. Other Regulations: OSHA: Hazardous by definition of Hazard Communication Standard (29 CFR 1910.1200).

Other
N/A

Section 16: Other Information

The information contained herein is based on current knowledge and experience; no responsibility is accepted that the information is sufficient or correct in all cases. Users should consider these data only as a supplement to other information gathered by them and must make independent determination of suitability and completeness of information from all sources to assure proper use and disposal of these materials and the safety and health of employees, customers and third parties and the protection of the environments.