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	PAXIL ORAL SUSPENSION
Registration number	-
Synonyms	SEROXAT LIQUID * SEROXAT SUSPENSION * DEROXAT SUSPENSION * FORMULA CODE B046 * PAROXETINE HYDROCHLORIDE, FORMULATED PRODUCT
Issue date	25-November-2013
Version number	13
Revision date	25-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

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.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
PAROXETINE HYDROCHLORIDE HEMIHYDRATE	< 1	110429-35-1 -	-	-	
Classification: **DSD:** Repr. Cat. 3;R62-63, Xn;R22, Xi;R37-41, N;R51-53 **CLP:** Acute Tox. 4;H302, Eye Dam. 1;H318, STOT SE 3;H335, Repr. 2;H361fd, STOT RE 1;H372, Aquatic Chronic 2;H411					
Titanium dioxide	< 1	13463-67-7 236-675-5	-	-	
Classification: **DSD:** - **CLP:** -					
CITRIC ACID ANHYDROUS	< 0.3	77-92-9 201-069-1	-	-	
Classification: **DSD:** Xi;R36 **CLP:** Eye Irrit. 2;H319					

Other components below reportable levels >98.0

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 In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). 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 Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Skin contact Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.

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). If ingestion of a large amount does occur, call a poison control centre immediately.

4.2. Most important symptoms and effects, both acute and delayed The following adverse effects have been noted with therapeutic use of this material: nausea; diarrhoea; constipation; dry mouth; drowsiness; dizziness; weakness; insomnia; sexual dysfunction; tremor; palpitations.

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 current prescribing information or to the local poison control information centre.

SECTION 5: Firefighting measures

General fire hazards No unusual fire or explosion hazards noted.

5.1. Extinguishing media

Suitable extinguishing media Water fog. Foam. Dry chemical powder. Carbon dioxide (CO_2).

Unsuitable extinguishing media None known.

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 In the event of fire, cool tanks with water spray.

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. 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 taste or swallow. Avoid prolonged exposure. Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. When using, do not eat, drink or smoke. Wash hands thoroughly after handling. Avoid release to the environment. Do not empty into drains.
7.2. Conditions for safe storage, including any incompatibilities	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
CITRIC ACID ANHYDROUS (CAS 77-92-9)	8 HR TWA	5000 mcg/m3	
	OHC	1	
PAROXETINE HYDROCHLORIDE HEMIHYDRATE (CAS 110429-35-1)	8 HR TWA	40 mcg/m3	
	OHC	3	Reproductive hazard

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value	Form
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	Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits. 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	Chemical goggles are recommended. (eg. EN 166) Eye wash fountains are required.
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	When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. 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	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 might be at greater risk from overexposure. 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	Contain spills and prevent releases and observe national regulations on emissions.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	
Physical state	Liquid.
Form	Suspension.
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	Not available.
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 Contact with incompatible materials.

10.5. Incompatible materials Strong oxidising agents. Fluorine.

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. Occupational exposure to the substance or mixture may cause adverse effects.

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 May be irritating to the skin.

Eye contact Irritation can occur following direct contact with this material. Risk of serious damage to eyes.

Symptoms The following adverse effects have been noted with therapeutic use of this material: nausea; diarrhoea; constipation; dry mouth; drowsiness; dizziness; weakness; insomnia; sexual dysfunction; tremor; palpitations.

11.1. Information on toxicological effects

Acute toxicity May be harmful if swallowed. May irritate eyes and skin.

Components	Species	Test results
CITRIC ACID ANHYDROUS (CAS 77-92-9)		
Acute		
Oral		
LD50	Rat	3000 mg/kg
PAROXETINE HYDROCHLORIDE HEMIHYDRATE (CAS 110429-35-1)		
Acute		
Oral		
LD50	Rat	374 mg/kg
Chronic		
Oral		
NOAEL	Monkey	3.5 mg/kg/day, 52 weeks
	Rat	5 mg/kg/day, 52 weeks
TD	Monkey	6 mg/kg/day, 52 weeks
	Rat	25 mg/kg/day, 52 weeks
Titanium dioxide (CAS 13463-67-7)		
Acute		
Inhalation		
LC50	Rat	6820 mcg/m3
Oral		
LD50	Rat	> 24 g/kg
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

Components	Species	Test results
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 Prolonged skin contact may cause temporary irritation.

