

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Desloratadine / Pseudoephedrine Formulation

Version 2.4 Revision Date: 09/13/2019 SDS Number: 2111462-00007 Date of last issue: 15.05.2019
Date of first issue: 23.10.2017

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

1.1 Product identifier

Trade name : Desloratadine / Pseudoephedrine Formulation

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

Use of the Sub-stance/Mixture : Pharmaceutical

1.3 Details of the supplier of the safety data sheet

Company : MSD
Shotton Lane
NE23 3JU Cramlington NU - Great Britain

Telephone : 44 1 670 59 30 00

Telefax : 908-735-1496

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

1-908-423-6000

SECTION 2: Hazards identification


2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Specific target organ toxicity - repeated exposure, Category 1 H372: Causes damage to organs through prolonged or repeated exposure.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms : 

Signal word : Danger

Hazard statements : H372 Causes damage to organs through prolonged or repeated exposure.

Precautionary statements : **Prevention:**
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Desloratadine / Pseudoephedrine Formulation

Version 2.4 Revision Date: 09/13/2019 SDS Number: 2111462-00007 Date of last issue: 15.05.2019
Date of first issue: 23.10.2017

Response:

P314 Get medical advice/ attention if you feel unwell.

Hazardous components which must be listed on the label:

Bis[[S-(R*,R*)]-(β-hydroxy-α-methylphenethyl)methylammonium] sulphate

2.3 Other hazards

None known.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Bis[[S-(R*,R*)]-(β-hydroxy-α-methylphenethyl)methylammonium] sulphate	7460-12-0 231-243-2	Acute Tox.4; H302 Acute Tox.4; H332 STOT RE1; H372 STOT RE1; H372	>= 20 - < 30
Disodium EDTA, dihydrate	6381-92-6	Acute Tox.4; H332 STOT RE2; H373	>= 1 - < 10
Citric acid	77-92-9 201-069-1	Eye Irrit.2; H319	>= 1 - < 10
Desloratadine	100643-71-8	Acute Tox.4; H302 Eye Dam.1; H318 Repr.2; H361fd Aquatic Chronic2; H411	>= 0,25 - < 1

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- If inhaled : If inhaled, remove to fresh air.
Get medical attention.
- In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Desloratadine / Pseudoephedrine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 15.05.2019
2.4	09/13/2019	2111462-00007	Date of first issue: 23.10.2017

Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

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.
Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

Risks : Causes damage to organs through prolonged or repeated exposure.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical

Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides
Nitrogen oxides (NO_x)
Metal oxides

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

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.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Desloratadine / Pseudoephedrine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 15.05.2019
2.4	09/13/2019	2111462-00007	Date of first issue: 23.10.2017

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.
Follow safe handling advice and personal protective equipment recommendations.

6.2 Environmental precautions

Environmental precautions : Discharge into the environment must be avoided.
Prevent further leakage or spillage if safe to do so.
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal.
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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

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

Local/Total ventilation : Use only with adequate ventilation.

Advice on safe handling : Do not swallow.
Avoid contact with eyes.
Avoid prolonged or repeated contact with skin.
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.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Desloratadine / Pseudoephedrine Formulation

Version 2.4 Revision Date: 09/13/2019 SDS Number: 2111462-00007 Date of last issue: 15.05.2019
Date of first issue: 23.10.2017

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep in properly labelled containers. Store in accordance with the particular national regulations.

Advice on common storage : Do not store with the following product types:
Strong oxidizing agents
Organic peroxides
Explosives
Gases

7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Bis[[S-(R*,R*)]-(β-hydroxy-α-methylphenethyl)methylammonium] sulphate	7460-12-0	TWA	50 µg/m ³ (OEB 3)	Internal
		Wipe limit	500 µg/100 cm ²	Internal
Starch, oxidized	65996-62-5	TWA (inhalable dust)	3 mg/m ³	FOR-2011-12-06-1358
Further information	The limit value for flour dust is established as inhalable dust, Substances considered to evoke allergies when coming into touch with the eyes or airways or evoking allergies after coming into contact with the skin			
Silicon dioxide	7631-86-9	TWA (respirable dust)	1,5 mg/m ³ (Silica)	FOR-2011-12-06-1358
Desloratadine	100643-71-8	TWA	20 µg/m ³ (OEB 3)	Internal
		Wipe limit	200 µg/100 cm ²	Internal

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

Substance name	End Use	Exposure routes	Potential health effects	Value
Silicon dioxide	Workers	Inhalation	Long-term systemic effects	4 mg/m ³

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

Substance name	Environmental Compartment	Value
Citric acid	Fresh water	0,44 mg/l
	Marine water	0,044 mg/l
	Sewage treatment plant	1000 mg/l
	Fresh water sediment	34,6 mg/kg dry weight (d.w.)

