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: 26 Talavera Road, Talavera Corp Centre, Macquarie Park
New South Wales, 2113 Australia
Telephone: (61)-02-8988-8000
Emergency telephone number: (61)-02-8988-8000
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
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: 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/ vapours/ spray.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
Response:
P314 Get medical advice/ attention if you feel unwell.
SAFETY DATA SHEET

Desloratadine / Pseudoephedrine Formulation

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>Celulose</td>
<td>9004-34-6</td>
</tr>
<tr>
<td>Bis[(R⁺,R⁺)-(β-hydroxy-α-methylphenethyl)methylammonium] sulphate</td>
<td>7460-12-0</td>
</tr>
<tr>
<td>Silicon dioxide</td>
<td>7631-86-9</td>
</tr>
<tr>
<td>Disodium EDTA, dihydrate</td>
<td>6381-92-6</td>
</tr>
<tr>
<td>Citric acid</td>
<td>77-92-9</td>
</tr>
<tr>
<td>Desloratadine</td>
<td>100643-71-8</td>
</tr>
</tbody>
</table>

SECTION 4. FIRST AID MEASURES

General advice:
In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled:
If inhaled, remove to fresh air.
Get medical attention.

In case of skin contact:
In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

In case of eye contact:
Flush eyes with water as a precaution.
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:
Causes damage to organs through prolonged or repeated exposure if swallowed.
Causes damage to organs through prolonged or repeated exposure if inhaled.

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

Notes to physician:
Treat symptomatically and supportively.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media:
Water spray
SAFETY DATA SHEET

Desloratadine / Pseudoephedrine Formulation

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

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:
- Use personal protective equipment.
- Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions:
- Avoid release to the environment.
- Prevent further leakage or spillage if safe to do so.
- Retain and dispose of contaminated wash water.
- Local authorities should be advised if significant 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 breathe dust, fume, gas, mist, vapours or spray.
- Do not swallow.
- Avoid contact with eyes.
- Avoid prolonged or repeated contact with skin.
- Wash skin thoroughly after handling.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the environment.

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

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

Materials to avoid: Do not store with the following product types: Strong oxidizing agents

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components 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>AU OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: This value is for inhalable dust containing no asbestos and &lt; 1% crystalline silica</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>AU OEL</td>
</tr>
<tr>
<td>Bis([\text{S-(R^,R^*)-}(\beta\text{-hydroxy-α-methylphenethyl})\text{methylammonium}]/\text{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></td>
<td>Wipe limit</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>500 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Silicon dioxide</td>
<td>7631-86-9</td>
<td>TWA (Respirable dust)</td>
<td>2 mg/m³</td>
<td>AU OEL</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></td>
<td>Wipe limit</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: solid

Colour: white, blue

Odour: No data available

Odour Threshold: No data available

pH: No data available

Melting point/freezing point: No data available

Initial boiling point and boiling range: No data available

Flash point: Not applicable

Evaporation rate: Not applicable

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

Flammability (liquids): No data available

Upper explosion limit / Upper flammability limit: No data available

Lower explosion limit / Lower flammability limit: No data available

Vapour pressure: Not applicable

Relative vapour density: Not applicable

Relative density: No data available

Density: 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**

Exposure routes: Skin contact
Ingestion
Eye contact

**Acute toxicity**
Not classified based on available information.

**Product:**

Acute oral toxicity: Acute toxicity estimate: > 2,000 mg/kg
Method: Calculation method

Acute inhalation toxicity: Acute toxicity estimate: > 5 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
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

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\(^{+},R^{+}\))-(\beta-hydroxy-\alpha-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\(^{+},R^{+}\))-(\beta-hydroxy-\alpha-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 sensitisation**

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

**Respiratory sensitisation**
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: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Result: negative
Remarks: Based on data from similar materials

**Desloratadine:**
Test Type: Maximisation Test
Exposure routes: Dermal
Species: Guinea pig
Result: negative

**Chronic toxicity**

**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*)]-ß-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

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

**Reproductive toxicity**
Not classified based on available information.

**Components:**

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

Effects on foetal 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 foetal development:
Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Oral
Result: No teratogenic effects
Test Type: Embryo-foetal 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 foetal development  
Test Type: Embryo-foetal 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 foetal development  
Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Ingestion  
Result: negative 
Remarks: Based on data from similar materials

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

Test Type: Embryo-foetal 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-methylphenethy]methylammonium] sulphate:
Exposure routes: Ingestion, Inhalation
Target Organs: Central nervous system, Cardio-vascular system
Assessment: Causes damage to organs through prolonged or repeated exposure.

