SAFETY DATA SHEET

Desloratadine / Pseudoephedrine Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Desloratadine / Pseudoephedrine Formulation

Manufacturer or supplier’s details
Company : MSD
Address : 855 Leandro N. Alem St., 8 Floor
Buenos Aires, Argentina C1001AFB
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com
Telefax : 908-735-1496

Recommended use of the chemical and restrictions on use
Recommended use : Pharmaceutical

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification
Acute toxicity (Oral) : Category 5
Acute toxicity (Inhalation) : Category 5
Specific target organ toxicity - repeated exposure (Oral) : Category 1 (Central nervous system)
Specific target organ toxicity - repeated exposure (Inhalation) : Category 1 (Cardio-vascular system)

GHS label elements
Hazard pictograms :

Signal Word : Danger
Hazard Statements : H303 + H333 May be harmful if swallowed or if inhaled.
H372 Causes damage to organs (Central nervous system) through prolonged or repeated exposure if swallowed.
H372 Causes damage to organs (Cardio-vascular system) through prolonged or repeated exposure if inhaled.
Precautionary Statements:

**Prevention:**
- P260 Do not breathe dust/ fume/ gas/ mist/ vapors/ spray.
- P264 Wash skin thoroughly after handling.
- P270 Do not eat, drink or smoke when using this product.

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

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

Other hazards which do not result in classification
None known.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mixture</td>
<td></td>
</tr>
</tbody>
</table>

<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>Silicon dioxide</td>
<td>7631-86-9</td>
<td>&gt;= 1 - &lt; 5</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>

### SECTION 4. FIRST AID MEASURES

<table>
<thead>
<tr>
<th>General advice</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>If inhaled</th>
</tr>
</thead>
<tbody>
<tr>
<td>If inhaled, remove to fresh air. Get medical attention.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>In case of skin contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>In case of eye contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>If swallowed</th>
</tr>
</thead>
<tbody>
<tr>
<td>If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Most important symptoms and effects, both acute and</th>
</tr>
</thead>
<tbody>
<tr>
<td>May be harmful if swallowed or if inhaled. Causes damage to organs through prolonged or repeated</td>
</tr>
</tbody>
</table>
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.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

Specific hazards during firefighting: Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides
Nitrogen oxides (NOx)
Metal oxides

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

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

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment.
Follow safe handling advice and personal protective equipment recommendations.

Environmental precautions: Discharge into the environment must be avoided.
Prevent further leakage or spillage if safe to do so.
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spills 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 swallow.
Avoid contact with eyes.
Avoid prolonged or repeated contact with skin.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
Take care to prevent spills, waste and minimize release to the environment.

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

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

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>CMP</td>
<td>10 mg/m³</td>
<td>AR OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>TWA 10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Bis[[S-(R*,R*)]-{β-hydroxy-α-methylphenethyl}methylammonium] sulphonate</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>Silicon dioxide</td>
<td>7631-86-9</td>
<td>CMP</td>
<td>10 mg/m³</td>
<td>AR OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>CMP 10 mg/m³</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: Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

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

Hygiene measures: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: solid

Color: white, blue

Odor: No data available

Odor Threshold: No data available

pH: No data available

Melting point/freezing point: No data available

Initial boiling point and boiling range: No data available

Flash point: Not applicable

Evaporation rate: Not applicable

Flammability (solid, gas): Not classified as a flammability hazard

Flammability (liquids): No data available

Upper explosion limit / Upper flammability limit: No data available
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Version 3.3  Revision Date: 23.03.2020  SDS Number: 2111477-00008  Date of last issue: 13.09.2019

Date of first issue: 23.10.2017

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

- **Cellulose**
  - Exposure time: 4 h
  - Test atmosphere: dust/mist
  - Method: Calculation method

- **Bis[[S-(R*,R*)]-β-hydroxy-α-methylphenethyl]methylammonium] sulphate**
  - Exposure time: 4 h
  - Test atmosphere: dust/mist

- **Silicon dioxide**
  - Exposure time: 4 h
  - Test atmosphere: dust/mist

- **Disodium EDTA, dihydrate**
  - Exposure time: 6 h
  - Test atmosphere: dust/mist

### Components:

<table>
<thead>
<tr>
<th>Component</th>
<th>Acute oral toxicity</th>
<th>Acute inhalation toxicity</th>
<th>Acute dermal toxicity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>LD50 (Rat): &gt; 5.000 mg/kg</td>
<td>LC50 (Rat): &gt; 5.8 mg/l</td>
<td>LD50 (Rabbit): &gt; 2.000 mg/kg</td>
</tr>
<tr>
<td>Bis[[S-(R*,R*)]-β-hydroxy-α-methylphenethyl]methylammonium] sulphate</td>
<td>LD50 (Rat): 660 mg/kg</td>
<td>LC50 (Rat): &gt; 2.37 mg/l</td>
<td>LD50 (Rat): &gt; 2.000 mg/kg</td>
</tr>
<tr>
<td>Silicon dioxide</td>
<td>LD50 (Rat): &gt; 5.000 mg/kg</td>
<td>LC50 (Rat): &gt; 2.08 mg/l</td>
<td>LD50 (Rabbit): &gt; 5.000 mg/kg</td>
</tr>
<tr>
<td>Disodium EDTA, dihydrate</td>
<td>LD50 (Rat): 2.800 mg/kg</td>
<td>LC50 (Rat): &gt; 1 mg/l</td>
<td></td>
</tr>
<tr>
<td>Citric acid</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Desloratadine / Pseudoephedrine Formulation

