SAFETY DATA SHEET

1. Identification

Product identifier **AUGMENTIN TABLETS**

Other means of identification

Synonyms AUGMENTIN 156.25 MG TABLETS * AUGMENTIN 250 MG TABLETS * AUGMENTIN 500 MG TABLETS * AUGMENTIN 187.5 MG TABLETS * AUGMENTIN 375 MG TABLETS * AUGMENTIN 625 MG TABLETS * AUGMENTAN TABLETS * AUGMENTIN 2:1 TABLETS * AUGMENTIN 4:1 TABLETS * CLAVULIN 250 TABLETS * CLAVULIN 500F TABLETS * AMOCLAV 375 MG TABLETS * AMOCLAV 625 MG TABLETS * CLAMOXYL TABLETS 250 MG * SPEKTRAMOX 375 MG FINAL TABLETS * NDC NO. 0029-6075-27 * NDC NO. 0029-6075-31 * NDC NO. 0029-6080-12 * NDC NO. 0029-6080-31 * AMOXICILLIN TRIHYDRATE AND POTASSIUM CLAVULANATE, 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- 7-OXO-, TRIHYDRATE * (2S,5R,6R)-6-(R-(-)-2,AMINO-2-(P-HYDROX YPHENYL)ACETAM IDO)-3,3-DIMETHYL -7-OXO-4-THIA-1-AZABICYCLO(3.2.0)HEP TANE-2-CARBOXYLIC ACID TRIHYDRATE * 4-THIA-1-AZABICYCLO(3.2.0)HEPTANE-2-CARBOXYLIC ACID, 6-((AMINO(4-HYDROXYPHENYL)ACETYL)AMINO)-3,3-D IMETHYL-7-OXO-, TRIHYDRATE, (2S-(2ALPHA,5ALPHA,6BETA(S*)))- * ALPHA-AMINO-P-HYDROXYBENZYLPENI CILLIN TRIHYDRATE * AX 250 * BRL-2333 * J1030 * RTECS XH8310000 * AMOXICILLIN * AMOXYCILLIN TRIHYDRATE	61336-70-7	35 - < 60
POTASSIUM CLAVULANATE	POTASSIUM CLAVULANATE (STERILE) * SKF-85472-Y * BRL-14151MM-F * ITEM NUMBER 8104750	61177-45-5	6 - < 24
MICROCRYSTALLINE CELLULOSE	AVICEL PH MICROCRYSTALLINE CELLULOSE * ABICEL * ALPHA-CELLULOSE * ARBOCEL * ARBOCELL B 600/30 * ARBOCELL BC 200 * AVICEL PH101 * AVICEL PH102 * AVICEL PH103 * AVICEL PH105 * AVICEL PH112 * AVICEL PH200 * BETA-AMYLOSE * CELLEX MX * CELLULOSE (8CI9CI) * CELLULOSE 248 * CELLULOSE CRYSTALLINE * CELLULOSE, FOOD GRADE * CELUFI * CRYSTALLINE CELLULOSE * EMOCEL * MCC * MICROCRYSTALLINE CELLULOSE * POWDERED CELLULOSE * RTECS FJ5691460 * SOLKA FLOC BW200 * CELLULOSA (FIBRA PAPEL) * CELLULOSE (PAPER FIBRES) * CELLULOSE-PAPER FIBER * CELULOSA (FIBRA PAPEL) * TSELLULOOS	9004-34-6	5.12
SODIUM STARCH GLYCOLATE	STARCH, CARBOXYMETHYL ETHER, SODIUM SALT * CARBOXYMETHYL STARCH SODIUM SALT * EXPLOTAB * SODIUM CARBOXYMETHYL STARCH * SODIUM CM-STARCH * 738 (GW ACN) * CARBOXYMETHYLSTÄRKE, NATRIUMSALZ * SODIUM STARCH GLYCOLATE	9063-38-1	2
MAGNESIUM STEARATE	STEARIC ACID, MAGNESIUM SALT * MAGNESIUM DISTEARATE * DIBASIC MAGNESIUM STEARATE * MAGNESIUM DISTEARATE, PURE	557-04-0	1
SILICON DIOXIDE	SILICA * SILICA GEL * AMORPHOUS SILICA * DIATOMACEOUS EARTH * INFUSORIAL EARTH * CAB-O-SIL M-5	7631-86-9	1
Other components below reportable levels			30 - < 40

*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
Foam. Dry chemical powder. Carbon dioxide (CO2). Water.

