



# 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](mailto:msds@gsk.com)  
Website: [www.gsk.com](http://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-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	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

<b>Inhalation</b>	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.
<b>Skin contact</b>	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.
<b>Eye contact</b>	Do not rub eyes. Rinse with water. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	Rinse mouth. Call a POISON CENTER or doctor/physician if you feel unwell.
<b>Most important symptoms/effects, acute and delayed</b>	Possible effects of overexposure in the workplace include: symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing), nausea, vomiting, diarrhoea.
<b>Indication of immediate medical attention and special treatment needed</b>	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.
<b>General information</b>	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

<b>Suitable extinguishing media</b>	Foam. Dry chemical powder. Carbon dioxide (CO <sub>2</sub> ). Water.
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	During fire, gases hazardous to health may be formed.
<b>Special protective equipment and precautions for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Fire-fighting equipment/instructions</b>	Move containers from fire area if you can do so without risk.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	Assume that this product is capable of sustaining combustion.

## 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	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.
<b>Methods and materials for containment and cleaning up</b>	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.
<b>Environmental precautions</b>	Avoid discharge into drains, water courses or onto the ground.

## 7. Handling and storage

<b>Precautions for safe handling</b>	Avoid contact with eyes, skin, and clothing. Avoid prolonged exposure. Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices.
<b>Conditions for safe storage, including any incompatibilities</b>	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 RESPIRATORY SENSITISER
		3	
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**

<b>Other</b>	Not normally needed. Wear suitable protective clothing as protection against splashing or contamination.
<b>Respiratory protection</b>	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.
<b>Thermal hazards</b>	Wear appropriate thermal protective clothing, when necessary.
<b>General hygiene considerations</b>	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

<b>Physical state</b>	Solid.
<b>Form</b>	Tablet.
<b>Color</b>	Not available.
<b>Odor</b>	Not available.
<b>Odor threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	Not available.
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Not available.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Contact with incompatible materials.
<b>Incompatible materials</b>	Strong oxidizing agents. Fluorine.
<b>Hazardous decomposition products</b>	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Ingestion</b>	Expected to be a low ingestion hazard. Health injuries are not known or expected under normal use.
<b>Inhalation</b>	Health injuries are not known or expected under normal use.
<b>Skin contact</b>	May cause an allergic skin reaction. Health injuries are not known or expected under normal use.
<b>Eye contact</b>	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)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg
MAGNESIUM STEARATE (CAS 557-04-0)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)		
<b>Acute</b>		
<i>Dermal</i>		
LD50	Rabbit	> 2000 mg/kg
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg
POTASSIUM CLAVULANATE (CAS 61177-45-5)		
<b>Acute</b>		
<i>Oral</i>		
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 structural 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 ( <i>Selenastrum capricornutum</i> )	530 mg/l, 72 hours
Crustacea	EC50	Water flea ( <i>Daphnia magna</i> )	> 2300 mg/l, 48 hours Static test
	NOEC	Water flea ( <i>Daphnia magna</i> )	2300 mg/l, 48 hours Static test
Fish	EC50	Bluegill sunfish (Adult <i>Lepomis macrochirus</i> )	> 930 mg/l, 96 hours Static test
		Rainbow trout (Adult <i>Oncorhynchus mykiss</i> )	> 1000 mg/l, 96 hours Static test
	NOEC	Bluegill sunfish (Adult <i>Lepomis macrochirus</i> )	930 mg/l, 96 hours Static test
		Rainbow trout (Adult <i>Oncorhynchus mykiss</i> )	1000 mg/l, 96 hours Static test
<b>MAGNESIUM STEARATE (CAS 557-04-0)</b>			
<b>Aquatic</b>			
<i>Acute</i>			
Fish	EC50	Orange-red killfish (Adult <i>Oryzias latipes</i> )	130 mg/l, 96 hours
Microtox	EC50	Microtox	12.5 mg/l, 15 minutes
<b>POTASSIUM CLAVULANATE (CAS 61177-45-5)</b>			
<b>Aquatic</b>			
<i>Acute</i>			
Algae	EC50	Green algae ( <i>Selenastrum capricornutum</i> )	56 mg/L, 72 hours
	NOEC	Green algae ( <i>Selenastrum capricornutum</i> )	9.4 mg/L, 72 hours
Crustacea	EC50	Water flea ( <i>Daphnia magna</i> )	1610 mg/L, 48 hours Static test
	NOEC	Water flea ( <i>Daphnia magna</i> )	530 mg/L, 48 hours Static test
Fish	EC50	Bluegill sunfish (Adult <i>Lepomis macrochirus</i> )	> 790 mg/L, 96 hours Static test
		Rainbow trout (Adult <i>Oncorhynchus mykiss</i> )	> 960 mg/L, 96 hours Static test
	NOEC	Bluegill sunfish (Adult <i>Lepomis macrochirus</i> )	790 mg/L, 96 hours Static test
		Rainbow trout (Adult <i>Oncorhynchus mykiss</i> )	960 mg/L, 96 hours Static test
<b>SILICON DIOXIDE (CAS 7631-86-9)</b>			
<b>Aquatic</b>			
<i>Acute</i>			
Algae	EC50	Green algae ( <i>Selenastrum capricornutum</i> )	440 mg/l, 72 hours
	NOEC	Green algae ( <i>Selenastrum capricornutum</i> )	60 mg/l, 72 hours
Crustacea	EC50	Water flea ( <i>Daphnia magna</i> )	> 10000 mg/l, 24 hours Static test
Fish	EC50	Common carp (Juvenile <i>Cyprinus carpio</i> )	> 10000 mg/l, 72 hours
		Zebra fish (Adult <i>Brachydanio rerio</i> )	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<sup>3</sup>/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

<b>Issue date</b>	07-11-2014
<b>Revision date</b>	07-11-2014
<b>Version #</b>	20
<b>Further information</b>	HMIS® is a registered trade and service mark of the NPCA.
<b>HMIS® ratings</b>	Health: 2* Flammability: 1 Physical hazard: 0
<b>NFPA ratings</b>	Health: 2 Flammability: 1 Instability: 0
<b>References</b>	GSK Hazard Determination
<b>Disclaimer</b>	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.
<b>Revision Information</b>	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