SAFETY DATA SHEET

Desloratadine / Pseudoephedrine Formulation

Version 3.3 Revision Date: 03/23/2020 SDS Number: 2095077-00008 Date of last issue: 09/13/2019
Date of first issue: 10/23/2017

SECTION 1. IDENTIFICATION

Product name: Desloratadine / Pseudoephedrine Formulation

Manufacturer or supplier’s details
Company name of supplier: Merck & Co., Inc
Address: 2000 Galloping Hill Road
Kenilworth - New Jersey - U.S.A. 07033
Telephone: 908-740-4000
Telefax: 908-735-1496
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATATESTER@merck.com

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

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with 29 CFR 1910.1200
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:
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:
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:
P308 + P313 IF exposed or concerned: Get medical advice/ attention.

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

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chemical name</td>
</tr>
<tr>
<td>Mixture</td>
<td>Cellulose</td>
</tr>
<tr>
<td></td>
<td>Bis[(S-(R^<em>,R^</em>)]-{(β-hydroxy-α-methylphenethyl)methylammonium] sulphate</td>
</tr>
<tr>
<td></td>
<td>Starch, oxidized</td>
</tr>
<tr>
<td></td>
<td>Silicon dioxide</td>
</tr>
<tr>
<td></td>
<td>Disodium EDTA, dihydrate</td>
</tr>
<tr>
<td></td>
<td>Citric acid</td>
</tr>
<tr>
<td></td>
<td>Desloratadine</td>
</tr>
</tbody>
</table>

Actual concentration is withheld as a trade secret

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: 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 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 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 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>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable)</td>
<td>5 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total)</td>
<td>10 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total dust)</td>
<td>15 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (respirable fraction)</td>
<td>5 mg/m³</td>
<td>OSHA Z-1</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>Silicon dioxide</td>
<td>7631-86-9</td>
<td>TWA (Dust)</td>
<td>20 Million particles per cubic foot (Silica)</td>
<td>OSHA Z-3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Dust)</td>
<td>80 mg/m³ / %SiO2 (Silica)</td>
<td>OSHA Z-3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>6 mg/m³</td>
<td>NIOSH REL</td>
</tr>
</tbody>
</table>
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| 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.

<table>
<thead>
<tr>
<th>Personal protective equipment</th>
<th></th>
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<th></th>
</tr>
</thead>
</table>
| Respiratory protection      | : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

<table>
<thead>
<tr>
<th>Hand protection</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
</table>
| Material       | : Chemical-resistant gloves

| 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
<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>solid</td>
</tr>
<tr>
<td>Color</td>
<td>white, blue</td>
</tr>
<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></td>
</tr>
<tr>
<td>Water solubility</td>
<td>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></td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>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>
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**: Not classified based on available information.
- **Ingestion**: Not classified based on available information.
- **Eye contact**: Not classified based on available information.

**Acute toxicity**

**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
Silicon dioxide:
- **Acute oral toxicity**: LD50 (Rat): > 5,000 mg/kg
  - Method: OECD Test Guideline 401
- **Acute inhalation toxicity**: LC50 (Rat): > 2.08 mg/l
  - Exposure time: 4 h
  - Test atmosphere: dust/mist
  - Assessment: The substance or mixture has no acute inhalation toxicity
- **Acute dermal toxicity**: LD50 (Rabbit): > 5,000 mg/kg

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

- **Silicon dioxide**:
### Species: Rabbit

**Method:** OECD Test Guideline 404

**Result:** No skin irritation

**Remarks:** Based on data from similar materials

#### 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

#### Silicon dioxide:

**Species:** Rabbit

**Result:** No eye irritation

**Method:** OECD Test Guideline 405

#### 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-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
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<table>
<thead>
<tr>
<th>Compound</th>
<th>Genotoxicity in vitro</th>
<th>Genotoxicity in vivo</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Silicon dioxide:</strong></td>
<td>Test Type: Micronucleus test&lt;br&gt;Species: Rat&lt;br&gt;Application Route: Oral&lt;br&gt;Result: negative&lt;br&gt;Remarks: Based on data from similar materials</td>
<td>Test Type: Bacterial reverse mutation assay (AMES)&lt;br&gt;Method: OECD Test Guideline 471&lt;br&gt;Result: negative</td>
</tr>
<tr>
<td><strong>Disodium EDTA, dihydrate:</strong></td>
<td>Test Type: Chromosome aberration test in vitro&lt;br&gt;Result: negative&lt;br&gt;Remarks: Based on data from similar materials</td>
<td>Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)&lt;br&gt;Species: Mouse&lt;br&gt;Application Route: Ingestion&lt;br&gt;Method: OECD Test Guideline 474&lt;br&gt;Result: negative&lt;br&gt;Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td><strong>Citric acid:</strong></td>
<td>Test Type: Bacterial reverse mutation assay (AMES)&lt;br&gt;Result: negative&lt;br&gt;Test Type: in vitro micronucleus test&lt;br&gt;Result: positive&lt;br&gt;Test Type: Bacterial reverse mutation assay (AMES)&lt;br&gt;Result: negative</td>
<td>Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)&lt;br&gt;Species: Rat&lt;br&gt;Application Route: Ingestion&lt;br&gt;Result: negative</td>
</tr>
<tr>
<td><strong>Desloratadine:</strong></td>
<td>Test Type: Bacterial reverse mutation assay (AMES)&lt;br&gt;Result: negative</td>
<td></td>
</tr>
</tbody>
</table>
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  

