



## Desloratadine / Pseudoephedrine Formulation

Version 2.2      Revision Date: 09/13/2019      SDS Number: 2095098-00007      Date of last issue: 2019/05/15  
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P501 Dispose of contents/ container to an approved waste disposal plant.

**Other hazards which do not result in classification**

None known.

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
Cellulose	9004-34-6	>= 30 - < 40	
Bis[[S-(R*,R*)]-(β-hydroxy-α-methylphenethyl)methylammonium] sulphate	7460-12-0	>= 20 - < 30	
Citric acid	77-92-9	>= 1 - < 10	2-1318
Disodium EDTA, dihydrate	6381-92-6	>= 1 - < 10	2-1265, 2-1265
Silicon dioxide	7631-86-9	>= 1 - < 10	1-548
Desloratadine	100643-71-8	>= 0.25 - < 1	

**4. FIRST AID MEASURES**

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
 When symptoms persist or in all cases of doubt seek medical advice.
- If inhaled : If inhaled, remove to fresh air.  
 Get medical attention.
- In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.  
 Remove contaminated clothing and shoes.  
 Get medical attention.  
 Wash clothing before reuse.  
 Thoroughly clean shoes before reuse.
- In case of eye contact : Flush eyes with water as a precaution.  
 Get medical attention if irritation develops and persists.
- If swallowed : If swallowed, DO NOT induce vomiting.  
 Get medical attention.  
 Rinse mouth thoroughly with water.
- Most important symptoms and effects, both acute and delayed : Causes damage to organs through prolonged or repeated exposure if swallowed.  
 Causes damage to organs through prolonged or repeated exposure if inhaled.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- Notes to physician : Treat symptomatically and supportively.

**5. FIREFIGHTING MEASURES**

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|---|---|---|
| Suitable extinguishing media                  | : | Water spray<br>Alcohol-resistant foam<br>Carbon dioxide (CO <sub>2</sub> )<br>Dry chemical  |
| Unsuitable extinguishing media                | : | None known.   |
| Specific hazards during fire-fighting         | : | Exposure to combustion products may be a hazard to health.  |
| Hazardous combustion products                 | : | Carbon oxides<br>Nitrogen oxides (NO <sub>x</sub> )<br>Metal oxides   |
| Specific extinguishing methods                | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for firefighters | : | In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment.  |

**6. ACCIDENTAL RELEASE MEASURES**

- |   |   |   |
|---|---|---|
| Personal precautions, protective equipment and emergency procedures | : | Use personal protective equipment.<br>Follow safe handling advice and personal protective equipment recommendations.  |
| Environmental precautions   | : | Discharge into the environment must be avoided.<br>Prevent further leakage or spillage if safe to do so.<br>Retain and dispose of contaminated wash water.<br>Local authorities should be advised if significant spillages cannot be contained.   |
| Methods and materials for containment and cleaning up               | : | Sweep up or vacuum up spillage and collect in suitable container for disposal.<br>Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.<br>Sections 13 and 15 of this SDS provide information regarding certain local or national requirements. |

**7. HANDLING AND STORAGE****Handling**

- |                         |   |   |
|-------------------------|---|---|
| Technical measures      | : | See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.   |
| Local/Total ventilation | : | Use only with adequate ventilation.   |
| Advice on safe handling | : | Do not swallow.<br>Avoid contact with eyes.<br>Avoid prolonged or repeated contact with skin.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment |

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Avoidance of contact : Take care to prevent spills, waste and minimize release to the environment.  
 Hygiene measures : Oxidizing agents  
 : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.  
 : When using do not eat, drink or smoke.  
 : Wash contaminated clothing before re-use.  
 : The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

**Storage**

Conditions for safe storage : Keep in properly labelled containers.  
 : Store in accordance with the particular national regulations.  
 Materials to avoid : Do not store with the following product types:  
 : Strong oxidizing agents  
 Packaging material : Unsuitable material: None known.

