

## **SAFETY DATA SHEETS**

**This SDS packet was issued with item:**

078932723

**The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).**

078932724

# SAFETY DATA SHEET

AMOXICILLIN AND CLAVULANATE POTASSIUM TABLETS USP  
250 mg/125 mg, 500 mg/125 mg & 875 mg/125 mg



## 1. IDENTIFICATION

- Product Identifier** : Amoxicillin and Clavulanate Potassium Tablets USP 250 mg/125 mg, 500 mg/125 mg & 875 mg/125 mg
- Synonyms** : Amoxicillin and Clavulanate Potassium Tablets, USP
- Recommended use** : Medicinal Product.  
(Indicated in the treatment of infections due to susceptible isolates of the designated bacteria).

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.

- Recommended restrictions** : No other uses are advised.

- Manufacturer** : *Manufactured by:*  
Micro Labs Limited,  
16, Veerasandra Industrial Area,  
Bangalore-560100, Karnataka, India.

*Manufactured for:*  
Micro Labs USA Inc.  
Princeton, NJ 08540.

- Emergency contact** : 1-855-839-8195

- Active ingredient** : Amoxicillin

- USAN : Amoxicillin USP

- Chemical name : (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

(or)

4-Thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid,6-[[amino(4-hydroxyphenyl)acetyl]amino-3,3-dimethyl-7-oxo, trihydrate 2S-[2 $\alpha$ ,[5 $\alpha$ ,6 $\beta$  (S\*)]]

- Molecular formula : C<sub>16</sub>H<sub>19</sub>N<sub>3</sub>O<sub>5</sub>S.3H<sub>2</sub>O

- Molecular weight : 419.4 g/mol

- (CAS) registry number (RN) : 61336-70-7

- Therapeutic Category : Antibiotic, Penicillin

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<b>Active ingredient</b>	: Diluted Potassium Clavulanate (with Microcrystalline cellulose in the ratio of 1:1)
USAN	: Clavulanate Potassium
Chemical name	: Potassium (Z) (2R, 5R)-3-(2-hydroxyethylidene)-7-oxo-4-oxa-1-azabicyclo [3.2.0] heptane-2-carboxylate
Molecular formula	: C <sub>8</sub> H <sub>8</sub> KNO <sub>5</sub> (Clavulanate Potassium) (C <sub>6</sub> H <sub>10</sub> O <sub>5</sub> ) <sub>n</sub> (Microcrystalline cellulose)
Molecular weight	: 237.3 (Clavulanate Potassium) 60.08 (Microcrystalline cellulose)
(CAS) registry number (RN)	: 61177-45-5
Therapeutic Category	: Beta-Lactamase Inhibitor

## 2. HAZARDS IDENTIFICATION

<b>Classified hazards</b>	Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.
<b>Label elements</b>	Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.
<b>Hazard(s) not otherwise classified (HNOC)</b>	Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.
<b>Unknown Acute Toxicity (GHS-US)</b>	No data available

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

<b>Chemical Name</b>	<b>CAS Number</b>	<b>% quantity</b>
Amoxicillin Trihydrate	61336-70-7	41.150% to 67.24%
Potassium Clavulanate	61177-45-5	20.343% to 43.572%
Microcrystalline Cellulose	9004-34-6	5.8825% to 8.6360 %
Colloidal Silicon Dioxide	7631-86-9	0.6695% to 0.9321%
Magnesium Stearate	557-04-0	0.9321% to 1.0043%
Sodium Starch Glycolate	9063-38-1	1.8643% to 1.9417%

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## **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.

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## 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 fire fighters</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).

