

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



ORGANON

## Desloratadine / Pseudoephedrine Formulation

Version 4.1      Revision Date: 2024/04/06      SDS Number: 2095116-00015      Date of last issue: 2023/09/30  
Date of first issue: 2017/10/23

### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Desloratadine / Pseudoephedrine Formulation

#### Manufacturer or supplier's details

Company : Organon & Co.

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

Telephone : +1-551-430-6000

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

E-mail address : EHSSTEWARD@organon.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

### 2. HAZARDS IDENTIFICATION

#### Emergency Overview

**Appearance** : solid  
**Colour** : white, blue  
**Odour** : No data available

May be harmful if swallowed or if inhaled. Causes damage to organs through prolonged or repeated exposure.

#### GHS Classification

Acute toxicity (Oral) : Category 5

Acute toxicity (Inhalation) : Category 5

Specific target organ toxicity - repeated exposure : Category 1

#### GHS label elements

Hazard pictograms :



Signal word : Danger

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Desloratadine / Pseudoephedrine Formulation

Version 4.1      Revision Date: 2024/04/06      SDS Number: 2095116-00015      Date of last issue: 2023/09/30  
Date of first issue: 2017/10/23

Hazard statements : H303 + H333 May be harmful if swallowed or if inhaled.  
H372 Causes damage to organs through prolonged or repeated exposure.

Precautionary statements : **Prevention:**  
P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.  
P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.  
**Response:**  
P304 + P312 IF INHALED: Call a POISON CENTER/ doctor if you feel unwell.  
P312 Call a POISON CENTER/ doctor if you feel unwell.  
**Disposal:**  
P501 Dispose of contents/ container to an approved waste disposal plant.

### Physical and chemical hazards

Not classified based on available information.

### Health hazards

May be harmful if swallowed. May be harmful if inhaled. Causes damage to organs through prolonged or repeated exposure.

### 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

Chemical name	CAS-No.	Concentration (% w/w)
Cellulose	9004-34-6	>= 30 -< 50
Bis[[S-(R*,R*)-(β-hydroxy-α-methylphenethyl)methylammonium] sulphate	7460-12-0	>= 20 -< 30
Starch, oxidized	65996-62-5	>= 1 -< 10
Disodium EDTA, dihydrate	6381-92-6	>= 1 -< 10
Citric acid	77-92-9	>= 1 -< 10
Desloratadine	100643-71-8	>= 0.25 -< 1

## 4. 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

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



ORGANON

## Desloratadine / Pseudoephedrine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
4.1	2024/04/06	2095116-00015	Date of first issue: 2017/10/23

---

	advice.
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.
Most important symptoms and effects, both acute and delayed	: May be harmful if swallowed or if inhaled. Causes damage to organs through prolonged or repeated exposure.
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).
Notes to physician	: Treat symptomatically and supportively.

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### 5. FIREFIGHTING MEASURES

Suitable extinguishing media	: Water spray Alcohol-resistant foam Carbon dioxide (CO <sub>2</sub> ) Dry chemical
Unsuitable extinguishing media	: None known.
Specific hazards during fire-fighting	: Exposure to combustion products may be a hazard to health.
Hazardous combustion products	: Carbon oxides Nitrogen oxides (NO <sub>x</sub> ) Metal oxides
Specific extinguishing methods	: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for firefighters	: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

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### 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	: Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
Environmental precautions	: Avoid release to the environment.

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Desloratadine / Pseudoephedrine Formulation

Version 4.1      Revision Date: 2024/04/06      SDS Number: 2095116-00015      Date of last issue: 2023/09/30  
Date of first issue: 2017/10/23

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.

Methods and materials for containment and 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.

