

Desloratadine Liquid Formulation

Version 1.15 Revision Date: 2025/07/01 SDS Number: 300000008252 Date of last issue: 2023/09/30
Date of first issue: 2016/06/23

SECTION 1. IDENTIFICATION

Product identifier : Desloratadine Liquid Formulation

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 : Not applicable

SECTION 2. HAZARDS IDENTIFICATION**GHS Classification 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	$\geq 0,025$ - $< 0,1$

SECTION 4. 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.

Desloratadine Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
1.15	2025/07/01	300000008252	Date of first issue: 2016/06/23

In case of eye contact	:	Get medical attention if symptoms occur. Flush eyes with water as a precaution.
If swallowed	:	Get medical attention if irritation develops and persists. 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	:	None known.
Protection of first-aiders	:	No special precautions are necessary for first aid responders.
Notes to physician	:	Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

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

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.

Desloratadine Liquid Formulation

Version 1.15 Revision Date: 2025/07/01 SDS Number: 300000008252 Date of last issue: 2023/09/30
 Date of first issue: 2016/06/23

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

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

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 rec-

Desloratadine Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
1.15	2025/07/01	300000008252	Date of first issue: 2016/06/23

Filter type	:	Recommended guidelines, use respiratory protection. Particulates type No personal respiratory protective equipment normally required.
Hand protection	:	
Remarks	:	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	:	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)	:	Not applicable
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
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

Desloratadine Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
1.15	2025/07/01	300000008252	Date of first issue: 2016/06/23

Partition coefficient: n-octanol/water	:	No data available
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	:	No data available
Particle characteristics	:	
Particle size	:	No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous 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
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.

Desloratadine Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/09/30
1.15 2025/07/01 300000008252 Date of first issue: 2016/06/23

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

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

Components:

Desloratadine:

Test Type : Maximization Test
Routes of exposure : Dermal
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

Desloratadine Liquid Formulation

Version 1.15 Revision Date: 2025/07/01 SDS Number: 300000008252 Date of last issue: 2023/09/30
Date of first issue: 2016/06/23

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.

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

Desloratadine Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
1.15	2025/07/01	300000008252	Date of first issue: 2016/06/23

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

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

STOT-repeated exposure

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

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

Desloratadine Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
1.15	2025/07/01	300000008252	Date of first issue: 2016/06/23

Exposure time : 3 Months
Symptoms : Gastrointestinal disturbance, Fatigue

Aspiration toxicity

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

Components:

Desloratadine:

Not applicable

Experience with human exposure

Components:

Desloratadine:

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

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

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) : NOEC (Daphnia magna (Water flea)): 0,48 mg/l
Exposure time: 21 d

Desloratadine Liquid Formulation

Version 1.15 Revision Date: 2025/07/01 SDS Number: 300000008252 Date of last issue: 2023/09/30
Date of first issue: 2016/06/23

ic toxicity) 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
Method: OECD Test Guideline 314

Result: Not readily biodegradable.
Biodegradation: 0 %
Exposure time: 28 d
Method: FDA 3.11

Stability in water : Hydrolysis: < 10 % at 50 °C(5 d)
Method: FDA 3.09

Bioaccumulative potential**Components:****Desloratadine:**

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

Mobility in soil**Components:****Desloratadine:**

Distribution among environ- : log Koc: 3,00
mental compartments Method: OECD Test Guideline 106

Other adverse effects

No data available

Desloratadine Liquid Formulation

Version 1.15 Revision Date: 2025/07/01 SDS Number: 300000008252 Date of last issue: 2023/09/30
Date of first issue: 2016/06/23

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****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

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

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Desloratadine Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
1.15	2025/07/01	300000008252	Date of first issue: 2016/06/23

Revision Date : 2025/07/01
Date format : yyyy/mm/dd

Further information

Sources 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

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information 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