

# **Desloratadine Solid Formulation**

♣ ORGANON

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 7.1 06.04.2024 49987-00021 Date of first issue: 23.01.2015

#### **Section 1: Identification**

Product name : Desloratadine Solid Formulation

Manufacturer or supplier's details

Company : Organon & Co.

Address : 30 Hudson Street, 33nd floor

Jersey City, New Jersey, U.S.A 07302

Telephone : +1-551-430-6000

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

E-mail address : EHSSTEWARD@organon.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical Restrictions on use : Not applicable

#### Section 2: Hazard identification

**GHS Classification** 

Serious eye damage/eye irri-

tation

Category 1

Carcinogenicity (Inhalation) : Category 2

Reproductive toxicity : Category 2

Hazardous to the aquatic environment - chronic hazard

Category 3

**GHS** label elements

Hazard pictograms :





Signal word : Danger

Hazard statements : H318 Causes serious eye damage.

H351 Suspected of causing cancer if inhaled.

H361fd Suspected of damaging fertility. Suspected of damag-

ing the unborn child.

H412 Harmful to aquatic life with long lasting effects.



# **Desloratadine Solid Formulation**



Version Revision Date: SDS Number: Date of last issue: 30.09.2023 7.1 06.04.2024 49987-00021 Date of first issue: 23.01.2015

Precautionary statements : Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read

and understood.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.

#### Response:

P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.

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

attention.

#### Storage:

P405 Store locked up.

#### Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

#### Other hazards which do not result in classification

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.	Concentration (% w/w) >= 20 -< 30 >= 10 -< 20	
Cellulose	9004-34-6		
Starch, oxidized	65996-62-5		
Desloratadine	100643-71-8	>= 3 -< 10	
Talc	14807-96-6	>= 1 -< 10	
Titanium dioxide	13463-67-7	>= 1 -< 10	

#### Section 4: First-aid measures

General advice : In the case of accident or if you feel unwell, seek medical ad-

vice 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.



# **Desloratadine Solid Formulation**



Date of last issue: 30.09.2023 Version Revision Date: SDS Number: 49987-00021 7.1 06.04.2024 Date of first issue: 23.01.2015

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. Causes serious eye damage.

Most important symptoms and effects, both acute and

delayed

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).

Treat symptomatically and supportively. Notes to physician

#### 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 prod-

ucts

Carbon oxides Metal oxides

Oxides of phosphorus

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment.

Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

SO.

Evacuate area.

Special protective equipment

for firefighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

#### Section 6: Accidental release measures

Personal precautions, protec: : tive equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective equipment recommendations (see section 8).

Environmental precautions Avoid release to the environment.





Version Revision Date: S 7.1 06.04.2024 4

SDS Number: 49987-00021

Date of last issue: 30.09.2023 Date of first issue: 23.01.2015

Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.

Methods and materials for containment and cleaning up

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

Avoid dispersal of dust in the air (i.e., clearing dust surfaces

with compressed air).

Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

#### Section 7: Handling and storage

Technical measures : Static electricity may accumulate and ignite suspended dust

causing an explosion.

Provide adequate precautions, such as electrical grounding

and bonding, or inert atmospheres.

Local/Total ventilation Advice on safe handling Use only with adequate ventilation.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 as-

sessment

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 labelled containers.

Store locked up. Keep tightly closed.

Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:

Strong oxidizing agents

# Public

# **Desloratadine Solid Formulation**



 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 7.1
 06.04.2024
 49987-00021
 Date of first issue: 23.01.2015

### Section 8: Exposure controls/personal protection

#### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Cellulose	9004-34-6	WES-TWA	10 mg/m3	NZ OEL
		TWA	10 mg/m3	ACGIH
Starch, oxidized	65996-62-5	TWA (inhal- able dust)	0.5 mg/m3	ACGIH
Desloratadine	100643-71-8	TWA	20 μg/m3 (OEB 3)	Internal
		Wipe limit	200 μg/100 cm <sup>2</sup>	Internal
Talc	14807-96-6	WES-TWA (Respirable dust)	2 mg/m3	NZ OEL
		TWA (Respirable particulate matter)	2 mg/m3	ACGIH
Titanium dioxide	13463-67-7	WES-TWA	10 mg/m3	NZ OEL

**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 expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type
Hand protection

Material

Particulates type

: Chemical-resistant gloves

Remarks : Choose gloves to protect hands against chemicals depending

on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the

end of workday.

Eye protection : Wear the following personal protective equipment:

Chemical resistant goggles must be worn.

