

## Safety Data Sheet

**Product Name: Marbofloxacin Tablet**  
**Strength : 25, 50, 100 and 200 mg**

**Revision No.: 01**

### Emergency Overview

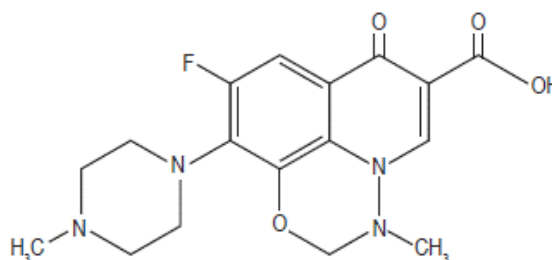
Unless wearing appropriate protective clothing. Avoid the generation of dusts during clean-up. Avoid inhalation of dust. Avoid contact with eyes, skin, and clothing. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS

### Section 1: Identification

**Product Name:** Marbofloxacin Tablet

**Formula:** C<sub>17</sub>H<sub>19</sub>FN<sub>4</sub>O<sub>4</sub>

**Chemical Name:** 9-fluoro-2,3-dihydro-3-methyl-10-(4-methyl-1-piperazinyl)-7-oxo-7H-pyrido[3,2,1-ij] [4,1,2] benzoxadiazine-6-carboxylic acid



**Molecular Weight:** 362.36 g/mol

**Description:** Marbofloxacin is a synthetic broad-spectrum antibacterial agent from the fluoroquinolone class of chemotherapeutic agents. Marbofloxacin is the non-proprietary designation for 9-fluoro-2,3-dihydro-3-methyl-10-(4-methyl-1-piperazinyl)-7-oxo-7H-pyrido[3,2,1-ij][4,1,2] benzoxadiazine-6-carboxylic acid. The empirical formula is C<sub>17</sub>H<sub>19</sub>FN<sub>4</sub>O<sub>4</sub> and the molecular weight is 362.36. The compound is soluble in water; however, solubility decreases in alkaline conditions. The N-octanol/water partition coefficient (K<sub>ow</sub>) is 0.835 measured at pH 7 and 25°C.

### Dosage forms and strengths:

Marbofloxacin tablets are available in the following strengths of marbofloxacin and bottle sizes:

Product Name	Strength	Pack count	NDC
Marbofloxacin Tablets	25 mg	Bottles Contain 100 Tablets	8611700107
		Bottles Contain 250 Tablets	8611700111
	50 mg	Bottles Contain 100 Tablets	8611700207
		Bottles Contain 250 Tablets	8611700211
	100 mg	Bottles Contain 50 Tablets	8611700304
	200 mg	Bottles Contain 50 Tablets	8611700404

### Manufacturer / supplier identification

**Company** Zydus Animal Health and Investments Limited,  
Ahmedabad, India  
**Contact for information** Tel.: +91 2717-683954  
**Emergency Telephone No** Tel.: +91 2717-683951  
**Distributed by:** ZyVet Animal Health Inc.  
Pennington, NJ 08534

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### Section 2: Hazard (s) Identification

**Physical hazards** Not classified.  
**Health hazards** Reproductive toxicity Category 2 Category 1 (connective tissue, nervous system)  
Specific target organ toxicity, repeated exposure  
**Environmental hazards** Not classified.  
**OSHA defined hazards** Not classified.  
**Label elements**



**Signal word** Danger  
**Hazard statement** Suspected of damaging fertility or the unborn child. Causes damage to organs (connective tissue, nervous system) through prolonged or repeated exposure.

#### Precautionary statement

**Prevention** Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe dust/fume/gas/mist/vapors/spray. Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Wear protective gloves/protective clothing/eye protection/face protection.

**Response** If exposed or concerned: Get medical advice/attention.

**Storage** Store locked up.

**Disposal** Dispose of contents/container in accordance with local/regional/national/international regulations.

**Hazard(s) not otherwise classified (HNOC)** None known.

### Section 3: Composition / information on ingredients

#### Mixtures

Chemical name	Common name and synonyms	CAS number	%
Marbofloxacin		115550-35-1	***
Microcrystalline cellulose		9004-34-6	*
Stearic acid		57-11-4	*

**Composition comments** \*\*\* 25, 50, 100 or 200 mg per tablet

\* Non-hazardous Ingredients

In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

### Section 4: First -aid measures

**Inhalation** Move to fresh air. If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician. For breathing difficulties, oxygen may be necessary.

