

MATERIAL SAFETY DATA SHEET

Product	: AMLODIPINE BESYLATE	
Date of Issue	: 26.05.2014	Revision No : 06

1. IDENTIFICATION OF SUBSTANCE

Trade Name : **AMLODIPINE BESYLATE**
Company : Cipla Limited
 Head Office - 289, Bellasis Road, Mumbai Central,
 Mumbai, Maharashtra, India (Pin Code - 400 008)
 Manufacturing division –
 Cipla Limited, Virgonagar,
 Old Madras road Bangalore-560049
Telephone : (+91 80) 28471180 **Fax** : (+91 80) 28472795
E-mail : ckkulkarni@cipla.com **Web Site** : www.cipla.com
Emergency Contact No : 022-23082891 / 022-23095521 / 022-23070160
Note : Active pharmaceutical ingredient for Human consumption

2. HAZARD IDENTIFICATION

Classification as per EC-

Physical : Not Classified
Health : Acute Toxicity, Category - 4
Environmental : Toxic to aquatic life with long lasting effects.
Label in accordance with EC-



Hazard Symbols :
Single Word : Warning
Contains : Amlodipine Besylate Pure Material
Hazard Statement –
 H302: Harmful if swallowed
 H318: causes serious eye damage.
 H411: Toxic to aquatic life with long lasting effects.

Precautionary Statement –
 P264: Wash hands and other exposed areas thoroughly after handling.
 P270: Do not eat, Drink or smoke when using this product.
 P273: Avoid release to the environment.
 P280: Wear Protective gloves/protective clothing /eye protection / face protection
 P301+P312: IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell
 P305+P351+P338: IF IN Eyes: Rinse cautiously with water for Several minutes. Remove contact lenses if present and easy to do. Continue rinsing.
 P310: Immediately call a POISON CENTER or doctor/physician.

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P330: Rinse mouth.
 P391: Collect spillage.
 P501: Dispose of contents/ container to Hazardous waste. Comply with applicable regulations.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Name : 3, 5-pyridinedicarboxylic acid, 2-[(2-aminoethoxy) methyl]-4-(2-chlorophenyl)-1, 4-dihydro-6- methyl-, 3-ethyl 5-methyl ester (±)-, monobenzenesulphonate.

Molecular Formula : C₂₆H₃₁ClN₂O₈S

Molecular Weight : 567.05

CAS No : 111470-99-6

EC No : 1901/2006

UN No : 3077

4. FIRST AID MEASURES

General Advice : Minimize dust generation and accumulation. avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment.

Inhalation : If inhaled, remove to fresh air. If not breathing, give artificial respiration.. If breathing is difficult, give oxygen. Get medical attention

Skin Contact : Wash with soap and water. get medical attention if irritation develops.

Eye Contact : Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15minutes. get medical attention if irritation develops.

Ingestion : Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately. Loosen tight clothing such as a collar, tie, belt or waistband.

NOTES TO HEALTH PROFESSIONALS

Medical Treatment : Treat symptomatically. Consult the physicians' desk reference for additional details.

Medical conditions caused or aggravated by exposure : No Specific data available.

Antidote : No Specific data available.

5. FIRE FIGHTING MEASURES

Fire and Explosion hazard : This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential build up of static electricity

Extinguishing media : Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.

Special fire fighting Procedure & protective Measures: As with all fires, evacuate personnel to a safe area. Fire- fighters should use self-contained breathing apparatus and protective clothing

Hazardous Combustion Products : Hazardous combustion or decomposition products are expected when the product is exposed to fire.

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6. ACCIDENTAL RELEASE MEASURES

Personal Precautions : Wear self-contained breathing apparatus, rubber boots & heavy rubber gloves.

Environmental Precaution : For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.

Clean – up procedure : Collect and place it in a suitable, properly labeled container for recovery or disposal. avoid the generation dust during clean-up.

Decontamination Procedure: Material should be disposed of in keeping with all local and national legislation. Packaging should be disposed of in keeping with all local and national legislation. Handle contaminated containers as product.

7. HANDLING AND STORAGE

Handling : Keep away from heat. Keep away from sources of ignition. Ground all equipment containing material. Do not ingest. Do not breathe dust. Wear suitable protective clothing. If ingested, seek medical advice immediately and show the container or the label.

