1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Desloratadine / Pseudoephedrine Formulation

Manufacturer or supplier’s details
Company : MSD
Address : 50 Tuas West Drive
          Singapore - Singapore 638408
Telephone : 908-740-4000
Emergency telephone number : 65 6697 2111 (24/7/365)
E-mail address : EHSDATASTEWARD@msd.com
Telefax : 908-735-1496

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

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.
3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mixture</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td>Bis[L-(R,R*)]-((β-hydroxy-α-methylphenethyl)methylammonium) sulphate</td>
<td>7460-12-0</td>
<td>&gt;= 20 - &lt; 30</td>
</tr>
<tr>
<td>Silicon dioxide</td>
<td>7631-86-9</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td>Disodium EDTA, dihydrate</td>
<td>6381-92-6</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td>Citric acid</td>
<td>77-92-9</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td>Desloratadine</td>
<td>100643-71-8</td>
<td>&gt;= 0.25 - &lt; 1</td>
</tr>
</tbody>
</table>

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.

5. FIREFIGHTING MEASURES

Suitable extinguishing media: Water spray.
**SAFETY DATA SHEET**

**Desloratadine / Pseudoephedrine Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
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<tbody>
<tr>
<td>2.2</td>
<td>13.09.2019</td>
<td>2095080-00007</td>
<td>15.05.2019</td>
<td>23.10.2017</td>
</tr>
</tbody>
</table>

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

Unsuitable extinguishing media: None known.

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

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

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

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

### 6. ACCIDENTAL RELEASE MEASURES

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

- Environmental precautions:
  - Discharge into the environment must be avoided.
  - Prevent further leakage or spillage if safe to do so.
  - Retain and dispose of contaminated wash water.
  - Local authorities should be advised if significant spills cannot be contained.

- Methods and materials for containment and cleaning up:
  - Sweep up or vacuum up spillage and collect in suitable container for disposal.
  - Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.

  Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

### 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 labelled containers. Store in accordance with the particular national regulations.

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

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>PEL (long term)</td>
<td>10 mg/m³</td>
<td>SG OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</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>PEL (long term)</td>
<td>10 mg/m³</td>
<td>SG 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>Wipe limit</td>
<td>200 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Engineering measures: All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices). Minimize open handling.

Personal protective equipment

Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type: Particulates type

Hand protection: 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.

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

Solubility(ies)
- Water solubility: No data available

Partition coefficient: n-
octanol/water
Auto-ignition temperature : No data available
Decomposition temperature : No data available
Viscosity
Viscosity, kinematic : Not applicable
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Particle size : No data available

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.

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: > 2,000 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
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*)]-\((\beta\text{-hydroxy-}\alpha\text{-methylphenethyl})\text{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\text{-hydroxy-}\alpha\text{-methylphenethyl})\text{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

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*)]-ß-hydroxy-α-methylphenethyl)methylammonium] sulphate:**

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

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

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

**Silicon dioxide:**

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

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

**Disodium EDTA, dihydrate:**

**Genotoxicity in vitro**
- Test Type: Chromosome aberration test in vitro
  - Result: negative
  - Remarks: Based on data from similar materials

**Genotoxicity in vivo**
- Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
  - Species: Mouse
  - Application Route: Ingestion
  - Method: OECD Test Guideline 474
  - Result: negative
  - Remarks: Based on data from similar materials

**Citric acid:**

**Genotoxicity in vitro**
- Test Type: Bacterial reverse mutation assay (AMES)
  - Result: negative

  Test Type: in vitro micronucleus test
  - Result: positive

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

Desloratadine:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Test Type: Chromosomal aberration
Test system: Human lymphocytes
Result: negative

Genotoxicity in vivo: Test Type: Micronucleus test
Species: Mouse
Cell type: Bone marrow
Application Route: Oral
Result: negative

Carcinogenicity
Not classified based on available information.

Components:

Cellulose:
Species: Rat
Application Route: Ingestion
Exposure time: 72 weeks
Result: negative

Bis[[S-(R*,R*)]-β-hydroxy-α-methylphenethyl)methylammonium] sulphate:
Species: Rat
Application Route: Oral
Exposure time: 2 Years
Result: negative
Remarks: Based on data from similar materials

Species: Mouse
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.

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 :

STOT - single exposure
Not classified based on available information.

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

Components:

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

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

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<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>
</tbody>
</table>

## Disodium EDTA, dihydrate:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<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>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>0.03 mg/l</td>
</tr>
<tr>
<td>Application Route</td>
<td>Inhalation (dust/mist/fume)</td>
</tr>
<tr>
<td>Exposure time</td>
<td>4 Weeks</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

## Citric acid:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<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>
</tbody>
</table>

## Desloratadine:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<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</td>
</tr>
<tr>
<td></td>
<td>The mechanism or mode of action may not be relevant in humans.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Monkey</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>6 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>12 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>Central nervous system</td>
</tr>
<tr>
<td>Symptoms</td>
<td>Gastrointestinal disturbance</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Monkey</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>40 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>17 Months</td>
</tr>
<tr>
<td>Remarks</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Monkey</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>6 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Desloratadine / Pseudoephedrine Formulation

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

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
<table>
<thead>
<tr>
<th>Component</th>
<th>Biodegradability</th>
<th>Result</th>
<th>Exposure time (d)</th>
<th>Test Type</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>Biodegradability</td>
<td>Result: Readily biodegradable.</td>
<td>28</td>
<td>Respiration inhibition</td>
<td>OECD Test Guideline 301B</td>
</tr>
<tr>
<td>Disodium EDTA, dihydrate</td>
<td>Biodegradability</td>
<td>Result: Inherently biodegradable.</td>
<td>28</td>
<td>Respiration inhibition</td>
<td>OECD Test Guideline 209</td>
</tr>
<tr>
<td>Citric acid</td>
<td>Biodegradability</td>
<td>Result: Readily biodegradable.</td>
<td>28</td>
<td>Respiration inhibition</td>
<td>OECD Test Guideline 314</td>
</tr>
<tr>
<td>Desloratadine</td>
<td>Biodegradability</td>
<td>Result: Not readily biodegradable.</td>
<td>28</td>
<td>Respiration inhibition</td>
<td>FDA 3.11</td>
</tr>
</tbody>
</table>
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

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.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG
Not regulated as a dangerous good
IATA-DGR
SAFETY DATA SHEET

Desloratadine / Pseudoephedrine Formulation

Version  2.2  Revision Date:  13.09.2019  SDS Number:  2095080-00007  Date of last issue:  15.05.2019

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.

15. REGULATORY INFORMATION

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

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

Environmental Protection and Management Act and Environmental Protection and Management (Hazardous Substances) Regulations
Not applicable

Fire Safety (Petroleum and Flammable Materials) Regulations
Not applicable

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

<table>
<thead>
<tr>
<th>Inventory</th>
<th>Determination</th>
</tr>
</thead>
<tbody>
<tr>
<td>AICS</td>
<td>not determined</td>
</tr>
<tr>
<td>DSL</td>
<td>not determined</td>
</tr>
<tr>
<td>IECSC</td>
<td>not determined</td>
</tr>
</tbody>
</table>

16. OTHER INFORMATION

Further information
Date format: dd.mm.yyyy

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
SG OEL: Singapore. Workplace Safety and Health Act - First Schedule Permissible Exposure Limits of Toxic Substances
ACGIH / TWA: 8-hour, time-weighted average
SG OEL / PEL (long term): Permissible Exposure Level (PEL) Long Term

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with
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.

SG / EN