

SAFETY DATA SHEET



Desloratadine / Pseudoephedrine Formulation



Version 5.0 Revision Date: 30.09.2023 SDS Number: 2095120-00014 Date of last issue: 04.04.2023
Date of first issue: 23.10.2017

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Desloratadine / Pseudoephedrine Formulation

Manufacturer or supplier's details

Company : Organon & Co.

Address : Rua Treze de Maio, 1161
Campinas, São Paulo, Brazil 13106-054

Telephone : +55 (19) 3758-2000

Emergency telephone : +55 (11) 3173-4931

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 in accordance with ABNT NBR 14725 Standard

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 in accordance with ABNT NBR 14725 Standard

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.

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Precautionary Statements : **Prevention:**
 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.

Other hazards which do not result in classification

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Classification	Concentration (% w/w)
Cellulose	9004-34-6		>= 30 -< 50
Bis[[S-(R*,R*)]-(β-hydroxy-α-methylphenethyl)methylammonium] sulphate	7460-12-0	Acute toxicity (Oral), Category 4 Acute toxicity (Inhalation), Category 4 Specific target organ toxicity - repeated exposure (Oral) (Central nervous system), Category 1 Specific target organ toxicity - repeated exposure (Inhalation) (Cardio-vascular system), Category 1	>= 20 -< 30
Starch, oxidized	65996-62-5		>= 1 -< 5
Disodium EDTA, dihydrate	6381-92-6	Acute toxicity (Oral), Category 5 Acute toxicity (Inhalation), Category 4 Specific target organ toxicity - repeated exposure (Respiratory Tract), Category 2	>= 1 -< 5
Citric acid	77-92-9	Eye irritation, Category 2A Specific target organ toxicity - single exposure, Category 3	>= 1 -< 5
Desloratadine	100643-71-8	Acute toxicity (Oral), Category 4 Serious eye damage, Category 1	>= 0,25 -< 1

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		Reproductive toxicity, Category 2 Short-term (acute) aquatic hazard, Category 2 Long-term (chronic) aquatic hazard, Category 2	
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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 delayed : May be harmful if swallowed or if inhaled.
Causes damage to organs through prolonged or repeated 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 (CO₂)
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

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- 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.
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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.
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SECTION 7. HANDLING AND STORAGE

- 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, 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.
- 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,
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- industrial hygiene monitoring, medical surveillance and the use of administrative controls.
- 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	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	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.

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.

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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.

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

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

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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
Method : OECD Test Guideline 404
Result : No skin irritation

Desloratadine:

Species : Rabbit

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||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 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

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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
 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

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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.

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

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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:**

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

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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:

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 rele-

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vant 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.

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
 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

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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

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
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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
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Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 140 mg/l Exposure time: 48 h Method: DIN 38412
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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
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	:	EC10 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: Based on data from similar materials
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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 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

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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.
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:

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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.
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.

Domestic regulation

ANTT

Not regulated as a dangerous good

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION

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

National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable

Brazil. List of chemicals controlled by the Federal : Not applicable

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Police

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/
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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

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
ACGIH / TWA	:	8-hour, time-weighted average

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,

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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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