

SAFETY DATA SHEET

Creation Date 04-March-2016

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Revision Number 4

1. Identification

Product Name Lamotrigine

Cat No. : AC460850000; AC460850010; AC460850050

CAS-No 84057-84-1

Synonyms 6-(2,3-Dichlorophenyl)-1,2,4-triazine-3,5-diamine

Recommended Use Laboratory chemicals.

Uses advised against Food, drug, pesticide or biocidal product use.

Details of the supplier of the safety data sheet

Company

Acros Organics BVBA
Janssen Pharmaceuticaaan 3a
2440 Geel, Belgium

Acros Organics
One Reagent Lane
Fair Lawn, NJ 07410

Manufacturer

Fisher Scientific Company
One Reagent Lane
Fair Lawn, NJ 07410
Tel: (201) 796-7100

Emergency Telephone Number For information **US** call: 001-800-ACROS-01 / **Europe** call: +32 14 57 52 11
Emergency Number **US**:001-201-796-7100 / **Europe**: +32 14 57 52 99
CHEMTREC Tel. No.**US**:001-800-424-9300 / **Europe**:001-703-527-3887

2. Hazard(s) identification

Classification

WHMIS 2015 Classification Classified as hazardous under the Hazardous Products Regulations (SOR/2015-17)

Acute oral toxicity Category 3

Label Elements

Signal Word

Danger

Hazard Statements

Toxic if swallowed

**Precautionary Statements****Prevention**

Wash face, hands and any exposed skin thoroughly after handling
Do not eat, drink or smoke when using this product

Response

IF SWALLOWED: Immediately call a POISON CENTER/doctor
Rinse mouth

Storage

Store locked up

Disposal

Dispose of contents/container to an approved waste disposal plant

3. Composition/Information on Ingredients

Component	CAS-No	Weight %
Lamotrigine	84057-84-1	>95

4. First-aid measures

General Advice	Show this safety data sheet to the doctor in attendance. Immediate medical attention is required.
Eye Contact	In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
Skin Contact	Wash off immediately with plenty of water for at least 15 minutes. Immediate medical attention is required.
Inhalation	Remove to fresh air. If not breathing, give artificial respiration. Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Immediate medical attention is required.
Ingestion	Do NOT induce vomiting. Call a physician or poison control center immediately.
Most important symptoms/effects	None reasonably foreseeable.
Notes to Physician	Treat symptomatically

5. Fire-fighting measures

Suitable Extinguishing Media	Water spray, carbon dioxide (CO ₂), dry chemical, alcohol-resistant foam.
Unsuitable Extinguishing Media	No information available
Flash Point	No information available
Method -	No information available
Autoignition Temperature	No information available

Explosion Limits

Upper	No data available
Lower	No data available
Sensitivity to Mechanical Impact	No information available
Sensitivity to Static Discharge	No information available

Specific Hazards Arising from the Chemical

Keep product and empty container away from heat and sources of ignition.

Hazardous Combustion Products

Carbon oxides. Hydrogen chloride. Nitrogen oxides (NO_x). Carbon dioxide (CO₂).

Protective Equipment and Precautions for Firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear. Thermal decomposition can lead to release of irritating gases and vapors.

NFPA

Health	Flammability	Instability	Physical hazards
3	1	0	N/A

6. Accidental release measures**Personal Precautions**

Ensure adequate ventilation. Use personal protective equipment as required. Avoid dust formation. Keep people away from and upwind of spill/leak. Evacuate personnel to safe areas.

Environmental Precautions

Should not be released into the environment.

Methods for Containment and Clean Up Sweep up and shovel into suitable containers for disposal. Avoid dust formation.

7. Handling and storage**Handling**

Wear personal protective equipment/face protection. Do not get in eyes, on skin, or on clothing. Avoid dust formation. Use only under a chemical fume hood. Do not breathe (dust, vapor, mist, gas). Do not ingest. If swallowed then seek immediate medical assistance.

Storage.

Keep container tightly closed in a dry and well-ventilated place. To maintain product quality: Keep refrigerated. Store under an inert atmosphere. Incompatible Materials. Strong oxidizing agents.

8. Exposure controls / personal protection**Exposure Guidelines**

This product does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Engineering Measures

Ensure adequate ventilation, especially in confined areas.

Wherever possible, engineering control measures such as the isolation or enclosure of the process, the introduction of process or equipment changes to minimise release or contact, and the use of properly designed ventilation systems, should be adopted to control hazardous materials at source

Personal protective equipment**Eye Protection**

Wear appropriate protective eyeglasses or chemical safety goggles as described by OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166.

Hand Protection

Wear appropriate protective gloves and clothing to prevent skin exposure.

Glove material	Breakthrough time	Glove thickness	Glove comments
Nitrile rubber	See manufacturers	-	

Neoprene Natural rubber PVC	recommendations	Splash protection only
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Inspect gloves before use. observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. (Refer to manufacturer/supplier for information) gloves are suitable for the task: Chemical compatability, Dexterity, Operational conditions, User susceptibility, e.g. sensitisation effects, also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion. gloves with care avoiding skin contamination.

Respiratory Protection

When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.

To protect the wearer, respiratory protective equipment must be the correct fit and be used and maintained properly

Recommended Filter type: Particulates filter conforming to EN 143

When RPE is used a face piece Fit Test should be conducted

Environmental exposure controls

No information available.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice. Keep away from food, drink and animal feeding stuffs. Do not eat, drink or smoke when using this product. Remove and wash contaminated clothing and gloves, including the inside, before re-use. Wash hands before breaks and after work.

