

SAFETY DATA SHEET



Desloratadine / Pseudoephedrine Formulation



Version 4.0 Revision Date: 2020/10/10 SDS Number: 2095098-00009 Date of last issue: 2020/03/23
Date of first issue: 2017/10/23

P501 Dispose of contents/ container to an approved waste disposal plant.

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)	ENCS No.
Cellulose	9004-34-6	$\geq 30 - < 40$	
Bis[[S-(R*,R*)-(β -hydroxy- α -methylphenethyl)methylammonium] sulphate	7460-12-0	$\geq 20 - < 30$	
Citric acid	77-92-9	$\geq 1 - < 10$	2-1318
Disodium EDTA, dihydrate	6381-92-6	$\geq 1 - < 10$	2-1265, 2-1265
Desloratadine	100643-71-8	$\geq 0.25 - < 1$	

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 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 : 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.

5. FIREFIGHTING MEASURES

Suitable extinguishing media : Water spray

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- Unsuitable extinguishing media : Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical
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 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.
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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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 as-
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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
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.

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**Threshold limit value and permissible exposure limits for each component in the work environment**

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
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

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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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : solid

Colour : white, blue

Odour : No data available

Odour Threshold : No data available

Melting point/freezing point : No data available

Boiling point, initial boiling point and boiling range : No data available

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

Flammability (liquids) : No data available

Lower explosion limit and upper explosion limit / flammability limit
Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Flash point : Not applicable

Decomposition temperature : No data available

pH : No data available

Evaporation rate : Not applicable

Auto-ignition temperature : No data available

Viscosity
Viscosity, kinematic : Not applicable

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Solubility(ies)
Water solubility : No data available

Partition coefficient: n-octanol/water : Not applicable

Vapour pressure : Not applicable

Density and / or relative density
Relative density : No data available

Density : No data available

Relative vapour density : Not applicable

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

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

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg
Method: Calculation method

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

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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.

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

Disodium EDTA, dihydrate:

Acute oral toxicity : LD50 (Rat): 2,800 mg/kg
 Remarks: Based on data from similar materials
 Acute inhalation toxicity : LC50 (Rat): > 1 mg/l
 Exposure time: 6 h
 Test atmosphere: dust/mist
 Method: OECD Test Guideline 412
 Remarks: Based on data from similar materials

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.

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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

Disodium EDTA, dihydrate:

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

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

Citric acid:

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

Disodium EDTA, dihydrate:

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

Desloratadine:

Species : Rabbit
Remarks : Severe eye irritation

Respiratory or skin sensitisation**Skin sensitisation**

Not classified based on available information.

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Respiratory sensitisation

Not classified based on available information.

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

Remarks : No data available

Disodium EDTA, dihydrate:

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

Desloratadine:

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

Germ cell mutagenicity

Not classified based on available information.

Components:**Cellulose:**

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES)
	Result: negative
Genotoxicity in vivo	: 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
Genotoxicity in vivo	: Remarks: Information given is based on data obtained from similar substances.
	: Test Type: Chromosomal aberration
Genotoxicity in vivo	Result: negative
	: Remarks: Information given is based on data obtained from similar substances.
	: Test Type: Micronucleus test
Genotoxicity in vivo	Species: Rat
	Application Route: Oral

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		Result: negative Remarks: Based on data from similar materials
	Citric acid:	
	Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
		Test Type: in vitro micronucleus test Result: positive
		Test Type: Bacterial reverse mutation assay (AMES) Result: negative
	Genotoxicity in vivo	: Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis) Species: Rat Application Route: Ingestion Result: negative
	Disodium EDTA, dihydrate:	
	Genotoxicity in vitro	: Test Type: Chromosome aberration test in vitro Result: negative Remarks: Based on data from similar materials
	Genotoxicity in vivo	: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Ingestion Method: OECD Test Guideline 474 Result: negative Remarks: Based on data from similar materials
	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.