**8. EXPOSURE CONTROLS/PERSONAL PROTECTION****Threshold limit value and permissible exposure limits for each component in the work environment**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Cellulose	9004-34-6	TWA	10 mg/m <sup>3</sup>	ACGIH
Bis[[S-(R*,R*)]-(β-hydroxy-α-methylphenethyl)methylammonium] sulphate	7460-12-0	TWA	50 µg/m <sup>3</sup> (OEB 3)	Internal
		Wipe limit	500 µg/100 cm <sup>2</sup>	Internal
Desloratadine	100643-71-8	TWA	20 µg/m <sup>3</sup> (OEB 3)	Internal
		Wipe limit	200 µg/100 cm <sup>2</sup>	Internal

**Engineering measures** : All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.  
 : Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).  
 : Minimize open handling.

**Personal protective equipment**

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.  
 Filter type : Particulates type  
 Hand protection :  
 Material : Chemical-resistant gloves



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Water solubility : No data available

Partition coefficient: n-octanol/water : Not applicable

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity  
Viscosity, kinematic : Not applicable

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Particle size : No data available

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**10. STABILITY AND REACTIVITY**

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : Can react with strong oxidizing agents.

Conditions to avoid : None known.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

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**11. TOXICOLOGICAL INFORMATION**

Information on likely routes of exposure : Skin contact  
Ingestion  
Eye contact

**Acute toxicity**

Not classified based on available information.

**Product:**

Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg  
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: > 5 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: Calculation method

**Components:****Cellulose:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5.8 mg/l  
Exposure time: 4 h

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Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

**Bis[[S-(R\*,R\*)]-(β-hydroxy-α-methylphenethyl)methylammonium] sulphate:**

Acute oral toxicity : LD50 (Rat): 660 mg/kg

LD50 (Mouse): 371 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 2.37 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg  
Remarks: Information given is based on data obtained from similar substances.

**Citric acid:**

Acute oral toxicity : LD50 (Mouse): 5,400 mg/kg

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg  
Method: OECD Test Guideline 402  
Assessment: The substance or mixture has no acute dermal toxicity

**Disodium EDTA, dihydrate:**

Acute oral toxicity : LD50 (Rat): 2,800 mg/kg  
Remarks: Based on data from similar materials

Acute inhalation toxicity : LC50 (Rat): > 1 mg/l  
Exposure time: 6 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 412  
Remarks: Based on data from similar materials

**Silicon dioxide:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
Method: OECD Test Guideline 401

Acute inhalation toxicity : LC50 (Rat): > 2.08 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Assessment: The substance or mixture has no acute inhalation toxicity

Acute dermal toxicity : LD50 (Rabbit): > 5,000 mg/kg

**Desloratadine:**

Acute oral toxicity : LD50 (Rat): > 549 mg/kg

LD50 (Mouse): 353 mg/kg

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LD50 (Monkey): > 250 mg/kg  
Symptoms: Vomiting  
Remarks: No mortality observed at this dose.

**Skin corrosion/irritation**

Not classified based on available information.

**Components:****Bis[[S-(R\*,R\*)-( $\beta$ -hydroxy- $\alpha$ -methylphenethyl)methylammonium] sulphate:**

Species : Rabbit  
Result : No skin irritation

**Citric acid:**

Species : Rabbit  
Method : OECD Test Guideline 404  
Result : No skin irritation

**Disodium EDTA, dihydrate:**

Species : Rabbit  
Result : No skin irritation  
Remarks : Based on data from similar materials

**Silicon dioxide:**

Species : Rabbit  
Method : OECD Test Guideline 404  
Result : No skin irritation

**Desloratadine:**

Species : Rabbit  
Result : No skin irritation

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****Bis[[S-(R\*,R\*)-( $\beta$ -hydroxy- $\alpha$ -methylphenethyl)methylammonium] sulphate:**

Species : Rabbit  
Result : No eye irritation

**Citric acid:**

Species : Rabbit  
Result : Irritation to eyes, reversing within 21 days  
Method : OECD Test Guideline 405

**Disodium EDTA, dihydrate:**

Species : Rabbit  
Result : No eye irritation



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Remarks : Based on data from similar materials

**Silicon dioxide:**

Species : Rabbit  
Result : No eye irritation  
Method : OECD Test Guideline 405

**Desloratadine:**

Species : Rabbit  
Remarks : Severe eye irritation

**Respiratory or skin sensitisation****Skin sensitisation**

Not classified based on available information.

