

according to GB/T 16483 and GB/T 17519

Desloratadine Liquid Formulation

Versic 1.7	on	Revision Date: 2020/10/01		S Number: 466-00008	Date of last issue: 2019/09/13 Date of first issue: 2016/06/23		
1. PR	1. PRODUCT AND COMPANY IDENTIFICATION						
Product name		:	Desloratadine Lic	quid Formulation			
	Manufacturer or supplier's de Company		letai :	ls Organon & Co.			
Address		:	30 Hudson Stree Jersey City, New	t, 33nd floor Jersey, U.S.A 07302			
Т	elepho	one	:	551-430-6000			
E	Emergency telephone number		:	215-631-6999			
E-mail address		:	EHSSTEWARD	@organon.com			
R	Recommended use of the chemical and restrictions on use						

Recommended use of the chemical and restrictions on use

Recommended use	:	Pharmaceutical

2. HAZARDS IDENTIFICATION

Emergency Overview

GHS Classification

Not a hazardous substance or mixture.

GHS label elements

Not a hazardous substance or mixture.

Physical and chemical hazards

Not classified based on available information.

Health hazards

Not classified based on available information.

Environmental hazards

Not classified based on available information.

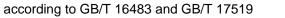
Other hazards which do not result in classification

None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components





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Chen	nical name		CAS-No.	Concentration (% w/w)		
	oratadine		100643-71-8	>= 0.025 -< 0.1		
. FIRST	AID MEASURES					
lf inha	aled		ove to fresh air. Itention if symptom	S OCCUI		
In ca	se of skin contact	: Wash with wat	ter and soap as a p ttention if symptom	precaution.		
In ca	se of eye contact	: Flush eyes wit	h water as a preca	ution.		
If swallowed		: If swallowed, I Get medical at	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.			
	important symptoms effects, both acute and red	: None known.	0,			
Prote	ction of first-aiders			ssary for first aid responders.		
Notes	s to physician	: Treat sympton	Treat symptomatically and supportively.			
. FIREFI	GHTING MEASURES					
Suita	ble extinguishing media	: Water spray Alcohol-resista Carbon dioxide Dry chemical				
Unsu media	itable extinguishing a	: None known.				
Spec fightir	ific hazards during fire- ng	: Exposure to co	Exposure to combustion products may be a hazard to health.			
Haza ucts	rdous combustion prod-	: Carbon oxides	i			
Specific extinguishing meth- ods		cumstances a	ning measures that nd the surrounding ay to cool unopene			
		Remove unda so. Evacuate area	-	from fire area if it is safe to do		
	ial protective equipment efighters	: Wear self-cont essary.		oparatus for firefighting if nec-		
. ACCID	ENTAL RELEASE MEAS	•				
tive e	onal precautions, protec- quipment and emer- y procedures			section 7) and personal pro- ons (see section 8).		
Envir	onmental precautions	Prevent furthe	to the environment r leakage or spillag ding over a wide ar			

barriers).

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			ose of contaminated wash water. s should be advised if significant spillages ained.
	ds and materials for nment and cleaning up	For large spills, ment to keep m be pumped, sto Clean up remai bent. Local or nationa posal of this ma employed in the mine which reg Sections 13 and	ert absorbent material. provide dyking or other appropriate contain- aterial from spreading. If dyked material can re recovered material in appropriate container. ning materials from spill with suitable absor- al regulations may apply to releases and dis- terial, as well as those materials and items e cleanup of releases. You will need to deter- ulations are applicable. d 15 of this SDS provide information regarding national requirements.

7. HANDLING AND STORAGE

Handling

Technical measures Local/Total ventilation Advice on safe handling	:	See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section. Use only with adequate ventilation. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as- sessment Take care to prevent spills, waste and minimize release to the environment.
Avoidance of contact	•	Oxidizing agents
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

Components with workplace control parameters

:

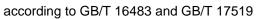
Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Desloratadine	100643-71-8	TWA	20 µg/m3 (OEB 3)	Internal
		Wipe limit	200 µg/100 cm ²	Internal

Engineering measures

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

Personal protective equipment

Respiratory protection :



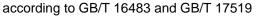


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Filter type Eye/face protection Skin and body protection Hand protection		ommended gu Particulates ty Wear the follo Safety glasses	wing personal protective equipment:
Remarks Hygiene measures		: If exposure to eye flushing s ing place. When using d	before breaks and at the end of workday. chemical is likely during typical use, provide ystems and safety showers close to the work- o not eat, drink or smoke. nated clothing before re-use.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	liquid
Colour	:	clear
Odour	:	sweet
Odour Threshold	:	No data available
рН	:	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
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	No data available





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Solubility(ies) Water solubility		: soluble	
	ition coefficient: n- nol/water	: No data availa	ble
	-ignition temperature	: No data availa	ble
Dec	omposition temperature	: No data availa	ble
	osity /iscosity, dynamic	: No data availa	ble
\vee	iscosity, kinematic	: No data availa	ble
Expl	osive properties	: Not explosive	
Oxic	lizing properties	: The substance	e or mixture is not classified as oxidizing.
Mole	ecular weight	: No data availa	ble
Particle size		: No data availa	ble

10. STABILITY AND REACTIVITY

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

11. TOXICOLOGICAL INFORMATION

Exposure routes	: Inhalation Skin contact Ingestion Eye contact
Acute toxicity	

Not classified based on available information.

