

Loratadine / Montelukast Formulation

Version 2.1 Revision Date: 30.09.2023 SDS Number: 4574884-00011 Date of last issue: 04.04.2023
Date of first issue: 08.07.2019

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Loratadine / Montelukast Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-stance/Mixture : Pharmaceutical

Recommended restrictions on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : Organon & Co.
30 Hudson Street, 33nd floor
07302 Jersey City, New Jersey, U.S.A

Telephone : +1-551-430-6000

E-mail address of person responsible for the SDS : EHSSTEWARD@organon.com

1.4 Emergency telephone number

+1-215-631-6999

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Reproductive toxicity, Category 2 H361f: Suspected of damaging fertility.
Long-term (chronic) aquatic hazard, Category 2 H411: Toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :  

Signal word : Warning

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

Precautionary statements : **Prevention:**

Loratadine / Montelukast Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.1	30.09.2023	4574884-00011	Date of first issue: 08.07.2019

P201 Obtain special instructions before use.
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.

Hazardous components which must be listed on the label:

Loratadine

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

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**3.2 Mixtures****Components**

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Montelukast	151767-02-1	Eye Irrit. 2; H319	>= 1 - < 10
Loratadine	79794-75-5	Repr. 2; H361f Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 1 M-Factor (Chronic aquatic toxicity): 1	>= 3 - < 10

For explanation of abbreviations see section 16.

SECTION 4: First aid measures**4.1 Description of first aid measures**

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

Loratadine / Montelukast Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.1	30.09.2023	4574884-00011	Date of first issue: 08.07.2019

vice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

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).

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.

4.2 Most important symptoms and effects, both acute and delayed

Risks : 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.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

SECTION 5: Firefighting measures**5.1 Extinguishing media**

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical

Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

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.

Loratadine / Montelukast Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.1	30.09.2023	4574884-00011	Date of first issue: 08.07.2019

Hazardous combustion products : Carbon oxides
Metal oxides

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

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.

SECTION 6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

Personal precautions : Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

Methods for 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage**7.1 Precautions for safe handling**

Technical measures : Static electricity may accumulate and ignite suspended dust

Loratadine / Montelukast Formulation

Version 2.1 Revision Date: 30.09.2023 SDS Number: 4574884-00011 Date of last issue: 04.04.2023
Date of first issue: 08.07.2019

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.

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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep in properly labelled containers. Store locked up. Store in accordance with the particular national regulations.

Advice on common storage : Do not store with the following product types:
Strong oxidizing agents

7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection**8.1 Control parameters****Occupational Exposure Limits**

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Cellulose	9004-34-6	OEL-RL	10 mg/m ³	ZA OEL
Further information: Occupational Exposure Limits - Restricted Limits For Hazardous Chemical Agents				
Montelukast	151767-02-1	TWA	40 µg/m ³ (OEB 3)	Internal
		Wipe limit	400 µg/100 cm ²	Internal
Loratadine	79794-75-5	TWA	40 µg/m ³ (OEB 3)	Internal
		Wipe limit	400 µg/100 cm ²	Internal

Loratadine / Montelukast Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.1	30.09.2023	4574884-00011	Date of first issue: 08.07.2019

8.2 Exposure controls**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

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.
Hand protection		
Material	:	Chemical-resistant gloves
Remarks	:	Consider double gloving.
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.
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 (P)

SECTION 9: Physical and chemical properties**9.1 Information on basic 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
Flash point	:	Not applicable
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	May form combustible dust concentrations in air during processing, handling or other means.
Upper explosion limit / Upper	:	No data available

Loratadine / Montelukast Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.1	30.09.2023	4574884-00011	Date of first issue: 08.07.2019

flammability limit

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.

9.2 Other information

Flammability (liquids) : Not applicable

Molecular weight : No data available

Particle size : No data available

SECTION 10: Stability and reactivity**10.1 Reactivity**

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

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

10.4 Conditions to avoid

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

Loratadine / Montelukast Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.1	30.09.2023	4574884-00011	Date of first issue: 08.07.2019

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information**11.1 Information on toxicological effects**

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

Acute toxicity

Not classified based on available information.

Components:**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 inhalation 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

Loratadine / Montelukast Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.1	30.09.2023	4574884-00011	Date of first issue: 08.07.2019

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.

Components:**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

Loratadine / Montelukast Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.1	30.09.2023	4574884-00011	Date of first issue: 08.07.2019

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
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:**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

Loratadine / Montelukast Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.1	30.09.2023	4574884-00011	Date of first issue: 08.07.2019

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

Reproductive toxicity

Suspected of damaging fertility.

Components:**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.
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	:	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
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Loratadine:

Effects on fertility	:	Species: Rat, male Application Route: Oral Fertility: LOAEL: 64 mg/kg body weight Result: Effects on fertility
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Effects on foetal development	:	Species: Rat Application Route: Oral Developmental Toxicity: LOAEL: 48 mg/kg body weight Result: Embryo-foetal toxicity
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	:	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
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Reproductive toxicity - Assessment	:	Some evidence of adverse effects on sexual function and fertility, based on animal experiments.
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Loratadine / Montelukast Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023
2.1 30.09.2023 4574884-00011 Date of first issue: 08.07.2019

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity**Components:****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.

Experience with human exposure**Components:****Montelukast:**

Skin contact : Remarks: May irritate skin.

