

## SAFETY DATA SHEET



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

<b>Material</b>	LAMICTAL ORALLY DISINTEGRATING TABLETS (ODT) TABLETS
<b>Synonym(s)</b>	LAMICTAL ORALLY DISINTEGRATING TABLETS (ODT) 25MG * LAMICTAL ORALLY DISINTEGRATING TABLETS (ODT) 50MG * LAMICTAL ORALLY DISINTEGRATING TABLETS (ODT) 100MG * LAMICTAL ORALLY DISINTEGRATING TABLETS (ODT) 200MG * NDC NO. 0173-0776-61 * NDC NO. 0173-0776-01 * NDC NO. 0173-0776-00 * NDC NO. 0173-0777-01 * NDC NO. 0173-0777-00 * NDC NO. 0173-0772-01 * NDC NO. 0173-0772-00 * NDC NO. 0173-0772-62 * NDC NO. 0173-0772-61 * NDC NO. 0173-0779-61 * NDC NO. 0173-0778-61 * NDC NO. 0173-0774-01 * NDC NO. 0173-0774-00 * NDC NO. 0173-0774-61 * NDC NO. 0173-0780-61 * LAMOTRIGINE, FORMULATED PRODUCT
<b>Trade Names</b>	LAMICTAL ORALLY DISINTEGRATING TABLETS (ODT) TABLETS *
<b>Company Name</b>	<p>GlaxoSmithKline, Corporate Environment, Health &amp; Safety            980 Great West Road            Brentford, Middlesex TW8 9GS UK</p> <p>UK General Information: +44-20-8047-5000            Transport Emergency (EU) +44-1865-407333            Medical Emergency +1-612-221-3999, Ext 221            Information and Advice: US number, available 24 hours            Multi-language response</p> <p>GlaxoSmithKline Corporate Environment, Health &amp; Safety            One Franklin Plaza, 200 N 16th Street            Philadelphia, PA 19102-1225 US</p> <p>US General Information: +1-888-825-5249            Transport Emergency (non EU) +1-703-527-3887            US number, available 24 hours            Multi-language response</p>

### 2. HAZARDS IDENTIFICATION

<b>Fire and Explosion Hazards</b>	Expected to be non-combustible.
<b>Health</b>	<p>Caution - Pharmaceutical agent.            Exposure might occur via eyes; skin; ingestion.            May produce allergic skin reactions.            Health effects information is based on hazards of components.</p>
<b>Environment</b>	Harmful to aquatic organisms. May cause long-term adverse effects in the aquatic environment.

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS #	Percent	EC-No.
LAMOTRIGINE	84057-84-1	25	281-901-8
Other components below reportable levels		75	

## 4. FIRST-AID MEASURES

<b>Ingestion</b>	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.
<b>Inhalation</b>	Physical form suggests that risk of inhalation exposure is negligible.
<b>Skin contact</b>	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.
<b>Eye contact</b>	Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.

## NOTES TO HEALTH PROFESSIONALS

<b>Medical Treatment</b>	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.
<b>Medical Conditions Caused or Aggravated by Exposure</b>	This material may cause or aggravate allergy to phenothiazines.
<b>Antidotes</b>	No specific antidotes are recommended.

## 5. FIRE-FIGHTING MEASURES

<b>Fire and Explosion Hazards</b>	Not expected for the product, although the packaging is combustible.
<b>Extinguishing Media</b>	Water, dry powder or foam extinguishers are recommended. Carbon dioxide extinguishers may be ineffective.
<b>Special Firefighting Procedures</b>	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.
<b>Hazardous Combustion Products</b>	Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

## 6. ACCIDENTAL RELEASE MEASURES

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

## 7. HANDLING AND STORAGE

<b>HANDLING</b>	
<b>General Requirements</b>	Avoid breaking or crushing tablets.
<b>STORAGE</b>	No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

## OCCUPATIONAL EXPOSURE LIMITS

<b>INGREDIENT</b>	LAMOTRIGINE
<b>GSK Occupational Hazard Category</b>	2
<b>GSK Occupational Exposure Limit</b>	200 mcg/m <sup>3</sup> (8 HR TWA)

**PERSONAL PROTECTIVE EQUIPMENT**

<b>Eye Protection</b>	Wear approved safety glasses with side shields if eye contact is possible.
<b>Other Equipment or Procedures</b>	Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.

