SAFETY DATA SHEET

Desloratadine / Pseudoephedrine Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Desloratadine / Pseudoephedrine Formulation

Manufacturer or supplier’s details
Company name of supplier: Organon & Co.
Address: Avenida 16 de Septiembre No. 301
Xaltocan - Xochimilco Mexico 16090
Telephone: 52 55 57284444
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
Reproductive toxicity: Category 2
Specific target organ toxicity - repeated exposure (Oral): Category 1 (Central nervous system)
Specific target organ toxicity - repeated exposure (Inhalation): Category 1 (Cardio-vascular system)
Specific target organ toxicity - repeated exposure: Category 2 (Respiratory Tract)

GHS label elements
Hazard pictograms:

Signal Word: Danger
Hazard Statements: H303 + H333 May be harmful if swallowed or if inhaled.
H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.
H372 Causes damage to organs (Central nervous system) through prolonged or repeated exposure if swallowed.
H372 Causes damage to organs (Cardio-vascular system) through prolonged or repeated exposure if inhaled.
H373 May cause damage to organs (Respiratory Tract) through prolonged or repeated exposure.

Precautionary Statements: Prevention:
SAFETY DATA SHEET

Desloratadine / Pseudoephedrine Formulation

Version 3.3  Revision Date: 10.10.2020  SDS Number: 2095094-00008  Date of last issue: 13.09.2019

Date of first issue: 23.10.2017

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

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

Storage:
P405 Store locked up.

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

Other hazards
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>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;= 0.1 &lt; 1</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.
If swallowed:

- Get medical attention if irritation develops and persists.
- 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.
- Suspected of damaging fertility. Suspected of damaging the unborn child.
- Causes damage to organs through prolonged or repeated exposure if swallowed.
- Causes damage to organs through prolonged or repeated exposure if inhaled.
- May cause damage to organs through prolonged or repeated exposure.

Protection of first-aiders:

- First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician:

- Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media:

- Water spray
- Alcohol-resistant foam
- Carbon dioxide (CO2)
- Dry chemical

 Unsuitable extinguishing media:

- None known.

Specific hazards during fire fighting:

- Exposure to combustion products may be a hazard to health.

Hazardous combustion products:

- Carbon oxides
- Nitrogen oxides (NOx)
- Metal oxides

Specific extinguishing methods:

- Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Use water spray to cool unopened containers.
- Remove undamaged containers from fire area if it is safe to do so.
- Evacuate area.

Special protective equipment for fire-fighters:

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

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency 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

<table>
<thead>
<tr>
<th>Ingredients with workplace control parameters</th>
</tr>
</thead>
<tbody>
<tr>
<td>Components</td>
</tr>
<tr>
<td>------------</td>
</tr>
<tr>
<td>Cellulose</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Bis[[S-(R*,R*)]-{(β-hydroxy-α-methylphenethyl)methylamino}</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Desloratadine / Pseudoephedrine Formulation

<table>
<thead>
<tr>
<th>Component</th>
<th>Wipe limit</th>
<th>Media</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nium sulphate</td>
<td>500 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Desloratadine</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

Material: Chemical-resistant gloves

Remarks: Consider double gloving.

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

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

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance: solid

Color: white, blue

Odor: No data available

Odor Threshold: No data available

pH: No data available

Melting point/freezing point: No data available

Initial boiling point and boiling range: No data available

Flash point: Not applicable
Evaporation rate : Not applicable
Flammability (solid, gas) : Not classified as a flammability hazard
Flammability (liquids) : No data available
Upper explosion limit / Upper flammability limit : No data available
Lower explosion limit / Lower flammability limit : No data available
Vapor pressure : Not applicable
Relative vapor density : Not applicable
Relative density : No data available
Density : No data available
Solubility(ies) : Water solubility : No data available
Partition coefficient: n-octanol/water : Not applicable
Autoignition temperature : No data available
Decomposition temperature : No data available
Viscosity : Viscosity, kinematic : Not applicable
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Particle size : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions : Can react with strong oxidizing agents.
Conditions to avoid : None known.
Incompatible materials : Oxidizing agents
Hazardous decomposition products : No hazardous decomposition products are known.
SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure
Skin contact
Ingestion
Eye contact

Acute toxicity
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

Genotoxicity in vitro:
- Test Type: Bacterial reverse mutation assay (AMES)
  - Result: negative
  - Remarks: Information given is based on data obtained from similar substances.

