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	TRIMOVATE CREAM
Registration number	-
Synonyms	TRIMOVATE CREAM 0.05% W/W * CLOBETASONE BUTYRATE, NYSTATIN AND CALCIUM OXYTETRACYCLINE, FORMULATED PRODUCT
Issue date	21-October-2013
Version number	07
Revision date	21-October-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 Caution - Pharmaceutical agent. See section 11 for additional information on health 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
GLYCERIN	10 - < 20	56-81-5 200-289-5	-	-	
Classification:	**DSD:** -				
	CLP: -				
PHARMACEUTICAL GRADE PETROLATUM	10 - < 20	8009-03-8 232-373-2	-	649-254-00-X	
Classification:	**DSD:** -				
	CLP: -				
CET-3	1 - < 3	29636-87-1 249-740-8	-	-	
Classification:	**DSD:** Xi;R36, R43				
	CLP: Skin Sens. 1;H317, Eye Irrit. 2;H319				
GLYCERYL MONOSTEARATE	1 - < 3	31566-31-1 250-705-4	-	-	
Classification:	**DSD:** -				
	CLP: -				
POLYETHYLENE GLYCOL STEARATE	1 - < 3	9004-99-3 -	-	-	
Classification:	**DSD:** Xi;R36/37/38				
	CLP: Skin Irrit. 2;H315, Eye Irrit. 2;H319, STOT SE 3;H335				
Titanium dioxide	1 - < 3	13463-67-7 236-675-5	-	-	
Classification:	**DSD:** -				
	CLP: -				
SODIUM METABISULFITE	< 1	7681-57-4 231-673-0	-	016-063-00-2	
Classification:	**DSD:** Xn;R22, Xi;R41, R31				
	CLP: Acute Tox. 4;H302, Eye Dam. 1;H318				
4-CHLORO-M-CRESOL	< 0.2	59-50-7 200-431-6	-	604-014-00-3	
Classification:	**DSD:** Xn;R21/22, Xi;R41, R43, N;R50				
	CLP: Acute Tox. 4;H302, Acute Tox. 4;H312, Skin Sens. 1;H317, Eye Dam. 1;H318, Aquatic Acute 1;H400				
CLOBETASONE BUTYRATE	0.05	25122-57-0 246-635-9	-	-	
Classification:	**DSD:** Repr. Cat. 2;R61, Repr. Cat. 3;R62, Xn;R48/20/21, R53				
	CLP: Repr. 1B;H360D, Repr. 2;H361f, STOT RE 2;H373, Aquatic Chronic 4;H413				

Other components below reportable levels 70 - < 80

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

The need for pre-placement and periodic health surveillance must be determined by risk assessment. Following assessment, if the risk of exposure is considered significant then exposed individuals should receive health surveillance focused on detecting skin conditions.
In the event of overexposure, individuals should receive post-exposure health surveillance focused on detecting skin conditions and adrenal suppression.

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.

Skin contact

Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes.

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).

4.2. Most important symptoms and effects, both acute and delayed

The following adverse effects have been noted with therapeutic use of this material: irritation; itching; burning; pain; symptoms of hypersensitivity (such as skin rash, hives, itching, and/or difficulty breathing).

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

Alcohol resistant 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. Do not touch or walk through spilled material. Avoid inhalation of vapours or mists. 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 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. 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

Do not breathe mist or vapour. Avoid contact with skin. Avoid prolonged exposure. Provide adequate ventilation. Wear appropriate personal protective equipment. 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 in a cool, dry place out of direct sunlight. 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	Note
CALCIUM OXYTETRACY CLINE (CAS 13303-91-8)	8 HR TWA	100 mcg/m3	
	OHC	2	Reproductive hazard
		2	SKIN SENSITISER
CET-3 (CAS 29636-87-1)	8 HR TWA	5000 mcg/m3	
	OHC	1	SKIN SENSITISER
CLOBETASONE BUTYRATE (CAS 25122-57-0)	8 HR TWA	20 mcg/m3	
	OHC	3	Skin
		3	Reproductive hazard
NYSTATIN (CAS 1400-61-9)	8 HR TWA	5000 mcg/m3	
	OHC	1	

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value	Form
GLYCERIN (CAS 56-81-5)	TWA	10 mg/m3	Mist.
SODIUM METABISULFITE (CAS 7681-57-4)	TWA	5 mg/m3	
Titanium dioxide (CAS 13463-67-7)	TWA	4 mg/m3	Respirable.
		10 mg/m3	Inhalable

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.

