



SAFETY DATA SHEET

1. Identification

Product identifier

AUGMENTIN 7:1 ORAL SUSPENSION

Other means of identification

Synonyms

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

Recommended use

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-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	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 CARBOXYMETHYL 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

Inhalation	In case of accident by inhalation: remove casualty to fresh air and keep at rest. If not breathing, give artificial respiration. If breathing is difficult, trained personnel should give oxygen. Get medical attention immediately.
Skin contact	Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention immediately.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
Ingestion	If swallowed, rinse mouth with water (only if the person is conscious). Call a physician or poison control center immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.
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). 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

Suitable extinguishing media	Water. Foam. Dry chemical powder.
Unsuitable extinguishing media	Carbon dioxide (CO ₂).
Specific hazards arising from the chemical	Thermal decomposition of this material can produce toxic, dense smoke containing oxides of carbon, sulphur and nitrogen together with acetaldehyde. Ash remaining after thermal decomposition may contain cyanide compounds and should not come into contact with acidic conditions which may result in the production of hydrogen cyanide gas.
Special protective equipment and precautions for 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. Use water spray to cool unopened containers.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	Assume that this material 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. 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.
Methods and materials for containment and cleaning up	Stop the flow of material, if this is without risk. If sweeping of a contaminated area is necessary use a dust suppressant agent which does not react with the product. Collect dust using a vacuum cleaner equipped with HEPA filter. 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.
Environmental precautions	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

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions. The purity of this material will be affected by exposure to moisture. This material can become unstable if subjected to heat, high levels of moisture or storage in large masses.
Possibility of hazardous reactions	Hazardous polymerization does not occur.
Conditions to avoid	Keep away from heat, sparks and open flame. Contact with incompatible materials. Avoid dispersion as a dust cloud. Moisture.
Incompatible materials	Water, moisture. Fluorine. Chlorine.
Hazardous decomposition products	Thermal decomposition of this material can produce toxic, dense smoke containing oxides of carbon, sulphur and nitrogen together with acetaldehyde. Ash remaining after thermal decomposition may contain cyanide compounds and should not come into contact with acidic conditions which may result in the production of hydrogen cyanide gas.

11. Toxicological information

Information on 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. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	May cause an allergic skin reaction.
Eye contact	Direct contact with eyes may cause temporary irritation.

Symptoms related to 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		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg
MAGNESIUM STEARATE (CAS 557-04-0)		
Acute		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg
POTASSIUM CLAVULANATE (CAS 61177-45-5)		
Acute		
<i>Oral</i>		
LD	Rat	> 5000 mg/kg
XANTHAN GUM (CAS 11138-66-2)		
Acute		
<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

Corrosivity	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.	
Skin sensitization	May cause an allergic skin reaction.	
	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.
	SILICON DIOXIDE COLLOIDAL (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 an aspiration hazard.
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			
<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
MAGNESIUM STEARATE (CAS 557-04-0)			
Aquatic			
<i>Acute</i>			
Fish	EC50	Orange-red killfish (Adult <i>Oryzias latipes</i>)	130 mg/l, 96 hours
POLYVINYLPOLYPYRROLIDONE (CAS 25249-54-1)			
<i>Acute</i>			
	IC50	Activated sludge	> 1000 mg/l, 3 hours Static test
Aquatic			
<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
POTASSIUM CLAVULANATE (CAS 61177-45-5)			
Aquatic			
<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
SILICON DIOXIDE (CAS 7631-86-9)			
Aquatic			
<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
SILICON DIOXIDE COLLOIDAL (CAS 7631-86-9)			
Aquatic			
<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
SODIUM BENZOATE (CAS 532-32-1)			
Aquatic			
<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
SODIUM CARBOXYMETHYL CELLULOSE (CAS 9004-32-4)			
<i>Acute</i>			
	IC50	Activated sludge	> 1000 mg/l, 3 hours
Aquatic			
<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
XANTHAN GUM (CAS 11138-66-2)			
Aquatic			
<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 m³/mol Calculated

ASPARTAME < 0 atm m³/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

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

Issue date	09-11-2014
Revision date	09-11-2014
Version #	20
Further information	HMIS® is a registered trade and service mark of the NPCA.
HMIS® ratings	Health: 2* Flammability: 2 Physical hazard: 2
NFPA ratings	Health: 2 Flammability: 2 Instability: 2
References	GSK Hazard Determination
Disclaimer	The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.
Revision Information	Hazard(s) identification: 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