SAFETY DATA SHEET
Desloratadine / Pseudoephedrine Formulation

Version 4.1  Revision Date: 04/09/2021  SDS Number: 2095119-00009  Date of last issue: 10/10/2020  Date of first issue: 10/23/2017

SECTION 1. IDENTIFICATION

Product name: Desloratadine / Pseudoephedrine Formulation
Other means of identification: No data available

Manufacturer or supplier’s details
Company name of supplier: Organon & Co.
Address: 30 Hudson Street, 33nd floor
Jersey City, New Jersey, U.S.A 07302
Telephone: 551-430-6000
Emergency telephone: 215-631-6999
E-mail address: EHSSTEWARD@organon.com

Recommended use of the chemical and restrictions on use
Recommended use: Pharmaceutical
Restrictions on use: Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations
Reproductive toxicity: Category 2
Specific target organ toxicity - repeated exposure (Oral): Category 1 (Central nervous system)
Specific target organ toxicity - repeated exposure (Inhalation): Category 1 (Cardio-vascular system)
Specific target organ toxicity - repeated exposure: Category 2 (Respiratory Tract)

GHS label elements
Hazard pictograms: 

Signal Word: Danger
Hazard Statements: H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.
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.
H373 May cause damage to organs (Respiratory Tract) through prolonged or repeated exposure.

Precautionary Statements: Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe dust, fume, gas, mist, vapors or spray.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P280 Wear protective gloves, protective clothing, eye protection and face protection.

Response:
P308 + P313 IF exposed or concerned: Get medical attention.

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents and container to an approved waste disposal plant.

Other hazards
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common Name/Synonym</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>No data available</td>
<td>9004-34-6</td>
<td>&gt;= 30 - &lt; 60 *</td>
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<tr>
<td>Bis[[S-(R*,R*)]-{β-hydroxy-α-methylphenethyl]methyl ammonium] sulphate</td>
<td>No data available</td>
<td>7460-12-0</td>
<td>&gt;= 10 - &lt; 30 *</td>
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<tr>
<td>Starch, oxidized</td>
<td>Tapioca Starch</td>
<td>65996-62-5</td>
<td>&gt;= 1 - &lt; 5 *</td>
</tr>
<tr>
<td>Disodium EDTA, dihydrate</td>
<td>Ethylenediaminetetraacetic acid disodium salt dihydrate</td>
<td>6381-92-6</td>
<td>&gt;= 1 - &lt; 5 *</td>
</tr>
<tr>
<td>Citric acid</td>
<td>2-hydroxypropane-1,2,3-tricarboxylic acid</td>
<td>77-92-9</td>
<td>&gt;= 1 - &lt; 5 *</td>
</tr>
<tr>
<td>Desloratadine</td>
<td>No data available</td>
<td>100643-71-8</td>
<td>&gt;= 0.1 - &lt; 1 *</td>
</tr>
</tbody>
</table>

* Actual concentration or concentration range is withheld as a trade secret

SECTION 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 attention.
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.

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:
Suspected of damaging fertility. Suspected of damaging the unborn child.
Causes damage to organs through prolonged or repeated exposure if swallowed.
Causes damage to organs through prolonged or repeated exposure if inhaled.
May cause damage to organs through prolonged or repeated exposure.

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.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media:
Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
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
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 fire-fighters:
In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency advice:
Use personal protective equipment.
Follow safe handling advice (see section 7) and personal
Emergency procedures  
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.

SECTION 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, vapors 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.

Conditions for safe storage  
Keep in properly labeled containers.  
Store in accordance with the particular national regulations.

Materials to avoid  
Do not store with the following product types:  
Strong oxidizing agents  
Organic peroxides  
Explosives  
Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Total dust)</td>
<td>10 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (respirable dust)</td>
<td>3 mg/m³</td>
<td>CA BC OEL</td>
</tr>
</tbody>
</table>
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: 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 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.

