

Loratadine / Montelukast Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 30.09.2023 4574881-00011 Date of first issue: 08.07.2019 4.1

Section 1: 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 +1-551-430-6000

Emergency telephone number: +1-215-631-6999

: EHSSTEWARD@organon.com E-mail address

Recommended use of the chemical and restrictions on use

Recommended use **Pharmaceutical** Restrictions on use Not applicable

Section 2: Hazard identification

GHS Classification

Reproductive toxicity Category 2

Hazardous to the aquatic environment - chronic hazard

Category 2

GHS label elements

Hazard pictograms





Signal word

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.

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 protec-

tion/ face protection.



Loratadine / Montelukast Formulation



 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 4.1
 30.09.2023
 4574881-00011
 Date of first issue: 08.07.2019

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.

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.

Section 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	>= 2.5 -< 10

Section 4: First-aid measures

General advice : In the case of accident or if you feel unwell, seek medical ad-

vice 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 : If in eyes, rinse well with water.

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

oms : Suspected of damaging fertility.

delayed

Contact with dust can cause mechanical irritation or drying of

the skin.

Dust contact with the eyes can lead to mechanical irritation.



Loratadine / Montelukast Formulation

**ORGANON

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 4.1
 30.09.2023
 4574881-00011
 Date of first issue: 08.07.2019

Protection of first-aiders : First Aid responders should pay attention to self-protection,

and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician : Treat symptomatically and supportively.

Section 5: Fire-fighting measures

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Specific hazards during fire-

fighting

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 prod-

ucts

Carbon oxides

Metal oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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.

Hazchem Code : 2Z

Section 6: Accidental release measures

Personal precautions, protective equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment.

Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.

Methods and materials for containment and cleaning up

Sweep up or vacuum up spillage and collect in suitable container for disposal.

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 deter-



Loratadine / Montelukast Formulation



 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 4.1
 30.09.2023
 4574881-00011
 Date of first issue: 08.07.2019

mine 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 : 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 Advice on safe handling Use only with adequate ventilation.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 as-

sessment

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.

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 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

Section 8: Exposure controls/personal protection

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Cellulose	9004-34-6	WES-TWA	10 mg/m3	NZ OEL
		TWA	10 mg/m3	ACGIH
Montelukast	151767-02-1	TWA	40 μg/m3 (OEB 3)	Internal
		Wipe limit	400 μg/100 cm ²	Internal



Loratadine / Montelukast Formulation

**ORGANON

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 4.1 30.09.2023 4574881-00011 Date of first issue: 08.07.2019

Loratadine	79794-75-5	TWA	40 μg/m3 (OEB 3)	Internal
		Wipe limit	400 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 con-

tainment devices).

Minimize open handling.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type

Hand protection

Material

: Chemical-resistant gloves

Particulates type

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, dis-

posable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

Section 9: Physical and chemical properties

Appearance : tablet

Colour : No data available

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



Loratadine / Montelukast Formulation

♣ ORGANON

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 4.1 30.09.2023 4574881-00011 Date of first issue: 08.07.2019

Flash point : Not applicable

Evaporation rate : Not applicable

Flammability (solid, gas) : May form combustible dust concentrations in air during pro-

cessing, 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

Particle size : No data available

Section 10: Stability and reactivity

Reactivity : Not classified as a reactivity hazard. Chemical stability : Stable under normal conditions.

Possibility of hazardous reac-

tions

May form combustible dust concentrations in air during pro-

cessing, handling or other means. Can react with strong oxidizing agents.



Loratadine / Montelukast Formulation



Version SDS Number: Date of last issue: 04.04.2023 Revision Date: 30.09.2023 4574881-00011 Date of first issue: 08.07.2019 4.1

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.

Incompatible materials

Oxidizing agents

Hazardous decomposition

products

No hazardous decomposition products are known.

Section 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:

LD50 (Rat): > 5,000 mg/kgAcute oral toxicity

LD50 (Mouse): > 5,000 mg/kg

Acute inhalation toxicity Remarks: No data available

Remarks: No data available Acute dermal toxicity

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-

tion toxicity

Skin corrosion/irritation

Not classified based on available information.

