



SAFETY DATA SHEET

1. Identification

Product identifier

AUGMENTIN TABLETS BID

Other means of identification

Synonyms

AUGMENTIN 875 MG TABLETS * AUGMENTIN 1000 MG TABLETS * AUGMENTIN 1 GRAM TABLETS * AUGMENTIN DUO TABLETS * AUGMENTAN FILMTABLETTEN 875/125 MG * CLAVULIN 875 TABLETS * PENILAN 875 MG/125 MG TABLETS * AUGMENTINE 875 MG/125 MG TABLETS * CLAMOXYL DUO 1 G TABLETS * NDC NO. 0029-6086-12 * NDC NO. 0029-6086-21 * POTASSIUM CLAVULANATE AND AMOXICILLIN TRIHYDRATE, 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	< 70
MICROCRYSTALLINE CELLULOSE	AVICEL PH MICROCRYSTALLINE CELLULOSE * ALPHA-CELLULOSE * AVICEL PH101 * AVICEL PH102 * AVICEL PH103 * AVICEL PH105 * AVICEL PH112 * AVICEL PH200 * CELLULOSE (8CI9CI) * CELLULOSE CRYSTALLINE * CELLULOSE, FOOD GRADE * CRYSTALLINE CELLULOSE	9004-34-6	< 20
POTASSIUM CLAVULANATE	POTASSIUM CLAVULANATE (STERILE) * SKF-85472-Y * BRL-14151MM-F * ITEM NUMBER 8104750	61177-45-5	< 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	2.04
MAGNESIUM STEARATE	STEARIC ACID, MAGNESIUM SALT * MAGNESIUM DISTEARATE * DIBASIC MAGNESIUM STEARATE * MAGNESIUM DISTEARATE, PURE	557-04-0	< 2
SILICON DIOXIDE	SILICA * SILICA GEL * AMORPHOUS SILICA * DIATOMACEOUS EARTH * INFUSORIAL EARTH * CAB-O-SIL M-5	7631-86-9	< 1 < 5

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

4. First-aid measures

Inhalation	Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if symptoms develop or persist. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.
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). If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center.
Most important symptoms/effects, acute and delayed	Accidental exposure or contact might produce: symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing) nausea, vomiting, diarrhoea, abdominal discomfort.

Indication of immediate medical attention and special treatment needed

No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center.

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.

5. Fire-fighting measures

Suitable extinguishing media

Water. Foam.

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

No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. 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 prolonged exposure. No special control measures required for the normal handling of this product. Avoid breaking or crushing tablets.

Conditions for safe storage, including any incompatibilities

Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

GSK

Components

Type

Value

Note

AMOXICILLIN
TRIHYDRATE (CAS
61336-70-7)

15 MIN STEL

100 mcg/m3

OHC

3

RESPIRATORY
SENSITISER
SKIN 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

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/m ³	Respirable fraction.
		15 mg/m ³	Total dust.

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

Components	Type	Value
SILICON DIOXIDE (CAS 7631-86-9)	TWA	0.8 mg/m ³
		20 mppcf

US. ACGIH Threshold Limit Values

Components	Type	Value
MAGNESIUM STEARATE (CAS 557-04-0)	TWA	10 mg/m ³
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	TWA	10 mg/m ³

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	TWA	5 mg/m ³	Respirable.
		10 mg/m ³	Total
SILICON DIOXIDE (CAS 7631-86-9)	TWA	6 mg/m ³	

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

Exposure guidelines

Appropriate engineering controls General ventilation normally adequate.

Individual protection measures, such as personal protective equipment

Eye/face protection If contact is likely, safety glasses with side shields are recommended.

Skin protection

Hand protection For prolonged or repeated skin contact use suitable protective gloves.

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. No personal respiratory protective equipment normally required.