Disodium EDTA, dihydrate:
Exposure routes: 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

<table>
<thead>
<tr>
<th>Substance</th>
<th>Exposure Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bis[[S-((R^<em>,R^</em>))-((\beta)-hydroxy-(\alpha)-methylphenethyl)methylammonium] sulphate:</td>
<td>90 Days</td>
</tr>
<tr>
<td>Silicon dioxide:</td>
<td></td>
</tr>
<tr>
<td>Species</td>
<td>Rat</td>
</tr>
<tr>
<td>NOAEL</td>
<td>1.3 mg/m3</td>
</tr>
<tr>
<td>Application Route</td>
<td>Inhalation (dust/mist/fume)</td>
</tr>
<tr>
<td>Exposure Time</td>
<td>13 Weeks</td>
</tr>
<tr>
<td>Disodium EDTA, dihydrate:</td>
<td></td>
</tr>
<tr>
<td>Species</td>
<td>Rat</td>
</tr>
<tr>
<td>NOAEL</td>
<td>500 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure Time</td>
<td>13 Weeks</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>Citric acid:</td>
<td></td>
</tr>
<tr>
<td>Species</td>
<td>Rat</td>
</tr>
<tr>
<td>NOAEL</td>
<td>4,000 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>8,000 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure Time</td>
<td>10 Days</td>
</tr>
<tr>
<td>Desloratadine:</td>
<td></td>
</tr>
<tr>
<td>Species</td>
<td>Rat</td>
</tr>
<tr>
<td>LOAEL</td>
<td>30 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure Time</td>
<td>3 Months</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Kidney</td>
</tr>
<tr>
<td>Remarks</td>
<td>Significant toxicity observed in testing. The mechanism or mode of action may not be relevant in humans.</td>
</tr>
</tbody>
</table>

### Species

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure Time</th>
<th>Target Organs</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monkey</td>
<td>6 mg/kg</td>
<td>12 mg/kg</td>
<td>Oral</td>
<td>3 Months</td>
<td>Central nervous system</td>
<td>Gastrointestinal disturbance</td>
</tr>
<tr>
<td>Monkey</td>
<td>40 mg/kg</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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:**

| Toxicity to fish (Chronic toxicity) | LC50 (Lepomis macrochirus (Bluegill sunfish)): 159 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials |
|------------------------------------|----------------------------------------------------------|
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | EC50 (Daphnia magna (Water flea)): 25 mg/l  
Exposure time: 21 d  
Remarks: Based on data from similar materials |
| Toxicity to microorganisms | EC50: < 500 mg/l  
Exposure time: 0.5 h  
Method: OECD Test Guideline 209  
Remarks: Based on data from similar materials |

**Citric acid:**

| Toxicity to fish | LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l  
Exposure time: 96 h |
|------------------|----------------------------------------------------------|
| Toxicity to daphnia and other aquatic invertebrates | EC50 (Daphnia magna (Water flea)): 1,535 mg/l  
Exposure time: 24 h |

**Desloratadine:**

| Toxicity to fish | LC50 (Lepomis macrochirus (Bluegill sunfish)): 9.2 mg/l  
Exposure time: 96 h  
Method: FDA 4.11 |
|------------------|----------------------------------------------------------|
| Toxicity to daphnia and other aquatic invertebrates | EC50 (Daphnia magna (Water flea)): 9.6 mg/l  
Exposure time: 48 h  
Method: FDA 4.08 |
Toxicity to algae/aquatic plants: EC50 (Pseudokirchneriella subcapitata (green algae)): 1.6 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
NOEC (Pseudokirchneriella subcapitata (green algae)): 0.36 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity): NOEC (Pimephales promelas (fathead minnow)): 0.12 mg/l
Exposure time: 32 d
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Daphnia magna (Water flea)): 0.48 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

Toxicity to microorganisms: EC50 (Natural microorganism): 53.7 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
NOEC (Natural microorganism): 12 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

Persistence and degradability
Components:

Cellulose:
Biodegradability: Result: Readily biodegradable.

Disodium EDTA, dihydrate:
Biodegradability: Result: Inherently biodegradable.
Biodegradation: 80 - 90 %
Exposure time: 28 d
Remarks: Based on data from similar materials

Citric acid:
Biodegradability: Result: Readily biodegradable.
Biodegradation: 97 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

Desloratadine:
Biodegradability: Result: Not readily biodegradable.
Biodegradation: 67.4 %
Exposure time: 28 d
Method: OECD Test Guideline 314

Result: Not readily biodegradable.
Biodegradation: 0 %
Exposure time: 28 d
Method: FDA 3.11

Stability in water:
Hydrolysis: < 10 % at 50 °C (5 d)
Method: FDA 3.09

Bioaccumulative potential

Components:

Bis[[S-(R,R*),(β-hydroxy-α-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.

**National Regulations**

**ADG**
Not regulated as a dangerous good

### SECTION 15. REGULATORY INFORMATION

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

**Prohibition/Licensing Requirements**

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<th>Requirement</th>
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<tbody>
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<td>DSL</td>
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<tr>
<td>IECSC</td>
<td>not determined</td>
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</tbody>
</table>

There is no applicable prohibition, authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regulations.

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

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<tr>
<th>Source</th>
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### SECTION 16. OTHER INFORMATION

**Further information**

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**Date format**

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<td>dd.mm.yyyy</td>
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**Full text of other abbreviations**

<table>
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<tr>
<th>Abbreviation</th>
<th>Full text</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH</td>
<td>USA. ACGIH Threshold Limit Values (TLV)</td>
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</table>
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.

AU / EN