SAFETY DATA SHEET

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Trade name or designation of the mixture	ALTABAX OINTMENT
Registration number	-
Synonyms	ALTABAX * ALTABAX OINTMENT 1% * ALTABAX OINTMENT 2% * ALTARGO OINTMENT * RETAPAMULIN OINTMENT * SB-275833 OINTMENT * TOPICAL PLEUROMUTILIN * RETAPAMULIN, FORMULATED PRODUCT
Issue date	07-November-2013
Version number	10
Revision date	07-November-2013

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses	Medicinal Product This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.
Uses advised against	No other uses are advised.

1.3. Details of the supplier of the safety data sheet

GlaxoSmithKline UK
980 Great West Road
Brentford, Middlesex TW8 9GS UK
UK General Information (normal business hours): +44-20-8047-5000
Email Address: msds@gsk.com
Website: www.gsk.com

1.4. Emergency telephone number

TRANSPORT EMERGENCIES::
UK In-country toll call: +(44)-870-8200418
International toll call: +1 703 527 3887
available 24 hrs/7 days; multi-language response

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

Classification according to Directive 67/548/EEC or 1999/45/EC as amended

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Classification according to Regulation (EC) No 1272/2008 as amended

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

2.2. Label elements

Label according to Regulation (EC) No. 1272/2008 as amended

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Supplemental label information Not applicable.

2.3. Other hazards This product will support combustion at elevated temperatures.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
RETAPAMULIN	98-99	224452-66-8 -	-	-	
Classification: **DSD:** R52-53 **CLP:** Aquatic Chronic 3;H412					
PHARMACEUTICAL GRADE PETROLATUM	1-2	8009-03-8 232-373-2	-	649-254-00-X	
Classification: **DSD:** - **CLP:** -					

CLP: Regulation No. 1272/2008.
DSD: Directive 67/548/EEC.
M: M-factor
vPvB: very persistent and very bioaccumulative substance.
PBT: persistent, bioaccumulative and toxic substance.
#: This substance has been assigned Community workplace exposure limit(s).

Composition comments The full text for all R- and H-phrases is displayed in section 16.

SECTION 4: First aid measures

General information 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.

4.1. Description of first aid measures

Inhalation In case of accident by inhalation: remove casualty to fresh air and keep at rest. If breathing is difficult, trained personnel should give oxygen. If not breathing, give artificial respiration. Get medical attention immediately.

Skin contact Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Remove and isolate contaminated clothing and shoes. Get medical attention immediately.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

Ingestion If swallowed, rinse mouth with water (only if the person is conscious). Call a physician or poison control centre immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconsious person.

4.2. Most important symptoms and effects, both acute and delayed Direct contact with eyes may cause temporary irritation.

4.3. Indication of any immediate medical attention and special treatment needed No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre.

SECTION 5: Firefighting measures

General fire hazards This product will support combustion at elevated temperatures.

5.1. Extinguishing media

Suitable extinguishing media Foam. Dry chemical powder. Carbon dioxide (CO2).

Unsuitable extinguishing media Water.

5.2. Special hazards arising from the substance or mixture During fire, gases hazardous to health may be formed.

5.3. Advice for firefighters

Special protective equipment for firefighters Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Special fire fighting procedures Use standard firefighting procedures and consider the hazards of other involved materials. Move containers from fire area if you can do so without risk.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate personal protective equipment. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8.

For emergency responders	Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the MSDS.
6.2. Environmental precautions	Avoid release to the environment. Contact local authorities in case of spillage to drain/aquatic environment. Prevent further leakage or spillage if safe to do so. Do not contaminate water. Avoid discharge into drains, water courses or onto the ground.
6.3. Methods and material for containment and cleaning up	Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Use water spray to reduce vapours or divert vapour cloud drift. Prevent product from entering drains. Following product recovery, flush area with water. Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination. Never return spills in original containers for re-use.
6.4. Reference to other sections	For personal protection, see section 8. For waste disposal, see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling	Avoid prolonged exposure. Observe good industrial hygiene practices.
7.2. Conditions for safe storage, including any incompatibilities	Keep away from heat and sources of ignition. Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the MSDS).
7.3. Specific end use(s)	Medicinal Product

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

GSK

Components	Type	Value
RETAPAMULIN (CAS 224452-66-8)	8 HR TWA	400 mcg/m3
	OHC	2

Biological limit values	No biological exposure limits noted for the ingredient(s).
Recommended monitoring procedures	Follow standard monitoring procedures.
Derived No Effect Level (DNEL)	Not available.
Predicted no effect concentrations (PNECs)	Not available.