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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:**

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

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		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.
Citric acid:		
Effects on foetal development	:	Test Type: One-generation reproduction toxicity study Species: Rat Application Route: Ingestion Result: negative
Disodium EDTA, dihydrate:		
Effects on fertility	:	Test Type: Four-generation reproduction toxicity study Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials
Effects on foetal development	:	Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials
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

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<p>Effects on foetal development</p>	<p>Remarks: The mechanism or mode of action may not be relevant in humans.</p> <p>Test Type: Fertility Species: Rat, female Fertility: NOAEL: 3 mg/kg body weight Symptoms: No effects on fertility Result: negative</p> <p>: Test Type: Embryo-foetal development Species: Rabbit Application Route: Oral Developmental Toxicity: NOAEL: 30 mg/kg body weight Result: No teratogenic effects</p> <p>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.</p> <p>Test Type: Two-generation study Species: Rat Application Route: Oral Developmental Toxicity: LOAEL: 18 mg/kg body weight Result: No adverse effects</p>
<p>Reproductive toxicity - Assessment</p>	<p>: 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.</p>

STOT - single exposure

Not classified based on available information.

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:**

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

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

Citric acid:

Species : Rat
 NOAEL : 4,000 mg/kg
 LOAEL : 8,000 mg/kg
 Application Route : Ingestion
 Exposure time : 10 Days

Disodium EDTA, dihydrate:

Species : Rat
 NOAEL : 500 mg/kg
 Application Route : Ingestion
 Exposure time : 13 Weeks
 Remarks : Based on data from similar materials

Species : Rat
 LOAEL : 0.03 mg/l
 Application Route : inhalation (dust/mist/fume)
 Exposure time : 4 Weeks
 Remarks : Based on data from similar materials

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

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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

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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Citric acid:

Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l Exposure time: 96 h
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Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 1,535 mg/l
 Exposure time: 24 h

Disodium EDTA, dihydrate:

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 159 mg/l
 Exposure time: 96 h
 Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 140 mg/l
 Exposure time: 48 h
 Remarks: Based on data from similar materials

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

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

Toxicity to fish (Chronic toxicity) : NOEC (Danio rerio (zebra fish)): 25.7 mg/l
 Exposure time: 35 d
 Method: OECD Test Guideline 210
 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
 Remarks: Based on data from similar materials

Toxicity to microorganisms : EC50: < 500 mg/l
 Exposure time: 0.5 h
 Method: OECD Test Guideline 209
 Remarks: Based on data from similar materials

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

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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.

Citric acid:

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

Disodium EDTA, dihydrate:

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

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

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

Partition coefficient: n-octanol/water : log Pow: 0.89

Citric acid:

Partition coefficient: n-octanol/water : log Pow: -1.72

Disodium EDTA, dihydrate:

Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)
 Bioconcentration factor (BCF): 1.8
 Remarks: Based on data from similar materials

Partition coefficient: n-octanol/water : log Pow: -4.3

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

Hazardous to the ozone layer

Not applicable

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues : 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**

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

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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.

National Regulations

Refer to section 15 for specific national regulation.

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law

Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law

Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture

Not applicable

Harmful Substances Required Permission for Manufacture

Not applicable

Substances Prevented From Impairment of Health

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

Substances Subject to be Notified Names

Not applicable

Substances Subject to be Indicated Names

Not applicable

Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

Ordinance on Prevention of Lead Poisoning

Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

Ordinance on Prevention of Organic Solvent Poisoning

Not applicable

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Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)

Not applicable

Poisonous and Deleterious Substances Control Law

Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

Not applicable

High Pressure Gas Safety Act

Not applicable

Explosive Control Law

Not applicable

Vessel Safety Law

Not regulated as a dangerous good

Aviation Law

Not regulated as a dangerous good

Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Noxious liquid substance(Category Z)

Pack transportation : Not classified as marine pollutant

Narcotics and Psychotropics Control Act

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

Waste Disposal and Public Cleansing Law

Industrial waste

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

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION**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/>

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

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Date format : yyyy/mm/dd

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, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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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