SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name: Desloratadine Solid Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture: Pharmaceutical

1.3 Details of the supplier of the safety data sheet

Company: Organon & Co.
30 Hudson Street, 33rd floor
07302 Jersey City, New Jersey, U.S.A

Telephone: 551-430-6000

E-mail address of person responsible for the SDS: EHSSTEWARD@organon.com

1.4 Emergency telephone number

215-631-6999

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification T.R. SEA No 28848

<table>
<thead>
<tr>
<th>Classification</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serious eye damage, Category 1</td>
<td>H318: Causes serious eye damage.</td>
</tr>
<tr>
<td>Carcinogenicity, Category 2</td>
<td>H351: Suspected of causing cancer if inhaled.</td>
</tr>
<tr>
<td>Reproductive toxicity, Category 2</td>
<td>H361fd: Suspected of damaging fertility. Suspected of damaging the unborn child.</td>
</tr>
<tr>
<td>Long-term (chronic) aquatic hazard, Category 3</td>
<td>H412: Harmful to aquatic life with long lasting effects.</td>
</tr>
</tbody>
</table>

2.2 Label elements

Labelling T.R. SEA No 28848

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.
- 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 or doctor/ physician.
- P308 + P313 IF exposed or concerned: Get medical advice/ attention.

**Storage:**
- P405 Store locked up.

Hazardous components which must be listed on the label:
- Desloratadine
- Titanium dioxide

### 2.3 Other hazards
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

#### 3.2 Mixtures

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Desloratadine</td>
<td>100643-71-8</td>
<td></td>
<td></td>
<td></td>
<td>Acute Tox. 4; H302 Eye Dam. 1; H318 Repr. 2; H361fd Aquatic Chronic 2; H411</td>
<td>&gt;= 3 - &lt; 10</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7 236-675-5</td>
<td>236-675-5</td>
<td></td>
<td></td>
<td>Carc. 2; H351</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
</tbody>
</table>

Substances with a workplace exposure limit:
- Cellulose 9004-34-6 232-674-9 | >= 20 - < 30 |
- Talc 14807-96-6 238-877-9 | >= 1 - < 10 |
Desloratadine Solid Formulation

SECTION 4: First aid measures

4.1 Description of first aid measures

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

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

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

In case of skin contact: In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.

In case of eye contact: 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.

4.2 Most important symptoms and effects, both acute and delayed

Risks: Causes serious eye damage. Suspected of damaging fertility. Suspected of damaging the unborn child. Contact with dust can cause mechanical irritation or drying of the skin.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment: Treat symptomatically and supportively.
**SECTION 5: Firefighting measures**

5.1 Extinguishing media

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

Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during 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

5.3 Advice for firefighters

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

Specific extinguishing methods:
- Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Use water spray to cool unopened containers.
- Remove undamaged containers from fire area if it is safe to do so.
- Evacuate area.

**SECTION 6: Accidental release measures**

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions:
- Use personal protective equipment.
- Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

Environmental precautions:
- Avoid release to the environment.
- Prevent further leakage or spillage if safe to do so.
- Retain and dispose of contaminated wash water.
- Local authorities should be advised if significant spillages cannot be contained.
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6.3 Methods and material for containment and cleaning up

Methods for cleaning up:
Sweep up or vacuum up spillage and collect in suitable container for disposal. 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.

6.4 Reference to other sections
See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures:
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.

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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers:
Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.

Advice on common storage:
Do not store with the following product types:
SAFETY DATA SHEET

According to 13 December 2014, No:29204, “Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I”.