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 If contact is likely, safety glasses with side shields are recommended. (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. With respect to the above precautions select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time).

- Other Wear suitable protective 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 Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. An occupational/industrial hygiene monitoring method has been developed for this material. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional. New or expectant mothers are at greater risk if exposed to the active ingredient which is readily absorbed through the skin. They should not handle unpackaged product. Risk assessments must take this into consideration. Female employees anticipating pregnancy or with a confirmed pregnancy must be encouraged to notify an occupational health professional or their line manager. This will act as the trigger for individual re-assessment of the employee's work practices.

Environmental exposure controls

Hazard guidance and control recommendations 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	Cream.
Colour	Not available.
Odour	Not available.
Odour threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
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)	Not available.
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	No relevant additional information available.

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	May be harmful if swallowed.
Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Pharmacological effects might occur following direct contact with skin. Repeated contact may increase sensitivity of skin to bruising.
Eye contact	May be irritating to eyes.
Symptoms	The following adverse effects have been noted with therapeutic use of this material: itching; burning; pain; symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing).

11.1. Information on toxicological effects

Acute toxicity May be harmful if swallowed. May be harmful in contact with skin.

Components	Species	Test results
4-CHLORO-M-CRESOL (CAS 59-50-7)		
Acute		
Oral		
LD50	Rat	1830 mg/kg
Subacute		
Oral		
NOAEL	Rat	400 mg/kg/day, 28 Day
Subchronic		
Oral		
NOAEL	Rat	150 ppm, 13 weeks, dietary study
CET-3 (CAS 29636-87-1)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
CLOBETASONE BUTYRATE (CAS 25122-57-0)		
Acute		
Oral		
LD50	Rat	> 6000 mg/kg
Subacute		
Dermal		
TDL0	Rat	17.5 mg/kg, 5 weeks
Other		
TDL0	Rat	3 mg/kg, 30 Day, subcutaneous injection
Subchronic		
Other		
TDL0	Rat	15.6 mg/kg, 26 weeks, subcutaneous injection
GLYCERIN (CAS 56-81-5)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
GLYCERYL MONOSTEARATE (CAS 31566-31-1)		
Acute		
Oral		
LD50	Rat	> 5000 mg/kg
PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)		
Acute		
Oral		
LD50	Rat	> 15 g/kg
Chronic		
Oral		
NOAEL	Rat	>= 3000, 2 years
Titanium dioxide (CAS 13463-67-7)		
Acute		
Inhalation		
LC50	Rat	6820 mcg/m3
Oral		
LD50	Rat	> 24 g/kg

Components	Species	Test results
Chronic		
Inhalation		
LOEC	Rat	8.6 mg/m3, 1 years, TiO2 accumulated in interstitial macrophages, aggregated interstitial cells and particle laden macrophrages in lymphoid tissue.
NOAEC	Rat	250 mg/m3, 2 years, Highest dose
		5 mg/m3, 24 months
Subacute		
Inhalation		
LOEL	Rat	0.1 - 35 mg/m3, 4 weeks, Mild macrophage hyperplasia, no change in bronchio-alveolar lavage fluid.
NOAEC	Guinea pig	26 mg/m3, 3 weeks, No evidence of significant inflammation in respiratory tract.
Oral		
NOAEL	Rat	100000 ppm, 14 Day, Dietary study, highest dose tested.
Subchronic		
Inhalation		
LOEC	Rat	3.2 - 20 mg/m3, 8 min, Accumulation of TiO2 in macrophages and evidence of pulmonary inflammation.

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

Skin corrosion/irritation Repeated contact may increase sensitivity of skin to bruising.

Corrosivity

4-CHLORO-M-CRESOL
2 %, Literature data
Result: Irritant
Species: Human

Irritation Corrosion - Skin

TITANIUM DIOXIDE
Acute dermal irritation; OECD 404, Literature data
Result: Non-irritant
Species: Rabbit
Literature data
Result: Non-irritant
Species: Guinea pig
Literature data
Result: Non-irritant
Species: Human

Serious eye damage/eye irritation May be irritating to eyes.

