

SAFETY DATA SHEET



Desloratadine Liquid Formulation



Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
8.0	2024/04/06	771472-00018	Date of first issue: 2016/06/23

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Desloratadine Liquid Formulation

Supplier's company name, address and phone number

Company name of supplier : Organon & Co.

Address : 30 Hudson Street, 33rd floor
Jersey City, New Jersey, U.S.A 07302

Telephone : +1-551-430-6000

E-mail address : EHSSTEWARD@organon.com

Emergency telephone number : +1-215-631-6999

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

GHS classification of chemical product

Not a hazardous substance or mixture according to the Globally Harmonised System (GHS).

GHS label elements

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required

Other hazards which do not result in classification

None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
Propylene glycol	57-55-6	$\geq 10 - < 20$	2-234
Desloratadine	100643-71-8	$\geq 0.025 - < 0.1$	
Ethylenediaminetetraacetic acid disodium salt	139-33-3	< 0.1	2-1265

4. FIRST AID MEASURES

Desloratadine Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
8.0	2024/04/06	771472-00018	Date of first issue: 2016/06/23

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	: None known.
Protection of first-aiders	: No special precautions are necessary for first aid responders.
Notes to physician	: Treat symptomatically and supportively.

5. FIREFIGHTING 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
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 firefighters	: Wear self-contained breathing apparatus for firefighting if necessary. Use personal protective equipment.

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	Revision Date:	SDS Number:	Date of last issue:
8.0	2024/04/06	771472-00018	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 dyking or other appropriate containment to keep material from spreading. If dyked 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.

7. HANDLING AND STORAGE

Handling

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.

Avoidance of contact : Oxidizing agents

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.

Storage

Conditions for safe storage : Keep in properly labelled containers.
Store in accordance with the particular national regulations.

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

Packaging material : Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

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

SAFETY DATA SHEET



Desloratadine Liquid Formulation



Version 8.0	Revision Date: 2024/04/06	SDS Number: 771472-00018	Date of last issue: 2023/09/30 Date of first issue: 2016/06/23
----------------	------------------------------	-----------------------------	---

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 : Particulates type
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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : liquid

Colour : clear

Odour : sweet

Odour Threshold : No data available

Melting point/freezing point : No data available

Boiling point, initial boiling point and boiling range : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Lower explosion limit and upper explosion limit / flammability limit

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Flash point : No data available

Decomposition temperature : No data available

pH : No data available

Evaporation rate : No data available

Auto-ignition temperature : No data available

SAFETY DATA SHEET



Desloratadine Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
8.0	2024/04/06	771472-00018	Date of first issue: 2016/06/23

Viscosity		
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Solubility(ies)		
Water solubility	:	soluble
Partition coefficient: n-octanol/water	:	No data available
Vapour pressure	:	No data available
Density and / or relative density		
Relative density	:	No data available
Density	:	No data available
Relative vapour density	:	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

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.

11. TOXICOLOGICAL INFORMATION

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

Acute toxicity

Not classified based on available information.

Desloratadine Liquid Formulation



Version	Revision Date:	SDS Number:	Date of last issue:
8.0	2024/04/06	771472-00018	2023/09/30
			Date of first issue: 2016/06/23

Components:**Propylene glycol:**

Acute oral toxicity	: LD50 (Rat): 22,000 mg/kg
Acute inhalation toxicity	: LC50 (Rat): > 44.9 mg/l Exposure time: 4 h Test atmosphere: dust/mist
Acute dermal toxicity	: LD50 (Rabbit): > 2,000 mg/kg Assessment: The substance or mixture has no acute dermal toxicity

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.
---------------------	--

Ethylenediaminetetraacetic acid disodium salt:

Acute oral toxicity	: LD50 (Rat): 2,800 mg/kg
Acute inhalation toxicity	: LC50 (Rat, male): > 1 mg/l Exposure time: 6 h Test atmosphere: dust/mist Method: OECD Test Guideline 412

Skin corrosion/irritation

Not classified based on available information.

Components:**Propylene glycol:**

Species	: Rabbit
Method	: OECD Test Guideline 404
Result	: No skin irritation

Desloratadine:

Species	: Rabbit
Result	: No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Desloratadine Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
8.0	2024/04/06	771472-00018	Date of first issue: 2016/06/23

Components:**Propylene glycol:**

Species	:	Rabbit
Result	:	No eye irritation
Method	:	OECD Test Guideline 405

Desloratadine:

Species	:	Rabbit
Remarks	:	Severe eye irritation

Ethylenediaminetetraacetic acid disodium salt:

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:**Propylene glycol:**

Test Type	:	Maximisation Test
Exposure routes	:	Skin contact
Species	:	Guinea pig
Result	:	negative

Desloratadine:

Test Type	:	Maximisation Test
Exposure routes	:	Dermal
Species	:	Guinea pig
Result	:	negative

Ethylenediaminetetraacetic acid disodium salt:

Test Type	:	Maximisation Test
Exposure routes	:	Skin contact
Species	:	Guinea pig
Method	:	OECD Test Guideline 406
Result	:	negative
Remarks	:	Based on data from similar materials

Germ cell mutagenicity

Not classified based on available information.

