

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

1.1. Product identifier

Product form	: Substance
Substance name	: Desloratadine for system suitability
Chemical name	: Desloratadine
CAS-No.	: 100643-71-8
Product code	: 202500585

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

Relevant identified uses

Use of the substance/mixture	: Scientific research and development Technical testing and analysis For professional use only
Function or use category	: Laboratory chemicals

Uses advised against

Restrictions on use	: Not for food, drug or home use
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1.3. Details of the supplier of the safety data sheet

European Directorate for the Quality of Medicines & Healthcare
EDQM, Council of Europe
7, Allée Kastner, CS30026
F 67081 Strasbourg
France
T +33(0)388412035, F +33(0)388412771
sds@edqm.eu, www.edqm.eu

1.4. Emergency telephone number

Emergency number	: +33(0)390215608
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SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Acute toxicity (oral), Category 4	H302
Serious eye damage/eye irritation, Category 1	H318
Reproductive toxicity, Category 2	H361f
Hazardous to the aquatic environment – Chronic Hazard, Category 2	H411

Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

Harmful if swallowed. Toxic to aquatic life with long lasting effects. Suspected of damaging fertility. Causes serious eye damage.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP)



Signal word (CLP)

: Danger

Hazard statements (CLP)

: H302 - Harmful if swallowed.
H318 - Causes serious eye damage.

Desloratadine for system suitability

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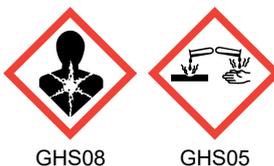
according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Precautionary statements (CLP)

- H361f - Suspected of damaging fertility.
H411 - Toxic to aquatic life with long lasting effects.
- : P201 - Obtain special instructions before use.
P202 - Do not handle until all safety precautions have been read and understood.
P264 - Wash hands, forearms and face thoroughly after handling.
P270 - Do not eat, drink or smoke when using this product.
P273 - Avoid release to the environment.
P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P301+P312 - IF SWALLOWED: Call a POISON CENTRE or doctor if you feel unwell.
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308+P313 - IF exposed or concerned: Get medical advice/attention.
P310 - Immediately call a POISON CENTER or doctor.
P330 - Rinse mouth.
P391 - Collect spillage.
P405 - Store locked up.
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Labelling according to: Exemption for inner packaging where the contents do not exceed 10ml.

Hazard pictograms (CLP)



2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Desloratadine	CAS-No.: 100643-71-8	≤ 100	Acute Tox. 4 (Oral), H302 (ATE=500 mg/kg bodyweight) Eye Dam. 1, H318 Repr. 2, H361f Aquatic Chronic 2, H411

Full text of H- and EUH-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

- First-aid measures general : In all cases of doubt, or when symptoms persist, seek medical attention.
- First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. Allow the victim to rest. If the person feels unwell : Get medical advice/attention.
- First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
- First-aid measures after eye contact : Rinse immediately and thoroughly, pulling the eyelids well away from the eye (15 minutes minimum). Remove contact lenses, if present and easy to do. Continue rinsing. Consult an eye specialist immediately.
- First-aid measures after ingestion : Rinse mouth out with water (only if the person is conscious). Never give anything by mouth to an unconscious person. Immediately call a POISON CENTER/doctor.

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according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects after eye contact : Causes serious eye damage. Redness, pain.

4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire. Carbon dioxide. Water spray. Dry powder. Extinguishing blanket.

Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Incomplete combustion releases dangerous carbon monoxide, carbon dioxide and other toxic gases. Toxic fumes may be released.

5.3. Advice for firefighters

Firefighting instructions : Prevent fire fighting water from entering the environment.

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Avoid contact with skin, eyes and clothing.

For non-emergency personnel

Emergency procedures : Evacuate unnecessary personnel.

For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

For containment : Absorb with an inert material and place in an appropriate waste disposal container.

Methods for cleaning up : Clean contaminated surfaces with an excess of water. Clean with the help of detergents.

6.4. Reference to other sections

See Section 13 for disposal information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Additional hazards when processed : Do not expose pregnant or breastfeeding women.

Precautions for safe handling : Avoid all unnecessary exposure. Ensure good ventilation of the work station.

Hygiene measures : Do not eat, drink or smoke when using this product. Contaminated work clothing should not be allowed out of the workplace. Wash hands before work breaks and after finishing work.

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according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	: Store in a well-ventilated place. Keep container tightly closed. Keep away from heat and direct sunlight.
Packaging materials	: Keep in original containers.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station. Both local exhaust and general room ventilation are usually required. Material should be handled in a laboratory hood whenever possible.

Personal protection equipment

Eye and face protection

Eye protection:

Wear eye protection. Safety glasses with side shields. (EN 166)

Skin protection

Skin and body protection:

Wear suitable protective clothing. Laboratory use : Lab coat. (EN 13034)

Hand protection:

Wear suitable gloves. Chemically resistant protective gloves. (EN 374)

Respiratory protection

Respiratory protection:

In case of dust formation use respirator with filter: P3

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: white. almost white.
Appearance	: Powder.
Molecular mass	: 310,8 g/mol
Odour	: Not available
Odour threshold	: Not available
Melting point	: ≈ 150 °C
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not available
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: Not available
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Water: < 0,1 g/l

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according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Partition coefficient n-octanol/water (Log Kow)	: Not available
Partition coefficient n-octanol/water (Log Pow)	: < 4
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not applicable
Particle size	: Not available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

No additional information available

10.3. Possibility of hazardous reactions

No additional information available

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

No additional information available

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Harmful if swallowed.
Acute toxicity (dermal)	: Not classified (Lack of data)
Acute toxicity (inhalation)	: Not classified (Lack of data)