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Version 4.0 Revision Date: 09.04.2021 SDS Number: 2805602-00006 Date of last issue: 02.10.2020 Date of first issue: 18.05.2018

Strong oxidizing agents

7.3 Specific end use(s)
Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>ZOAD/TWA (Total dust)</td>
<td>15 mg/m³</td>
<td>TR OEL DU</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: Allowable occupational exposure limit values of chemicals in dust form</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>ZOAD/TWA (Respirable dust)</td>
<td>5 mg/m³</td>
<td>TR OEL DU</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: Allowable occupational exposure limit values of chemicals in dust form</td>
<td></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>ZOAD/TWA</td>
<td>80 mg/m³ / %SiO2+2</td>
<td>TR OEL DU</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: Allowable occupational exposure limit values of mineral dusts</td>
<td></td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>ZOAD/TWA (Total dust)</td>
<td>15 mg/m³</td>
<td>TR OEL DU</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: Allowable occupational exposure limit values of chemicals in dust form</td>
<td></td>
</tr>
</tbody>
</table>

8.2 Exposure controls

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
Eye protection: Wear the following personal protective equipment:
  Chemical resistant goggles must be worn.
  If splashes are likely to occur, wear:
  Face-shield
  Equipment should conform to TS EN 166

Hand protection
SAFETY DATA SHEET
According to 13 December 2014, No:29204, “Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I”.

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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.

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).

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to TS EN 143

Filter type : Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic 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.
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
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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.

9.2 Other information
Flammability (liquids) : No data available
Molecular weight : No data available
Particle size : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
Hazardous reactions : May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid : Heat, flames and sparks.
Avoid dust formation.

10.5 Incompatible materials
Materials to avoid : Oxidizing agents
10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

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:

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.

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

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

Talc:
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
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Skin corrosion/irritation
Not classified based on available information.

Components:

Desloratadine:
Species: Rabbit
Result: No skin irritation

Titanium dioxide:
Species: Rabbit
Result: No skin irritation

Talc:
Species: Rabbit
Result: No skin irritation

Serious eye damage/eye irritation
Causes serious eye damage.

Components:

Desloratadine:
Species: Rabbit
Remarks: Severe eye irritation

Titanium dioxide:
Species: Rabbit
Result: No eye irritation

Talc:
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
# SAFETY DATA SHEET

According to 13 December 2014, No:29204, “Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I”.

## Desloratadine Solid Formulation

<table>
<thead>
<tr>
<th>Version</th>
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<tbody>
<tr>
<td>4.0</td>
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<td>2805602-00006</td>
<td>02.10.2020</td>
<td>18.05.2018</td>
</tr>
</tbody>
</table>

### Exposure routes
- **Species**: Guinea pig
- **Result**: negative

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

### Talc:
- **Exposure routes**: Skin contact
- **Species**: Humans
- **Result**: negative

### Germ cell mutagenicity
Not classified based on available information.

### Components:

#### 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

#### 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

#### Cellulose:
- **Genotoxicity in vitro**:
  - **Test Type**: Bacterial reverse mutation assay (AMES)
  - **Result**: negative
  - **Test Type**: In vitro mammalian cell gene mutation test
  - **Result**: negative
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Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Ingestion
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

Carcinogenicity
Suspected of causing cancer if inhaled.

Components:

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.

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.
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</tbody>
</table>

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

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

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

**Components:**

**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
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</tbody>
</table>

### 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.

### 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

### 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:

**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
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<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Gastrointestinal disturbance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Monkey</td>
</tr>
<tr>
<td>NOAEL</td>
<td>40 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>17 Months</td>
</tr>
<tr>
<td>Remarks</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Gastrointestinal disturbance, Fatigue</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Monkey</td>
</tr>
<tr>
<td>NOAEL</td>
<td>6 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>3 Months</td>
</tr>
</tbody>
</table>

Titanium dioxide:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>24.000 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>28 Days</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>10 mg/m3</td>
</tr>
<tr>
<td>Application Route</td>
<td>inhalation (dust/mist/fume)</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 yr</td>
</tr>
</tbody>
</table>

Cellulose:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>&gt;= 9.000 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>90 Days</td>
</tr>
</tbody>
</table>

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Desloratadine:

<table>
<thead>
<tr>
<th>Inhalation</th>
<th>Remarks: May cause respiratory tract irritation.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye contact</td>
<td>Symptoms: Eye irritation</td>
</tr>
<tr>
<td>Ingestion</td>
<td>Symptoms: dry mouth, muscle pain, Fatigue, Drowsiness, sore throat, painful menstration</td>
</tr>
</tbody>
</table>
12.1 Toxicity

