

## Desloratadine / Pseudoephedrine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2020/10/10
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**1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Desloratadine / Pseudoephedrine Formulation

**Manufacturer or supplier's details**

Company : Organon & Co.  
 Address : JL Raya Pandaan KM. 48  
 Pandaan, Jawa Timur - Indonesia  
 Telephone : 551-430-6000  
 Emergency telephone number : 215-631-6999  
 E-mail address : EHSSTEWARD@organon.com

**Recommended use of the chemical and restrictions on use**


Recommended use : Pharmaceutical

**2. HAZARDS IDENTIFICATION****GHS Classification**

Specific target organ toxicity - repeated exposure (Oral) : Category 1 (Central nervous system)

Specific target organ toxicity - repeated exposure (Inhalation) : Category 1 (Cardio-vascular system)

**GHS label elements**

Hazard pictograms : 

Signal word : Danger

Hazard statements : H372 Causes damage to organs (Central nervous system) through prolonged or repeated exposure if swallowed.  
 H372 Causes damage to organs (Cardio-vascular system) through prolonged or repeated exposure if inhaled.

Precautionary statements : **Prevention:**  
 P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.  
 P264 Wash skin thoroughly after handling.  
 P270 Do not eat, drink or smoke when using this product.

**Response:**  
 P314 Get medical advice/ attention if you feel unwell.

**Disposal:**

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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)
Cellulose	9004-34-6	>= 30 -< 60
Bis[[S-(R*,R*)-(β-hydroxy-α-methylphenethyl)methylammonium] sulphate	7460-12-0	>= 10 -< 30
Disodium EDTA, dihydrate	6381-92-6	< 10
Citric acid	77-92-9	< 10
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

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

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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 Nitrogen oxides (NOx) Metal oxides
Specific extinguishing methods	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for firefighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

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**6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protective equipment and emergency procedures	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
Environmental precautions	:	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. 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. 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. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

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**7. HANDLING AND STORAGE**

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 breathe dust, fume, gas, mist, vapours or spray. Do not swallow. Avoid contact with eyes. Avoid prolonged or repeated contact with skin. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the environment.

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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

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

## Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Cellulose	9004-34-6	NAB	10 mg/m <sup>3</sup>	ID OEL
		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

Remarks : Consider double gloving.

Eye protection : Wear safety glasses with side shields or goggles.  
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.  
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection : Work uniform or laboratory coat.  
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.  
Use appropriate degowning techniques to remove potentially contaminated clothing.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the work-

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ing 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.

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	solid
Colour	:	white, blue
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	Not applicable
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	Not classified as a flammability hazard
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	Not applicable
Relative vapour density	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Solubility(ies) Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Auto-ignition temperature	:	No data available

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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  
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

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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.

**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

**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

**Desloratadine:**

Acute oral toxicity : LD50 (Rat): > 549 mg/kg  
  
LD50 (Mouse): 353 mg/kg  
  
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\*)-(β-hydroxy-α-methylphenethyl)methylammonium] sulphate:**

Species : Rabbit  
Result : No skin irritation

**Disodium EDTA, dihydrate:**

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

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**Citric acid:**

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\*)]-(β-hydroxy-α-methylphenethyl)methylammonium] sulphate:**

Species	:	Rabbit
Result	:	No eye irritation

**Disodium EDTA, dihydrate:**

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

**Citric acid:**

Species	:	Rabbit
Result	:	Irritation to eyes, reversing within 21 days
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
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**Disodium EDTA, dihydrate:**

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



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**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  
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

**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

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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

**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\*)]-( $\beta$ -hydroxy- $\alpha$ -methylphenethyl)methylammonium] sulphate:**

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

Species : Mouse

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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

**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

Effects on foetal development : Test Type: Fertility/early embryonic development  
 Species: Rat  
 Application Route: Ingestion  
 Result: negative

**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

Effects on foetal development : Test Type: Embryo-foetal development  
 Species: Rabbit

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Application Route: Oral  
Result: No teratogenic effects

Test Type: Embryo-foetal development  
Application Route: Oral  
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.

**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

**Citric acid:**

Effects on foetal development : Test Type: One-generation reproduction toxicity study  
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

Test Type: Embryo-foetal development  
Species: Rat

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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

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

Remarks : No data available

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**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

**Citric acid:**

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

**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

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

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**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure****Components:****Bis[[S-(R\*,R\*)-(β-hydroxy-α-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

**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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**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 ( <i>Desmodesmus subspicatus</i> (green algae)): > 100 mg/l Exposure time: 72 h Remarks: Based on data from similar materials
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	:	NOEC ( <i>Desmodesmus subspicatus</i> (green algae)): 100 mg/l Exposure time: 72 h Remarks: Based on data from similar materials
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Toxicity to fish (Chronic toxicity)	:	NOEC ( <i>Danio rerio</i> (zebra fish)): 25.7 mg/l Exposure time: 35 d Method: OECD Test Guideline 210 Remarks: Based on data from similar materials
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Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC ( <i>Daphnia magna</i> (Water flea)): 25 mg/l Exposure time: 21 d Remarks: Based on data from similar materials
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Toxicity to microorganisms : EC50: < 500 mg/l  
 Exposure time: 0.5 h  
 Method: OECD Test Guideline 209  
 Remarks: Based on data from similar materials

**Citric acid:**

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l  
 Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 1,535 mg/l  
 Exposure time: 24 h

**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  
 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



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

Biodegradability : Result: Readily biodegradable.

**Disodium EDTA, dihydrate:**

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

**Citric acid:**

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

**Desloratadine:**

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

Result: Not readily biodegradable.  
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

**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

**Citric acid:**

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

**Desloratadine:**

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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

#### **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.

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## 15. REGULATORY INFORMATION

### **Safety, health and environmental regulations/legislation specific for the substance or mixture**

**Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.**

### **Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health**

Hazardous substances that must be registered : Not applicable

### **Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances**

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Hazardous substances approved for use : Not applicable

Prohibited substances : Not applicable

Restricted substances : Not applicable

**Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials**

Type of Hazardous Materials Restricted to Import, Distribution and Supervision : Not applicable

**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)

ID OEL : Indonesia. Occupational Exposure Limits

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

ID OEL / NAB : Long term exposure limit

AIIC - Australian Inventory of Industrial Chemicals; 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; KECI - 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

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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 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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