Desloratadine Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
8.0	2024/04/06	771472-00018	Date of first issue: 2016/06/23

Components:**Propylene glycol:**

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: Chromosome aberration test in vitro Method: OECD Test Guideline 473 Result: negative
Genotoxicity in vivo	: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Intraperitoneal injection Result: negative

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

Ethylenediaminetetraacetic acid disodium salt:

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative Remarks: Based on data from similar materials Test Type: In vitro mammalian cell gene mutation test Result: negative Test Type: Chromosome aberration test in vitro Result: negative Remarks: Based on data from similar materials
Genotoxicity in vivo	: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Ingestion Method: OECD Test Guideline 474 Result: negative

Desloratadine Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
8.0	2024/04/06	771472-00018	Date of first issue: 2016/06/23

Carcinogenicity

Not classified based on available information.

Components:**Propylene glycol:**

Species	: Rat
Application Route	: Ingestion
Exposure time	: 2 Years
Result	: negative

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.

Ethylenediaminetetraacetic acid disodium salt:

Species	: Rat
Application Route	: Ingestion
Exposure time	: 103 weeks
Result	: negative
Remarks	: Based on data from similar materials

Reproductive toxicity

Not classified based on available information.

Components:**Propylene glycol:**

Effects on fertility	: Test Type: Two-generation reproduction toxicity study Species: Mouse Application Route: Ingestion Result: negative
Effects on foetal development	: Test Type: Embryo-foetal development Species: Mouse Application Route: Ingestion Result: negative

Desloratadine:

Desloratadine Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue:
8.0	2024/04/06	771472-00018	2023/09/30
			Date of first issue: 2016/06/23

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 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.

Ethylenediaminetetraacetic acid disodium salt:

Effects on fertility	: Test Type: Four-generation reproduction toxicity study Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials
Effects on foetal development	: Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Result: negative

Desloratadine Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
8.0	2024/04/06	771472-00018	Date of first issue: 2016/06/23

II

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Components:**Ethylenediaminetetraacetic acid disodium salt:**

Exposure routes	: inhalation (dust/mist/fume)
Target Organs	: Respiratory Tract
Assessment	: May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity**Components:****Propylene glycol:**

Species	: Rat, male
NOAEL	: $\geq 1,700$ mg/kg
Application Route	: Ingestion
Exposure time	: 2 yr

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

Desloratadine Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
8.0	2024/04/06	771472-00018	Date of first issue: 2016/06/23

Application Route	: Oral
Exposure time	: 3 Months
Symptoms	: Gastrointestinal disturbance, Fatigue

Ethylenediaminetetraacetic acid disodium salt:

Species	: Rat
NOAEL	: 500 mg/kg
Application Route	: Ingestion
Exposure time	: 13 Weeks

Species	: Rat
LOAEL	: 0.03 mg/l
Application Route	: inhalation (dust/mist/fume)
Exposure time	: 4 Weeks
Method	: OECD Test Guideline 412

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

12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****Propylene glycol:**

Toxicity to fish	: LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	: ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to daphnia and other aquatic invertebrates (Chron-	: NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l Exposure time: 7 d

Desloratadine Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue:
8.0	2024/04/06	771472-00018	2023/09/30
			Date of first issue: 2016/06/23

ic toxicity)

Toxicity to microorganisms : NOEC (*Pseudomonas putida*): > 20,000 mg/l
Exposure time: 18 h

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

Ethylenediaminetetraacetic acid disodium salt:

Toxicity to fish : LC50 (*Lepomis macrochirus* (Bluegill sunfish)): > 100 mg/l
Exposure time: 96 h
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EC50 (*Daphnia magna* (Water flea)): 140 mg/l
Exposure time: 48 h
Method: DIN 38412

Toxicity to algae/aquatic : ErC50 (*Pseudokirchneriella subcapitata* (green algae)): > 100

Desloratadine Liquid Formulation



Version	Revision Date:	SDS Number:	Date of last issue:
8.0	2024/04/06	771472-00018	2023/09/30
			Date of first issue: 2016/06/23

plants	
	mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: Based on data from similar materials
	EC10 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC (Daphnia magna (Water flea)): 25 mg/l Exposure time: 21 d
Toxicity to microorganisms	: EC10 (activated sludge): > 500 mg/l Exposure time: 30 min Method: OECD Test Guideline 209