### 7. HANDLING AND STORAGE

#### Handling

Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.  
Local/Total ventilation : Use only with adequate ventilation.  
Advice on safe handling : Do not breathe dust, fume, gas, mist, vapours or spray.  
Do not swallow.  
Avoid contact with eyes.  
Avoid prolonged or repeated contact with skin.  
Wash skin thoroughly after handling.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Do not eat, drink or smoke when using this product.  
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 parameters / Permissible concentration	Basis
Cellulose	9004-34-6	PC-TWA	10 mg/m <sup>3</sup>	CN OEL

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Desloratadine / Pseudoephedrine Formulation

Version 4.1      Revision Date: 2024/04/06      SDS Number: 2095116-00015      Date of last issue: 2023/09/30  
Date of first issue: 2017/10/23

		TWA	10 mg/m <sup>3</sup>	ACGIH
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)	0.5 mg/m <sup>3</sup>	ACGIH
Desloratadine	100643-71-8	TWA	20 µg/m <sup>3</sup> (OEB 3)	Internal
		Wipe limit	200 µg/100 cm <sup>2</sup>	Internal

**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

**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

**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.

**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.

**Hand protection**

**Material** : Chemical-resistant gloves

**Remarks** : Consider double gloving.

**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 GB/T 16483 and GB/T 17519



ORGANON

## Desloratadine / Pseudoephedrine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
4.1	2024/04/06	2095116-00015	Date of first issue: 2017/10/23

### 9. 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
Evaporation rate	: Not applicable
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
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

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Desloratadine / Pseudoephedrine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
4.1	2024/04/06	2095116-00015	Date of first issue: 2017/10/23

Explosive properties : Not explosive

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

Particle characteristics  
Particle size : No data available

### 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : Can react with strong oxidizing agents.

Conditions to avoid : None known.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

### 11. TOXICOLOGICAL INFORMATION

Exposure routes : Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

May be harmful if swallowed or if inhaled.

#### Product:

Acute oral toxicity : Acute toxicity estimate: 2,451 mg/kg  
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: 5.4 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: Calculation method

#### Components:

##### Cellulose:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5.8 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

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

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



ORGANON

## Desloratadine / Pseudoephedrine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
4.1	2024/04/06	2095116-00015	Date of first issue: 2017/10/23

---

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

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



# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



ORGANON

## Desloratadine / Pseudoephedrine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
4.1	2024/04/06	2095116-00015	Date of first issue: 2017/10/23

---

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:

Species : Rabbit  
Result : No eye irritation

#### Citric acid:

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

#### 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

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



ORGANON

## Desloratadine / Pseudoephedrine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
4.1	2024/04/06	2095116-00015	Date of first issue: 2017/10/23

---

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:

#### Cellulose:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  
Test Type: In vitro mammalian cell gene mutation test  
Result: negative  
Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Ingestion  
Result: negative

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

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Desloratadine / Pseudoephedrine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
4.1	2024/04/06	2095116-00015	Date of first issue: 2017/10/23

---

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

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.

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



ORGANON

## Desloratadine / Pseudoephedrine Formulation

Version 4.1      Revision Date: 2024/04/06      SDS Number: 2095116-00015      Date of last issue: 2023/09/30  
Date of first issue: 2017/10/23

---

### Components:

#### **Cellulose:**

Species : Rat  
Application Route : Ingestion  
Exposure time : 72 weeks  
Result : negative

#### **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:

#### **Cellulose:**

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



ORGANON

## Desloratadine / Pseudoephedrine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
4.1	2024/04/06	2095116-00015	Date of first issue: 2017/10/23

---

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

Effects on foetal development : Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Ingestion  
Result: negative

### **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  
Result: negative

### **Desloratadine:**

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Desloratadine / Pseudoephedrine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
4.1	2024/04/06	2095116-00015	Date of first issue: 2017/10/23

---

Effects on fertility : Test Type: Fertility  
Species: Rat, male  
Application Route: Oral  
Fertility: LOAEL: 12 mg/kg body weight  
Symptoms: Reduced fertility  
Result: positive  
Remarks: The mechanism or mode of action may not be relevant in humans.

Test Type: Fertility  
Species: Rat, female  
Fertility: NOAEL: 3 mg/kg body weight  
Symptoms: No effects on fertility  
Result: negative

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rabbit  
Application Route: Oral  
Developmental Toxicity: NOAEL: 30 mg/kg body weight  
Result: No teratogenic effects

Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: LOAEL: 9 mg/kg body weight  
Symptoms: Preimplantation loss, Reduced body weight  
Result: Specific developmental abnormalities  
Remarks: The mechanism or mode of action may not be relevant in humans.

Test Type: Two-generation study  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: LOAEL: 18 mg/kg body weight  
Result: No adverse effects

Reproductive toxicity - Assessment : Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Some evidence of adverse effects on development, based on animal experiments.

### STOT - single exposure

Not classified based on available information.