9. Physical and chemical properties

Physical State	Solid
Appearance	White to off-white
Odor	No information available
Odor Threshold	No information available
pH	No information available
Melting Point/Range	218 °C / 424.4 °F
Boiling Point/Range	No information available
Flash Point	No information available
Evaporation Rate	Not applicable
Flammability (solid,gas)	No information available
Flammability or explosive limits	
Upper	No data available
Lower	No data available
Vapor Pressure	No information available
Vapor Density	Not applicable
Specific Gravity	No information available
Solubility	Insoluble in water
Partition coefficient; n-octanol/water	No data available
Autoignition Temperature	No information available
Decomposition Temperature	No information available
Viscosity	Not applicable
Molecular Formula	C9 H7 Cl2 N5
Molecular Weight	256.09

10. Stability and reactivity

Reactive Hazard	None known, based on information available
Stability	heat sensitive. Air sensitive.
Conditions to Avoid	Incompatible products. Exposure to air. Heat.

Incompatible Materials Strong oxidizing agents

Hazardous Decomposition Products Carbon oxides, Hydrogen chloride, Nitrogen oxides (NO_x), Carbon dioxide (CO₂)

Hazardous Polymerization Hazardous polymerization does not occur.

Hazardous Reactions None under normal processing.

11. Toxicological information

Acute Toxicity

Product Information Component Information

Component	LD50 Oral	LD50 Dermal	LC50 Inhalation
Lamotrigine	LD50 = 205 mg/kg (Rat)	Not listed	Not listed

Toxicologically Synergistic Products No information available

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Irritation No information available

Sensitization No information available

Carcinogenicity The table below indicates whether each agency has listed any ingredient as a carcinogen.

Component	CAS-No	IARC	NTP	ACGIH	OSHA	Mexico
Lamotrigine	84057-84-1	Not listed	Not listed	Not listed	Not listed	Not listed

Mutagenic Effects No information available

Reproductive Effects No information available.

Developmental Effects No information available.

Teratogenicity No information available.

STOT - single exposure None known

STOT - repeated exposure None known

Aspiration hazard No information available

Symptoms / effects, both acute and delayed No information available

Endocrine Disruptor Information No information available

Other Adverse Effects The toxicological properties have not been fully investigated.

12. Ecological information

Ecotoxicity

Do not empty into drains.

Persistence and Degradability Insoluble in water

Bioaccumulation/ Accumulation No information available.

Mobility Is not likely mobile in the environment due its low water solubility.

13. Disposal considerations

Waste Disposal Methods

Chemical waste generators must determine whether a discarded chemical is classified as a hazardous waste. Chemical waste generators must also consult local, regional, and national hazardous waste regulations to ensure complete and accurate classification.

14. Transport information

DOT

UN-No UN2811
 Proper Shipping Name TOXIC SOLIDS, ORGANIC, N.O.S.
 Technical Name Lamotrigine
 Hazard Class 6.1
 Packing Group III

TDG

UN-No UN2811
 Proper Shipping Name Toxic solid, organic, n.o.s.
 Hazard Class 6.1
 Packing Group III

IATA

UN-No UN2811
 Proper Shipping Name Toxic solid, organic, n.o.s.
 Hazard Class 6.1
 Packing Group III

IMDG/IMO

UN-No UN2811
 Proper Shipping Name Toxic solid, organic, n.o.s.
 Hazard Class 6.1
 Packing Group III

15. Regulatory information

International Inventories

Component	CAS-No	DSL	NDSL	TSCA	TSCA Inventory notification - Active-Inactive	EINECS	ELINCS	NLP
Lamotrigine	84057-84-1	-	-	-	-	281-901-8	-	-

Component	CAS-No	IECSC	KECL	ENCS	ISHL	TCSI	AICS	NZIoC	PICCS
Lamotrigine	84057-84-1	-	-	-	X	X	-	X	-

Legend:

X - Listed '-' - Not Listed

KECL - NIER number or KE number (<http://ncis.nier.go.kr/en/main.do>)

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances

IECSC - Chinese Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

ENCS - Japanese Existing and New Chemical Substances

AICS - Australian Inventory of Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

Canada

SDS in compliance with provisions of information as set out in Canadian Standard - Part 4, Schedule 1 and 2 of the Hazardous Products Regulations (HPR) and meets the requirements of the HPR (Paragraph 13(1)(a) of the Hazardous Products Act (HPA)).

Other International Regulations**Authorisation/Restrictions according to EU REACH**

Safety, health and environmental regulations/legislation specific for the substance or mixture

Component	CAS-No	OECD HPV	Persistent Organic Pollutant	Ozone Depletion Potential	Restriction of Hazardous Substances (RoHS)
Lamotrigine	84057-84-1	Not applicable	Not applicable	Not applicable	Not applicable

Component	CAS-No	Seveso III Directive (2012/18/EC) - Qualifying Quantities for Major Accident Notification	Seveso III Directive (2012/18/EC) - Qualifying Quantities for Safety Report Requirements	Rotterdam Convention (PIC)	Basel Convention (Hazardous Waste)
Lamotrigine	84057-84-1	Not applicable	Not applicable	Not applicable	Not applicable

16. Other information

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Revision Summary

This document has been updated to comply with the requirements of WHMIS 2015 to align with the Globally Harmonised System (GHS) for the Classification and Labelling of Chemicals.

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text

End of SDS