

SAFETY DATA SHEETS

This SDS packet was issued with item:

078937290

N/A

SAFETY DATA SHEET
for
AMLODIPINE BESYLATE TABLETS (2.5MG, 5MG, 10MG);
ALP-2.5, ALP-5, ALP-10

1. Identification

Product Name: AMLODIPINE BESYLATE TABLETS (2.5MG, 5MG, 10MG); ALP-2.5, ALP-5, ALP-10

Synonyms: Norvasc, Amlodipine Benzenesulfonate, Amlodipine Besilate

CAS Number: Mixture

Product Use: For use as a prescription only human therapeutic.

Manufacturer/Supplier: Upsher-Smith Laboratories, LLC

Address: 6701 Evenstad Drive, Maple Grove, MN 55369

General Information: 1-763-315-2000; 1-800-654-2299


Emergency Contact: INFOTRAC 1-800-535-5053

2. Hazards Identification

GHS Classification:

Health	Environmental	Physical
Acute Toxicity: Category 4 Skin Corrosion: Category 3 Eye Corrosion: 2B Skin Sensitization: Not available Carcinogenicity: Category 2 Reproductive/Developmental: Category 2 Target Organ Toxicity (Repeated): Heart, circulatory system	Not classified	Not classified

GHS Label: Warning

<p>Symbols: </p> <p>Signal word: Warning</p>	
<p style="text-align: center;"><u>Hazard Statements</u></p> <p>H302: Harmful if swallowed. H315: Causes skin irritation. H319: Causes serious eye irritation. H351: Suspected of causing cancer. H361: Suspected of damaging fertility or unborn child.</p>	<p style="text-align: center;"><u>Precautionary Statements</u></p> <p>P201: Obtain special instructions before use. P202: Do not handle until all safety precautions have been read and understood. P264: Wash hands and skin thoroughly after handling. P270: Do not eat, drink or smoke when using this product. P280: Wear protective gloves/protective clothing/eye</p>

	<p>protection/face protection.</p> <p>P281: Use personal protective equipment as required.</p> <p>P301+312: IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.</p> <p>P302+P352: IF ON SKIN: Wash with plenty of soap and water.</p> <p>P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> <p>P308+P313: IF exposed or concerned: Get medical advice/attention.</p> <p>P321: Specific treatment.</p> <p>P332+P313: If skin irritation occurs: Get medical advice/attention.</p> <p>P337+P313: If eye irritation persists: Get medical advice/attention.</p> <p>P362: Take off contaminated clothing and wash before reuse.</p> <p>P405: Store locked up.</p> <p>P501: Dispose of contents/container to an approved waste disposal facility.</p>
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3. Composition / Information on Ingredients

Component	CAS Number	Weight %
Amlodipine Besylate	111470-99-6	< 5
Microcrystalline Cellulose	9004-34-6	< 70
Dihydrate Dibasic Calcium Phosphate	7757-93-9	<35
Sodium Starch Glycolate	9063-38-1	< 5
Magnesium Stearate	557-04-0	1

4. First Aid Measures

- Eye:** In case of eye contact, flush with copious amounts of water for at least 15 minutes. Hold eyelids away from eyeball to ensure thorough rinsing. Seek medical attention immediately.
- Skin:** If redness, dryness or other signs of irritation develop, wash the affected area with plenty of warm water and soap. If irritation persists, seek medical attention immediately.
- Inhalation:** In the final form, not a likely route of exposure. However, in case of inhalation, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult administer oxygen. Seek medical attention immediately.
- Ingestion:** In case of accidental ingestion, give the victim several glasses of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Do not force an unconscious or

convulsing person to drink liquids or to vomit. Seek medical attention immediately.

5. Fire Fighting Measures

Suitable Extinguishing Media:	Use an appropriate media including water spray, dry powder, foam, carbon dioxide.
Firefighting Procedures:	Wear self-contained breathing apparatus and personal protective equipment to prevent contact with skin and eyes.
Unusual Fire and Explosion Hazards	None reported.
Combustion Products	When heated to decomposition it emits toxic gases such as carbon oxides (CO and CO ₂), nitrogen oxides (NO and NO ₂) and hydrogen chloride.

6. Accidental Release Measures

Spill Response Instructions:

The following spill response instructions only apply to bulk quantities of the material. Report emergency situations immediately. Non-essential personnel should be evacuated from the affected area. Spills should be cleaned up in a manner that minimizes exposure to personnel. Personnel involved in the clean up of spills should wear the appropriate respiratory protection, gloves, eye protection, and protective coveralls. Minimize dust generation. Remove all sources of heat and ignition. Cover spill with absorbent material and collect for disposal. Ventilate the area and clean spill area thoroughly with soap and water. Collect wash with absorbent material and transfer all waste to a labeled container for disposal. Observe all applicable regulations when disposing of this substance.

7. Handling and Storage

General Handling

In a manufacturing setting or other situation where exposure to aerosols may occur appropriate personal protective equipment, including respiratory protection, must be worn. Use good personal hygiene – wash hands and exposed skin thoroughly with soap and water after use. Remove any contaminated clothing and clean before reuse. Destroy contaminated belts and shoes and other items that cannot be decontaminated.

Keep away from heat and flame. Keep operating temperatures below ignition temperatures at all times. Use non-sparking tools. Ground all equipment containing material.

Storage

When not in use, store in a cool, dry, well-ventilated area, in tightly sealed containers that

are labeled in accordance with OSHA's Hazard Communication Standard [29 CFR 1910.1200]. Keep away from ignition sources including electrostatic charge, heat, sparks, open flame, and strong oxidizers. In case of insufficient ventilation, wear suitable respiratory protection. Keep this drug out of the reach of children. Protect from physical damage. Do not cut, grind, or weld on or near containers unless precautions are taken against these hazards.

