

## 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

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-HYDROXYBENZYL PENICILLIN TRIHYDRATE * AX 250 * BRL-2333 * J1030 * RTECS XH8310000 * AMOXICILLIN * AMOXYCILLIN TRIHYDRATE	61336-70-7	62.01
SILICON DIOXIDE COLLOIDAL		7631-86-9	12.67
POTASSIUM CLAVULANATE	POTASSIUM CLAVULANATE (STERILE) * SKF-85472-Y * BRL-14151MM-F * ITEM NUMBER 8104750	61177-45-5	9.64
SODIUM CARBOXYMETHYL CELLULOSE	CELLULOSE, CARBOXYMETHYL ETHER, SODIUM SALT * CELLULOSE SODIUM GLYCOLATE * SODIUM CELLULOSE GLYCOLATE * SODIUM GLYCOLATE CELLULOSE * CARBOXYMETHYLCELLULOSE SODIUM * CARBOXYMETHYLCELLULOSE SODIUM SALT * ALMELOSE * CMC-NA * CMC * CARBOXYMETHYL CELLULOSE * SODIUM CARBOXYMETHYLCELLULOSE * AQUALON(R) CELLULOSE GUM * AQUACIDE II * OHS80080 * RTECS FJ5950000 * CELLULOSE CARBOXY METHYL ETHER, SODIUM SALT	9004-32-4	5.8
ASPARTAME	ASPARTYLPHENYLALANINE METHYL ESTER * NUTRASWEET	22839-47-0	2.2
POLYVINYLPIRROLIDONE	CROSPVIDONE * CROSPVIDONE (KOLLIDON CL-SF) * PVPP * POLY[1-(2-OXO-1-PYRROLIDINYL)-1,2-ETHANEDIYL]	25249-54-1	1.86
SODIUM BENZOATE	BENZOIC ACID, SODIUM SALT * BENZOATE OF SODA * SODIUM BENZOIC ACID	532-32-1	1.18
XANTHAN GUM	ACTIGUM CX 9 * BIOPOLYMER XB-23 XANTHAN GUM * BIOZAN R * ENORFLO X * FLOCON 1035 * GALAXY XB * KELFLO * KELITROL (GUM) * KELZAN * KENTROL * POLYSACCHARIDE B 1459 * RHODOPOL 23 * XANFLOOD * XANTHOMONAS GUM	11138-66-2	0.59
SILICON DIOXIDE	SILICA * SILICA GEL * AMORPHOUS SILICA * DIATOMACEOUS EARTH * INFUSORIAL EARTH * CAB-O-SIL M-5	7631-86-9	0.35
MAGNESIUM STEARATE	STEARIC ACID, MAGNESIUM SALT * MAGNESIUM DISTEARATE * DIBASIC MAGNESIUM STEARATE * MAGNESIUM DISTEARATE, PURE	557-04-0	0.23
Other components below reportable levels			3.47

\*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>	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.
<b>Skin contact</b>	Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention immediately.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
<b>Ingestion</b>	If swallowed, rinse mouth with water (only if the person is conscious). Call a physician or poison control center immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.
<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). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. 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.

## 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Water. Foam. Dry chemical powder.
<b>Unsuitable extinguishing media</b>	Carbon dioxide (CO <sub>2</sub> ).
<b>Specific hazards arising from the chemical</b>	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.
<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. Use water spray to cool unopened containers.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	Assume that this material 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. Avoid inhalation of dust. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the 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 of the SDS.
<b>Methods and materials for containment and cleaning up</b>	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. Minimize 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 of the SDS.
<b>Environmental precautions</b>	Avoid discharge into drains, water courses or onto the ground.

## 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/personal protection

### Occupational exposure limits

#### GSK

#### Components

Components	Type	Value	Note
AMOXICILLIN TRIHYDRATE (CAS 61336-70-7)	15 MIN STEL	100 mcg/m3	
	OHC	3	RESPIRATORY SENSITISER
		3	SKIN 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	
SODIUM BENZOATE (CAS 532-32-1)	8 HR TWA	5000 mcg/m3	
	OHC	1	
SODIUM CARBOXYMETHYL CELLULOSE (CAS 9004-32-4)	OHC	1	
XANTHAN GUM (CAS 11138-66-2)	OHC	1	

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

#### Components

Components	Type	Value
SILICON DIOXIDE (CAS 7631-86-9)	TWA	0.8 mg/m3
		20 mppcf
SILICON DIOXIDE COLLOIDAL (CAS 7631-86-9)	TWA	0.8 mg/m3
		20 mppcf

#### US. ACGIH Threshold Limit Values

#### Components

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

#### US. NIOSH: Pocket Guide to Chemical Hazards

#### Components

Components	Type	Value
SILICON DIOXIDE (CAS 7631-86-9)	TWA	6 mg/m3
SILICON DIOXIDE COLLOIDAL (CAS 7631-86-9)	TWA	6 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. 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, such as personal protective equipment**

**Eye/face protection** Wear eye/face protection. 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** Wear suitable protective clothing as protection against splashing or contamination.

