

SAFETY DATA SHEET



Desloratadine / Pseudoephedrine Formulation



Version 5.0 Revision Date: 30.09.2023 SDS Number: 2111477-00015 Date of last issue: 04.04.2023
Date of first issue: 23.10.2017

SECTION 1. IDENTIFICATION

Product name : Desloratadine / Pseudoephedrine Formulation

Manufacturer or supplier's details

Company : Organon & Co.

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

Telephone : 1-551-430-6000

Emergency telephone : 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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Acute toxicity (Oral) : Category 5

Acute toxicity (Inhalation) : Category 5

Specific target organ toxicity - : Category 1 (Central nervous system)
repeated exposure (Oral)

Specific target organ toxicity - : Category 1 (Cardio-vascular system)
repeated exposure
(Inhalation)

GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H303 + H333 May be harmful if swallowed or if inhaled.
H372 Causes damage to organs (Central nervous system) through prolonged or repeated exposure if swallowed.
H372 Causes damage to organs (Cardio-vascular system) through prolonged or repeated exposure if inhaled.

SAFETY DATA SHEET



Desloratadine / Pseudoephedrine Formulation



Version 5.0 Revision Date: 30.09.2023 SDS Number: 2111477-00015 Date of last issue: 04.04.2023
Date of first issue: 23.10.2017

Precautionary Statements : **Prevention:**
P260 Do not breathe dust/ fume/ gas/ mist/ vapors/ 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.

Other hazards which do not result in classification

None known.

SECTION 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 -< 5
Disodium EDTA, dihydrate	6381-92-6	>= 1 -< 5
Citric acid	77-92-9	>= 1 -< 5
Desloratadine	100643-71-8	>= 0,25 -< 1

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

Desloratadine / Pseudoephedrine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.0	30.09.2023	2111477-00015	Date of first issue: 23.10.2017

delayed	exposure if swallowed. Causes damage to organs through prolonged or repeated exposure if inhaled.
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.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	: Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) Dry chemical
Unsuitable extinguishing media	: None known.
Specific hazards during fire fighting	: Exposure to combustion products may be a hazard to health.
Hazardous combustion products	: Carbon oxides Nitrogen oxides (NO _x) 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 fire-fighters	: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 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. 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.

SECTION 7. HANDLING AND STORAGE

Technical measures	: See Engineering measures under EXPOSURE
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SAFETY DATA SHEET



Desloratadine / Pseudoephedrine Formulation



Version 5.0 Revision Date: 30.09.2023 SDS Number: 2111477-00015 Date of last issue: 04.04.2023
Date of first issue: 23.10.2017

Local/Total ventilation : CONTROLS/PERSONAL PROTECTION section.
Advice on safe handling : Use only with adequate ventilation.
Do not breathe dust, fume, gas, mist, vapors 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.

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

Materials to avoid : Do not store with the following product types:
Strong oxidizing agents
Self-reactive substances and mixtures
Organic peroxides
Explosives
Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Cellulose	9004-34-6	CMP	10 mg/m ³	AR OEL
		TWA	10 mg/m ³	ACGIH
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	CMP (inhalable dust)	0,5 mg/m ³	AR OEL
		Further information: Sensitization		
		TWA (inhalable dust)	0,5 mg/m ³	ACGIH
Desloratadine	100643-71-8	TWA	20 µg/m ³ (OEB 3)	Internal
		Wipe limit	200 µg/100 cm ²	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.

Desloratadine / Pseudoephedrine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.0	30.09.2023	2111477-00015	Date of first issue: 23.10.2017

Personal protective equipment

Respiratory protection	:	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Filter type	:	Particulates type
Hand protection	:	
Material	:	Chemical-resistant gloves
Remarks	:	Consider double gloving.
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.
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.
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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	solid
Color	:	white, blue
Odor	:	No data available
Odor 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

SAFETY DATA SHEET



Desloratadine / Pseudoephedrine Formulation



Version 5.0 Revision Date: 30.09.2023 SDS Number: 2111477-00015 Date of last issue: 04.04.2023
Date of first issue: 23.10.2017

Flammability (liquids) : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapor pressure : Not applicable

Relative vapor 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

Autoignition 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.

Particle size : No data available

SECTION 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.

