1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Desloratadine / Pseudoephedrine Formulation

Supplier’s company name, address and phone number
Company name of supplier : MSD
Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd. Menuma factory
Telephone : 048-588-8411
E-mail address : EHSDATASTEWARD@msd.com
Emergency telephone number : 1-908-423-6000

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

2. HAZARDS IDENTIFICATION

GHS classification of chemical product
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.
Disposal:
P501 Dispose of contents/container to an approved waste disposal plant.

Other hazards which do not result in classification
None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 30 - &lt; 40</td>
<td></td>
</tr>
<tr>
<td>Bis[[S-(R*,R*)]-β-hydroxy-α-methylphenethyl]methylammonium</td>
<td>7460-12-0</td>
<td>&gt;= 20 - &lt; 30</td>
<td></td>
</tr>
<tr>
<td>sulphate</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Citric acid</td>
<td>77-92-9</td>
<td>&gt;= 1 - &lt; 10</td>
<td>2-1318</td>
</tr>
<tr>
<td>Disodium EDTA, dihydrate</td>
<td>6381-92-6</td>
<td>&gt;= 1 - &lt; 10</td>
<td>2-1265, 2-1265</td>
</tr>
<tr>
<td>Silicon dioxide</td>
<td>7631-86-9</td>
<td>&gt;= 1 - &lt; 10</td>
<td>1-548</td>
</tr>
<tr>
<td>Desloratadine</td>
<td>100643-71-8</td>
<td>&gt;= 0.25 - &lt; 1</td>
<td></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
- 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 spillages cannot be contained.

### Methods and materials for containment and cleaning up
- Sweep up or vacuum up spillage and collect in suitable container for disposal.
- Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
- Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

## 7. HANDLING AND STORAGE

### Handling

#### 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.

Avoidance of contact:
- Oxidizing agents

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.

Storage
- 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

Packaging material:
- Unsuitable material: None known.

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Threshold limit value and permissible exposure limits for each component in the work environment

<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>Bis[S-((R*,R*)-(ß-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></td>
<td>Wipe limit 500 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Desloratadine</td>
<td>100643-71-8</td>
<td>TWA</td>
<td>20 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Wipe limit 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
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.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

- **Physical state**: solid
- **Colour**: white, blue
- **Odour**: No data available
- **Odour Threshold**: No data available
- **Melting point/freezing point**: No data available
- **Boiling point, initial boiling point and boiling range**: No data available
- **Flammability (solid, gas)**: Not classified as a flammability hazard
- **Flammability (liquids)**: No data available
- **Lower explosion limit and upper explosion limit / flammability limit**
  - **Upper explosion limit / Upper flammability limit**: No data available
  - **Lower explosion limit / Lower flammability limit**: No data available
- **Flash point**: Not applicable
- **Decomposition temperature**: No data available
- **pH**: No data available
- **Evaporation rate**: Not applicable
- **Auto-ignition temperature**: No data available
- **Viscosity**
  - **Viscosity, kinematic**: Not applicable
- **Solubility(ies)**
### 10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactivity</td>
<td>Not classified as a reactivity hazard.</td>
</tr>
<tr>
<td>Chemical stability</td>
<td>Stable under normal conditions.</td>
</tr>
<tr>
<td>Possibility of hazardous reactions</td>
<td>Can react with strong oxidizing agents.</td>
</tr>
<tr>
<td>Conditions to avoid</td>
<td>None known.</td>
</tr>
<tr>
<td>Incompatible materials</td>
<td>Oxidizing agents</td>
</tr>
<tr>
<td>Hazardous decomposition products</td>
<td>No hazardous decomposition products are known.</td>
</tr>
</tbody>
</table>

### 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.

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

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

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

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

Citric acid:
Species: Rabbit
Result: No skin irritation

Disodium EDTA, dihydrate:
Species: Rabbit
Result: No skin irritation
Remarks: Based on data from similar materials

Silicon dioxide:
Species: Rabbit
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

Citric acid:
Species: Rabbit
Result: Irritation to eyes, reversing within 21 days
Method: OECD Test Guideline 405
Disodium EDTA, dihydrate:
- **Species**: Rabbit
- **Result**: No eye irritation
- **Remarks**: Based on data from similar materials