**Skin contact** Wash off immediately with soap and plenty of water. If skin irritation or rash occurs: Get advice/attention. Wash contaminated clothing before reuse. There is a risk of photosensitization within a few hours after excessive exposure to quinolones. If excessive exposure does occur, avoid direct sunlight and wash skin with soap and water.

**Eye contact** Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. Remove contact lenses, if present and easy to do.

**Ingestion** Rinse mouth. Call a physician or poison control center immediately. Do not induce vomiting without advice from poison control center. Never give anything by mouth to a victim who is unconscious or is having convulsions.

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### Most important symptoms/effects, acute and delayed

Direct contact with eyes may cause temporary irritation. Exposed individuals may experience eye tearing, redness, and discomfort. Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions. Rash. (allergic skin rash); Difficulty in breathing. Quinolones may effect connective tissue structures. Tendonitis and tendon rupture have occurred as late as several months after quinolone treatment. Convulsions, increased intracranial pressure, and toxic psychosis have been reported in patients receiving quinolones. The most common adverse reactions associated with the use of quinolones include gastrointestinal distress, such as nausea or diarrhea, and central nervous system (CNS) effects, including insomnia, dizziness, and seizures. sensory/motor nerve injury (peripheral neuropathy) may occur.

### Indication of immediate medical attention and special treatment needed General information

IF exposed or concerned: Get medical advice/attention. For personal protection, see section 8 of the SDS. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Show this safety data sheet to the doctor in attendance. CAUTION! - Individuals with a history of hypersensitivity to this material or members of the quinolone class of antimicrobials and those with known seizure disorders.

## Section 5: Fire-fighting measures

<b>Suitable extinguishing media</b>	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO <sub>2</sub> ).
<b>Unsuitable extinguishing Media</b>	Do not use water jet as an extinguisher, as this will spread the fire.
<b>Specific hazards arising from the chemical</b>	During fire, gases hazardous to health may be formed.
<b>Special protective equipment and precautions for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Firefighting equipment/instructions</b>	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>	No unusual fire or explosion hazards noted.

## Section 6: Accidental Release Measures

### Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Ensure adequate ventilation. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid the generation of dusts during clean-up. Avoid inhalation of dust. Avoid contact with eyes, skin, and clothing. 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

Ensure adequate ventilation. Remove sources of ignition.

Large Spills: Stop the flow of material, if this is without risk. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

### Environmental precautions

Avoid discharge into drains, water courses or onto the ground.

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### Section 7: Handling and Storage

#### Precautions for safe handling

Do not taste or swallow. Avoid contact with eyes, skin, and clothing. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes. Avoid prolonged exposure. Minimize dust generation and accumulation. When using, do not eat, drink or smoke. Wash thoroughly after handling. Wear appropriate personal protective equipment. Avoid release to the environment.

#### Conditions for safe storage, including any incompatibilities

Store in a well-ventilated place. Keep away from heat and sources of ignition. Store in original tightly closed container. @ 15-30°C (59-86°F). Store away from incompatible materials (see Section 10 of the SDS). Keep out of the reach of children. Protect from moisture.

### Section 8: Exposure controls/personal protection

#### Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

Components	Type	Value
Marbofloxacin (CAS 115550-35-1)	TWA	0.2 mg/m <sup>3</sup>

#### US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
Microcrystalline cellulose (CAS 9004-34-6) Respirable fraction	PEL	5 mg/m <sup>3</sup>	
		15 mg/m <sup>3</sup>	Total dust

#### US. ACGIH Threshold Limit Values

Components	Type	Value
Microcrystalline cellulose (CAS 9004-34-6)	TWA	10 mg/m <sup>3</sup>
Stearic acid (CAS 57-11-4)	TWA	10 mg/m <sup>3</sup>

#### 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

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

**Control banding approach** Not available.

#### 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. General room ventilation is adequate unless the process generates dust, mist or aerosols.

#### Individual protection measures, such as personal protective equipment Eye/face protection Skin protection

**Hand protection** If contact is likely, safety glasses with side shields are recommended  
Wear appropriate chemical resistant gloves.

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**Other** Wear suitable protective clothing. Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.