Unsuitable extinguishing media
None known.

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
Assume that this product is capable of sustaining combustion.

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
Avoid contact with eyes, skin, and clothing. Avoid prolonged exposure. Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities
Store in original tightly closed container. Store in a well-ventilated place. 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	SKIN SENSITISER
		3	RESPIRATORY SENSITISER
MAGNESIUM STEARATE (CAS 557-04-0)	OHC	1	
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	OHC	1	
POTASSIUM CLAVULANATE (CAS 61177-45-5)	8 HR TWA	5000 mcg/m3	
	OHC	1	
SILICON DIOXIDE (CAS 7631-86-9)	OHC	1	
SODIUM STARCH GLYCOLATE (CAS 9063-38-1)	OHC	1	

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

Components	Type	Value	Form
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	PEL	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.

US. OSHA Table Z-3 (29 CFR 1910.1000)

Components	Type	Value
SILICON DIOXIDE (CAS 7631-86-9)	TWA	0.8 mg/m3
		20 millions of particle

US. ACGIH Threshold Limit Values

Components	Type	Value
MAGNESIUM STEARATE (CAS 557-04-0)	TWA	10 mg/m3
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	TWA	10 mg/m3

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	TWA	5 mg/m3	Respirable.
		10 mg/m3	Total
SILICON DIOXIDE (CAS 7631-86-9)	TWA	6 mg/m3	

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

Appropriate engineering controls Not available.

Individual protection measures, such as personal protective equipment

Eye/face protection Not normally needed. If contact is likely, safety glasses with side shields are recommended.

Hand protection Not normally needed. For prolonged or repeated skin contact use suitable protective gloves.

Skin protection

Other	Not normally needed. Wear suitable protective clothing as protection against splashing or contamination.
Respiratory protection	No personal respiratory protective equipment normally required. When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.
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	The product is stable and non-reactive under normal conditions of use, storage and transport.
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
MAGNESIUM STEARATE (CAS 557-04-0)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)		
Acute		
Dermal		
LD50	Rabbit	> 2000 mg/kg
Oral		
LD50	Rat	> 2000 mg/kg
POTASSIUM CLAVULANATE (CAS 61177-45-5)		
Acute		
Oral		
LD	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/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

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 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

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.

IARC Monographs. Overall Evaluation of Carcinogenicity

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

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
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.

Further 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

Components		Species	Test Results
	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
Microtox	EC50	Microtox	12.5 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
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

* 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

Photolysis

UV/visible spectrum wavelength

MAGNESIUM STEARATE	210 nm

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
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-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)

MAGNESIUM STEARATE	> 9999 Estimated

Mobility in soil

Adsorption

Sludge/biomass distribution coefficient - log Kd

AMOXICILLIN TRIHYDRATE	-0.17 Estimated

Soil/sediment sorption - log Koc

MAGNESIUM STEARATE	5.86 Estimated

Mobility in general

Volatility

Henry's law

AMOXICILLIN TRIHYDRATE	0 atm m^3/mol Calculated

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Dispose in accordance with all applicable 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 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.

15. Regulatory information

US federal regulations One or more components are not listed on TSCA.

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.

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

MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)
SILICON DIOXIDE (CAS 7631-86-9)

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

MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)
SILICON DIOXIDE (CAS 7631-86-9)

US. Pennsylvania Worker and Community Right-to-Know Law

MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)
SILICON DIOXIDE (CAS 7631-86-9)

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

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

Country(s) or region	Inventory name	On inventory (yes/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 07-11-2014

Revision date 07-11-2014

Version # 20

Further information HMIS® is a registered trade and service mark of the NPCA.

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
Physical & Chemical Properties:
Transport Information: Material Transportation Information
Regulatory Information: United States
HazReg Data: Transportation
GHS: Classification