

**Desloratadine / Pseudoephedrine Formulation**

Version            Revision Date:            SDS Number:            Date of last issue: 05/15/2019  
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**SECTION 1. IDENTIFICATION**

Product name                                : Desloratadine / Pseudoephedrine Formulation  
Other means of identification            : No data available

**Manufacturer or supplier's details**

Company name of supplier                : Merck & Co., Inc  
Address                                        : 2000 Galloping Hill Road  
    Kenilworth - New Jersey - U.S.A. 07033  
Telephone                                    : 908-740-4000  
Telefax                                        : 908-735-1496  
Emergency telephone                      : 1-908-423-6000  
E-mail address                               : EHSDATASTEWARD@merck.com

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


Recommended use                         : Pharmaceutical

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**SECTION 2. HAZARDS IDENTIFICATION****GHS classification in accordance with the Hazardous Products Regulations**

Reproductive toxicity                      : Category 2  
  
Specific target organ toxicity            : Category 1 (Central nervous system)  
- repeated exposure (Oral)  
  
Specific target organ toxicity            : Category 1 (Cardio-vascular system)  
- repeated exposure  
(Inhalation)  
  
Specific target organ toxicity            : Category 2 (Respiratory Tract)  
- repeated exposure

**GHS label elements**

Hazard pictograms                         : 

Signal Word                                 : Danger

Hazard Statements                         : 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.

Precautionary Statements                : **Prevention:**  
P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read

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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:**

P308 + P313 IF exposed or concerned: Get medical advice/ attention.

**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 - < 60
Bis[[S-(R*,R*)-(β-hydroxy-α-methylphenethyl)methylammonium] sulphate	7460-12-0	>= 10 - < 30
Starch, oxidized	65996-62-5	>= 1 - < 5
Silicon dioxide	7631-86-9	>= 1 - < 5
Disodium EDTA, dihydrate	6381-92-6	>= 1 - < 5
Citric acid	77-92-9	>= 1 - < 5
Desloratadine	100643-71-8	>= 0.1 - < 1

Actual concentration or concentration range is withheld as a trade secret

### 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.

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If swallowed	:	Get medical attention if irritation develops and persists. If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	:	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 (CO <sub>2</sub> ) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire fighting	:	Exposure to combustion products may be a hazard to health.
Hazardous combustion products	:	Carbon oxides Nitrogen oxides (NO <sub>x</sub> ) Metal oxides
Specific extinguishing methods	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for 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 and personal protective equipment recommendations.
Environmental precautions	:	Discharge into the environment must be avoided. 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

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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 swallow.  
 Avoid contact with eyes.  
 Avoid prolonged or repeated contact with skin.  
 Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
 Take care to prevent spills, waste and minimize release to the environment.
- Conditions for safe storage : Keep in properly labeled containers.  
 Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:  
 Strong oxidizing agents  
 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 <sup>3</sup>	CA AB OEL
		TWA (Total dust)	10 mg/m <sup>3</sup>	CA BC OEL
		TWA (respirable dust fraction)	3 mg/m <sup>3</sup>	CA BC OEL
		TWAEV (total dust)	10 mg/m <sup>3</sup>	CA QC OEL
		TWA	10 mg/m <sup>3</sup>	ACGIH
Bis[[S-(R*,R*)-(β-hydroxy-α-methylphenethyl)methylammonium] sulphate	7460-12-0	TWA	50 µg/m <sup>3</sup> (OEB 3)	Internal
		Wipe limit	500 µg/100 cm <sup>2</sup>	Internal
Starch, oxidized	65996-62-5	TWA (Total particulates)	0.5 mg/m <sup>3</sup>	CA AB OEL
		TWA (inhalable dust)	0.5 mg/m <sup>3</sup>	CA BC OEL
Silicon dioxide	7631-86-9	TWAEV (respirable)	6 mg/m <sup>3</sup>	CA QC OEL

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		dust)		
		TWA (Respirable)	1.5 mg/m <sup>3</sup>	CA BC OEL
		TWA (Total)	4 mg/m <sup>3</sup>	CA BC OEL
		TWA (Respirable)	1.5 mg/m <sup>3</sup>	CA BC OEL
		TWA (Total)	4 mg/m <sup>3</sup>	CA BC OEL
Desloratadine	100643-71-8	TWA	20 µg/m <sup>3</sup> (OEB 3)	Internal
		Wipe limit	200 µg/100 cm <sup>2</sup>	Internal

**Engineering measures** : All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices). Minimize open handling.

**Personal protective equipment**

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Particulates type

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Eye protection : Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection : Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

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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
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

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**SECTION 10. STABILITY AND REACTIVITY**

Reactivity : Not classified as a reactivity hazard.  
Chemical stability : Stable under normal conditions.  
Possibility of hazardous reactions : Can react with strong oxidizing agents.  
Conditions to avoid : None known.  
Incompatible materials : Oxidizing agents  
Hazardous decomposition products : No hazardous decomposition products are known.

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**SECTION 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: 2,451 mg/kg  
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: 5.3 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.

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**Silicon dioxide:**

- Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
Method: OECD Test Guideline 401
- Acute inhalation toxicity : LC50 (Rat): > 2.08 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Assessment: The substance or mixture has no acute inhalation toxicity
- Acute dermal toxicity : LD50 (Rabbit): > 5,000 mg/kg

**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

**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\*)]-( $\beta$ -hydroxy- $\alpha$ -methylphenethyl)methylammonium] sulphate:**

- Species : Rabbit  
Result : No skin irritation

**Silicon dioxide:**

- Species : Rabbit



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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

**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

**Silicon dioxide:**

Species : Rabbit  
Result : No eye irritation  
Method : OECD Test Guideline 405

**Disodium EDTA, dihydrate:**

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

**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.

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**Respiratory sensitization**

Not classified based on available information.

