SAFETY DATA SHEET

1. Identification

Product identifier **AUGMENTIN 7:1 ORAL SUSPENSION**

Other means of identification

Synonyms AUGMENTIN DUO 200/28.5 MG/5 ML * AUGMENTIN DUO 400/57 MG/5 ML * AUGMENTIN 200 MG/5 ML * AUGMENTIN 400 MG/5 ML * AUGMENTIN 400 SUSPENSION * AUGMENTIN BD PAEDIATRIC SUSPENSION 400/57 MG/5 ML * AUGMENTIN PAEDIATRIC SUSPENSION 200/28.5 MG/5 ML * AUGMENTIN PAEDIATRIC SUSPENSION 400/57 MG/5 ML * AUGMENTIN DUO SUSPENSION * AUGMENTIN DUO B/D SUSPENSION * AUGMENTAN PAEDIATRIC ORAL SUSPENSION 400 MG/57 MG/5 ML * AUGMENTAN KINDERSAFT * AUGMENTIN 7:1 SF SUSPENSION * CLAVULIN BID ORAL SUSPENSION * CLAVULIN SUSPENSION 200 MG * CLAVULIN SUSPENSION 400 MG * CLAVULOX DUO * NDC NO. 0029-6092-51 * AMOXICILLIN TRIHYDRATE AND POTASSIUM CLAVULANATE, FORMULATED PRODUCT

Recommended use of the chemical and restrictions on use

Recommended use 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.

Restrictions on use No other uses are advised.

Details of manufacturer or importer

Manufacturer

GlaxoSmithKline Australia
1061 Mountain Highway
Melbourne, Victoria 3155
Australia
Australia General Information (Normal Business Hours): (03) 9721 6000

TRANSPORTATION EMERGENCY NUMBERS
(available 24hrs/7days: multi-language response)
Australia Toll Free +(61) 2 9037 2994
International Toll Call +(1) 703 527 3887

2. Hazard(s) identification

Classification of the hazardous chemical

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Label elements, including precautionary statements

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Other hazards which do not result in classification

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

3. Composition/information on ingredients

Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients
AMOXICILLIN TRIHYDRATE (2S-(2ALPHA,5ALPHA,6BETA(S*)))-4-THIA-1-AZABICYCLO(3.2.0)HEPTANE -2- CARBOXYLIC ACID, 6-((AMINO(4-HYDROXYPHENYL)ACETYL)AMINO)-3,3-DIMETHYL- 7-OXO-, TRIHYDRATE (2S,5R,6R)-6-(R-(-)-2,AMINO-2-(P-HYDROXYPHENYL)ACETAMIDO)-3,3-DI METHYL -7-OXO-4-THIA-1-AZABICYCLO(3.2.0)HEPTANE-2-CARBOXYLIC ACID TRIHYDRATE 4-THIA-1-AZABICYCLO(3.2.0)HEPTANE-2-CARBOXYLIC ACID, 6-((AMINO(4- HYDROXYPHENYL)ACETYL)AMINO)-3,3-DIMETHYL-7-OXO-, TRIHYDRATE, (2S- (2ALPHA,5ALPHA,6BETA(S*)))-ALPHA-AMINO-P-HYDROXYBENZYLPENICILLIN TRIHYDRATE AX 250 BRL-2333 J1030 RTECS XH8310000 AMOXICILLIN AMOXYCILLIN TRIHYDRATE	61336-70-7	62.01
POTASSIUM CLAVULANATE POTASSIUM CLAVULANATE (STERILE) SKF-85472-Y BRL-14151MM-F ITEM NUMBER 8104750	61177-45-5	9.64
ASPARTAME ASPARTYLPHENYLALANINE METHYL ESTER NUTRASWEET	22839-47-0	1 - < 3
Silicon dioxide Silica Silica gel Amorphous silica DIATOMACEOUS EARTH INFUSORIAL EARTH CAB-O-SIL M-5	7631-86-9	< 1
XANTHAN GUM ACTIGUM CX 9 BIOPOLYMER XB-23 XANTHAN GUM BIOZAN R ENORFLO X FLOCON 1035 GALAXY XB KELFLO KELTROL (GUM) KELZAN KENTROL POLYSACCHARIDE B 1459 RHODOPOL 23 XANFLOOD XANTHOMONAS GUM	11138-66-2	< 1
MAGNESIUM STEARATE STEARIC ACID, MAGNESIUM SALT MAGNESIUM DISTEARATE DIBASIC MAGNESIUM STEARATE MAGNESIUM DISTEARATE, PURE	557-04-0	< 0.3
Other components below reportable levels		20 - < 30

4. First-aid measures

Description of necessary 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. Get medical attention immediately.

