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	COREG TABLETS
Registration number	-
Synonyms	COREG 3,125 MG TABLETS * COREG 6,25 MG TABLETS * COREG 12,5 MG TABLETS * COREG 25 MG TABLETS * CARZEC TABLETS * CARVEDILOL, FORMULATED PRODUCT
Issue date	29-February-2016
Version number	20
Revision date	29-February-2016

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
CARVEDILOL	5 - < 10	72956-09-3 474-310-3	-	-	
Classification:	Skin Sens. 1;H317, Aquatic Acute 1;H400, Aquatic Chronic 1;H410				
POLYVINYLPOLYPYRROLIDONE	3 - < 5	25249-54-1 -	-	-	
Classification:	Aquatic Chronic 3;H412				
Silicon dioxide	1 - < 3	7631-86-9 231-545-4	-	-	
Classification:	-				
Sucrose	1 - < 3	57-50-1 200-334-9	-	-	
Classification:	-				
Titanium dioxide	< 1	13463-67-7 236-675-5	-	-	
Classification:	Carc. 2;H351				
Other components below reportable levels	80 - < 90				

List of abbreviations and symbols that may be used above

#: This substance has been assigned Union workplace exposure limit(s).
M: M-factor
PBT: persistent, bioaccumulative and toxic substance.
vPvB: very persistent and very bioaccumulative substance.

Composition comments The full text for all H-statements 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. 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. Do not induce vomiting without advice from poison control center.

4.2. Most important symptoms and effects, both acute and delayed May cause an allergic skin reaction. Dermatitis. Rash. Sensitisation. Irritation of eyes and mucous membranes. The following adverse effects have been noted with therapeutic use of this material: dizziness; fatigue; decrease in blood pressure; diarrhoea; weakness; decrease in heart rate.

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. 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 appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. 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 SDS.
6.2. Environmental precautions	Avoid release to the environment. Inform appropriate managerial or supervisory personnel of all environmental releases. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.
6.3. Methods and material for containment and cleaning up	Prevent entry into waterways, sewer, basements or confined areas. Stop the flow of material, if this is without risk. Following product recovery, flush area with water.
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 breathing dust/fume/gas/mist/vapours/spray. Avoid contact with eyes, skin, and clothing. Avoid prolonged exposure. Provide adequate ventilation. Wear appropriate personal protective equipment. Avoid release to the environment. Observe good industrial hygiene practices.
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).
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
CARVEDILOL (CAS 72956-09-3)	8 HR TWA	30 mcg/m3	
	OHC	3	SKIN SENSITISER

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.
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	Not normally needed. Wear suitable protective clothing as protection against splashing or contamination. (EN 14605 for splashes, EN ISO 13982 for dust).
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. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.
Environmental exposure controls	
Hazard guidance and control recommendations	Inform appropriate managerial or supervisory personnel of all environmental 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 explosive.
Oxidising properties	Not oxidising.
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.

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 Health injuries are not known or expected under normal use. Inhalation of dusts may cause respiratory irritation.

Skin contact Health injuries are not known or expected under normal use. May cause an allergic skin reaction.

Eye contact Dust or powder may irritate eye tissue. Health injuries are not known or expected under normal use.

Ingestion Health injuries are not known or expected under normal use. May be harmful if swallowed.

Symptoms Sensitisation. Irritation of eyes and mucous membranes. The following adverse effects have been noted with therapeutic use of this material: dizziness; fatigue; decrease in blood pressure; diarrhoea; weakness; decrease in heart rate.

11.1. Information on toxicological effects

Acute toxicity Health injuries are not known or expected under normal use. Adverse effects might occur with repeated ingestion.

Components	Species	Test results
CARVEDILOL (CAS 72956-09-3)		
Acute		
Oral		
LD	Rat	> 8000 mg/kg
Chronic		
Oral		
LOEL	Rat	100 mg/kg/day 90-Day Study
NOAEL	Rat	30 mg/kg/day 90-Day Study
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
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.

Irritation Corrosion - Skin

Titanium dioxide	0, Literature data Result: Non-irritant Species: Guinea pig 0, Literature data Result: Non-irritant Species: Human
CARVEDILOL	Acute dermal irritation, Primary dermal irritation index = 0 Result: negative Species: Rabbit
Titanium dioxide	Acute dermal irritation; OECD 404, Literature data Result: Non-irritant Species: Rabbit

Serious eye damage/eye irritation Dust or powder may irritate eye tissue. Health injuries are not known or expected under normal use.

Eye

CARVEDILOL	Acute ocular irritation, Kay and Calandra score = 3 Result: Mild irritant
Titanium dioxide	OECD 405, Literature data Result: Mild irritant Species: Rabbit

Respiratory sensitisation Not available.

