# SAFETY DATA SHEET

**Creation Date** 04-Mar-2016 **Revision Date** 09-Mar-2016 **Revision Number** 1

## SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### 1.1. Product identification

| | |
|---|---|
| **Product Description:** | **Lamotrigine** |
| **Cat No. :** | **460850000; 460850010; 460850050** |
| **Synonyms** | 6-(2,3-Dichlorophenyl)-1,2,4-triazine-3,5-diamine |
| **CAS-No** | 84057-84-1 |
| **EC-No.** | 281-901-8 |
| **Molecular Formula** | C9 H7 Cl2 N5 |

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

| | |
|---|---|
| **Recommended Use** | Laboratory chemicals. |
| **Uses advised against** | No Information available |

### 1.3. Details of the supplier of the safety data sheet

| | |
|---|---|
| **Company** | Acros Organics BVBA<br>Janssen Pharmaceuticalaan 3a<br>2440 Geel, Belgium |
| **E-mail address** | begel.sdsdesk@thermofisher.com |

### 1.4. 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

## SECTION 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the substance or mixture

**CLP Classification - Regulation (EC) No 1272/2008**

**Physical hazards**
Based on available data, the classification criteria are not met

**Health hazards**

| | |
|---|---|
| Acute oral toxicity | Category 3 |

**Environmental hazards**
Based on available data, the classification criteria are not met

### 2.2. Label elements

**Signal Word** **Danger**

**Hazard Statements**

H301 - Toxic if swallowed

**Precautionary Statements**

P264 - Wash face, hands and any exposed skin thoroughly after handling

P301 + P310 - IF SWALLOWED: Immediately call a POISON CENTER or doctor/ physician

### 2.3. Other hazards

No information available

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1. Substances

| Component | CAS-No | EC-No. | Weight % | CLP Classification - Regulation (EC) No 1272/2008 |
|---|---|---|---|---|
| Lamotrigine | 84057-84-1 | EEC No. 281-901-8 | >95 | Acute Tox. 3 (H301) |

*Full text of Hazard Statements: see section 16*

## SECTION 4: FIRST AID MEASURES

### 4.1. Description of 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.

**Ingestion** Do not induce vomiting. Call a physician or Poison Control Center immediately.

**Inhalation** Move 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.

**Protection of First-aiders** Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination.

### 4.2. Most important symptoms and effects, both acute and delayed

None reasonably foreseeable.

### 4.3. Indication of any immediate medical attention and special treatment needed

**Notes to Physician** Treat symptomatically.

## SECTION 5: FIREFIGHTING MEASURES

### 5.1. Extinguishing media

**Suitable Extinguishing Media**
Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

**Extinguishing media which must not be used for safety reasons**
No information available.

### 5.2. Special hazards arising from the substance or mixture

Thermal decomposition can lead to release of irritating gases and vapors.

**Hazardous Combustion Products**
Carbon oxides, Carbon dioxide (CO2), Hydrogen chloride, Nitrogen oxides (NOx).

### 5.3. Advice 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.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

### 6.1. Personal precautions, protective equipment and emergency procedures

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

### 6.2. Environmental precautions

Should not be released into the environment.

### 6.3. Methods and material for containment and cleaning up

Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dust formation.

### 6.4. Reference to other sections

Refer to protective measures listed in Sections 8 and 13.

## SECTION 7: HANDLING AND STORAGE

### 7.1. Precautions for safe handling

Wear personal protective equipment. Do not get in eyes, on skin, or on clothing. Avoid dust formation. Use only under a chemical fume hood. Do not breathe vapors/dust. Do not ingest.

**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 before re-use. Wash hands before breaks and at the end of workday.

### 7.2. Conditions for safe storage, including any incompatibilities

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

### 7.3. Specific end use(s)

Use in laboratories

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control parameters

**Exposure limits**
This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies

**Biological limit values**
This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies.

**Monitoring methods**
BS EN 14042:2003 Title Identifier: Workplace atmospheres. Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents.
MDHS14/3 General methods for sampling and gravimetric analysis of respirable and inhalable dust

**Derived No Effect Level (DNEL)** No information available

| Route of exposure | Acute effects (local) | Acute effects (systemic) | Chronic effects (local) | Chronic effects (systemic) |
|---|---|---|---|---|
| **Oral** | | | | |
| **Dermal** | | | | |
| **Inhalation** | | | | |

**Predicted No Effect Concentration (PNEC)** No information available.

### 8.2. Exposure controls

**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** Safety glasses with side-shields (European standard - EN 166)

**Hand Protection** Protective gloves

| Glove material | Breakthrough time | Glove thickness | EU standard | Glove comments |
|---|---|---|---|---|
| Nitrile rubber<br>Neoprene<br>Natural rubber<br>PVC | See manufacturers recommendations | - | EN 374 | (minimum requirement) |