Silicon dioxide:
- **Species**: Rabbit
- **Result**: No eye irritation
- **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
<table>
<thead>
<tr>
<th>Component</th>
<th>Test Type</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bis[[S-(R*,R*)]-[β-hydroxy-α-methylphenethyl)methylammonium] sulphate</td>
<td>T&lt;sub&gt;est&lt;/sub&gt; Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)</td>
<td>negative</td>
<td>Based on data obtained from similar substances.</td>
</tr>
<tr>
<td></td>
<td>Species: Mouse</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Application Route: Ingestion</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>T&lt;sub&gt;est&lt;/sub&gt; Type: Bacterial reverse mutation assay (AMES)</td>
<td>negative</td>
<td>Based on data obtained from similar substances.</td>
</tr>
<tr>
<td></td>
<td>Remarks: Information given is based on data obtained from similar substances.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>T&lt;sub&gt;est&lt;/sub&gt; Type: Chromosomal aberration</td>
<td>negative</td>
<td>Based on data obtained from similar substances.</td>
</tr>
<tr>
<td></td>
<td>Remarks: Information given is based on data obtained from similar substances.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Citric acid</td>
<td>T&lt;sub&gt;est&lt;/sub&gt; Type: Bacterial reverse mutation assay (AMES)</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td></td>
<td>T&lt;sub&gt;est&lt;/sub&gt; Type: in vitro micronucleus test</td>
<td>positive</td>
<td></td>
</tr>
<tr>
<td></td>
<td>T&lt;sub&gt;est&lt;/sub&gt; Type: Bacterial reverse mutation assay (AMES)</td>
<td>negative</td>
<td></td>
</tr>
<tr>
<td>Disodium EDTA, dihydrate</td>
<td>T&lt;sub&gt;est&lt;/sub&gt; Type: Chromosome aberration test in vitro</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td></td>
<td>T&lt;sub&gt;est&lt;/sub&gt; Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td></td>
<td>Species: Mouse</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Application Route: Ingestion</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 474</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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

Desloratadine:

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

Genotoxicity in vitro: 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-methylphenethy1)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

Disodium EDTA, dihydrate:

Species: Rat
Application Route: Ingestion
## Exposure time
- **Species:** Rat
- **Application Route:** Ingestion
- **Exposure time:** 103 weeks
- **Result:** negative
- **Remarks:** Based on data from similar materials

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

## Desloratadine:
- **Species:** Mouse
- **Application Route:** Oral
- **Exposure time:** 2 Years
- **Result:** negative

## LOAEL
- **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.

**Citric acid:**

Effects on foetal development : Test Type: One-generation reproduction toxicity study
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

**Silicon dioxide:**

Effects on foetal development : Test Type: Embryo-foetal development
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
Desloratadine / Pseudoephedrine Formulation

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-methylphenethyl)methylammonium] sulphonate:

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
SAFETY DATA SHEET

Desloratadine / Pseudoephedrine Formulation

Exposure time : 90 Days

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

Citric acid:
Species : Rat
NOAEL : 4,000 mg/kg
LOAEL : 8,000 mg/kg
Application Route : Ingestion
Exposure time : 10 Days

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

Species : Rat
LOAEL : 0.03 mg/l
Application Route : inhalation (dust/mist/fume)
Exposure time : 4 Weeks
Remarks : Based on data from similar materials

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

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

Species : Monkey
NOAEL : 6 mg/kg
LOAEL : 12 mg/kg
Application Route : Oral
Exposure time : 3 Months
Target Organs : Central nervous system
Symptoms : Gastrointestinal disturbance

Species : Monkey
NOAEL : 40 mg/kg
Application Route: Oral
Exposure time: 17 Months
Remarks: No significant adverse effects were reported

Species: Monkey
NOAEL: 6 mg/kg
Application Route: Oral
Exposure time: 3 Months
Symptoms: Gastrointestinal disturbance, Fatigue

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Bis[[S-(R*,R*)]-β-hydroxy-α-methylphenethyl)methylammonium] sulphate:
Inhalation: Remarks: May cause irritation of respiratory tract.
Eye contact: Remarks: May irritate eyes.
Ingestion: Symptoms: central nervous system effects, tachycardia, Palpitation

Desloratadine:
Inhalation: Remarks: May cause respiratory tract irritation.
Eye contact: Symptoms: Eye irritation
Ingestion: Symptoms: dry mouth, muscle pain, Fatigue, Drowsiness, sore throat, painful 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

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

Disodium EDTA, dihydrate:
Toxicity to fish: \( \text{LC50} \) (\textit{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: \( \text{EC50} \) (\textit{Daphnia magna} (Water flea)): 140 mg/l
Exposure time: 48 h
Remarks: Based on data from similar materials

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

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

Toxicity to microorganisms: \( \text{EC50} \): < 500 mg/l
Exposure time: 0.5 h
Method: OECD Test Guideline 209
Remarks: Based on data from similar materials

