Desloratadine / Pseudoephedrine Formulation

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
   Trade name : Desloratadine / Pseudoephedrine Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
   Use of the Substance/Mixture : Pharmaceutical

1.3 Details of the supplier of the safety data sheet
   Company : MSD
   Shotton Lane
   NE23 3JU Cramlington NU - Great Britain
   Telephone : 44 1 670 59 30 00
   Telefax : 908-735-1496
   E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
   1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
   Classification (REGULATION (EC) No 1272/2008)
   Specific target organ toxicity - repeated exposure, Category 1
   H372: Causes damage to organs through prolonged or repeated exposure.

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008)
   Hazard pictograms : 
   Signal word : Danger
   Hazard statements : H372 Causes damage to organs through prolonged or repeated exposure.
   Precautionary statements : Prevention:
   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.

Hazardous components which must be listed on the label:
Bis[[S-(R,R*)]-\(\beta\)-hydroxy-\(\alpha\)-methylphenethyl)methylammonium] sulphate

2.3 Other hazards
None known.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bis[[S-(R*,R*)]-(\beta)-hydroxy-(\alpha)-methylphenethyl)methylammonium] sulphate</td>
<td>7460-12-0 231-243-2</td>
<td></td>
<td></td>
<td></td>
<td>Acute Tox. 4; H302 Acute Tox. 4; H332 STOT RE 1; H372 STOT RE 1; H372</td>
<td>&gt;= 20 - &lt; 30</td>
</tr>
<tr>
<td>Disodium EDTA, dihydrate</td>
<td>6381-92-6</td>
<td></td>
<td></td>
<td></td>
<td>Acute Tox. 4; H332 STOT RE 2; H373</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td>Citric acid</td>
<td>77-92-9 201-069-1</td>
<td></td>
<td></td>
<td></td>
<td>Eye Irrit. 2; H319</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td>Desloratadine</td>
<td>100643-71-8</td>
<td></td>
<td></td>
<td></td>
<td>Acute Tox. 4; H302 Eye Dam. 1; H318 Repr. 2; H361fd Aquatic Chronic 2; H411</td>
<td>&gt;= 0.25 - &lt; 1</td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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.

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).

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.

4.2 Most important symptoms and effects, both acute and delayed
Risks: Causes damage to organs through prolonged or repeated exposure.

4.3 Indication of any immediate medical attention and special treatment needed
Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media
Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture
Specific hazards during firefighting: Exposure to combustion products may be a hazard to health.

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

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

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.
SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions: Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.

6.2 Environmental precautions

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

6.3 Methods and material for containment and cleaning up

Methods for 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

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

Local/Total ventilation: Use only with adequate ventilation.

Advice on safe handling: Do not swallow. Avoid contact with eyes. Avoid prolonged or repeated contact with skin. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.

Take care to prevent spills, waste and minimize release to the environment.

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.
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Desloratadine / Pseudoephedrine Formulation

Version 2.4 Revision Date: 09/13/2019 SDS Number: 2111467-00007 Date of last issue: 15.05.2019
Date of first issue: 23.10.2017

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers:
Keep in properly labelled containers. Store in accordance with the particular national regulations.

Advice on common storage:
Do not store with the following product types:
- Strong oxidizing agents
- Organic peroxides
- Explosives
- Gases

7.3 Specific end use(s)
Specific use(s):
No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA (inhalable dust)</td>
<td>10 mg/m3</td>
<td>GB EH40</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable dust)</td>
<td>4 mg/m3</td>
<td>GB EH40</td>
</tr>
<tr>
<td>Further information</td>
<td></td>
<td>STEL (inhalable dust)</td>
<td>20 mg/m3</td>
<td>GB EH40</td>
</tr>
<tr>
<td>Bis[[S-(R*,R*)]-{(β-hydroxy-α-7460-12-0} TWA</td>
<td>50 µg/m3 (OEB 3)</td>
<td>Internal</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Further information

