

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



ORGANON

## Desloratadine / Pseudoephedrine Formulation

Version 5.0      Revision Date: 06.04.2024      SDS Number: 2111462-00017      Date of last issue: 30.09.2023  
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

Recommended restrictions on use : Not applicable

#### 1.3 Details of the supplier of the safety data sheet

Company : Organon & Co.  
30 Hudson Street, 33rd floor  
07302 Jersey City, New Jersey, U.S.A

Telephone : +1-551-430-6000

E-mail address of person responsible for the SDS : EHSSTEWARD@organon.com

#### 1.4 Emergency telephone number

+1-215-631-6999

---

### 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.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Desloratadine / Pseudoephedrine Formulation

Version 5.0      Revision Date: 06.04.2024      SDS Number: 2111462-00017      Date of last issue: 30.09.2023  
Date of first issue: 23.10.2017

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

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

## 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 RE 1; H372 (Central nervous system) STOT RE 1; H372 (Cardio-vascular system)  Acute toxicity estimate  Acute oral toxicity: 660 mg/kg Acute inhalation toxicity (dust/mist): 2,38 mg/l	>= 20 - < 30
Disodium EDTA, dihydrate	6381-92-6	Acute Tox. 4; H332	>= 1 - < 10

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



ORGANON

## Desloratadine / Pseudoephedrine Formulation

Version 5.0      Revision Date: 06.04.2024      SDS Number: 2111462-00017      Date of last issue: 30.09.2023  
Date of first issue: 23.10.2017

		STOT RE 2; H373 (Respiratory Tract)	
Citric acid	77-92-9 201-069-1 607-750-00-3	Eye Irrit. 2; H319 STOT SE 3; H335	$\geq 1 - < 10$
Desloratadine	100643-71-8	Acute Tox. 4; H302 Eye Dam. 1; H318 Repr. 2; H361fd Aquatic Chronic 2; H411	$\geq 0,25 - < 1$

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.  
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.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



ORGANON

## Desloratadine / Pseudoephedrine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.0	06.04.2024	2111462-00017	Date of first issue: 23.10.2017

---

### SECTION 5: Firefighting measures

#### 5.1 Extinguishing media

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
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<sub>x</sub>)  
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.

---

### SECTION 6: Accidental release measures

#### 6.1 Personal precautions, protective equipment and emergency procedures

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

#### 6.2 Environmental precautions

Environmental precautions : Avoid release to the environment.  
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 dis-

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



ORGANON

## Desloratadine / Pseudoephedrine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.0	06.04.2024	2111462-00017	Date of first issue: 23.10.2017

---

posal 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 breathe dust, fume, gas, mist, vapours or spray.<br>Do not swallow.<br>Avoid contact with eyes.<br>Avoid prolonged or repeated contact with skin.<br>Wash skin thoroughly after handling.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Do not eat, drink or smoke when using this product.<br>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.<br>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. |

### 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:<br>Strong oxidizing agents<br>Self-reactive substances and mixtures<br>Organic peroxides<br>Explosives<br>Gases |

### 7.3 Specific end use(s)

- |                 |   |                   |
|-----------------|---|-------------------|
| Specific use(s) | : | No data available |
|-----------------|---|-------------------|

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



ORGANON

## Desloratadine / Pseudoephedrine Formulation

Version 5.0      Revision Date: 06.04.2024      SDS Number: 2111462-00017      Date of last issue: 30.09.2023  
Date of first issue: 23.10.2017

### 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 <sup>3</sup> (OEB 3)	Internal
		Wipe limit	500 µg/100 cm <sup>2</sup>	Internal
Starch, oxidized	65996-62-5	TWA (inhalable dust)	3 mg/m <sup>3</sup>	FOR-2011-12-06-1358
	Further information: 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 <sup>3</sup> (Silica)	FOR-2011-12-06-1358
Desloratadine	100643-71-8	TWA	20 µg/m <sup>3</sup> (OEB 3)	Internal
		Wipe limit	200 µg/100 cm <sup>2</sup>	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 <sup>3</sup>
Disodium EDTA, dihydrate	Workers	Inhalation	Long-term systemic effects	1,5 mg/m <sup>3</sup>
	Workers	Inhalation	Acute systemic effects	3 mg/m <sup>3</sup>
	Workers	Inhalation	Long-term local effects	1,5 mg/m <sup>3</sup>
	Workers	Inhalation	Acute local effects	3 mg/m <sup>3</sup>
	Consumers	Inhalation	Long-term local effects	0,6 mg/m <sup>3</sup>
	Consumers	Inhalation	Acute local effects	1,2 mg/m <sup>3</sup>
	Consumers	Ingestion	Long-term systemic effects	25 mg/kg bw/day

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

Substance name	Environmental Compartment	Value
Disodium EDTA, dihydrate	Fresh water	2,5 mg/l
	Marine water	0,25 mg/l
	Sewage treatment plant	50 mg/l
	Soil	1,1 mg/kg dry weight (d.w.)
Citric acid	Fresh water	0,44 mg/l

