SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Desloratadine / Pseudoephedrine Formulation

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

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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification
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 :
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:
SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Substance / Mixture**: Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 30 - &lt; 60</td>
</tr>
<tr>
<td>Bis[(S-(R*,R*)]-{β-hydroxy-α-methylphenethyl)methyl]ammonium] sulphate</td>
<td>7460-12-0</td>
<td>&gt;= 10 - &lt; 30</td>
</tr>
<tr>
<td>Silicon dioxide</td>
<td>7631-86-9</td>
<td>&lt; 10</td>
</tr>
<tr>
<td>Disodium EDTA, dihydrate</td>
<td>6381-92-6</td>
<td>&lt; 10</td>
</tr>
<tr>
<td>Citric acid</td>
<td>77-92-9</td>
<td>&lt; 10</td>
</tr>
<tr>
<td>Desloratadine</td>
<td>100643-71-8</td>
<td>&lt; 1</td>
</tr>
</tbody>
</table>

SECTION 4. FIRST AID MEASURES

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

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

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

**In case of eye contact**: Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.

**If swallowed**: If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.

**Most important symptoms and effects, both acute and delayed**: Causes damage to organs through prolonged or repeated exposure if swallowed. Causes damage to organs through prolonged or repeated exposure if inhaled.

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

**Notes to physician**: Treat symptomatically and supportively.

SECTION 5. FIREFIGHTING MEASURES

**Suitable extinguishing media**: Water spray

Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

None known.

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

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

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

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

Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.

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

See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Use only with adequate ventilation.
Do not breathe dust, fume, gas, mist, vapours or spray.
Do not swallow.
Avoid contact with eyes.
Avoid prolonged or repeated contact with skin.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.

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

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

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

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>AU OEL</td>
</tr>
<tr>
<td>Further information: This value is for inhalable dust containing no asbestos and &lt; 1% crystalline silica</td>
<td></td>
<td></td>
<td></td>
<td></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>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>500 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Silicon dioxide</td>
<td>7631-86-9</td>
<td>TWA (Respirable dust)</td>
<td>2 mg/m³</td>
<td>AU OEL</td>
</tr>
<tr>
<td>Desloratadine</td>
<td>100643-71-8</td>
<td>TWA</td>
<td>20 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: solid

Colour: white, blue

Odour: No data available

Odour Threshold: No data available

pH: No data available

Melting point/freezing point: No data available

Initial boiling point and boiling range: No data available

Flash point: Not applicable

Evaporation rate: Not applicable

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

Flammability (liquids): No data available

Upper explosion limit / Upper flammability limit: No data available

Lower explosion limit / Lower flammability limit: No data available

Vapour pressure: Not applicable

Relative vapour density: Not applicable

Relative density: No data available

Density: No data available

Solubility(ies):
Water solubility : No data available
Partition coefficient: n-octanol/water : Not applicable
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

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions : Can react with strong oxidizing agents.
Conditions to avoid : None known.
Incompatible materials : Oxidizing agents
Hazardous decomposition products : No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Exposure routes : Skin contact
Ingestion
Eye contact

Acute toxicity
Not classified based on available information.

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

Acute inhalation toxicity : Acute toxicity estimate: > 5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Components:
Cellulose:
Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5.8 mg/l
Exposure time: 4 h
SAFETY DATA SHEET
Desloratadine / Pseudoephedrine Formulation

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
### SAFETY DATA SHEET

**Desloratadine / Pseudoephedrine Formulation**

**Version**: 2.3  
**Revision Date**: 10.10.2020  
**SDS Number**: 2095132-00008  
**Date of last issue**: 13.09.2019  
**Date of first issue**: 23.10.2017

### 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*)]-\(\beta\)-hydroxy-\(\alpha\)-methylphenethyl)methylammonium] sulphate:
- **Remarks**: No data available

#### Disodium EDTA, dihydrate:
- **Test Type**: Maximisation Test  
- **Exposure routes**: Skin contact  
- **Species**: Guinea pig  
- **Result**: negative  
- **Remarks**: Based on data from similar materials

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

### Chronic toxicity

**Germ cell mutagenicity**
Not classified based on available information.

### Components:

#### Cellulose:
- **Genotoxicity in vitro**: Test Type: Bacterial reverse mutation assay (AMES)  
  - Result: negative  
  - Test Type: In vitro mammalian cell gene mutation test  
  - Result: negative

- **Genotoxicity in vivo**: Test Type: Mammalian erythrocyte micronucleus test (in vivo
cytogenetic assay)  
Species: Mouse  
Application Route: Ingestion  
Result: negative

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

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

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

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

**Silicon dioxide:**

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

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

**Disodium EDTA, dihydrate:**

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

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

**Citric acid:**

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

Test Type: in vitro micronucleus test  
Result: positive
Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

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

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

Test Type: Chromosomal aberration  
Test system: Human lymphocytes  
Result: negative

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

Carcinogenicity  
Not classified based on available information.