Eye

4-CHLORO-M-CRESOL
0.1 %, Literature data
Result: Severe Irritant
Species: Rabbit

TITANIUM DIOXIDE
OECD 405, Literature data
Result: Mild irritant
Species: Rabbit

Respiratory sensitisation None known.

Skin sensitisation Allergic skin reactions might occur following repeated contact with this material in susceptible individuals.

Maximisation assay (Magnusson and Kligman)

CET-3
10 %
Result: positive
Species: Guinea pig

Sensitisation

TITANIUM DIOXIDE
5 % Optimisation Test, Literature data - Vehicle: petrolatum
Result: negative
Species: Guinea pig
Test Duration: 48 hour exposure

4-CHLORO-M-CRESOL
OECD 406 - Maximisation test, Literature data
Result: positive
Species: Guinea pig

Sensitisation

TITANIUM DIOXIDE	Patch test, Literature data Result: negative Species: Human
CLOBETASONE BUTYRATE	SAR / QSAR, DEREK, Lhasa, UK Result: positive SAR / QSAR, OECD QSAR Toolbox, Laboratory of Mathematical Chemistry, Bulgaria Result: positive

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Germ cell mutagenicity

Mutagenicity

4-CHLORO-M-CRESOL	125 mg/kg In vivo Micronucleus, Intra-peritoneal injection. Result: negative Species: Mouse Organ: Bone marrow Ames Result: Equivocal
CLOBETASONE BUTYRATE	Ames Result: negative
TITANIUM DIOXIDE	Ames, Literature data Result: negative
4-CHLORO-M-CRESOL	HPRT gene mutation in human lymphocytes Result: negative
CLOBETASONE BUTYRATE	In vitro cytogenetics assay Result: negative L5178Y mouse lymphoma thymidine kinase locus assay Result: negative
TITANIUM DIOXIDE	Micronucleus Assay in vitro, CHO cells, Literature data Result: negative Micronucleus Assay in vitro, cultured human peripheral lymphocytes, Literature data Result: positive Syrian Hamster Embryo (SHE) cell transformation assay Result: negative WIL2-NS HPRT/ t-Thioguanidine - Human B-Cell lymphoblastoid, Literature data Result: positive
CLOBETASONE BUTYRATE	Yeast mutation Result: negative in vivo cytogenetics assay Result: Equivocal

Carcinogenicity This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA. Contains a material (petrolatum) classified as a carcinogen by external agencies. These effects are suspected to be due to impurities that are not expected to be present in purified material used in this product. Titanium Dioxide produced carcinogenic effects in a lifetime study in mice. High concentrations or doses administered over an extended period of time were required to produce adverse effects.

TITANIUM DIOXIDE	0.5 mg/m3, Literature data Result: negative Species: Rat Test Duration: 24 months 0.72 - 14.8 mg/m3, Literature data Result: negative Species: Mouse 10 - 250 mg/m3, Dietary study - Literature data. Result: Inflammation at all doses with alveolar/bronchiolar adenoma at the highest concentration. Species: Rat Test Duration: 24 months
4-CHLORO-M-CRESOL	104 mg/kg/day, Literature data Result: NOAEL for renal necrosis and fibrosis Species: Rat
TITANIUM DIOXIDE	25000 - 50000 ppm, Dietary study Result: negative Species: Mouse 25000 - 50000 ppm, Dietary study - Literature data. Result: negative Species: Rat

Carcinogenicity

TITANIUM DIOXIDE	7.2 - 14.8 mg/m3, Literature data Result: Lung tumour Species: Rat Test Duration: 24 months
PHARMACEUTICAL GRADE PETROLATUM	>= 3000 mg/kg/day oral Result: NOAEL Species: Rat dermal Result: negative Species: Mouse

IARC Monographs. Overall Evaluation of Carcinogenicity

SODIUM METABISULFITE (CAS 7681-57-4)	3 Not classifiable as to carcinogenicity to humans.
Titanium dioxide (CAS 13463-67-7)	2B Possibly carcinogenic to humans.

Reproductive toxicity Components in this product have been shown to cause birth defects and reproductive disorders in laboratory animals.