Skin contact	Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Remove and isolate contaminated clothing and shoes. Get medical attention immediately.
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). Call a physician or poison control centre immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconsious person.
Personal protection for first-aid responders	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. Show this safety data sheet to the doctor in attendance. Keep victim under observation. Keep victim warm. Wash contaminated clothing before reuse. 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.
Symptoms caused by exposure	Possible effects of overexposure in the workplace include: symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing), nausea, vomiting, diarrhoea.
Medical attention and special treatment	Provide general supportive measures and treat symptomatically. Keep victim warm. Keep victim under observation. Symptoms may be delayed. Medical treatment in cases of overexposure should be treated as an overdose of penicillin antibiotic. In allergic individuals, exposure to this material may require treatment for initial or delayed allergic symptoms and signs. This may include immediate and/or delayed treatment of anaphylactic reactions. Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre. This material may cause or aggravate allergy to penicillin antibiotics. The need for pre-placement and periodic health surveillance must be determined by risk assessment. Following assessment, if the risk of exposure is considered significant then exposed individuals should receive health surveillance focused on detecting respiratory symptoms and including respiratory function testing. In the event of overexposure, individuals should receive post exposure health surveillance focused on detecting respiratory conditions and other allergy symptoms. Ocular symptoms may be indicative of allergic reaction. Pulmonary symptoms may indicate allergic reaction or asthma.

5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media	Water. Foam. Dry chemical powder.
Unsuitable extinguishing media	Carbon dioxide (CO_2).
Specific hazards arising from the chemical	Thermal decomposition of this material can produce toxic, dense smoke containing oxides of carbon, sulphur and nitrogen together with acetaldehyde. Ash remaining after thermal decomposition may contain cyanide compounds and should not come into contact with acidic conditions which may result in the production of hydrogen cyanide gas.
Special protective equipment and precautions for fire fighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	Move containers from fire area if you can do so without risk. Use water spray to cool unopened containers.
Hazchem Code	Not available.
General fire hazards	Assume that this material is capable of sustaining combustion.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Wear appropriate protective equipment and clothing during clean-up. Avoid inhalation of dust. Wear a dust mask if dust is generated above exposure limits. 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.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

Methods and materials for containment and cleaning up

Stop the flow of material, if this is without risk. If sweeping of a contaminated area is necessary use a dust suppressant agent which does not react with the product. Collect dust using a vacuum cleaner equipped with HEPA filter. Minimise dust generation and accumulation. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water. Sweep up or vacuum up spillage and collect in suitable container for disposal. For waste disposal, see section 13.

7. Handling and storage

Precautions for safe handling

Keep cool. Avoid breathing dust. Avoid contact with eyes, skin, and clothing. Avoid prolonged exposure.

Conditions for safe storage, including any incompatibilities

Keep away from heat, sparks and open flame. Store in original tightly closed container. Keep away from moisture. Store in a cool, dry place out of direct sunlight. Store in a well-ventilated place. Store away from other materials. Maintain air gap between stacks/pallets.

8. Exposure controls and personal protection

Control parameters

Follow standard monitoring procedures.

Occupational exposure limits

GSK

Components	Type	Value	Note
AMOXICILLIN TRIHYDRATE (CAS 61336-70-7)	15 MIN STEL	100 mcg/m3	
	OHC	3	SKIN SENSITISER
		3	RESPIRATORY SENSITISER
ASPARTAME (CAS 22839-47-0)	8 HR TWA	5000 mcg/m3	
	OHC	1	
MAGNESIUM STEARATE (CAS 557-04-0)	OHC	1	
POTASSIUM CLAVULANATE (CAS 61177-45-5)	8 HR TWA	5000 mcg/m3	
	OHC	1	
Silicon dioxide (CAS 7631-86-9)	OHC	1	
XANTHAN GUM (CAS 11138-66-2)	OHC	1	

Australia. National Workplace OELs (Workplace Exposure Standards for Airborne Contaminants, Appendix A)

Components	Type	Value	Form
MAGNESIUM STEARATE (CAS 557-04-0)	TWA	10 mg/m3	Inhalable dust.
Silicon dioxide (CAS 7631-86-9)	TWA	2 mg/m3	Respirable dust.