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Desloratadine / Pseudoephedrine Formulation

Version 2.4 Revision Date: 09/13/2019 SDS Number: 2111462-00007 Date of last issue: 15.05.2019
Date of first issue: 23.10.2017

	Marine sediment	3,46 mg/kg dry weight (d.w.)
	Soil	33,1 mg/kg dry weight (d.w.)

8.2 Exposure controls

Engineering measures

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).

Minimize open handling.

Personal protective equipment

- Eye protection : Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
- Hand protection
- Material : Chemical-resistant gloves
- Remarks : Consider double gloving.
- Skin and body protection : Work uniform or laboratory coat.
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
Use appropriate degowning techniques to remove potentially contaminated clothing.
- 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 (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

- Appearance : solid
- Colour : white, blue
- Odour : No data available
- Odour 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 : Not applicable

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Desloratadine / Pseudoephedrine Formulation

Version 2.4 Revision Date: 09/13/2019 SDS Number: 2111462-00007 Date of last issue: 15.05.2019
Date of first issue: 23.10.2017

Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	Not classified as a flammability hazard
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	Not applicable
Relative vapour density	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	Not applicable
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

9.2 Other information

Flammability (liquids)	:	No data available
Particle size	:	No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : None known.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Desloratadine / Pseudoephedrine Formulation

Version 2.4 Revision Date: 09/13/2019 SDS Number: 2111462-00007 Date of last issue: 15.05.2019
Date of first issue: 23.10.2017

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

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

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 2.000 mg/kg
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: > 5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Components:

Bis[[S-(R*,R*)]-(β-hydroxy-α-methylphenethyl)methylammonium] sulphate:

Acute oral toxicity : LD50 (Rat): 660 mg/kg

LD50 (Mouse): 371 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 2,37 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rat): > 2.000 mg/kg
Remarks: Information given is based on data obtained from similar substances.

Disodium EDTA, dihydrate:

Acute oral toxicity : LD50 (Rat): 2.800 mg/kg
Remarks: Based on data from similar materials

Acute inhalation toxicity : LC50 (Rat): > 1 mg/l
Exposure time: 6 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 412
Remarks: Based on data from similar materials

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Desloratadine / Pseudoephedrine Formulation

Version 2.4 Revision Date: 09/13/2019 SDS Number: 2111462-00007 Date of last issue: 15.05.2019
Date of first issue: 23.10.2017

Citric acid:

Acute oral toxicity : LD50 (Mouse): 5.400 mg/kg

Acute dermal toxicity : LD50 (Rat): > 2.000 mg/kg
Method: OECD Test Guideline 402
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.

Skin corrosion/irritation

Not classified based on available information.

Components:

Bis[[S-(R*,R*)]-(β-hydroxy-α-methylphenethyl)methylammonium] sulphate:

Species : Rabbit
Result : No skin irritation

Disodium EDTA, dihydrate:

Species : Rabbit
Result : No skin irritation
Remarks : Based on data from similar materials

Citric acid:

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.

Components:

Bis[[S-(R*,R*)]-(β-hydroxy-α-methylphenethyl)methylammonium] sulphate:

Species : Rabbit
Result : No eye irritation

Disodium EDTA, dihydrate:

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Desloratadine / Pseudoephedrine Formulation

Version 2.4 Revision Date: 09/13/2019 SDS Number: 2111462-00007 Date of last issue: 15.05.2019
Date of first issue: 23.10.2017

Species : Rabbit
Result : No eye irritation
Remarks : Based on data from similar materials

Citric acid:

Species : Rabbit
Method : OECD Test Guideline 405
Result : Irritation to eyes, reversing within 21 days

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:

Bis[[S-(R*,R*)]-(β-hydroxy-α-methylphenethyl)methylammonium] sulphate:

Remarks : No data available

Disodium EDTA, dihydrate:

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

Desloratadine:

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

Germ cell mutagenicity

Not classified based on available information.

Components:

Bis[[S-(R*,R*)]-(β-hydroxy-α-methylphenethyl)methylammonium] sulphate:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Remarks: Information given is based on data obtained from similar substances.

Test Type: Chromosomal aberration

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Desloratadine / Pseudoephedrine Formulation

Version 2.4 Revision Date: 09/13/2019 SDS Number: 2111462-00007 Date of last issue: 15.05.2019
Date of first issue: 23.10.2017

Result: negative
Remarks: Information given is based on data obtained from similar substances.

