SAFETY DATA SHEET

GlaxoSmithKline

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

Material **LAMICTAL TABLETS**

Synonyms 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 * NDC NO 0173-0633-02 * NDC NO 0173-0633-08 * NDC NO 0173-0642-55 * NDC NO 0173-0643-60 * NDC NO 0173-0644-60 * NDC NO 0173-0633-09 * NDC NO 0173-0633-06 * NDC NO 0173-0594-00 * LAMOTRIGINE, FORMULATED PRODUCT

Company Name

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US General Information:	+1-888-825-5249
Transport Emergency (non EU)	+1-703-527-3887
	US number, available 24 hours
	Multi-language response

2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS RN	Percentage
LAMOTRIGINE	84057-84-1	31 to 50
NON-HAZARDOUS INGREDIENTS	Unassigned	50 to 69

3. HAZARDS IDENTIFICATION

Fire and Explosion Expected to be non-combustible.

Health Caution - Pharmaceutical agent.
Exposure might occur via eyes; skin; ingestion.
May produce allergic skin reactions.
Health effects information is based on hazards of components.

Environment	Harmful to aquatic organisms. May cause long-term adverse effects in the aquatic environment.

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.

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

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. TOXICOLOGICAL INFORMATION

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	Irritation is not expected following direct contact with eyes.
Target Organ Effects	Adverse effects might occur in the following organ(s) following overexposure: central nervous system; red blood cells.
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	Not expected to produce adverse effects on fertility or development under occupational exposure conditions.
Pharmacological Effects	This preparation contains ingredient(s) with the following activity: a sodium channel antagonist.
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 pharmaceutical 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 pharmaceutical 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 pharmaceutical ingredient that is harmful to algae.

IC50: 39.7 mg/l, 72 Hours, Selenastrum capricornutum, green algae, Static test

NOEL: 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

NOEL: 30 mg/l, 48 Hours, Daphnia magna, Static test

Fish

This mixture contains an active pharmaceutical ingredient that is harmful to fish.

Adult Oncorhyncus mykiss, rainbow trout

EC50: 85 mg/l, 96 Hours, Static test

Adult Oncorhyncus mykiss, rainbow trout

NOEL: 60 mg/l, 96 Hours, Static test

MOBILITY

Solubility

This mixture contains an active pharmaceutical ingredient that for environmental fate predictions has limited solubility in water.

Adsorption

This mixture contains an active pharmaceutical ingredient that is not likely to adsorb to soil or sediment if released directly to the environment. This mixture contains an active pharmaceutical 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

Biodegradation This mixture contains an active pharmaceutical 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 This material contains an active pharmaceutical 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 material.

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 Transportation and shipping of this product is not restricted. It has no known, significant hazards requiring special packaging or labelling for air, maritime, US or European ground transport purposes.

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

Date Approved/Revised 04-Nov-2004 **SDS Version Number** 8

SDS Sections Updated

Sections **Subsections**

ECOLOGICAL INFORMATION

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.