Irritation Corrosion - Skin

TITANIUM DIOXIDE	Acute dermal irritation; OECD 404, Literature data Result: Non-irritant Species: Rabbit
PAROXETINE HYDROCHLORIDE HEMIHYDRATE	Acute dermal irritation; OECD 404, Primary Irritation Index: 0 Result: Non-irritating to intact skin Species: Rabbit Acute dermal irritation; OECD 404, Primary Irritation Index: 3 Result: Irritating to damaged skin. Species: Rabbit
TITANIUM DIOXIDE	Literature data Result: Non-irritant Species: Guinea pig Literature data Result: Non-irritant Species: Human

Serious eye damage/eye irritation

Eye

PAROXETINE HYDROCHLORIDE HEMIHYDRATE	OECD 405, Kay and Calndra - Grade 8. Result: Very severe irritant Species: Rabbit
TITANIUM DIOXIDE	OECD 405, Literature data Result: Mild irritant Species: Rabbit

Respiratory sensitisation Due to partial or complete lack of data the classification is not possible.

Skin sensitisation This product is not expected to cause skin sensitisation.

Sensitisation

TITANIUM DIOXIDE	5 % Optimisation Test, Literature data - Vehicle: petrolatum Result: negative Species: Guinea pig Test Duration: 48 hour exposure
PAROXETINE HYDROCHLORIDE HEMIHYDRATE	OECD 406, 0 % Response rate. Result: negative Species: Guinea pig
TITANIUM DIOXIDE	Patch test, Literature data Result: negative Species: Human

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

PAROXETINE HYDROCHLORIDE HEMIHYDRATE	Ames - Screen Result: negative
TITANIUM DIOXIDE	Ames, Literature data Result: negative
PAROXETINE HYDROCHLORIDE HEMIHYDRATE	Chromosomal Aberration Assay In Vitro Result: negative

Mutagenicity

PAROXETINE HYDROCHLORIDE HEMIHYDRATE	GreenScreen mammalian cell mutation assay Result: negative L5178Y mouse lymphoma thymidine kinase locus assay, GLP 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
PAROXETINE HYDROCHLORIDE HEMIHYDRATE	Micronucleus Assay, GLP Result: negative Species: Mouse Mutation in Drosophila melanogaster Result: negative Sister Chromatid Exchange Result: negative
TITANIUM DIOXIDE	Syrian Hamster Embryo (SHE) cell transformation assay Result: negative
PAROXETINE HYDROCHLORIDE HEMIHYDRATE	Unscheduled DNA Synthesis, in vivo - in vitro Result: negative Species: Rat
TITANIUM DIOXIDE	WIL2-NS HPRT/ t-Thioguanidine - Human B-Cell lymphoblastoid, Literature data Result: positive

Carcinogenicity Titanium Dioxide is listed as a carcinogen by external agencies. Carcinogenic activity was seen in inhalation studies using laboratory animals. 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 25000 - 50000 ppm, Dietary study Result: negative Species: Mouse 25000 - 50000 ppm, Dietary study - Literature data. Result: negative Species: Rat 7.2 - 14.8 mg/m3, Literature data Result: Lung tumour Species: Rat Test Duration: 24 months
PAROXETINE HYDROCHLORIDE HEMIHYDRATE	Result: negative Species: Mouse Test Duration: 18 months Result: negative Species: Rat Test Duration: 2 years

IARC Monographs. Overall Evaluation of Carcinogenicity

Titanium dioxide (CAS 13463-67-7)	2B Possibly carcinogenic to humans.

Reproductive toxicity Epidemiology studies have identified the ingredient paroxetine hydrochloride hemihydrate as a possible cause of developmental toxicity in humans.

Reproductive toxicity

Reproductivity

PAROXETINE HYDROCHLORIDE HEMIHYDRATE	13 mg/kg/day Fertility, Female Result: Maternal toxicity; adverse effects on offspring. Species: Rat 13 mg/kg/day Fertility, Male Result: Parental toxicity, no adverse effects on fertility. Species: Rat

Reproductivity

PAROXETINE HYDROCHLORIDE HEMIHYDRATE

3 mg/kg/day Embryo-foetal development
Result: Maternal NOAEL
Species: Rabbit
4.3 mg/kg/day Fertility, Female
Result: NOAEL
Species: Rat
5 mg/kg/day Embryo-foetal development
Result: NOAEL
Species: Rat
6 mg/kg/day Embryofetal Development
Result: Maternal toxicity; Foetal NOAEL
Species: Rabbit
>= 50 mg/kg/day Embryo-foetal development
Result: Maternal toxicity; adverse foetal effects
Species: Rat
Embryo-foetal development, Possible association with clinical use reported in epidemiology studies.
Species: Human
Organ: Cardiovascular malformations
Fertility, Male, Possible association with clinical use reported in epidemiology studies.
Result: Reversible effects on sperm quality.
Species: Human

Specific target organ toxicity - single exposure Central nervous system.

