1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Desloratadine Solid Formulation

Supplier’s company name, address and phone number

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

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

2. HAZARDS IDENTIFICATION

GHS classification of chemical product

Serious eye damage/eye irritation : Category 1
Carcinogenicity (Inhalation) : Category 2
Reproductive toxicity : Category 2
Short-term (acute) aquatic hazard : Category 3
Long-term (chronic) aquatic hazard : Category 3

GHS label elements

Hazard pictograms : 

Signal word : Danger
Hazard statements : H318 Causes serious eye damage.
H351 Suspected of causing cancer if inhaled.
H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements : Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification
Important symptoms and outlines of the emergency assumed:
Contact with dust can cause mechanical irritation or drying of the skin.
May form explosive dust-air mixture during processing, handling or other means.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 20 - &lt; 30</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Desloratadine</td>
<td>100643-71-8</td>
<td>&gt;= 3 - &lt; 10</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Talc</td>
<td>14807-96-6</td>
<td>&gt;= 1 - &lt; 10</td>
<td>1-468</td>
</tr>
<tr>
<td></td>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>&gt;= 1 - &lt; 10</td>
<td>1-558, 5-5225</td>
</tr>
<tr>
<td></td>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>&gt;= 0.1 - &lt; 1</td>
<td>2-234</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

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

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

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
### 5. FIREFIGHTING MEASURES

<table>
<thead>
<tr>
<th>Suitable extinguishing media</th>
<th>Water spray</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Alcohol-resistant foam</td>
</tr>
<tr>
<td></td>
<td>Carbon dioxide (CO2)</td>
</tr>
<tr>
<td></td>
<td>Dry chemical</td>
</tr>
</tbody>
</table>

| Unsuitable extinguishing media                     | None known. |

| Specific hazards during firefighting              | Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health. |

<table>
<thead>
<tr>
<th>Hazardous combustion products</th>
<th>Carbon oxides</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Metal oxides</td>
</tr>
<tr>
<td></td>
<td>Oxides of phosphorus</td>
</tr>
</tbody>
</table>

| 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. |

### 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. |
### 7. HANDLING AND STORAGE

#### Handling

**Technical measures:** Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

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

**Advice on safe handling:**
- Do not breathe dust.
- Do not swallow.
- Do not get in 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.
- Keep container tightly closed.
- Minimize dust generation and accumulation.
- Keep container closed when not in use.
- Keep away from heat and sources of ignition.
- Take precautionary measures against static discharges.
- Take care to prevent spills, waste and minimize release to the environment.

**Avoidance of contact:** Oxidizing agents

**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.

#### Storage

**Conditions for safe storage:**
- Keep in properly labelled containers.
- Store locked up.
- Keep tightly closed.
- Store in accordance with the particular national regulations.

**Materials to avoid:** Do not store with the following product types:
SAFETY DATA SHEET
Desloratadine Solid Formulation

Version 5.2  Revision Date: 2021/04/09  SDS Number: 49983-00015  Date of last issue: 2020/10/02
Date of first issue: 2015/01/23

Strong oxidizing agents

Packaging material: Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>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>
<tr>
<td>Talc</td>
<td>14807-96-6</td>
<td>OEL-M (Respirable dust)</td>
<td>0.5 mg/m³</td>
<td>JP OEL JSOH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Further information: Class 1 Dust</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>OEL-M (Total dust)</td>
<td>2 mg/m³</td>
<td>JP OEL JSOH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Further information: Class 1 Dust</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>2 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>OEL-M (Respirable dust)</td>
<td>1 mg/m³ (Titanium)</td>
<td>JP OEL JSOH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Further information: Class 2 Dust</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>OEL-M (Total dust)</td>
<td>4 mg/m³ (Titanium)</td>
<td>JP OEL JSOH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Further information: Class 2 Dust</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m³ (Titanium dioxide)</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

Engineering measures: Ensure adequate ventilation, especially in confined areas. Minimize workplace exposure concentrations. Apply measures to prevent dust explosions. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).