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

Silicon dioxide:
Species: Rabbit
Method: OECD Test Guideline 404
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
<table>
<thead>
<tr>
<th>Component</th>
<th>Species</th>
<th>Result</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Silicon dioxide</td>
<td>Rabbit</td>
<td>No eye irritation</td>
<td>OECD Test Guideline 405</td>
</tr>
<tr>
<td>Disodium EDTA, dihydrate</td>
<td>Rabbit</td>
<td>No eye irritation</td>
<td>OECD Test Guideline 405</td>
</tr>
<tr>
<td>Citric acid</td>
<td>Rabbit</td>
<td>Irritation to eyes, reversing within 21 days</td>
<td>OECD Test Guideline 405</td>
</tr>
<tr>
<td>Desloratadine</td>
<td>Rabbit</td>
<td>Severe eye irritation</td>
<td></td>
</tr>
</tbody>
</table>

**Respiratory or skin sensitization**

**Skin sensitization**
Not classified based on available information.

**Respiratory sensitization**
Not classified based on available information.

**Components:**

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

- **Disodium EDTA, dihydrate:**
  Test Type: Maximization Test
  Routes of exposure: Skin contact
  Species: Guinea pig
  Result: negative
  Remarks: Based on data from similar materials

- **Desloratadine:**
  Test Type: Maximization Test
  Routes of exposure: Dermal
  Species: Guinea pig
  Result: negative

**Germ cell mutagenicity**
Not classified based on available information.
Components:

Cellulose:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  
Test Type: In vitro mammalian cell gene mutation test  
Result: negative

Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Ingestion  
Result: negative

Bis[[S-((R,R*)-(β-hydroxy-α-methylphenethyl)methylammonium]] sulphate:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  
Remarks: Information given is based on data obtained from similar substances.

Test Type: Chromosomal aberration  
Result: negative  
Remarks: Information given is based on data obtained from similar substances.

Genotoxicity in vivo: Test Type: Micronucleus test  
Species: Rat  
Application Route: Oral  
Result: negative  
Remarks: Based on data from similar materials

Silicon dioxide:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
Result: negative

Genotoxicity in vivo: Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)  
Species: Rat  
Application Route: Ingestion  
Result: negative

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
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<table>
<thead>
<tr>
<th>Application Route</th>
<th>Oral</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>2 Years</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

Silicon dioxide:
- **Species**: Rat
- **Application Route**: Ingestion
- **Exposure time**: 103 weeks
- **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

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>103 weeks</td>
</tr>
<tr>
<td>Result</td>
<td>equivocal</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Liver</td>
</tr>
</tbody>
</table>
| Remarks           | Based on data from similar materials

LOAEL: 10 mg/kg body weight

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

<table>
<thead>
<tr>
<th>Effects on fetal development</th>
<th>Test Type: Fertility/early embryonic development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Rat</td>
</tr>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Effects on fertility</th>
<th>Test Type: Fertility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Rat</td>
</tr>
</tbody>
</table>

12 / 21
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.

Silicon dioxide:
Effects on fetal development: Test Type: Embryo-fetal development
Species: Rat
Application Route: Ingestion
Result: negative

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

Effects on fetal development: Test Type: Embryo-fetal development
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Citric acid:
Effects on fetal development: Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative

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

Test Type: Fertility
Species: Rat, female  
Fertility: NOAEL: 3 mg/kg body weight  
Symptoms: No effects on fertility.  
Result: negative

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

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

Test Type: Two-generation study  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: LOAEL: 18 mg/kg body weight  
Result: No adverse effects.

Reproductive toxicity - Assessment:  
Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Some evidence of adverse effects on development, based on animal experiments.

STOT-single exposure  
Not classified based on available information.

STOT-repeated exposure  
Causes damage to organs (Central nervous system) through prolonged or repeated exposure if swallowed.  
Causes damage to organs (Cardio-vascular system) through prolonged or repeated exposure if inhaled.

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

Silicon dioxide:
Species: Rat
NOAEL: 1.3 mg/m³
Application Route: inhalation (dust/mist/fume)
Exposure time: 13 Weeks

Disodium EDTA, dihydrate:
Species: Rat
NOAEL: 500 mg/kg
Application Route: Ingestion
Exposure time: 13 Weeks
Remarks: Based on data from similar materials

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

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

Species: Monkey
NOAEL: 6 mg/kg
# SAFETY DATA SHEET

## Desloratadine / Pseudoephedrine Formulation

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<th>Revision Date:</th>
<th>SDS Number:</th>
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<td>2111477-00008</td>
<td>13.09.2019</td>
<td>23.10.2017</td>
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**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

**Silicon dioxide:**

- **Toxicity to fish** : LC50 (Danio rerio (zebra fish)): > 10.000 mg/l  
  Exposure time: 96 h  
  Method: OECD Test Guideline 203

- **Toxicity to daphnia and other** : EC50 (Daphnia magna (Water flea)): > 1.000 mg/l
### Aquatic Invertebrates

**Exposure time:** 24 h  
**Method:** OECD Test Guideline 202

### Toxicity to Algae/Aquatic Plants

**EC50 (Desmodesmus subspicatus (green algae)):** > 10.000 mg/l  
**Exposure time:** 72 h  
**Method:** OECD Test Guideline 201  
**Remarks:** Based on data from similar materials

**NOEC (Desmodesmus subspicatus (green algae)):** 10.000 mg/l  
**Exposure time:** 72 h  
**Method:** OECD Test Guideline 201  
**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

### 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 %
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 % at50 °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.

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture
- Argentina. Carcinogenic Substances and Agents Registry: Not applicable
- Control of precursors and essential chemicals for the preparation of drugs: Bis[[S-(R*,R*)]-β-hydroxy-α-methylphenethyl)methylammonium] sulphate

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
SAFETY DATA SHEET

Desloratadine / Pseudoephedrine Formulation

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

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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