8. Exposure Controls / Personal Protection

Exposure Limits

Component Name	WEEL (TWA)	OSHA PEL (TWA)	ACGIH TLV (TWA)	NIOSH REL
Amlodipine Besylate	N.E.	N.E.	N.E.	N.E.
Microcrystalline Cellulose	N.E.	15 mg/m ³	10 mg/m ³	10 mg/m ³
Dihydrate Dibasic Calcium Phosphate	N.E.	N.E.	N.E.	N.E.
Sodium Starch Glycolate	N.E.	N.E.	N.E.	N.E.
Magnesium Stearate	N.E.	N.E.	10 mg/m ³	N.E.

N.E. = Not Established

Engineering Controls: In a manufacturing setting, local exhaust ventilation may be necessary to control air contaminants to their exposure limits. The use of local ventilation is recommended to control emissions near the source. Provide mechanical ventilation for confined spaces. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal Protective Equipment (PPE)

In a manufacturing setting, the following personal protective equipment requirements apply:

Eye Protection: Wear appropriate chemical safety goggles, safety glasses or face shield as described by OSHA's eye and face protection regulations in 29 CFR 1910.133. Have eyewash stations available where eye contact can occur.

Skin Protection: Avoid skin contact. Wear gloves impervious to conditions of use. Additional protection may be necessary to prevent skin contact including the use of an apron, face shield, boots, or full body protection. A safety shower should be located in the work area.

Respiratory Protection: If exposure limits are exceeded, approved respiratory protection should be worn. Seek professional assistance for proper selection of respiratory protection.

9. Physical and Chemical Properties

Flash Point: N/A	Lower Flammability Limit: N/A
Autoignition Temperature: N/A	Upper Flammability Limit: N/A
Boiling Point: N/A	Specific Gravity: N/A
Melting Point: N/A	% Volatile: N/A
Vapor Pressure: N/A	Evaporation Rate (Water=1): N/A
Vapor Density: N/A	Viscosity: N/A
% Solubility in Water: N/A	Octanol/Water Partition Coefficient: N/A
Pour Point: N/A	pH: N/A
Molecular Formula: Mixture	Molecular Weight: Mixture
Odor/Appearance: White tablets.	

N/A = Not available

10. Stability and Reactivity

Stability/Incompatibility: The mixture is stable under normal conditions of use.

11. Toxicology Information

Signs and Symptoms of Overexposure: In its final form overexposure is unlikely. Signs and symptoms of reported overexposures include flushing, palpitations, swelling in extremities, abdominal pain, nausea, dizziness, headache, sleepiness, fatigue, chest pain, heart attack and swelling around the face.

Eye Contact: Causes serious eye irritation. Avoid contact with eyes.

Skin Contact: Causes skin irritation. Avoid contact with skin.

Inhalation: In the final form, not a likely route of exposure. However, in case of inhalation, respiratory tract irritation may occur.

Ingestion: Ingestion may cause flushing, palpitations, swelling in extremities, abdominal pain, nausea, dizziness, headache, sleepiness, fatigue, chest pain, heart attack and swelling around the face.

Target Organ Effects: Amlodipine Besylate targets the heart and circulatory system.

Genotoxic Effects: Not mutagenic in standard battery of genotoxicity tests.

Chronic Effects: Not carcinogenic in standard carcinogenicity tests.

Acute Toxicity Values:

LD₅₀ (rat oral) = 393 mg/kg (for Amlodipine Besylate)

LD₅₀ (rat oral) = 5,000 mg/kg (for Microcrystalline Cellulose)

LD₅₀ (rat oral) > 10,000 mg/kg (for Dihydrate Dibasic Calcium Phosphate)

LD₅₀ (rat oral) = Not available (for Sodium Starch Glycolate)

LD₅₀ (rat oral) > 2,000 mg/kg (for Magnesium Stearate)

12. Ecological Information

Ecological impact data has not been determined for this mixture.

13. Disposal Considerations

Disposal Procedure: Must dispose of in accordance with all local, state, and federal regulations.

14. Transportation Information

Based on available data this drug product has been determined non-hazardous according to USDOT/IATA criteria.

15. Regulatory Information

U. S. Federal Regulations

Not regulated.

Toxic Substance Control Act (TSCA): Microcrystalline Cellulose, Dihydrate Dibasic Calcium Phosphate and Magnesium Stearate are included on the TSCA inventory.

Clean Water Act (CWA): There are no ingredients in this mixture listed in the Clean Water Act.

Clean Air Act (CAA): There are no ingredients in this mixture listed under the Clean Air Act.

Superfund Amendments and Reauthorization Act (SARA) Title III Information: There are no ingredients in this mixture listed under SARA.

California: This product contains chemical(s) known to the State of California to cause cancer, birth defects or reproductive harm, which would require a warning under the statute: Magnesium Stearate and Sodium Starch Glycolate.

Canadian Environmental Protection Act: Microcrystalline Cellulose, Sodium Starch Glycolate, Dihydrate Dibasic Calcium Phosphate and Magnesium Stearate are listed on the Canadian Domestic Substances list (DSL).

European Inventory of Existing Chemicals (EINECS): There are three components contained in this product that are included on the European Inventory of Existing

Commercial Chemical Substances: Microcrystalline Cellulose, Dihydrate Dibasic Calcium Phosphate and Magnesium Stearate.

EU Classification: European labeling in accordance with EC directives.

16. Other Information

National Fire Protection Association (NFPA) Warnings

Health: 2 Flammability: 1 Reactivity: 1 Other: 0

Creation Date: 6/3/2009 Revision Date: 01/05/2018

Disclaimer: **Upsher-Smith Laboratories, LLC believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, express or implied.**

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