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	ZANTAC TABLETS
Registration number	-
Synonyms	ZANTAC 150 TABLETS * ZANTAC 300 TABLETS * ANTAK TABLETS * AZANTAC TABLETS * SOSTRIL TABLETS * ZANDINE TABLETS * ZANTIC TABLETS * ZINETAC TABLETS * RANITIDINE HYDROCHLORIDE, FORMULATED PRODUCT
Issue date	07-November-2014
Version number	12
Revision date	07-November-2014

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.

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
RANITIDINE HYDROCHLORIDE	50 - < 60	66357-59-3 266-333-0	-	-	
Classification: **DSD:** F;R11, Xn;R22, R42/43 **CLP:** Flam. Sol. 1;H228, Acute Tox. 4;H302, Skin Sens. 1;H317, Resp. Sens. 1;H334					
MICROCRYSTALLINE CELLULOSE	15 - < 45	9004-34-6 232-674-9	-	-	
Classification: **DSD:** - **CLP:** -					
MAGNESIUM STEARATE	0.1 - < 5	557-04-0 209-150-3	-	-	
Classification: **DSD:** - **CLP:** -					
Titanium dioxide	<5	13463-67-7 236-675-5	-	-	
Classification: **DSD:** - **CLP:** -					
Other components below reportable levels	10 - < 20				

List of abbreviations and symbols that may be used above

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). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

4.1. Description of first aid measures

Inhalation Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if symptoms develop or persist.

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. Do not induce vomiting without advice from poison control center.

4.2. Most important symptoms and effects, both acute and delayed Accidental exposure or contact might produce: Irritation of eyes and mucous membranes. Sensitisation. Skin irritation. May cause an allergic skin reaction. Dermatitis. Rash.
The following adverse effects have been noted with therapeutic use of this material: decrease in heart rate; decrease in blood pressure; temporary decrease in white blood cell counts; coughing; increased mucous secretion.

4.3. Indication of any immediate medical attention and special treatment needed 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. Foam. Dry chemical powder. Carbon dioxide (CO2).

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

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 protective clothing and equipment consistent with the degree of hazard. Keep out of low areas. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. For personal protection, see section 8.
For emergency responders	Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS.
6.2. Environmental precautions	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.
6.3. Methods and material for containment and cleaning up	Collect and place it in a suitable, properly labelled container for recovery or disposal. Stop the flow of material, if this is without risk. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water. No specific decontamination or detoxification procedures have been identified for this product.
6.4. Reference to other sections	For personal protection, see section 8. For waste disposal, see section 13 of the SDS.

SECTION 7: Handling and storage

7.1. Precautions for safe handling	Avoid prolonged exposure. Avoid breaking or crushing tablets.
7.2. Conditions for safe storage, including any incompatibilities	Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS). No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.
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
RANITIDINE HYDROCHLORIDE (CAS 66357-59-3)	15 MIN STEL	50 mcg/m3	SKIN SENSITISER
		50 mcg/m3	RESPIRATORY SENSITISER
	OHC	3	

Ireland. Occupational Exposure Limits

Components	Type	Value	Form
MAGNESIUM STEARATE (CAS 557-04-0)	TWA	10 mg/m3	
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	STEL	20 mg/m3	Total inhalable dust.
	TWA	4 mg/m3	Respirable dust.
		10 mg/m3	Total inhalable dust.
Titanium dioxide (CAS 13463-67-7)	TWA	4 mg/m3	Respirable dust.
		10 mg/m3	Total inhalable dust.

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.

Exposure guidelines

8.2. Exposure controls

Appropriate engineering controls	General ventilation normally adequate.

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	Not normally needed. If contact is likely, safety glasses with side shields are recommended. (e.g. EN 166). Eye wash fountain is recommended.
Skin protection	
- Hand protection	Not normally needed. For prolonged or repeated skin contact use suitable protective gloves. Select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time).
- Other	Wear suitable protective clothing as protection against splashing or contamination. (EN 14605 for splashes, EN ISO 13982 for dust). Not normally needed.
Respiratory protection	No personal respiratory protective equipment normally required. 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	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.

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	Solid.
Form	Tablet.
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)

Solubility (water)	Not available.
Solubility (other)	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	This product is expected to be stable.
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	None known. Irritating and/or toxic fumes and gases may be emitted upon the product's 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

Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard. Prolonged inhalation may be harmful.
Skin contact	Health injuries are not known or expected under normal use.
Eye contact	Health injuries are not known or expected under normal use.
Ingestion	Health injuries are not known or expected under normal use. Expected to be a low ingestion hazard. However, ingestion is not likely to be a primary route of occupational exposure.
Symptoms	Accidental exposure or contact might produce: Irritation of eyes and mucous membranes. Sensitisation. Skin irritation. Dermatitis. May cause an allergic skin reaction. Rash. The following adverse effects have been noted with therapeutic use of this material: decrease in heart rate; decrease in blood pressure; temporary decrease in white blood cell counts; coughing; increased mucous secretion.