**Components:****Bis[[S-(R\*,R\*)]-( $\beta$ -hydroxy- $\alpha$ -methylphenethyl)methylammonium] sulphate:**

Remarks : No data available

**Disodium EDTA, dihydrate:**

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

**Desloratadine:**

Test Type	: Maximization Test
Routes of exposure	: Dermal
Species	: Guinea pig
Result	: negative

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****Cellulose:**

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

**Bis[[S-(R\*,R\*)]-( $\beta$ -hydroxy- $\alpha$ -methylphenethyl)methylammonium] sulphate:**

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

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Result: negative  
Remarks: Based on data from similar materials

### Silicon dioxide:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
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

### 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

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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

**Silicon dioxide:**

Species                                : Rat  
Application Route                    : Ingestion  
Exposure time                        : 103 weeks  
Result                                    : negative

**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

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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.

**Silicon dioxide:**

Effects on fetal development : Test Type: Embryo-fetal development  
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

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Effects on fetal development : Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Ingestion  
Result: negative  
Remarks: Based on data from similar materials

**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 - 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.

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**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.

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                     : 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

**Silicon dioxide:**

Species                         : Rat  
NOAEL                         : 1.3 mg/m<sup>3</sup>  
Application Route             : inhalation (dust/mist/fume)  
Exposure time                 : 13 Weeks

**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

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

**Citric acid:**

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

**Desloratadine:**

Species : Rat  
 LOAEL : 30 mg/kg  
 Application Route : Oral  
 Exposure time : 3 Months  
 Target Organs : Kidney  
 Remarks : Significant toxicity observed in testing  
 The mechanism or mode of action may not be relevant in humans.

Species : Monkey  
 NOAEL : 6 mg/kg  
 LOAEL : 12 mg/kg  
 Application Route : Oral  
 Exposure time : 3 Months  
 Target Organs : Central nervous system  
 Symptoms : Gastrointestinal disturbance

Species : Monkey  
 NOAEL : 40 mg/kg  
 Application Route : Oral  
 Exposure time : 17 Months  
 Remarks : No significant adverse effects were reported

Species : Monkey  
 NOAEL : 6 mg/kg  
 Application Route : Oral  
 Exposure time : 3 Months  
 Symptoms : Gastrointestinal disturbance, Fatigue

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure****Components:****Bis[[S-(R\*,R\*)]-(β-hydroxy-α-methylphenethyl)methylammonium] sulphate:**

Inhalation : Remarks: May cause irritation of respiratory tract.  
 Eye contact : Remarks: May irritate eyes.  
 Ingestion : Symptoms: central nervous system effects, tachycardia, Palpi-



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**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 ( <i>Oryzias latipes</i> (Japanese medaka)): > 100 mg/l Exposure time: 48 h Remarks: Based on data from similar materials
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##### **Silicon dioxide:**

Toxicity to fish	:	LC50 ( <i>Danio rerio</i> (zebra fish)): > 10,000 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	EC50 ( <i>Daphnia magna</i> (Water flea)): > 1,000 mg/l Exposure time: 24 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	EC50 ( <i>Desmodesmus subspicatus</i> (green algae)): > 10,000 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: Based on data from similar materials
		NOEC ( <i>Desmodesmus subspicatus</i> (green algae)): 10,000 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: Based on data from similar materials

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

Toxicity to fish	:	LC50 ( <i>Lepomis macrochirus</i> (Bluegill sunfish)): 159 mg/l Exposure time: 96 h Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates	:	EC50 ( <i>Daphnia magna</i> (Water flea)): 140 mg/l Exposure time: 48 h Remarks: Based on data from similar materials
Toxicity to algae/aquatic plants	:	EC50 ( <i>Desmodesmus subspicatus</i> (green algae)): > 100 mg/l Exposure time: 72 h Remarks: Based on data from similar materials
		NOEC ( <i>Desmodesmus subspicatus</i> (green algae)): 100 mg/l

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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

### 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

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Method: OECD Test Guideline 209

NOEC (Natural microorganism): 12 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

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

Biodegradability : Result: Readily biodegradable.

**Disodium EDTA, dihydrate:**

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

**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): 1.8  
Remarks: Based on data from similar materials

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

**Citric acid:**

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

**Desloratadine:**

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

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

Distribution among environmental compartments : log Koc: 3.00  
Method: OECD Test Guideline 106

**Other adverse effects**

No data available

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**SECTION 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.

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**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****TDG**

Not regulated as a dangerous good

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**SECTION 15. REGULATORY INFORMATION**

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

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

## SECTION 16. OTHER INFORMATION

## Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
CA AB OEL	:	Canada. Alberta, Occupational Health and Safety Code (table 2: OEL)
CA BC OEL	:	Canada. British Columbia OEL
CA QC OEL	:	Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants
ACGIH / TWA	:	8-hour, time-weighted average
CA AB OEL / TWA	:	8-hour Occupational exposure limit
CA BC OEL / TWA	:	8-hour time weighted average
CA QC OEL / TWA EV	:	Time-weighted average exposure value

AICS - Australian Inventory of Chemical Substances; 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

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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/>

Revision Date : 09/13/2019

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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