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Rat
Application Route: Oral
Result: negative
Remarks: Based on data from similar materials

Disodium EDTA, dihydrate:

Genotoxicity in vitro : 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
Remarks: Based on data from similar materials

Citric acid:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: in vitro micronucleus test
Result: positive

Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
Species: Rat
Application Route: Ingestion
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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Desloratadine / Pseudoephedrine Formulation

Version 2.4 Revision Date: 09/13/2019 SDS Number: 2111462-00007 Date of last issue: 15.05.2019
Date of first issue: 23.10.2017

Carcinogenicity

Not classified based on available information.

Components:

Bis[[S-(R*,R*)]-(β-hydroxy-α-methylphenethyl)methylammonium] sulphate:

Species : Rat
Application Route : Oral
Exposure time : 2 Years
Result : negative
Remarks : Based on data from similar materials

Species : Mouse
Application Route : Oral
Exposure time : 2 Years
Result : negative
Remarks : Based on data from similar materials

Disodium EDTA, dihydrate:

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

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

Not classified based on available information.

Components:

Bis[[S-(R*,R*)]-(β-hydroxy-α-methylphenethyl)methylammonium] sulphate:

Effects on fertility : Test Type: Fertility
Species: Rat
Application Route: Oral
Fertility: LOAEL: 80 mg/kg body weight
Symptoms: male reproductive effects

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Desloratadine / Pseudoephedrine Formulation

Version 2.4 Revision Date: 09/13/2019 SDS Number: 2111462-00007 Date of last issue: 15.05.2019
Date of first issue: 23.10.2017

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Oral
Result: No teratogenic effects

Test Type: Embryo-foetal development
Application Route: Oral
Developmental Toxicity: LOAEL: 27 mg/kg body weight
Result: No embryotoxic effects have been observed in animal tests., No teratogenic effects
Remarks: Maternal toxicity observed.

Disodium EDTA, dihydrate:

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
Remarks: Based on data from similar materials

Citric acid:

Effects on foetal development : Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative

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 foetal development : Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: NOAEL: 30 mg/kg body weight

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Desloratadine / Pseudoephedrine Formulation

Version 2.4 Revision Date: 09/13/2019 SDS Number: 2111462-00007 Date of last issue: 15.05.2019
Date of first issue: 23.10.2017

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.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Causes damage to organs through prolonged or repeated exposure.

Components:

Bis[[S-(R*,R*)]-(β-hydroxy-α-methylphenethyl)methylammonium] sulphate:

Exposure routes : Ingestion, Inhalation
Target Organs : Central nervous system, Cardio-vascular system
Assessment : Causes damage to organs through prolonged or repeated exposure.

Disodium EDTA, dihydrate:

Exposure routes : inhalation (dust/mist/fume)
Target Organs : Respiratory Tract
Assessment : Shown to produce significant health effects in animals at concentrations of >0.02 to 0.2 mg/l/6h/d.

Repeated dose toxicity

Components:

Bis[[S-(R*,R*)]-(β-hydroxy-α-methylphenethyl)methylammonium] sulphate:

Remarks : No data available

Disodium EDTA, dihydrate:

Species : Rat
NOAEL : 500 mg/kg

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Desloratadine / Pseudoephedrine Formulation

Version 2.4 Revision Date: 09/13/2019 SDS Number: 2111462-00007 Date of last issue: 15.05.2019
Date of first issue: 23.10.2017

Application Route : Ingestion
Exposure time : 13 Weeks
Remarks : Based on data from similar materials

Species : Rat
LOAEL : 0,03 mg/l
Application Route : inhalation (dust/mist/fume)
Exposure time : 4 Weeks
Remarks : Based on data from similar materials

Citric acid:

Species : Rat
NOAEL : 4.000 mg/kg
LOAEL : 8.000 mg/kg
Application Route : Ingestion
Exposure time : 10 Days

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
Exposure time : 3 Months
Symptoms : Gastrointestinal disturbance, Fatigue

Aspiration toxicity

Not classified based on available information.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Desloratadine / Pseudoephedrine Formulation

Version 2.4 Revision Date: 09/13/2019 SDS Number: 2111462-00007 Date of last issue: 15.05.2019
Date of first issue: 23.10.2017

Experience with human exposure

Components:

Bis[[S-(R*,R*)]-(β-hydroxy-α-methylphenethyl)methylammonium] sulphate:

Inhalation : Remarks: May cause irritation of respiratory tract.
Eye contact : Remarks: May irritate eyes.
Ingestion : Symptoms: central nervous system effects, tachycardia, Palpitation

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

12.1 Toxicity

Components:

Disodium EDTA, dihydrate:

