SAFETY DATA SHEET

GlaxoSmithKline

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

Material **AMERGE TABLETS**

Synonyms AMERGE TABLET 1.0 MG * AMERGE TABLET 2.5 MG * NARAMIG TABLET 2.5MG * NDC NO 0173-0561-02 * NDC NO 0173-0561-00 * NDC NO 0173-0562-01 * NDC NO 0173-0562-02 * NDC NO 0173-0562-00 * NARATRIPTAN HYDROCHLORIDE, FORMULATED PRODUCT

Company Name

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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
NARATRIPTAN HYDROCHLORIDE	143388-64-1	0.3 to 0.8
NON-HAZARDOUS INGREDIENTS	Unassigned	99.2 to 99.7

3. HAZARDS IDENTIFICATION

Fire and Explosion 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 No information is available about the potential of this product to produce adverse environmental effects.

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	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	Refer to prescribing information for detailed description of medical conditions caused by or aggravated by overexposure to this product.
Health Surveillance Procedures	Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment.
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	NARATRIPTAN HYDROCHLORIDE
GSK Occupational Hazard Category	3
GSK Occupational Exposure Limit	50 mcg/m3 (15 MIN STEL) 25 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

Colour	White.
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	Not expected to be toxic following ingestion.
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: cardiovascular system.
Sensitisation	Sensitisation (allergic skin reaction) is not expected.
Genetic Toxicity	Not expected to be genotoxic under occupational exposure conditions.
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 product contains active ingredient(s) with the following activity: a 5-hydroxytryptamine agonist. It is an agent intended for the treatment of migraine. Adverse effects of overexposure might include: symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing); increased blood pressure; vomiting; nausea; tingling.
*** Other Adverse Effects**	None known for occupational exposure.

12. ECOLOGICAL INFORMATION

*** Summary** This material contains an active pharmaceutical ingredient that has been tested, and no environmental effects have been identified. Local regulations and procedures should be consulted prior to environmental release.

Specific information on the active pharmaceutical ingredient is provided below.

ECOTOXICITY

Aquatic

*** Activated Sludge Respiration**

This material contains an active pharmaceutical ingredient that is not toxic to activated sludge microorganisms.

IC50: 100 to 1000 mg/l, 3 Hours, Activated sludge

*** Algal**

This material contains an active pharmaceutical ingredient that is not toxic to algae.

IC50: > 100 mg/l, 72 Hours, Scenedesmus subspicatus, green algae, Static test

NOEL: 100 mg/l, 72 Hours, Scenedesmus subspicatus, green algae, Static test

*** Daphnid**

This material contains an active pharmaceutical ingredient that is not toxic to daphids.

EC50: 300 mg/l, 48 Hours, Daphnia magna, Static test

NOEL: 160 mg/l, 48 Hours, Daphnia magna, Static test

*** Fish**

This material contains an active pharmaceutical ingredient that is not toxic to fish.

Juvenile Oncorhyncus mykiss, rainbow trout

EC50: > 100 mg/l, 96 Hours, Static renewal test

Juvenile Oncorhyncus mykiss, rainbow trout

NOEL: 100 mg/l, 96 Hours, Static renewal test

MOBILITY

*** Solubility**

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

*** Volatility**

This material contains an active pharmaceutical ingredient that will not readily enter into the air from hard surfaces or from a container of the pure substance. This material contains an active pharmaceutical ingredient that will not readily enter into air from water.

Henry's Law Constant Estimated at 25 C

*** Adsorption**

This material contains an active pharmaceutical ingredient that is likely to adsorb to soil or sediment. The active pharmaceutical ingredient may persist in soil or sediment if this mixture is released directly to the environment.

Soil Sediment Sorption (log Koc): 3.18 to 3.36, Measured

*** Partitioning**

This material 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, Calculated

*** Photolysis**

This material contains an active pharmaceutical ingredient that is unlikely to undergo photodegradation.

UV/Visible Spectrum: 282.5 nm

*** Biodegradation** This material contains an active pharmaceutical ingredient that is not readily biodegradable but is inherently biodegradable (as defined by 1993 OECD Testing Guidelines) and is not expected to persist in the environment.

Aerobic - Ready

Percent Degradation: < 1 %, 28 days, Modified Sturm test.

Aerobic - Inherent

Percent Degradation: 27 %, 28 days, Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge

Percent Degradation: 3 %, 28 days, Modified Zahn-Wellens, DOC removal., Activated sludge

Aerobic - Soil

Percent Degradation: 3 to 36 %, 64 days

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 18-Nov-2004 **SDS Version Number** 6

SDS Sections Updated

Sections	Subsections
COMPOSITION / INFORMATION ON INGREDIENTS	
ECOLOGICAL INFORMATION	

SDS Sections Updated

Sections	Subsections
REGULATORY INFORMATION	European Union Classification and Labelling Requirements
TOXICOLOGY INFORMATION	Other Adverse 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.