

SAFETY DATA SHEET

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



ORGANON

Desloratadine Solid Formulation

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

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

1.1 Product identifier

Trade name : Desloratadine Solid Formulation

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

Use of the Substance/Mixture : Pharmaceutical

1.3 Details of the supplier of the safety data sheet

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

Telephone : 551-430-6000

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

1.4 Emergency telephone number

215-631-6999

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification T.R. SEA No 28848

Serious eye damage, Category 1

Carcinogenicity, Category 2

Reproductive toxicity, Category 2

Long-term (chronic) aquatic hazard, Category 3

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.

2.2 Label elements

Labelling T.R. SEA No 28848

Hazard pictograms :



Signal word : Danger

Hazard statements : H318 Causes serious eye damage.
H351 Suspected of causing cancer if inhaled.
H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.

SAFETY DATA SHEET

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



ORGANON

Desloratadine Solid Formulation

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

H412 Harmful to aquatic life with long lasting effects.

Precautionary statements :

Prevention:

P201 Obtain special instructions before use.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/ physician.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.

Storage:

P405 Store locked up.

Hazardous components which must be listed on the label:

Desloratadine

Titanium dioxide

2.3 Other hazards

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

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Desloratadine	100643-71-8	Acute Tox. 4; H302 Eye Dam. 1; H318 Repr. 2; H361fd Aquatic Chronic 2; H411	>= 3 - < 10
Titanium dioxide	13463-67-7 236-675-5	Carc. 2; H351	>= 1 - < 10
Substances with a workplace exposure limit :			
Cellulose	9004-34-6 232-674-9		>= 20 - < 30
Talc	14807-96-6 238-877-9		>= 1 - < 10

SAFETY DATA SHEET

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



ORGANON

Desloratadine Solid Formulation

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

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- If inhaled : If inhaled, remove to fresh air.
Get medical attention.
- In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.
- In case of eye contact : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.
If easy to do, remove contact lens, if worn.
Get medical attention immediately.
- If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

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

4.3 Indication of any immediate medical attention and special treatment needed

- Treatment : Treat symptomatically and supportively.

SAFETY DATA SHEET

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



ORGANON

Desloratadine Solid Formulation

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

SECTION 5: Firefighting measures

5.1 Extinguishing media

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

Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during 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

5.3 Advice for firefighters

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

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

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

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

6.2 Environmental precautions

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

SAFETY DATA SHEET

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



ORGANON

Desloratadine Solid Formulation

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

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal.
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation : Use only with adequate ventilation.

Advice on safe handling : Do not breathe dust.
Do not swallow.
Do not get in eyes.
Avoid prolonged or repeated contact with skin.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Keep container tightly closed.
Minimize dust generation and accumulation.
Keep container closed when not in use.
Keep away from heat and sources of ignition.
Take precautionary measures against static discharges.
Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

7.2 Conditions for safe storage, including any incompatibilities

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

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

SAFETY DATA SHEET

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



ORGANON

Desloratadine Solid Formulation

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

Strong oxidizing agents

7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Cellulose	9004-34-6	ZOAD/TWA (Total dust)	15 mg/m ³	TR OEL DU
	Further information: Allowable occupational exposure limit values of chemicals in dust form			
		ZOAD/TWA (Respirable dust)	5 mg/m ³	TR OEL DU
	Further information: Allowable occupational exposure limit values of chemicals in dust form			
Desloratadine	100643-71-8	TWA	20 µg/m ³ (OEB 3)	Internal
		Wipe limit	200 µg/100 cm ²	Internal
Talc	14807-96-6	ZOAD/TWA	80 mg/m ³ / %SiO ₂ +2	TR OEL DU
	Further information: Allowable occupational exposure limit values of mineral dusts			
Titanium dioxide	13463-67-7	ZOAD/TWA (Total dust)	15 mg/m ³	TR OEL DU
	Further information: Allowable occupational exposure limit values of chemicals in dust form			

8.2 Exposure controls

Engineering measures

Ensure adequate ventilation, especially in confined areas.
Minimize workplace exposure concentrations.
Apply measures to prevent dust explosions.
Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).

Personal protective equipment

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

Hand protection

SAFETY DATA SHEET

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



Desloratadine Solid Formulation

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

Material	:	Chemical-resistant gloves
Remarks	:	Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.
Skin and body protection	:	Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential. Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).
Respiratory protection	:	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to TS EN 143
Filter type	:	Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

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

SAFETY DATA SHEET

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



ORGANON

Desloratadine Solid Formulation

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

Relative density	:	No data available
Density	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

9.2 Other information

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

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

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

10.4 Conditions to avoid

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

10.5 Incompatible materials

Materials to avoid	:	Oxidizing agents
--------------------	---	------------------

SAFETY DATA SHEET

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



ORGANON

Desloratadine Solid Formulation

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

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Information on likely routes of exposure : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 2.000 mg/kg
Method: Calculation method

Components:

Desloratadine:

Acute oral toxicity : LD50 (Rat): > 549 mg/kg
LD50 (Mouse): 353 mg/kg
LD50 (Monkey): > 250 mg/kg
Symptoms: Vomiting
Remarks: No mortality observed at this dose.