Persistence and degradability**Components:****Propylene glycol:**

Biodegradability	: Result: Readily biodegradable. Biodegradation: 98.3 % Exposure time: 28 d Method: OECD Test Guideline 301F
------------------	---

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
--------------------	--

Ethylenediaminetetraacetic acid disodium salt:

Biodegradability	: Result: Not readily biodegradable. Biodegradation: 2 % Exposure time: 28 d Method: OECD Test Guideline 301D
------------------	--

Desloratadine Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue:
8.0	2024/04/06	771472-00018	2023/09/30
			Date of first issue: 2016/06/23

Bioaccumulative potential**Components:****Propylene glycol:**

Partition coefficient: n-octanol/water	:	log Pow: -1.07 Method: Regulation (EC) No. 440/2008, Annex, A.8
--	---	--

Desloratadine:

Partition coefficient: n-octanol/water	:	log Pow: 1.24 Method: OECD Test Guideline 107
--	---	--

Ethylenediaminetetraacetic acid disodium salt:

Bioaccumulation	:	Species: Lepomis macrochirus (Bluegill sunfish) Bioconcentration factor (BCF): < 500 Remarks: Based on data from similar materials
-----------------	---	--

Partition coefficient: n-octanol/water	:	log Pow: -4.3
--	---	---------------

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

Distribution among environmental compartments	:	log Koc: 3.00 Method: OECD Test Guideline 106
---	---	--

Hazardous to the ozone layer

Not applicable

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues	:	Dispose of in accordance with local regulations. Do not dispose of waste into sewer.
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.

14. TRANSPORT INFORMATION**International Regulations****UNRTDG**

UN number	:	Not applicable
Proper shipping name	:	Not applicable

SAFETY DATA SHEET



Desloratadine Liquid Formulation



Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
8.0	2024/04/06	771472-00018	Date of first issue: 2016/06/23

Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Environmentally hazardous : no

IATA-DGR

UN/ID No. : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Packing instruction (cargo aircraft) : Not applicable
Packing instruction (passenger aircraft) : Not applicable

IMDG-Code

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
EmS Code : Not applicable
Marine pollutant : Not applicable

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

Not applicable for product as supplied.

National Regulations

Refer to section 15 for specific national regulation.

Special precautions for user

Not applicable

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law

Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law

Priority Assessment Chemical Substance

Chemical name	Number
Propane-1,2-diol	106
Sodium salt of 2,2',2'',2'''-(ethane-1,2-diylidinitrilo)tetraacetic acid	268

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture

Not applicable

Desloratadine Liquid Formulation

Version 8.0	Revision Date: 2024/04/06	SDS Number: 771472-00018	Date of last issue: 2023/09/30 Date of first issue: 2016/06/23
----------------	------------------------------	-----------------------------	---

Harmful Substances Required Permission for Manufacture

Not applicable

Substances Prevented From Impairment of Health

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

Substances Subject to be Notified Names

Article 57-2 (Enforcement Order Table 9)

Chemical name	Concentration (%)	Remarks
propane-1,2-diol	>=10 - <20	From April 1st, 2025

Substances Subject to be Indicated Names

Article 57 (Enforcement Order Article 18)

Chemical name	Remarks
propane-1,2-diol	From April 1st, 2025

Carcinogenic Substances (Article 577-2 of the Occupational Health and Safety Regulations)

Not applicable

Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

Ordinance on Prevention of Lead Poisoning

Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

Ordinance on Prevention of Organic Solvent Poisoning

Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)

Not applicable

Poisonous and Deleterious Substances Control Law

Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

Not applicable

High Pressure Gas Safety Act

Not applicable

Desloratadine Liquid Formulation

Version 8.0	Revision Date: 2024/04/06	SDS Number: 771472-00018	Date of last issue: 2023/09/30 Date of first issue: 2016/06/23
----------------	------------------------------	-----------------------------	---

Explosive Control Law

Not applicable

Vessel Safety Law

Not regulated as a dangerous good

Aviation Law

Not regulated as a dangerous good

Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Not classified as noxious liquid substance

Pack transportation : Not classified as marine pollutant

Narcotics and Psychotropics Control Act

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

Waste Disposal and Public Cleansing Law

Industrial waste

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

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION

In this SDS, if the concentration of substances subject to notification under the Industrial Safety and Health Law is indicated as a range, it includes cases where it is a trade secret.

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/>

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

Date format : yyyy/mm/dd

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

Desloratadine Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
8.0	2024/04/06	771472-00018	Date of first issue: 2016/06/23

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 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.

JP / EN