Australia. OELs. (Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment)

Components	Type	Value	Form
MAGNESIUM STEARATE (CAS 557-04-0)	TWA	10 mg/m3	Inspirable dust.
Silicon dioxide (CAS 7631-86-9)	TWA	2 mg/m3	Respirable fraction.

US. ACGIH Threshold Limit Values

Components	Type	Value
MAGNESIUM STEARATE (CAS 557-04-0)	TWA	10 mg/m3

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.

Biological limit values	No biological exposure limits noted for the ingredient(s).
Exposure guidelines	No exposure standards allocated.
Appropriate engineering controls	If material is ground, cut, or used in any operation which may generate dusts, use appropriate local exhaust ventilation to keep exposures below the 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, for example personal protective equipment (PPE)

Eye/face protection	Wear eye/face protection. 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.
Other	Wear suitable protective clothing as protection against splashing or contamination.
Respiratory protection	When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.
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.

9. Physical and chemical properties

Appearance

Physical state	Solid.
Form	Powder.Bottle.
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.
Explosive limit - lower (%)	Not available.
Explosive limit – upper (%)	Not available.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density	Not available.

Solubility(ies)

Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions. The purity of this material will be affected by exposure to moisture. This material can become unstable if subjected to heat, high levels of moisture or storage in large masses.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Keep away from heat, sparks and open flame. Contact with incompatible materials. Avoid dispersion as a dust cloud. Moisture.
Incompatible materials	Water, moisture. Fluorine. Chlorine.
Hazardous decomposition products	Thermal decomposition of this material can produce toxic, dense smoke containing oxides of carbon, sulphur and nitrogen together with acetaldehyde. Ash remaining after thermal decomposition may contain cyanide compounds and should not come into contact with acidic conditions which may result in the production of hydrogen cyanide gas.

11. Toxicological information

Information on possible routes of exposure

Ingestion	Expected to be a low ingestion hazard. Health injuries are not known or expected under normal use.
Inhalation	Health injuries are not known or expected under normal use. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	May cause an allergic skin reaction.
Eye contact	Direct contact with eyes may cause temporary irritation.
Symptoms related to exposure	Possible effects of overexposure in the workplace include: symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing), nausea, vomiting, diarrhoea.
Acute toxicity	Health injuries are not known or expected under normal use.

Components	Species	Test results
AMOXICILLIN TRIHYDRATE (CAS 61336-70-7)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
MAGNESIUM STEARATE (CAS 557-04-0)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
POTASSIUM CLAVULANATE (CAS 61177-45-5)		
Acute		
Oral		
LD	Rat	> 5000 mg/kg
XANTHAN GUM (CAS 11138-66-2)		
Acute		
Inhalation		
LC50	Rat	> 21 mg/l, 1 hour exposure
Oral		
LD50	Rat	> 5000 mg/kg

* 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.

Corrosivity

AMOXICILLIN TRIHYDRATE	Acute dermal irritation Result: negative Species: Rabbit
POTASSIUM CLAVULANATE	OECD 404 Result: Non-irritant

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

MAGNESIUM STEARATE	0

Serious eye damage/irritation Direct contact with eyes may cause temporary irritation. Health injuries are not known or expected under normal use.

Eye

POTASSIUM CLAVULANATE	OECD 405 Result: Non-Irritating

Eye / Kay and Calandra class - Intact

MAGNESIUM STEARATE	4 Recovery Period: 2 days
AMOXICILLIN TRIHYDRATE	Result: Minimal irritant Species: Rabbit Recovery Period: 2 days

Respiratory or skin sensitisation

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

Skin sensitisation May cause an allergic skin reaction.

Sensitisation

AMOXICILLIN TRIHYDRATE	Epidemiology Result: positive Species: Human
POTASSIUM CLAVULANATE	Maximisation assay (Magnusson and Kligman) Result: negative Species: Guinea pig SAR Result: No structural alerts identified.

