SAFETY DATA SHEET

Desloratadine / Pseudoephedrine Formulation

Section 1: Identification

Product name : Desloratadine / Pseudoephedrine Formulation

Manufacturer or supplier’s details

Company : MSD
Address : 33 Whakatiki Street - Private Bag 908
          Upper Hutt - New Zealand
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

Section 2: Hazard 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.

Section 3: Composition/information on ingredients

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 30 - &lt; 60</td>
</tr>
<tr>
<td>Bis[[S-(R*,R*)]-{(β-hydroxy-α-methylphenethyl)methylammonium] sulphate</td>
<td>7460-12-0</td>
<td>&gt;= 10 - &lt; 30</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: Fire-fighting measures

Suitable extinguishing media: Water spray
Alcohol-resistant foam
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Date of first issue: 23.10.2017

Unsuitable extinguishing media: None known.

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

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

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

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

Section 6: Accidental release measures

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

Environmental precautions:
  - Avoid release to the environment.
  - Prevent further leakage or spillage if safe to do so.
  - Retain and dispose of contaminated wash water.
  - Local authorities should be advised if significant 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.

Section 7: Handling and storage

Technical measures:
  - See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation:
  - Use only with adequate ventilation.

Advice on safe handling:
  - Do not breathe dust, fume, gas, mist, vapours or spray.
  - Do not swallow.
  - Avoid contact with eyes.
  - Avoid prolonged or repeated contact with skin.
  - Wash skin thoroughly after handling.
  - Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
  - Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.

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

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

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

Section 8: Exposure controls/personal protection

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>WES-TWA</td>
<td>10 mg/m³</td>
<td>NZ OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>TWA</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>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:
- Material: Chemical-resistant gloves
- Remarks: Consider double gloving.

Eye protection:
- Material: 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

<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 (miscellaneous)</td>
<td>No data available</td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
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Date of first issue: 23.10.2017

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
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.

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

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

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

Citric acid:
Species: Rabbit
Result: Irritation to eyes, reversing within 21 days
Method: OECD Test Guideline 405

Desloratadine:
Species: Rabbit
Remarks: Severe eye irritation

Respiratory or skin sensitisation
Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

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

Disodium EDTA, dihydrate:
Test Type: Maximisation Test
**Exposure routes**
- Skin contact

**Species**
- Guinea pig

**Result**
- negative

**Remarks**
- Based on data from similar materials

**Desloratadine**

**Test Type**
- Maximisation Test

**Exposure routes**
- Dermal

**Species**
- Guinea pig

**Result**
- negative

**Chronic toxicity**

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

**Components**

**Cellulose**

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

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

**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

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

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
Effects on foetal development:
- 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
    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
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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*)]-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
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**Exposure time**: 90 Days

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

**Disodium EDTA, dihydrate**:  
- **Species**: Rat  
- **NOAEL**: 500 mg/kg  
- **Application Route**: Ingestion  
- **Exposure time**: 13 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  
- **NOAEL**: 30 mg/kg  
- **LOAEL**: 12 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

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
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<table>
<thead>
<tr>
<th>Toxicity</th>
<th>NOEC/Daphnia magna (Water flea)</th>
<th>Exposure time</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</td>
<td>25 mg/l</td>
<td>21 d</td>
<td></td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>Toxicity to microorganisms</td>
<td>EC50: &lt; 500 mg/l</td>
<td>0.5 h</td>
<td>OECD Test Guideline 209</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>Citric acid</td>
<td>LC50 (Pimephales promelas (fathead minnow)): &gt; 100 mg/l</td>
<td>96 h</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Desloratadine</td>
<td>LC50 (Lepomis macrochirus (Bluegill sunfish)): 9.2 mg/l</td>
<td>96 h</td>
<td>FDA 4.11</td>
<td></td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates</td>
<td>EC50 (Daphnia magna (Water flea)): 9.6 mg/l</td>
<td>48 h</td>
<td>FDA 4.08</td>
<td></td>
</tr>
<tr>
<td>Toxicity to algae/aquatic plants</td>
<td>EC50 (Pseudokirchneriella subcapitata (green algae)): 1.6 mg/l</td>
<td>72 h</td>
<td>OECD Test Guideline 201</td>
<td></td>
</tr>
<tr>
<td>Toxicity to fish (Chronic toxicity)</td>
<td>NOEC (Pimephales promelas (fathead minnow)): 0.12 mg/l</td>
<td>32 d</td>
<td>OECD Test Guideline 210</td>
<td></td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</td>
<td>NOEC (Daphnia magna (Water flea)): 0.48 mg/l</td>
<td>21 d</td>
<td>OECD Test Guideline 211</td>
<td></td>
</tr>
<tr>
<td>Toxicity to microorganisms</td>
<td>EC50 (Natural microorganism): 53.7 mg/l</td>
<td>3 h</td>
<td>OECD Test Guideline 209</td>
<td></td>
</tr>
<tr>
<td></td>
<td>NOEC (Natural microorganism): 12 mg/l</td>
<td>3 h</td>
<td>OECD Test Guideline 209</td>
<td></td>
</tr>
</tbody>
</table>
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

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

Bioaccumulative potential

**Components:**

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

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

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

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

**Desloratadine:**
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Date of first issue: 23.10.2017

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

NZS 5433
Not regulated as a dangerous good

Section 15: Regulatory information

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

HSNO Approval Number
HSR100425 Pharmaceutical Active Ingredients Group Standard 2017

HSW Controls
Certified handler certificate not required.
Tracking hazardous substance not required.
Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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

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

Section 16: Other information

Further information

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

Date format: dd.mm.yyyy

Full text of other abbreviations
ACGIH: USA, ACGIH Threshold Limit Values (TLV)
NZ OEL: New Zealand, Workplace Exposure Standards for Atmospheric Contaminants
ACGIH / TWA: 8-hour, time-weighted average
NZ OEL / WES-TWA: Workplace Exposure Standard - Time Weighted average

AIIIC - Australian Inventory of Industrial Chemicals; 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
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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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