

SAFETY DATA SHEET



* 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Material	LAMICTAL TABLETS										
Synonym(s)	LAMICTAL TABLET 25MG * LAMICTAL TABLET 50MG * LAMICTAL TABLET 100MG * LAMICTAL TABLET 150MG * LAMICTAL TABLET 200MG * LAMICTAL VALPROATE STARTER PACK 25MG * LAMICTAL MONOTHERAPY STARTER PACK 25MG * LAMICTAL NON-VALPROATE STARTER PACK 50MG * LAMICTAL COMPRIMES * LAMICTAL COMPRIMIDOS * LAMICTIN TABLETS * NDC NO 0173-0526-00 * NDC NO 0173-0527-00 * NDC NO 0173-0633-02 * NDC NO 0173-0642-55 * NDC NO 0173-0643-60 * NDC NO 0173-0644-60 * NDC NO 0173-0594-01 * NDC NO 0173-0594-02 * NDC NO 0173-0633-10 * LAMOTRIGINE, FORMULATED PRODUCT										
Recommended Use	Medicinal Product										
Note	This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.										
Company Name	<p>GlaxoSmithKline UK 980 Great West Road Brentford, Middlesex TW8 9GS UK UK General Information (normal business hours): +44-20-8047-5000</p> <p>GlaxoSmithKline US 5 Moore Drive Research Triangle Park, NC 27709 USA US General Information (normal business hours): +1-888-825-5249</p> <p>Email Address: msds@gsk.com Website: www.gsk.com</p> <p>EMERGENCY PHONE NUMBERS -</p> <p>TRANSPORT EMERGENCIES (by country / geographic region):</p> <table border="0" style="width: 100%;"> <tr> <td>Africa / EU / Israel / Middle East (English / European languages):</td> <td style="text-align: right;">+44 (0) 1235 239 670</td> </tr> <tr> <td>Asia Pacific (except China):</td> <td style="text-align: right;">+65 3158 1074</td> </tr> <tr> <td>China:</td> <td style="text-align: right;">+86 10 5100 3039</td> </tr> <tr> <td>Middle East / Africa (Arabic-speaking countries):</td> <td style="text-align: right;">+44 (0) 1235 239 671</td> </tr> <tr> <td>US:</td> <td style="text-align: right;">+1 703 527 3887</td> </tr> </table> <p>available 24 hrs/7 days; multi-language response</p> <p>MEDICAL EMERGENCIES: +1 612 221 3999, Ext 221 available 24 hrs/7 days; multi-language response</p>	Africa / EU / Israel / Middle East (English / European languages):	+44 (0) 1235 239 670	Asia Pacific (except China):	+65 3158 1074	China:	+86 10 5100 3039	Middle East / Africa (Arabic-speaking countries):	+44 (0) 1235 239 671	US:	+1 703 527 3887
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* 2. HAZARDS IDENTIFICATION

Fire and Explosion Hazards

Expected to be non-combustible.

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Health	Caution - Pharmaceutical agent. Not expected to be a significant health hazard unless product is crushed or broken. Exposure might occur via eyes; skin; ingestion. Possible effects of overexposure in the workplace include: irritability; symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing); changes in behaviour; visual disturbances; nausea; headache; dizziness; drowsiness. Health effects information is based on hazards of components.
Environment	Harmful to aquatic organisms. May cause long-term adverse effects in the aquatic environment.

* 3. COMPOSITION / INFORMATION ON INGREDIENTS
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Ingredients	CAS #	Percent	EC-No.
LAMOTRIGINE	84057-84-1	31.0 to 50.0	281-901-8
Other components below reportable levels		50.0 - 69.0	

4. FIRST-AID MEASURES

Ingestion	Never attempt to induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. If the exposed subject is fully conscious, give plenty of water to drink. Obtain medical attention.
Inhalation	Physical form suggests that risk of inhalation exposure is negligible.
Skin contact	Using appropriate personal protective equipment, remove contaminated clothing and flush exposed area with large amounts of water. Obtain medical attention if skin reaction occurs, which may be immediate or delayed.
Eye contact	Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.