Components:

**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 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
- **Toxicity to fish (Chronic toxicity)**: NOEC: 0.12 mg/l
  - Exposure time: 32 d
  - Species: Pimephales promelas (fathead minnow)
  - Method: OECD Test Guideline 210
- **Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)**: NOEC: 0.48 mg/l
  - Exposure time: 21 d
  - Species: Daphnia magna (Water flea)
  - Method: OECD Test Guideline 211

**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**: EC50 (Daphnia magna (Water flea)): > 100 mg/l
Desloratadine Solid Formulation

12.2 Persistence and degradability

Components:

Desloratadine:

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

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

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

Cellulose:

Biodegradability: Result: Readily biodegradable.

12.3 Bioaccumulative potential

Components:

Desloratadine:

Partition coefficient: n-octanol/water: log Pow: 1.24
Method: OECD Test Guideline 107
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12.4 Mobility in soil

Components:

Desloratadine:

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

12.5 Results of PBT and vPvB assessment

Not relevant

12.6 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product: Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number

Not regulated as a dangerous good

14.2 UN proper shipping name

Not regulated as a dangerous good

14.3 Transport hazard class(es)

Not regulated as a dangerous good

14.4 Packing group

Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks: Not applicable for product as supplied.
SECTION 15: Regulatory information

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

<table>
<thead>
<tr>
<th>Regulation</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>KKDIK (30105 (Bis)) - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex 17)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Regulation on Persistent Organic Pollutants (Number 30595)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Regulation on prevention of major industrial accidents. Reg number 30702</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

Other regulations:

- According to 13 December 2014, No:29204, “Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I”.
- Regulation on Classification, Labelling and Packaging of Substances and Mixtures. Dated 11 December 2013, Numbered 28848 (Bis) Ministry of Environment and Forestry.
- Regulation on Dust Control (No: 28812, 2013). Occupational Dust Exposure Limit Values (Annex 1)

The components of this product are reported in the following inventories:

- AICS: not determined
- DSL: not determined
- IECSC: not determined

SECTION 16: Other information

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

The SDS has been prepared by: Name: Gökhan Ardıç; Contact email: sds@chemleg.com; Telephone number: +90 216 706 1307; Certificate Number: Lonca KDU 34 / 2020.08; Certificate Date: 22 September 2020; Valid Until: 22 September 2025

Full text of H-statements:

- H302: Harmful if swallowed.
- H318: Causes serious eye damage.
- H351: Suspected of causing cancer if inhaled.
- H361fd: Suspected of damaging fertility. Suspected of damaging the unborn child.
- H411: Toxic to aquatic life with long lasting effects.

The Turkish SDS has been prepared according to the Regulation on Safety Data Sheets for Hazardous Substances and Mixtures No. 29204.
SAFETY DATA SHEET
According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I”.

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Full text of other abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Tox.</td>
<td>Acute toxicity</td>
</tr>
<tr>
<td>Aquatic Chronic</td>
<td>Long-term (chronic) aquatic hazard</td>
</tr>
<tr>
<td>Carc.</td>
<td>Carcinogenicity</td>
</tr>
<tr>
<td>Eye Dam.</td>
<td>Serious eye damage</td>
</tr>
<tr>
<td>Repr.</td>
<td>Reproductive toxicity</td>
</tr>
<tr>
<td>TR OEL DU</td>
<td>Turkey. Regulation on Dust Control. Occupational Dust Exposure Limit Values (Annex 1)</td>
</tr>
<tr>
<td>TR OEL DU / ZOAD/TWA</td>
<td>Time Weighted Average Value</td>
</tr>
</tbody>
</table>

Further information


Classification of the mixture: Eye Dam. 1

Classification procedure: Calculation method
SAFETY DATA SHEET
According to 13 December 2014, No:29204, “Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I”.

**Desloratadine Solid Formulation**

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

| Carc. 2 | H351 | Calculation method |
| Repr. 2 | H361fd | Calculation method |
| Aquatic Chronic 3 | H412 | Calculation method |

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

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.

TR / EN