SAFETY DATA SHEET
Loratadine / Montelukast Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Loratadine / Montelukast Formulation

Manufacturer or supplier's details
Company name of supplier: Organon & Co.
Address: Avenida 16 de Septiembre No. 301
Xaltocan - Xochimilco Mexico 16090
Telephone: 52 55 57284444
Emergency telephone: 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: ![Warning]

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

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

Storage:
P405 Store locked up.

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

Other hazards
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.
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SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td>Montelukast</td>
<td>151767-02-1</td>
<td>&gt;= 5 - &lt; 10</td>
</tr>
<tr>
<td>Loratadine</td>
<td>79794-75-5</td>
<td>&gt;= 5 - &lt; 10</td>
</tr>
</tbody>
</table>

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.

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

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). 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 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 labeled 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

**Ingredients with workplace control parameters**

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>VLE-PPT</td>
<td>10 mg/m³</td>
<td>NOM-010-STPS-2014</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Montelukast</td>
<td>151767-02-1</td>
<td>TWA</td>
<td>40 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>400 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Loratadine</td>
<td>79794-75-5</td>
<td>TWA</td>
<td>40 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>400 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

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

**Personal protective equipment**

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

- **Hand protection**
  - **Material**: Chemical-resistant gloves

- **Remarks**
  - Consider double gloving.

- **Eye protection**
  - Wear safety glasses with side shields or goggles.
  - If the work environment or activity involves dusty conditions,
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Date of first issue: 08.07.2019

Skin and body protection:
- 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.
- 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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
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</tr>
<tr>
<td>Color</td>
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<td>Odor</td>
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<tr>
<td>pH</td>
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<tr>
<td>Melting point/freezing point</td>
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<tr>
<td>Initial boiling point and boiling range</td>
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</tr>
<tr>
<td>Flash point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not applicable</td>
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<tr>
<td>Flammability (solid, gas)</td>
<td>May form combustible dust concentrations in air during processing, handling or other means.</td>
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<tr>
<td>Flammability (liquids)</td>
<td>Not applicable</td>
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<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
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<tr>
<td>Lower explosion limit / Lower flammability limit</td>
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<tr>
<td>Vapor pressure</td>
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<tr>
<td>Relative vapor density</td>
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<tr>
<td>Density</td>
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<tr>
<td>Solubility(ies)</td>
<td>Water solubility</td>
</tr>
<tr>
<td>Partition coefficient: n-</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
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octanol/water Autoignition temperature: No data available
Decomposition temperature: No data available
Viscosity
Viscosity, kinematic: Not applicable
Explosive properties: Not explosive
Oxidizing properties: The substance or mixture is not classified as oxidizing.
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

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

Acute toxicity
Not classified based on available information.

Components:

Cellulose:
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity: LC50 (Rat): > 5.8 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg

Montelukast:
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
LD50 (Mouse): > 5,000 mg/kg

Acute inhalation toxicity: Remarks: No data available

Acute dermal toxicity: Remarks: No data available

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

**Respiratory or skin sensitization**

**Skin sensitization**
Not classified based on available information.

**Respiratory sensitization**
Not classified based on available information.
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Components:

Montelukast:
Remarks : No data available

Loratadine:
Test Type : Maximization Test
Routes of exposure : Dermal
Species : Guinea pig
Assessment : Does not cause skin sensitization.
Result : negative

Germ cell mutagenicity
Not classified based on available information.

Components:

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

Montelukast:
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Test Type: In vitro mammalian cell gene mutation test
Test system: Chinese hamster fibroblasts
Result: negative
Test Type: Chromosomal aberration
Test system: Chinese hamster ovary cells
Result: negative
Test Type: Alkaline elution assay
Test system: rat hepatocytes
Result: negative
Genotoxicity in vivo : Test Type: Chromosomal aberration
Species: Mouse
Cell type: Bone marrow
Application Route: Oral
Result: negative

Loratadine:
Genotoxicity in vitro:
- Test Type: Bacterial reverse mutation assay (AMES)  
  Result: negative
- Test Type: In vitro mammalian cell gene mutation test  
  Result: negative
- Test Type: Chromosome aberration test in vitro  
  Result: negative
- Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)  
  Result: negative

Genotoxicity in vivo:
- Test Type: Micronucleus test  
  Species: Mouse  
  Cell type: Bone marrow  
  Application Route: Oral  
  Result: negative

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

Carcinogenicity:
Not classified based on available information.

Components:

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

**Montelukast:**
- Species: Rat  
  Application Route: Oral  
  Exposure time: 2 Years  
  Result: negative
- Species: Mouse  
  Application Route: Oral  
  Exposure time: 92 weeks  
  Result: negative

**Loratadine:**
- Species: Rat  
  Application Route: Oral  
  Exposure time: 2 Years  
  LOAEL: 10 mg/kg body weight  
  Result: positive
- Species: Monkey  
  Application Route: Oral
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 fetal development: Test Type: Fertility/early embryonic development
  Species: Rat
  Application Route: Ingestion
  Result: negative

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

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

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

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

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

  Species: Rabbit
  Application Route: Oral
  Developmental Toxicity: LOAEL: 48 mg/kg body weight
Result: Embryo-fetal 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:**
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, Diarrhea, 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
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

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

Biodegradation: 0 %
Exposure time: 28 d

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

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

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

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

Bioaccumulative potential

Components:

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

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

Mobility in soil

Components:

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

Other adverse effects
No data available

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.
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.

**Domestic regulation**

**NOM-002-SCT**
- UN number: UN 3077
- Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Loratadine)
- Class: 9
- Packing group: III
- Labels: 9

**Special precautions for user**
- The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet.
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

Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills.

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

<table>
<thead>
<tr>
<th>Inventory</th>
<th>Determination</th>
</tr>
</thead>
<tbody>
<tr>
<td>AICS</td>
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</tr>
<tr>
<td>DSL</td>
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</tr>
<tr>
<td>IECSC</td>
<td>not determined</td>
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</table>

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH</td>
<td>USA. ACGIH Threshold Limit Values (TLV)</td>
</tr>
<tr>
<td>NOM-010-STPS-2014</td>
<td>Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting the Work Environment - Identification, Assessment and Control - Appendix 1 Occupational Exposure Limits</td>
</tr>
<tr>
<td>ACGIH / TWA</td>
<td>8-hour, time-weighted average</td>
</tr>
<tr>
<td>NOM-010-STPS-2014 / VLE-PPT</td>
<td>Time weighted average limit value</td>
</tr>
</tbody>
</table>

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 Substanc-
## SAFETY DATA SHEET

**Loratadine / Montelukast Formulation**

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<th>Version</th>
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Sources of key data used to compile the Material Safety Data Sheet:

Revision Date: 09.04.2021

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

MX / Z8