Loratadine / Montelukast Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.1	30.09.2023	4574884-00011	Date of first issue: 08.07.2019

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**12.1 Toxicity****Components:****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 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

Toxicity to fish (Chronic toxicity) : NOEC: 0,073 mg/l
 Exposure time: 32 d
 Species: Pimephales promelas (fathead minnow)
 Method: OECD Test Guideline 210
 Remarks: No toxicity at the limit of solubility

NOEC: 0,0816 mg/l
 Exposure time: 7 d
 Species: Cyprinodon variegatus (sheepshead minnow)
 Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates (Chronic) : NOEC: 0,23 mg/l
 Exposure time: 21 d

Version 2.1 Revision Date: 30.09.2023 SDS Number: 4574884-00011 Date of last issue: 04.04.2023
Date of first issue: 08.07.2019

ic toxicity) Species: *Daphnia magna* (Water flea)
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 : EC50 (*Daphnia magna* (Water flea)): 0,83 mg/l
aquatic invertebrates Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic : EC50 (*Pseudokirchneriella subcapitata* (green algae)): > 0,95
plants 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- : 1
icity)

Toxicity to microorganisms : EC50 : > 1.000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

Toxicity to fish (Chronic tox- : NOEC: 0,084 mg/l
icity) Exposure time: 32 d
Species: *Pimephales promelas* (fathead minnow)
Method: OECD Test Guideline 210

Toxicity to daphnia and other : NOEC: 0,078 mg/l
aquatic invertebrates (Chronic : Exposure time: 21 d
icity) Species: *Daphnia magna* (Water flea)
Method: OECD Test Guideline 211

M-Factor (Chronic aquatic : 1
toxicity)

12.2 Persistence and degradability**Components:****Montelukast:**

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

Stability in water : Hydrolysis: 50 % (21,7 h)

Loratadine:

Loratadine / Montelukast Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.1	30.09.2023	4574884-00011	Date of first issue: 08.07.2019

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

12.3 Bioaccumulative potential

Components:

Montelukast:

Partition coefficient: n-octanol/water : log Pow: > 4,3

Loratadine:

Partition coefficient: n-octanol/water : log Pow: 2,35

12.4 Mobility in soil

Components:

Loratadine:

Distribution among environmental compartments : log Koc: 5,25
Method: OECD Test Guideline 106

12.5 Results of PBT and vPvB assessment

Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects

Product:

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.
According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.
Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.
Do not dispose of waste into sewer.

Loratadine / Montelukast Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.1	30.09.2023	4574884-00011	Date of first issue: 08.07.2019

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information**14.1 UN number**

ADN	:	UN 3077
ADR	:	UN 3077
RID	:	UN 3077
IMDG	:	UN 3077
IATA	:	UN 3077

14.2 UN proper shipping name

ADN	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Loratadine)
ADR	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Loratadine)
RID	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Loratadine)
IMDG	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Loratadine)
IATA	:	Environmentally hazardous substance, solid, n.o.s. (Loratadine)

14.3 Transport hazard class(es)

	Class	Subsidiary risks
ADN	:	9
ADR	:	9
RID	:	9
IMDG	:	9
IATA	:	9

14.4 Packing group

ADN	
Packing group	: III
Classification Code	: M7
Hazard Identification Number	: 90
Labels	: 9
ADR	
Packing group	: III
Classification Code	: M7

SAFETY DATA SHEET



Loratadine / Montelukast Formulation



Version Revision Date: SDS Number: Date of last issue: 04.04.2023
2.1 30.09.2023 4574884-00011 Date of first issue: 08.07.2019

Hazard Identification Number : 90
Labels : 9
Tunnel restriction code : (-)

RID

Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9

IMDG

Packing group : III
Labels : 9
EmS Code : F-A, S-F

IATA (Cargo)

Packing instruction (cargo aircraft) : 956
Packing instruction (LQ) : Y956
Packing group : III
Labels : Miscellaneous

IATA (Passenger)

Packing instruction (passenger aircraft) : 956
Packing instruction (LQ) : Y956
Packing group : III
Labels : Miscellaneous

14.5 Environmental hazards

ADN

Environmentally hazardous : yes

ADR

Environmentally hazardous : yes

RID

Environmentally hazardous : yes

IMDG

Marine pollutant : yes

IATA (Passenger)

Environmentally hazardous : yes

IATA (Cargo)

Environmentally hazardous : yes

14.6 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.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

Loratadine / Montelukast Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.1	30.09.2023	4574884-00011	Date of first issue: 08.07.2019

SECTION 15: Regulatory information**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

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

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

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information	:	Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.
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Full text of H-Statements

H319	:	Causes serious eye irritation.
H361f	:	Suspected of damaging fertility.
H400	:	Very toxic to aquatic life.
H410	:	Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Aquatic Acute	:	Short-term (acute) aquatic hazard
Aquatic Chronic	:	Long-term (chronic) aquatic hazard
Eye Irrit.	:	Eye irritation
Repr.	:	Reproductive toxicity
ZA OEL	:	South Africa. The Regulations for Hazardous Chemical Agents, Occupational Exposure Limits
ZA OEL / OEL-RL	:	Occupational Exposure Limit Restricted limit - 8- hour exposure or equivalent (12 hour shifts)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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

Loratadine / Montelukast Formulation

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- 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; 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

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/>

Classification of the mixture:

Repr. 2	H361f
Aquatic Chronic 2	H411

Classification procedure:

Calculation method
Calculation method

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.

ZA / EN