

## SAFETY DATA SHEET



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

<b>Material</b>	<b>RELIFEX TABLETS</b>
<b>Synonyms</b>	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
<b>Company Name</b>	GlaxoSmithKline, Corporate Environment, Health & Safety 980 Great West Road Brentford, Middlesex TW8 9GS UK 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  GlaxoSmithKline, Corporate Environment, Health & Safety 2200 Renaissance Blvd, Suite 105 King of Prussia, PA 19406 US 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
NABUMETONE	42924-53-8	78.9
NON-HAZARDOUS INGREDIENTS	Unassigned	21.1

### 3. HAZARDS IDENTIFICATION

<b>Fire and Explosion</b>	Expected to be non-combustible.
<b>Health</b>	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.
<b>Environment</b>	Dangerous for the environment. Very toxic to aquatic organisms.

### 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>	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.
<b>Medical Conditions Caused or Aggravated by Exposure</b>	None for occupational exposure.
<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>	Prevent entry into waterways, sewers, surface drainage systems and poorly ventilated areas.
<b>Clean-up Methods</b>	Spread an inert absorbent on the spill and place 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

#### 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

<b>INGREDIENT</b>	NABUMETONE
<b>GSK Occupational Hazard Category</b>	1
<b>GSK Occupational Exposure Limit</b>	1000 MCG/M3 (8 HR TWA)
<b>Other Equipment or Procedures</b>	Wash hands and arms thoroughly after handling. None required for normal handling.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### Appearance

<b>Colour</b>	Dark red.
<b>Physical Form</b>	Film-coated tablet.

## 10. STABILITY AND REACTIVITY

<b>Stability</b>	This product is expected to be stable.
<b>Conditions to Avoid</b>	None for normal handling of this product.

## 11. TOXICOLOGICAL INFORMATION

<b>Oral Toxicity</b>	Not expected to be toxic following ingestion.
<b>Skin Effects</b>	Irritation is not expected following direct contact.
<b>Eye Effects</b>	Irritation is not expected following direct contact with eyes.
<b>Target Organ Effects</b>	No specific target organ effects have been identified.
<b>Sensitisation</b>	Sensitisation (allergic skin reaction) is not expected.
<b>Genetic Toxicity</b>	Not expected to be genotoxic under occupational exposure conditions.
<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>Pharmacological Effects</b>	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.
<b>Other Adverse Effects</b>	None known for occupational exposure.

## 12. ECOLOGICAL INFORMATION

<b>* Summary</b>	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.
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Specific information on the active pharmaceutical ingredient is provided below.

### ECOTOXICITY

#### Aquatic

<b>Activated Sludge Respiration</b>	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
<b>Microtox</b>	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
<b>* Algal</b>	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
<b>* Daphnid</b>	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
<b>Fish</b>	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**

<b>* Solubility</b>	This material contains an active pharmaceutical ingredient that for environmental fate predictions has very low solubility in water.
<b>Volatility</b>	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 <sup>3</sup> /mol, Measured
<b>* Adsorption</b>	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
<b>* Partitioning</b>	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**

<b>Photolysis</b>	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
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- \* 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

ECOLOGICAL INFORMATION

##### Subsections

Activated Sludge Respiration  
Adsorption  
Algal  
Bioaccumulation  
Biodegradation

**SDS Sections Updated****Sections**

ECOLOGICAL INFORMATION

**Subsections**

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.