Personal protective equipment

Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type: Particulates type

Hand protection: Chemical-resistant gloves

Material: Chemical-resistant gloves

Remarks: Choose gloves to protect hands against chemicals depending
SAFETY DATA SHEET
Desloratadine Solid Formulation

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<thead>
<tr>
<th>Version</th>
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</thead>
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</tr>
</tbody>
</table>

on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.

Eye protection : Wear the following personal protective equipment:
Chemical resistant goggles must be worn.
If splashes are likely to occur, wear: Face-shield

Skin and body protection : Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential.
Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Physical state</th>
<th>powder</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour</td>
<td>white</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>Boiling point, initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>May form explosive dust-air mixture during processing, handling or other means.</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit and upper explosion limit / flammability limit</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>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
</tbody>
</table>
Viscosity, dynamic : No data available
Viscosity, kinematic : No data available
Solubility(ies)
Water solubility : No data available
Partition coefficient: n-octanol/water : No data available
Vapour pressure : No data available
Density and / or relative density
Relative density : No data available
Density : No data available
Relative vapour density : No data available
Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.
Molecular weight : No data available
Particle characteristics
Particle size : No data available

10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions
May form explosive dust-air mixture during processing, handling or other means.
Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.
Avoid dust formation.
Incompatible materials : Oxidizing agents
Hazardous decomposition products : No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Inhalation
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

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

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.

Talc:
Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Remarks: Based on data from similar materials

Titanium dioxide:
Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity : LC50 (Rat): > 6.82 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Assessment: The substance or mixture has no acute inhalation toxicity

Propylene glycol:
Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity : LC50 (Rabbit): > 159 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg
Assessment: The substance or mixture has no acute dermal toxicity

Skin corrosion/irritation
Not classified based on available information.
Components:

Desloratadine:
Species: Rabbit
Result: No skin irritation

Talc:
Species: Rabbit
Result: No skin irritation

Titanium dioxide:
Species: Rabbit
Result: No skin irritation

Propylene glycol:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

Serious eye damage/eye irritation
Causes serious eye damage.

Components:

Desloratadine:
Species: Rabbit
Remarks: Severe eye irritation

Talc:
Species: Rabbit
Result: No eye irritation

Titanium dioxide:
Species: Rabbit
Result: No eye irritation

Propylene glycol:
Species: Rabbit
Result: No eye irritation
Method: OECD Test Guideline 405

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.
Components:

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

Talc:
Exposure routes: Skin contact
Species: Humans
Result: negative

Titanium dioxide:
Test Type: Local lymph node assay (LLNA)
Exposure routes: Skin contact
Species: Mouse
Result: negative

Propylene glycol:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Result: negative

Germ cell mutagenicity
Not classified based on available information.

Components:

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

Genotoxicity in vivo: Test Type: In vitro mammalian cell gene mutation test
Result: negative

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

Genotoxicity in vivo: Test Type: Micronucleus test
**SAFETY DATA SHEET**

**Desloratadine Solid Formulation**

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<thead>
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</tr>
</tbody>
</table>

Species: Mouse
Cell type: Bone marrow
Application Route: Oral
Result: negative

**Talc:**
Genotoxicity in vitro: Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Result: negative

Genotoxicity in vivo: Test Type: Chromosome aberration test in vitro
Species: Rat
Application Route: Ingestion
Result: negative

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

Genotoxicity in vivo: Test Type: In vivo micronucleus test
Species: Mouse
Result: negative

**Propylene glycol:**
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: Intraperitoneal injection
Result: negative

**Carcinogenicity**
Suspected of causing cancer if inhaled.

**Components:**

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

**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.

**Talc:**  
Species: Mouse  
Application Route: Inhalation (dust/mist/fume)  
Exposure time: 2 Years  
Result: negative

**Titanium dioxide:**  
Species: Rat  
Application Route: Inhalation (dust/mist/fume)  
Exposure time: 2 Years  
Method: OECD Test Guideline 453  
Result: positive  
Remarks: The mechanism or mode of action may not be relevant in humans.