Titanium dioxide:

Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg
Acute inhalation toxicity : LC50 (Rat): > 6,82 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Assessment: The substance or mixture has no acute inhalation toxicity

Cellulose:

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

Talc:

Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg

SAFETY DATA SHEET

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



ORGANON

Desloratadine Solid Formulation

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

Remarks: Based on data from similar materials

Skin corrosion/irritation

Not classified based on available information.

Components:

Desloratadine:

Species : Rabbit
Result : No skin irritation

Titanium dioxide:

Species : Rabbit
Result : No skin irritation

Talc:

Species : Rabbit
Result : No skin irritation

Serious eye damage/eye irritation

Causes serious eye damage.

Components:

Desloratadine:

Species : Rabbit
Remarks : Severe eye irritation

Titanium dioxide:

Species : Rabbit
Result : No eye irritation

Talc:

Species : Rabbit
Result : No eye irritation

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Desloratadine:

Test Type : Maximisation Test

SAFETY DATA SHEET

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



ORGANON

Desloratadine Solid Formulation

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

Exposure routes : Dermal
Species : Guinea pig
Result : negative

Titanium dioxide:

Test Type : Local lymph node assay (LLNA)
Exposure routes : Skin contact
Species : Mouse
Result : negative

Talc:

Exposure routes : Skin contact
Species : Humans
Result : negative

Germ cell mutagenicity

Not classified based on available information.

Components:

Desloratadine:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: Chromosomal aberration
Test system: Human lymphocytes
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse
Cell type: Bone marrow
Application Route: Oral
Result: negative

Titanium dioxide:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Genotoxicity in vivo : Test Type: In vivo micronucleus test
Species: Mouse
Result: negative

Cellulose:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Result: negative

SAFETY DATA SHEET

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



ORGANON

Desloratadine Solid Formulation

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

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Ingestion
Result: negative

Talc:

Genotoxicity in vitro : Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Result: negative

Genotoxicity in vivo : Test Type: Chromosome aberration test in vitro
Species: Rat
Application Route: Ingestion
Result: negative

Carcinogenicity

Suspected of causing cancer if inhaled.

Components:

Desloratadine:

Species : Mouse
Application Route : Oral
Exposure time : 2 Years
Result : negative

Species : Rat
Application Route : Oral
LOAEL : 10 mg/kg body weight
Result : equivocal
Target Organs : Liver
Remarks : Based on data from similar materials
The mechanism or mode of action may not be relevant in humans.

Titanium dioxide:

Species : Rat
Application Route : inhalation (dust/mist/fume)
Exposure time : 2 Years
Method : OECD Test Guideline 453
Result : positive
Remarks : The mechanism or mode of action may not be relevant in humans.

Carcinogenicity - Assessment : Limited evidence of carcinogenicity in inhalation studies with animals.

SAFETY DATA SHEET

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



ORGANON

Desloratadine Solid Formulation

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

Cellulose:

Species : Rat
Application Route : Ingestion
Exposure time : 72 weeks
Result : negative

Talc:

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

Reproductive toxicity

Suspected of damaging fertility. Suspected of damaging the unborn child.

Components:

Desloratadine:

Effects on fertility : Test Type: Fertility
Species: Rat, male
Application Route: Oral
Fertility: LOAEL: 12 mg/kg body weight
Symptoms: Reduced fertility
Result: positive
Remarks: The mechanism or mode of action may not be relevant in humans.

Test Type: Fertility
Species: Rat, female
Fertility: NOAEL: 3 mg/kg body weight
Symptoms: No effects on fertility
Result: negative

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

Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 9 mg/kg body weight
Symptoms: Preimplantation loss, Reduced body weight
Result: Specific developmental abnormalities
Remarks: The mechanism or mode of action may not be relevant in humans.

Test Type: Two-generation study
Species: Rat
Application Route: Oral

SAFETY DATA SHEET

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



Desloratadine Solid Formulation

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

	Developmental Toxicity: LOAEL: 18 mg/kg body weight Result: No adverse effects
Reproductive toxicity - Assessment	: Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Some evidence of adverse effects on development, based on animal experiments.
Cellulose:	
Effects on fertility	: Test Type: One-generation reproduction toxicity study Species: Rat Application Route: Ingestion Result: negative
Effects on foetal development	: Test Type: Fertility/early embryonic development Species: Rat Application Route: Ingestion Result: negative
Talc:	
Effects on foetal development	: Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Result: negative

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

Desloratadine:

Species	: Rat
LOAEL	: 30 mg/kg
Application Route	: Oral
Exposure time	: 3 Months
Target Organs	: Kidney
Remarks	: Significant toxicity observed in testing The mechanism or mode of action may not be relevant in humans.
Species	: Monkey
NOAEL	: 6 mg/kg
LOAEL	: 12 mg/kg
Application Route	: Oral
Exposure time	: 3 Months
Target Organs	: Central nervous system