PAROXETINE HYDROCHLORIDE HEMIHYDRATE — Organ: Central nervous system.

Specific target organ toxicity - repeated exposure May cause damage to organs through prolonged or repeated exposure.

PAROXETINE HYDROCHLORIDE HEMIHYDRATE — Epidemiology
Organ: Bone; Testes (reversible).

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

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. Contains a substance which causes risk of hazardous effects to the environment. The product contains a substance which may cause long-term adverse effects in the environment.

Components		Species	Test results
CITRIC ACID ANHYDROUS (CAS 77-92-9)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	120 mg/l, 72 hours, Static test
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	1516 mg/l, 96 hours, Static test
		Golden ide/orfe (Adult Leuciscus idus)	440 - 760 mg/l, 96 hours, Static test
Microtox	EC50	Microtox	14 mg/l, 15 minutes
PAROXETINE HYDROCHLORIDE HEMIHYDRATE (CAS 110429-35-1)			
Aquatic			
Acute			
Activated Sludge Respiration	IC50	Residential sludge	25 mg/l, 3 hours
Crustacea	EC50	Water flea (Daphnia magna)	2.5 mg/l, 48 hours, Static test, OECD 202
	NOEC	Water flea (Daphnia magna)	0.49 mg/l, 48 hours
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	1.6 mg/l, 96 hours, Static test, OECD 203
	NOEC	Bluegill sunfish (Adult Lepomis macrochirus)	0.18 mg/l, 96 hours, Static test
Microtox	EC50	Microtox	8.2 mg/l, 15 minutes

Components		Species	Test results
Chronic			
Crustacea	LOEC	Water flea (Ceriodaphnia dubia)	0.5 mg/l, 7 days, Static renewal test, EPA 2002
	NOEC	Water flea (Ceriodaphnia dubia)	0.25 mg/l, 7 days
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

Persistence and degradability

Photolysis

Half-life (Photolysis-aqueous)

PAROXETINE HYDROCHLORIDE HEMIHYDRATE 2.4 Hours Measured, Deionized Water

UV/visible spectrum wavelength

PAROXETINE HYDROCHLORIDE HEMIHYDRATE 292 nm, pH 5-9

Hydrolysis

Half-life (Hydrolysis-neutral)

PAROXETINE HYDROCHLORIDE HEMIHYDRATE > 1 years Measured, Deionized Water

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

CITRIC ACID ANHYDROUS 98 %, 2 days Modified Zahn-Wellens, Activated sludge

12.3. Bioaccumulative potential

Partition coefficient n-octanol/water (log Kow)

PAROXETINE HYDROCHLORIDE HEMIHYDRATE 1.3

12.4. Mobility in soil

Adsorption

Sludge/biomass distribution coefficient - log Kd

PAROXETINE HYDROCHLORIDE HEMIHYDRATE 2.94 Measured

Soil/sediment sorption - log Koc

PAROXETINE HYDROCHLORIDE HEMIHYDRATE 0.8 Estimated

Mobility in general

Volatility

Henry's law

CITRIC ACID ANHYDROUS < 0 atm m^3/mol Calculated, 25 °C

PAROXETINE HYDROCHLORIDE HEMIHYDRATE 0 atm m3/mol Calculated

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

Not listed.

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

Not listed.

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

Not listed.

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

Not listed.

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

Not listed.

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	R22 Harmful if swallowed. R36 Irritating to eyes. R37 Irritating to respiratory system. R41 Risk of serious damage to eyes. R51 Toxic to aquatic organisms. R53 May cause long term adverse effects in the aquatic environment. R62 Possible risk of impaired fertility. R63 Possible risk of harm to the unborn child. H302 Harmful if swallowed. H318 Causes serious eye damage. H319 Causes serious eye irritation. H335 May cause respiratory irritation. H361fd Suspected of damaging fertility. Suspected of damaging the unborn child. H411 Toxic to aquatic life with long lasting effects.
Revision information	Product and Company Identification: Physical States Composition / Information on Ingredients: Ingredients 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.