SAFETY DATA SHEET

1. Identification

Product identifier **AUGMENTIN XR**

Other means of identification Not available.

Synonym(s) AUGMENTIN XR 1 GRAM EXTENDED RELEASE TABLETS * AUGMENTIN XR EXTENDED RELEASE TABLETS * AUGMENTIN SR * AUGMENTIN SR 1000 MG/62.5 MG SUSTAINED RELEASE TABLETS * AUGMENTIN RETARD * AUGMENTIN 16:1 TABLETS * NDC NO. 0029-6096-48 * NDC NO. 0029-6096-60 * POTASSIUM CLAVULANATE, AMOXYCILLIN TRIHYDRATE AND SODIUM AMOXYCILLIN, FORMULATED PRODUCT

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.

Recommended restrictions No other uses are advised.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

GlaxoSmithKline US
5 Moore Drive
Research Triangle Park, NC 27709 USA
US General Information (normal business hours): +1-888-825-5249
Email Address: msds@gsk.com
Website: www.gsk.com
EMERGENCY PHONE NUMBERS -
TRANSPORT EMERGENCIES::
US / International toll call +1 703 527 3887
available 24 hrs/7 days; multi-language response

2. Hazard(s) identification

Classified hazards

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

Label elements

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

Hazard(s) not otherwise classified (HNOC)

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

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
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- (2S,5R,6R)-6-(R-(-)-2,AMINO-2-(P-HYDROXYPHENYL)ACETAMIDO)-3,3-DIMETHYL-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	< = 40
AMOXYCILLIN SODIUM	AMOXICILLIN SODIUM SODIUM AMOXYCILLIN SODIUM [2S-[2.ALPHA.,5.ALPHA.,6.BETA.(S*)]]-6-[[AMINO(4-HYDROXYPHENYL)ACETYL]AMINO]-3,3-DIMETHYL-7-OXO-4-THIA-1-AZABICYCLO[3.2.0]HEPTANE-2-CARBOXYLATE, MONOSODIUM [2S-[2.ALPHA.,5.ALPHA.,6.BETA.(S*)]]-6-[[AMINO(4-HYDROXYPHENYL)ACETYL]AMINO]-3,3-DIMETHYL-7-OXO-4-THIA-1-AZABICYCLO[3.2.0]HEPTAN-2-CARBOXYLATE	34642-77-8	< 30
CITRIC ACID ANHYDROUS	BETA-HYDROXYTRICARBALLYLIC ACID ANHYDROUS CITRIC ACID 2-HYDROXY-1,2,3-PROPANETRICARBOXYLIC ACID CITIRIC ACID	77-92-9	< 5
POTASSIUM CLAVULANATE	POTASSIUM CLAVULANATE (STERILE) SKF-85472-Y BRL-14151MM-F ITEM NUMBER 8104750	61177-45-5	< 5
TITANIUM DIOXIDE	TITANIUM OXIDE TITANIUM(IV) OXIDE TITANIUM PEROXIDE (TiO2) PIGMENT WHITE 6	13463-67-7	< 1
Other components below reportable levels			20 - < 30

*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

4. First-aid measures

Inhalation
If dust from the material is inhaled, remove the affected person immediately to fresh air. Oxygen or artificial respiration if needed. Do not use mouth-to-mouth method if victim inhaled the substance. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.

Skin contact
Remove contaminated clothing immediately and wash skin with soap and water. In case of eczema or other skin disorders: Seek medical attention and take along these instructions. For minor skin contact, avoid spreading material on unaffected skin.

Eye contact
Do not rub eyes. Rinse with water. Get medical attention if irritation develops and persists.

Ingestion
Rinse mouth. Call a POISON CENTER or doctor/physician if you feel unwell.

Most important symptoms/effects, acute and delayed
Possible effects of overexposure in the workplace include: symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing), nausea, vomiting, diarrhoea.

Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. 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.
General information	In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Wash contaminated clothing before reuse.