SAFETY DATA SHEET

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



ORGANON

Desloratadine Solid Formulation

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

|| Symptoms : Gastrointestinal disturbance
|| Species : Monkey
|| NOAEL : 40 mg/kg
|| Application Route : Oral
|| Exposure time : 17 Months
|| Remarks : No significant adverse effects were reported

|| Species : Monkey
|| NOAEL : 6 mg/kg
|| Application Route : Oral
|| Exposure time : 3 Months
|| Symptoms : Gastrointestinal disturbance, Fatigue

Titanium dioxide:

|| Species : Rat
|| NOAEL : 24.000 mg/kg
|| Application Route : Ingestion
|| Exposure time : 28 Days

|| Species : Rat
|| NOAEL : 10 mg/m³
|| Application Route : inhalation (dust/mist/fume)
|| Exposure time : 2 yr

Cellulose:

|| Species : Rat
|| NOAEL : >= 9.000 mg/kg
|| Application Route : Ingestion
|| Exposure time : 90 Days

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

SAFETY DATA SHEET

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



Desloratadine Solid Formulation

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

SECTION 12: Ecological information

12.1 Toxicity

Components:

Desloratadine:

Toxicity to fish	:	LC50 (Lepomis macrochirus (Bluegill sunfish)): 9,2 mg/l Exposure time: 96 h Method: FDA 4.11
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 9,6 mg/l Exposure time: 48 h Method: FDA 4.08
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): 1,6 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 NOEC (Pseudokirchneriella subcapitata (green algae)): 0,36 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to microorganisms	:	EC50 (Natural microorganism): 53,7 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209 NOEC (Natural microorganism): 12 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209
Toxicity to fish (Chronic toxicity)	:	NOEC: 0,12 mg/l Exposure time: 32 d Species: Pimephales promelas (fathead minnow) Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC: 0,48 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211

Titanium dioxide:

Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other	:	EC50 (Daphnia magna (Water flea)): > 100 mg/l

SAFETY DATA SHEET

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



Desloratadine Solid Formulation

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

aquatic invertebrates	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
Cellulose:	
Toxicity to fish	: LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l Exposure time: 48 h Remarks: Based on data from similar materials
Talc:	
Toxicity to fish	: LC50 (Brachydanio rerio (zebrafish)): > 100.000 mg/l Exposure time: 24 h

12.2 Persistence and degradability

Components:

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

Cellulose:

Biodegradability	: Result: Readily biodegradable.
------------------	----------------------------------

12.3 Bioaccumulative potential

Components:

Desloratadine:

Partition coefficient: n-octanol/water	: log Pow: 1,24 Method: OECD Test Guideline 107
--	--

SAFETY DATA SHEET

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



ORGANON

Desloratadine Solid Formulation

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

12.4 Mobility in soil

Components:

Desloratadine:

Distribution among environmental compartments : log Koc: 3,00
Method: OECD Test Guideline 106

12.5 Results of PBT and vPvB assessment

Not relevant

12.6 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

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

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

SECTION 14: Transport information

14.1 UN number

Not regulated as a dangerous good

14.2 UN proper shipping name

Not regulated as a dangerous good

14.3 Transport hazard class(es)

Not regulated as a dangerous good

14.4 Packing group

Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

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

Remarks : Not applicable for product as supplied.

SAFETY DATA SHEET

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



ORGANON

Desloratadine Solid Formulation

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

SECTION 15: Regulatory information

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

KKDIK (30105 (Bis)) - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex 17) : Not applicable

Regulation on Persistent Organic Pollutants (Number 30595) : Not applicable

Regulation on prevention of major industrial accidents. Reg number 30702 : Not applicable

Other regulations:

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

Regulation on Classification, Labelling and Packaging of Substances and Mixtures. Dated 11 December 2013, Numbered 28848 (Bis) Ministry of Environment and Forestry.

Regulation on Dust Control (No: 28812, 2013). Occupational Dust Exposure Limit Values (Annex 1)

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

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16: Other information

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

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

Full text of H-Statements

H302 : Harmful if swallowed.

H318 : Causes serious eye damage.

H351 : Suspected of causing cancer if inhaled.

H361fd : Suspected of damaging fertility. Suspected of damaging the unborn child.

H411 : Toxic to aquatic life with long lasting effects.

The Turkish SDS has been prepared according to the Regulation on Safety Data Sheets for Hazardous Substances and Mixtures No. 29204.

SAFETY DATA SHEET

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



ORGANON

Desloratadine Solid Formulation

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

Full text of other abbreviations

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

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance 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

Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Classification of the mixture:

Eye Dam. 1 H318

Classification procedure:

Calculation method

SAFETY DATA SHEET

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



Desloratadine Solid Formulation

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

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

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

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

TR / EN