

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



ORGANON

## Loratadine / Montelukast Formulation

Version 1.4      Revision Date: 2021/04/09      SDS Number: 4574850-00005      Date of last issue: 2020/10/10  
Date of first issue: 2019/07/08

### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Loratadine / Montelukast Formulation

#### Manufacturer or supplier's details

Company : Organon & Co.

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

Telephone : 551-430-6000

Emergency telephone number : 215-631-6999

E-mail address : EHSSTEWARD@organon.com

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

Recommended use : Pharmaceutical

### 2. HAZARDS IDENTIFICATION

#### Emergency Overview

**Appearance** : tablet  
**Colour** : No data available  
**Odour** : No data available

Suspected of damaging fertility. Toxic to aquatic life with long lasting effects.

#### GHS Classification

Reproductive toxicity : Category 2

Short-term (acute) aquatic hazard : Category 2

Long-term (chronic) aquatic hazard : Category 2

#### GHS label elements

Hazard pictograms :

Signal word : Warning

Hazard statements : H361f Suspected of damaging fertility.  
H411 Toxic to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**  
P201 Obtain special instructions before use.

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Loratadine / Montelukast Formulation

Version 1.4      Revision Date: 2021/04/09      SDS Number: 4574850-00005      Date of last issue: 2020/10/10  
Date of first issue: 2019/07/08

P202 Do not handle until all safety precautions have been read and understood.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

### Response:

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

P391 Collect spillage.

### Storage:

P405 Store locked up.

### Disposal:

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

### Physical and chemical hazards

Not classified based on available information.

### Health hazards

Suspected of damaging fertility.

### Environmental hazards

Toxic to aquatic life. Toxic to aquatic life with long lasting effects.

### Other hazards which do not result in classification

Dust contact with the eyes can lead to mechanical irritation.

Contact with dust can cause mechanical irritation or drying of the skin.

May form combustible dust concentrations in air during processing, handling or other means.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Concentration (% w/w)
Cellulose	9004-34-6	>= 30 -< 50
Montelukast	151767-02-1	>= 1 -< 10
Loratadine	79794-75-5	>= 3 -< 10

## 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.

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Loratadine / Montelukast Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2020/10/10
1.4	2021/04/09	4574850-00005	Date of first issue: 2019/07/08

---

In case of eye contact	:	Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse. If in eyes, rinse well with water.
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. Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation.
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 Alcohol-resistant foam Carbon dioxide (CO <sub>2</sub> ) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire-fighting	:	Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.
Hazardous combustion products	:	Carbon 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.

### 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.

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Loratadine / Montelukast Formulation

Version 1.4      Revision Date: 2021/04/09      SDS Number: 4574850-00005      Date of last issue: 2020/10/10  
Date of first issue: 2019/07/08

Methods and materials for containment and cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal.  
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).  
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.  
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.

### 7. HANDLING AND STORAGE

#### Handling

Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.  
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation : Use only with adequate ventilation.

Advice on safe handling : Do not breathe dust.  
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  
Minimize dust generation and accumulation.  
Keep container closed when not in use.  
Keep away from heat and sources of ignition.  
Take precautionary measures against static discharges.  
Take care to prevent spills, waste and minimize release to the environment.

Avoidance of contact : Oxidizing agents

#### Storage

Conditions for safe storage : Keep in properly labelled containers.  
Store locked up.  
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

#### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Loratadine / Montelukast Formulation

Version 1.4      Revision Date: 2021/04/09      SDS Number: 4574850-00005      Date of last issue: 2020/10/10  
Date of first issue: 2019/07/08

Cellulose	9004-34-6	PC-TWA	10 mg/m <sup>3</sup>	CN OEL
		TWA	10 mg/m <sup>3</sup>	ACGIH
Montelukast	151767-02-1	TWA	40 µg/m <sup>3</sup> (OEB 3)	Internal
		Wipe limit	400 µg/100 cm <sup>2</sup>	Internal
Loratadine	79794-75-5	TWA	40 µg/m <sup>3</sup> (OEB 3)	Internal
		Wipe limit	400 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

Eye/face 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.