### Components:

#### **Citric acid:**

Assessment : May cause respiratory irritation.

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Desloratadine / Pseudoephedrine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
4.1	2024/04/06	2095116-00015	Date of first issue: 2017/10/23

---

### 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:

##### **Cellulose:**

Species	: Rat
NOAEL	: >= 9,000 mg/kg
Application Route	: Ingestion
Exposure time	: 90 Days

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

Remarks	: No data available
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##### **Starch, oxidized:**

Species	: Rat
NOAEL	: 22,500 mg/kg
Application Route	: Ingestion
Exposure time	: 90 Days

##### **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

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Desloratadine / Pseudoephedrine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
4.1	2024/04/06	2095116-00015	Date of first issue: 2017/10/23

---

### 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.

### 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:



# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



ORGANON

## Desloratadine / Pseudoephedrine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
4.1	2024/04/06	2095116-00015	Date of first issue: 2017/10/23

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:

##### **Cellulose:**

Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l  
Exposure time: 48 h  
Remarks: Based on data from similar materials

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

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

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

Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials

EC10 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 25 mg/l  
Exposure time: 21 d

Toxicity to microorganisms : EC10 (activated sludge): > 500 mg/l  
Exposure time: 30 min  
Method: OECD Test Guideline 209

##### **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

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Desloratadine / Pseudoephedrine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
4.1	2024/04/06	2095116-00015	Date of first issue: 2017/10/23

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### Desloratadine:

- Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 9.2 mg/l  
Exposure time: 96 h  
Method: FDA 4.11
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 9.6 mg/l  
Exposure time: 48 h  
Method: FDA 4.08
- Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 1.6 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201
- NOEC (Pseudokirchneriella subcapitata (green algae)): 0.36 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201
- Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 0.12 mg/l  
Exposure time: 32 d  
Method: OECD Test Guideline 210
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.48 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211
- Toxicity to microorganisms : EC50 (Natural microorganism): 53.7 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209
- NOEC (Natural microorganism): 12 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

### Persistence and degradability

#### Components:

##### Cellulose:

Biodegradability : Result: Readily biodegradable.

##### Disodium EDTA, dihydrate:

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

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



ORGANON

## Desloratadine / Pseudoephedrine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
4.1	2024/04/06	2095116-00015	Date of first issue: 2017/10/23

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### 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

### 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

### Mobility in soil

#### Components:

#### **Desloratadine:**

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Desloratadine / Pseudoephedrine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
4.1	2024/04/06	2095116-00015	Date of first issue: 2017/10/23

Distribution among environmental compartments : log K<sub>oc</sub>: 3.00  
Method: OECD Test Guideline 106

### Other adverse effects

No data available

## 13. DISPOSAL CONSIDERATIONS

### Disposal methods

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

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

## 14. TRANSPORT INFORMATION

### International Regulations

#### UNRTDG

UN number : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
Environmentally hazardous : no

#### IATA-DGR

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

#### IMDG-Code

UN number : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
EmS Code : Not applicable  
Marine pollutant : no

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



ORGANON

## Desloratadine / Pseudoephedrine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
4.1	2024/04/06	2095116-00015	Date of first issue: 2017/10/23

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

Not applicable for product as supplied.

### National Regulations

#### GB 6944/12268

UN number	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
Marine pollutant	:	no

### Special precautions for user

Not applicable

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## 15. REGULATORY INFORMATION

### National regulatory information

#### Law on the Prevention and Control of Occupational Diseases

#### Regulation on the Administration of Precursor Chemicals

Catalogue and Classification of Precursor Chemicals : Not listed

#### Yangtze River Protection Law

This product does not contain any dangerous chemicals prohibited for inland river transport.

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

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

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## 16. OTHER INFORMATION

Revision Date : 2024/04/06

### 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/>

Date format : yyyy/mm/dd

### Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
CN OEL	:	Occupational exposure limits for hazardous agents in the workplace - Chemical hazardous agents.

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# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



ORGANON

## Desloratadine / Pseudoephedrine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
4.1	2024/04/06	2095116-00015	Date of first issue: 2017/10/23

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ACGIH / TWA : 8-hour, time-weighted average  
CN OEL / PC-TWA : Permissible concentration - time weighted average

AIIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECL - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

### 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.

CN / EN