

Desloratadine Syrup Formulation

Version 1.0 Revision Date: 2026/04/06 SDS Number: 300000003730 Date of last issue: -
Date of first issue: 2026/04/06

SECTION 1. IDENTIFICATION

Product identifier : Desloratadine Syrup Formulation

Other means of identification : DESALEX® (desloratadine) Syrup
Prescription Medicine

Manufacturer or supplier's details

Company : Organon & Co.

Address : Rua Treze de Maio, 1161
Campinas, São Paulo, Brazil 13106-054

Telephone : +1 551-430-6000 US | +55 (19) 3758-2000 BR

Emergency telephone : For 24/7 emergency response advice, call CHEMTREC at +55
11 4349-1359 (Local) or 0800 892 0479 (toll-free). Global 24/7:
+1-800-424-9300 (United States, English only).

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Restrictions on use : To be dispensed by or on the prescription of physician.

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification of the substance or mixture in accordance with ABNT NBR 14725 Standard

Not classified as hazardous in accordance with ABNT NBR 14725

GHS label elements in accordance with ABNT NBR 14725 Standard

Not classified as hazardous in accordance with ABNT NBR 14725

Other hazards which do not result in classification

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Classification	Concentration (% w/w)
Desloratadine	100643-71-8	Acute Tox. (Oral), 4 Eye Dam., 1 Repr., 2 Aquatic Acute, 2 Aquatic Chronic, 2	0,05
Sucrose	57-50-1		45 -50

Desloratadine Syrup Formulation

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	2026/04/06	300000003730	Date of first issue: 2026/04/06

SECTION 4. FIRST AID MEASURES

Description of necessary first-aid measures

- If inhaled : If inhaled, remove to fresh air.
Get medical attention if symptoms occur.
- In case of skin contact : Wash with water and soap as a precaution.
Get medical attention if symptoms occur.
- In case of eye contact : Flush eyes with water as a precaution.
Get medical attention if irritation develops and persists.
- If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention if symptoms occur.
Rinse mouth thoroughly with water.
- Most important symptoms and effects, both acute and delayed : Reference Section 11: Experience with human exposure.
- Protection of first-aiders : No special precautions are necessary for first aid responders.

Indication of any immediate medical attention and special treatment needed

- Notes to physician : Treat symptomatically and supportively.
-

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 : Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides
Water
- Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do so.
Evacuate area.
- Special protective equipment for fire-fighters : Wear self-contained breathing apparatus for firefighting if necessary.
Use personal protective equipment.
-

SECTION 6. ACCIDENTAL RELEASE MEASURES

Desloratadine Syrup Formulation

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	2026/04/06	300000003730	Date of first issue: 2026/04/06

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

Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Prevent spreading over a wide area (e.g., by containment or oil barriers).
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 : Soak up with inert absorbent material.
For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.
Clean up remaining materials from spill with suitable absorbent.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : Use only with adequate ventilation.

Advice on safe handling : Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
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 labeled containers.
Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:
Strong oxidizing agents
Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Desloratadine Syrup Formulation

Version 1.0 Revision Date: 2026/04/06 SDS Number: 300000003730 Date of last issue: -
Date of first issue: 2026/04/06

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Desloratadine	100643-71-8	TWA	20 µg/m ³ (OEB 3)	Internal
		Wipe limit	200 µg/100 cm ²	Internal
Sucrose	57-50-1	TWA	10 mg/m ³	ACGIH

Engineering measures : Ensure adequate ventilation, especially in confined areas. Minimize workplace exposure concentrations.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Dust/mist/aerosol
No personal respiratory protective equipment normally required.

Hand protection

Remarks : Chemical-resistant gloves Wash hands before breaks and at the end of workday.

Eye protection : Wear the following personal protective equipment:
Safety glasses

Skin and body protection : Skin should be washed after contact.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : liquid

Color : clear

Odor : sweet

Odor Threshold : No data available

pH : 5 - 6

Melting point/freezing point : Not applicable

Initial boiling point and boiling range : No data available

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Upper explosion limit / Upper flammability limit : No data available

Desloratadine Syrup Formulation

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	2026/04/06	300000003730	Date of first issue: 2026/04/06

Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Relative density	:	No data available
Density	:	No data available
Solubility(ies)		
Water solubility	:	soluble
Partition coefficient: n-octanol/water	:	Not applicable
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	Not applicable
Particle characteristics		
Particle size	:	Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Can react with strong oxidizing agents.
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure	:	Inhalation Skin contact
--	---	----------------------------

Desloratadine Syrup Formulation

Version 1.0 Revision Date: 2026/04/06 SDS Number: 300000003730 Date of last issue: -
Date of first issue: 2026/04/06

Ingestion
Eye contact

Acute toxicity

Based on available data, the classification criteria are not met.

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.

Sucrose:

Acute oral toxicity : LD50 (Rat): 29.700 mg/kg

Skin corrosion/irritation

Based on available data, the classification criteria are not met.

Components:

Desloratadine:

Species : Rabbit
Result : No skin irritation

Serious eye damage/eye irritation

Based on available data, the classification criteria are not met.