NOTES TO HEALTH PROFESSIONALS

Medical Treatment	Medical treatment in cases of overexposure should be treated as an overdose of a sodium channel antagonist. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre.
Medical Conditions Caused or Aggravated by Exposure	This material may cause or aggravate allergy to phenothiazines.
Antidotes	No specific antidotes are recommended.

5. FIRE-FIGHTING MEASURES

Fire and Explosion Hazards	Not expected for the product, although the packaging is combustible.
Extinguishing Media	Water, dry powder or foam extinguishers are recommended. Carbon dioxide extinguishers may be ineffective.
Special Firefighting Procedures	For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapours might be evolved from fires involving this product and associated packaging, self contained breathing apparatus and full protective equipment are recommended for firefighters. If possible, contain and collect firefighting water for later disposal.
Hazardous Combustion Products	Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions	Wear protective clothing and equipment consistent with the degree of hazard.
Environmental Precautions	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.
Clean-up Methods	Collect and place it in a suitable, properly labelled container for recovery or disposal.
Decontamination Procedures	No specific decontamination or detoxification procedures have been identified for this product.

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7. HANDLING AND STORAGE

HANDLING**General Requirements** Avoid breaking or crushing tablets.**STORAGE**

No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

OCCUPATIONAL EXPOSURE LIMITS

INGREDIENT LAMOTRIGINE
GSK Occupational Hazard Category 2
GSK Occupational Exposure Limit 200 mcg/m³ (8 HR TWA)

PERSONAL PROTECTIVE EQUIPMENT**Eye Protection** Wear approved safety glasses with side shields if eye contact is possible.**Other Equipment or Procedures**

Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance**Physical Form** Tablet.

10. STABILITY AND REACTIVITY

Stability

This product is expected to be stable.

Conditions to Avoid

None for normal handling of this product.

* 11. TOXICOLOGY INFORMATION

Pharmacological Effects

This preparation contains ingredient(s) with the following activity: a sodium channel antagonist. Adverse effects of overexposure might include: irritability; symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing); changes in behaviour; visual disturbances; nausea; headache; dizziness; drowsiness.

Target Organ Effects

Adverse effects might occur in the following organ(s) following overexposure: central nervous system; red blood cells.

Routes of Exposure**Oral Toxicity** Adverse effects might occur following ingestion.**Inhalation Toxicity** No studies have been conducted.**Skin Effects** Irritation is not expected following direct contact.**Eye Effects** Minor irritation might occur following direct contact with eyes.**Sensitisation**

Allergic skin reactions might occur following repeated contact with this material in susceptible individuals.

Genetic Toxicity

Not expected to be genotoxic, based on effects of individual components.

Carcinogenicity

No components are listed as carcinogens by GSK, IARC, NTP or US OSHA.

Reproductive Effects

The ingredient lamotrigine has caused adverse effects on the development of unborn offspring in animal studies. This material produced developmental toxicity in offspring of animals only at doses toxic to the mothers. Clinical use of this active ingredient during pregnancy has resulted in reversible, adverse drug effects in infants. No components are identified as having adverse effects on female fertility. No components are identified as having adverse effects on male fertility.

Other Adverse Effects

None known for occupational exposure.

