SAFETY DATA SHEET

GlaxoSmithKline

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

Material **RELIFEX TABLETS**

Synonyms FLAMBATE TABLETS * MEBUTAN TABLETS * BALMOX TABLETS * RELIFEX TABLETS 400 MG * RELIFEX TABLETS 500 MG * RELIFEX TABLETS 750 MG * RELIFEX TABLETS 1000 MG * RELAFEN TABLETS * NDC NO 0029-4851-20 * NDC NO 0029-4851-21 * NDC NO 0029-4852-20 * NABUMETONE, FORMULATED PRODUCT

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2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS RN	Percentage
NABUMETONE	42924-53-8	78.9
NON-HAZARDOUS INGREDIENTS	Unassigned	21.1

3. HAZARDS IDENTIFICATION

Fire and Explosion Expected to be non-combustible.

Health Exposure might occur via skin; eyes; ingestion.
Caution - Pharmaceutical agent. Possible effects of overexposure in the workplace include: irritation; coughing; increased mucous secretion; headache; nausea; dizziness; sedation. Health effects information is based on hazards of components. Handling this product in its final form presents minimal risk from occupational exposure.

Environment Dangerous for the environment. Very toxic to aquatic organisms.

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 local poison control information centre. Medical treatment in cases of overexposure should be treated as an overdose of an anti-inflammatory.
Medical Conditions Caused or Aggravated by Exposure	None for occupational exposure.
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	Prevent entry into waterways, sewers, surface drainage systems and poorly ventilated areas.
Clean-up Methods	Spread an inert absorbent on the spill and place 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	NABUMETONE
GSK Occupational Hazard Category	1
GSK Occupational Exposure Limit	1000 MCG/M3 (8 HR TWA)
Other Equipment or Procedures	Wash hands and arms thoroughly after handling. None required for normal handling.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Colour	Dark red.
Physical Form	Film-coated 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	No specific target organ effects have been identified.
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 preparation contains ingredient(s) with the following activity: a non-steroidal anti-inflammatory substance. Adverse effects of overexposure might include: irritation; coughing; increased mucous secretion; headache; nausea; dizziness; sedation.
Other Adverse Effects	None known for occupational exposure.

12. ECOLOGICAL INFORMATION

*** Summary**	This material contains an active pharmaceutical ingredient that has been tested, and which may be very toxic to aquatic organisms 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. Specific information on the active pharmaceutical ingredient is provided below.

ECOTOXICITY

Aquatic

Activated Sludge Respiration

No toxicity to sludge microorganisms was observed for the active pharmaceutical ingredient in this mixture, but the upper range of the test was limited by the low water solubility of the compound.

IC50: > 10 mg/L, 3 Hours, Residential sludge

Microtox

Microtox is a general toxicity test which utilizes a sensitive marine photo bacteria as the test species. This material contains an active pharmaceutical ingredient that is toxic to these microorganisms.

EC50: 0.4 mg/L, 15 Minutes

*** Algal**

This material contains an active pharmaceutical ingredient that is very toxic to algae.

IC50: 0.68 mg/L, 96 Hours, Selenastrum capricornutum, green algae, Static test

*** Daphnid**

This material contains an active pharmaceutical ingredient that is toxic to daphids.

EC50: 3.5 mg/L, 48 Hours, Daphnia magna, Static test

NOEL: 1.1 mg/L, 48 Hours, Daphnia magna, Static test

Fish

No toxicity to fish was observed for the active pharmaceutical ingredient, but the upper range of the test was limited by the low water solubility of the compound.

Adult Lepomis macrochirus, bluegill sunfish

EC50: > 4.4 mg/L, 96 Hours, Static test

Adult Lepomis macrochirus, bluegill sunfish

NOEL: 1.4 mg/L, 96 Hours, Static test

MOBILITY

*** Solubility**

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

Volatility

This material contains an active pharmaceutical ingredient that will not readily enter into air from water.

Henry's Law Constant < 1.00E-05 atm m^3/mol, Measured

*** Adsorption**

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

Soil Sediment Sorption (log Koc): 2.9, Calculated

Sludge Biomass Distribution Coefficient (log Kd): 1.62 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 may have the tendency to distribute into fats.

PERSISTENCE/DEGRADATION

Photolysis

This material contains an active pharmaceutical ingredient that has been shown to be chemically unstable in water when exposed to light. Aqueous photolysis may be a significant depletion mechanism.

Half-Life, Aqueous: 58 Hours, Measured, Deionized Water

*** 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 - Inherent

Percent Degradation: 50 %, 2.1 hours, Batch activated sludge (BAS), Activated sludge

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

Bioconcentration Factor: 82 Calculated

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 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 17-Dec-2004 **SDS Version Number** 11

SDS Sections Updated

Sections	Subsections
ECOLOGICAL INFORMATION	
	Activated Sludge Respiration
	Adsorption
	Algal
	Bioaccumulation
	Biodegradation

SDS Sections Updated

Sections	Subsections
ECOLOGICAL INFORMATION	Daphnid
	Fish
	Microtox
	Partitioning
	Photolysis
	Solubility
	Summary
	Volatility

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.