**Respiratory sensitisation**

Not classified based on available information.

**Components:****Bis[[S-(R\*,R\*)]-(β-hydroxy-α-methylphenethyl)methylammonium] sulphate:**

Remarks : No data available

**Disodium EDTA, dihydrate:**

Test Type : Maximisation Test  
Exposure routes : Skin contact  
Species : Guinea pig  
Result : negative  
Remarks : Based on data from similar materials

**Desloratadine:**

Test Type : Maximisation Test  
Exposure routes : Dermal  
Species : Guinea pig  
Result : negative

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****Cellulose:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  
  
Test Type: In vitro mammalian cell gene mutation test  
Result: negative  
  
Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo  
cytogenetic assay)  
Species: Mouse

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Application Route: Ingestion

Result: negative

**Bis[[S-(R\*,R\*)]-(β-hydroxy-α-methylphenethyl)methylammonium] sulphate:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  
Remarks: Information given is based on data obtained from similar substances.

Test Type: Chromosomal aberration

Result: negative

Remarks: Information given is based on data obtained from similar substances.

Genotoxicity in vivo : Test Type: Micronucleus test  
Species: Rat  
Application Route: Oral  
Result: negative  
Remarks: Based on data from similar materials

**Citric acid:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

Test Type: in vitro micronucleus test

Result: positive

Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)  
Species: Rat  
Application Route: Ingestion  
Result: negative

**Disodium EDTA, dihydrate:**

Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro  
Result: negative  
Remarks: Based on data from similar materials

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Ingestion  
Method: OECD Test Guideline 474  
Result: negative  
Remarks: Based on data from similar materials

**Silicon dioxide:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471

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Result: negative

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)  
Species: Rat  
Application Route: Ingestion  
Result: negative

**Desloratadine:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

Test Type: Chromosomal aberration  
Test system: Human lymphocytes  
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test  
Species: Mouse  
Cell type: Bone marrow  
Application Route: Oral  
Result: negative

**Carcinogenicity**

Not classified based on available information.

**Components:****Cellulose:**

Species : Rat  
Application Route : Ingestion  
Exposure time : 72 weeks  
Result : negative

**Bis[[S-(R\*,R\*)-(β-hydroxy-α-methylphenethyl)methylammonium] sulphate:**

Species : Rat  
Application Route : Oral  
Exposure time : 2 Years  
Result : negative  
Remarks : Based on data from similar materials

Species : Mouse  
Application Route : Oral  
Exposure time : 2 Years  
Result : negative  
Remarks : Based on data from similar materials

**Disodium EDTA, dihydrate:**

Species : Rat  
Application Route : Ingestion  
Exposure time : 103 weeks  
Result : negative  
Remarks : Based on data from similar materials

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**Silicon dioxide:**

Species	: Rat
Application Route	: Ingestion
Exposure time	: 103 weeks
Result	: negative

**Desloratadine:**

Species	: Mouse
Application Route	: Oral
Exposure time	: 2 Years
Result	: negative

Species	: Rat
Application Route	: Oral
LOAEL	: 10 mg/kg body weight
Result	: equivocal
Target Organs	: Liver
Remarks	: Based on data from similar materials The mechanism or mode of action may not be relevant in humans.

**Reproductive toxicity**

Not classified based on available information.

**Components:****Cellulose:**

Effects on fertility	: Test Type: One-generation reproduction toxicity study Species: Rat Application Route: Ingestion Result: negative
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Effects on foetal development	: Test Type: Fertility/early embryonic development Species: Rat Application Route: Ingestion Result: negative
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**Bis[[S-(R\*,R\*)]-(β-hydroxy-α-methylphenethyl)methylammonium] sulphate:**

Effects on fertility	: Test Type: Fertility Species: Rat Application Route: Oral Fertility: LOAEL: 80 mg/kg body weight Symptoms: male reproductive effects
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Effects on foetal development	: Test Type: Embryo-foetal development Species: Rabbit Application Route: Oral Result: No teratogenic effects
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	: Test Type: Embryo-foetal development Application Route: Oral
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Developmental Toxicity: LOAEL: 27 mg/kg body weight  
 Result: No embryotoxic effects have been observed in animal tests., No teratogenic effects  
 Remarks: Maternal toxicity observed.