**Respiratory protection** No personal respiratory protective equipment normally required. In case of insufficient ventilation, wear suitable respiratory equipment. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

**Thermal hazards** Not applicable.

### General hygiene

**Considerations** Observe any medical surveillance requirements. 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.

## Section 9: Physical and chemical properties

<b>Appearance</b>	Film-coated tablets
<b>Physical state</b>	Solid
<b>Form</b>	Solid
<b>Color</b>	Beige
<b>Odor</b>	Not available
<b>Odor threshold</b>	Not available
<b>pH</b>	Not available
<b>Melting point/freezing point</b>	Not available
<b>Initial boiling point and boiling range</b>	Not available
<b>Flash point</b>	Not available
<b>Evaporation rate</b>	Not available
<b>Flammability (solid, gas)</b>	Not available
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available
<b>Flammability limit - upper (%)</b>	Not available
<b>Explosive limit - lower (%)</b>	Not available
<b>Explosive limit - upper (%)</b>	Not available
<b>Vapor pressure</b>	Not available
<b>Vapor density</b>	Not available
<b>Relative density</b>	Not available
<b>Solubility(ies) 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
<b>Other information</b>	
<b>Explosive properties</b>	Not explosive
<b>Oxidizing properties</b>	Not oxidizing

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### Section 10: Stability and reactivity

**Reactivity:** The product is stable and non-reactive under normal conditions of use, storage and transport. 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. Heat, flames and sparks. Moisture.

### Section 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. May cause hypersensitivity reactions in susceptible individuals.

**Skin contact** Prolonged skin contact may cause temporary irritation. May cause hypersensitivity reactions in susceptible individuals. Photosensitivity may occur.

Stearic acid	Species: Rabbit Severity: Moderate
Marbofloxacin	Species: Rabbit Severity: Non-irritating

Microcrystalline cellulose	Species: Rabbit Severity: Non-irritating
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**Eye contact** Direct contact with eyes may cause temporary irritation

Stearic acid	Species: Rabbi Severity: Mild
Marbofloxacin	Species: Rabbit Severity: Minimal
	Species: Rabbit Severity: Non-irritating

Microcrystalline cellulose	Species: Rabbit Severity: Non-irritating
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**Ingestion** Ingestion may result in mild gastrointestinal irritation with nausea, vomiting, or diarrhea. However, ingestion is not likely to be a primary route of occupational exposure.

#### Symptoms related to the physical, chemical and toxicological characteristics

Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions. Rash. (allergic skin rash); Difficulty in breathing. Quinolones may effect connective tissue structures. Tendonitis and tendon rupture have occurred as late as several months after quinolone treatment. Conlvusions, increased intracranial pressure, and toxic psychosis have been reported in patients receiving quinolones. The most common adverse reactions associated with the use of quinolones include gastrointestinal distress, such as nausea or diarrhea, and central nervous system (CNS) effects, including insomnia, dizziness, and seizures. sensory/motor nerve injury (peripheral neuropathy) may occur.

#### Information on toxicological effects

**Acute toxicity** Ingestion may result in mild gastrointestinal irritation with nausea, vomiting, or diarrhea.

Components	Species	Test Results
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Marbofloxacin (CAS 115550-35-1)

**Acute Oral**

LD50	Mouse	1781 - 1822
mg/kg	Rat	2720 - 3772
mg/kg		

**Chronic Oral**

NOAEL	Mouse	600 mg/kg/day, 106 weeks (Not carcinogenic)
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NOEL	Rat	250 mg/kg/day, 104 weeks (Not carcinogenic)
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**Subacute Oral**

NOAEL	Dog	< 11 mg/kg/day, 14 days (Target organs: Connective tissue)
	Rat	250 mg/kg/day, 4 weeks (Target organs: None identified)

**Subchronic**

**Oral**

NOAEL	Rat	4 mg/kg/day, 13 weeks (Target organs: Male reproductive system, Connective tissue)
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Microcrystalline cellulose (CAS 9004-34-6)

**Acute Dermal**

LD50	Rabbit	> 2000 mg/kg
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**Oral**

LD50	Rat	> 5000 mg/kg
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Stearic acid (CAS 57-11-4)

**Acute Dermal**

LD50	Rabbit	> 5000 mg/kg
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**Oral**

LD50	Rat	> 4640 mg/kg 4.6 g/kg
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**Chronic Oral**

LOAEL	Rat	300 ppm, 30 weeks Adipose tissue
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**Subcutaneous**

LOAEL	Mouse	0.05 mg/kg/week, 52 weeks Tumors
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NOAEL	Rat	0.5 mg/kg/week, 26 weeks Not carcinogenic
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**Skin corrosion/irritation**      Prolonged skin contact may cause temporary irritation.

