# SAFETY DATA SHEET

## Desloratadine Solid Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 2023/09/30 |
|---|---|---|---|
| 10.0 | 2024/04/06 | 49983-00022 | Date of first issue: 2015/01/23 |

## 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 : +1-551-430-6000

E-mail address : EHSSTEWARD@organon.com

Emergency telephone number : +1-215-631-6999

**Recommended use of the chemical and restrictions on use**

Recommended use : Pharmaceutical
Restrictions on use : Not applicable

## 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 damag-

ing 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

**Components**

| Chemical name | CAS-No. | Concentration (% w/w) | ENCS No. |
|---|---|---|---|
| Cellulose | 9004-34-6 | >= 20 - < 30 | |
| Starch, oxidized | 65996-62-5 | >= 10 - < 20 | 8-99 |
| Desloratadine | 100643-71-8 | >= 3 - < 10 | |
| Talc | 14807-96-6 | > 0 - < 10 | 1-468 |
| Titanium dioxide | 13463-67-7 | > 0 - < 10 | 1-558, 5-5225 |
| Propylene glycol | 57-55-6 | >= 0.1 - < 1 | 2-234 |

## 4. FIRST AID MEASURES

| | | |
|---|---|---|
| General advice | : | In the case of accident or if you feel unwell, seek medical advice immediately.<br>When symptoms persist or in all cases of doubt seek medical advice. |
| If inhaled | : | If inhaled, remove to fresh air.<br>Get medical attention. |
| In case of skin contact | : | In case of contact, immediately flush skin with soap and plenty of water.<br>Remove contaminated clothing and shoes.<br>Get medical attention.<br>Wash clothing before reuse.<br>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.<br>If easy to do, remove contact lens, if worn.<br>Get medical attention immediately. |
| If swallowed | : | If swallowed, DO NOT induce vomiting.<br>Get medical attention.<br>Rinse mouth thoroughly with water. |
| Most important symptoms and effects, both acute and delayed | : | Causes serious eye damage.<br>Suspected of causing cancer if inhaled.<br>Suspected of damaging fertility. Suspected of damaging the unborn child.<br>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<br>Alcohol-resistant foam<br>Carbon dioxide (CO2)<br>Dry chemical |
| Unsuitable extinguishing media | : | None known. |
| Specific hazards during fire-fighting | : | 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.<br>Exposure to combustion products may be a hazard to health. |
| Hazardous combustion products | : | Carbon oxides<br>Metal oxides<br>Oxides of phosphorus |
| Specific extinguishing methods | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |

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

## 6. ACCIDENTAL RELEASE MEASURES

| | | |
|---|---|---|
| Personal precautions, protective equipment and emergency procedures | : | Use personal protective equipment.<br>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8). |
| Environmental precautions | : | Avoid release to the environment.<br>Prevent further leakage or spillage if safe to do so.<br>Retain and dispose of contaminated wash water.<br>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.<br>Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).<br>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.<br>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.<br>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.<br>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.<br>Do not swallow.<br>Do not get in eyes.<br>Avoid prolonged or repeated contact with skin.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Keep container tightly closed.<br>Minimize dust generation and accumulation.<br>Keep container closed when not in use.<br>Keep away from heat and sources of ignition.<br>Take precautionary measures against static discharges.<br>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

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**

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Reference concentration / Permissible concentration | Basis |
|---|---|---|---|---|
| Cellulose | 9004-34-6 | TWA | 10 mg/m3 | ACGIH |
| Starch, oxidized | 65996-62-5 | TWA (inhalable dust) | 0.5 mg/m3 | ACGIH |
| Desloratadine | 100643-71-8 | TWA | 20 µg/m3 (OEB 3) | Internal |
| | | Wipe limit | 200 µg/100 cm² | Internal |
| Talc | 14807-96-6 | OEL-M (Respirable particulate matter) | 1 mg/m3 | JP OEL JSOH |
| | | OEL-M (Total particulate matter) | 4 mg/m3 | JP OEL JSOH |
| | | TWA (Respirable particulate matter) | 2 mg/m3 | ACGIH |
| Titanium dioxide | 13463-67-7 | OEL-M (Respirable particulate matter) | 1.5 mg/m3 (Titanium) | JP OEL JSOH |
| | Further information: Group 2B: possibly carcinogenic to humans | | | |
| | | OEL-M (Total particulate matter) | 2 mg/m3 (Titanium) | JP OEL JSOH |

| | |
|---|---|
| | Further information: Group 2B: possibly carcinogenic to humans |