12. ECOLOGICAL INFORMATION

Summary	This product contains an active ingredient that has been tested and which may be harmful if released directly to the environment. Consult the MSDS of the active ingredient for specific information about potential environmental effects. Appropriate precautions should be taken to limit release of this mixture to the environment. Local regulations and procedures should be consulted prior to environmental release.
ECOTOXICITY	
Aquatic	
Activated Sludge Respiration	This material contains an active ingredient that is not toxic to activated sludge microorganisms. IC50: > 1000 mg/l, 3 Hours, Activated sludge
Microbial Growth Inhibition	This material contains an active ingredient that is not toxic to these microorganisms.
Minimum Inhibition Concentration:	> 185 mg/l, , Aspergillus flavus > 185 mg/l, , Azotobacter chroococcum > 185 mg/l, , Chaetomium globosum > 185 mg/l, , Nostoc sp. > 185 mg/l, , Pseudomonas acidovorans
Algal	This mixture contains an active ingredient that is harmful to algae. IC50: 39.7 mg/l, 72 Hours, Selenastrum capricornutum, green algae, Static test NOEC: 7.5 mg/l, 72 Hours, Selenastrum capricornutum, green algae, Static test
Daphnid	This mixture contains an active pharmaceutical ingredient that is harmful to daphnids. EC50: 56 mg/l, 48 Hours, Daphnia magna, Static test NOEC: 30 mg/l, 48 Hours, Daphnia magna, Static test Chronic LOEC: > 10 mg/l, 7 Days, Ceriodaphnia dubia Chronic NOEC: 10 mg/l
Fish	This mixture contains an active ingredient that is harmful to fish. EC50: 85 mg/l, 96 Hours, Adult Oncorhynchus mykiss, rainbow trout, Static test NOEC: 60 mg/l, 96 Hours, Adult Oncorhynchus mykiss, rainbow trout, Static test
MOBILITY	
Solubility	This mixture contains an active ingredient that for environmental fate predictions has limited solubility in water.
Adsorption	This mixture contains an active ingredient that is not likely to adsorb to soil or sediment if released directly to the environment. This mixture contains an active ingredient that is not likely to adsorb to sludge or biomass if released directly to the environment. Sludge Biomass Distribution Coefficient (log Kd): 1.15 Measured Measured at pH 7
Partitioning	This mixture contains an active pharmaceutical ingredient with octanol/water partition coefficient data that suggests that for environmental fate predictions the active pharmaceutical ingredient will not have the tendency to distribute into fats.
PERSISTENCE/DEGRADATION	
Hydrolysis	This material contains an active pharmaceutical ingredient that has been shown to be chemically stable in water. Hydrolysis is unlikely to be a significant depletion mechanism. Half-Life, Neutral: > 1 Years, Measured
Photolysis	This mixture contains an active pharmaceutical ingredient that is likely to undergo photodegradation. UV/Visible Spectrum: 300 nm at pH > 6, Measured

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Biodegradation

This mixture contains an active ingredient that is not readily nor inherently biodegradable (as defined by 1993 OECD Testing Guidelines) and may persist in the environment.

Aerobic - Ready

Percent Degradation: 0 %, 28 days, Modified Sturm test.

Aerobic - Inherent

Percent Degradation: 0 %, 14 days, Modified Zahn-Wellens, Activated sludge

BIOACCUMULATION**Bioaccumulation**

This material contains an active ingredient that will not have a tendency to bioaccumulate in the food chain.

13. DISPOSAL CONSIDERATIONS

Disposal Recommendations

Collect for recycling or recovery if possible. The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used.

Regulatory Requirements

Observe all local and national regulations when disposing of this product.

* 14. TRANSPORT INFORMATION

The SDS should accompany all shipments for reference in the event of spillage or accidental release. Only authorised persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous goods for transport.

UN Classification and Labelling**Transport Information**

Not regulated in transport.

15. REGULATORY INFORMATION

The information included below is an overview of the major regulatory requirements. It should not be considered to be an exhaustive summary. Local regulations should be consulted for additional requirements.

EU Classification and Labelling

Exempt from requirements of EU Dangerous Preparations directive - product regulated as a medicinal product, cosmetic product or medical device.

US OSHA Standard (29 CFR Part 1910.1200)**Classification**

This dosage form is exempt from the requirements of the OSHA Hazard Communication Standard.

Other US Regulations**TSCA Status**

Exempt

16. OTHER INFORMATION

References

GSK Hazard Determination

SDS Version Number

11

SDS Sections Updated**Sections**

COMPOSITION / INFORMATION ON INGREDIENTS

HAZARDS IDENTIFICATION

IDENTIFICATION OF SUBSTANCE / PREPARATION AND OF COMPANY

TOXICOLOGY INFORMATION

TRANSPORT INFORMATION

Subsections

Health

Product use

Pharmacological Effects

Reproductive Effects

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.