Components:

Desloratadine:

Acute oral toxicity	: LD50 (Rat): > 549 mg/kg
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LD50 (Mouse): 353 mg/kg

LD50 (Monkey): > 250 mg/kg Symptoms: Vomiting Remarks: No mortality observed at this dose.

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Skin corrosion/irritation

Not classified based on available information.

Components:

Desloratadine:

Species	:	Rabbit
Result	:	No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Desloratadine:

Species	:	Rabbit
Remarks	:	Severe eye irritation

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Desloratadine:

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

Germ cell mutagenicity

Not classified based on available information.

Components:

Desloratadine:

Genotoxicity in vitro :	Test Type: Bacterial reverse mutation assay (AMES) Result: negative
	Test Type: Chromosomal aberration Test system: Human lymphocytes Result: negative
Genotoxicity in vivo :	Test Type: Micronucleus test Species: Mouse Cell type: Bone marrow Application Route: Oral Result: negative

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Carcinogenicity

Not classified based on available information.

Components:

Desloratadine:

Species Application Route Exposure time Result	:	Mouse Oral 2 Years negative
Species Application Route LOAEL Result Target Organs Remarks		Rat Oral 10 mg/kg body weight equivocal Liver Based on data from similar materials The mechanism or mode of action may not be relevant in hu- mans.

Reproductive toxicity

Not classified based on available information.

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 rele- vant 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 develop- : ment	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

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ersion .7	Revision Date: 2020/10/01	SDS Number: 771466-00008	Date of last issue: 2019/09/13 Date of first issue: 2016/06/23
			c developmental abnormalities mechanism or mode of action may not be rele 3.
		Species: Rat Application Ro	Toxicity: LOAEL: 18 mg/kg body weight
Repro sessn	oductive toxicity - As- nent	fertility, based	e of adverse effects on sexual function and on animal experiments., Some evidence of s on development, based on animal experi-
STOT	- single exposure		
Not cl	lassified based on avai	lable information.	
STOT	- repeated exposure		
Not cl	lassified based on avai	lable information.	
Repe	ated dose toxicity		
<u>Comp</u>	oonents:		
Desic	oratadine:		
Speci LOAE		: Rat : 30 mg/kg	
	cation Route	: Oral	
Expos	sure time	: 3 Months	
l arge Rema	et Organs	: Kidney Significant toxi	city observed in testing
Neme	ans		n or mode of action may not be relevant in hu
Speci	es	: Monkey	
NOAE		: 6 mg/kg	
LOAE Applic	L Cation Route	: 12 mg/kg : Oral	
	sure time	: 3 Months	
	et Organs	: Central nervou	
Symp	otoms	: Gastrointestina	Il disturbance
Speci	00	: Monkey	
NOAE	ΞL	: 40 mg/kg	
NOAE Applic	EL cation Route	: 40 mg/kg : Oral	
NOAE Applic	EL cation Route sure time	: 40 mg/kg : Oral : 17 Months	adverse effects were reported
NOAE Applic Expos Rema Speci	EL cation Route sure time arks es	: 40 mg/kg : Oral : 17 Months	adverse effects were reported
NOAE Applic Expos Rema Speci NOAE	EL cation Route sure time arks es EL	: 40 mg/kg : Oral : 17 Months : No significant a : Monkey : 6 mg/kg	adverse effects were reported
NOAE Applic Expos Rema Speci NOAE Applic	EL cation Route sure time arks es	: 40 mg/kg : Oral : 17 Months : No significant a : Monkey	adverse effects were reported

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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:

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 tox- icity)	:	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 (Chron-ic 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	

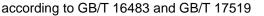
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				spiration inhibition D Test Guideline 209	
Persi	stence and degradab	ility			
<u>Com</u>	oonents:				
Desloratadine: Biodegradability		:	Result: Not readily biodegradable. Biodegradation: 67.4 % Exposure time: 28 d Method: OECD Test Guideline 314		
			Result: Not readily biodegradable. Biodegradation: 0 % Exposure time: 28 d Method: FDA 3.11		
Stabil	ity in water	:	Hydrolysis: < 1 Method: FDA 3	0 % at50 °C(5 d) 3.09	
Bioad	cumulative potential				
Com	oonents:				
Partiti	oratadine: ion coefficient: n- ol/water	:	log Pow: 1.24 Method: OECI) Test Guideline 107	
Mobi	lity in soil				
<u>Com</u>	oonents:				
Distril	pratadine: pution among environ- al compartments	:	log Koc: 3.00 Method: OECI) Test Guideline 106	
	r adverse effects ata available				
. DISPC	SAL CONSIDERATIO	NS			
Dispo	osal methods				
Waste	e from residues aminated packaging	:	Empty contain dling site for re	accordance with local regulations. ers should be taken to an approved waste ha cycling or disposal. e specified: Dispose of as unused product.	

International Regulations





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UNRT Not re	DG gulated as a dangerou	s 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.							
Natio	National Regulations						
	GB 6944/12268 Not regulated as a dangerous good						
	al precautions for us	er					
		211					

15. REGULATORY INFORMATION

National regulatory information Law on the Prevention and Control of Occupational Diseases

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

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

16. OTHER INFORMATION

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 Agen- cy, http://echa.europa.eu/
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 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



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- 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; 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

Disclaimer

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.

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