11.1. Information on toxicological effects

Acute toxicity May be harmful if swallowed.

Components	Species	Test results
MAGNESIUM STEARATE (CAS 557-04-0)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)		
Acute		
Dermal		
LD50	Rabbit	> 2000 mg/kg
Oral		
LD50	Rat	> 2000 mg/kg
RANITIDINE HYDROCHLORIDE (CAS 66357-59-3)		
Acute		
Oral		
LD50	Rat	> 1000 mg/kg
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 Health injuries are not known or expected under normal use. Due to partial or complete lack of data the classification is not possible.

Irritation Corrosion - Skin

TITANIUM DIOXIDE	0, Literature data Result: Non-irritant Species: Guinea pig 0, Literature data Result: Non-irritant Species: Human Acute dermal irritation; OECD 404, Literature data Result: Non-irritant Species: Rabbit
RANITIDINE HYDROCHLORIDE	Acute dermal irritation; OECD 404, Primary dermal irritation index = 0 Result: negative Species: Rabbit

Irritation Corrosion - Skin: P.I.I. value

MAGNESIUM STEARATE	0

Serious eye damage/eye irritation Direct contact with eyes may cause temporary irritation.

Eye

RANITIDINE HYDROCHLORIDE	Acute ocular irritation; OECD 405, Kay and Calandra score = 3 Result: Minimal Irritant Species: Rabbit IRE Assay Result: Negative; not likely to be a severe irritant Species: Rabbit
TITANIUM DIOXIDE	OECD 405, Literature data Result: Mild irritant Species: Rabbit

Eye / Kay and Calandra class - Intact

MAGNESIUM STEARATE	4 Recovery Period: 2 days

Respiratory sensitisation May cause allergy or asthma symptoms or breathing difficulties if inhaled.

RANITIDINE HYDROCHLORIDE	Occupational exposure Result: positive Species: Human

Skin sensitisation May cause an allergic skin reaction.

Sensitisation

TITANIUM DIOXIDE	5 % Optimisation Test, Literature data - Vehicle: petrolatum Result: negative Species: Guinea pig Test Duration: 48 hour exposure
RANITIDINE HYDROCHLORIDE	Occupational exposure Result: positive Species: Human Optimisation Test Result: Weak sensitiser 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.

Mutagenicity

RANITIDINE HYDROCHLORIDE	Ames Assay, GLP assay Result: negative
TITANIUM DIOXIDE	Ames, Literature data Result: negative
RANITIDINE HYDROCHLORIDE	Chromosomal Aberration Assay In Vitro, human lymphocytes, Ranitidine bismuth citrate tested Result: positive Chromosomal Aberration Assay In Vivo; germ cells, Maximum dose = 1000 mg/kg Result: negative Species: Mouse GreenScreen 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
RANITIDINE HYDROCHLORIDE	Micronucleus Test Result: negative Species: Rat Mouse Lymphoma Cell (L5178Y) Mutation Assay, GLP assay Result: negative SOS/umu Assay Result: negative
TITANIUM DIOXIDE	Syrian Hamster Embryo (SHE) cell transformation assay Result: negative
RANITIDINE HYDROCHLORIDE	Unscheduled DNA Synthesis in vivo, Maximum dose = 200 mg/kg Result: negative Species: Rat Organ: Stomach
TITANIUM DIOXIDE	WIL2-NS HPRT/ t-Thioguanidine - Human B-Cell lymphoblastoid, Literature data Result: positive
RANITIDINE HYDROCHLORIDE	Yeast Mutation Assay Result: negative

Carcinogenicity Carcinogenic effects are not expected as a result of occupational exposure.

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
RANITIDINE HYDROCHLORIDE	2 year bioassay, Maximum dose = 2000 mg/kg/day Result: negative Species: Mouse

Carcinogenicity

RANITIDINE HYDROCHLORIDE	2 year bioassay, Maximum dose = 2000 mg/kg/day Result: negative Species: Rat
TITANIUM DIOXIDE	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

IARC Monographs. Overall Evaluation of Carcinogenicity

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

Reproductive toxicity Contains no ingredient listed as toxic to reproduction Based on available data, the classification criteria are not met.

