1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Desloratadine Solid Formulation

Manufacturer or supplier's details
Company name of supplier: MSD
Address: Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd. Menuma factory
Telephone: 048-588-8411
E-mail address: EHSDATASTEWARD@msd.com
Emergency telephone number: 1-908-423-6000

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

2. HAZARDS IDENTIFICATION

GHS Classification
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.
SAFETY DATA SHEET

Desloratadine Solid Formulation

Version 4.3  Revision Date: 09/13/2019  SDS Number: 49983-00012  Date of last issue: 2019/05/15  Date of first issue: 2015/01/23

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

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>&gt;= 0.1 - &lt; 1</td>
<td>2-234</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 20 - &lt; 30</td>
<td></td>
</tr>
<tr>
<td>Desloratadine</td>
<td>100643-71-8</td>
<td>&gt;= 3 - &lt; 10</td>
<td></td>
</tr>
<tr>
<td>Talc</td>
<td>14807-96-6</td>
<td>&gt;= 1 - &lt; 10</td>
<td></td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>&gt;= 1 - &lt; 10</td>
<td>1-558, 5-5225</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. Remove contaminated clothing and shoes.
Get medical attention. 
Wash clothing before reuse. 
Thoroughly clean shoes before reuse.

In case of eye contact: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. 
If easy to do, remove contact lens, if worn.
Get medical attention immediately.

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

Most important symptoms and effects, both acute and delayed: 
Causes serious eye damage. 
Suspected of causing cancer if inhaled. 
Suspected of damaging fertility. Suspected of damaging the unborn child. 
Contact with dust can cause mechanical irritation or drying of the skin.

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

Notes to physician: Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

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

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.

Hazardous combustion products: Carbon oxides 
Metal oxides 
Oxides of phosphorus

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 and personal protective equipment recommendations.

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.

Methods and materials for containment and cleaning up:
- Sweep up or vacuum up spillage and collect in suitable container for disposal.
- Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
- Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
- 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.

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: Strong oxidizing agents
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) Internal</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>200 µg/100 cm² Internal</td>
<td></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>OEL-M (Total dust)</td>
<td>2 mg/m³</td>
<td>JP OEL JSOH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable fraction)</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>OEL-M (Total dust)</td>
<td>4 mg/m³ (Titanium)</td>
<td>JP OEL JSOH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Titanium dioxide)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

Further information:
- Class 1 Dust
- Class 2 Dust

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

Remarks: Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous sub-
stance 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>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>powder</td>
</tr>
<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>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</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>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
</tbody>
</table>
Solubility(ies)
   Water solubility : No data available

Partition coefficient: n-octanol/water
   Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity
   Viscosity, dynamic : No data available
   Viscosity, kinematic : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : No data available

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:
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

**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

**Skin corrosion/irritation**
Not classified based on available information.

**Components:**

**Propylene glycol:**

Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation
Desloratadine Solid Formulation

Desloratadine:
Species: Rabbit
Result: No skin irritation

Talc:
Species: Rabbit
Result: No skin irritation

Titanium dioxide:
Species: Rabbit
Result: No skin irritation

**Serious eye damage/eye irritation**
Causes serious eye damage.

**Components:**

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

Desloratadine:
Species: Rabbit
Remarks: Severe eye irritation

Talc:
Species: Rabbit
Result: No eye irritation

Titanium dioxide:
Species: Rabbit
Result: No eye irritation

**Respiratory or skin sensitisation**

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

**Components:**

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

Germ cell mutagenicity  
Not classified based on available information.

Components:  

**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

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

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

**Desloratadine:**  
**Genotoxicity in vitro**: Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  
Test Type: Chromosomal aberration  
Test system: Human lymphocytes
Genotoxicity in vivo: Test Type: Micronucleus test  
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

Carcinogenicity
Suspected of causing cancer if inhaled.

Components:

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

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.

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

**Components:**

**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

**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: 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.

Talc:

Effects on foetal development

- Test Type: Embryo-foetal development
  - Species: Rat
  - 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:**

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

**Cellulose:**
| Species     | Rat                        |
| NOAEL       | >= 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 |

**Titanium dioxide:**
| Species     | Rat                        |
| NOAEL       | 24,000 mg/kg               |
| Application Route | Ingestion               |
| Exposure time | 28 Days                  |
NOAEL: 10 mg/m³
Application Route: inhalation (dust/mist/fume)
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 menstruation

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Propylene glycol:
- Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l Exposure time: 96 h
- Toxicity to daphnia and other aquatic invertebrates: EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l Exposure time: 48 h
- Toxicity to algae/aquatic plants: ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l Exposure time: 7 d
- Toxicity to microorganisms: NOEC (Pseudomonas putida): > 20,000 mg/l Exposure time: 18 h

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
  Method: OECD Test Guideline 201

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

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

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

**Talc:**

Toxicity to fish: 
- LC50 (Brachydanio rerio (zebrafish)): > 100,000 mg/l
  Exposure time: 24 h

**Titanium dioxide:**

Toxicity to fish: 
- LC50 (Oncorhyncus mykiss (rainbow trout)): > 100 mg/l
  Exposure time: 96 h
  Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates: 
- EC50 (Daphnia magna (Water flea)): > 100 mg/l
  Exposure time: 48 h

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

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

**Persistence and degradability**

**Components:**

**Propylene glycol:**
### Biodegradability
- **Cellulose:**
  - Biodegradability: 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

### Bioaccumulative potential
#### Components:
- **Propylene glycol:**
  - Partition coefficient: n-octanol/water: log Pow: -1.07
- **Desloratadine:**
  - Partition coefficient: n-octanol/water: log Pow: 1.24
    - Method: OECD Test Guideline 107

### Mobility in soil
#### Components:
- **Desloratadine:**
  - Distribution among environmental compartments: log Koc: 3.00
    - Method: OECD Test Guideline 106

### Hazardous to the ozone layer
Not applicable

### 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**

<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**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Article 57-2 (Enforcement Order Table 9)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Titanium(IV) oxide | 191 | >=1 - <10

### 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:
16. OTHER INFORMATION

Further information

Date format: yyyy/mm/dd

Full text of other abbreviations
ACGIH / TWA: 8-hour, time-weighted average
ACGIH / OEL JSOH / OEL-M: Occupational Exposure Limit-Mean

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System
The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

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