**Citric acid:**

Effects on foetal development : Test Type: One-generation reproduction toxicity study  
 Species: Rat  
 Application Route: Ingestion  
 Result: negative

**Disodium EDTA, dihydrate:**

Effects on fertility : Test Type: Four-generation reproduction toxicity study  
 Species: Rat  
 Application Route: Ingestion  
 Result: negative  
 Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Embryo-foetal development  
 Species: Rat  
 Application Route: Ingestion  
 Result: negative  
 Remarks: Based on data from similar materials

**Silicon dioxide:**

Effects on foetal development : Test Type: Embryo-foetal development  
 Species: Rat  
 Application Route: Ingestion  
 Result: negative

**Desloratadine:**

Effects on fertility : Test Type: Fertility  
 Species: Rat, male  
 Application Route: Oral  
 Fertility: LOAEL: 12 mg/kg body weight  
 Symptoms: Reduced fertility  
 Result: positive  
 Remarks: The mechanism or mode of action may not be relevant in humans.

Test Type: Fertility  
 Species: Rat, female  
 Fertility: NOAEL: 3 mg/kg body weight  
 Symptoms: No effects on fertility  
 Result: negative

Effects on foetal development : Test Type: Embryo-foetal development  
 Species: Rabbit  
 Application Route: Oral  
 Developmental Toxicity: NOAEL: 30 mg/kg body weight  
 Result: No teratogenic effects

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Test Type: Embryo-foetal development  
 Species: Rat  
 Application Route: Oral  
 Developmental Toxicity: LOAEL: 9 mg/kg body weight  
 Symptoms: Preimplantation loss, Reduced body weight  
 Result: Specific developmental abnormalities  
 Remarks: The mechanism or mode of action may not be relevant in humans.

Test Type: Two-generation study  
 Species: Rat  
 Application Route: Oral  
 Developmental Toxicity: LOAEL: 18 mg/kg body weight  
 Result: No adverse effects

Reproductive toxicity - Assessment : Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Some evidence of adverse effects on development, based on animal experiments.

**STOT - single exposure**

Not classified based on available information.

**STOT - repeated exposure**

Causes damage to organs (Central nervous system) through prolonged or repeated exposure if swallowed.

Causes damage to organs (Cardio-vascular system) through prolonged or repeated exposure if inhaled.

**Components:****Bis[[S-(R\*,R\*)]-(β-hydroxy-α-methylphenethyl)methylammonium] sulphate:**

Exposure routes : Ingestion, Inhalation  
 Target Organs : Central nervous system, Cardio-vascular system  
 Assessment : Causes damage to organs through prolonged or repeated exposure.

**Disodium EDTA, dihydrate:**

Exposure routes : inhalation (dust/mist/fume)  
 Target Organs : Respiratory Tract  
 Assessment : Shown to produce significant health effects in animals at concentrations of >0.02 to 0.2 mg/l/6h/d.

**Repeated dose toxicity****Components:****Cellulose:**

Species : Rat  
 NOAEL : >= 9,000 mg/kg  
 Application Route : Ingestion  
 Exposure time : 90 Days

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**Bis[[S-(R\*,R\*)]-(β-hydroxy-α-methylphenethyl)methylammonium] sulphate:**

Remarks : No data available

**Citric acid:**

Species : Rat  
NOAEL : 4,000 mg/kg  
LOAEL : 8,000 mg/kg  
Application Route : Ingestion  
Exposure time : 10 Days

**Disodium EDTA, dihydrate:**

Species : Rat  
NOAEL : 500 mg/kg  
Application Route : Ingestion  
Exposure time : 13 Weeks  
Remarks : Based on data from similar materials

Species : Rat  
LOAEL : 0.03 mg/l  
Application Route : inhalation (dust/mist/fume)  
Exposure time : 4 Weeks  
Remarks : Based on data from similar materials

**Silicon dioxide:**

Species : Rat  
NOAEL : 1.3 mg/m<sup>3</sup>  
Application Route : inhalation (dust/mist/fume)  
Exposure time : 13 Weeks

**Desloratadine:**

Species : Rat  
LOAEL : 30 mg/kg  
Application Route : Oral  
Exposure time : 3 Months  
Target Organs : Kidney  
Remarks : Significant toxicity observed in testing  
The mechanism or mode of action may not be relevant in humans.