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Desloratadine / Pseudoephedrine Formulation

Version 5.0      Revision Date: 06.04.2024      SDS Number: 2111462-00017      Date of last issue: 30.09.2023  
Date of first issue: 23.10.2017

	Marine water	0,044 mg/l
	Sewage treatment plant	1000 mg/l
	Fresh water sediment	34,6 mg/kg dry weight (d.w.)
	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/face 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.  
Equipment should conform to NS EN 143
- Filter type : Particulates type (P)

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

- Physical state : solid
- Colour : white, blue
- Odour : No data available
- Odour Threshold : No data available

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



ORGANON

## Desloratadine / Pseudoephedrine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.0	06.04.2024	2111462-00017	Date of first issue: 23.10.2017

---

Melting point/freezing point : No data available

Initial boiling point and boiling range : No data available

Flammability (solid, gas) : Not classified as a flammability hazard

Flammability (liquids) : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Flash point : Not applicable

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : No data available

Viscosity  
Viscosity, kinematic : Not applicable

Solubility(ies)  
Water solubility : No data available

Partition coefficient: n-octanol/water : Not applicable

Vapour pressure : Not applicable

Relative density : No data available

Density : No data available

Relative vapour density : Not applicable

Particle characteristics  
Particle size : No data available

### 9.2 Other information

Explosives : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.



# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



ORGANON

## Desloratadine / Pseudoephedrine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.0	06.04.2024	2111462-00017	Date of first issue: 23.10.2017

Evaporation rate : Not applicable

### 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.

#### 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 hazard classes as defined in Regulation (EC) No 1272/2008

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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



ORGANON

## Desloratadine / Pseudoephedrine Formulation

Version 5.0      Revision Date: 06.04.2024      SDS Number: 2111462-00017      Date of last issue: 30.09.2023  
Date of first issue: 23.10.2017

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

### 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

#### Citric acid:

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

#### Desloratadine:

Species : Rabbit  
Result : No skin irritation

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Desloratadine / Pseudoephedrine Formulation

Version 5.0      Revision Date: 06.04.2024      SDS Number: 2111462-00017      Date of last issue: 30.09.2023  
Date of first issue: 23.10.2017

---

### 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:**

Species : Rabbit  
Result : No eye irritation

##### **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  
Method : OECD Test Guideline 406  
Result : negative  
Remarks : Based on data from similar materials

##### **Desloratadine:**

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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Desloratadine / Pseudoephedrine Formulation

Version 5.0      Revision Date: 06.04.2024      SDS Number: 2111462-00017      Date of last issue: 30.09.2023  
Date of first issue: 23.10.2017

### 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  
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: 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

#### **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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



ORGANON

## Desloratadine / Pseudoephedrine Formulation

Version 5.0      Revision Date: 06.04.2024      SDS Number: 2111462-00017      Date of last issue: 30.09.2023  
Date of first issue: 23.10.2017

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

### Carcinogenicity

Not classified based on available information.

### Components:

#### Bis[[S-(R\*,R\*)-( $\beta$ -hydroxy- $\alpha$ -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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Desloratadine / Pseudoephedrine Formulation

Version 5.0      Revision Date: 06.04.2024      SDS Number: 2111462-00017      Date of last issue: 30.09.2023  
Date of first issue: 23.10.2017

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

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

#### Citric acid:

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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Desloratadine / Pseudoephedrine Formulation

Version 5.0      Revision Date: 06.04.2024      SDS Number: 2111462-00017      Date of last issue: 30.09.2023  
Date of first issue: 23.10.2017

	Result: negative
<b>Desloratadine:</b>	
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.

### STOT - single exposure

Not classified based on available information.

### Components:

#### Citric acid:

|| Assessment : May cause respiratory irritation.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



ORGANON

## Desloratadine / Pseudoephedrine Formulation

Version 5.0      Revision Date: 06.04.2024      SDS Number: 2111462-00017      Date of last issue: 30.09.2023  
Date of first issue: 23.10.2017

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

### 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  
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

##### **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



# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



ORGANON

## Desloratadine / Pseudoephedrine Formulation

Version 5.0      Revision Date: 06.04.2024      SDS Number: 2111462-00017      Date of last issue: 30.09.2023  
Date of first issue: 23.10.2017

|| 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.

