

SAFETY DATA SHEET



Desloratadine Solid Formulation



Version 6.0 Revision Date: 06.04.2024 SDS Number: 49973-00020 Date of last issue: 30.09.2023
Date of first issue: 23.01.2015

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Manufacturer or supplier's details

Company : Organon & Co.
Address : Rua Treze de Maio, 1161
Campinas, São Paulo, Brazil 13106-054
Telephone : +55 (19) 3758-2000
Emergency telephone : +55 (11) 3173-4931
E-mail address : EHSSTEWARD@organon.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard

Serious eye damage : 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 in accordance with ABNT NBR 14725 Standard

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:**

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

Storage:

P405 Store locked up.

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

| Chemical name | CAS-No. | Classification | Concentration (% w/w) |
|------------------|-------------|---|-----------------------|
| Cellulose | 9004-34-6 | | >= 20 -< 30 |
| Starch, oxidized | 65996-62-5 | | >= 10 -< 20 |
| Desloratadine | 100643-71-8 | Acute toxicity (Oral), Category 4 Serious eye damage, Category 1 Reproductive toxicity, Category 2 Short-term (acute) aquatic hazard, Category 2 Long-term (chronic) aquatic hazard, Category 2 | >= 3 -< 5 |
| Talc | 14807-96-6 | | >= 1 -< 5 |
| Titanium dioxide | 13463-67-7 | Carcinogenicity (Inhalation), Category 2 | >= 1 -< 5 |

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.

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- 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 fire-fighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.
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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).

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- 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 determine 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.
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.
- Conditions for safe storage : Keep in properly labeled 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

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SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
|------------------|-------------|-------------------------------------|--|----------|
| Cellulose | 9004-34-6 | TWA | 10 mg/m ³ | ACGIH |
| Starch, oxidized | 65996-62-5 | TWA (inhalable dust) | 0,5 mg/m ³ | ACGIH |
| Desloratadine | 100643-71-8 | TWA | 20 µg/m ³ (OEB 3) | Internal |
| | | Wipe limit | 200 µg/100 cm ² | Internal |
| Talc | 14807-96-6 | TWA (Respirable particulate matter) | 2 mg/m ³ | ACGIH |

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 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

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| | | |
|--|---|---|
| Appearance | : | powder |
| Color | : | white |
| Odor | : | No data available |
| Odor 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 |
| Vapor pressure | : | No data available |
| Relative vapor 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 |
| Autoignition temperature | : | No data available |
| Decomposition temperature | : | No data available |
| Viscosity Viscosity, dynamic | : | No data available |
| Viscosity, kinematic | : | No data available |
| Explosive properties | : | Not explosive |

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

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: > 5.000 mg/kg
Method: Calculation method

Components:

Cellulose:

Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg
Acute inhalation toxicity : LC50 (Rat): > 5,8 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Acute dermal toxicity : LD50 (Rabbit): > 2.000 mg/kg

Desloratadine:

Acute oral toxicity : LD50 (Rat): > 549 mg/kg
LD50 (Mouse): 353 mg/kg
LD50 (Monkey): > 250 mg/kg
Symptoms: Vomiting

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||| 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

Talc:

||| Species : Rabbit
 ||| Result : No eye irritation

Titanium dioxide:

||| Species : Rabbit
 ||| Result : No eye irritation

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Respiratory or skin sensitization**Skin sensitization**

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:**Desloratadine:**

| | | |
|--------------------|---|-------------------|
| Test Type | : | Maximization Test |
| Routes of exposure | : | Dermal |
| Species | : | Guinea pig |
| Result | : | negative |

Talc:

| | | |
|--------------------|---|--------------|
| Routes of exposure | : | Skin contact |
| Species | : | Humans |
| Result | : | negative |

Titanium dioxide:

| | | |
|--------------------|---|-------------------------------|
| Test Type | : | Local lymph node assay (LLNA) |
| Routes of exposure | : | Skin contact |
| Species | : | Mouse |
| Result | : | negative |

Germ cell mutagenicity

Not classified based on available information.

Components:**Cellulose:**

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

Desloratadine:

| | | |
|-----------------------|---|--|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES) |
| | | Result: negative |
| Genotoxicity in vitro | : | Test Type: Chromosomal aberration |
| | | Test system: Human lymphocytes |
| | | Result: negative |

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| | | |
|----------------------|---|---|
| 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 |
| 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 |
|---------|---|-------|

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| | | |
|-------------------|---|-----------------------------|
| 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 fetal development | : | Test Type: Fertility/early embryonic development Species: Rat Application Route: Ingestion Result: negative |

Desloratadine:

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

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Test Type: Embryo-fetal 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 fetal development : Test Type: Embryo-fetal 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

Starch, oxidized:

Species : Rat
 NOAEL : 22.500 mg/kg
 Application Route : Ingestion
 Exposure time : 90 Days

Desloratadine:

Species : Rat
 NOAEL : 30 mg/kg
 Application Route : Oral

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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 y

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

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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

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Titanium dioxide:

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|---|--|
| 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:

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|--------------------|--|
| Biodegradability | : Result: Not readily biodegradable. Biodegradation: 67,4 % Exposure time: 28 d Method: OECD Test Guideline 314 |
| | : Result: Not readily biodegradable. Biodegradation: 0 % Exposure time: 28 d Method: FDA 3.11 |
| Stability in water | : Hydrolysis: < 10 % at 50 °C(5 d) Method: FDA 3.09 |

Bioaccumulative potential**Components:****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 |
|---|--|

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Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

| | | |
|------------------------|---|---|
| Waste from residues | : | Do not dispose of waste into sewer. 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.

Domestic regulation**ANTT**

Not regulated as a dangerous good

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION**Safety, health and environmental regulations/legislation specific for the substance or mixture**

National List of Carcinogenic Agents for Humans - (LINACH)

Group 2B: Possibly carcinogenic to humans

Titanium dioxide

13463-67-7

Brazil. List of chemicals controlled by the Federal Police : Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

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SECTION 16. OTHER INFORMATION

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Further information

Sources of key data used to compile the Material 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.

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA : 8-hour, time-weighted average

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; TECl - 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

SAFETY DATA SHEET



Desloratadine Solid Formulation



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relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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