Skin sensitisation May cause an allergic skin reaction. Health injuries are not known or expected under normal use.

Sensitisation

Titanium dioxide	5 % Optimisation Test, Literature data - Vehicle: petrolatum Result: negative Species: Guinea pig Test Duration: 48 hour exposure
CARVEDILOL	Maximisation assay (Magnusson and Kligman), 20% of treated animals responding; graded as a mild sensitiser Result: Equivocal Species: Guinea pig Occupational exposure Result: Contact sensitiser.
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

CARVEDILOL	Ames Assay, GLP assay Result: negative
Titanium dioxide	Ames, Literature data Result: negative
CARVEDILOL	Chinese Hamster Ovarian Cell Test, HGPRT locus mutation Result: negative Chromosomal Aberration Assay In Vitro, human lymphocytes Result: negative 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
CARVEDILOL	Micronucleus Test, Maximum dose = 1500 mg/kg Result: negative Species: Hamster
Titanium dioxide	Syrian Hamster Embryo (SHE) cell transformation assay Result: negative WIL2-NS HPRT/ t-Thioguanidine - Human B-Cell lymphoblastoid, Literature data Result: Positive

Carcinogenicity Health injuries are not known or expected under normal use. 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.

Carcinogenicity

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
CARVEDILOL	2 year bioassay Result: negative Species: Mouse 2 year bioassay 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

Silicon dioxide (CAS 7631-86-9)	3 Not classifiable as to carcinogenicity to humans.
Titanium dioxide (CAS 13463-67-7)	2B Possibly carcinogenic to humans.

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

Reproductivity

CARVEDILOL	Embryo-foetal development - Oral, Dose = 15 mg/kg/day Result: Maternal toxicity; Foetal NOAEL Species: Rabbit Embryo-foetal development - Oral, Dose = 75 mg/kg/day Result: Maternal toxicity; increaed post-implantation loss Species: Rabbit Embryo-foetal development - Oral, Dose >/= 300 mg/kg/day; equivalent to 50X maximum recommended human dose Result: Maternal toxicity; delayed foetal skeletal development and reduced foetal weight; increased post-implantation loss Species: Rat Female Fertility / Early Embryonic & Embryo-foetal Development, Dose = 60 mg/kg/day Result: Maternal toxicity; Foetal NOAEL Species: Rat Female Fertility / Early Embryonic & Embryo-foetal Development, Dose >/= 200 mg/kg/day Result: Maternal toxiciity; reduced successful matings, decreased number of corpora lutea, foetal resorption Species: Rat

Specific target organ toxicity - single exposure None known.

Specific target organ toxicity - repeated exposure None known.

Aspiration hazard Not available.

Mixture versus substance information No information available.

Other information Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.

SECTION 12: Ecological information

12.1. Toxicity Contains a substance which causes risk of hazardous effects to the environment.

Components		Species	Test results
CARVEDILOL (CAS 72956-09-3)			
Aquatic			
Acute			
Activated Sludge Respiration	IC50	Residential sludge	98 mg/l, 3 hours
Algae	EC50	Green algae (Scenedesmus subspicatus)	1,6 mg/l, 72 hours
	NOEC	Green algae (Scenedesmus subspicatus)	0,46 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	1,8 mg/l, 48 hours Static test
	NOEC	Water flea (Daphnia magna)	0,35 mg/l, 48 hours Static test
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	0,99 mg/l, 96 hours Static test
		Rainbow trout (Juvenile Oncorhyncus mykiss)	0,29 mg/l, 96 hours semi-static test conditions
	NOEC	Bluegill sunfish (Adult Lepomis macrochirus)	< 0,43 mg/l, 96 hours Static test
		Rainbow trout (Juvenile Oncorhyncus mykiss)	0,025 mg/l, 96 hours semi-static test conditions
Microtox	EC50	Microtox	5,43 mg/l, 15 minutes
Chronic			
Crustacea	LOEC	Water flea (Ceriodaphnia dubia)	0,8 mg/l, 8 days Static renewal test
	NOEC	Water flea (Daphnia magna)	0,25 mg/l, 8 days
POLYVINYLPOLYPYRROLIDONE (CAS 25249-54-1)			
Acute			
	IC50	Activated sludge	> 1000 mg/l, 3 hours Static test
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	84 mg/l, 48 hours Static test
	NOEC	Water flea (Daphnia magna)	32 mg/l, 48 hours Static test
Silicon dioxide (CAS 7631-86-9)			
Aquatic			
Acute			
Algae	EC50	Green algae (Selenastrum capricornutum)	440 mg/l, 72 hours
	NOEC	Green algae (Selenastrum capricornutum)	60 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	> 10000 mg/l, 24 hours Static test
Fish	EC50	Common carp (Juvenile Cyprinus carpio)	> 10000 mg/l, 72 hours
		Zebra fish (Adult Brachydanio rerio)	5000 mg/l, 96 hours Static test
Microtox	EC50	Microtox	8700 mg/l, 15 minutes
Titanium dioxide (CAS 13463-67-7)			
Aquatic			
Fish	LC50	Mummichog (Fundulus heteroclitus)	> 1000 mg/l, 96 hours
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)