8.2. Exposure controls

Appropriate engineering controls	An Exposure Control Approach (ECA) is established for operations involving this material based upon the OEL/Occupational Hazard Category and the outcome of a site- or operation-specific risk assessment. Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits.

Individual protection measures, such as personal protective equipment

General information	Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment. Follow all local regulations if personal protective equipment (PPE) is used in the workplace.
Eye/face protection	Wear safety glasses with side shields. (eg. EN 166)
Skin protection	
- Hand protection	The choice of an appropriate glove does not only depend on its material but also on other quality features and is different from one producer to the other. Glove selection must take into account any solvents and other hazards present. Select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time).
- Other	Wear appropriate chemical resistant clothing. (EN 14605 for splashes, EN ISO 13982 for dust)
Respiratory protection	Where breathable aerosols/dust are formed, use suitable combination filter for gases/vapours of organic, inorganic, acid inorganic, alkaline compounds and toxic particles (eg. EN 14387).
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
Hygiene measures	For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

Environmental exposure controls

Hazard guidance and control recommendations	Contain spills and prevent releases and observe national regulations on emissions. Environmental manager must be informed of all major releases.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state	Liquid.
Form	Paste.
Colour	Not available.
Odour	Not available.
Odour threshold	Not available.
pH	Not available.
Melting point/freezing point	38 - 54 °C (100.4 - 129.2 °F) (Estimation based on components).
Initial boiling point and boiling range	> 260 °C (> 500 °F) (Estimation based on components).
Flash point	> 182 °C (> 359.6 °F) Closed cup (Estimation based on components).
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density	Not available.
Solubility(ies)	Expected to be insoluble in water.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Explosive properties	Not available.
Oxidizing properties	Not available.

9.2. Other information

Percent volatile	5 % estimated

SECTION 10: Stability and reactivity

10.1. Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
10.2. Chemical stability	Material is stable under normal conditions.
10.3. Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
10.4. Conditions to avoid	Avoid heat, sparks, open flames and other ignition sources. Avoid temperatures exceeding the flash point. Contact with incompatible materials.
10.5. Incompatible materials	Strong oxidising agents.
10.6. Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

SECTION 11: Toxicological information

General information Caution - Pharmaceutical agent.

Information on likely routes of exposure

Ingestion	Expected to be a low ingestion hazard.
Inhalation	Not expected to occur during normal handling of this product.
Skin contact	Irritation is not expected following direct contact.
Eye contact	Direct contact with eyes may cause temporary irritation.
Symptoms	Direct contact with eyes may cause temporary irritation.

11.1. Information on toxicological effects

Acute toxicity Based on available data, the classification criteria are not met.

Components	Species	Test results
PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)		
Acute		
Oral		
LD50	Rat	> 15 g/kg
Chronic		
Oral		
NOAEL	Rat	>= 3000, 2 years
RETAPAMULIN (CAS 224452-66-8)		
Acute		
Oral		
LD	Rat	> 450 mg/kg
Subacute		
Oral		
NOAEL	Monkey	50 mg/kg/day, 14 day study
	Rat	50 mg/kg/day, 14 day study
Subchronic		
Dermal		
NOAEL	Rabbit	2 %, 13 week study

* Estimates for product may be based on additional component data not shown.

Skin corrosion/irritation Based on available data, the classification criteria are not met.

Irritation Corrosion - Skin

RETAPAMULIN
5 % Acute dermal irritation, 5% in ointment base on intact skin
Result: negative
Species: Rabbit

Serious eye damage/eye irritation Based on available data, the classification criteria are not met.

Eye

RETAPAMULIN
Acute occular irritation
Result: MIld-moderate

Respiratory sensitisation Not available.

Skin sensitisation Based on available data, the classification criteria are not met.

Sensitisation

RETAPAMULIN
Epidemiology
Result: negative
Species: Human
Local lymph node assay, S.I. 5% (1.2)
Result: negative
Maximisation assay (Magnusson and Kligman), 5% responding
Result: negative

Germ cell mutagenicity Based on available data, the classification criteria are not met.

Germ cell mutagenicity

Mutagenicity

RETAPAMULIN
Chromosomal Aberration Assay In Vitro
Result: negative
In vivo Micronucleus
Result: negative
Mouse Lymphoma Cel (L5178Y) Assay
Result: negative
sister chromatid exchange
Result: negative

Carcinogenicity

PHARMACEUTICAL GRADE PETROLATUM
>= 3000 mg/kg/day oral
Result: NOAEL
Species: Rat
dermal
Result: negative
Species: Mouse

Reproductive toxicity This product is not expected to cause reproductive or developmental effects.