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^*\}\-(\beta-hydroxy-\alpha\_methylphenethyl)methylammonium\}] sulphate:
- Species: Rat
- 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
Suspected of damaging fertility. Suspected of damaging the unborn child.

Components:

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

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

Bis[[(S)-(R*,R*)]-β-hydroxy-α-methylphenethyl)methylammonium] sulphate:
Effects on fertility: Test Type: Fertility
Species: Rat
Application Route: Oral
Fertility: LOAEL: 80 mg/kg body weight
Symptoms: male reproductive effects

Effects on fetal development: Test Type: Embryo-fetal development
Species: Rabbit
Application Route: Oral
Result: No teratogenic effects.

Test Type: Embryo-fetal development
Application Route: Oral
Developmental Toxicity: LOAEL: 27 mg/kg body weight
Result: No embryotoxic effects have been observed in animal tests., No teratogenic effects.
Remarks: Maternal toxicity observed.

Disodium EDTA, dihydrate:
Effects on fertility: Test Type: Four-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Effects on fetal development: Test Type: Embryo-fetal development
Species: Rat
Application Route: Ingestion
### Citric acid:

<table>
<thead>
<tr>
<th>Effect / Development Type</th>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effects on fetal development</td>
<td>One-generation reproduction toxicity study</td>
<td>Rat</td>
<td>Ingestion</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

### Desloratadine:

<table>
<thead>
<tr>
<th>Effect / Development Type</th>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effects on fertility</td>
<td>Fertility</td>
<td>Rat, male</td>
<td>Oral</td>
<td>positive</td>
<td>The mechanism or mode of action may not be relevant in humans.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Test Type: Fertility</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Species: Rat, female</td>
<td></td>
<td></td>
<td>Fertility: NOAEL: 3 mg/kg body weight</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Fertility: LOAEL: 12 mg/kg body weight</td>
<td></td>
<td></td>
<td>No effects on fertility.</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Effect / Development Type</th>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reproductive toxicity - Assessment</td>
<td>Two-generation study</td>
<td>Rat</td>
<td>Oral</td>
<td>No adverse effects.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Test Type: Two-generation study</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Species: Rat</td>
<td></td>
<td></td>
<td>Developmental Toxicity: LOAEL: 18 mg/kg body weight</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Effect / Development Type</th>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reproductive toxicity - Assessment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Some evidence of adverse effects on sexual function and fertility, based on animal experiments.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Some evidence of adverse effects on development, based on animal experiments.</td>
</tr>
</tbody>
</table>

### STOT-single exposure

Not classified based on available information.
STOT-repeated exposure
Causes damage to organs (Central nervous system) through prolonged or repeated exposure if swallowed.
Causes damage to organs (Cardio-vascular system) through prolonged or repeated exposure if inhaled.
May cause damage to organs (Respiratory Tract) through prolonged or repeated exposure.

Components:

Bis[[S-(R,R*)]-[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, Palsitation

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

---

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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
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-methylphenethyl)methylammonium] sulphate:
Partition coefficient: n-octanol/water: log Pow: 0.89

Disodium EDTA, dihydrate:
Bioaccumulation:
Species: Lepomis macrochirus (Bluegill sunfish)
Bioconcentration factor (BCF): 1.8
Remarks: Based on data from similar materials

Partition coefficient: n-octanol/water: log Pow: -4.3

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

Desloratadine:
Partition coefficient: n-octanol/water: log Pow: 1.24
Method: OECD Test Guideline 107

Mobility in soil

Components:
Desloratadine:
Distribution among environmental compartments: log Koc: 3.00
Method: OECD Test Guideline 106

Other adverse effects
No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues: Dispose of in accordance with local regulations.
Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

Domestic regulation

NOM-002-SCT
Not regulated as a dangerous good

Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

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

Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills.

Bis[[S-(R*,R*)]-({β-hydroxy-α-methylphenethyl)methyl]ammonium} sulphate

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

AICS: not determined

DSL: not determined

IECSC: not determined

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

ACGIH: USA. ACGIH Threshold Limit Values (TLV)

NOM-010-STPS-2014: Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting the Work Environment - Identification, Assessment and Control - Appendix 1 Occupational Exposure Limits

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

NOM-010-STPS-2014 / VLE-PPT: Time weighted average limit value
### 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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</table>

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

<table>
<thead>
<tr>
<th>Sources of key data used to compile the Material Safety Data Sheet</th>
<th>Description</th>
</tr>
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</table>

**Revision Date**

10.10.2020

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

MX / Z8