9. PHYSICAL AND CHEMICAL PROPERTIES
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**Appearance**

<b>Physical Form</b>	Tablet.
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10. STABILITY AND REACTIVITY
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<b>Stability</b>	This product is expected to be stable.
<b>Conditions to Avoid</b>	None for normal handling of this product.

11. TOXICOLOGY INFORMATION
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<b>Pharmacological Effects</b>	This preparation contains ingredient(s) with the following activity: a sodium channel antagonist.
<b>Target Organ Effects</b>	Adverse effects might occur in the following organ(s) following overexposure: central nervous system; red blood cells.
<b>Routes of Exposure</b>	
<b>Oral Toxicity</b>	Adverse effects might occur following ingestion.
<b>Inhalation Toxicity</b>	No studies have been conducted.
<b>Skin Effects</b>	Irritation is not expected following direct contact.
<b>Eye Effects</b>	Minor irritation might occur following direct contact with eyes.
<b>Sensitisation</b>	Allergic skin reactions might occur following repeated contact with this material in susceptible individuals.
<b>Genetic Toxicity</b>	Not expected to be genotoxic, based on effects of individual components.
<b>Carcinogenicity</b>	No components are listed as carcinogens by GSK, IARC, NTP or US OSHA.
<b>Reproductive Effects</b>	Not expected to produce adverse effects on fertility or development under occupational exposure conditions.
<b>Other Adverse Effects</b>	None known for occupational exposure.

12. ECOLOGICAL INFORMATION
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<b>Summary</b>	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.
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**ECOTOXICITY****Aquatic**

<b>Activated Sludge Respiration</b>	This material contains an active pharmaceutical ingredient that is not toxic to activated sludge microorganisms. IC50: > 1000 mg/l, 3 Hours, Activated sludge
<b>Microbial Growth Inhibition</b>	This material contains an active pharmaceutical ingredient that is not toxic to these microorganisms.
<b>Minimum Inhibition Concentration:</b>	> 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
<b>Algal</b>	This mixture contains an active pharmaceutical ingredient that is harmful to algae.

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	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
<b>Daphnid</b>	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
<b>Fish</b>	This mixture contains an active pharmaceutical ingredient that is harmful to fish.	
	EC50:	85 mg/l, 96 Hours, Static test Adult Oncorhyncus mykiss, rainbow trout
	NOEC:	60 mg/l, 96 Hours, Static test Adult Oncorhyncus mykiss, rainbow trout
<b>MOBILITY</b>		
<b>Solubility</b>	This mixture contains an active pharmaceutical ingredient that for environmental fate predictions has limited solubility in water.	
<b>Adsorption</b>	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
<b>Partitioning</b>	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.	
<b>PERSISTENCE/DEGRADATION</b>		
<b>Hydrolysis</b>	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
<b>Photolysis</b>	This mixture contains an active pharmaceutical ingredient that is likely to undergo photodegradation.	
	UV/Visible Spectrum:	300 nm at pH > 6, Measured
<b>Biodegradation</b>	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
<b>BIOACCUMULATION</b>		
<b>Bioaccumulation</b>	This material contains an active pharmaceutical ingredient that will not have a tendency to bioaccumulate in the food chain.	

**13. DISPOSAL CONSIDERATIONS**

<b>Disposal Recommendations</b>	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.
<b>Regulatory Requirements</b>	Observe all local and national regulations when disposing of this product.

14. TRANSPORT INFORMATION
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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**

<b>Transport Information</b>	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.
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15. REGULATORY INFORMATION
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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)**

<b>Classification</b>	This dosage form is exempt from the requirements of the OSHA Hazard Communication Standard.
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**Other US Regulations**

<b>TSCA Status</b>	Exempt
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16. OTHER INFORMATION
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<b>References</b>	GSK Hazard Determination
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<b>SDS Version Number</b>	3
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**SDS Sections Updated**

<b>Sections</b>	<b>Subsections</b>
IDENTIFICATION OF SUBSTANCE / PREPARATION AND OF COMPANY	

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.