

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Desloratadine Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
3.1	02.10.2020	51001-00014	Date of first issue: 23.01.2015

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 Sub-
stance/Mixture : Pharmaceutical

1.3 Details of the supplier of the safety data sheet

Company : MSD
Shotton Lane
NE23 3JU Cramlington NU - Great Britain

Telephone : 44 1 670 59 30 00

Telefax : 908-735-1496

E-mail address of person
responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Serious eye damage, Category 1	H318: Causes serious eye damage.
Reproductive toxicity, Category 2	H361fd: Suspected of damaging fertility. Suspected of damaging the unborn child.
Long-term (chronic) aquatic hazard, Category 3	H412: Harmful to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Danger

Hazard statements : H318 Causes serious eye damage.
H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.
H412 Harmful to aquatic life with long lasting effects.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Desloratadine Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
3.1	02.10.2020	51001-00014	Date of first issue: 23.01.2015

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/ doctor.
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

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

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).

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Desloratadine Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
3.1	02.10.2020	51001-00014	Date of first issue: 23.01.2015

- | | | |
|-------------------------|---|---|
| If inhaled | : | If inhaled, remove to fresh air.
Get medical attention. |
| In case of skin contact | : | In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse. |
| In case of eye contact | : | In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.
If easy to do, remove contact lens, if worn.
Get medical attention immediately. |
| If swallowed | : | If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water. |

4.2 Most important symptoms and effects, both acute and delayed

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

4.3 Indication of any immediate medical attention and special treatment needed

- | | | |
|-----------|---|---|
| Treatment | : | Treat symptomatically and supportively. |
|-----------|---|---|

SECTION 5: Firefighting measures

5.1 Extinguishing media

- | | | |
|--------------------------------|---|--|
| Suitable extinguishing media | : | Water spray
Alcohol-resistant foam
Carbon dioxide (CO ₂)
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 |

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Desloratadine Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
3.1	02.10.2020	51001-00014	Date of first issue: 23.01.2015

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.

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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Desloratadine Solid Formulation

Version 3.1 Revision Date: 02.10.2020 SDS Number: 51001-00014 Date of last issue: 23.03.2020
Date of first issue: 23.01.2015

Local/Total ventilation : and bonding, or inert atmospheres.
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 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:
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
Starch, oxidized	65996-62-5	TWA (inhalable dust)	3 mg/m ³	FOR-2011-12-06-1358
Further information: The limit value for flour dust is established as inhalable dust, Substances considered to evoke allergies when coming into touch with the eyes or airways or evoking allergies after coming into contact with the skin				
Desloratadine	100643-71-8	TWA	20 µg/m ³ (OEB 3)	Internal
		Wipe limit	200 µg/100 cm ²	Internal
Talc	14807-96-6	TWA (respirable dust)	2 mg/m ³	FOR-2011-12-06-1358
		TWA (total dust)	6 mg/m ³	FOR-2011-12-06-1358

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Desloratadine Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
3.1	02.10.2020	51001-00014	Date of first issue: 23.01.2015

Titanium dioxide	13463-67-7	TWA	5 mg/m3	FOR-2011-12-06-1358
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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 NS EN 166
Hand protection	:	
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 NS 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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Desloratadine Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
3.1	02.10.2020	51001-00014	Date of first issue: 23.01.2015

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
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.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Desloratadine Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
3.1	02.10.2020	51001-00014	Date of first issue: 23.01.2015

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

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

10.4 Conditions to avoid

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

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

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

Acute toxicity

Not classified based on available information.

Product:

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

Components:

Desloratadine:

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

Skin corrosion/irritation

Not classified based on available information.

Components:

Desloratadine:

Species : Rabbit
Result : No skin irritation

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Desloratadine Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
3.1	02.10.2020	51001-00014	Date of first issue: 23.01.2015

Serious eye damage/eye irritation

Causes serious eye damage.

Components:

Desloratadine:

Species	:	Rabbit
Remarks	:	Severe 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

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

Carcinogenicity

Not classified based on available information.

Components:

Desloratadine:

Species	:	Mouse
Application Route	:	Oral

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Desloratadine Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
3.1	02.10.2020	51001-00014	Date of first issue: 23.01.2015

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.

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.
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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
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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
Developmental Toxicity: LOAEL: 18 mg/kg body weight
Result: No adverse effects

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Desloratadine Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
3.1	02.10.2020	51001-00014	Date of first issue: 23.01.2015

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.

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
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

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Desloratadine:

Inhalation : Remarks: May cause respiratory tract irritation.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Desloratadine Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
3.1	02.10.2020	51001-00014	Date of first issue: 23.01.2015

Eye contact	: Symptoms: Eye irritation
Ingestion	: Symptoms: dry mouth, muscle pain, Fatigue, Drowsiness, sore throat, painful menstruation

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

12.2 Persistence and degradability

Components:

Desloratadine:

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Desloratadine Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
3.1	02.10.2020	51001-00014	Date of first issue: 23.01.2015

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

12.3 Bioaccumulative potential

Components:

Desloratadine:

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

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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Desloratadine Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
3.1	02.10.2020	51001-00014	Date of first issue: 23.01.2015

14.2 UN proper shipping name

Not regulated as a dangerous good

14.3 Transport hazard class(es)

Not regulated as a dangerous good

14.4 Packing group

Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

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

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Not applicable

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.
Not applicable

Other regulations:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

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

AICS : not determined

DSL : not determined

IECSC : not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Desloratadine Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
3.1	02.10.2020	51001-00014	Date of first issue: 23.01.2015

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.

Full text of H-Statements

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

Full text of other abbreviations

Acute Tox. : Acute toxicity
Aquatic Chronic : Long-term (chronic) aquatic hazard
Eye Dam. : Serious eye damage
Repr. : Reproductive toxicity
FOR-2011-12-06-1358 : Norway. Occupational Exposure limits
FOR-2011-12-06-1358 / TWA : Long term exposure limit

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; AIIC - 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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Desloratadine Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
3.1	02.10.2020	51001-00014	Date of first issue: 23.01.2015

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
Repr. 2	H361fd
Aquatic Chronic 3	H412

Classification procedure:

Calculation method
Calculation method
Calculation method

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.

NO / EN