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

Mutagenicity

POTASSIUM CLAVULANATE	Ames Result: negative
AMOXICILLIN TRIHYDRATE	GreenScreen Result: negative Mouse Lymphoma Cell Assay Result: negative
POTASSIUM CLAVULANATE	Mouse Lymphoma Cell Assay Result: negative SAR Result: No structural alerts identified.

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

POTASSIUM CLAVULANATE	SAR Result: No structual alerts identified.

ACGIH Carcinogens

MAGNESIUM STEARATE (CAS 557-04-0)	A4 Not classifiable as a human carcinogen.

IARC Monographs. Overall Evaluation of Carcinogenicity

SILICON DIOXIDE (CAS 7631-86-9)	3 Not classifiable as to carcinogenicity to humans.

Reproductive toxicity Health injuries are not known or expected under normal use.

Specific target organ toxicity - single exposure None known.

Specific target organ toxicity - repeated exposure None known.

Aspiration hazard Not an aspiration hazard.

Chronic effects Prolonged inhalation may be harmful.

Other information Caution - Pharmaceutical agent.

12. Ecological information

Ecotoxicity Not expected to be harmful to aquatic organisms.

Components		Species	Test results
AMOXICILLIN TRIHYDRATE (CAS 61336-70-7)			
Aquatic			
Acute			
Algae	EC50	Green algae (Selenastrum capricornutum)	630 mg/l, 72 hours
	NOEC	Green algae (Selenastrum capricornutum)	530 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	> 2300 mg/l, 48 hours Static test
	NOEC	Water flea (Daphnia magna)	2300 mg/l, 48 hours Static test
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	> 930 mg/l, 96 hours Static test
		Rainbow trout (Adult Oncorhyncus mykiss)	> 1000 mg/l, 96 hours Static test
	NOEC	Bluegill sunfish (Adult Lepomis macrochirus)	930 mg/l, 96 hours Static test
		Rainbow trout (Adult Oncorhyncus mykiss)	1000 mg/l, 96 hours Static test
MAGNESIUM STEARATE (CAS 557-04-0)			
Aquatic			
Acute			
Fish	EC50	Orange-red killfish (Adult Oryzias latipes)	130 mg/l, 96 hours
POTASSIUM CLAVULANATE (CAS 61177-45-5)			
Aquatic			
Acute			
Algae	EC50	Green algae (Selenastrum capricornutum)	56 mg/l, 72 hours
	NOEC	Green algae (Selenastrum capricornutum)	9.4 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	1610 mg/l, 48 hours Static test
	NOEC	Water flea (Daphnia magna)	530 mg/l, 48 hours Static test
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	> 790 mg/l, 96 hours Static test
		Rainbow trout (Adult Oncorhyncus mykiss)	> 960 mg/l, 96 hours Static test
	NOEC	Bluegill sunfish (Adult Lepomis macrochirus)	790 mg/l, 96 hours Static test
		Rainbow trout (Adult Oncorhyncus mykiss)	960 mg/l, 96 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

Components		Species	Test results
XANTHAN GUM (CAS 11138-66-2)			
Aquatic			
Acute			
Fish	EC50	Rainbow trout (Adult Oncorhyncus mykiss)	420 mg/l, 96 hours Static test

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

Persistence and degradability

Photolysis

Half-life (Photolysis-atmospheric)

MAGNESIUM STEARATE	17 Hours Estimated

UV/visible spectrum wavelength

MAGNESIUM STEARATE	210 nm

Hydrolysis

Half-life (Hydrolysis-acidic)

POTASSIUM CLAVULANATE	11.9 Hours Measured

Half-life (Hydrolysis-basic)

ASPARTAME	< 1 Days Measured
POTASSIUM CLAVULANATE	9.92 Hours Measured

Half-life (Hydrolysis-neutral)

AMOXICILLIN TRIHYDRATE	50 - 113 Days Measured
POTASSIUM CLAVULANATE	28.3 Hours Measured

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

AMOXICILLIN TRIHYDRATE	88 %, 28 days Zahn-Wellens, Activated sludge
MAGNESIUM STEARATE	77 %, 28 days BOD
POTASSIUM CLAVULANATE	90 %, 28 days Zahn-Wellens, Activated sludge

Percent degradation (Aerobic biodegradation-ready)

ASPARTAME	60 - 90 %, 5 days
MAGNESIUM STEARATE	95 %, 22 days Sturm test

Percent degradation (Aerobic biodegradation-soil)

MAGNESIUM STEARATE	50 %, 13 days

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

AMOXICILLIN TRIHYDRATE	-1.56
POTASSIUM CLAVULANATE	-5.8 (Estimated).

