

## Desloratadine Solid Formulation

Version 3.6      Revision Date: 04/09/2021      SDS Number: 49974-00015      Date of last issue: 10/02/2020  
Date of first issue: 01/23/2015

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**SECTION 1. IDENTIFICATION**

Product name : Desloratadine Solid Formulation  
Other means of identification : No data available

**Manufacturer or supplier's details**

Company name of supplier : Organon & Co.  
Address : 30 Hudson Street, 33rd floor  
Jersey City, New Jersey, U.S.A 07302  
Telephone : 551-430-6000  
Emergency telephone : 215-631-6999  
E-mail address : EHSSTEWARD@organon.com

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

Recommended use : Pharmaceutical  
Restrictions on use : Not applicable

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**SECTION 2. HAZARDS IDENTIFICATION****GHS classification in accordance with the Hazardous Products Regulations**

Serious eye damage : 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 damaging 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 protective gloves, protective clothing, eye protection and 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

# SAFETY DATA SHEET



## Desloratadine Solid Formulation



Version 3.6      Revision Date: 04/09/2021      SDS Number: 49974-00015      Date of last issue: 10/02/2020  
Date of first issue: 01/23/2015

CENTER.  
P308 + P313 IF exposed or concerned: Get medical attention.

**Storage:**  
P405 Store locked up.

**Disposal:**  
P501 Dispose of contents and container to an approved waste disposal plant.

### 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

Substance / Mixture : Mixture

### Components

Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
Cellulose	No data available	9004-34-6	$\geq 10 - < 30$ *
Starch, oxidized	Tapioca Starch	65996-62-5	$\geq 10 - < 30$ *
Desloratadine	No data available	100643-71-8	$\geq 1 - < 5$ *
Talc	Talc (Mg <sub>3</sub> H <sub>2</sub> (SiO <sub>3</sub> ) <sub>4</sub> )	14807-96-6	$\geq 1 - < 5$ *
Titanium dioxide	Titanic anhydride	13463-67-7	$\geq 1 - < 5$ *

\* Actual concentration or concentration range is withheld as a trade secret

## 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.

# SAFETY DATA SHEET



## Desloratadine Solid Formulation



Version 3.6      Revision Date: 04/09/2021      SDS Number: 49974-00015      Date of last issue: 10/02/2020  
Date of first issue: 01/23/2015

---

- 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.
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### SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
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).
- 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

## Desloratadine Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10/02/2020
3.6	04/09/2021	49974-00015	Date of first issue: 01/23/2015

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.<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. |
| Conditions for safe storage | : | Keep in properly labeled containers.<br>Store locked up.<br>Keep tightly closed.<br>Store in accordance with the particular national regulations.   |
| Materials to avoid          | : | Do not store with the following product types:<br>Strong oxidizing agents   |

**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 <sup>3</sup>	CA AB OEL
		TWA (Total dust)	10 mg/m <sup>3</sup>	CA BC OEL
		TWA (respirable dust fraction)	3 mg/m <sup>3</sup>	CA BC OEL
		TWAEV (total dust)	10 mg/m <sup>3</sup>	CA QC OEL
		TWA	10 mg/m <sup>3</sup>	ACGIH
Starch, oxidized	65996-62-5	TWA (Total	0.5 mg/m <sup>3</sup>	CA AB OEL

# SAFETY DATA SHEET



## Desloratadine Solid Formulation



Version  
3.6

Revision Date:  
04/09/2021

SDS Number:  
49974-00015

Date of last issue: 10/02/2020  
Date of first issue: 01/23/2015

		particulates)		
		TWA (inhalable dust)	0.5 mg/m <sup>3</sup>	CA BC OEL
Desloratadine	100643-71-8	TWA	20 µg/m <sup>3</sup> (OEB 3)	Internal
		Wipe limit	200 µg/100 cm <sup>2</sup>	Internal
Talc	14807-96-6	TWAEV (respirable dust)	3 mg/m <sup>3</sup>	CA QC OEL
		TWA (Respirable particulates)	2 mg/m <sup>3</sup>	CA AB OEL
		TWA (Respirable)	2 mg/m <sup>3</sup>	CA BC OEL
		TWA	2 fibres per cubic centimeter	CA ON OEL
		TWA (Respirable fraction)	2 mg/m <sup>3</sup>	CA ON OEL
		TWA (Respirable particulate matter)	2 mg/m <sup>3</sup>	ACGIH
Titanium dioxide	13463-67-7	TWA	10 mg/m <sup>3</sup>	CA AB OEL
		TWAEV (total dust)	10 mg/m <sup>3</sup>	CA QC OEL
		TWA (Total dust)	10 mg/m <sup>3</sup>	CA BC OEL
		TWA (respirable dust fraction)	3 mg/m <sup>3</sup>	CA BC OEL
		TWA	10 mg/m <sup>3</sup> (Titanium dioxide)	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). Dust formation may be relevant in the processing of this product. In addition to substance-specific OELs, general limitations of concentrations of particulates in the air at workplaces have to be considered in workplace risk assessment. Relevant limits include: OSHA PEL for Particulates Not Otherwise Regulated of 15 mg/m<sup>3</sup> - total dust, 5 mg/m<sup>3</sup> - respirable fraction; and ACGIH TWA for Particles (insoluble or poorly soluble) Not Otherwise Specified of 3 mg/m<sup>3</sup> - respirable particles, 10 mg/m<sup>3</sup> - inhalable particles.

### Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the

# SAFETY DATA SHEET



## Desloratadine Solid Formulation



Version 3.6      Revision Date: 04/09/2021      SDS Number: 49974-00015      Date of last issue: 10/02/2020  
Date of first issue: 01/23/2015

---

Filter type	:	recommended guidelines, use respiratory protection.
Hand protection	:	Particulates type
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).
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.

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### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

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	:	No data available

# SAFETY DATA SHEET



## Desloratadine Solid Formulation



Version 3.6      Revision Date: 04/09/2021      SDS Number: 49974-00015      Date of last issue: 10/02/2020  
Date of first issue: 01/23/2015

---

flammability limit

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

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

Molecular weight : No data available

Particle size : No data available

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### 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.

## Desloratadine Solid Formulation

Version 3.6      Revision Date: 04/09/2021      SDS Number: 49974-00015      Date of last issue: 10/02/2020  
Date of first issue: 01/23/2015

---

**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  
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.



## Desloratadine Solid Formulation

Version 3.6      Revision Date: 04/09/2021      SDS Number: 49974-00015      Date of last issue: 10/02/2020  
Date of first issue: 01/23/2015

---

**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

**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

## Desloratadine Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10/02/2020
3.6	04/09/2021	49974-00015	Date of first issue: 01/23/2015

---

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

**Desloratadine:**

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
	Test Type: Chromosomal aberration Test system: Human lymphocytes 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
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## Desloratadine Solid Formulation

Version 3.6      Revision Date: 04/09/2021      SDS Number: 49974-00015      Date of last issue: 10/02/2020  
Date of first issue: 01/23/2015

---

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  
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.

## Desloratadine Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10/02/2020
3.6	04/09/2021	49974-00015	Date of first issue: 01/23/2015

---

**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:**

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.

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.

## Desloratadine Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10/02/2020
3.6	04/09/2021	49974-00015	Date of first issue: 01/23/2015

---

**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

**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

## Desloratadine Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10/02/2020
3.6	04/09/2021	49974-00015	Date of first issue: 01/23/2015

---

**Titanium dioxide:**

Species	:	Rat
NOAEL	:	24,000 mg/kg
Application Route	:	Ingestion
Exposure time	:	28 Days

Species	:	Rat
NOAEL	:	10 mg/m <sup>3</sup>
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
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**Desloratadine:**

Toxicity to fish	:	LC50 (Lepomis macrochirus (Bluegill sunfish)): 9.2 mg/l Exposure time: 96 h Method: FDA 4.11
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Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 9.6 mg/l Exposure time: 48 h Method: FDA 4.08
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Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): 1.6 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
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	:	NOEC (Pseudokirchneriella subcapitata (green algae)): 0.36 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
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## Desloratadine Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10/02/2020
3.6	04/09/2021	49974-00015	Date of first issue: 01/23/2015

---

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 %

# SAFETY DATA SHEET



## Desloratadine Solid Formulation



Version	Revision Date:	SDS Number:	Date of last issue: 10/02/2020
3.6	04/09/2021	49974-00015	Date of first issue: 01/23/2015

---

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

### Other adverse effects

No data available

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## 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.

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## 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

#### **TDG**

Not regulated as a dangerous good

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## Desloratadine Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10/02/2020
3.6	04/09/2021	49974-00015	Date of first issue: 01/23/2015

**SECTION 15. REGULATORY INFORMATION****The ingredients of this product are reported in the following inventories:**

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

**SECTION 16. OTHER INFORMATION****Full text of other abbreviations**

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
CA AB OEL	:	Canada. Alberta, Occupational Health and Safety Code (table 2: OEL)
CA BC OEL	:	Canada. British Columbia OEL
CA ON OEL	:	Ontario Table of Occupational Exposure Limits made under the Occupational Health and Safety Act.
CA QC OEL	:	Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for air-borne contaminants
ACGIH / TWA	:	8-hour, time-weighted average
CA AB OEL / TWA	:	8-hour Occupational exposure limit
CA BC OEL / TWA	:	8-hour time weighted average
CA ON OEL / TWA	:	Time-Weighted Average Limit (TWA)
CA QC OEL / TWA	:	Time-weighted average exposure value

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; KECl - 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,

# SAFETY DATA SHEET



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Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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/>

Revision Date : 04/09/2021  
Date format : mm/dd/yyyy

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.

CA / Z8