

SAFETY DATA SHEET



Desloratadine / Pseudoephedrine Formulation



Version 4.0 Revision Date: 30.09.2023 SDS Number: 2095094-00013 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 name of supplier : Organon & Co.
Address : Avenida 16 de Septiembre No. 301
Xaltocan - Xochimilco Mexico 16090
Telephone : +52 55 57284444
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
Reproductive toxicity : Category 2
Specific target organ toxicity - repeated exposure (Oral) : Category 1 (Central nervous system)
Specific target organ toxicity - repeated exposure (Inhalation) : Category 1 (Cardio-vascular system)
Specific target organ toxicity - repeated exposure : Category 2 (Respiratory Tract)

GHS label elements

Hazard pictograms : 

Signal Word : Danger

Hazard Statements : H303 + H333 May be harmful if swallowed or if inhaled.
H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.
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.
H373 May cause damage to organs (Respiratory Tract) through prolonged or repeated exposure.

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Precautionary Statements : **Prevention:**
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
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.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P304 + P312 IF INHALED: Call a POISON CENTER or doctor/ physician if you feel unwell.
P312 Call a POISON CENTER or doctor/ physician if you feel unwell.

Storage:
P405 Store locked up.

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

Other hazards

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	>= 0.1 -< 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.

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- In case of eye contact : Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.
: 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.
Suspected of damaging fertility. Suspected of damaging the unborn child.
Causes damage to organs through prolonged or repeated exposure if swallowed.
Causes damage to organs through prolonged or repeated exposure if inhaled.
May cause damage to organs through prolonged or repeated exposure.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- Notes to physician : Treat symptomatically and supportively.
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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
- 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

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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 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, 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

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Cellulose	9004-34-6	VLE-PPT	10 mg/m ³	NOM-010-STPS-2014
		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	VLE-PPT (inhalable dust)	0.5 mg/m ³	NOM-010-STPS-2014
		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.

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

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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
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

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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

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:

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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.
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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

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

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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
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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

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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

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

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Genotoxicity in vivo	:	Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis) Species: Rat Application Route: Ingestion Result: negative
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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
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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

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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

Suspected of damaging fertility. Suspected of damaging the unborn child.

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
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		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 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 - As-	: Some evidence of adverse effects on sexual function and

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Assessment : 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.

May cause damage to organs (Respiratory Tract) through prolonged or repeated exposure.

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

Starch, oxidized:

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

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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
Application Route	: Oral
Exposure time	: 3 Months
Symptoms	: Gastrointestinal disturbance, Fatigue

Aspiration toxicity

Not classified based on available information.

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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
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

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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

Persistence and degradability**Components:****Cellulose:**

Biodegradability	:	Result: Readily biodegradable.
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Disodium EDTA, dihydrate:

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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:

Partition coefficient: n-octanol/water : log Pow: 1.24
Method: OECD Test Guideline 107

Mobility in soil**Components:****Desloratadine:**

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Distribution among environmental compartments : log K_{oc}: 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

NOM-002-SCT

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

Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills. : Bis[[S-(R*,R*)]-(β-hydroxy-α-methylphenethyl)methylammonium] sulphate

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

AICS : not determined

DSL : not determined

IECSC : not determined

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SECTION 16. OTHER INFORMATION

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

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
NOM-010-STPS-2014 : Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting the Work Environment - Identification, Assessment and Control - Appendix 1 Occupational Exposure Limits
ACGIH / TWA : 8-hour, time-weighted average
NOM-010-STPS-2014 / VLE- : Time weighted average limit value
PPT

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

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.

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The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

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