Carcinogenicity - Assessment: Limited evidence of carcinogenicity in inhalation studies with animals.

**Propylene glycol:**  
Species: Rat  
Application Route: Ingestion  
Exposure time: 2 Years  
Result: negative

**Reproductive toxicity**  
Suspected of damaging fertility. Suspected of damaging the unborn child.

**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

**Desloratadine:**  
Effects on fertility: Test Type: Fertility  
Species: Rat, male  
Application Route: Oral  
Fertility: LOAEL: 12 mg/kg body weight
### Symptoms

- **Symptoms**: Reduced fertility
- **Result**: positive
- **Remarks**: The mechanism or mode of action may not be relevant in humans.

### Test Type
- **Test Type**: Fertility
- **Species**: Rat, female
- **Fertility**: NOAEL: 3 mg/kg body weight
- **Symptoms**: No effects on fertility
- **Result**: negative

### Test Type
- **Test Type**: Embryo-foetal development
- **Species**: Rabbit
- **Application Route**: Oral
- **Developmental Toxicity**: NOAEL: 30 mg/kg body weight
- **Result**: No teratogenic effects

### Test Type
- **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
- **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
- **Symptoms**: 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.

### Talc:
- **Effects on foetal development**
  - **Test Type**: Embryo-foetal development
  - **Species**: Rat
  - **Application Route**: Ingestion
  - **Result**: negative

### Propylene glycol:
- **Effects on fertility**
  - **Test Type**: Three-generation reproduction toxicity study
  - **Species**: Mouse
  - **Application Route**: Ingestion
  - **Result**: negative
- **Effects on foetal development**
  - **Test Type**: Embryo-foetal development
  - **Species**: Mouse
  - **Application Route**: Ingestion
  - **Result**: negative
STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Not classified based on available information.

Repeated dose toxicity

Components:

Cellulose:
Species: Rat
NOAEL: &gt;= 9,000 mg/kg
Application Route: Ingestion
Exposure time: 90 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

Titanium dioxide:
Species: Rat
NOAEL: 24,000 mg/kg
Application Route: Ingestion
Exposure time: 28 Days

Species: Rat
NOAEL: 10 mg/m3
Application Route: inhalation (dust/mist/fume)
Exposure time: 2 yr

**Propylene glycol:**
Species: Rat, male
NOAEL: 1,700 mg/kg
Application Route: Ingestion
Exposure time: 2 yr

**Aspiration toxicity**
Not classified based on available information.

**Experience with human exposure**

**Components:**

**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

**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

**Desloratadine:**
- Toxicity to fish:
  - LC50 (Lepomis macrochirus (Bluegill sunfish)): 9.2 mg/l
  - Exposure time: 96 h
  - Method: FDA 4.11
- Toxicity to daphnia and other aquatic invertebrates:
  - EC50 (Daphnia magna (Water flea)): 9.6 mg/l
  - Exposure time: 48 h
  - Method: FDA 4.08
- Toxicity to algae/aquatic plants:
  - EC50 (Pseudokirchneriella subcapitata (green algae)): 1.6 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201
  - NOEC (Pseudokirchneriella subcapitata (green algae)): 0.36 mg/l
  - Exposure time: 72 h
### Toxicity to fish (Chronic toxicity)
- **Desloratadine Solid Formulation**
  - NOEC (Pimephales promelas (fathead minnow)): 0.12 mg/l
  - Exposure time: 32 d
  - Method: OECD Test Guideline 210

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

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

- NOEC (Natural microorganism): 12 mg/l
  - Exposure time: 3 h
  - Test Type: Respiration inhibition
  - Method: OECD Test Guideline 209

### Talc:
- **Desloratadine Solid Formulation**
  - LC50 (Brachydanio rerio (zebrafish)): > 100,000 mg/l
  - Exposure time: 24 h