Reproductive toxicity

Reproductivity

RETAPAMULIN

1 % Dermal NeoNatal
Result: NOAEL
Species: Rat
50 mg/kg/day Embryofetal Development, Decreased fetal body weight and delayed skeletal ossification at 150 mg/kg/day
Result: NOAEL
Species: Rat
7.2 mg/kg/day Embryofetal Development, Maternal Toxicity at >7.2 mg/kg/day
Result: NOAEL
Species: Rabbit

Specific target organ toxicity - single exposure None known.

Specific target organ toxicity - repeated exposure None known.

Aspiration hazard Not likely, due to the form of the product.

Mixture versus substance information No information available.

Other information Not available.

SECTION 12: Ecological information

12.1. Toxicity No information is available about the potential of this product to produce adverse environmental effects. Contains a substance which causes risk of hazardous effects to the environment.

Components		Species	Test results
RETAPAMULIN (CAS 224452-66-8)			
Aquatic			
Acute			
Activated Sludge Respiration	IC50	Residential sludge	5.3 mg/l, 3 hours, , OECD 209
	NOEC	Residential sludge	0.1 mg/l, 3 hours
Crustacea	EC50	Water flea (Daphnia magna)	40 mg/l, 48 hours, Measured, OECD 202
	NOEC	Water flea (Daphnia magna)	18 mg/l, 48 hours
Microtox	EC50	Microtox	103.6 mg/l, 15 minutes

* Estimates for product may be based on additional component data not shown.

12.2. Persistence and degradability

Persistence and degradability

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

RETAPAMULIN

45 %, 5 days Batch activated sludge (BAS), Activated sludge
9 %, 28 days Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge

12.3. Bioaccumulative potential

Partition coefficient n-octanol/water (log Kow)

RETAPAMULIN 4.06 (Measured).

12.4. Mobility in soil No data available.

Adsorption

Sludge/biomass distribution coefficient - log Kd

RETAPAMULIN 0.57 Measured, pH 6.8

Mobility in general

Distribution

Octanol/water distribution coefficient log DOW

RETAPAMULIN 1.89, pH 7.4

12.5. Results of PBT and vPvB assessment	Not available.
12.6. Other adverse effects	Not available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Residual waste	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.
EU waste code	The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Disposal methods/information	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Dispose of contents/container in accordance with local/regional/national/international regulations.
Special precautions	Dispose in accordance with all applicable regulations.

SECTION 14: Transport information

ADR

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	MARPOL Annex II applies to liquids used in a ship's operation that pose a threat to the marine environment. These materials may not be transported in bulk.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulations

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I

Not listed.

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex II

Not listed.

Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex V as amended

Not listed.

Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry

Not listed.

Regulation (EC) No. 1907/2006, REACH Article 59(1) Candidate List as currently published by ECHA

Not listed.

Authorisations

Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended

Not listed.

Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended

PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)

Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work

PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)

Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breastfeeding

PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)

Other EU regulations

Directive 96/82/EC (Seveso II) on the control of major-accident hazards involving dangerous substances

Not listed.

Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)

Directive 94/33/EC on the protection of young people at work

PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)

Other regulations	The product is classified and labelled in accordance with EC directives or respective national laws. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006.
National regulations	Follow national regulation for work with chemical agents.
15.2. Chemical safety assessment	No Chemical Safety Assessment has been carried out.

SECTION 16: Other information

List of abbreviations	Not available.
References	GSK Hazard Determination
Information on evaluation method leading to the classification of mixture	The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.
Full text of any statements or R-phrases and H-statements under Sections 2 to 15	R52 Harmful to aquatic organisms. R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment. R53 May cause long term adverse effects in the aquatic environment. H412 Harmful to aquatic life with long lasting effects.
Revision information	Product and Company Identification: Business Units Hazards Identification: EU Hazard Classifications Composition / Information on Ingredients: Ingredients Physical & Chemical Properties: TOXICOLOGICAL INFORMATION: Ecological Information: GSK Environmental Hazard Assessment Concentration Transport Information: Agency Name and Packaging Type/Transport Mode Selection Regulatory Information: Risk Phrases - Class. GHS: Classification
Training information	Follow training instructions when handling this material.
Disclaimer	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.