Reproductive toxicity

Reproductivity

CLOBETASONE BUTYRATE	Embryofetal Development Result: Developmental abnormalities. Species: Rabbit Embryofetal Development Result: Maternal toxicity; adverse foetal effects Species: Rat Fertility, Glucocorticoid Result: Effects on fertility, foetal toxicity Species: Rat

Specific target organ toxicity - single exposure None known.

Specific target organ toxicity - repeated exposure Adrenal glands. Bone tissue. Immune system. May cause damage to organs through prolonged or repeated exposure.

Aspiration hazard Not established.

Mixture versus substance information No information available.

Other information Caution - Pharmaceutical agent.

SECTION 12: Ecological information

12.1. Toxicity No information is available about the potential of this product to produce adverse environmental effects. The product contains a substance which may cause long-term adverse effects in the environment.

Components		Species	Test results
CLOBETASONE BUTYRATE (CAS 25122-57-0)			
Aquatic			
Acute			
Activated Sludge Respiration	IC50	Residential sludge	> 100 mg/l, 3 hours, Nominal, OECD 209
	NOEC	Residential sludge	100 mg/l, 3 hours
Crustacea	EC50	Water flea (Daphnia magna)	> 0.43 mg/l, 48 hours, Measured. OECD 202
	NOEC	Water flea (Daphnia magna)	0.43 mg/l, 48 hours
SODIUM METABISULFITE (CAS 7681-57-4)			
Chronic			
Other	LC50	Pseudomonas putida	56 mg/l, 17 hours
Aquatic			
Acute			
Algae	EC50	Green algae (Scenedesmus subspicatus)	40 mg/l, 96 hours
Crustacea	EC50	Water flea (Daphnia magna)	89 mg/l, 24 hours
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	32 mg/l, 96 hours
		Rainbow trout (Adult Oncorhyncus mykiss)	100 - 200 mg/l, 96 hours

Components		Species	Test results
Titanium dioxide (CAS 13463-67-7)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	> 1000 mg/l, 48 hours, Static test

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

12.2. Persistence and degradability Not available.

Persistence and degradability

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

CLOBETASONE BUTYRATE	20 %, 8 days Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge

12.3. Bioaccumulative potential

Partition coefficient n-octanol/water (log Kow)

4-CHLORO-M-CRESOL	2.78 - 3.1 3.1
CET-3	-0.4
CLOBETASONE BUTYRATE	3.63 (Measured).
GLYCERIN	-1.76

12.4. Mobility in soil Not available.

Mobility in general Not available.

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. This material and its container must be disposed of as hazardous waste. 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

4-CHLORO-M-CRESOL (CAS 59-50-7)
PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)
SODIUM METABISULFITE (CAS 7681-57-4)

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

4-CHLORO-M-CRESOL (CAS 59-50-7)
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. Pregnant women should not work with the product, if there is the least risk of exposure.
National regulations	Young people under 18 years old are not allow to work with this product according to the EU Directive 94/33/EC on the protection of young people at work. 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	R21/22 Harmful in contact with skin and if swallowed. R22 Harmful if swallowed. R31 Contact with acids liberates toxic gas. R36 Irritating to eyes. R36/37/38 Irritating to eyes, respiratory system and skin. R41 Risk of serious damage to eyes. R43 May cause sensitization by skin contact. R48/20 Harmful: danger of serious damage to health by prolonged exposure through inhalation.

R48/20/21 Harmful: danger of serious damage to health by prolonged exposure through inhalation and in contact with skin.
R50 Very toxic to aquatic organisms.
R53 May cause long term adverse effects in the aquatic environment.
R61 May cause harm to the unborn child.
R62 Possible risk of impaired fertility.
H302 Harmful if swallowed.
H312 Harmful in contact with skin.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
H360D May damage the unborn child.
H361f Suspected of damaging fertility.
H373 May cause damage to organs through prolonged or repeated exposure.
H400 Very toxic to aquatic life.
H413 May cause long lasting harmful effects to aquatic life.

Revision information

Product and Company Identification: Business Units
Composition / Information on Ingredients: Ingredients
EXPOSURE CONTROLS/PERSONAL PROTECTION:
Physical & Chemical Properties:
Transport Information: Agency Name and Packaging Type/Transport Mode Selection

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.