### Titanium dioxide:
- **Desloratadine Solid Formulation**
  - LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l
  - Exposure time: 96 h
  - Method: OECD Test Guideline 203

### Propylene glycol:
- **Desloratadine Solid Formulation**
  - LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l
  - Exposure time: 96 h

- EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l
  - Exposure time: 48 h

- EC50 (Skeletonema costatum (marine diatom)): > 10,000 mg/l
  - Exposure time: 72 h

- EC50: > 1,000 mg/l
  - Exposure time: 3 h
  - Method: OECD Test Guideline 209

- NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l
  - Exposure time: 7 d

- ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201
Toxicity to microorganisms: NOEC (Pseudomonas putida): > 20,000 mg/l
Exposure time: 18 h

Persistence and degradability

Components:

Cellulose:
Biodegradability: Result: Readily biodegradable.

Desloratadine:
Biodegradability:
Result: Not readily biodegradable.
Biodegradation: 67.4 %
Exposure time: 28 d
Method: OECD Test Guideline 314

Result: Not readily biodegradable.
Biodegradation: 0 %
Exposure time: 28 d
Method: FDA 3.11

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

Propylene glycol:
Biodegradability: Result: Readily biodegradable.
Biodegradation: 98.3 %
Exposure time: 28 d
Method: OECD Test Guideline 301F

Bioaccumulative potential

Components:

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

Propylene glycol:
Partition coefficient: n-octanol/water: log Pow: -1.07

Mobility in soil

Components:

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

Hazardous to the ozone layer
Not applicable
SAFETY DATA SHEET

Desloratadine Solid Formulation

Version 5.2
Revision Date: 2021/04/09
SDS Number: 49983-00015
Date of last issue: 2020/10/02
Date of first issue: 2015/01/23

Other adverse effects
No data available

13. DISPOSAL CONSIDERATIONS

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

14. TRANSPORT INFORMATION

International Regulations

UNRTDG
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

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

National Regulations
Refer to section 15 for specific national regulation.

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law
Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law
Priority Assessment Chemical Substance

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propane-1,2-diol</td>
<td>106</td>
</tr>
</tbody>
</table>

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture
Not applicable

Harmful Substances Required Permission for Manufacture
Not applicable

Substances Prevented From Impairment of Health
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity
Not applicable
Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity
Not applicable

Substances Subject to be Notified Names
Article 57-2 (Enforcement Order Table 9)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Titanium(IV) oxide</td>
<td>191</td>
<td>&gt;=1 - &lt;10</td>
</tr>
</tbody>
</table>

Substances Subject to be Indicated Names
Article 57 (Enforcement Order Article 18)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Titanium(IV) oxide</td>
<td>191</td>
</tr>
</tbody>
</table>

Ordinance on Prevention of Hazards Due to Specified Chemical Substances
Not applicable

Ordinance on Prevention of Lead Poisoning
Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning
Not applicable

Ordinance on Prevention of Organic Solvent Poisoning
Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)
Not applicable

Poisonous and Deleterious Substances Control Law
Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof
Not applicable

High Pressure Gas Safety Act
Not applicable

Explosive Control Law
Not applicable

Vessel Safety Law
Not regulated as a dangerous good

Aviation Law
Not regulated as a dangerous good

Marine Pollution and Sea Disaster Prevention etc Law
Bulk transportation : Noxious liquid substance (Category Z)
Pack transportation : Not classified as marine pollutant

Narcotics and Psychotropics Control Act
Narcotic or Psychotropic Raw Material (Export / Import Permission)
Not applicable
Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
Not applicable

Waste Disposal and Public Cleansing Law
Industrial waste

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

16. OTHER INFORMATION

Further information

Date format: yyyy/mm/dd

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA : 8-hour, time-weighted average
JP OEL JSOH / OEL-M : Occupational Exposure Limit-Mean

All of the abbreviations are defined within the document. For a complete list of abbreviations and their full text, refer to the full text of other abbreviations section.
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.