If splashes are likely to occur, wear:



# **Desloratadine Solid Formulation**



Version Revision Date: SDS Number: Date of last issue: 30.09.2023 7.1 06.04.2024 49987-00021 Date of first issue: 23.01.2015

Face-shield

Skin and body protection : Select appropriate protective clothing based on chemical

resistance data and an assessment of the local exposure

potential.

Skin contact must be avoided by using impervious protective

clothing (gloves, aprons, boots, etc).

Section 9: Physical and chemical properties

Appearance : powder

Colour : white

Odour : No data available

Odour Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : May form explosive dust-air mixture during processing, han-

dling or other means.

Flammability (liquids) : No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

: No data available

Auto-ignition temperature

No data available



# **Desloratadine Solid Formulation**

♣ ORGANON

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 7.1 06.04.2024 49987-00021 Date of first issue: 23.01.2015

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 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 reac-

tions

: May form explosive dust-air mixture during processing, han-

dling or other means.

Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.

Oxidizing agents

Incompatible materials

Hazardous decomposition

products

No hazardous decomposition products are known.

# **Section 11: Toxicological information**

Exposure routes : Inhalation

Skin contact Ingestion Eye contact

**Acute toxicity** 

Not classified based on available information.

**Product:** 

Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg

Method: Calculation method

Components:

Cellulose:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg



# **Desloratadine Solid Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 7.1
 06.04.2024
 49987-00021
 Date of first issue: 23.01.2015

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 inhala-

tion 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.



# **Desloratadine Solid Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 7.1
 06.04.2024
 49987-00021
 Date of first issue: 23.01.2015

**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 sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

**Components:** 

**Desloratadine:** 

Test Type : Maximisation Test

Exposure routes : Dermal Species : Guinea pig Result : negative

Talc:

Exposure routes : Skin contact Species : Humans Result : negative

Titanium dioxide:

Test Type : Local lymph node assay (LLNA)

Exposure routes : Skin contact
Species : Mouse
Result : negative

**Chronic toxicity** 

Germ cell mutagenicity

Not classified based on available information.

**Components:** 

Cellulose:



# **Desloratadine Solid Formulation**



Version Revision Date: SDS Number: Date of last issue: 30.09.2023 7.1 06.04.2024 49987-00021 Date of first issue: 23.01.2015

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 syn-

thesis 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.



# **Desloratadine Solid Formulation**

Version SDS Number: Date of last issue: 30.09.2023 Revision Date: 06.04.2024 49987-00021 Date of first issue: 23.01.2015 7.1

# 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

10 mg/kg body weight LOAEL

Result equivocal **Target Organs** Liver

Remarks Based on data from similar materials

The mechanism or mode of action may not be relevant in hu-

mans.

Talc:

**Species** Mouse

**Application Route** inhalation (dust/mist/fume)

Exposure time 2 Years Result negative

Titanium dioxide:

Species Rat

inhalation (dust/mist/fume) **Application Route** 

Exposure time 2 Years

Method OECD Test Guideline 453

positive Result

Remarks The mechanism or mode of action may not be relevant in hu-

mans.

Carcinogenicity - Assess-

ment

animals.

Limited evidence of carcinogenicity in inhalation studies with

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



# **Desloratadine Solid Formulation**

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 7.1 06.04.2024 49987-00021 Date of first issue: 23.01.2015

Result: negative

Effects on foetal develop-

ment

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 rele-

vant 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 develop-

ment

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 rele-

vant 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 - As-

sessment

 Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Some evidence of

adverse effects on development, based on animal experi-

ments.

Talc:

Effects on foetal develop- : Test Type: Embryo-foetal development



# **Desloratadine Solid Formulation**

Version SDS Number: Date of last issue: 30.09.2023 Revision Date: 06.04.2024 49987-00021 Date of first issue: 23.01.2015 7.1

Species: Rat ment

**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 90 Days

Exposure time

Starch, oxidized:

**Species** Rat

**NOAEL** 22,500 mg/kg **Application Route** Ingestion Exposure time 90 Days

**Desloratadine:** 

**Species** Rat LÖAEL 30 mg/kg **Application Route** Oral Exposure time 3 Months **Target Organs** Kidney

Significant toxicity observed in testing Remarks

The mechanism or mode of action may not be relevant in hu-

mans.

**Species** Monkey **NOAEL** 6 mg/kg LOAEL 12 mg/kg Application Route Oral 3 Months Exposure time

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



# **Desloratadine Solid Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 7.1
 06.04.2024
 49987-00021
 Date of first issue: 23.01.2015

NOAEL : 6 mg/kg
Application Route : Oral
Exposure time : 3 Months

Symptoms : Gastrointestinal disturbance, Fatigue

Titanium dioxide:

Species : Rat

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

Species : Rat

NOAEL : 10 mg/m3

Application Route : inhalation (dust/mist/fume)

Exposure time : 2 yr

**Aspiration toxicity** 

Not classified based on available information.