**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

Material : Chemical-resistant gloves

Remarks : Choose gloves to protect hands against chemicals depending 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

| | | |
|---|---|---|
| Physical state | : | powder |
| Colour | : | white |
| Odour | : | No data available |
| Odour Threshold | : | No data available |
| Melting point/freezing point | : | No data available |
| Boiling point, initial boiling point and boiling range | : | No data available |

| | | |
|---|---|---|
| Flammability (solid, gas) | : | May form explosive dust-air mixture during processing, handling or other means. |
| Flammability (liquids) | : | No data available |
| Lower explosion limit and upper explosion limit / flammability limit | | |
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available |
| Flash point | : | No data available |
| Decomposition temperature | : | No data available |
| pH | : | No data available |
| Evaporation rate | : | No data available |
| Auto-ignition temperature | : | No data available |
| Viscosity | | |
| 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.<br>Can react with strong oxidizing agents. |
| Conditions to avoid | : | Heat, flames and sparks.<br>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<br>Skin contact<br>Ingestion<br>Eye contact |

**Acute toxicity**

Not classified based on available information.

**Product:**

| | | |
|---|---|---|
| Acute oral toxicity | : | Acute toxicity estimate: > 2,000 mg/kg<br>Method: Calculation method |

**Components:**

**Cellulose:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): > 5,000 mg/kg |
| Acute inhalation toxicity | : | LC50 (Rat): > 5.8 mg/l<br>Exposure time: 4 h<br>Test atmosphere: dust/mist |
| Acute dermal toxicity | : | LD50 (Rabbit): > 2,000 mg/kg |

**Desloratadine:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): > 549 mg/kg<br><br>LD50 (Mouse): 353 mg/kg<br><br>LD50 (Monkey): > 250 mg/kg<br>Symptoms: Vomiting<br>Remarks: No mortality observed at this dose. |

**Talc:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): > 5,000 mg/kg<br>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<br>Exposure time: 4 h<br>Test atmosphere: dust/mist<br>Assessment: The substance or mixture has no acute inhalation toxicity |

**Propylene glycol:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): 22,000 mg/kg |
| Acute inhalation toxicity | : | LC50 (Rat): > 44.9 mg/l<br>Exposure time: 4 h<br>Test atmosphere: dust/mist |
| Acute dermal toxicity | : | LD50 (Rabbit): > 2,000 mg/kg<br>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)<br>Result: negative<br><br>Test Type: In vitro mammalian cell gene mutation test<br>Result: negative |
| Genotoxicity in vivo | : | Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)<br>Species: Mouse<br>Application Route: Ingestion<br>Result: negative |

**Desloratadine:**

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative<br><br>Test Type: Chromosomal aberration<br>Test system: Human lymphocytes<br>Result: negative |
| Genotoxicity in vivo | : | Test Type: Micronucleus test<br>Species: Mouse<br>Cell type: Bone marrow<br>Application Route: Oral<br>Result: negative |

**Talc:**

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)<br>Result: negative |
| Genotoxicity in vivo | : | Test Type: Chromosome aberration test in vitro<br>Species: Rat<br>Application Route: Ingestion<br>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<br>Species: Mouse<br>Result: negative |

**Propylene glycol:**

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative<br><br>Test Type: Chromosome aberration test in vitro<br>Method: OECD Test Guideline 473<br>Result: negative |
| Genotoxicity in vivo | : | Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)<br>Species: Mouse<br>Application Route: Intraperitoneal injection<br>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<br>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<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative |
| Effects on foetal development | : | Test Type: Fertility/early embryonic development<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative |

**Desloratadine:**

| | | |
|---|---|---|
| Effects on fertility | : | Test Type: Fertility<br>Species: Rat, male<br>Application Route: Oral<br>Fertility: LOAEL: 12 mg/kg body weight<br>Symptoms: Reduced fertility<br>Result: positive<br>Remarks: The mechanism or mode of action may not be relevant in humans.<br><br>Test Type: Fertility<br>Species: Rat, female<br>Fertility: NOAEL: 3 mg/kg body weight<br>Symptoms: No effects on fertility |

