SAFETY DATA SHEET

Desloratadine / Pseudoephedrine Formulation

SECTION 1. IDENTIFICATION

Product name: Desloratadine / Pseudoephedrine Formulation

Manufacturer or supplier’s details
Company name of supplier: Organon & Co.
Address: 30 Hudson Street, 33nd floor
Jersey City, New Jersey, U.S.A 07302
Telephone: 551-430-6000
Emergency telephone: 215-631-6999
E-mail address: EHSSTEWARD@organon.com

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

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (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 or spray.
SAFETY DATA SHEET

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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 and face protection.

Response:
P308 + P313 IF exposed or concerned: Get medical attention.

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents and 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>Concentration (% w/w)</th>
<th>CAS-No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mixture</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cellulose</td>
<td>&gt;= 30 - &lt; 50</td>
<td>9004-34-6</td>
</tr>
<tr>
<td>Bis[S-(R*,R*)]-{(β-hydroxy-α-methylphenethyl)methylammonium] sulphate</td>
<td>&gt;= 20 - &lt; 30</td>
<td>7460-12-0</td>
</tr>
<tr>
<td>Starch, oxidized</td>
<td>&gt;= 1 - &lt; 5</td>
<td>65996-62-5</td>
</tr>
<tr>
<td>Silicon dioxide</td>
<td>&gt;= 1 - &lt; 5</td>
<td>7631-86-9</td>
</tr>
<tr>
<td>Disodium EDTA, dihydrate</td>
<td>&gt;= 1 - &lt; 5</td>
<td>6381-92-6</td>
</tr>
<tr>
<td>Citric acid</td>
<td>&gt;= 1 - &lt; 5</td>
<td>77-92-9</td>
</tr>
<tr>
<td>Desloratadine</td>
<td>&gt;= 0.1 - &lt; 1</td>
<td>100643-71-8</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.

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.

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).

Treat symptomatically and supportively.

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

None known.

Exposure to combustion products may be a hazard to health.
Carbon oxides
Nitrogen oxides (NOx)
Metal oxides

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.

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

Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

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.

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.

**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>
</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: 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.

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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>solid</td>
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<tr>
<td>Color</td>
<td>white, blue</td>
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<tr>
<td>Odor</td>
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</tr>
<tr>
<td>Odor Threshold</td>
<td>No data available</td>
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<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>
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<tr>
<td>Solubility(ies)</td>
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<tr>
<td>Water solubility</td>
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<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>
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<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>
</tbody>
</table>
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
Not classified based on available information.

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.

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

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)
Specie: 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
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

### 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
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.
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^*\})-(\beta-hydroxy-\alpha-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: Ingestion, 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: \(\geq 9,000\) mg/kg
Application Route: Ingestion
Exposure time: 90 Days

Bis[[S(\{R^*,R^*\})-(\beta-hydroxy-\alpha-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
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

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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

**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:

Toxicity to fish
- LC50 (Lepomis macrochirus (Bluegill sunfish)): 159 mg/l
- Exposure time: 96 h
- Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates
- EC50 (Daphnia magna (Water flea)): 140 mg/l
- Exposure time: 48 h
- Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants
- EC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l
- Exposure time: 72 h
- Remarks: Based on data from similar materials

- NOEC (Desmodesmus subspicatus (green algae)): 100 mg/l
- Exposure time: 72 h
- Remarks: Based on data from similar materials

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

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)
- NOEC (Daphnia magna (Water flea)): 25 mg/l
- Exposure time: 21 d
- Remarks: Based on data from similar materials

Toxicity to microorganisms
- EC50: < 500 mg/l
- Exposure time: 0.5 h
- Method: OECD Test Guideline 209
- Remarks: Based on data from similar materials

Citric acid:

Toxicity to fish
- LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l
- Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates
- EC50 (Daphnia magna (Water flea)): 1,535 mg/l
- Exposure time: 24 h

Desloratadine:

Toxicity to fish
- LC50 (Lepomis macrochirus (Bluegill sunfish)): 9.2 mg/l
- Exposure time: 96 h
- Method: FDA 4.11

Toxicity to daphnia and other aquatic invertebrates
- EC50 (Daphnia magna (Water flea)): 9.6 mg/l
- Exposure time: 48 h
- Method: FDA 4.08

Toxicity to algae/aquatic plants
- EC50 (Pseudokirchneriella subcapitata (green algae)): 1.6 mg/l
- Exposure time: 72 h
- Method: OECD Test Guideline 201
- NOEC (Pseudokirchneriella subcapitata (green algae)): 0.36
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
SAFETY DATA SHEET
Desloratadine / Pseudoephedrine Formulation

Version 3.4
Revision Date: 10/10/2020
SDS Number: 2095077-00009
Date of last issue: 03/23/2020
Date of first issue: 10/23/2017

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

49 CFR
Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

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:

Flammability

Health

Instability

Special hazard

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

AIIIC - Australian Inventory of Industrial Chemicals; 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 Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime
### SAFETY DATA SHEET

**Desloratadine / Pseudoephedrine Formulation**

<table>
<thead>
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<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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<td>10/10/2020</td>
<td>2095077-00009</td>
<td>03/23/2020</td>
<td>10/23/2017</td>
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Sources of key data used to compile the Material Safety Data Sheet:

Revision Date: 10/10/2020

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.

US / Z8