CARVEDILOL 1,48 Hours Measured

Hydrolysis

Half-life (Hydrolysis-acidic)

CARVEDILOL > 1 years Measured, pH 4 buffer solution

Hydrolysis

Half-life (Hydrolysis-basic)

CARVEDILOL	> 1 years Measured, pH 9 buffer solution

Half-life (Hydrolysis-neutral)

CARVEDILOL	> 1 years Measured, pH 7 Buffer Solution

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

CARVEDILOL	50 %, 28 days Batch activated sludge (BAS), Activated sludge
POLYVINYLPOLYPYRROLIDONE	0 %, 28 days Modified MITI test, Activated sludge
Sucrose	69 % BOD5

Percent degradation (Aerobic biodegradation-ready)

CARVEDILOL	25 %, 28 days OECD 301B, CO2 Evolution, Activated sludge

12.3. Bioaccumulative potential

Partition coefficient n-octanol/water (log Kow)

CARVEDILOL	1,61 (Calculated), pH 7 2,7 (Measured), pH 7,4 2,79 (Measured), pH 10,1
Sucrose	-3

12.4. Mobility in soil

Adsorption

Sludge/biomass distribution coefficient - log Kd

CARVEDILOL	3,74 - 4,31 Measured

Soil/sediment sorption - log Koc

CARVEDILOL	> 5,63 Measured

Mobility in general

Volatility

Henry's law

CARVEDILOL	0 atm m3/mol Measured
Sucrose	< 0 atm m^3/mol Estimated

Distribution

Octanol/water distribution coefficient log DOW

CARVEDILOL	1,98, pH 5 2,73, pH 7 3,03, 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 Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

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

14.1. UN number UN3077

14.2. UN proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S (CARVEDILOL, FORMULATED PRODUCT)

14.3. Transport hazard class(es)

Class 9

Subsidiary risk -

Label(s)	9
Hazard No. (ADR)	90
Tunnel code	E
14.4. Packing group	III
14.5. Environmental hazards	No.
14.6. Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.

IATA

14.1. UN number	UN3077
14.2. UN proper shipping name	Environmentally hazardous substance, solid, n.o.s. (CARVEDILOL, FORMULATED PRODUCT)
14.3. Transport hazard class(es)	9
Subsidiary class(es)	-
14.4. Packing group	III
14.5. Environmental hazards	No.
Labels required	Not available.
ERG Code	9L
14.6. Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.
Other information	
Cargo aircraft only	Allowed with restrictions.
Additional Information:	
Passenger & cargo	Allowed with restrictions.

IMDG

14.1. UN number	UN3077
14.2. UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (CARVEDILOL, FORMULATED PRODUCT), MARINE POLLUTANT
14.3. Transport hazard class(es)	
Class	9
Subsidiary risk	-
14.4. Packing group	III
14.5. Environmental hazards	
Marine pollutant	Yes
EmS	F-A, S-F
14.6. Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.

Read safety instructions, SDS and emergency procedures before handling.

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.

ADR; IATA; IMDG

Marine pollutant

General information IMDG Regulated Marine Pollutant.

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 and II, as amended

Not listed.

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

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 1 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 2 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 3 as amended

Not listed.

Regulation (EU) No. 649/2012 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, as amended

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, as amended

Not listed.

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

Not listed.

Other EU regulations

Directive 2012/18/EU on 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, as amended

Not listed.

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

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, as amended.
National regulations	Follow national regulation for work with chemical agents. Young people under 18 years old are not allowed to work with this product according to EU Directive 94/33/EC on the protection of young people at work, as amended.
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 H-statements not written out in full under Sections 2 to 15	H317 May cause an allergic skin reaction. H351 Suspected of causing cancer. H400 Very toxic to aquatic life. H410 Very toxic to aquatic life with long lasting effects.

	H412 Harmful to aquatic life with long lasting effects.
Revision information	Product and Company Identification: Product and Company Identification Composition / Information on Ingredients: Ingredients Toxicological Information: Toxicological Data Transport Information: Material Transportation Information 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.