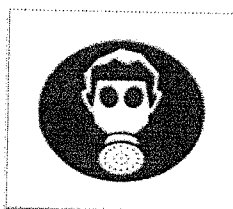
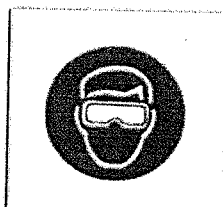
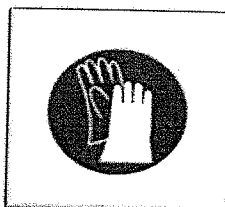
Storage:

- Bulk Storage** – Store in tight, light-resistant container at 15 to 30 °C.
- Department storage** – Store in tight, light-resistant container at 15 to 30 °C. Keep out of reach of children and Store away from food stuffs.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Limits: 0.1mg/m³

Personal protective equipments ensure before use – Pictograms



Respiratory protection : Dust respirator. Be sure to use an approved/certified respirator or equivalent. A self contained breathing apparatus should be used to avoid inhalation of the product.

Hand protection : Gloves, Lab coat

Eye protection : Splash goggles

Skin protection : Splash goggles, Full suit & Boots.

Exposure control Ventilation: Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to below the exposure limit.

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Hygiene Measure : Immediately change contaminated clothing. Wash hands and face after working with substance.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance and odour : White or almost white powder and odorless.

Vapour pressure : Not applicable	Vapor density : Not applicable
Flash point : Not applicable	Viscosity : Not applicable
Melting range : 199-201 °C	Boiling Point : Not Applicable
Specific gravity : Not applicable	Auto-ignition : Not applicable
Relative density : Not applicable	Flammability : Not applicable
Solubility : Freely soluble in methanol. Sparingly soluble in alcohol.	

10. STABILITY AND REACTIVITY

Stability : Stable under recommended storage conditions.

Incompatibilities / Condition to avoid : No data available. Avoid exposure to light and heat.

Hazardous decomposition products : when heated to decomposition, emits dangerous fumes. Large amounts: not applicable

Hazardous reactions : No data available.

Hazardous polymerization : Will not occur.

11. TOXICOLOGICAL INFORMATION

Oral Toxicity : Not expected to be toxic following ingestion of recommended maximum daily dose.

Sensitization : No data available.

Inhalation Toxicity : No data available.

Genetic Toxicity : No data available.

Skin effects : Irritation might occur following direct contact.

Carcinogenicity : No data available.

Eye Effects : Irritation might occur following direct contact with eyes.

Reproductive Effects : No data available.

Target Organ Effects : No data available.

Toxicity data

ORL-RAT LD 50 : 393 mg/kg	SCU-RAT LD 50 : No data available.
ORL- MICE LD 50 : No data available.	SCU-MUS LD 50 : No data available.

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12. ENVIRONMENTAL / ECOLOGICAL INFORMATION

Summary : The environmental characteristics of this mixture have not been fully evaluated. Releases to the environment should be avoided.

Ecotoxicity : Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. This material and its container must be disposed of as hazardous waste. avoid release to the environment.

Degradability : Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise. The products of degradation are as toxic as the product itself.

13. DISPOSAL CONSIDERATION

Disposal Recommendations : Dispose material as Hazardous Waste and as per applicable local, state and federal regulatory procedures and laws.

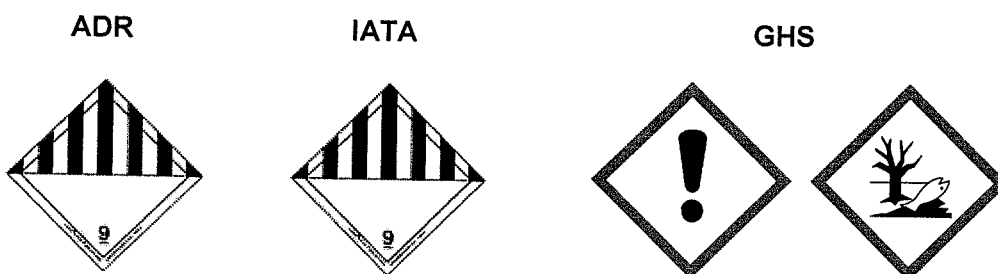
Regulatory Requirements : Dispose material as Hazardous Waste and as per applicable local, state and federal regulatory procedures and laws.

14. TRANSPORT INFORMATION (UN Classifications and Labeling)

ADR Packing group - III

ADR Class - 9

Additional Pictograms -



Other information : Environmentally Hazardous substance, solid, N.O.S.

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15. REGULATORY INFORMATION

Labeling according to EEC directives : As mentioned in section 14 of this document.

National legislation regulation any other regulatory information : No data available.

16. OTHER INFORMATION

Therapeutic category of material : Antihypertensive.

Reference:

1. Globally Harmonized System of Classification and Labelling Of Chemicals (GHS)
2. Safety data sheet from EDQM (dated 27.06.2013 version 7.0)
3. Material safety data sheet from USP.USA

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