1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Desloratadine / Pseudoephedrine Formulation

Manufacturer or supplier’s details
Company: Organon & Co.
Address: 30 Hudson Street, 33rd floor
        Jersey City, New Jersey, U.S.A 07302
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

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989
Classification
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

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 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/ vapours/ spray.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.

**Response:**
P301 + P304 + P317 IF SWALLOWED OR IF INHALED: Get medical help.
P319 Get medical help 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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td>Bis[(S-(R*,R*)]-{(β-hydroxy-α-methylphenethyl)methylammonium] sulphate</td>
<td>7460-12-0</td>
<td>&gt;= 20 - &lt; 30</td>
</tr>
<tr>
<td>Disodium EDTA, dihydrate</td>
<td>6381-92-6</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td>Citric acid</td>
<td>77-92-9</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td>Desloratadine</td>
<td>100643-71-8</td>
<td>&gt;= 0.25 - &lt; 1</td>
</tr>
</tbody>
</table>

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: May be harmful if swallowed or if inhaled.
Causes damage to organs through prolonged or repeated
SAFETY DATA SHEET

Desloratadine / Pseudoephedrine Formulation

Version 3.4  
Revision Date: 10.10.2020  
SDS Number: 2111465-00009  
Date of last issue: 23.03.2020  
Date of first issue: 23.10.2017

delayed 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 (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 firefighters:  
In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.

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.

7. HANDLING AND STORAGE

Technical measures:  
See Engineering measures under EXPOSURE
SAFETY DATA SHEET

Desloratadine / Pseudoephedrine Formulation

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.

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

<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>ACGIH</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>Desloratadine</td>
<td>100643-71-8</td>
<td>TWA</td>
<td>20 µg/m³ (OEB 3)</td>
<td>Internal</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.

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
### 10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactivity</td>
<td>Not classified as a reactivity hazard.</td>
</tr>
<tr>
<td>Chemical stability</td>
<td>Stable under normal conditions.</td>
</tr>
<tr>
<td>Possibility of hazardous reactions</td>
<td>Can react with strong oxidizing agents.</td>
</tr>
<tr>
<td>Conditions to avoid</td>
<td>None known.</td>
</tr>
<tr>
<td>Incompatible materials</td>
<td>Oxidizing agents</td>
</tr>
<tr>
<td>Hazardous decomposition products</td>
<td>No hazardous decomposition products are known.</td>
</tr>
</tbody>
</table>

### 11. TOXICOLOGICAL INFORMATION

#### 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 sensitisation

Skin sensitisation
Not classified based on available information.
Respiratory sensitisation
Not classified based on available information.

Components:

Bis[[S-(R*,R*)]-β-hydroxy-α-methylphenethyl)methylammonium] sulphate:
Remarks: No data available

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

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

Germ cell mutagenicity
Not classified based on available information.

Components:

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

Genotoxicity in vitro: 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.

Genotoxicity in vitro: 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
## 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 erythocyte 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

---

## Desloradatine:

### Genotoxicity in vitro

- Test Type: Bacterial reverse mutation assay (AMES)
  - Result: negative
  - Test Type: Chromosomal aberration
  - Test system: Human lymphocytes
  - Result: negative

### Genotoxicity in vivo

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

---

## Carcinogenicity

Not classified based on available information.
Components:

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

Bis[[S-(R',R')]-β-hydroxy-α-methylphenethyl)methylammonium] sulphate:
Species: Rat
Application Route: Oral
Exposure time: 2 Years
Result: negative
Remarks: Based on data from similar materials

