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 * NDC NO. 0007-4139-20 * NDC NO. 0007-4140-20 * NDC NO. 0007-4141-20 * NDC NO. 0007-4142-20 * CARVEDILOL, FORMULATED PRODUCT
Issue date	30-September-2013
Version number	19
Revision date	30-September-2013
Supersedes date	10-September-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.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
CARVEDILOL	8	72956-09-3 474-310-3	-	-	
Classification: **DSD:** R43, N;R50-53 **CLP:** Skin Sens. 1;H317, Aquatic Acute 1;H400, Aquatic Chronic 1;H410					
POLYVINYLPOLYPYRROLIDONE	3 - < 5	25249-54-1 -	-	-	
Classification: **DSD:** R52 **CLP:** Aquatic Chronic 3;H412					
Silicon dioxide	1 - < 3	7631-86-9 231-545-4	-	-	
Classification: **DSD:** - **CLP:** -					
Sucrose	2	57-50-1 200-334-9	-	-	
Classification: **DSD:** - **CLP:** -					
Titanium dioxide	1 - < 3	13463-67-7 236-675-5	-	-	
Classification: **DSD:** - **CLP:** -					
POLYETHYLENE GLYCOLS	< 1	25322-68-3 500-038-2	-	-	
Classification: **DSD:** - **CLP:** -					
Other components below reportable levels	80 - < 90				

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 Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment.

4.1. Description of first aid measures

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

Skin contact Take off contaminated clothing and wash before reuse. Wash off with soap and plenty of water.

Eye contact Immediately flush eyes with plenty of water for at least 15 minutes.

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 May cause allergic skin reaction.
weakness; The following adverse effects have been noted with therapeutic use of this material: dizziness; fatigue; decrease in blood pressure; diarrhoea; 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 Use standard firefighting procedures and consider the hazards of other involved materials. Move containers from fire area if you can do so without risk. 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. Do not touch or walk through spilled material. 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 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.

6.4. Reference to other sections For personal protection, see section 8. For waste disposal, see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling Avoid breaking or crushing tablets. 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 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
CARVEDILOL (CAS 72956-09-3)	8 HR TWA	30 mcg/m3	
	OHC	3	SKIN SENSITISER
Silicon dioxide (CAS 7631-86-9)	OHC	1	

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value	Form
Silicon dioxide (CAS 7631-86-9)	TWA	6 mg/m3	Inhalable dust.
		2.4 mg/m3	Respirable dust.
Sucrose (CAS 57-50-1)	STEL	20 mg/m3	
	TWA	10 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	Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. 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. Select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time).
- Other	Not normally needed.
Respiratory protection	No personal respiratory protective equipment normally required.
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.

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

Information on likely routes of exposure

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

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 Health injuries are not known or expected under normal use.

Irritation Corrosion - Skin

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 Literature data Result: Non-irritant Species: Guinea pig Literature data Result: Non-irritant Species: Human

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
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

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

Mutagenicity

CARVEDILOL	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.

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.

Reproductive toxicity

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

Reproductivity

CARVEDILOL — 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 Not available.

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
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

Components		Species	Test results
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			
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)

CARVEDILOL	1.48 Hours Measured

Hydrolysis

Half-life (Hydrolysis-acidic)

CARVEDILOL	> 1 years Measured, pH 4 buffer solution

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	2.7 (Measured), pH 7.4
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).
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

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
Tunnel code	E
Labels required	9
Additional information:	
LTD QTY index	LQ27
Special Provisions	274, 335, 601

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
Labels required	Not available.
Additional Information:	
Passenger & cargo	Allowed.
Packaging Instruction	956
Pkg Inst cargo only	956
Pkg Inst pasenger & cargo LQ	Y956
SP See 44	A97,A158,A179
Max net qty pkg	400 kg
Max net qty pkg cargo only	400 kg
Max net qty pkg LQ	30 kg G

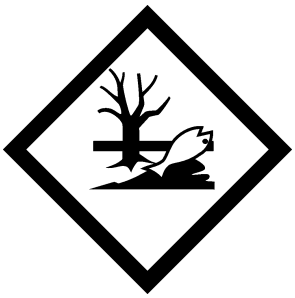
IMDG

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	
Marine pollutant	Yes
Labels required	Not available.
EmS	F-A, S-F
14.6. Special precautions for user	Not available.

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



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	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	R43 May cause sensitization by skin contact. R50 Very toxic to aquatic organisms. R52 Harmful to aquatic organisms. R53 May cause long term adverse effects in the aquatic environment. H317 May cause an allergic skin reaction. 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	This document has undergone significant changes and should be reviewed in its entirety.
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.