Reproductivity

RANITIDINE HYDROCHLORIDE	Embryo-foetal development - Oral Result: Foetal NOAEL = 100 mg/kg/day (maximum dose); Maternal NOAEL = 25 mg/kg/day (decreased weight gain at 50 and 100 mg/kg/day) Species: Rat Embryo-foetal development - Oral Result: NOAEL = 100 mg/kg/day (maximum dose) Species: Rabbit Fertility Result: NOAEL / fertility = 100 mg/kg/day (male) and 200 mg/kg/day (female) (maximum doses) Species: Rat

Specific target organ toxicity - single exposure None known. Due to partial or complete lack of data the classification is not possible.

Specific target organ toxicity - repeated exposure None known. Due to partial or complete lack of data the classification is not possible.

Aspiration hazard Due to partial or complete lack of data the classification is not possible.

Mixture versus substance information No information available.

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

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
MAGNESIUM STEARATE (CAS 557-04-0)			
Aquatic			
Acute			
Fish	EC50	Orange-red killfish (Adult Oryzias latipes)	130 mg/l, 96 hours
RANITIDINE HYDROCHLORIDE (CAS 66357-59-3)			
Aquatic			
Acute			
Activated Sludge Respiration	IC50	Residential sludge	> 1000 mg/l, 3 hours OECD 209
Algae	EC50	Green algae (Selenastrum capricornutum)	167 mg/l, 72 hours OECD 201
	NOEC	Green algae (Selenastrum capricornutum)	56 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	730 mg/l, 48 hours Static test, OECD 202
	NOEC	Water flea (Daphnia magna)	347 mg/l, 48 hours Static test
Fish	EC50	Rainbow trout (Juvenile Oncorhyncus mykiss)	> 112 mg/l, 14 days Flow-through test, OECD 203

Components		Species	Test results
	NOEC	Rainbow trout (Juvenile Oncorhyncus mykiss)	112 mg/l, 14 days Flow-through test
Chronic			
Crustacea	LOEC	Water flea (Ceriodaphnia dubia)	100 mg/l, 8 days Static renewal test, EPA 1002
	NOEC	Water flea (Ceriodaphnia dubia)	32 mg/l, 8 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

Photolysis

Half-life (Photolysis-aqueous)

RANITIDINE HYDROCHLORIDE: 70 Minutes Measured, Lake water

Half-life (Photolysis-atmospheric)

MAGNESIUM STEARATE: 17 Hours Estimated

UV/visible spectrum wavelength

MAGNESIUM STEARATE: 210 nm

RANITIDINE HYDROCHLORIDE: 313 nm Measured, pH 7

Hydrolysis

Half-life (Hydrolysis-neutral)

RANITIDINE HYDROCHLORIDE: > 1 years Measured

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

MAGNESIUM STEARATE: 77 %, 28 days BOD

RANITIDINE HYDROCHLORIDE: 2 %, 28 days Modified Zahn-Wellens, DOC removal., Activated sludge
43 %, 28 days Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge

Percent degradation (Aerobic biodegradation-ready)

MAGNESIUM STEARATE: 95 %, 22 days Sturm test

RANITIDINE HYDROCHLORIDE: < 1 %, 28 days Modified Sturm test.

Percent degradation (Aerobic biodegradation-soil)

MAGNESIUM STEARATE: 50 %, 13 days

RANITIDINE HYDROCHLORIDE: 3 - 10 %, 67 days

Percent degradation (Anaerobic biodegradation)

RANITIDINE HYDROCHLORIDE: 12 %, 35 days

12.3. Bioaccumulative potential

Partition coefficient n-octanol/water (log Kow)

RANITIDINE HYDROCHLORIDE: 0.0815

Bioconcentration factor (BCF)

MAGNESIUM STEARATE: > 9999 Estimated

12.4. Mobility in soil

Adsorption

Soil/sediment sorption - log Koc

MAGNESIUM STEARATE: 5.86 Estimated

RANITIDINE HYDROCHLORIDE: 2.51 - 4.49, pH 5-7

Mobility in general

Volatility

Henry's law

RANITIDINE HYDROCHLORIDE: 0 atm m^3/mol, 24 C Estimated

Distribution

Octanol/water distribution coefficient log DOW

RANITIDINE HYDROCHLORIDE: -1.09, pH 7
-2.5, pH 5
0.14, pH 9

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). Avoid discharge into water courses or onto the ground.
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 discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable 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(10) 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	Young people under 18 years old are not allowed 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	R11 Highly flammable. R22 Harmful if swallowed. R42/43 May cause sensitization by inhalation and skin contact. H228 Flammable solid. H302 Harmful if swallowed. H317 May cause an allergic skin reaction. H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Revision information	Product and Company Identification: Product and Company Identification Composition / Information on Ingredients: Ingredients Physical & Chemical Properties: Ecological Information: Mobility Transport Information: Material Transportation Information Regulatory Information: United States 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.