Components:

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

Bis[[S-(R*,R*)]-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
Remarks: Based on data from similar materials

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
SAFETY DATA SHEET

Desloratadine / Pseudoephedrine Formulation

Version 2.3  Revision Date: 10.10.2020  SDS Number: 2095132-00008  Date of last issue: 13.09.2019

Date of first issue: 23.10.2017

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*)]-ß-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:
Species : Rat
NOAEL : 1.3 mg/m³
Application Route : inhalation (dust/mist/fume)
Exposure time : 13 Weeks

Disodium EDTA, dihydrate:
Species : Rat
NOAEL : 500 mg/kg
Application Route : Ingestion
Exposure time : 13 Weeks
Remarks : Based on data from similar materials
Species : Rat
LOAEL : 0.03 mg/l
Application Route : inhalation (dust/mist/fume)
Exposure time : 4 Weeks
Remarks : Based on data from similar materials

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

Desloratadine:
Species : Rat
LOAEL : 30 mg/kg
Application Route : Oral
Exposure time : 3 Months
Target Organs : Kidney
Remarks : Significant toxicity observed in testing
The mechanism or mode of action may not be relevant in humans.
Species : Monkey
NOAEL : 6 mg/kg
LOAEL : 12 mg/kg
Application Route : Oral
Exposure time : 3 Months
Target Organs : Central nervous system
Symptoms : Gastrointestinal disturbance
Species : Monkey
NOAEL : 40 mg/kg
Application Route : Oral
Exposure time: 17 Months
Remarks: No significant adverse effects were reported

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

**SECTION 12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

**Components:**

**Cellulose:**
- Toxicity to fish: LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l
  Exposure time: 48 h
  Remarks: Based on data from similar materials

**Silicon dioxide:**
- Toxicity to fish: LC50 (Danio rerio (zebra fish)): > 10,000 mg/l
  Exposure time: 96 h
  Method: OECD Test Guideline 203

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

- Toxicity to algae/aquatic plants: EC50 (Desmodesmus subspicatus (green algae)): > 10,000 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201
  Remarks: Based on data from similar materials
Disodium EDTA, dihydrate:

Toxicity to fish:
- 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

Exposure time:
- 72 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

Remarks:
- Based on data from similar materials

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

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

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

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

Remarks:
- Based on data from similar materials

Citric acid:

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

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

Desloratadine:

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

Toxicity to daphnia and other aquatic invertebrates:
- EC50 (Daphnia magna (Water flea)): 9.6 mg/l
- Exposure time: 48 h
- Method: FDA 4.08
### Toxicity to algae/aquatic plants:
- **EC₅₀ (Pseudokirchneriella subcapitata (green algae)):** 1.6 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201
- **NOEC (Pseudokirchneriella subcapitata (green algae)):** 0.36 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201

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

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

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

### Persistence and degradability

#### Components:

#### Cellulose:
- **Biodegradability:** Result: Readily biodegradable.

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

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

#### Desloratadine:
- **Biodegradability:** Result: Not readily biodegradable.
  - Biodegradation: 67.4%
  - Exposure time: 28 d
  - Method: OECD Test Guideline 314
Result: Not readily biodegradable.
Biodegradation: 0 %
Exposure time: 28 d
Method: FDA 3.11

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

Bioaccumulative potential

Components:

Bis[[S-(R*,R*)]-β-hydroxy-α-methylphenethyl]methylammonium] sulphate:
Partition coefficient: n-octanol/water: log Pow: 0.89

Disodium EDTA, dihydrate:
Bioaccumulation: Species: Lepomis macrochirus (Bluegill sunfish)
Biocaccumulation factor (BCF): 1.8
Remarks: Based on data from similar materials

Partition coefficient: n-octanol/water: log Pow: -4.3

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

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

Mobility in soil

Components:

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

Other adverse effects
No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues: Dispose of in accordance with local regulations.
Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.
SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations

ADG
Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

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

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

The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

SECTION 16. OTHER INFORMATION

Further information
Revision Date : 10.10.2020

Date format : dd.mm.yyyy
Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
SAFETY DATA SHEET

Desloratadine / Pseudoephedrine Formulation

Version 2.3
Revision Date: 10.10.2020
SDS Number: 2095132-00008
Date of last issue: 13.09.2019
Date of first issue: 23.10.2017

AU OEL: Australia. Workplace Exposure Standards for Airborne Contaminants.

ACGIH / TWA: 8-hour, time-weighted average

AU OEL / TWA: Exposure standard - time weighted average

AUIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for 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 Chemicals and 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.

AU / EN