## 11.2 Information on other hazards

### Endocrine disrupting properties

#### Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

### 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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Desloratadine / Pseudoephedrine Formulation

Version 5.0      Revision Date: 06.04.2024      SDS Number: 2111462-00017      Date of last issue: 30.09.2023  
Date of first issue: 23.10.2017

### SECTION 12: Ecological information

#### 12.1 Toxicity

##### Components:

##### **Disodium EDTA, dihydrate:**

Toxicity to fish	:	LC50 ( <i>Lepomis macrochirus</i> (Bluegill sunfish)): > 100 mg/l Exposure time: 96 h Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates	:	EC50 ( <i>Daphnia magna</i> (Water flea)): 140 mg/l Exposure time: 48 h Method: DIN 38412
Toxicity to algae/aquatic plants	:	ErC50 ( <i>Pseudokirchneriella subcapitata</i> (green algae)): > 100 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: Based on data from similar materials
		EC10 ( <i>Pseudokirchneriella subcapitata</i> (green algae)): > 1 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: Based on data from similar materials
Toxicity to microorganisms	:	EC10 (activated sludge): > 500 mg/l Exposure time: 30 min Method: OECD Test Guideline 209
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC: 25 mg/l Exposure time: 21 d Species: <i>Daphnia magna</i> (Water flea)

##### **Citric acid:**

Toxicity to fish	:	LC50 ( <i>Pimephales promelas</i> (fathead minnow)): > 100 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 ( <i>Daphnia magna</i> (Water flea)): 1.535 mg/l Exposure time: 24 h

##### **Desloratadine:**

Toxicity to fish	:	LC50 ( <i>Lepomis macrochirus</i> (Bluegill sunfish)): 9,2 mg/l Exposure time: 96 h Method: FDA 4.11
Toxicity to daphnia and other aquatic invertebrates	:	EC50 ( <i>Daphnia magna</i> (Water flea)): 9,6 mg/l Exposure time: 48 h Method: FDA 4.08

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



ORGANON

## Desloratadine / Pseudoephedrine Formulation

Version 5.0      Revision Date: 06.04.2024      SDS Number: 2111462-00017      Date of last issue: 30.09.2023  
Date of first issue: 23.10.2017

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:**

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

##### **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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



ORGANON

## Desloratadine / Pseudoephedrine Formulation

Version 5.0      Revision Date: 06.04.2024      SDS Number: 2111462-00017      Date of last issue: 30.09.2023  
Date of first issue: 23.10.2017

Stability in water : Result: Not readily biodegradable.  
Biodegradation: 0 %  
Exposure time: 28 d  
Method: FDA 3.11  
: 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): < 500  
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

### 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

#### Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Desloratadine / Pseudoephedrine Formulation

Version 5.0      Revision Date: 06.04.2024      SDS Number: 2111462-00017      Date of last issue: 30.09.2023  
Date of first issue: 23.10.2017

---

### 12.6 Endocrine disrupting properties

**Product:**

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

---

## 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. 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.

---

## SECTION 14: Transport information

### 14.1 UN number or ID number

ADN : Not regulated as a dangerous good  
ADR : Not regulated as a dangerous good  
RID : Not regulated as a dangerous good  
IMDG : Not regulated as a dangerous good  
IATA : Not regulated as a dangerous good

### 14.2 UN proper shipping name

ADN : Not regulated as a dangerous good  
ADR : Not regulated as a dangerous good  
RID : Not regulated as a dangerous good  
IMDG : Not regulated as a dangerous good  
IATA : Not regulated as a dangerous good

### 14.3 Transport hazard class(es)

ADN : Not regulated as a dangerous good  
ADR : Not regulated as a dangerous good  
RID : Not regulated as a dangerous good  
IMDG : Not regulated as a dangerous good

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



ORGANON

## Desloratadine / Pseudoephedrine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.0	06.04.2024	2111462-00017	Date of first issue: 23.10.2017

**IATA** : Not regulated as a dangerous good

### 14.4 Packing group

**ADN** : Not regulated as a dangerous good

**ADR** : Not regulated as a dangerous good

**RID** : Not regulated as a dangerous good

**IMDG** : Not regulated as a dangerous good

**IATA (Cargo)** : Not regulated as a dangerous good

**IATA (Passenger)** : 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 Maritime transport in bulk according to IMO instruments

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Conditions of restriction for the following entries should be considered:  
Number on list 75

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not.

If you intend to use this product as tattoo ink, please contact your vendor.

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 (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



ORGANON

## Desloratadine / Pseudoephedrine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.0	06.04.2024	2111462-00017	Date of first issue: 23.10.2017

---

of dangerous chemicals

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:

Note the regulation on organization, leadership and participation, chapter 12 on the work of children and young people.

### 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.  
H335 : May cause respiratory irritation.  
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.

### 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  
STOT SE : Specific target organ toxicity - single exposure  
FOR-2011-12-06-1358 : Norway. Occupational Exposure limits  
FOR-2011-12-06-1358 / : Long term exposure limit

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



ORGANON

## Desloratadine / Pseudoephedrine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.0	06.04.2024	2111462-00017	Date of first issue: 23.10.2017

TWA

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; 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; 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

### 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

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

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.



# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Desloratadine / Pseudoephedrine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.0	06.04.2024	2111462-00017	Date of first issue: 23.10.2017

---

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