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## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Components	Type	Value	Note
Amoxicillin Trihydrate (CAS 61336-70-7)	15 MIN	100 mcg/m <sup>3</sup>	
	OHC	3	Skin sensitiser
		3	Respiratory sensitiser
Magnesium stearate (CAS 557-04-0)	OHC	1	
Microcrystalline cellulose (CAS 9004-34-6)	OHC	1	
Potassium Clavulanate (CAS 61177-45-5)	8 HR TWA	5000 mcg/m <sup>3</sup>	
	OHC	1	
Colloidal 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/m <sup>3</sup>	Respirable fraction
		15 mg/m <sup>3</sup>	Total dust

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

Components	Type	Value
Colloidal silicon dioxide (CAS 7631-86-9)	TWA	0.8 mg/m <sup>3</sup>
		20 millions of particle

### US. ACGIH Threshold Limit Values

Components	Type	Value
Magnesium stearate (CAS 557-04-0)	TWA	10 mg/m <sup>3</sup>
Microcrystalline cellulose (CAS 9004-34-6)	TWA	10 mg/m <sup>3</sup>

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## US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
Microcrystalline cellulose (CAS 9004-34-6)	TWA	5 mg/m <sup>3</sup>	Respirable
		10 mg/m <sup>3</sup>	Total
Colloidal silicon dioxide (CAS 7631-86-9)	TWA	6 mg/m <sup>3</sup>	

**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** Not normally needed. Wear suitable protective clothing as protection against splashing or contamination.

**Other**

**Respiratory protection** No personal respiratory protective equipment normally required. When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.

**Thermal hazards** Wear appropriate thermal protective clothing, when necessary.

**General hygiene considerations** An occupational/industrial hygiene monitoring method has been developed for this material. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### Appearance

Physical state	Solid.
Form	Tablet.
Color	White to off-white
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.

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<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.
<b>Symptoms related to the physical, chemical and toxicological characteristics</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>Information on toxicological effects</b>	
<b>Acute toxicity</b>	Health injuries are not known or expected under normal use.

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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.		
<b>Skin corrosion/irritation</b>	Health injuries are not known or expected under normal use.	
<b>Corrosivity</b>		
AMOXICILLIN TRIHYDRATE	Acute dermal irritation Result: Negative Species: Rabbit	
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	

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## 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

POTASSIUM CLAVULANATE

Health injuries are not known or expected under normal use.

SAR

Result: No structural alerts identified.

## IARC Monographs. Overall Evaluation of Carcinogenicity

SILICON DIOXIDE

3 Not classifiable as to carcinogenicity to humans.

(CAS 7631-86-9)

## 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

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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)		
<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	

MAGNESIUM STEARATE (CAS 557-04-0)

### **Aquatic**

#### *Acute*

Fish	EC50	Orange-red killfish (Adult <i>Oryzias latipes</i> ) 130 mg/l, 96 hours
Microtox	EC50	Microtox 12.5 mg/l, 15 minutes

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## POTASSIUM CLAVULANATE (CAS 61177-45-5)

### Aquatic

#### Acute

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

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

### Aquatic

#### Acute

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

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## 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
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## 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
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## Mobility in soil

### Adsorption

#### Sludge/biomass distribution coefficient - log Kd

AMOXICILLIN TRIHYDRATE	-0.17 Estimated
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#### Soil/sediment sorption - log Koc

MAGNESIUM STEARATE	5.86 Estimated
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## Mobility in general

### Volatility

#### Henry's law

AMOXICILLIN TRIHYDRATE	0 atm m <sup>3</sup> /mol Calculated
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## Other adverse effects

Not available.

## 13. DISPOSAL CONSIDERATION

### 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.

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## 14. TRANSPORT INFORMATION

### DOT

Not regulated as a dangerous good.

### IATA

Not regulated as dangerous goods.

### IMDG

Not regulated as dangerous goods.

## 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)

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## 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.

## 16. OTHER INFORMATION

<b>Date of preparation</b>	04-May-2017
<b>HMIS ratings</b>	Health: 2 Flammability: 1 Physical hazard: 0
<b>NFPA ratings</b>	Health: 2 Flammability: 1 Instability: 0

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.

**End of Safety Data Sheet**