**Corrosivity**

Marbofloxacin	Species: Rabbit Severity: Non-irritating
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**Serious eye damage/eye irritation**      Direct contact with eyes may cause temporary irritation.

**Eye Contact**

Stearic acid	Species: Rabbit Severity: Mild
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Marbofloxacin	Species: Rabbit Severity: Minimal
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Species: Rabbit  
Severity: Non-irritating

Microcrystalline cellulose

Species: Rabbit  
Severity: Non-irritating

### Respiratory or skin sensitization

#### Respiratory sensitization

Due to partial or complete lack of data the classification is not possible. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions.

#### Skin sensitization

Due to partial or complete lack of data the classification is not possible. Skin sensitization and/or photosensitization potential (allergic response after UV exposure) of other quinolones have been demonstrated in guinea pigs, mice, and humans.

#### Germ cell mutagenicity

No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

### Mutagenicity

Marbofloxacin

Bacterial Mutagenicity (Ames)  
Result: Positive  
Species: Salmonella

Stearic acid

In Vitro Bacterial Mutagenicity (Ames)  
Result: Negative  
Species: Salmonella

Marbofloxacin

In Vitro Chromosome Aberration  
Result: Negative  
Species: Human Lymphocytes

In Vivo Micronucleus  
Result: Negative  
Species: Mouse Bone Marrow

In Vivo Unscheduled DNA Synthesis  
Result: Negative  
Species: Rat Hepatocyte

Stearic acid

Unscheduled DNA Synthesis  
Result: Negative  
Species: E. coli

### Carcinogenicity

This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

**IARC Monographs. Overall Evaluation of Carcinogenicity**

Not listed.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)**

Not regulated.

**US. National Toxicology Program (NTP) Report on Carcinogens**

Not listed.

**Reproductive toxicity Developmental effects** Suspected of damaging fertility or the unborn child.

### Developmental Effects

Marbofloxacin

700 mg/kg/day Prenatal & Postnatal Development, Not Teratogenic,  
Maternal Toxicity  
Result: NOAEL  
Species: Rat  
Organ: Oral



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80 mg/kg/day Prenatal & Postnatal Development, Not Teratogenic, Maternal Toxicity  
Result: NOAEL  
Species: Rabbit  
Organ: Oral

### Reproductivity

Marbofloxacin 10 mg/kg/day 2 Generation Reproductive Toxicity, Fertility, Embryotoxicity, Fetotoxicity  
Result: NOAEL  
Species: Rat  
Organ: Oral

**Specific target organ toxicity – Not classified.  
single exposure**

**Specific target organ toxicity –  
repeated exposure**

Causes damage to organs (connective tissue, nervous system) through prolonged or repeated exposure.

**Aspiration hazard**

Not an aspiration hazard.

**Chronic effects**

Danger of serious damage to health by prolonged exposure.

**Further information**

Danger of very serious irreversible effects. sensory/motor nerve injury (peripheral neuropathy) may occur. This compound may cause cartilage deterioration in knee joints and adverse reproductive effects (based on animal data). Quinolones may effect connective tissue structures. Tendonitis and tendon rupture have occurred as late as several months after quinolone treatment

## Section 12: Ecological information

**Ecotoxicity:** The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment. Avoid release to the environment.

**Components**

**Species**

**Test Results**

Marbofloxacin

Daphnia magna (Water Flea) 62.3 mg/L, 48 Hours

(CAS 115550-35-1) LC50

**Persistence and degradability**

No data is available on the degradability of this product.

**Bioaccumulative potential**

No data available.

**Mobility in soil**

No data available.

**Other adverse effects**

No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

## Section 13: Disposal consideration

**Disposal instructions**

Avoid release to the environment. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases.

This may include destructive techniques for waste and wastewater. Dispose of contents/container in accordance with local/regional/national/international regulations.

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**Local disposal regulations** Dispose in accordance with all applicable regulations.  
**Hazardous waste code** None known.  
**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** Since emptied containers may retain product residue, follow label warnings even after container is emptied.

### Section 14: Transport information

**DOT** Not regulated as dangerous goods.  
**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** Not applicable

### Section 15: Regulatory information

**US federal regulations** This product is 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 regulated.

**Superfund Amendments and Reauthorization Act of 1986 (SARA) Hazard categories**

Immediate Hazard - No

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** 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.

### Section 16: Other information

**References:** Nil.

**Issue date:** 28-01-2023

The information contained herein is based on the state of our knowledge. It characterizes the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product