SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Desloratadine / Pseudoephedrine Formulation

Manufacturer or supplier’s details
Company: 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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification
Acute toxicity (Oral): Category 5
Acute toxicity (Inhalation): Category 5
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: H303 + H333 May be harmful if swallowed or if inhaled.
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/ vapors/ spray.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.

Response:
P304 + P312 IF INHALED: Call a POISON CENTER/ doctor if you feel unwell.
P312 Call a POISON CENTER/ doctor if you feel unwell.

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

Other hazards which do not result in classification
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixture</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Components</strong></td>
<td></td>
</tr>
<tr>
<td>Chemical name</td>
<td>CAS-No.</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
</tr>
<tr>
<td>Bis[[S-(R*,R*)]-{(β-hydroxy-α-methylphenethyl)methylammonium} sulphate</td>
<td>7460-12-0</td>
</tr>
<tr>
<td>Disodium EDTA, dihydrate</td>
<td>6381-92-6</td>
</tr>
<tr>
<td>Citric acid</td>
<td>77-92-9</td>
</tr>
<tr>
<td>Desloratadine</td>
<td>100643-71-8</td>
</tr>
</tbody>
</table>

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 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: May be harmful if swallowed or if inhaled.
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.
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 firefighting: 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 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.

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>CMP</td>
<td>10 mg/m³</td>
<td>AR OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: Irritation</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Bis[[S-(R*,R*)]-[(β-hydroxy-α-methylphenethyl)methylammonium] sulphate</td>
<td>7460-12-0</td>
<td>TWA</td>
<td>50 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>500 µg/100 cm²</td>
</tr>
<tr>
<td>Desloratadine</td>
<td>100643-71-8</td>
<td>TWA</td>
<td>20 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>200 µg/100 cm²</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**

**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,
SAFETY DATA SHEET
Desloratadine / Pseudoephedrine Formulation

Version 4.0  Revision Date: 10.10.2020  SDS Number: 2111477-00009  Date of last issue: 23.03.2020

Date of first issue: 23.10.2017

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) : No data available
Water solubility : No data available
Partition coefficient: n-octanol/water : Not applicable
Autoignition temperature : No data available
Decomposition temperature : No data available
Viscosity : Not applicable
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
May be harmful if swallowed or if inhaled.

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
- **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
- **Method:** OECD Test Guideline 405
- **Result:** Irritation to eyes, reversing within 21 days

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  
Remarks: Based on data from similar materials

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

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
<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Effects on fertility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bis[[S-{(R^<em>,R^</em>)}-(\beta)-hydroxy-(\alpha)-methylphenethyl)methylammonium] sulphate:</td>
<td>Test Type: Fertility  Species: Rat  Application Route: Oral  Fertility: LOAEL: 80 mg/kg body weight  Symptoms: male reproductive effects</td>
</tr>
<tr>
<td></td>
<td>Test Type: Embryo-fetal development  Species: Rabbit  Application Route: Oral  Result: No teratogenic effects.</td>
</tr>
<tr>
<td></td>
<td>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.</td>
</tr>
<tr>
<td>Disodium EDTA, dihydrate:</td>
<td>Test Type: Four-generation reproduction toxicity study  Species: Rat  Application Route: Ingestion  Result: negative  Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td></td>
<td>Test Type: Embryo-fetal development  Species: Rat  Application Route: Ingestion  Result: negative  Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td>Citric acid:</td>
<td>Test Type: One-generation reproduction toxicity study  Species: Rat  Application Route: Ingestion  Result: negative</td>
</tr>
<tr>
<td>Desloratadine:</td>
<td>Test Type: Fertility  Species: Rat, male  Application Route: Oral  Fertility: LOAEL: 12 mg/kg body weight  Symptoms: Reduced fertility  Result: positive</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET
Desloratadine / Pseudoephedrine Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
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<tr>
<td>4.0</td>
<td>10.10.2020</td>
<td>2111477-00009</td>
<td>23.03.2020</td>
<td>23.10.2017</td>
</tr>
</tbody>
</table>

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. |

**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: |
| 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*)]-(β-hydroxy-α-methylphenethyl)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
ic toxicity) 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
  - 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:

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.
SAFETY DATA SHEET
Desloratadine / Pseudoephedrine Formulation

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture
Argentina. Carcinogenic Substances and Agents : Not applicable
Registry.
Control of precursors and essential chemicals for the preparation of drugs : Not applicable
International Regulations

The ingredients of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

SECTION 16. OTHER INFORMATION

Further information

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
AR OEL : Argentina. Occupational Exposure Limits
ACGIH / TWA : 8-hour, time-weighted average
AR OEL / CMP : TLV (Threshold Limit Value)

AICIC - 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 Con-
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