SAFETY DATA SHEET

Desloratadine / Pseudoephedrine Formulation

Version 2.2  Revision Date: 09/13/2019  SDS Number: 2095101-00007  Date of last issue: 2019/05/15
Date of first issue: 2017/10/23

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Desloratadine / Pseudoephedrine Formulation

Manufacturer or supplier’s details
Company: MSD
Address: JL Raya Pandaan KM. 48
         Pandaan, Jawa Timur - Indonesia
Telephone: 908-740-4000
Emergency telephone number: 1-908-423-6000
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.
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

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

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
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: 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>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>NAB</td>
<td>10 mg/m³</td>
<td>ID OEL</td>
</tr>
</tbody>
</table>

Further information: Chemicals with a limit value higher than the Allowable Exposure Limit (PEL) of OSHA and/or the recommended NIOSH limit value

| Desloratadine                       | 100643-71-8   | TWA                          | 20 µg/m³ (OEB 3)                              | Internal |
|                                     |               | Wipe limit                   | 200 µg/100 cm²                                | Internal |

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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>solid</td>
</tr>
<tr>
<td>Colour</td>
<td>white, blue</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not classified as a flammability hazard</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Desloratadine / Pseudoephedrine Formulation

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*}]-β-hydroxy-α-methylphenethyl)methylammonium] sulphate:**
Species: Rabbit
Result: No skin irritation

**Silicon dioxide:**
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

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

**Citric acid:**
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

**Desloratadine:**
Species: Rabbit
Result: No skin irritation

**Serious eye damage/eye irritation**
Not classified based on available information.

**Components:**

**Bis[[S-{R*,R*}]-β-hydroxy-α-methylphenethyl)methylammonium] sulphate:**
Species: Rabbit
Result: No eye irritation

**Silicon dioxide:**
Species: Rabbit
Result: No eye irritation
Method: OECD Test Guideline 405

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

Desloratadine:
Species: Rabbit
Remarks: Severe eye irritation

Respiratory or skin 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*)]-{(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.

- **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

---

**Notes:**

- Information provided is based on data obtained from similar substances or materials.
Genotoxicity in vivo: Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
Species: Rat
Application Route: Ingestion
Result: negative

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

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

Carcinogenicity
Not classified based on available information.

Components:

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

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

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

Disodium EDTA, dihydrate:
Species: Rat
Desloratadine / Pseudoephedrine Formulation

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: 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] 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>Parameter</th>
<th>Value</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Rat</td>
<td></td>
</tr>
<tr>
<td>NOAEL</td>
<td>1.3 mg/m³</td>
<td>Inhalation (dust/mist/fume)</td>
</tr>
<tr>
<td>Exposure time</td>
<td>13 Weeks</td>
<td></td>
</tr>
</tbody>
</table>

### Disodium EDTA, dihydrate:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Rat</td>
<td></td>
</tr>
<tr>
<td>NOAEL</td>
<td>500 mg/kg</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>13 Weeks</td>
<td></td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
<td></td>
</tr>
</tbody>
</table>

### Citric acid:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Rat</td>
<td></td>
</tr>
<tr>
<td>NOAEL</td>
<td>4,000 mg/kg</td>
<td></td>
</tr>
<tr>
<td>LOAEL</td>
<td>8,000 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
<td></td>
</tr>
<tr>
<td>Exposure time</td>
<td>10 Days</td>
<td></td>
</tr>
</tbody>
</table>

### Desloratadine:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Rat</td>
<td></td>
</tr>
<tr>
<td>LOAEL</td>
<td>30 mg/kg</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>3 Months</td>
<td></td>
</tr>
<tr>
<td>Target Organs</td>
<td>Kidney</td>
<td></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>
<td></td>
</tr>
</tbody>
</table>

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

### Desloratadine / Pseudoephedrine Formulation

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

| 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

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
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

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*}]-\(\beta\)-hydroxy-\(\alpha\)-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
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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health
Hazardous substances that must be registered : Not applicable

**Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances**
Hazardous substances approved for use : Not applicable
Prohibited substances : Not applicable
Restricted substances : Not applicable

**Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials**
Type of Hazardous Materials Restricted to Import, Distribution and Supervision : Not applicable

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**
Date format : yyyy/mm/dd
Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ID OEL : Indonesia. Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average
ID OEL / NAB : Long term exposure limit

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; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; 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 - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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.

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