**Respiratory protection** 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** 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.

**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

<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. 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.
<b>Possibility of hazardous reactions</b>	Hazardous polymerization does not occur.
<b>Conditions to avoid</b>	Keep away from heat, sparks and open flame. Contact with incompatible materials. Avoid dispersion as a dust cloud. Moisture.
<b>Incompatible materials</b>	Water, moisture. Fluorine. Chlorine.
<b>Hazardous decomposition products</b>	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 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. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
<b>Skin contact</b>	May cause an allergic skin reaction.
<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.

<b>Components</b>	<b>Species</b>	<b>Test Results</b>
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
POTASSIUM CLAVULANATE (CAS 61177-45-5)		
<b>Acute</b>		
<i>Oral</i>		
LD	Rat	> 5000 mg/kg
XANTHAN GUM (CAS 11138-66-2)		
<b>Acute</b>		
<i>Inhalation</i>		
LC50	Rat	> 21 mg/l, 1 hour exposure
<i>Oral</i>		
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

<b>Corrosivity</b>	POTASSIUM CLAVULANATE	OECD 404 Result: Non-irritant
<b>Irritation Corrosion - Skin: P.I.I. value</b>	MAGNESIUM STEARATE	0
<b>Serious eye damage/eye irritation</b>	Direct contact with eyes may cause temporary irritation. Health injuries are not known or expected under normal use.	
<b>Eye</b>	POTASSIUM CLAVULANATE	OECD 405 Result: Non-Irritating
<b>Eye / Kay and Calandra class - Intact</b>	MAGNESIUM STEARATE	4 Recovery Period: 2 days
	AMOXICILLIN TRIHYDRATE	Result: Minimal irritant Species: Rabbit Recovery Period: 2 days
<b>Respiratory or skin sensitization</b>		
<b>Respiratory sensitization</b>	May cause allergy or asthma symptoms or breathing difficulties if inhaled.	
<b>Skin sensitization</b>	May cause an allergic skin reaction.	
	<b>Sensitization</b>	
	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.
<b>Germ cell mutagenicity</b>	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.	
	<b>Mutagenicity</b>	
	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.
<b>Carcinogenicity</b>	Health injuries are not known or expected under normal use.	
	POTASSIUM CLAVULANATE	SAR Result: No structural alerts identified.
<b>IARC Monographs. Overall Evaluation of Carcinogenicity</b>		
	SILICON DIOXIDE (CAS 7631-86-9)	3 Not classifiable as to carcinogenicity to humans.
	SILICON DIOXIDE COLLOIDAL (CAS 7631-86-9)	3 Not classifiable as to carcinogenicity to humans.
<b>OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)</b>		
	Not listed.	
<b>Reproductive toxicity</b>	Health injuries are not known or expected under normal use.	
	<b>Reproductivity</b>	
	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

<b>Specific target organ toxicity - single exposure</b>	None known.
<b>Specific target organ toxicity - repeated exposure</b>	None known.
<b>Aspiration hazard</b>	Not an aspiration hazard.
<b>Chronic effects</b>	Prolonged inhalation may be harmful.
<b>Further information</b>	Caution - Pharmaceutical agent.

## 12. Ecological information

**Ecotoxicity** Not expected to be harmful to aquatic organisms.

Components		Species	Test Results
<b>AMOXICILLIN TRIHYDRATE (CAS 61336-70-7)</b>			
<b>Aquatic</b>			
<i>Acute</i>			
Algae	EC50	Green algae ( <i>Selenastrum capricornutum</i> )	630 mg/l, 72 hours
	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
<b>POLYVINYLPOLYPYRROLIDONE (CAS 25249-54-1)</b>			
<i>Acute</i>			
	IC50	Activated sludge	> 1000 mg/l, 3 hours Static test
<b>Aquatic</b>			
<i>Acute</i>			
Crustacea	EC50	Water flea ( <i>Daphnia magna</i> )	84 mg/l, 48 hours Static test
	NOEC	Water flea ( <i>Daphnia magna</i> )	32 mg/l, 48 hours Static test
<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



Components		Species	Test Results
	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
<b>SILICON DIOXIDE COLLOIDAL (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
<b>SODIUM BENZOATE (CAS 532-32-1)</b>			
<b>Aquatic</b>			
<i>Acute</i>			
Crustacea	EC50	Water flea ( <i>Daphnia magna</i> )	> 100 mg/L, 96 hours Static test
Fish	EC50	Fathead minnow (Juvenile <i>Pimephales promelas</i> )	484 mg/L, 96 hours Flow-through test
<b>SODIUM CARBOXYMETHYL CELLULOSE (CAS 9004-32-4)</b>			
<i>Acute</i>			
	IC50	Activated sludge	> 1000 mg/l, 3 hours
<b>Aquatic</b>			
<i>Acute</i>			
Crustacea	EC50	Water flea ( <i>Daphnia magna</i> )	> 100 mg/l, 48 hours Static test
	NOEC	Water flea ( <i>Daphnia magna</i> )	100 mg/l, 48 hours Static test
Fish	EC50	Rainbow trout (Adult <i>Oncorhynchus mykiss</i> )	> 20000 mg/l, 96 hours Static test
<b>XANTHAN GUM (CAS 11138-66-2)</b>			
<b>Aquatic</b>			
<i>Acute</i>			
Fish	EC50	Rainbow trout (Adult <i>Oncorhynchus mykiss</i> )	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

