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

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 : Organon & Co.
              30 Hudson Street, 33rd floor
              07302 Jersey City, New Jersey, U.S.A
   Telephone : 551-430-6000
   E-mail address of person responsible for the SDS : EHSSTEWARD@organon.com

1.4 Emergency telephone number
   215-631-6999

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*)]-[β-hydroxy-α-methylphenethyl)methylammonium] sulphate

2.3 Other hazards
This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Components</th>
<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></td>
<td>Bis[(S-(R*,R*)]-[β-hydroxy-α-methylphenethyl)methylammonium] sulphate</td>
<td>7460-12-0</td>
<td>231-243-2</td>
<td></td>
<td></td>
<td>Acute Tox. 4; H302 Acute Tox. 4; H332 STOT RE 1; H372 (Central nervous system) STOT RE 1; H372 (Cardio-vascular system)</td>
<td>&gt;= 20 - &lt; 30</td>
</tr>
<tr>
<td></td>
<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 (Respiratory Tract)</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td></td>
<td>Citric acid</td>
<td>77-92-9</td>
<td>201-069-1</td>
<td></td>
<td></td>
<td>Eye Irrit. 2; H319</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td></td>
<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 fire-: Exposure to combustion products may be a hazard to health.
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 (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

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.

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 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.

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>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>Starch, oxidized</td>
<td>65996-62-5</td>
<td>TWA (inhalable dust)</td>
<td>3 mg/m3</td>
<td>FOR-2011-12-06-1358</td>
</tr>
</tbody>
</table>

Further information: The limit value for flour dust is established as inhalable dust. Substances considered to evoke allergies when coming into touch with the eyes or airways or evoking allergies after coming into contact with the skin.
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: 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.
Respiratory protection: If adequate local exhaust ventilation is not available or expo-
sure assessment demonstrates exposures outside the recom-
mended guidelines, use respiratory protection.
Equipment should conform to NS EN 143
Filter type : Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</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>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>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>Flash point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Solubility(ies)</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>
<tr>
<td>Vapour pressure</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>Relative vapour density</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Particle characteristics</td>
<td></td>
</tr>
</tbody>
</table>
9.2 Other information
Explosives : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Evaporation rate : Not applicable

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 hazard classes as defined in Regulation (EC) No 1272/2008
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:
LD50 (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:
LD50 (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
<table>
<thead>
<tr>
<th>Component</th>
<th>Genotoxicity in vitro</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Disodium EDTA, dihydrate:</strong></td>
<td>Test Type: Maximisation Test</td>
</tr>
<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>
<tr>
<td><strong>Desloratadine:</strong></td>
<td>Test Type: Maximisation Test</td>
</tr>
<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>
<tr>
<td><strong>Germ cell mutagenicity</strong></td>
<td>Not classified based on available information.</td>
</tr>
</tbody>
</table>

**Components:**

<table>
<thead>
<tr>
<th>Component</th>
<th>Genotoxicity in vitro</th>
</tr>
</thead>
<tbody>
<tr>
<td><em><em>Bis[[S-(R</em>,R</em>)]-β-hydroxy-α-methylphenethyl)methylammonium] sulphate:**</td>
<td>Test Type: Bacterial reverse mutation assay (AMES)</td>
</tr>
<tr>
<td>Result: negative</td>
<td></td>
</tr>
<tr>
<td>Remarks: Information given is based on data obtained from similar substances.</td>
<td></td>
</tr>
<tr>
<td>Test Type: Chromosomal aberration</td>
<td></td>
</tr>
<tr>
<td>Result: negative</td>
<td></td>
</tr>
<tr>
<td>Remarks: Information given is based on data obtained from similar substances.</td>
<td></td>
</tr>
<tr>
<td><strong>Genotoxicity in vivo</strong></td>
<td>Test Type: Micronucleus test</td>
</tr>
<tr>
<td>Species: Rat</td>
<td></td>
</tr>
<tr>
<td>Application Route: Oral</td>
<td></td>
</tr>
<tr>
<td>Result: negative</td>
<td></td>
</tr>
<tr>
<td>Remarks: Based on data from similar materials</td>
<td></td>
</tr>
</tbody>
</table>

| **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  
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 / Pseudoephedrine Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
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<tbody>
<tr>
<td>2.7</td>
<td>09.04.2021</td>
<td>2111462-00010</td>
<td>10.10.2020</td>
<td>23.10.2017</td>
</tr>
</tbody>
</table>

### 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

**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.
  - **Remarks**: Maternal toxicity observed.

**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.

Effects on fertility: 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

Effects on foetal development: 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.

Effects on foetal development: 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.
Desloratadine / Pseudoephedrine Formulation

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
- 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.

11.2 Information on other hazards
Endocrine disrupting properties

Product:
Assessment: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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

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
### 12.2 Persistence and degradability

**Components:**

**Disodium EDTA, dihydrate:**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biodegradability</td>
<td>Result: Inherently biodegradable.</td>
</tr>
<tr>
<td>Biodegradation</td>
<td>80 - 90 %</td>
</tr>
<tr>
<td>Exposure time</td>
<td>28 d</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Citric acid:**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biodegradability</td>
<td>Result: Readily biodegradable.</td>
</tr>
<tr>
<td>Biodegradation</td>
<td>97 %</td>
</tr>
<tr>
<td>Exposure time</td>
<td>28 d</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 301B</td>
</tr>
</tbody>
</table>

**Desloratadine:**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biodegradability</td>
<td>Result: Not readily biodegradable.</td>
</tr>
<tr>
<td>Biodegradation</td>
<td>67.4 %</td>
</tr>
</tbody>
</table>
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

**Product:**
Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.
12.6 Other adverse effects

**Product:**
- **Endocrine disrupting potential:** The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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 or ID 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 Maritime transport in bulk according to IMO instruments
- **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 - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII):** Not applicable
- **REACH - Candidate List of Substances of Very High Concern:** Not applicable
Concern for Authorisation (Article 59).
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 (EU) 2019/1021 on persistent organic pollutants (recast): Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals: Not applicable

Other regulations:
Young people under the age of 18 are not allowed to use or be exposed to the product professionally. Young people above the age of 15 are, however, except from this rule if the product is a necessary part of their education.

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
Desloratadine / Pseudoephedrine Formulation

Eye Dam. : Serious eye damage
Eye Irrit. : Eye irritation
Repr. : Reproductive toxicity
STOT RE : Specific target organ toxicity - repeated exposure
FOR-2011-12-06-1358 : Norway. Occupational Exposure limits
FOR-2011-12-06-1358 / TWA : Long term exposure limit

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; AIIC - Australian Inventory of Industrial Chemicals; 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 Organisation for Standardization; KEGI - 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; 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

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.

NO / EN