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 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 product's decomposition.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Health injuries are not known or expected under normal use.
Eye contact	Health injuries are not known or expected under normal use.
Ingestion	Health injuries are not known or expected under normal use. Expected to be a low ingestion hazard. However, ingestion is not likely to be a primary route of occupational exposure.

Symptoms related to the physical, chemical and toxicological characteristics

Accidental exposure or contact might produce: symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing) nausea, vomiting, diarrhoea, abdominal discomfort.

Information on toxicological effects

Acute toxicity Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

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

Components	Species	Test Results
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)		
Acute		
<i>Dermal</i>		
LD50	Rabbit	> 2000 mg/kg
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg
POTASSIUM CLAVULANATE (CAS 61177-45-5)		
Acute		
<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.

Irritation Corrosion - Skin

AMOXICILLIN TRIHYDRATE	Acute dermal irritation, Primary Irritation Index: 0 Result: Non-irritant Species: Rabbit
POTASSIUM CLAVULANATE	Acute dermal irritation; OECD 404 Result: Non-irritant

Irritation Corrosion - Skin: P.I.I. value

MAGNESIUM STEARATE	0
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Serious eye damage/eye irritation Direct contact with eyes may cause temporary irritation. Health injuries are not known or expected under normal use.

Eye

AMOXICILLIN TRIHYDRATE	Acute ocular irritation, Kay and Calandra score = 3; maximum group mean score = 6.7 Result: Minimal Irritant Species: Rabbit
POTASSIUM CLAVULANATE	Acute ocular irritation; OECD 405 Result: Non-Irritating

Eye / Kay and Calandra class - Intact

MAGNESIUM STEARATE	4 Recovery Period: 2 days
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Respiratory or skin sensitization

Respiratory sensitization Under normal conditions of intended use, this material is not expected to be an inhalation hazard. May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Skin sensitization This product is not expected to cause skin sensitization.

Sensitization

AMOXICILLIN TRIHYDRATE	Epidemiology Result: Positive Species: Human
POTASSIUM CLAVULANATE	Maximisation assay (Magnusson and Kligman), clavulanic acid tested 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 Assay, GLP assay; clavulanic acid tested Result: Negative
AMOXICILLIN TRIHYDRATE	GreenScreen, amoxicillin sodium tested Result: Negative
POTASSIUM CLAVULANATE	Micronucleus Assay, clavulanic acid tested Result: Negative
AMOXICILLIN TRIHYDRATE	Mouse Lymphoma Cell (L5178Y) Mutation Assay, GLP assay; amoxicillin sodium tested Result: Negative

Mutagenicity

POTASSIUM CLAVULANATE

SAR, DEREK, Lhasa, UK
Result: No structural alerts identified.**Carcinogenicity**

Carcinogenic effects are not expected as a result of occupational exposure. Not classifiable as to carcinogenicity to humans.

POTASSIUM CLAVULANATE

SAR, DEREK, Lhasa, UK
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

Contains no ingredient listed as toxic to reproduction

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**

Not assigned.

Specific target organ toxicity - repeated exposure

Not assigned.

Aspiration hazard

Not likely, due to the form of the product.

Further information

Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.

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

Components	Species	Test Results
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
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
	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

* 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

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

Biodegradability

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 m³/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. Do not discharge into drains, water courses or onto the ground. 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). Avoid discharge into water courses or onto the ground.

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

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. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)

Not listed.

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
New Zealand	New Zealand Inventory	Yes
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 11-04-2014

Material name: AUGMENTIN TABLETS BID

128372 Version #: 07 Revision date: 11-04-2014 Issue date: 11-04-2014

SDS US

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Revision date 11-04-2014
Version # 07
Further information HMIS® is a registered trade and service mark of the NPCA.
HMIS® ratings Health: 2*
Flammability: 0
Physical hazard: 0
NFPA ratings Health: 2
Flammability: 0
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: Undisclosed Ingredient Statement
Regulatory Information: Risk Phrases - Class.
GHS: Classification