**Skin and body protection** Long sleeved clothing

Inspect gloves before use.
Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. (Refer to manufacturer/supplier for information)
Ensure 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.
Remove gloves with care avoiding skin contamination.

| | |
|---|---|
| **Respiratory Protection** | When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.<br>To protect the wearer, respiratory protective equipment must be the correct fit and be used and maintained properly |
| **Large scale/emergency use** | Use a NIOSH/MSHA or European Standard EN 136 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced<br>**Recommended Filter type:** Particulates filter conforming to EN 143 |
| **Small scale/Laboratory use** | Use a NIOSH/MSHA or European Standard EN 149:2001 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.<br>**Recommended half mask:-** Particle filtering: EN149:2001<br>When RPE is used a face piece Fit Test should be conducted |
| **Environmental exposure controls** | No information available. |

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on basic physical and chemical properties

| | | |
|---|---|---|
| **Appearance** | White to off-white | |
| **Physical State** | Solid | |
| **Odor** | No information available | |
| **Odor Threshold** | No data available | |
| **pH** | No information available | |
| **Melting Point/Range** | 218 °C / 424.4 °F | |
| **Softening Point** | No data available | |
| **Boiling Point/Range** | No information available | |
| **Flash Point** | No information available | **Method -** No information available |
| **Evaporation Rate** | Not applicable | Solid |
| **Flammability (solid,gas)** | No information available | |
| **Explosion Limits** | No data available | |
| **Vapor Pressure** | No data available | |
| **Vapor Density** | Not applicable | Solid |
| **Specific Gravity / Density** | No data available | |
| **Bulk Density** | No data available | |
| **Water Solubility** | Insoluble | |
| **Solubility in other solvents** | No information available | |
| **Partition Coefficient (n-octanol/water)** | | |
| **Autoignition Temperature** | Not applicable | |
| **Decomposition Temperature** | No data available | |
| **Viscosity** | Not applicable | Solid |
| **Explosive Properties** | No information available | |
| **Oxidizing Properties** | No information available | |

### 9.2. Other information

| | |
|---|---|
| **Molecular Formula** | C9 H7 Cl2 N5 |
| **Molecular Weight** | 256.09 |

## SECTION 10: STABILITY AND REACTIVITY

### 10.1. Reactivity

None known, based on information available

### 10.2. Chemical stability

heat sensitive. Air sensitive

**10.3. Possibility of hazardous reactions**

**Hazardous Polymerization** No information available.
**Hazardous Reactions** None under normal processing.

**10.4. Conditions to avoid**

Incompatible products. Exposure to air. Heat.

**10.5. Incompatible materials**

Strong oxidizing agents.

**10.6. Hazardous decomposition products**

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

## SECTION 11: TOXICOLOGICAL INFORMATION

**11.1. Information on toxicological effects**

**Product Information**

**(a) acute toxicity;**
**Oral** Category 3
**Dermal** No data available
**Inhalation** No data available

| Component | LD50 Oral | LD50 Dermal | LC50 Inhalation |
|---|---|---|---|
| Lamotrigine | LD50 = 205 mg/kg ( Rat ) | | |

**(b) skin corrosion/irritation;** No data available

**(c) serious eye damage/irritation;** No data available

**(d) respiratory or skin sensitization;**
**Respiratory** No data available
**Skin** No data available

**(e) germ cell mutagenicity;** No data available

**(f) carcinogenicity;** No data available

There are no known carcinogenic chemicals in this product

**(g) reproductive toxicity;** No data available

**(h) STOT-single exposure;** No data available

**(i) STOT-repeated exposure;** No data available

**Target Organs** None known.

**(j) aspiration hazard;** Not applicable
Solid

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

**Symptoms / effects,both acute and delayed** No information available

## SECTION 12: ECOLOGICAL INFORMATION

**12.1. Toxicity**

**Ecotoxicity effects** Contains no substances known to be hazardous to the environment or that are not degradable in waste water treatment plants.

**12.2. Persistence and degradability**

**Persistence** Insoluble in water.

**12.3. Bioaccumulative potential** May have some potential to bioaccumulate

**12.4. Mobility in soil** Spillage unlikely to penetrate soil Is not likely mobile in the environment due its low water solubility.