Components:

Desloratadine:

Species : Rabbit
Remarks : Severe eye irritation

Respiratory or skin sensitization

Skin sensitization

Based on available data, the classification criteria are not met.

Respiratory sensitization

Not classified due to lack of data.

Components:

Desloratadine:

Test Type : Maximization Test
Routes of exposure : Dermal

Desloratadine Syrup Formulation

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	2026/04/06	300000003730	Date of first issue: 2026/04/06

Species : Guinea pig
Result : negative

Germ cell mutagenicity

Based on available data, the classification criteria are not met.

Components:**Desloratadine:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay
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

Sucrose:

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

Carcinogenicity

Based on available data, the classification criteria are not met.

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.

Reproductive toxicity

Based on available data, the classification criteria are not met.

Desloratadine Syrup Formulation

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	2026/04/06	300000003730	Date of first issue: 2026/04/06

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

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

Test Type: Two-generation study
 Species: Rat
 Application Route: Oral
 Developmental Toxicity: LOAEL: 18 mg/kg body weight
 Result: No adverse effects.

Reproductive toxicity - Assessment : Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Some evidence of adverse effects on development, based on animal experiments.

STOT-single exposure

Not classified due to lack of data.

STOT-repeated exposure

Based on available data, the classification criteria are not met.

Desloratadine Syrup Formulation

Version 1.0 Revision Date: 2026/04/06 SDS Number: 300000003730 Date of last issue: -
Date of first issue: 2026/04/06

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

Aspiration toxicity

Not classified due to lack of data.

Components:

Desloratadine:

Not applicable

Experience with human exposure

Product:

Inhalation : Remarks: May cause respiratory tract irritation.
Eye contact : Symptoms: Eye irritation
Ingestion : Symptoms: dry mouth, muscle pain, fatigue, Drowsiness, sore throat, painful menstration

Endocrine disrupting properties

Product:

Assessment : Does not have endocrine disrupting properties for human health.

Desloratadine Syrup Formulation

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	2026/04/06	300000003730	Date of first issue: 2026/04/06

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

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 fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 0,12 mg/l
Exposure time: 32 d
Method: OECD Test Guideline 210
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0,48 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211
- Toxicity to microorganisms : EC50 (Natural microorganism): 53,7 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
- NOEC (Natural microorganism): 12 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

Persistence and degradability

Components:

Desloratadine:

- Biodegradability : Result: Not readily biodegradable.
Biodegradation: 67,4 %
Exposure time: 28 d

Desloratadine Syrup Formulation

Version 1.0 Revision Date: 2026/04/06 SDS Number: 300000003730 Date of last issue: -
Date of first issue: 2026/04/06

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

Sucrose:

Partition coefficient: n-octanol/water : Pow: < 1

Mobility in soil

Components:

Desloratadine:

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

Other adverse effects

Endocrine disrupting properties

Product:

Assessment : Does not have endocrine disrupting properties for the environment.

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Dispose of in accordance with local regulations.
Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

Desloratadine Syrup Formulation

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	2026/04/06	300000003730	Date of first issue: 2026/04/06

UNRTDG

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

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

Not applicable for product as supplied.

Domestic regulation**ANTT**

Not regulated as a dangerous good

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION**Safety, health and environmental regulations/legislation specific for the substance or mixture**

National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable

Brazil. List of chemicals controlled by the Federal Police : Not applicable

Brazil. List of Narcotics (ANVISA Ordinance No. 344/98, Annex I, Lists A1 & A2), as amended : Not applicable

Brazil. Restricted Retinoid, Immunosuppressant, Anabolic, and other Substances (ANVISA Ordinance No. 344/98, Annex I, Lists C1, C2, C3 and C5), as amended : Not applicable

Brazil. Precursors Subject to Control (ANVISA Ordinance No. 344/98, Annex I, List D1), as amended : Not applicable

Brazil. Chemical for the Production of Narcotics and Psychotropic (ANVISA Ordinance No. 344/98, Annex I, List D2), as amended : Not applicable

Brazil. Prohibited Narcotics, Psychotropics and other Substances (ANVISA Ordinance No. 344/98, Annex I, Lists F1, F2 & List F4), as amended : Not applicable

Brazil. Prohibited Precursors (ANVISA Ordinance No. 344/98, Annex I, List F3), as amended : Not applicable

Desloratadine Syrup Formulation

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	2026/04/06	300000003730	Date of first issue: 2026/04/06

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

AICS : not determined

CA. DSL : not determined

CN IECSC : not determined

SECTION 16. OTHER INFORMATION

Revision Date : 2026/04/06

Date format : yyyy/mm/dd

Further informationSources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>**Full text of other abbreviations**

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

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

AIC - 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 Standardization; 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 Organization 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; MERCOSUR - The Agreement for the Facilitation of the Transport of Dangerous Goods; 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, Authorization 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

Desloratadine Syrup Formulation

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	2026/04/06	300000003730	Date of first issue: 2026/04/06

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 given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

BR / EN