

## SAFETY DATA SHEET



GlaxoSmithKline

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

|                     |   |
|---------------------|---|
| <b>Material</b>     | <b>ALTABAX OINTMENT</b>   |
| <b>Synonyms</b>     | ALTABAX OINTMENT 1% * ALTABAX OINTMENT 2% * ALTARGO OINTMENT * SB-275833 OINTMENT * TOPICAL PLEUROMUTILIN * NDC NO. 0007-5180-05 * NDC NO. 0007-5180-10 * NDC NO. 0007-5180-22 * NDC NO. 0007-5180-61 * NDC NO. 0007-5180-62 * RETAPAMULIN, FORMULATED PRODUCT  |
| <b>Company Name</b> | <p>GlaxoSmithKline, Corporate Environment, Health &amp; Safety<br/>           980 Great West Road<br/>           Brentford, Middlesex TW8 9GS UK</p> <p>UK General Information: +44-20-8047-5000<br/>           Transport Emergency (EU) +44-1865-407333<br/>           Medical Emergency +1-612-221-3999, Ext 221<br/>           Information and Advice: US number, available 24 hours<br/>           Multi-language response</p> <p>GlaxoSmithKline, Corporate Environment, Health &amp; Safety<br/>           One Franklin Plaza, 200 N 16th Street<br/>           Philadelphia, PA 19102-1225 US</p> <p>US General Information: +1-888-825-5249<br/>           Transport Emergency (non EU) +1-703-527-3887<br/>           US number, available 24 hours<br/>           Multi-language response</p> |

### 2. COMPOSITION / INFORMATION ON INGREDIENTS

| Ingredients               | CAS RN      | Percentage   |
|---------------------------|-------------|--------------|
| SB-275833                 | 224452-66-8 | 1 to 2       |
| NON-HAZARDOUS INGREDIENTS | Unassigned  | 98.0 to 99.0 |

### 3. HAZARDS IDENTIFICATION

|                           |  |
|---------------------------|--|
| <b>Fire and Explosion</b> | Expected to be non-combustible.  |
| <b>Health</b>             | Caution - Pharmaceutical agent. Exposure might occur via ingestion; skin; eyes.<br>Health effects information is based on hazards of components. |
| <b>Environment</b>        | No information is available about the potential of this product to produce adverse environmental effects.  |

### 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 current prescribing information or to the local poison control information centre.             |
| <b>Medical Conditions Caused or Aggravated by Exposure</b> | None for occupational exposure.   |
| <b>Health Surveillance Procedures</b>                      | 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. |
| <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 is recommended for fires involving packaging.   |
| <b>Special Firefighting Procedures</b> | For single units (packages): No special requirements needed.<br>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.<br>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> | Detergent solutions can be used for clean-up and decontamination operations. No specific decontamination or detoxification procedures have been identified for this product. |

**7. HANDLING AND STORAGE****HANDLING**

**General Requirements** No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product.

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

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**INGREDIENT** SB-275833

**GSK Occupational Hazard Category** 2

**GSK Occupational Exposure Limit** 400 mcg/m<sup>3</sup> (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** Ointment.

## 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.

**Inhalation Toxicity** No studies have been conducted.

**Skin Effects** Irritation is not expected following direct contact.

**Eye Effects** Minor irritation might occur following direct contact with eyes.

**Target Organ Effects** No specific target organ effects have been identified.

**Sensitisation** Allergic skin reactions might occur following dermal exposure.

**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.

**Pharmacological Effects** This preparation contains ingredient(s) with the following activity: an antibiotic.

**Other Adverse Effects** None known for occupational exposure.

## 12. ECOLOGICAL INFORMATION

**Summary** This product contains an active ingredient that has been tested and which may be harmful if released directly 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** This material contains an active pharmaceutical ingredient that is harmful to activated sludge microorganisms.

IC50: 5.3 mg/l, 3 Hours, Activated sludge, Nominal

NOEC: 0.1 mg/l, 3 Hours

**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 not toxic to these microorganisms.

EC50: 103.6 mg/l, 15 Minutes

**Daphnid** This material contains an active pharmaceutical ingredient that is harmful to daphnids.

EC50: 40 mg/l, 48 Hours, Daphnia magna, Measured

NOEL: 18 mg/l, 48 Hours

## MOBILITY

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

### Distribution

Octanol/Water 1.89 at pH 7.4

Distribution Coefficient  
(log Dow):

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

Sludge Biomass 0.57 Measured Measured at pH 6.8

Distribution Coefficient  
(log Kd):

**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

**Hydrolysis** This material contains an active pharmaceutical ingredient that has been shown to be chemically stable in water.

**Biodegradation** This mixture 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. This material is likely to have low removal in a wastewater treatment plant.

Aerobic - Inherent

Percent Degradation: 45 %, 5 days, Batch activated sludge (BAS),  
Activated sludge

Percent Degradation: 9 %, 28 days, Modified Zahn-Wellens, primary  
biodegradation, loss of parent., Activated sludge

## 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 product is classified as hazardous according to the OSHA Hazard Communication Standard.

### Other US Regulations

**TSCA Status** Exempt

## 16. OTHER INFORMATION

**References** GSK Hazard Determination

**Date Approved/Revised** 23-Mar-2007

**SDS Version Number** 7

### SDS Sections Updated

#### Sections

IDENTIFICATION OF SUBSTANCE / PREPARATION AND OF COMPANY

#### Subsections

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.