SECTION 11. TOXICOLOGICAL INFORMATION

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

Desloratadine / Pseudoephedrine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.0	30.09.2023	2111477-00015	Date of first issue: 23.10.2017

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:

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 / Pseudoephedrine Formulation

Version 5.0 Revision Date: 30.09.2023 SDS Number: 2111477-00015 Date of last issue: 04.04.2023
Date of first issue: 23.10.2017

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

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

Desloratadine / Pseudoephedrine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.0	30.09.2023	2111477-00015	Date of first issue: 23.10.2017

Respiratory or skin sensitization**Skin sensitization**

Not classified based on available information.

Respiratory sensitization

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 : Maximization Test
 Routes of exposure : Skin contact
 Species : Guinea pig
 Method : OECD Test Guideline 406
 Result : negative
 Remarks : Based on data from similar materials

Desloratadine:

Test Type : Maximization Test
 Routes of exposure : 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*)]-(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

Desloratadine / Pseudoephedrine Formulation

Version 5.0 Revision Date: 30.09.2023 SDS Number: 2111477-00015 Date of last issue: 04.04.2023
Date of first issue: 23.10.2017

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

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

Desloratadine / Pseudoephedrine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.0	30.09.2023	2111477-00015	Date of first issue: 23.10.2017

Species:	Mouse
Cell type:	Bone marrow
Application Route:	Oral
Result:	negative

Carcinogenicity

Not classified based on available information.

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.

Desloratadine / Pseudoephedrine Formulation

Version 5.0 Revision Date: 30.09.2023 SDS Number: 2111477-00015 Date of last issue: 04.04.2023
 Date of first issue: 23.10.2017

Reproductive toxicity

Not classified based on available information.

Components:**Cellulose:**

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

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

Test Type: Embryo-fetal 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 fetal development : Test Type: Embryo-fetal development
 Species: Rat
 Application Route: Ingestion
 Result: negative

Citric acid:

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

Desloratadine / Pseudoephedrine Formulation

Version 5.0 Revision Date: 30.09.2023 SDS Number: 2111477-00015 Date of last issue: 04.04.2023
Date of first issue: 23.10.2017

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

STOT-repeated exposure

Causes damage to organs (Central nervous system) through prolonged or repeated exposure if swallowed.

Desloratadine / Pseudoephedrine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.0	30.09.2023	2111477-00015	Date of first issue: 23.10.2017

Causes damage to organs (Cardio-vascular system) through prolonged or repeated exposure if inhaled.

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

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

Disodium EDTA, dihydrate:

Routes of exposure	: 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

Citric acid:

Species	: Rat
NOAEL	: 4.000 mg/kg

Desloratadine / Pseudoephedrine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.0	30.09.2023	2111477-00015	Date of first issue: 23.10.2017

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:

Inhalation	: Remarks: May cause respiratory tract irritation.
Eye contact	: Symptoms: Eye irritation
Ingestion	: Symptoms: dry mouth, muscle pain, Fatigue, Drowsiness, sore throat, painful menstration

Desloratadine / Pseudoephedrine Formulation

Version 5.0 Revision Date: 30.09.2023 SDS Number: 2111477-00015 Date of last issue: 04.04.2023
 Date of first issue: 23.10.2017

SECTION 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

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 : EC50 (*Daphnia magna* (Water flea)): 9,6 mg/l

Desloratadine / Pseudoephedrine Formulation

Version 5.0 Revision Date: 30.09.2023 SDS Number: 2111477-00015 Date of last issue: 04.04.2023
Date of first issue: 23.10.2017

aquatic invertebrates	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

Citric acid:

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

Desloratadine:

Biodegradability : Result: Not readily biodegradable.

Desloratadine / Pseudoephedrine Formulation

Version 5.0 Revision Date: 30.09.2023 SDS Number: 2111477-00015 Date of last issue: 04.04.2023
Date of first issue: 23.10.2017

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:**

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

Other adverse effects

No data available

SECTION 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.

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.0	30.09.2023	2111477-00015	Date of first issue: 23.10.2017

If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

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

Not applicable for product as supplied.

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION

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

Argentina. Carcinogenic Substances and Agents Registry. : Not applicable

Control of precursors and essential chemicals for the preparation of drugs. : Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Revision Date : 30.09.2023
Date format : dd.mm.yyyy

Further information

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

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

Full text of other abbreviations

SAFETY DATA SHEET



Desloratadine / Pseudoephedrine Formulation



Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.0	30.09.2023	2111477-00015	Date of first issue: 23.10.2017

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
AR OEL	:	Argentina. Occupational Exposure Limits
ACGIH / TWA	:	8-hour, time-weighted average
AR OEL / CMP	:	TLV (Threshold Limit Value)

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

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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