Substances that can cause occupational asthma (also known as asthmagens and respiratory sensitisers) can induce a state of specific airway hyper-responsiveness via an immunological irritant or other mechanism. Once the airways have become hyper-responsive, further exposure to the substance, sometimes even in tiny quantities, may cause respiratory symptoms. These symptoms can range in severity from a runny nose to asthma. Not all workers who are exposed to a sensitisre will become hyper-responsive and it is impossible to identify in advance those who are likely to become hyper-responsive. Substances that can cause occupational asthma should be distinguished from substances which may trigger the symptoms of asthma in people with pre-existing airway hyper-responsiveness, but which do not include the disease themselves. The latter substances are not classified as asthmagens or respiratory sensitisers. Further information can be found in the HSE publication Asthmagen? Critical assessments of the evidence for agents implicated in occupational asthma., Wherever it is reasonably practicable, exposure to substances that can cause occupational asthma should be prevented. Where this is not possible, the primary aim is to apply adequate standards of control to prevent workers from becoming hyper-responsive. For substances that can cause occupational asthma, COSHH requires that exposure be reduced to as low as is reasonably practicable. Activities giving rise to short-term peak concentrations should receive particular attention when risk management is being considered. Health surveillance is appropriate for all employees exposed or liable to be exposed to a substance which may cause occupational asthma and there should be appropriate consultation with an occupational health professional over the degree of risk and level of surveillance., Flour dust is taken to be finely ground particles of cereals or pulses (including contaminants) that result from any grinding process and from any subsequent handling and use of that 'flour'. Any additives (eg flour improvers) are included in this definition only after they have been added to the final product mix., Where dusts contain components that have their own assigned WEL, all the relevant limits should be complied with., Capable of causing occupational asthma., The 'Sen' notation in the list of WELs has been assigned only to those substances which may cause occupational asthma in the categories shown in Table 1. It should be remembered that other substances not in these tables may cause occupational asthma. HSE's asthma web pages (www.hse.gov.uk/asthma) provide further information.

<table>
<thead>
<tr>
<th>Substance</th>
<th>TWA (inhalable dust)</th>
<th>STEL (inhalable dust)</th>
<th>GB EH40</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starch, oxidized</td>
<td>65996-62-5</td>
<td>10 mg/m³</td>
<td>GB EH40</td>
</tr>
<tr>
<td>Silicon dioxide</td>
<td>7631-86-9</td>
<td>30 mg/m³</td>
<td>GB EH40</td>
</tr>
</tbody>
</table>

Further information

For the purposes of these limits, respirable dust and inhalable dust are those fractions of airborne dust which will be collected when sampling is undertaken in accordance with the methods described in MDHS14/4 General methods for sampling and gravimetric analysis or respirable, thoracic and inhalable aerosols. The COSHH definition of a substance hazardous to health includes dust of any kind when present at a concentration in air equal to or greater than 10
mg.m-3 8-hour TWA of inhalable dust or 4 mg.m-3 8-hour TWA of respirable dust. This means that any dust will be subject to COSHH if people are exposed to dust above these levels. Some dusts have been assigned specific WELs and exposure to these must comply with the appropriate limits. Most industrial dusts contain particles of a wide range of sizes. The behaviour, deposition and fate of any particular particle after entry into the human respiratory system, and the body response that it elicits, depend on the nature and size of the particle. HSE distinguishes two size fractions for limit-setting purposes termed ‘inhalable’ and ‘respirable’. Inhalable dust approximates to the fraction of airborne material that enters the nose and mouth during breathing and is therefore available for deposition in the respiratory tract. Respirable dust approximates to the fraction that penetrates to the gas exchange region of the lung. Fuller definitions and explanatory material are given in MDHS14/4. Where dusts contain components that have their own assigned WEL, all the relevant limits should be complied with. Where no specific short-term exposure limit is listed, a figure three times the long-term exposure limit should be used.

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Silicon dioxide</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>4 mg/m3</td>
</tr>
</tbody>
</table>

### Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Citric acid</td>
<td>Fresh water</td>
<td>0.44 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.044 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>1000 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>34.6 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>3.46 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>33.1 mg/kg dry weight (d.w.)</td>
</tr>
</tbody>
</table>

### Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

8.2 Exposure controls

**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**
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.

Hand protection

Material: Chemical-resistant gloves

Remarks: Consider double gloving.

Skin and body protection:

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.

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 (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic 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

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
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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.

9.2 Other information
  Flammability (liquids) : No data available
  Particle size : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity
  Not classified as a reactivity hazard.

10.2 Chemical stability
  Stable under normal conditions.

10.3 Possibility of hazardous reactions
  Hazardous reactions : Can react with strong oxidizing agents.

10.4 Conditions to avoid
  Conditions to avoid : None known.

10.5 Incompatible materials
  Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products
  No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects
  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:

**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
Method: OECD Test Guideline 405
Result: Irritation to eyes, reversing within 21 days

**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:**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>: Maximisation Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure routes</td>
<td>: Skin contact</td>
</tr>
<tr>
<td>Species</td>
<td>: Guinea pig</td>
</tr>
<tr>
<td>Result</td>
<td>: negative</td>
</tr>
<tr>
<td>Remarks</td>
<td>: Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Desloratadine:**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>: Maximisation Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure routes</td>
<td>: Dermal</td>
</tr>
<tr>
<td>Species</td>
<td>: Guinea pig</td>
</tr>
<tr>
<td>Result</td>
<td>: negative</td>
</tr>
</tbody>
</table>

Germ cell mutagenicity
Not classified based on available information.

Components:

**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 |

**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:
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
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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:

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.
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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:
- 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 through prolonged or repeated exposure.