Species : Monkey  
NOAEL : 6 mg/kg  
LOAEL : 12 mg/kg  
Application Route : Oral  
Exposure time : 3 Months  
Target Organs : Central nervous system  
Symptoms : Gastrointestinal disturbance

Species : Monkey  
NOAEL : 40 mg/kg  
Application Route : Oral  
Exposure time : 17 Months  
Remarks : No significant adverse effects were reported

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Species	:	Monkey
NOAEL	:	6 mg/kg
Application Route	:	Oral
Exposure time	:	3 Months
Symptoms	:	Gastrointestinal disturbance, Fatigue

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure****Components:****Bis[[S-(R\*,R\*)]-( $\beta$ -hydroxy- $\alpha$ -methylphenethyl)methylammonium] sulphate:**

Inhalation	:	Remarks: May cause irritation of respiratory tract.
Eye contact	:	Remarks: May irritate eyes.
Ingestion	:	Symptoms: central nervous system effects, tachycardia, Palpitation

**Desloratadine:**

Inhalation	:	Remarks: May cause respiratory tract irritation.
Eye contact	:	Symptoms: Eye irritation
Ingestion	:	Symptoms: dry mouth, muscle pain, Fatigue, Drowsiness, sore throat, painful menstration

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**12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****Cellulose:**

Toxicity to fish	:	LC50 ( <i>Oryzias latipes</i> (Japanese medaka)): > 100 mg/l Exposure time: 48 h Remarks: Based on data from similar materials
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**Citric acid:**

Toxicity to fish	:	LC50 ( <i>Pimephales promelas</i> (fathead minnow)): > 100 mg/l Exposure time: 96 h
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Toxicity to daphnia and other aquatic invertebrates	:	EC50 ( <i>Daphnia magna</i> (Water flea)): 1,535 mg/l Exposure time: 24 h
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**Disodium EDTA, dihydrate:**

Toxicity to fish	:	LC50 ( <i>Lepomis macrochirus</i> (Bluegill sunfish)): 159 mg/l Exposure time: 96 h Remarks: Based on data from similar materials
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Toxicity to daphnia and other aquatic invertebrates	:	EC50 ( <i>Daphnia magna</i> (Water flea)): 140 mg/l Exposure time: 48 h Remarks: Based on data from similar materials
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Toxicity to algae/aquatic plants : EC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l  
Exposure time: 72 h  
Remarks: Based on data from similar materials

NOEC (Desmodesmus subspicatus (green algae)): 100 mg/l  
Exposure time: 72 h  
Remarks: Based on data from similar materials

Toxicity to fish (Chronic toxicity) : NOEC (Danio rerio (zebra fish)): 25.7 mg/l  
Exposure time: 35 d  
Method: OECD Test Guideline 210  
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 25 mg/l  
Exposure time: 21 d  
Remarks: Based on data from similar materials

Toxicity to microorganisms : EC50: < 500 mg/l  
Exposure time: 0.5 h  
Method: OECD Test Guideline 209  
Remarks: Based on data from similar materials

**Silicon dioxide:**

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 10,000 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 1,000 mg/l  
Exposure time: 24 h  
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EC50 (Desmodesmus subspicatus (green algae)): > 10,000 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials

NOEC (Desmodesmus subspicatus (green algae)): 10,000 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials

**Desloratadine:**

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 9.2 mg/l  
Exposure time: 96 h  
Method: FDA 4.11

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 9.6 mg/l  
Exposure time: 48 h  
Method: FDA 4.08

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 1.6 mg/l

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Exposure time: 72 h  
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 0.36 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 0.12 mg/l  
Exposure time: 32 d  
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.48 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211

Toxicity to microorganisms : EC50 (Natural microorganism): 53.7 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

NOEC (Natural microorganism): 12 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

**Persistence and degradability****Components:****Cellulose:**

Biodegradability : Result: Readily biodegradable.