### Photolysis

#### 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

POLYVINYLPIRROLIDONE 0 %, 28 days Modified MITI test, Activated sludge

POTASSIUM CLAVULANATE 90 %, 28 days Zahn-Wellens, Activated sludge

SODIUM CARBOXYMETHYL CELLULOSE 7 %, 28 days Zahn-Wellens, Activated sludge

#### Percent degradation (Aerobic biodegradation-soil)

MAGNESIUM STEARATE 50 %, 13 days

#### Percent degradation (Anaerobic biodegradation)

SODIUM BENZOATE 93 %, 7 days Other degradation test system, Mixed Residential/Industrial

### Bioaccumulative potential

#### Partition coefficient n-octanol / water (log Kow)

AMOXICILLIN TRIHYDRATE -1.56

POTASSIUM CLAVULANATE -5.8 (Estimated).

SODIUM BENZOATE 1.89

#### Bioconcentration factor (BCF)

ASPARTAME 1 Estimated

MAGNESIUM STEARATE > 9999 Estimated

### Mobility in soil

#### 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

SODIUM BENZOATE 1.16 Calculated

### Mobility in general

#### Volatility

##### Henry's law

AMOXICILLIN TRIHYDRATE 0 atm m<sup>3</sup>/mol Calculated

ASPARTAME < 0 atm m<sup>3</sup>/mol Estimated

**Other adverse effects** Not available.

## 13. Disposal considerations

**Disposal instructions** Consult authorities before disposal. 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

<b>DOT</b>	
<b>UN number</b>	UN3088
<b>UN proper shipping name</b>	Self-heating solid, organic, n.o.s. (AMOXICILLIN TRIHYDRATE AND POTASSIUM CLAVULANATE, FORMULATED PRODUCT)
<b>Transport hazard class(es)</b>	
<b>Class</b>	4.2
<b>Subsidiary risk</b>	-
<b>Label(s)</b>	4.2
<b>Packing group</b>	II
<b>Special precautions for user</b>	Not available.
<b>Special provisions</b>	IB6, IP2, T3, TP33
<b>Packaging exceptions</b>	None
<b>Packaging non bulk</b>	212
<b>Packaging bulk</b>	241
<b>IATA</b>	
<b>UN number</b>	UN3088
<b>UN proper shipping name</b>	Self-heating solid, organic, n.o.s. (AMOXICILLIN TRIHYDRATE AND POTASSIUM CLAVULANATE, FORMULATED PRODUCT)
<b>Transport hazard class(es)</b>	4.2
<b>Subsidiary class(es)</b>	-
<b>Packaging group</b>	II
<b>Labels required</b>	4.2
<b>Environmental hazards</b>	No.
<b>ERG Code</b>	Not available.
<b>Special precautions for user</b>	Not available.
<b>Other information</b>	
<b>Cargo aircraft only</b>	Forbidden.
<b>IMDG</b>	
<b>UN number</b>	UN3088
<b>UN proper shipping name</b>	SELF-HEATING SOLID, ORGANIC, N.O.S. (AMOXICILLIN TRIHYDRATE AND POTASSIUM CLAVULANATE, FORMULATED PRODUCT)
<b>Transport hazard class(es)</b>	
<b>Class</b>	4.2
<b>Subsidiary risk</b>	-
<b>Label(s)</b>	4.2
<b>Packing group</b>	II
<b>Environmental hazards</b>	
<b>Marine pollutant</b>	No.
<b>EmS</b>	F-A, S-J
<b>Special precautions for user</b>	Not available.
<b>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>	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.

**DOT**



**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****US federal regulations**

One or more components are not listed on TSCA.  
This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

**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 - No  
Fire Hazard - Yes  
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**

SILICON DIOXIDE (CAS 7631-86-9)  
SILICON DIOXIDE COLLOIDAL (CAS 7631-86-9)

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

SILICON DIOXIDE (CAS 7631-86-9)  
SILICON DIOXIDE COLLOIDAL (CAS 7631-86-9)

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

SILICON DIOXIDE (CAS 7631-86-9)  
SILICON DIOXIDE COLLOIDAL (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
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>	09-11-2014
<b>Revision date</b>	09-11-2014
<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: 2 Physical hazard: 2
<b>NFPA ratings</b>	Health: 2 Flammability: 2 Instability: 2
<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>	Hazard(s) identification: Hazard(s) not otherwise classified (HNOC) 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