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

- 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
Desloratadine / Pseudoephedrine Formulation

<table>
<thead>
<tr>
<th>Application Route</th>
<th>Exposure time</th>
<th>Desloratadine:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Rat</td>
<td>LOAEL: 30 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>10 Days</td>
<td>Application Route: Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>10 Days</td>
<td>Exposure time: 3 Months</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Kidney</td>
<td>Symptoms: Kidney</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 |
| LOAEL             | 12 mg/kg |
| Application Route | Oral |
| Exposure time     | 3 Months |
| Target Organs     | Central nervous system |
| Symptoms          | Gastrointestinal disturbance |
| Remarks           | No significant adverse effects were reported |

| Species           | Monkey |
| NOAEL             | 40 mg/kg |
| Application Route | Oral |
| Exposure time     | 17 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:

<table>
<thead>
<tr>
<th>Inhalation</th>
<th>Remarks: May cause irritation of respiratory tract.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye contact</td>
<td>Remarks: May irritate eyes.</td>
</tr>
<tr>
<td>Ingestion</td>
<td>Symptoms: central nervous system effects, tachycardia, Palpitation</td>
</tr>
</tbody>
</table>

Desloratadine:

<table>
<thead>
<tr>
<th>Inhalation</th>
<th>Remarks: May cause respiratory tract irritation.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye contact</td>
<td>Symptoms: Eye irritation</td>
</tr>
<tr>
<td>Ingestion</td>
<td>Symptoms: dry mouth, muscle pain, Fatigue, Drowsiness, sore throat, painful menstration</td>
</tr>
</tbody>
</table>
SECTION 12: Ecological information

12.1 Toxicity

**Components:**

**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 microorganisms  
EC50: < 500 mg/l  
Exposure time: 0.5 h  
Method: OECD Test Guideline 209  
Remarks: Based on data from similar materials

Toxicity to fish (Chronic toxicity)  
NOEC: 25.7 mg/l  
Exposure time: 35 d  
Species: Danio rerio (zebra fish)  
Method: OECD Test Guideline 210  
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)  
NOEC: 25 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)  
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
aquatic invertebrates

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 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

Toxicity to fish (Chronic toxicity)

NOEC: 0.12 mg/l
Exposure time: 32 d
Species: Pimephales promelas (fathead minnow)
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

NOEC: 0.48 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

12.2 Persistence and degradability

Components:

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 %
12.3 Bioaccumulative potential

**Components:**

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

- **Disodium EDTA, dihydrate:**
  - Bioaccumulation: Species: Lepomis macrochirus (Bluegill sunfish)
    - Bioconcentration factor (BCF): 1.8
    - Remarks: Based on data from similar materials
  - Partition coefficient: n-octanol/water: log Pow: -4.3

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

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

12.4 Mobility in soil

**Components:**

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

12.5 Results of PBT and vPvB assessment

Not relevant

12.6 Other adverse effects

No data available

**SECTION 13: Disposal considerations**

13.1 Waste treatment methods

- **Product:** Dispose of in accordance with local regulations.
According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

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

14.1 UN number
Not regulated as a dangerous good

14.2 UN proper shipping name
Not regulated as a dangerous good

14.3 Transport hazard class(es)
Not regulated as a dangerous good

14.4 Packing group
Not regulated as a dangerous good

14.5 Environmental hazards
Not regulated as a dangerous good

14.6 Special precautions for user
Not applicable

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
Remarks:
Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).
: Not applicable
REACH - List of substances subject to authorisation (Annex XIV)
: Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer
: Not applicable
Regulation (EC) No 850/2004 on persistent organic pollutants
: Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals
: Not applicable
REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII)
: Not applicable

Other regulations:
Desloratadine / Pseudoephedrine Formulation

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

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

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-Statements

H302 : Harmful if swallowed.
H318 : Causes serious eye damage.
H319 : Causes serious eye irritation.
H332 : Harmful if inhaled.
H361fd : Suspected of damaging fertility. Suspected of damaging the unborn child.
H372 : Causes damage to organs through prolonged or repeated exposure if inhaled.
H372 : Causes damage to organs through prolonged or repeated exposure if swallowed.
H373 : May cause damage to organs through prolonged or repeated exposure.
H411 : Toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox. : Acute toxicity
Aquatic Chronic : Long-term (chronic) aquatic hazard
Eye Dam. : Serious eye damage
Eye Irrit. : Eye irritation
Repr. : Reproductive toxicity
STOT RE : Specific target organ toxicity - repeated exposure
GB EH40 : UK. EH40 WEL - Workplace Exposure Limits
GB EH40 / TWA : Long-term exposure limit (8-hour TWA reference period)
GB EH40 / STEL : Short-term exposure limit (15-minute reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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 Organization 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

Classification of the mixture: STOT RE 1 H372

Classification procedure: Calculation method

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.

GB / EN