| | | |
|---|---|---|
| | | Result: negative |
| Effects on foetal development | : | Test Type: Embryo-foetal development<br>Species: Rabbit<br>Application Route: Oral<br>Developmental Toxicity: NOAEL: 30 mg/kg body weight<br>Result: No teratogenic effects<br><br>Test Type: Embryo-foetal development<br>Species: Rat<br>Application Route: Oral<br>Developmental Toxicity: LOAEL: 9 mg/kg body weight<br>Symptoms: Preimplantation loss, Reduced body weight<br>Result: Specific developmental abnormalities<br>Remarks: The mechanism or mode of action may not be relevant in humans.<br><br>Test Type: Two-generation study<br>Species: Rat<br>Application Route: Oral<br>Developmental Toxicity: LOAEL: 18 mg/kg body weight<br>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<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative |

**Propylene glycol:**

| | | |
|---|---|---|
| Effects on fertility | : | Test Type: Two-generation reproduction toxicity study<br>Species: Mouse<br>Application Route: Ingestion<br>Result: negative |
| Effects on foetal development | : | Test Type: Embryo-foetal development<br>Species: Mouse<br>Application Route: Ingestion<br>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 | : | >= 9,000 mg/kg |
| Application Route | : | Ingestion |
| Exposure time | : | 90 Days |

**Starch, oxidized:**

| | | |
|---|---|---|
| Species | : | Rat |
| NOAEL | : | 22,500 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<br>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 |

## 12. ECOLOGICAL INFORMATION

**Ecotoxicity**

**Components:**

**Cellulose:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l<br>Exposure time: 48 h<br>Remarks: Based on data from similar materials |

**Desloratadine:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Lepomis macrochirus (Bluegill sunfish)): 9.2 mg/l<br>Exposure time: 96 h<br>Method: FDA 4.11 |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): 9.6 mg/l<br>Exposure time: 48 h<br>Method: FDA 4.08 |
| Toxicity to algae/aquatic plants | : | EC50 (Pseudokirchneriella subcapitata (green algae)): 1.6 mg/l |

| | | |
|---|---|---|
| | | Exposure time: 72 h<br>Method: OECD Test Guideline 201<br><br>NOEC (Pseudokirchneriella subcapitata (green algae)): 0.36 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201 |
| Toxicity to fish (Chronic toxicity) | : | NOEC (Pimephales promelas (fathead minnow)): 0.12 mg/l<br>Exposure time: 32 d<br>Method: OECD Test Guideline 210 |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Daphnia magna (Water flea)): 0.48 mg/l<br>Exposure time: 21 d<br>Method: OECD Test Guideline 211 |
| Toxicity to microorganisms | : | EC50 (Natural microorganism): 53.7 mg/l<br>Exposure time: 3 h<br>Test Type: Respiration inhibition<br>Method: OECD Test Guideline 209<br><br>NOEC (Natural microorganism): 12 mg/l<br>Exposure time: 3 h<br>Test Type: Respiration inhibition<br>Method: OECD Test Guideline 209 |

**Talc:**

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

**Titanium dioxide:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l<br>Exposure time: 96 h<br>Method: OECD Test Guideline 203 |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): > 100 mg/l<br>Exposure time: 48 h |
| Toxicity to algae/aquatic plants | : | EC50 (Skeletonema costatum (marine diatom)): > 10,000 mg/l<br>Exposure time: 72 h |
| Toxicity to microorganisms | : | EC50: > 1,000 mg/l<br>Exposure time: 3 h<br>Method: OECD Test Guideline 209 |

**Propylene glycol:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l<br>Exposure time: 96 h |
| Toxicity to daphnia and other | : | EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l |

| | | |
|---|---|---|
| aquatic invertebrates | | Exposure time: 48 h |
| Toxicity to algae/aquatic plants | : | ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201 |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l<br>Exposure time: 7 d |
| Toxicity to microorganisms | : | NOEC (Pseudomonas putida): > 20,000 mg/l<br>Exposure time: 18 h |

**Persistence and degradability**

**Components:**

**Cellulose:**

| | | |
|---|---|---|
| Biodegradability | : | Result: Readily biodegradable. |

**Desloratadine:**

| | | |
|---|---|---|
| Biodegradability | : | Result: Not readily biodegradable.<br>Biodegradation: 67.4 %<br>Exposure time: 28 d<br>Method: OECD Test Guideline 314<br><br>Result: Not readily biodegradable.<br>Biodegradation: 0 %<br>Exposure time: 28 d<br>Method: FDA 3.11 |
| Stability in water | : | Hydrolysis: < 10 % at 50 °C(5 d)<br>Method: FDA 3.09 |