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

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

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:
<table>
<thead>
<tr>
<th>Substance</th>
<th>Effects on fertility</th>
<th>Effects on foetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Desloratadine</strong></td>
<td>Test Type: One-generation reproduction toxicity study</td>
<td>Test Type: Fertility/early embryonic development</td>
</tr>
<tr>
<td></td>
<td>Species: Rat</td>
<td>Species: Rat</td>
</tr>
<tr>
<td></td>
<td>Application Route: Ingestion</td>
<td>Application Route: Ingestion</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
<td>Result: negative</td>
</tr>
<tr>
<td><em><em>Bis[(S-(R,R</em>)]-β-hydroxy-α-methylphenethyl)methylammonium] sulphate</em>*</td>
<td>Test Type: Fertility</td>
<td>Test Type: Embryo-foetal development</td>
</tr>
<tr>
<td></td>
<td>Species: Rat</td>
<td>Species: Rabbit</td>
</tr>
<tr>
<td></td>
<td>Application Route: Oral</td>
<td>Application Route: Oral</td>
</tr>
<tr>
<td></td>
<td>Fertility: LOAEL: 80 mg/kg body weight</td>
<td>Result: No teratogenic effects</td>
</tr>
<tr>
<td></td>
<td>Symptoms: male reproductive effects</td>
<td>Test Type: Embryo-foetal development</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Application Route: Oral</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Result: No embryotoxic effects have been observed in animal tests.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Remarks: Maternal toxicity observed.</td>
</tr>
<tr>
<td><strong>Disodium EDTA, dihydrate</strong></td>
<td>Test Type: Four-generation reproduction toxicity study</td>
<td>Test Type: Embryo-foetal development</td>
</tr>
<tr>
<td></td>
<td>Species: Rat</td>
<td>Species: Rat</td>
</tr>
<tr>
<td></td>
<td>Application Route: Ingestion</td>
<td>Application Route: Ingestion</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
<td>Result: negative</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td>Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td><strong>Citric acid</strong></td>
<td>Test Type: One-generation reproduction toxicity study</td>
<td>Test Type: Embryo-foetal development</td>
</tr>
<tr>
<td></td>
<td>Species: Rat</td>
<td>Species: Rat</td>
</tr>
<tr>
<td></td>
<td>Application Route: Ingestion</td>
<td>Application Route: Ingestion</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
<td>Result: negative</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td><strong>Desloratadine</strong></td>
<td>Test Type: Fertility</td>
<td>Test Type: Fertility</td>
</tr>
<tr>
<td></td>
<td>Species: Rat, male</td>
<td>Species: Rat</td>
</tr>
<tr>
<td></td>
<td>Application Route: Oral</td>
<td>Application Route: Oral</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>
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
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:

<table>
<thead>
<tr>
<th>Exposure routes</th>
<th>Inhalation (dust/mist/fume)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target Organs</td>
<td>Respiratory Tract</td>
</tr>
<tr>
<td>Assessment</td>
<td>Shown to produce significant health effects in animals at concentrations of &gt;0.02 to 0.2 mg/l/6h/d.</td>
</tr>
</tbody>
</table>

Repeated dose toxicity

Components:

**Cellulose:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>&gt;= 9,000 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>90 Days</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

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

| Remarks | No data available |

**Disodium EDTA, dihydrate:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>500 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>13 Weeks</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

| Remarks | Based on data from similar materials |

**Citric acid:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>4,000 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>8,000 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>10 Days</td>
</tr>
</tbody>
</table>

**Desloratadine:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>30 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>3 Months</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Kidney</td>
</tr>
<tr>
<td>Remarks</td>
<td>Significant toxicity observed in testing The mechanism or mode of action may not be relevant in humans.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Monkey</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>6 mg/kg</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Desloratadine / Pseudoephedrine Formulation

Version 3.4
Revision Date: 10.10.2020
SDS Number: 2111465-00009
Date of last issue: 23.03.2020
Date of first issue: 23.10.2017

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

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

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Cellulose:
Toxicity to fish
Exposure time: 48 h
Remarks: Based on data from similar materials

Disodium EDTA, dihydrate:
Toxicity to fish
Exposure time: 96 h
Remarks: Based on data from similar materials

Toxicity to daphnia and other:
EC50 (Daphnia magna (Water flea)): 140 mg/l
aquatic invertebrates: 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 microorganisms:
EC50: < 500 mg/l
Exposure time: 0.5 h
Method: OECD Test Guideline 209
Remarks: Based on data from similar materials

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

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
NOEC: 25 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
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 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

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

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

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

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. |

14. TRANSPORT INFORMATION

**International Regulations**

**UNRTDG**
Not regulated as a dangerous good

**IATA-DGR**
Not regulated as a dangerous good
SAFETY DATA SHEET

Desloratadine / Pseudoephedrine Formulation

IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to IMO instruments
Not applicable for product as supplied.

15. REGULATORY INFORMATION

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

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

<table>
<thead>
<tr>
<th>Inventory</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>AICS</td>
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</tr>
<tr>
<td>DSL</td>
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</tr>
<tr>
<td>IECSC</td>
<td>not determined</td>
</tr>
</tbody>
</table>

16. OTHER INFORMATION

Further information
Sources of key data used to compile the Safety Data Sheet:

Date format: dd.mm.yyyy

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
ACGIH / TWA: 8-hour, time-weighted average

AICL - 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 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 Develop-
Desloratadine / Pseudoephedrine Formulation

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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