**Experience with human exposure** 

**Components:** 

**Desloratadine:** 

Inhalation : Remarks: May cause respiratory tract irritation.

Eye contact : Symptoms: Eye irritation

Ingestion : Symptoms: dry mouth, muscle pain, Fatigue, Drowsiness,

sore throat, painful menstration

Section 12: Ecological information

**Ecotoxicity** 

**Components:** 

Cellulose:

Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l

Exposure time: 48 h

Remarks: Based on data from similar materials

**Desloratadine:** 

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 9.2 mg/l

Exposure time: 96 h Method: FDA 4.11

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 9.6 mg/l

Exposure time: 48 h Method: FDA 4.08

Toxicity to algae/aquatic

plants

: EC50 (Pseudokirchneriella subcapitata (green algae)): 1.6

mg/l



# **Desloratadine Solid Formulation**

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 7.1 06.04.2024 49987-00021 Date of first issue: 23.01.2015

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 0.36

mq/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to fish (Chronic tox-

icity)

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 (Chron-

ic 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

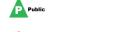
Method: OECD Test Guideline 209

Persistence and degradability

Components:

Cellulose:

Biodegradability : Result: Readily biodegradable.



**™**ORGANON

# **Desloratadine Solid Formulation**

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 7.1 06.04.2024 49987-00021 Date of first issue: 23.01.2015

**Desloratadine:** 

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 67.4 % Exposure time: 28 d

Method: OECD Test Guideline 314

Result: Not readily biodegradable.

Biodegradation: 0 % Exposure time: 28 d Method: FDA 3.11

Stability in water : Hydrolysis: < 10 % at 50 °C(5 d)

Method: FDA 3.09

**Bioaccumulative potential** 

**Components:** 

**Desloratadine:** 

Partition coefficient: n- : log Pow: 1.24

octanol/water Method: OECD Test Guideline 107

Mobility in soil

**Components:** 

**Desloratadine:** 

Distribution among environ-

mental compartments

log Koc: 3.00

Method: OECD Test Guideline 106

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 han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

**Section 14: Transport information** 

**International Regulations** 

UNRTDG

UN number : Not applicable



# **Desloratadine Solid Formulation**

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 7.1 06.04.2024 49987-00021 Date of first issue: 23.01.2015

Proper shipping name : Not applicable Class : Not applicable Subsidiary risk : Not applicable Packing group : Not applicable Labels : Not applicable

Environmentally hazardous : no

**IATA-DGR** 

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

aircraft)

Packing instruction (passen- : Not applicable

ger aircraft)

**IMDG-Code** 

**UN** number Not applicable Proper shipping name Not applicable Class Not applicable Subsidiary risk Not applicable Not applicable Packing group Labels Not applicable EmS Code Not applicable Not applicable Marine pollutant

# Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

#### **National Regulations**

**NZS 5433** 

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Hazchem Code : Not applicable

# Special precautions for user

Not applicable

#### **Section 15: Regulatory information**

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

#### **HSNO Approval Number**

HSR100425 Pharmaceutical Active Ingredients Group Standard



# **Desloratadine Solid Formulation**



Version Revision Date: SDS Number: Date of last issue: 30.09.2023 7.1 06.04.2024 49987-00021 Date of first issue: 23.01.2015

Tolerable Exposure Limits (TEL)

Not applicable

**Environmental Exposure Limits (EEL)** 

Not applicable

#### **HSW Controls**

Certified handler certificate not required.

Tracking hazardous substance not required.

Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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

AICS : not determined

DSL : not determined

IECSC : not determined

#### Section 16: Other information

Revision Date : 06.04.2024

**Further information** 

Sources of key data used to

compile the Safety Data Sheet

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

NZ OEL : New Zealand. Workplace Exposure Standards for Atmospher-

cy, http://echa.europa.eu/

Internal technical data, data from raw material SDSs, OECD

eChem Portal search results and European Chemicals Agen-

ic Contaminants

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

NZ OEL / WES-TWA : Workplace Exposure Standard - 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 Con-



# **Desloratadine Solid Formulation**

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 7.1 06.04.2024 49987-00021 Date of first issue: 23.01.2015

centration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate: NOM - Official Mexican Norm: NTP - National Toxicology Program: NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

NZ / EN