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

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.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : tablet

Colour : No data available

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



ORGANON

## Loratadine / Montelukast Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2020/10/10
1.4	2021/04/09	4574850-00005	Date of first issue: 2019/07/08

---

Odour	:	No data available
Odour 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)	:	May form combustible dust concentrations in air during processing, handling or other means.
Flammability (liquids)	:	Not applicable
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	Not applicable
Relative vapour 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
Auto-ignition 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.
Molecular weight	:	No data available

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



ORGANON

## Loratadine / Montelukast Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2020/10/10
1.4	2021/04/09	4574850-00005	Date of first issue: 2019/07/08

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 : May form combustible dust concentrations in air during processing, handling or other means.  
Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.  
Avoid dust formation.

Incompatible materials : Oxidizing agents  
Hazardous decomposition products : No hazardous decomposition products are known.

### 11. TOXICOLOGICAL INFORMATION

Exposure routes : Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Not classified based on available information.

#### 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

##### Montelukast:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
LD50 (Mouse): > 5,000 mg/kg  
Acute inhalation toxicity : Remarks: No data available  
Acute dermal toxicity : Remarks: No data available

##### Loratadine:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
Acute inhalation toxicity : LC50 (Rat): > 0.05 mg/l  
Exposure time: 1 h  
Test atmosphere: dust/mist  
Assessment: The substance or mixture has no acute inhala-

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Loratadine / Montelukast Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2020/10/10
1.4	2021/04/09	4574850-00005	Date of first issue: 2019/07/08

---

tion toxicity

### Skin corrosion/irritation

Not classified based on available information.

#### Components:

##### Montelukast:

Species : Rabbit  
Result : Mild skin irritation

##### Loratadine:

Species : Rabbit  
Result : No skin irritation

### Serious eye damage/eye irritation

Not classified based on available information.

#### Components:

##### Montelukast:

Species : Rabbit  
Result : Severe irritation

##### Loratadine:

Species : Rabbit  
Result : No eye irritation

### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

#### Respiratory sensitisation

Not classified based on available information.

#### Components:

##### Montelukast:

Remarks : No data available

##### Loratadine:

Test Type : Maximisation Test  
Exposure routes : Dermal  
Species : Guinea pig  
Assessment : Does not cause skin sensitisation.  
Result : negative

### Germ cell mutagenicity

Not classified based on available information.



# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Loratadine / Montelukast Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2020/10/10
1.4	2021/04/09	4574850-00005	Date of first issue: 2019/07/08

---

### 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

#### **Montelukast:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

Test Type: In vitro mammalian cell gene mutation test  
Test system: Chinese hamster fibroblasts  
Result: negative

Test Type: Chromosomal aberration  
Test system: Chinese hamster ovary cells  
Result: negative

Test Type: Alkaline elution assay  
Test system: rat hepatocytes  
Result: negative

Genotoxicity in vivo : Test Type: Chromosomal aberration  
Species: Mouse  
Cell type: Bone marrow  
Application Route: Oral  
Result: negative

#### **Loratadine:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

Test Type: In vitro mammalian cell gene mutation test  
Result: negative

Test Type: Chromosome aberration test in vitro  
Result: negative

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)  
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test  
Species: Mouse

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



ORGANON

## Loratadine / Montelukast Formulation

Version 1.4      Revision Date: 2021/04/09      SDS Number: 4574850-00005      Date of last issue: 2020/10/10  
Date of first issue: 2019/07/08

---

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

Germ cell mutagenicity - Assessment : Weight of evidence does not support classification as a germ cell mutagen.

### Carcinogenicity

Not classified based on available information.

#### Components:

##### Cellulose:

Species : Rat  
Application Route : Ingestion  
Exposure time : 72 weeks  
Result : negative

##### Montelukast:

Species : Rat  
Application Route : Oral  
Exposure time : 2 Years  
Result : negative

Species : Mouse  
Application Route : Oral  
Exposure time : 92 weeks  
Result : negative

##### Loratadine:

Species : Rat  
Application Route : Oral  
Exposure time : 2 Years  
LOAEL : 10 mg/kg body weight  
Result : positive

Species : Monkey  
Application Route : Oral  
Exposure time : 17 Months  
NOAEL : 40 mg/kg body weight  
Result : negative

### Reproductive toxicity

Suspected of damaging fertility.