**Propylene glycol:**

| | | |
|---|---|---|
| Biodegradability | : | Result: Readily biodegradable.<br>Biodegradation: 98.3 %<br>Exposure time: 28 d<br>Method: OECD Test Guideline 301F |

**Bioaccumulative potential**

**Components:**

**Desloratadine:**

| | | |
|---|---|---|
| Partition coefficient: n-octanol/water | : | log Pow: 1.24<br>Method: OECD Test Guideline 107 |

**Propylene glycol:**

| | | |
|---|---|---|
| Partition coefficient: n- | : | log Pow: -1.07 |

| | |
|---|---|
| octanol/water | Method: Regulation (EC) No. 440/2008, Annex, A.8 |

**Mobility in soil**

**Components:**

**Desloratadine:**

| | | |
|---|---|---|
| Distribution among environmental compartments | : | log Koc: 3.00<br>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.<br>Do not dispose of waste into sewer. |
| Contaminated packaging | : | Empty containers should be taken to an approved waste handling site for recycling or disposal.<br>If not otherwise specified: Dispose of as unused product. |

## 14. TRANSPORT INFORMATION

**International Regulations**

**UNRTDG**

| | | |
|---|---|---|
| UN number | : | Not applicable |
| Proper shipping name | : | Not applicable |
| Class | : | Not applicable |
| Subsidiary risk | : | Not applicable |
| Packing group | : | Not applicable |
| Labels | : | Not applicable |
| Environmentally hazardous | : | no |

**IATA-DGR**

| | | |
|---|---|---|
| UN/ID No. | : | Not applicable |
| Proper shipping name | : | Not applicable |
| Class | : | Not applicable |
| Subsidiary risk | : | Not applicable |
| Packing group | : | Not applicable |
| Labels | : | Not applicable |
| Packing instruction (cargo aircraft) | : | Not applicable |
| Packing instruction (passenger aircraft) | : | Not applicable |

**IMDG-Code**

| | | |
|---|---|---|
| UN number | : | Not applicable |

| | | |
|---|---|---|
| Proper shipping name | : | Not applicable |
| Class | : | Not applicable |
| Subsidiary risk | : | Not applicable |
| Packing group | : | Not applicable |
| Labels | : | Not applicable |
| EmS Code | : | Not applicable |
| Marine pollutant | : | Not applicable |

**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.

**Special precautions for user**

Not applicable

## 15. REGULATORY INFORMATION

**Related Regulations**

**Fire Service Law**

Not applicable to dangerous materials / designated flammables.

**Chemical Substance Control Law**

Priority Assessment Chemical Substance

| Chemical name | Number |
|---|---|
| Propane-1,2-diol | 106 |

**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)

| Chemical name | Concentration (%) | Remarks |
|---|---|---|
| Talc (Mg3H2(SiO3)4) (without asbestos and quartz) | >0 - <10 | From April 1st, 2025 |
| Titanium(IV) oxide | >0 - <10 | - |

**Substances Subject to be Indicated Names**

Article 57 (Enforcement Order Article 18)

| Chemical name | Remarks |
|---|---|
| Talc (Mg3H2(SiO3)4) | From April 1st, 2025 |
| Titanium(IV) oxide | - |

**Carcinogenic Substances (Article 577-2 of the Occupational Health and Safety Regulations)**

Not applicable

**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 | : | Not classified as noxious liquid substance |
| 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

In this SDS, if the concentration of substances subject to notification under the Industrial Safety and Health Law is indicated as a range, it includes cases where it is a trade secret.

**Further information**

| | | |
|---|---|---|
| Sources of key data used to compile the Safety Data Sheet | : | Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/ |

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

| | | |
|---|---|---|
| Date format | : | yyyy/mm/dd |

**Full text of other abbreviations**

| | | |
|---|---|---|
| ACGIH | : | USA. ACGIH Threshold Limit Values (TLV) |
| JP OEL JSOH | : | Japan. The Japan Society for Occupational Health. Recommendation of Occupational Exposure Limits |
| ACGIH / TWA | : | 8-hour, time-weighted average |
| JP OEL JSOH / OEL-M | : | Occupational Exposure Limit-Mean |

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect

Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 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; TECI - Thailand Existing Chemicals 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; 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.

JP / EN