Bioconcentration factor (BCF)

ASPARTAME	1 Estimated
MAGNESIUM STEARATE	> 9999 Estimated

Mobility in soil Not available.

Adsorption

Sludge/biomass distribution coefficient - log Kd

AMOXICILLIN TRIHYDRATE	-0.17 Estimated

Soil/sediment sorption - log Koc

ASPARTAME	1.78 Estimated
MAGNESIUM STEARATE	5.86 Estimated

Volatility

Henry's law

AMOXICILLIN TRIHYDRATE	0 atm m^3/mol Calculated
ASPARTAME	< 0 atm m^3/mol Estimated

Other adverse effects Not available.

13. Disposal considerations

Disposal methods Consult authorities before disposal. Dispose in accordance with all applicable regulations.

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.

14. Transport information

IATA

UN number	3088
UN proper shipping name	Self-heating solid, organic, n.o.s. (AMOXICILLIN TRIHYDRATE AND POTASSIUM CLAVULANATE, FORMULATED PRODUCT)
Transport hazard class(es)	
Class	4.2
Subsidiary risk	-
Label(s)	4.2
Packing group	II
Environmental hazards	No.
Special precautions for user	Not available.
Other information	
Passenger and cargo aircraft	Forbidden.
Cargo aircraft only	Forbidden.

IMDG

UN number	3088
UN proper shipping name	SELF-HEATING SOLID, ORGANIC, N.O.S. (AMOXICILLIN TRIHYDRATE AND POTASSIUM CLAVULANATE, FORMULATED PRODUCT)
Transport hazard class(es)	
Class	4.2
Subsidiary risk	-
Label(s)	4.2
Packing group	II
Environmental hazards	
Marine pollutant	No.
EmS	F-A, S-J
Special precautions for user	Not available.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not available.

IATA; IMDG

General information	REGULATED IN TRANSPORT for packages of greater than 3 cubic metres volume. EXEMPT if transported in packages of not more than 3 cubic metres volume per UN Manual of Tests and Criteria (33.3.1.3.3.1).

15. Regulatory information

Safety, health and environmental regulations

National regulations	This Material Safety Data Sheet was prepared in accordance with the Australia National Code of Practice for the Preparation of Material Safety Data Sheets (NOHSC: 2011.)

Australia Medicines & Poisons Appendix A

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix B

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix C

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix D

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix E

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix F

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix G

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix H

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix I

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix J

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix K

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 2

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 3

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 4

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 5

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 6

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 7

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 8

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 9

Poisons schedule number not allocated.

High Volume Industrial Chemicals (HVIC)

SILICON DIOXIDE (CAS 7631-86-9)	1000 - 9999 TONNES See the regulation for additional information.

Importation of Ozone Deleting Substances (Customs(Prohibited imports) Regulations 1956, Schedule 10)

Not listed.

National Pollutant Inventory (NPI) substance reporting list

Not listed.

Prohibited Carcinogenic Substances

Not regulated.

Prohibited Substances (National Model Regulation for the control of Workplace Hazardous Substances, Schedule 2 NOHSC:1005 (1994) as amended)

Not listed.

Resricted Importation of Organochlorine Chemicals (Customs(Prohibited Imports) Regulations 1956, Schedule 9)

Not listed.

Restricted Carcinogenic Substances

Not regulated.

International regulations

Stockholm Convention

Not applicable.

Rotterdam Convention

Not applicable.

Kyoto protocol

Not applicable.

Montreal Protocol

Not applicable.

Basel Convention

Not applicable.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information

Issue date 11-September-2014

Revision date 11-September-2014

References GSK Hazard Determination

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.

Revision Information Hazard(s) identification: Other hazards which do not result in classification
Fire-fighting measures: Specific hazards arising from the chemical
Fire-fighting measures: General fire hazards
Handling and storage: Precautions for safe handling
Handling and storage: Conditions for safe storage, including any incompatibilities
Stability and reactivity: Conditions to avoid
Stability and reactivity: Hazardous decomposition products
Stability and reactivity: Incompatible materials
Stability and reactivity: Chemical stability
Transport information: General information
GHS: Classification