#### Components:

##### Cellulose:

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

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



ORGANON

## Loratadine / Montelukast Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2020/10/10
1.4	2021/04/09	4574850-00005	Date of first issue: 2019/07/08

---

Effects on foetal development : Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Ingestion  
Result: negative

### Montelukast:

Effects on fertility : Test Type: Fertility  
Species: Rat, male  
Application Route: Oral  
Fertility: NOAEL: 800 mg/kg body weight  
Result: Animal testing did not show any effects on fertility.

Test Type: Fertility  
Species: Rat, female  
Application Route: Oral  
Fertility: LOAEL: 200 mg/kg body weight  
Symptoms: Reduced fertility

Test Type: Fertility  
Species: Rat, female  
Application Route: Oral  
Fertility: NOAEL: 100 mg/kg body weight  
Symptoms: Reduced fertility

### Loratadine:

Effects on fertility : Species: Rat, male  
Application Route: Oral  
Fertility: LOAEL: 64 mg/kg body weight  
Result: Effects on fertility

Effects on foetal development : Species: Rat  
Application Route: Oral  
Developmental Toxicity: LOAEL: 48 mg/kg body weight  
Result: Embryo-foetal toxicity

Species: Rabbit  
Application Route: Oral  
Developmental Toxicity: LOAEL: 48 mg/kg body weight  
Result: Embryo-foetal toxicity

Species: Rat  
Application Route: Oral  
Developmental Toxicity: LOAEL: 12 mg/kg body weight

Reproductive toxicity - Assessment : Some evidence of adverse effects on sexual function and fertility, based on animal experiments.

### STOT - single exposure

Not classified based on available information.

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Loratadine / Montelukast Formulation

Version 1.4      Revision Date: 2021/04/09      SDS Number: 4574850-00005      Date of last issue: 2020/10/10  
Date of first issue: 2019/07/08

---

### STOT - repeated exposure

Not classified based on available information.

### Repeated dose toxicity

#### Components:

##### Cellulose:

Species : Rat  
NOAEL :  $\geq 9,000$  mg/kg  
Application Route : Ingestion  
Exposure time : 90 Days

##### Montelukast:

Species : Monkey, male and female  
NOAEL : 150 - 300 mg/kg  
Application Route : Oral  
Exposure time : 53 Weeks  
Remarks : No significant adverse effects were reported

Species : Rat  
NOAEL : 50 mg/kg  
Application Route : Oral  
Exposure time : 53 Weeks  
Remarks : No significant adverse effects were reported

Species : Mouse  
NOAEL : 50 mg/kg  
Application Route : Oral  
Exposure time : 14 Weeks  
Remarks : No significant adverse effects were reported

##### Loratadine:

Species : Rat  
NOAEL : 4 mg/kg  
LOAEL : 8 mg/kg  
Application Route : Oral  
Exposure time : 180 Days  
Target Organs : Central nervous system  
Remarks : Effects are of limited toxicological significance.

Species : Monkey  
NOAEL : 0.4 mg/kg  
LOAEL : 4 mg/kg  
Application Route : Oral  
Exposure time : 180 Days  
Target Organs : Central nervous system  
Remarks : Effects are of limited toxicological significance.

### Aspiration toxicity

Not classified based on available information.

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



ORGANON

## Loratadine / Montelukast Formulation

Version 1.4      Revision Date: 2021/04/09      SDS Number: 4574850-00005      Date of last issue: 2020/10/10  
Date of first issue: 2019/07/08

### Experience with human exposure

#### Components:

##### **Montelukast:**

Skin contact : Remarks: May irritate skin.  
Eye contact : Symptoms: Severe irritation  
Ingestion : Symptoms: upper respiratory tract infection, pharyngitis, Headache, Cough, Abdominal pain, Diarrhoea, Fever

##### **Loratadine:**

Ingestion : Symptoms: Fatigue, Headache, dry mouth, Nausea

## 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

##### **Montelukast:**

Toxicity to fish : LC50 (*Pimephales promelas* (fathead minnow)): > 0.0778 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203  
Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates : EC50 (*Daphnia magna* (Water flea)): > 0.0675 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202  
Remarks: No toxicity at the limit of solubility