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 159 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
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants : EC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l
Exposure time: 72 h
Remarks: Based on data from similar materials

NOEC (Desmodesmus subspicatus (green algae)): 100 mg/l
Exposure time: 72 h
Remarks: Based on data from similar materials

Toxicity to microorganisms : EC50 : < 500 mg/l
Exposure time: 0,5 h
Method: OECD Test Guideline 209
Remarks: Based on data from similar materials

Toxicity to fish (Chronic toxicity) : NOEC: 25,7 mg/l
Exposure time: 35 d
Species: Danio rerio (zebra fish)
Method: OECD Test Guideline 210
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 25 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Remarks: Based on data from similar materials

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Desloratadine / Pseudoephedrine Formulation

Version 2.4 Revision Date: 09/13/2019 SDS Number: 2111462-00007 Date of last issue: 15.05.2019
Date of first issue: 23.10.2017

Citric acid:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 1.535 mg/l
Exposure time: 24 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 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

Toxicity to fish (Chronic toxicity) : NOEC: 0,12 mg/l
Exposure time: 32 d
Species: Pimephales promelas (fathead minnow)
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 0,48 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

12.2 Persistence and degradability

Components:

Disodium EDTA, dihydrate:

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Desloratadine / Pseudoephedrine Formulation

Version 2.4 Revision Date: 09/13/2019 SDS Number: 2111462-00007 Date of last issue: 15.05.2019
Date of first issue: 23.10.2017

Biodegradability : Result: Inherently biodegradable.
Biodegradation: 80 - 90 %
Exposure time: 28 d
Remarks: Based on data from similar materials

Citric acid:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 97 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

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

12.3 Bioaccumulative potential

Components:

Bis[[S-(R*,R*)]-(β-hydroxy-α-methylphenethyl)methylammonium] sulphate:

Partition coefficient: n-octanol/water : log Pow: 0,89

Disodium EDTA, dihydrate:

Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)
Bioconcentration factor (BCF): 1,8
Remarks: Based on data from similar materials

Partition coefficient: n-octanol/water : log Pow: -4,3

Citric acid:

Partition coefficient: n-octanol/water : log Pow: -1,72

Desloratadine:

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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Desloratadine / Pseudoephedrine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 15.05.2019
2.4	09/13/2019	2111462-00007	Date of first issue: 23.10.2017

12.4 Mobility in soil

Components:

Desloratadine:

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

12.5 Results of PBT and vPvB assessment

Not relevant

12.6 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.
According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.
Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

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

14.1 UN number

Not regulated as a dangerous good

14.2 UN proper shipping name

Not regulated as a dangerous good

14.3 Transport hazard class(es)

Not regulated as a dangerous good

14.4 Packing group

Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Desloratadine / Pseudoephedrine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 15.05.2019
2.4	09/13/2019	2111462-00007	Date of first issue: 23.10.2017

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Not applicable

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

Regulation (EC) No 850/2004 on persistent organic pollutants : Not applicable

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances. : Not applicable

Other regulations:

Young people under the age of 18 are not allowed to use or be exposed to the product professionally. Young people above the age of 15 are, however, except from this rule if the product is a necessary part of their education.

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

AICS : not determined

DSL : not determined

IECSC : not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-Statements

H302 : Harmful if swallowed.

H318 : Causes serious eye damage.

H319 : Causes serious eye irritation.

H332 : Harmful if inhaled.

H361fd : Suspected of damaging fertility. Suspected of damaging the unborn child.

H372 : Causes damage to organs through prolonged or repeated exposure if inhaled.

H372 : Causes damage to organs through prolonged or repeated exposure if swallowed.

H373 : May cause damage to organs through prolonged or repeated exposure.

H411 : Toxic to aquatic life with long lasting effects.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Desloratadine / Pseudoephedrine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 15.05.2019
2.4	09/13/2019	2111462-00007	Date of first issue: 23.10.2017

Full text of other abbreviations

Acute Tox.	:	Acute toxicity
Aquatic Chronic	:	Long-term (chronic) aquatic hazard
Eye Dam.	:	Serious eye damage
Eye Irrit.	:	Eye irritation
Repr.	:	Reproductive toxicity
STOT RE	:	Specific target organ toxicity - repeated exposure
FOR-2011-12-06-1358	:	Norway. Occupational Exposure limits
FOR-2011-12-06-1358 /	:	Long term exposure limit
TWA		

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance 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

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/>

Classification of the mixture:

STOT RE 1 H372

Classification procedure:

Calculation method

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Desloratadine / Pseudoephedrine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 15.05.2019
2.4	09/13/2019	2111462-00007	Date of first issue: 23.10.2017

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.

NO / EN