Components:

Montelukast:



Loratadine / Montelukast Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 4.1 30.09.2023 4574881-00011 Date of first issue: 08.07.2019

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

Chronic toxicity

Germ cell mutagenicity

Not classified based on available information.

Components:

Cellulose:

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

Result: negative



Loratadine / Montelukast Formulation

♣ ORGANON

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 4.1 30.09.2023 4574881-00011 Date of first issue: 08.07.2019

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 syn-

thesis in mammalian cells (in vitro)

Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test

Species: Mouse

Cell type: Bone marrow Application Route: Oral

Result: negative



Loratadine / Montelukast Formulation

Version SDS Number: Date of last issue: 04.04.2023 Revision Date: 30.09.2023 4574881-00011 Date of first issue: 08.07.2019 4.1

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

Assessment 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



Loratadine / Montelukast Formulation

♣ ORGANON

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 4.1
 30.09.2023
 4574881-00011
 Date of first issue: 08.07.2019

Effects on foetal develop-

ment

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 develop-

ment

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 - As-

sessment

Some evidence of adverse effects on sexual function and

fertility, based on animal experiments.

STOT - single exposure

Not classified based on available information.



Loratadine / Montelukast Formulation



 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 4.1
 30.09.2023
 4574881-00011
 Date of first issue: 08.07.2019

STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

Cellulose:

Species : Rat

NOAEL : >= 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.



Loratadine / Montelukast Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 4.1
 30.09.2023
 4574881-00011
 Date of first issue: 08.07.2019

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

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

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 tox-

icity)

: 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



Loratadine / Montelukast Formulation

ORGANON

Version SDS Number: Date of last issue: 04.04.2023 Revision Date: 30.09.2023 4574881-00011 Date of first issue: 08.07.2019 4.1

NOEC (Cyprinodon variegatus (sheepshead minnow)): 0.0816

Exposure time: 7 d

Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic 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 tox-

icity)

: 1

Toxicity to fish (Chronic tox-

icity)

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 (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 0.078 mg/l

Exposure time: 21 d

Method: OECD Test Guideline 211

M-Factor (Chronic aquatic

toxicity)

Toxicity to microorganisms

EC50: > 1,000 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209



Loratadine / Montelukast Formulation

Version SDS Number: Date of last issue: 04.04.2023 Revision Date: 30.09.2023 4574881-00011 Date of first issue: 08.07.2019 4.1

Persistence and degradability

Components:

Cellulose:

Biodegradability Result: Readily biodegradable.

Montelukast:

Biodegradability Result: not rapidly degradable

> Biodegradation: 0 % Exposure time: 28 d

Hydrolysis: 50 %(21.7 h) Stability in water

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 environ-

log Koc: 5.25

mental compartments 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.



Loratadine / Montelukast Formulation



 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 4.1
 30.09.2023
 4574881-00011
 Date of first issue: 08.07.2019

Contaminated packaging : Empty containers should be taken to an approved waste han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

Section 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
Environmentally hazardous : yes

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 : 956

aircraft)

Packing instruction (passen- :

ger aircraft)

Environmentally hazardous : yes

IMDG-Code

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

956

(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

NZS 5433

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Loratadine)

Class : 9 Packing group : III



Loratadine / Montelukast Formulation



Version Revision Date: SDS Number: Date of last issue: 04.04.2023 4.1 30.09.2023 4574881-00011 Date of first issue: 08.07.2019

Labels : 9
Hazchem Code : 2Z
Marine pollutant : no

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.

Section 15: Regulatory information

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

HSNO Approval Number

HSR100425 Pharmaceutical Active Ingredients Group Standard

HSW Controls

Certified handler certificate not required.

Tracking hazardous substance not required.

Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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

AICS : not determined

DSL : not determined

IECSC : not determined

Section 16: Other information

Revision Date : 30.09.2023

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 Agen-

cy, http://echa.europa.eu/

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

NZ OEL : New Zealand. Workplace Exposure Standards for Atmospher-

ic Contaminants

ACGIH / TWA : 8-hour, time-weighted average

NZ OEL / WES-TWA : Workplace Exposure Standard - Time Weighted average



Loratadine / Montelukast Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 4.1
 30.09.2023
 4574881-00011
 Date of first issue: 08.07.2019

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

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.

NZ / EN