Desloratadine (100643-71-8)

LD50 oral rat	> 300 – ≤ 2000 mg/kg (estimated value)
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Skin corrosion/irritation	: Not classified (Based on available data, the classification criteria are not met)
Serious eye damage/irritation	: Causes serious eye damage.
Respiratory or skin sensitisation	: Not classified (Based on available data, the classification criteria are not met)
Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (Based on available data, the classification criteria are not met)
Reproductive toxicity	: Suspected of damaging fertility.
STOT-single exposure	: Not classified (Based on available data, the classification criteria are not met)
STOT-repeated exposure	: Not classified (Based on available data, the classification criteria are not met)
Aspiration hazard	: Not classified (Lack of data)

11.2. Information on other hazards

No additional information available

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according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute) : Not classified (Based on available data, the classification criteria are not met)

Hazardous to the aquatic environment, long-term (chronic) : Toxic to aquatic life with long lasting effects.

Desloratadine (100643-71-8)	
LC50 - Fish [1]	9,2 mg/l (96 Hours, Lepomis macrochirus (Bluegill)) (FDA 4.11)
EC50 - Crustacea [1]	9,6 mg/l (48 Hours, Daphnia magna (Water flea)) (FDA 4.08)
EC50 72h - Algae [1]	1,6 mg/l (72 Hours, Pseudokirchneriella subcapitata (Green algae)) (FDA 4.08)
NOEC chronic fish	0,12 mg/l (32 days, Pimephales promelas) (OECD 210 method)
NOEC chronic crustacea	0,48 mg/l (21 days, Daphnia magna (Water flea)) (OECD 211 method)

12.2. Persistence and degradability

Desloratadine (100643-71-8)	
Persistence and degradability	Not rapidly degradable

12.3. Bioaccumulative potential

Desloratadine (100643-71-8)	
Partition coefficient n-octanol/water (Log Pow)	< 4

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

No additional information available

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA

ADR	IMDG	IATA
14.1. UN number or ID number		
UN 3077	UN 3077	UN 3077

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according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

ADR	IMDG	IATA
14.2. UN proper shipping name		
ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.	Environmentally hazardous substance, solid, n.o.s.
Transport document description		
UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., 9, III, (-)	UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., 9, III, MARINE POLLUTANT	UN 3077 Environmentally hazardous substance, solid, n.o.s., 9, III
14.3. Transport hazard class(es)		
9	9	9
		
14.4. Packing group		
III	III	III
14.5. Environmental hazards		
Dangerous for the environment: Yes	Dangerous for the environment: Yes Marine pollutant: Yes EmS-No. (Fire): F-A EmS-No. (Spillage): S-F	Dangerous for the environment: Yes
No supplementary information available		

14.6. Special precautions for user

Overland transport

Classification code (ADR)	: M7
Special provisions (ADR)	: 274, 335, 375, 601
Limited quantities (ADR)	: 5kg
Excepted quantities (ADR)	: E1
Packing instructions (ADR)	: P002, IBC08, LP02, R001
Special packing provisions (ADR)	: PP12, B3
Mixed packing provisions (ADR)	: MP10
Portable tank and bulk container instructions (ADR)	: T1, BK1, BK2, BK3
Portable tank and bulk container special provisions (ADR)	: TP33
Tank code (ADR)	: SGAV, LGBV
Vehicle for tank carriage	: AT
Transport category (ADR)	: 3
Special provisions for carriage - Packages (ADR)	: V13
Special provisions for carriage - Bulk (ADR)	: VC1, VC2
Special provisions for carriage - Loading, unloading and handling (ADR)	: CV13
Hazard identification number (Kemler No.)	: 90
Orange plates	: 
Tunnel restriction code (ADR)	: -

Transport by sea

Special provisions (IMDG)	: 274, 335, 375, 966, 967, 969
Limited quantities (IMDG)	: 5 kg
Excepted quantities (IMDG)	: E1
Packing instructions (IMDG)	: LP02, P002

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Special packing provisions (IMDG)	: PP12
IBC packing instructions (IMDG)	: IBC08
IBC special provisions (IMDG)	: B3
Tank instructions (IMDG)	: BK1, BK2, BK3, T1
Tank special provisions (IMDG)	: TP33
Stowage category (IMDG)	: A
Stowage and handling (IMDG)	: SW23

Air transport

PCA Excepted quantities (IATA)	: E1
PCA Limited quantities (IATA)	: Y956
PCA limited quantity max net quantity (IATA)	: 30kgG
PCA packing instructions (IATA)	: 956
PCA max net quantity (IATA)	: 400kg
CAO packing instructions (IATA)	: 956
CAO max net quantity (IATA)	: 400kg
Special provisions (IATA)	: A97, A158, A179, A197, A215
ERG code (IATA)	: 9L

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

EU-Regulations

REACH Annex XVII (Restriction List)

Not listed on REACH Annex XVII

REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

Council Regulation (EC) for the control of dual-use items

Not listed on the COUNCIL REGULATION (EC) of dual-use items.

Explosives Precursors Regulation (EU 2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (EC 273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

Full text of H- and EUH-statements:

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Chronic 2	Hazardous to the aquatic environment – Chronic Hazard, Category 2
Eye Dam. 1	Serious eye damage/eye irritation, Category 1

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according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Full text of H- and EUH-statements:

H302	Harmful if swallowed.
H318	Causes serious eye damage.
H361f	Suspected of damaging fertility.
H411	Toxic to aquatic life with long lasting effects.
Repr. 2	Reproductive toxicity, Category 2

Safety Data Sheet (SDS), EU

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