

MATERIAL SAFETY DATA SHEET

Product : Amlodipine Besylate Tablets USP 2.5 mg, 5mg and 10mg
Date of issue : 15.12.2014
Revision No. : 01

1 IDENTIFICATION OF SUBSTANCE

Trade Name: AMLODIPINE BESYLATE TABLETS USP 2.5mg, 5mg and 10mg

Company : Cipla Ltd. L-139 to L-146, Verna Industrial Estate,
Verna Salcette Goa – 403 722 India

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2 HAZARD IDENTIFICATION

Classification as per EC -

Physical : Information not available.
Health : May cause eye irritation; may be harmful if swallowed (based on component)
Antihypertensive drug: has a blood pressure lowering property.
Environmental : Dangerous for the Environment.

Label in accordance with EC : Information not available.

Single Word : Warning

Contains : Amlodipine Besylate, Excipients Q.S.

Hazard Statements : Toxic to aquatic life with long lasting effects.

Precautionary Statements : Do not Dispose in Environment.

Supplementary Precautionary Statement : Hazardous Substance

3 COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Name (API) : 3,5-Pyridinecarboxylic acid, 2-((aminoethoxy)methyl)-4-(2-chlorophenyl)-1,4-dihydro-6 methyl, 3-ethyl-5-methyl ester, monobenzenesulfonate


Molecular Formula (API) : C₂₀H₂₅ClN₂O₅.C₆H₆O₃S

Molecular Weight (API) : Information not available.

CAS No. (API) : 111470-99-6

UN. No. : Information not available.

EC No. : Information not available.


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4 FIRST AID MEASURES

General advice

Skin Contact

: Remove contaminated clothing. Flush area large with amounts of water. Use soap. Seek medical attention.

Eye Contact

: Flush with water while holding open for atleast 15 minutes. Seek medical attention immediately.

Ingestion

: Do not induce vomiting. Flush out mouth with copious quantities of water. Receive immediate medical attention.

Inhalation

: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

NOTES TO HEALTH PROFESSIONALS

Medical Treatment

: Information not available

Medical conditions caused or aggravated by exposure

: Information not available

Antidote

: Information not available

5 FIRE FIGHTING MEASURES

Fire and Exposure hazard

: Not applicable.

Extinguishing media

: Use carbon dioxide, dry chemical, or water spray.

Special fire fighting procedures and protective measures

: As with all fires evacuate persons to safe area. Fire Fighter should use Self Contained Breathing apparatus and full protective gear to prevent contact with skin and Eyes.

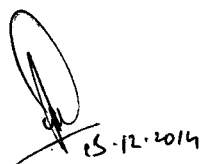
Hazardous Combustion Products

: Carbon monoxide, carbon dioxide, oxides of nitrogen, oxides of sulfur, hydrochloride and other chlorine containing components.

6 ACCIDENTAL RELEASE MEASURES

Personal Precautions

: Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure.



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Environmental Precaution	: Place waste in an appropriate labeled, sealed container for disposal. Care should be taken to avoid environmental release.
Clean-up Procedure	: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spill of dry solids. Clean spill area thoroughly.
Decontamination Procedure	: No specific decontamination procedure has been identified.

7 HANDLING AND STORAGE

Handling	: Minimize dust generation and accumulation. If tablets are crushed and / or broken, avoid breathing dust and avoid contact with eye, skin, and clothing. When handling, use appropriate personal protective equipment. Wash hand and any exposed skin after removal of PPE. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure on environment.
Storage -	Store as directed by product packaging.
1. Bulk Storage	: Information not available.
2. Department Storage	: Information not available.
Pictograms	: Information not available.

8 EXPOSURE CONTROLS / PERSONAL PROTECTION

Hazard category and Exposure Limits	: 100 µg/m ³
Personal Protective equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).	
Respiratory protection	: If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposure to below the OEL.
Hand protection	: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
Eye protection	: Wear safety glasses or goggles if eye contact is possible.
Skin protection	: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.


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Exposure Control Ventilation : Refer to specific Member State Legislation for requirements under Community environment legislation.

Hygiene Measure : Information not available

9 PHYSICAL AND CHEMICAL PROPERTIES

Appearance and odour : Amlodipine Besylate Tablets USP 2.5mg: White to off white, round tablets with "C" debossed on one side and "126" on other side.

Amlodipine Besylate Tablets USP 5.0mg: White to off white, round tablets with "C" debossed on one side and "127" on other side.

Amlodipine Besylate Tablets USP 10.0mg: White to off white, round tablets with "C" debossed on one side and "128" on other side.

Vapour pressure : Information not available

Vapour density : Information not available

Flash point : Information not available

Viscosity : Information not available

Boiling point : Information not available

Melting range : Information not available

Specific gravity : Information not available

Auto-ignition : Information not available

Relative density : Information not available

Flammability : Information not available

Solubility : Information not available

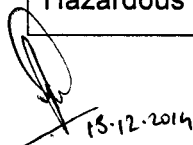
10 STABILITY AND REACTIVITY

Stability : Stable under normal condition for use.

Incompatibilities / Conditions to avoid : Fine particles (such as dust and mists) may fuel fires/explosions. As precautionary measure, keep away from strong oxidizers.

Hazardous decomposition products : None Known.

Hazardous reactions : Information not available.



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Hazardous polymerization : Information not available.

11 TOXICOLOGICAL INFORMATION

Health Hazard : Information not available
Acute Toxicity : Information not available
Oral Toxicity : Information not available
Sensitization : Information not available
Inhalation Toxicity : Information not available
Genetic Toxicity : Information not available
Skin Effects : Information not available
Carcinogenicity : Information not available
Eye Effects : Information not available
Reproductive effects : Information not available


Target Organ Effects : Information not available
Toxicity data -
ORL-RAT LD 50 : Information not available
ORL -MICE LD 50 : Information not available
SCU-RAT LD 50 : Information not available
SCU- MUS LD 50 : Information not available

12 ENVIRONMENTAL / ECOLOGICAL INFORMATION

Summary : Avoid release into the Environment.
Ecotoxicity : Harmfull effects to aquatic organism could occur.
Degradability : Information not available

13 DISPOSAL CONSIDERATION

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


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

14 TRANSPORT INFORMATION (Un Classification and Labelling)

ADR packing Group : Information not available.

ADR Class : Information not available.

Additional Pictogram : Information not available.

Other Information : Information not available.

15 REGULATORY INFORMATION

Labelling according to EEC directives : Information not available.

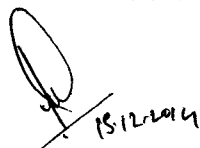
National legislation/regulations : Information not available.

Any other regulatory Information : Information not available.

16 OTHER INFORMATION

Therapeutic Category of material : Antihypertensive
Reference : As per API and excipient MSDS received from Vendors.

The information contained herein is based on the present state of our knowledge and does not therefore guarantee certain properties. The information given was obtained from sources which we believe are reliable. The information and recommendations given are to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any




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warranty, express or implied. Recipients of material must take responsibility for observing existing laws, regulations and suitability of material for handling transport and any particular purpose. We do not assume responsibility and expressly disclaim liability for loss, damage and expenses arising out of or in any way connected with the handling storage, use and disposal of the product information mentioned in this document relates only to the specific material designated and may not be valid for such material used in combination with other material or in any process.


15.12.2014

Prepared By
Safety


15.12.2014

Approved By
Unit Quality Assurance Head


15.12.2014

Noted By
Unit Head