SAFETY DATA SHEET
Desloratadine Solid Formulation

Section 1: Identification

Product name: Desloratadine Solid Formulation

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

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

Section 2: Hazard identification

GHS Classification
Serious eye damage/eye irritation: Category 1
Carcinogenicity (Inhalation): Category 2
Reproductive toxicity: Category 2

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.

Precautionary statements:
Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P280 Wear eye protection/ face protection.
P281 Use personal protective equipment as required.

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 or doctor/physician. 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**
Contact with dust can cause mechanical irritation or drying of the skin. May form explosive dust-air mixture during processing, handling or other means.

### Section 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>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 10 - &lt; 30</td>
</tr>
<tr>
<td>Desloratadine</td>
<td>100643-71-8</td>
<td>&gt;= 3 - &lt; 10</td>
</tr>
<tr>
<td>Talc</td>
<td>14807-96-6</td>
<td>&lt; 10</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
</tbody>
</table>

### Section 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.

Section 5: Fire-fighting measures

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

Section 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. 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 deter-
mine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

Section 7: Handling and storage

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.
- Take care to prevent spills, waste and minimize release to the environment.
- Keep away from heat and sources of ignition.

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.

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

Section 8: Exposure controls/personal protection

Components with workplace control parameters

<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>WES-TWA</td>
<td>10 mg/m³</td>
<td>NZ OEL</td>
</tr>
<tr>
<td></td>
<td></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>WES-TWA (Respirable dust)</td>
<td>2 mg/m³</td>
<td>NZ OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>WES-TWA</td>
<td>0.1 fibres per millilitre</td>
<td>NZ OEL</td>
</tr>
</tbody>
</table>
Further information: Confirmed carcinogen, Regulation 9(1) of the Health and Safety at Work (Asbestos) Regulations 2016 (the 'Asbestos Regulations') requires PCBUs with management or control of a workplace to ensure that exposure of a person at the workplace to airborne asbestos is eliminated so far as is reasonably practicable. If it is not reasonably practicable to eliminate exposure to airborne asbestos, exposure must be minimised so far as is reasonably practicable. Regulation 9(2) of the Asbestos Regulations requires PCBUs with management or control of a workplace to ensure that the airborne contamination standard for asbestos is not exceeded at the workplace (however, in relation to an asbestos removal area where class A asbestos removal work is being carried out, the regulations impose a more stringent standard). These requirements work together to ensure that there is a limit to the amount of asbestos that is permitted in the air of a workplace, without implying or meaning that the level delineates what is acceptable for personal exposure. Personal exposure must be eliminated or minimised so far as is reasonably practicable. The WES provided within this guide for asbestos must be applied accordingly.

<table>
<thead>
<tr>
<th>Component</th>
<th>TWA (Respirable particulate matter)</th>
<th>TWA</th>
<th>ACGIH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Titanium dioxide</td>
<td>2 mg/m3</td>
<td>10 mg/m3</td>
<td>NZ OEL</td>
</tr>
<tr>
<td></td>
<td>WES-TWA</td>
<td>WES-</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>10 mg/m3</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(Titanium dioxide)</td>
<td></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 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).

Section 9: Physical and chemical properties

- **Appearance**: powder
- **Colour**: white
- **Odour**: No data available
- **Odour Threshold**: No data available
- **pH**: No data available
- **Melting point/freezing point**: No data available
- **Initial boiling point and boiling range**: No data available
- **Flash point**: No data available
- **Evaporation rate**: No data available
- **Flammability (solid, gas)**: May form explosive dust-air mixture during processing, handling or other means.
- **Flammability (liquids)**: No data available
- **Upper explosion limit / Upper flammability limit**: No data available
- **Lower explosion limit / Lower flammability limit**: No data available
- **Vapour pressure**: No data available
- **Relative vapour density**: No data available
- **Relative density**: No data available
- **Density**: No data available
- **Solubility(ies)**
  - **Water solubility**: No data available
- **Partition coefficient: n-octanol/water**: No data available
- **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

Section 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.

Section 11: Toxicological information
Exposure routes  :  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
Desloratadine Solid Formulation

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:

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:

Desloratadine:
Species: Rabbit
Remarks: Severe eye irritation
SAFETY DATA SHEET

Desloratadine Solid Formulation

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:

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

Chronic toxicity

Germ cell mutagenicity
Not classified based on available information.

Components:

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

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:  
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
**SAFETY DATA SHEET**

**Desloratadine Solid Formulation**

**Version** 3.11  **Revision Date:** 02.10.2020  **SDS Number:** 49987-00014  **Date of last issue:** 23.03.2020  **Date of first issue:** 23.01.2015

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**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:**

**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:

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

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

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
Section 12: 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
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 (Oncorhynchus 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:

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 % at50 °C(5 d)
   Method: FDA 3.09

Bioaccumulative potential

Components:

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
Section 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.

Section 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**
- **NZS 5433**: Not regulated as a dangerous good

Section 15: Regulatory information

**Safety, health and environmental regulations/legislation specific for the substance or mixture**

**HSNO Approval Number**
HSR100425 Pharmaceutical Active Ingredients Group Standard 2017

**HSW Controls**
Certified handler certificate not required.
Tracking hazardous substance not required.
Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

**The components of this product are reported in the following inventories:**
- **AICS**: not determined
- **DSL**: not determined
- **IECSC**: not determined
## Section 16: Other information

### Further information

**Sources of key data used to compile the Safety Data Sheet**

**Date format**
- dd.mm.yyyy

### Full text of other abbreviations

- **ACGIH**: USA. ACGIH Threshold Limit Values (TLV)
- **NZ OEL**: New Zealand. Workplace Exposure Standards for Atmospheric Contaminants
- **ACGIH / TWA**: 8-hour, time-weighted average
- **NZ OEL / WES-TWA**: Workplace Exposure Standard - Time Weighted average

**Abbreviations**
- 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
- 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
- ICAO: International Civil Aviation Organization
- IC50: Half maximal inhibitory concentration
- IC50: Lethal Concentration to 50% of a test population
- IC50: Median Lethal Dose
- IC50: International Convention for the Prevention of Pollution from Ships
- ICH: International Conference on Harmonisation
- ILO: International Labour 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
- LC50: Workers' Exposure Standard
- LC50: Lethal Dose to 50% of a test population
- LEL: Lower Explosive Limit
- LOEC: Limit of Occurrence
- LOEL: Limit of Observation
- LTR: Lethal Toxicity Rate
- MARPOL: International Convention for the Prevention of Pollution from Ships
- MCL: Maximum Contaminant Limit
- MDC: Maximum Daily Contaminant
- MEL: Maximum Exposure Limit
- 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
- NTP: New Zealand Inventory of Chemicals
- OECD: Organization for Economic Co-operation and Development
- OPPTS: Office of Pollution Prevention and Toxic Substances
- PBT: Persistent, Bioaccumulative and Toxic substance
- PICCS: Philippines Inventory of Chemicals and Chemical Substances
- (Q)SAR: Quantitative Structure Activity Relationship
- SADT: Self-Accelerating Decomposition Temperature
- SDS: Safety Data Sheet
- TCSI: Taiwan Chemical Substance Inventory
- TDG: Transport of Dangerous Goods
- TSCA: Toxic Substances Control Act (United States)
- UN: United Nations
- vPvB: Very Persistent and Very Bioaccumulative
- WHMIS: Workplace Hazardous Materials Information System

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