SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Desloratadine / Pseudoephedrine Formulation

Manufacturer or supplier’s details
Company : Organon & Co.
Address : Rua Treze de Maio, 1161, Campinas, São Paulo, Brazil B-2220
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 in accordance with ABNT NBR 14725 Standard
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 in accordance with ABNT NBR 14725 Standard
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:
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.

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-</td>
<td>7460-12-0</td>
</tr>
<tr>
<td>methylphenethyl)methylammonium]</td>
<td></td>
</tr>
<tr>
<td>sulphate</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Disodium EDTA, dihydrate</td>
<td>6381-92-6</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Citric acid</td>
<td>77-92-9</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Desloratadine</td>
<td>100643-71-8</td>
</tr>
<tr>
<td></td>
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<tr>
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<td></td>
</tr>
</tbody>
</table>

Date of last issue: 23.03.2020
Date of first issue: 23.10.2017
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 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 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.

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.

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>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></td>
<td></td>
<td>Wipe limit</td>
<td>500 µg/100 cm²</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>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>200 µg/100 cm²</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:

Material: Chemical-resistant gloves

Remarks: Consider double gloving.

Eye protection:

Material: Wear safety glasses with side shields or goggles.

Remarks: 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:

Material: Work uniform or laboratory coat.

Remarks: 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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: solid

Color: white, blue
## SECTION 10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor</td>
<td>No data available</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not classified as a flammability hazard</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative vapor density</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td>Water solubility: No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Autoignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>Viscosity, kinematic: Not applicable</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
<tr>
<td>Particle size</td>
<td>No data available</td>
</tr>
</tbody>
</table>
### 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
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-methylphenethy]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
- Result: negative
- Remarks: Based on data from similar materials

**Disodium EDTA, dihydrate:**
- Species: Rat
- Application Route: Ingestion
- Exposure time: 103 weeks
- Result: negative
- Remarks: Based on data from similar materials
Desloratadine:
Species: Mouse
Application Route: Oral
Exposure time: 2 Years
Result: negative

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

Reproductive toxicity
Not classified based on available information.

Components:

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

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

Bis[1S-(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

<table>
<thead>
<tr>
<th>Test Type: Four-generation reproduction toxicity study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rat</td>
</tr>
<tr>
<td>Application Route: Ingestion</td>
</tr>
<tr>
<td>Result: negative</td>
</tr>
<tr>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

### Effects on fetal development

<table>
<thead>
<tr>
<th>Test Type: Embryo-fetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rat</td>
</tr>
<tr>
<td>Application Route: Ingestion</td>
</tr>
<tr>
<td>Result: negative</td>
</tr>
<tr>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

### Citric acid:

<table>
<thead>
<tr>
<th>Effects on fetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Type: One-generation reproduction toxicity study</td>
</tr>
<tr>
<td>Species: Rat</td>
</tr>
<tr>
<td>Application Route: Ingestion</td>
</tr>
<tr>
<td>Result: negative</td>
</tr>
</tbody>
</table>

### Desloratadine:

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

<table>
<thead>
<tr>
<th>Effects on fetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Type: Embryo-fetal development</td>
</tr>
<tr>
<td>Species: Rabbit</td>
</tr>
<tr>
<td>Application Route: Oral</td>
</tr>
<tr>
<td>Developmental Toxicity: NOAEL: 30 mg/kg body weight</td>
</tr>
<tr>
<td>Result: No teratogenic effects.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Effects on fetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Type: Embryo-fetal development</td>
</tr>
<tr>
<td>Species: Rat</td>
</tr>
<tr>
<td>Application Route: Oral</td>
</tr>
<tr>
<td>Developmental Toxicity: LOAEL: 9 mg/kg body weight</td>
</tr>
<tr>
<td>Symptoms: Preimplantation loss., Reduced body weight</td>
</tr>
<tr>
<td>Result: Specific developmental abnormalities.</td>
</tr>
<tr>
<td>Remarks: The mechanism or mode of action may not be relevant in humans.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Effects on fetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Type: Two-generation study</td>
</tr>
<tr>
<td>Species: Rat</td>
</tr>
<tr>
<td>Application Route: Oral</td>
</tr>
<tr>
<td>Developmental Toxicity: LOAEL: 18 mg/kg body weight</td>
</tr>
<tr>
<td>Result: No adverse effects.</td>
</tr>
</tbody>
</table>
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:
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

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

Citric acid:
Species: Rat
NOAEL: 4.000 mg/kg
LOAEL: 8.000 mg/kg
Application Route: Ingestion
Exposure time: 10 Days

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

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

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

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

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

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-methylphenethy1)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

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
SAFETY DATA SHEET

Desloratadine / Pseudoephedrine Formulation

Version: 4.1
Revision Date: 10.10.2020
SDS Number: 2095120-0009
Date of last issue: 23.03.2020
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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

ANTT
Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

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

National List of Carcinogenic Agents for Humans - (LINACH): Not applicable

Brazil. List of chemicals controlled by the Federal Police: 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
Sources of key data used to: Internal technical data, data from raw material SDSs, OECD

**Full text of other abbreviations**

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

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

AIIIC - 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 i

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