**Silicon dioxide:**

Toxicity to fish: \( \text{LC50} \) (\textit{Danio rerio} (zebra fish)): > 10,000 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates: \( \text{EC50} \) (\textit{Daphnia magna} (Water flea)): > 1,000 mg/l
Exposure time: 24 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants: \( \text{EC50} \) (\textit{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 (\textit{Desmodesmus subspicatus} (green algae)): 10,000 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

**Desloratadine:**

Toxicity to fish: \( \text{LC50} \) (\textit{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

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

**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.
Citric acid:

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

Disodium EDTA, dihydrate:

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

Desloratadine:

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

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

Disodium EDTA, dihydrate:

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

Desloratadine:

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

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

**Citric acid:**
- Partition coefficient: n-octanol/water : log Pow: -1.72

**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

**Desloratadine:**
- Partition coefficient: n-octanol/water : log Pow: 1.24
  Method: OECD Test Guideline 107

**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

**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

**Desloratadine:**
- Distribution among environmental compartments : log Koc: 3.00
  Method: OECD Test Guideline 106

Hazardous to the ozone layer
Not applicable

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
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
Refer to section 15 for specific national regulation.

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law
Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law
Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture
Not applicable

Harmful Substances Required Permission for Manufacture
Not applicable

Substances Prevented From Impairment of Health
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity
Not applicable
SAFETY DATA SHEET

Desloratadine / Pseudoephedrine Formulation

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<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
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<td>2019/09/13</td>
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**Substances Subject to be Notified Names**
Article 57-2 (Enforcement Order Table 9)

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<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
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<td>Crystalline silica</td>
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**Substances Subject to be Indicated Names**
Article 57 (Enforcement Order Article 18)

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<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crystalline silica</td>
<td>165 2</td>
</tr>
</tbody>
</table>

**Ordinance on Prevention of Hazards Due to Specified Chemical Substances**
Not applicable

**Ordinance on Prevention of Lead Poisoning**
Not applicable

**Ordinance on Prevention of Tetraalkyl Lead Poisoning**
Not applicable

**Ordinance on Prevention of Organic Solvent Poisoning**
Not applicable

**Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)**
Not applicable

**Poisonous and Deleterious Substances Control Law**
Not applicable

**Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof**
Not applicable

**High Pressure Gas Safety Act**
Not applicable

**Explosive Control Law**
Not applicable

**Vessel Safety Law**
Not regulated as a dangerous good

**Aviation Law**
Not regulated as a dangerous good

**Marine Pollution and Sea Disaster Prevention etc Law**

- Bulk transportation: Noxious liquid substance (Category Z)
- Pack transportation: Not classified as marine pollutant

**Narcotics and Psychotropics Control Act**

- Narcotic or Psychotropic Raw Material (Export / Import Permission)
  Not applicable

- Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
  Not applicable

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23 / 25
Waste Disposal and Public Cleansing Law

Industrial waste

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

- AICS: not determined
- DSL: not determined
- IECSC: not determined

16. OTHER INFORMATION

Further information

Sources of key data used to compile the Safety Data Sheet:

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format: yyyy/mm/dd

Full text of other abbreviations

- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- ACGIH / TWA: 8-hour, time-weighted average

Abbreviations:
- 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 x% response
- 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
- 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 Dangerous Goods
- IMO: International Maritime Organization
- ISHL: Industrial Safety and Health Law (Japan)
- ISO: International Organisation for Standardization
- KECI: Korea Existing Chemicals Inventory
- LC50: Lethal Concentration to 50% of a test population
- LD50: Lethal Dose to 50% of a test population (Median Lethal Dose)
- MARPOL: International Convention for the Prevention of Pollution from Ships
- n.o.s.: Not Otherwise Specified
- Nch: Chilean Norm
- NO(A)EC: No Observed (Adverse) Effect Concentration
- NO(A)EL: No Observed (Adverse) Effect Level
- NOELR: No Observable Effect Loading Rate
- NOM: Official Mexican Norm
- NTP: National Toxicology Program
- NZIoC: New Zealand Inventory of Chemicals
- OECD: Organization for Economic Co-operation and Development
- OPPTS: Office of Chemical Safety and Pollution Prevention
- PBT: Persistent, Bioaccumulative and Toxic substance
- PICCS: Philippines Inventory of Chemicals and Chemical Substances
- (Q)SAR: (Quantitative) Structure Activity Relationship
- SADT: Self-Accelerating Decomposition Temperature
- SDS: Safety Data Sheet
- TCSI: Taiwan Chemical Substance Inventory
- TDG: Transportation of Dangerous Goods
- TSCA: Toxic Substances Control Act (United States)
- UN: Unit-

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.

JP / EN