**12.5. Results of PBT and vPvB assessment** No data available for assessment.

**12.6. Other adverse effects**

**Endocrine Disruptor Information** This product does not contain any known or suspected endocrine disruptors
**Persistent Organic Pollutant** This product does not contain any known or suspected substance
**Ozone Depletion Potential** This product does not contain any known or suspected substance

## SECTION 13: DISPOSAL CONSIDERATIONS

**13.1. Waste treatment methods**

**Waste from Residues / Unused Products** Waste is classified as hazardous. Dispose of in accordance with the European Directives on waste and hazardous waste. Dispose of in accordance with local regulations.

**Contaminated Packaging** Dispose of this container to hazardous or special waste collection point.

**European Waste Catalogue (EWC)** According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.

**Other Information** Waste codes should be assigned by the user based on the application for which the product was used. Do not empty into drains.

## SECTION 14: TRANSPORT INFORMATION

**IMDG/IMO**

**14.1. UN number** UN2811
**14.2. UN proper shipping name** TOXIC SOLID, ORGANIC, N.O.S
**14.3. Transport hazard class(es)** 6.1
**14.4. Packing group** III

**ADR**

**14.1. UN number** UN2811
**14.2. UN proper shipping name** TOXIC SOLID, ORGANIC, N.O.S
**14.3. Transport hazard class(es)** 6.1
**14.4. Packing group** III

**IATA**

**14.1. UN number** UN2811
**14.2. UN proper shipping name** TOXIC SOLID, ORGANIC, N.O.S
**14.3. Transport hazard class(es)** 6.1
**14.4. Packing group** III

**14.5. Environmental hazards** No hazards identified

**14.6. Special precautions for user** No special precautions required

**14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable, packaged goods

## SECTION 15: REGULATORY INFORMATION

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

**International Inventories** X = listed

| Component | EINECS | ELINCS | NLP | TSCA | DSL | NDSL | PICCS | ENCS | IECSC | AICS | KECL |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Lamotrigine | 281-901-8 | - | | - | - | - | - | - | - | - | - |

**National Regulations**

Take note of Control of Substances Hazardous to Health Regulations (COSHH) 2002 and 2005 Amendment.
Take note of Dir 94/33/EC on the protection of young people at work
Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

**15.2. Chemical safety assessment**

A Chemical Safety Assessment/Report (CSA/CSR) has not been conducted

## SECTION 16: OTHER INFORMATION

**Full Text of H-/EUH-Statements Referred to Under Section 3**
H301 - Toxic if swallowed

**Legend**

**CAS** - Chemical Abstracts Service

**EINECS/ELINCS** - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances
**PICCS** - Philippines Inventory of Chemicals and Chemical Substances
**IECSC** - Chinese Inventory of Existing Chemical Substances
**KECL** - Korean Existing and Evaluated Chemical Substances

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory
**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List
**ENCS** - Japanese Existing and New Chemical Substances
**AICS** - Australian Inventory of Chemical Substances
**NZIoC** - New Zealand Inventory of Chemicals

**WEL** - Workplace Exposure Limit
**ACGIH** - American Conference of Governmental Industrial Hygienists
**DNEL** - Derived No Effect Level
**RPE** - Respiratory Protective Equipment
**LC50** - Lethal Concentration 50%
**NOEC** - No Observed Effect Concentration
**PBT** - Persistent, Bioaccumulative, Toxic

**TWA** - Time Weighted Average
**IARC** - International Agency for Research on Cancer
**PNEC** - Predicted No Effect Concentration
**LD50** - Lethal Dose 50%
**EC50** - Effective Concentration 50%
**POW** - Partition coefficient Octanol:Water
**vPvB** - very Persistent, very Bioaccumulative

**ADR** - European Agreement Concerning the International Carriage of Dangerous Goods by Road
**IMO/IMDG** - International Maritime Organization/International Maritime Dangerous Goods Code
**OECD** - Organisation for Economic Co-operation and Development
**BCF** - Bioconcentration factor

**ICAO/IATA** - International Civil Aviation Organization/International Air Transport Association
**MARPOL** - International Convention for the Prevention of Pollution from Ships
**ATE** - Acute Toxicity Estimate
**VOC** - Volatile Organic Compounds

**Key literature references and sources for data**
Suppliers safety data sheet, Chemadvisor - LOLI, Merck index, RTECS

**Training Advice**
Chemical hazard awareness training, incorporating labelling, Safety Data Sheets (SDS), Personal Protective Equipment (PPE) and hygiene.
Use of personal protective equipment, covering appropriate selection, compatibility, breakthrough thresholds, care, maintenance, fit

and standards.
First aid for chemical exposure, including the use of eye wash and safety showers.

| | |
|---|---|
| **Creation Date** | 04-Mar-2016 |
| **Revision Date** | 09-Mar-2016 |
| **Revision Summary** | Not applicable. |

## This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006

**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 Safety Data Sheet