Silicon dioxide:  
Species: Rat  
Application Route: Ingestion  
Exposure time: 103 weeks  
Result: negative

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
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<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>
</tr>
</thead>
<tbody>
<tr>
<td>3.3</td>
<td>03/23/2020</td>
<td>2095077-00008</td>
<td>09/13/2019</td>
<td>10/23/2017</td>
</tr>
</tbody>
</table>

**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.

**IARC**: No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA**: No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

**NTP**: No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

### 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.
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.
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</tr>
</tbody>
</table>

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.
- 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
**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
- **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 menstruation

---

**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 aquatic invertebrates:** EC50 (Daphnia magna (Water flea)): > 1,000 mg/l
  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:

<table>
<thead>
<tr>
<th>Category</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Toxicity to fish</strong></td>
<td>LC50 (Lepomis macrochirus (Bluegill sunfish)): 159 mg/l Exposure time: 96 h Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td><strong>Toxicity to daphnia and other aquatic invertebrates</strong></td>
<td>EC50 (Daphnia magna (Water flea)): 140 mg/l Exposure time: 48 h Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td><strong>Toxicity to algae/aquatic plants</strong></td>
<td>EC50 (Desmodesmus subspicatus (green algae)): &gt; 100 mg/l Exposure time: 72 h Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td></td>
<td>NOEC (Desmodesmus subspicatus (green algae)): 100 mg/l Exposure time: 72 h Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td><strong>Toxicity to fish (Chronic toxicity)</strong></td>
<td>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</td>
</tr>
<tr>
<td><strong>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</strong></td>
<td>NOEC (Daphnia magna (Water flea)): 25 mg/l Exposure time: 21 d Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td><strong>Toxicity to microorganisms</strong></td>
<td>EC50: &lt; 500 mg/l Exposure time: 0.5 h Method: OECD Test Guideline 209 Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

## Citric acid:

<table>
<thead>
<tr>
<th>Category</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Toxicity to fish</strong></td>
<td>LC50 (Pimephales promelas (fathead minnow)): &gt; 100 mg/l Exposure time: 96 h</td>
</tr>
<tr>
<td><strong>Toxicity to daphnia and other aquatic invertebrates</strong></td>
<td>EC50 (Daphnia magna (Water flea)): 1,535 mg/l Exposure time: 24 h</td>
</tr>
</tbody>
</table>

## Desloratadine:

<table>
<thead>
<tr>
<th>Category</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Toxicity to fish</strong></td>
<td>LC50 (Lepomis macrochirus (Bluegill sunfish)): 9.2 mg/l Exposure time: 96 h Method: FDA 4.11</td>
</tr>
<tr>
<td><strong>Toxicity to daphnia and other aquatic invertebrates</strong></td>
<td>EC50 (Daphnia magna (Water flea)): 9.6 mg/l Exposure time: 48 h Method: FDA 4.08</td>
</tr>
<tr>
<td><strong>Toxicity to algae/aquatic plants</strong></td>
<td>EC50 (Pseudokirchneriella subcapitata (green algae)): 1.6 mg/l Exposure time: 72 h Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td></td>
<td>NOEC (Pseudokirchneriella subcapitata (green algae)): 0.36</td>
</tr>
</tbody>
</table>

---
Toxicity to fish (Chronic toxicity):
NoEC (Pimelphales 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*)]-ß-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
SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know

CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards
- Reproductive toxicity
- Specific target organ toxicity (single or repeated exposure)

SARA 313
This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know
Cellulose 9004-34-6
Bis[(S-(R*,R*))-(β-hydroxy-α-methylphenethyl)methylammonium] sulphate 7460-12-0
Hydroxypropyl methylcellulose 9004-65-3
Starch, oxidized 65996-62-5
Polyvinyl pyrrolidone 9003-39-8
Silicon dioxide 7631-86-9

California List of Hazardous Substances
Polyvinyl pyrrolidone 9003-39-8
Silicon dioxide 7631-86-9

California Permissible Exposure Limits for Chemical Contaminants
Cellulose 9004-34-6
Starch, oxidized 65996-62-5
Silicon dioxide 7631-86-9

The ingredients of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
SECTION 16. OTHER INFORMATION

Further information

**NFPA 704:**

**HMIS® IV:**

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "\" represents the absence of a chronic hazard.

Full text of other abbreviations

ACGIH       : USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL   : USA. NIOSH Recommended Exposure Limits
OSHA Z-1    : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
OSHA Z-3    : USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts
ACGIH / TWA : 8-hour, time-weighted average
NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA Z-1 / TWA : 8-hour time weighted average
OSHA Z-3 / TWA : 8-hour time weighted average

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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 Organiza-
SAFETY DATA SHEET

Desloratadine / Pseudoephedrine Formulation

Version: 3.3  Revision Date: 03/23/2020  SDS Number: 2095077-00008  Date of last issue: 09/13/2019  Date of first issue: 10/23/2017


Revision Date: 03/23/2020

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US / Z8