Toxicity to algae/aquatic plants : NOEC (*Pseudokirchneriella subcapitata* (green algae)): 100 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: No toxicity at the limit of solubility

EC50 (*Pseudokirchneriella subcapitata* (green algae)): > 100 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: No toxicity at the limit of solubility

Toxicity to fish (Chronic toxicity) : NOEC (*Pimephales promelas* (fathead minnow)): 0.073 mg/l  
Exposure time: 32 d  
Method: OECD Test Guideline 210  
Remarks: No toxicity at the limit of solubility

NOEC (*Cyprinodon variegatus* (sheepshead minnow)): 0.0816 mg/l

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



ORGANON

## Loratadine / Montelukast Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2020/10/10
1.4	2021/04/09	4574850-00005	Date of first issue: 2019/07/08

---

Exposure time: 7 d  
Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.23 mg/l  
Exposure time: 21 d  
Remarks: No toxicity at the limit of solubility

Toxicity to microorganisms : EC50: > 100 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209  
Remarks: No toxicity at the limit of solubility

### Loratadine:

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 0.382 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 0.83 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): > 0.95 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 0.053 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity) : 1

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 0.084 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)): 0.078 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity) : 1

Toxicity to microorganisms : EC50: > 1,000 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Loratadine / Montelukast Formulation

Version 1.4      Revision Date: 2021/04/09      SDS Number: 4574850-00005      Date of last issue: 2020/10/10  
Date of first issue: 2019/07/08

---

### Persistence and degradability

#### Components:

##### **Cellulose:**

Biodegradability : Result: Readily biodegradable.

##### **Montelukast:**

Biodegradability : Result: not rapidly degradable  
Biodegradation: 0 %  
Exposure time: 28 d

Stability in water : Hydrolysis: 50 %(21.7 h)

##### **Loratadine:**

Biodegradability : Result: not rapidly degradable  
Biodegradation: 50 %  
Exposure time: 20 d  
Method: OECD Test Guideline 314

Stability in water : Degradation half life (DT50): 283 d

### Bioaccumulative potential

#### Components:

##### **Montelukast:**

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

##### **Loratadine:**

Partition coefficient: n-octanol/water : log Pow: 2.35

### Mobility in soil

#### Components:

##### **Loratadine:**

Distribution among environmental compartments : log Koc: 5.25  
Method: OECD Test Guideline 106

### 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.

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Loratadine / Montelukast Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2020/10/10
1.4	2021/04/09	4574850-00005	Date of first issue: 2019/07/08

### 14. TRANSPORT INFORMATION

#### International Regulations

##### UNRTDG

UN number : UN 3077  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
(Loratadine)  
Class : 9  
Packing group : III  
Labels : 9

##### IATA-DGR

UN/ID No. : UN 3077  
Proper shipping name : Environmentally hazardous substance, solid, n.o.s.  
(Loratadine)  
Class : 9  
Packing group : III  
Labels : Miscellaneous  
Packing instruction (cargo aircraft) : 956  
Packing instruction (passenger aircraft) : 956  
Environmentally hazardous : yes

##### IMDG-Code

UN number : UN 3077  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
(Loratadine)  
Class : 9  
Packing group : III  
Labels : 9  
EmS Code : F-A, S-F  
Marine pollutant : yes

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

Not applicable for product as supplied.

#### National Regulations

##### GB 6944/12268

UN number : UN 3077  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
(Loratadine)  
Class : 9  
Packing group : III  
Labels : 9

#### Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.



# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



ORGANON

## Loratadine / Montelukast Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2020/10/10
1.4	2021/04/09	4574850-00005	Date of first issue: 2019/07/08

### 15. REGULATORY INFORMATION

#### National regulatory information

#### Law on the Prevention and Control of Occupational Diseases

#### 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/>

Date format : yyyy/mm/dd

#### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
CN OEL : Occupational exposure limits for hazardous agents in the workplace - Chemical hazardous agents.

ACGIH / TWA : 8-hour, time-weighted average  
CN OEL / PC-TWA : Permissible concentration - 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; KECl - 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, Bioaccumu-

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Loratadine / Montelukast Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2020/10/10
1.4	2021/04/09	4574850-00005	Date of first issue: 2019/07/08

---

lative 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

### Disclaimer

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.

CN / EN