5. Fire-fighting measures

Suitable extinguishing media	Water. Foam.
Unsuitable extinguishing media	Carbon dioxide or dry powder extinguishers may be ineffective.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	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.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	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. 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 of the SDS.
Methods and materials 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. For waste disposal, see section 13 of the SDS.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	No special control measures required for the normal handling of this product. Avoid contact with skin. Avoid contact with eyes. Avoid prolonged exposure. Avoid contact with clothing.
Conditions for safe storage, including any incompatibilities	Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

GSK

Components	Type	Value	Note
AMOXICILLIN TRIHYDRATE (CAS 61336-70-7)	15 MIN STEL	100 mcg/m3	
	OHC	3	RESPIRATORY SENSITISER
		3	SKIN SENSITISER
AMOXYCILLIN SODIUM (CAS 34642-77-8)	15 MIN STEL	100 mcg/m3	
	OHC	3	SKIN SENSITISER
		3	RESPIRATORY SENSITISER
CITRIC ACID ANHYDROUS (CAS 77-92-9)	8 HR TWA	5000 mcg/m3	
	OHC	1	

GSK

Components	Type	Value	Note
POTASSIUM CLAVULANATE (CAS 61177-45-5)	8 HR TWA	5000 mcg/m3	
	OHC	1	

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
TITANIUM DIOXIDE (CAS 13463-67-7)	PEL	15 mg/m3	Total dust.

US. ACGIH Threshold Limit Values

Components	Type	Value
TITANIUM DIOXIDE (CAS 13463-67-7)	TWA	10 mg/m3

Biological limit values No biological exposure limits noted for the ingredient(s).

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

Eye/face protection Not normally needed.

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.

Other Not normally needed.

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.

General hygiene considerations 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.

9. Physical and chemical properties

Appearance

Physical state Solid.

Form Tablet.

Color Not available.

Odor Not available.

Odor 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.

Vapor pressure Not available.

Vapor 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	Not available.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents. Fluorine.
Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

11. Toxicological information

Information on likely 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.
Skin contact	May cause an allergic skin reaction. Health injuries are not known or expected under normal use.
Eye contact	Direct contact with eyes may cause temporary irritation.
Symptoms related to the physical, chemical and toxicological characteristics	Possible effects of overexposure in the workplace include: symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing), nausea, vomiting, diarrhoea.

Information on toxicological effects

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
CITRIC ACID ANHYDROUS (CAS 77-92-9)		
Acute		
Oral		
LD50	Rat	3000 mg/kg
POTASSIUM CLAVULANATE (CAS 61177-45-5)		
Acute		
Oral		
LD	Rat	> 5000 mg/kg
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.

Components	Species	Test Results
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.

Corrosivity

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

Irritation Corrosion - Skin

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 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
TITANIUM DIOXIDE	OECD 405, Literature data Result: Mild irritant Species: Rabbit

Eye / Kay and Calandra class - Intact

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

Respiratory or skin sensitization

Respiratory sensitization May cause allergy or asthma symptoms or breathing difficulties if inhaled. Health injuries are not known or expected under normal use.

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

Sensitization

TITANIUM DIOXIDE	5 % Optimisation Test, Literature data - Vehicle: petrolatum Result: Negative Species: Guinea pig Test Duration: 48 hour exposure
AMOXICILLIN TRIHYDRATE	Epidemiology Result: Positive Species: Human
AMOXYCILLIN SODIUM	Epidemiology Result: Positive Species: Human

Sensitization

POTASSIUM CLAVULANATE	Maximisation assay (Magnusson and Kligman) Result: Negative Species: Guinea pig
TITANIUM DIOXIDE	Patch test, Literature data Result: Negative Species: Human
POTASSIUM CLAVULANATE	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
TITANIUM DIOXIDE	Ames, Literature data Result: Negative
AMOXICILLIN TRIHYDRATE	GreenScreen 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
AMOXICILLIN TRIHYDRATE	Mouse Lymphoma Cell Assay Result: Negative
POTASSIUM CLAVULANATE	Mouse Lymphoma Cell Assay Result: Negative SAR Result: No structural alerts identified.
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	0.5 mg/m3, Literature data Result: Negative Species: Rat Test Duration: 24 months 0.72 - 14.8 mg/m3, Literature data Result: Negative Species: Mouse 10 - 250 mg/m3, Dietary study - Literature data. Result: Inflammation at all doses with alveolar/bronchiolar adenoma at the highest concentration. Species: Rat Test Duration: 24 months 25000 - 50000 ppm, Dietary study Result: Negative Species: Mouse 25000 - 50000 ppm, Dietary study - Literature data. Result: Negative Species: Rat 7.2 - 14.8 mg/m3, Literature data Result: Lung tumour Species: Rat Test Duration: 24 months
POTASSIUM CLAVULANATE	SAR Result: No structual alerts identified.

IARC Monographs. Overall Evaluation of Carcinogenicity

TITANIUM DIOXIDE (CAS 13463-67-7) 2B Possibly carcinogenic to humans.

