

Loratadine / Montelukast Formulation

Version 1.4 Revision Date: 09.04.2021 SDS Number: 4574874-00005 Date of last issue: 10.10.2020
Date of first issue: 08.07.2019

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Loratadine / Montelukast Formulation

Manufacturer or supplier's details

Company : Organon & Co.

Address : 30 Hudson Street, 33rd 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

SECTION 2. HAZARDS IDENTIFICATION**GHS Classification**

Reproductive toxicity : Category 2

GHS label elements

Hazard pictograms :



Signal word : Warning

Hazard statements : H361f Suspected of damaging fertility.

Precautionary statements :

Prevention:

P201 Obtain special instructions before use.

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

P281 Use personal protective equipment as required.

Response:

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

Storage:

P405 Store locked up.

Disposal:

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

Loratadine / Montelukast Formulation

Version 1.4 Revision Date: 09.04.2021 SDS Number: 4574874-00005 Date of last issue: 10.10.2020
Date of first issue: 08.07.2019

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 -< 60
Montelukast	151767-02-1	< 10
Loratadine	79794-75-5	>= 3 -< 10

SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.
Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

In case of eye contact : 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 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.

SECTION 5. FIREFIGHTING 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

Loratadine / Montelukast Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
1.4	09.04.2021	4574874-00005	Date of first issue: 08.07.2019

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.

Hazchem Code : 2Z

SECTION 6. ACCIDENTAL RELEASE MEASURES

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

Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages 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 determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures : 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

Loratadine / Montelukast Formulation

Version 1.4 Revision Date: 09.04.2021 SDS Number: 4574874-00005 Date of last issue: 10.10.2020
Date of first issue: 08.07.2019

- 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.
- 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	TWA	10 mg/m ³	AU OEL
	Further information: This value is for inhalable dust containing no asbestos and < 1% crystalline silica			
		TWA	10 mg/m ³	ACGIH
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

- 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

SAFETY DATA SHEET



Loratadine / Montelukast Formulation



Version 1.4 Revision Date: 09.04.2021 SDS Number: 4574874-00005 Date of last issue: 10.10.2020
Date of first issue: 08.07.2019

Hand protection

Material : Chemical-resistant gloves

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

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

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : 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.

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

Loratadine / Montelukast Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
1.4	09.04.2021	4574874-00005	Date of first issue: 08.07.2019

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 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.

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

Loratadine / Montelukast Formulation

Version 1.4 Revision Date: 09.04.2021 SDS Number: 4574874-00005 Date of last issue: 10.10.2020
Date of first issue: 08.07.2019

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 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

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

Loratadine / Montelukast Formulation

Version 1.4 Revision Date: 09.04.2021 SDS Number: 4574874-00005 Date of last issue: 10.10.2020
Date of first issue: 08.07.2019

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

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

Loratadine / Montelukast Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
1.4	09.04.2021	4574874-00005	Date of first issue: 08.07.2019

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
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 / Montelukast Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
1.4	09.04.2021	4574874-00005	Date of first issue: 08.07.2019

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

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

Loratadine / Montelukast Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
1.4	09.04.2021	4574874-00005	Date of first issue: 08.07.2019

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.

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:

Loratadine / Montelukast Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
1.4	09.04.2021	4574874-00005	Date of first issue: 08.07.2019

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

Montelukast:

Toxicity to fish	:	LC50 (<i>Pimephales promelas</i> (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 (<i>Daphnia magna</i> (Water flea)): > 0.0675 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 Remarks: No toxicity at the limit of solubility
---	---	---

Loratadine / Montelukast Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
1.4	09.04.2021	4574874-00005	Date of first issue: 08.07.2019

- 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
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
- Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 0.084 mg/l
Exposure time: 32 d
Method: OECD Test Guideline 210

Loratadine / Montelukast Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
1.4	09.04.2021	4574874-00005	Date of first issue: 08.07.2019

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

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

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

Loratadine / Montelukast Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
1.4	09.04.2021	4574874-00005	Date of first issue: 08.07.2019

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues : Dispose of in accordance with local regulations.
 Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
 If not otherwise specified: Dispose of as unused product.

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

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**ADG**

UN number : UN 3077
 Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

Loratadine / Montelukast Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
1.4	09.04.2021	4574874-00005	Date of first issue: 08.07.2019

	N.O.S. (Loratadine)
Class	: 9
Packing group	: III
Labels	: 9
Hazchem Code	: 2Z

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**

Prohibition/Licensing Requirements	:	There is no applicable prohibition, authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regulations.
------------------------------------	---	---

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

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

SECTION 16. OTHER INFORMATION**Further information**

Revision Date	:	09.04.2021
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	:	dd.mm.yyyy

Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
AU OEL	:	Australia. Workplace Exposure Standards for Airborne Contaminants.
ACGIH / TWA	:	8-hour, time-weighted average
AU OEL / TWA	:	Exposure standard - 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 -

SAFETY DATA SHEET



Loratadine / Montelukast Formulation



Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
1.4	09.04.2021	4574874-00005	Date of first issue: 08.07.2019

Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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.

AU / EN