**Citric acid:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 97 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301B

**Disodium EDTA, dihydrate:**

Biodegradability : Result: Inherently biodegradable.  
Biodegradation: 80 - 90 %  
Exposure time: 28 d  
Remarks: Based on data from similar materials

**Desloratadine:**

Biodegradability : Result: Not readily biodegradable.  
Biodegradation: 67.4 %  
Exposure time: 28 d  
Method: OECD Test Guideline 314

Result: Not readily biodegradable.

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Biodegradation: 0 %  
Exposure time: 28 d  
Method: FDA 3.11

Stability in water : Hydrolysis: < 10 % at 50 °C (5 d)  
Method: FDA 3.09

**Bioaccumulative potential****Components:****Bis[[S-(R\*,R\*)-(β-hydroxy-α-methylphenethyl)methylammonium] sulphate:**

Partition coefficient: n-octanol/water : log Pow: 0.89

**Citric acid:**

Partition coefficient: n-octanol/water : log Pow: -1.72

**Disodium EDTA, dihydrate:**

Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)  
Bioconcentration factor (BCF): 1.8  
Remarks: Based on data from similar materials

Partition coefficient: n-octanol/water : log Pow: -4.3

**Desloratadine:**

Partition coefficient: n-octanol/water : log Pow: 1.24  
Method: OECD Test Guideline 107

**Mobility in soil****Components:****Desloratadine:**

Distribution among environmental compartments : log Koc: 3.00  
Method: OECD Test Guideline 106

**Hazardous to the ozone layer**

Not applicable

**Other adverse effects**

No data available

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**13. DISPOSAL CONSIDERATIONS****Disposal methods**

Waste from residues : Dispose of in accordance with local regulations.  
Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

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**14. TRANSPORT INFORMATION****International Regulations****UNRTDG**

Not regulated as a dangerous good

**IATA-DGR**

Not regulated as a dangerous good

**IMDG-Code**

Not regulated as a dangerous good

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable for product as supplied.

**National Regulations**

Refer to section 15 for specific national regulation.

**15. REGULATORY INFORMATION****Related Regulations****Fire Service Law**

Not applicable to dangerous materials / designated flammables.

**Chemical Substance Control Law**

Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

**Industrial Safety and Health Law****Harmful Substances Prohibited from Manufacture**

Not applicable

**Harmful Substances Required Permission for Manufacture**

Not applicable

**Substances Prevented From Impairment of Health**

Not applicable

**Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity**

Not applicable

**Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity**

Not applicable

**Substances Subject to be Notified Names**

Article 57-2 (Enforcement Order Table 9)

Chemical name	Number	Concentration (%)
Crystalline silica	165 の 2	>=1 - <10

**Substances Subject to be Indicated Names**

Article 57 (Enforcement Order Article 18)

Chemical name	Number
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Crystalline silica

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**Ordinance on Prevention of Hazards Due to Specified Chemical Substances**

Not applicable

**Ordinance on Prevention of Lead Poisoning**

Not applicable

**Ordinance on Prevention of Tetraalkyl Lead Poisoning**

Not applicable

**Ordinance on Prevention of Organic Solvent Poisoning**

Not applicable

**Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)**

Not applicable

**Poisonous and Deleterious Substances Control Law**

Not applicable

**Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof**

Not applicable

**High Pressure Gas Safety Act**

Not applicable

**Explosive Control Law**

Not applicable

**Vessel Safety Law**

Not regulated as a dangerous good

**Aviation Law**

Not regulated as a dangerous good

**Marine Pollution and Sea Disaster Prevention etc Law**

Bulk transportation : Noxious liquid substance(Category Z)

Pack transportation : Not classified as marine pollutant

**Narcotics and Psychotropics Control Act**

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

**Waste Disposal and Public Cleansing Law**

Industrial waste

**The components of this product are reported in the following inventories:**

AICS : not determined

DSL : not determined

IECSC : not determined

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**16. OTHER INFORMATION****Further information**

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Date format : yyyy/mm/dd

**Full text of other abbreviations**

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA : 8-hour, time-weighted average

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECl - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their

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intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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