

MATERIAL SAFETY DATA SHEET

Product : LAMOTRIGINE	
Date of Issue : 22.04.2014	Revision No: 01

1. IDENTIFICATION OF SUBSTANCE

Trade Name : LAMOTRIGINE
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

2. HAZARD IDENTIFICATION

Classification as per EC-

Physical : Not classified
Health : Acute Toxicity, Category - 3
Environmental : Harmful to aquatic life with long lasting effects.
 Label in accordance with EC-



Single Word – : Danger
Contains : Lamotrigine pure material.
Hazard Statement-- H300: Fatal if swallowed.
Precautionary Statement - P264: wash ...thoroughly after handling.
 P270: Do not eat, Drink or smoke when using this product.
 P301 + P312: IF SWALLOWED: Call a POISON CENTER or doctor/physician. if you feel unwell
 P330: Rinse mouth.
 P405: Store locked up.
 P501: Dispose of contents/container to...

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Name : 3, 5-Diamino-6-(2, 3-dichlorophenyl)-1, 2, 4-triazine			
Molecular Formula : C ₉ H ₇ Cl ₂ N ₅	Molecular Weight	:	256.09
CAS No : 84057-84-1	UN No	:	2811
EC No : 281-901-8			

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4. FIRST AID MEASURES

General Advice

Consult a physician. Show this safety data sheet to the doctor in attendance. move out of dangerous area.

Inhalation : If breathed in, move person into fresh air. If not breathing, give artificial respiration. consult a physician.

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 : If swallowed, rinse mouth out with water, contact local poison centre and call a physician

NOTES TO HEALTH PROFESSIONALS

Medical Treatment : Medical treatment in cases of overexposure should be treated as an overdose of the product. Treat according to locally approved protocols.

Medical conditions caused or aggravated by exposure : No specific data available

Antidote : No specific data available.

5. FIRE FIGHTING MEASURES

Fire and Explosion hazard : In case of fire, the product emits toxic fumes

Extinguishing media : Water spray, Dry chemical powder (DCP), Carbon Dioxide 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: Under fire conditions - May emit toxic fumes, carbon monoxide. Toxic, corrosive or flammable thermal decomposition products may expected under fire condition

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions : Use personal protective equipment. avoid dust formation. avoid breathing vapors, mist or gas. ensure adequate ventilation. evacuate personnel to safe areas. avoid breathing dust.

Environmental Precaution : Prevent further leakage or spillage if safe to do so. Do not let Product enter drains

Clean – up procedure : Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

Decontamination Procedure: As specific country, federal, state and local environmental regulations are varied and change frequently, we recommend that you contact your local department for Health Services for information on the correct disposal of this product.

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7. HANDLING AND STORAGE

Handling: Avoid contact with skin and eyes. avoid formation of dust and aerosols. provide appropriate exhaust, ventilation at places where dust is formed. engineering controls should be used as the primary means to control exposures. Use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

Storage:

- 1. Bulk Storage** – Store at controlled room temperature 15 - 30 °C in tightly closed containers protected from light.
- 2. Department storage** – Store at controlled room temperature 15 - 30 °C in tightly closed containers protected from light.
Keep out of reach of children and Store away from food stuffs.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure limits : Data not available

Personal protective equipments Ensure before use

Pictograms



Respiratory protection : Be sure to use an approved/certified respirator or equivalent tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU). Self contained breathing apparatus should be used to avoid inhalation of the product.

Hand protection : Chemical resistant rubber gloves.

Eye protection : Wear protective safety glasses or chemical safety goggles.

Skin protection : Protective clothing including apron / suit, shoes

Exposure control Ventilation: Use only with adequate ventilation. If user operations generate dust, fumes, vapor or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits.

Hygiene Measure : Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance and odour : A white to pale cream coloured powder.

Vapour pressure : Data not available

Flash point : Data not available

Vapor density : Data not available

Viscosity : Data not available

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Melting range	: 216-218 °C	Boiling point	: Data not available
Specific gravity	: Data not available	Auto-ignition	: Data not available
Relative density	: Data not available	Flammability	: Data not available
Solubility	: Slightly soluble in methanol and acetone.		

10. STABILITY AND REACTIVITY

Stability	: Stable under recommended storage conditions.
Incompatibilities / Condition to avoid	: Data not available
Hazardous decomposition products	: When heated to decomposition, material emits toxic fumes
Hazardous reactions	: No dangerous reaction known under conditions of normal use.
Hazardous polymerization	: Will not occur

11. TOXICOLOGICAL INFORMATION

Oral Toxicity	: Data not available	Sensitization	: Data not available
Inhalation Toxicity	: Data not available	Genetic Toxicity	: Data not available
Skin effects	: May cause irritation	Carcinogenicity	: Data not available
Eye Effects	: May cause irritation	Reproductive Effects	: Data not available
Target Organ Effects	: Data not available		
Toxicity data			
Oral-Rat LD 50	: 185 mg/kg	SCU-RAT LD 50	: Data Not available
Oral – Mice LD 50	: Data Not available	SCU-MUS LD 50	: Data Not available

12. ENVIRONMENTAL / ECOLOGICAL INFORMATION

Summary : This product may be harmful if releases directly to the environment. appropriate precautions should be taken to limit release of this material in the environment. Local regulations and procedures should be consulted prior to environmental release.

Ecotoxicity : Harmful to aquatic life with long lasting effects.

Degradability : Data not available.

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.

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14. TRANSPORT INFORMATION (UN Classifications and Labeling)

ADR Packing group – III
Additional Pictograms –

ADR Class – 6.1

ADR



IATA



GHS



Other information : Toxic Solid, Organic, N.O.S.

15. REGULATORY INFORMATION

Labeling according to EEC directives : As mentioned in section 14 of this document
National legislation regulation : No data available.
any other regulatory information

16. OTHER INFORMATION

Therapeutic category of material : Anticonvulsant

Reference:

1. Globally Harmonized System Of Classification And Labelling Of Chemicals (GHS)
2. Safety Data Sheet of material published by EDQM (Date :27.06.2013 version 4.0)

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