

SAFETY DATA SHEET



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

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|------------------------|---|
| Material | HORIZANT ER TABLETS |
| Synonym(s) | XP135512 * XN001 * HORIZANT ER TABLETS, 300MG * HORIZANT ER TABLETS, 450MG * HORIZANT ER TABLETS, 600MG * GABAPENTIN ENACARBIL ER TABLETS, 300MG, 450MG AND 600MG * GABAPENTIN ENACARBIL, FORMULATED PRODUCT |
| Recommended Use | Medicinal Product |
| 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): 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 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> |

2. HAZARDS IDENTIFICATION

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| Fire and Explosion Hazards | Expected to be non-combustible. |
| Health | Handling this product in its final form presents minimal risk from occupational exposure. Health effects information is based on hazards of components. |
| Environment | There is insufficient information to determine the scope of the environmental effects this material may cause. |

3. COMPOSITION / INFORMATION ON INGREDIENTS

| Ingredients | CAS # | Percent | EC-No. |
|--|-------------|---------|-----------|
| DODECYL SODIUM SULFATE | 151-21-3 | 1.83 | 205-788-1 |
| GABAPENTIN ENACARBIL | 478296-72-9 | 45.8 | |
| Other components below reportable levels | | 52.37 | |

4. FIRST-AID MEASURES

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| 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

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| Medical Treatment | None. |
| Medical Conditions Caused or Aggravated by Exposure | None for occupational exposure. |
| Antidotes | No specific antidotes are recommended. |

5. FIRE-FIGHTING MEASURES

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| Fire and Explosion Hazards | Not expected for the product, although the packaging is combustible. |
| Extinguishing Media | Water or foam extinguishers are recommended. Carbon dioxide or dry powder 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

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| 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

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| General Requirements | Avoid breaking or crushing tablets. |
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STORAGE

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

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

OCCUPATIONAL EXPOSURE LIMITS

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|---|------------------------|
| INGREDIENT | DODECYL SODIUM SULFATE |
| GSK Occupational Hazard Category | 2 |

INGREDIENT GABAPENTIN ENACARBIL**GSK Occupational Hazard Category** 1**GSK Occupational Exposure Limit** 5000 mcg/m3 (8 HR TWA)**Other Equipment or Procedures** None required for normal handling. 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

Target Organ Effects Adverse effects might occur in the following organ(s) following overexposure: central nervous system.**Symptoms of Overexposure** Possible effects of overexposure in the workplace include: drowsiness; dizziness; nausea; vomiting.**Routes of Exposure****Oral Toxicity** Not expected to be toxic following ingestion.**Inhalation Toxicity** Overexposure may result in irritation of the respiratory tract.**Skin Effects** Irritation is not expected following direct contact.**Eye Effects** Minor irritation might occur following direct contact with eyes.**Sensitisation** Sensitisation (allergic skin reaction) is not expected.**Genetic Toxicity** Not expected to be genotoxic under occupational exposure conditions.**Carcinogenicity** Not expected to produce cancer in humans under occupational exposure conditions. 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.**Other Adverse Effects** None known for occupational exposure.

12. ECOLOGICAL INFORMATION

Summary This material contains an active ingredient that has had limited testing and no adverse environmental effects were observed in the tests conducted. Local regulations and procedures should be consulted prior to environmental release.

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** Exempt when packaged for sale to consumers in a retail establishment.**Other US Regulations****TSCA Status** Exempt

16. OTHER INFORMATION

References GSK Hazard Determination**SDS Version Number** 3**SDS Sections Updated****Sections****Subsections**

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.