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- **Appearance**: solid
- **Color**: white, blue
- **Odor**: No data available
- **Odor 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
- **Vapor pressure**: Not applicable
- **Relative vapor 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
- **Autoignition 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

SECTION 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.

SECTION 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: 2,451 mg/kg
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: 5.3 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
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

Citric acid:
Species: Rabbit
Method: OECD Test Guideline 404
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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 sensitization**

Skin sensitization
Not classified based on available information.

Respiratory sensitization
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 : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig
Result : negative
Remarks : Based on data from similar materials
Desloratadine:
Test Type: Maximization Test
Routes of exposure: 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
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*)]-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
<table>
<thead>
<tr>
<th><strong>Disodium EDTA, dihydrate:</strong></th>
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</tr>
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<tbody>
<tr>
<td><strong>Species:</strong></td>
<td>Rat</td>
</tr>
<tr>
<td><strong>Application Route:</strong></td>
<td>Ingestion</td>
</tr>
<tr>
<td><strong>Exposure time:</strong></td>
<td>103 weeks</td>
</tr>
<tr>
<td><strong>Result:</strong></td>
<td>negative</td>
</tr>
<tr>
<td><strong>Remarks:</strong></td>
<td>Based on data from similar materials</td>
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</table>

<table>
<thead>
<tr>
<th><strong>Desloratadine:</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Species:</strong></td>
<td>Mouse</td>
</tr>
<tr>
<td><strong>Application Route:</strong></td>
<td>Oral</td>
</tr>
<tr>
<td><strong>Exposure time:</strong></td>
<td>2 Years</td>
</tr>
<tr>
<td><strong>Result:</strong></td>
<td>negative</td>
</tr>
</tbody>
</table>

| **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

Suspected of damaging fertility. Suspected of damaging the unborn child.

#### Components:

**Cellulose:**

| Effects on fertility | Test Type: One-generation reproduction toxicity study Species: Rat Application Route: Ingestion Result: negative |
| Effects on fetal 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 fetal development | Test Type: Embryo-fetal development Species: Rabbit Application Route: Oral Result: No teratogenic effects. |
Test Type: Embryo-fetal 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 fetal development: Test Type: Embryo-fetal development
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Citric acid:

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

Test Type: Embryo-fetal 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.  
May cause damage to organs (Respiratory Tract) through prolonged or repeated exposure.

**Components:**

**Bis[[S-(R*,R*)]-\(\beta\)-hydroxy-\(\alpha\)-methylphenethy]methylammonium] sulphate:**  
Routes of exposure: Ingestion, Inhalation  
Target Organs: Central nervous system, Cardio-vascular system  
Assessment: Causes damage to organs through prolonged or repeated exposure.

**Disodium EDTA, dihydrate:**  
Routes of exposure: 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*)]-\(\beta\)-hydroxy-\(\alpha\)-methylphenethy]methylammonium] sulphate:**  
Remarks: No data available
Disodium EDTA, dihydrate:
Species: Rat
NOAEL: 500 mg/kg
Application Route: Ingestion
Exposure time: 13 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

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

### SECTION 12. ECOLOGICAL INFORMATION

**Ecotoxicity**

**Components:**

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

**Disodium EDTA, dihydrate:**
- **Toxicity to fish**: LC50 (Lepomis macrochirus (Bluegill sunfish)): 159 mg/l
  Exposure time: 96 h
  Remarks: Based on data from similar materials

- **Toxicity to daphnia and other aquatic invertebrates**: EC50 (Daphnia magna (Water flea)): 140 mg/l
  Exposure time: 48 h
  Remarks: Based on data from similar materials

- **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

**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

**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

- **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**:
  - 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

SECTION 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.

SECTION 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.

Domestic regulation

TDG
Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

The ingredients of this product are reported in the following inventories:

AICS: not determined

DSL: not determined

IECSC: not determined

SECTION 16. OTHER INFORMATION

Full text of other abbreviations
Sources of key data used to compile the Material Safety Data Sheet:

Revision Date:
04/09/2021

Date format:
mm/dd/yyyy

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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