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

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

Reproductivity

POTASSIUM CLAVULANATE	Fertility (IV) Result: Reproductive and developmental NOAEL 75 mg/kg/day Species: Rat

Reproductivity

AMOXICILLIN TRIHYDRATE	Fertility/foetal development, Rat and Mouse Result: No effect
POTASSIUM CLAVULANATE	Reproduction/Fertility Study (IV) Result: Reproductive performance NOAEL 150 mg/kg/day Species: Rabbit Reproduction/Fertility Study (IV) Result: Teratogenic and embryotoxic NOAEL 150 mg/kg/day Species: Rat

Specific target organ toxicity - single exposure None known.

Specific target organ toxicity - repeated exposure None known.

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

Chronic effects Prolonged inhalation may be harmful. Prolonged exposure may cause chronic effects.

Further information Caution - Pharmaceutical agent.

12. Ecological information

Ecotoxicity No information is available about the potential of this product to produce adverse environmental effects. Contains a substance which causes risk of hazardous effects to the environment. The product contains a substance which may cause long-term adverse effects in the environment.

Components		Species	Test Results
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
AMOXYCILLIN SODIUM (CAS 34642-77-8)			
Aquatic			
Acute			
Algae	EC50	Green algae (Selenastrum capricornutum)	581 mg/l, 72 hours
	NOEC	Green algae (Selenastrum capricornutum)	489 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	> 2123 mg/l, 48 hours Static test
	NOEC	Water flea (Daphnia magna)	2123 mg/l, 48 hours Static test
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	> 858 mg/l, 96 hours Static test
		Rainbow trout (Adult Oncorhyncus mykiss)	> 923 mg/l, 96 hours Static test
	NOEC	Bluegill sunfish (Adult Lepomis macrochirus)	858 mg/l, 96 hours Static test
		Rainbow trout (Adult Oncorhyncus mykiss)	923 mg/l, 96 hours Static test
CITRIC ACID ANHYDROUS (CAS 77-92-9)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	120 mg/l, 72 hours Static test

Components		Species	Test Results
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	1516 mg/l, 96 hours Static test
		Golden ide/orfe (Adult Leuciscus idus)	440 - 760 mg/l, 96 hours Static test
Microtox	EC50	Microtox	14 mg/l, 15 minutes
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
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.

Persistence and degradability

Hydrolysis

Half-life (Hydrolysis-acidic)	
POTASSIUM CLAVULANATE	11.9 Hours Measured
Half-life (Hydrolysis-basic)	
POTASSIUM CLAVULANATE	9.92 Hours Measured
Half-life (Hydrolysis-neutral)	
AMOXICILLIN TRIHYDRATE	50 - 113 Days Measured
AMOXYCILLIN SODIUM	50 - 113 Days Measured
POTASSIUM CLAVULANATE	28.3 Hours Measured

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)	
AMOXICILLIN TRIHYDRATE	-1.56
POTASSIUM CLAVULANATE	-5.8 (Estimated).

Mobility in soil

Adsorption

Sludge/biomass distribution coefficient - log Kd	
AMOXICILLIN TRIHYDRATE	-0.17 Estimated
AMOXYCILLIN SODIUM	-0.17 Estimated

Mobility in general

Volatility

Henry's law	
AMOXICILLIN TRIHYDRATE	0 atm m^3/mol Calculated
CITRIC ACID ANHYDROUS	< 0 atm m^3/mol Calculated, 25 °C

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Dispose of contents/container in accordance with local/regional/national/international regulations.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products	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

DOT

Not regulated as a dangerous good.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

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

15. Regulatory information

US federal regulations

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories	Immediate Hazard - Yes Delayed Hazard - Yes Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical	No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA)	Not regulated.

US state regulations

US. Massachusetts RTK - Substance List

TITANIUM DIOXIDE (CAS 13463-67-7)

US. New Jersey Worker and Community Right-to-Know Act

Not regulated.

US. Pennsylvania RTK - Hazardous Substances

TITANIUM DIOXIDE (CAS 13463-67-7)

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

WARNING: This product contains a chemical known to the State of California to cause cancer.

US - California Proposition 65 - CRT: Listed date/Carcinogenic substance

TITANIUM DIOXIDE (CAS 13463-67-7) Listed: September 2, 2011

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, including date of preparation or last revision

Issue date 06-06-2014

Revision date 06-06-2014

Version # 13

Further information HMIS® is a registered trade and service mark of the NPCA. Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling.

HMIS® ratings
Health: 2*
Flammability: 1
Physical hazard: 0

NFPA ratings
Health: 2
Flammability: 1
Instability: 0

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
Product and Company Identification: Product and Company Identification
Composition / Information on Ingredients: Ingredients
Regulatory Information: United States
GHS: Classification