1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Montelukast Tablet Formulation

Supplier’s company name, address and phone number
Company name of supplier : Organon & Co.
Address : 30 Hudson Street, 33nd floor
           Jersey City, New Jersey, U.S.A 07302
Telephone : 551-430-6000
E-mail address : EHSSTEWARD@organon.com
Emergency telephone number : 215-631-6999

Recommended use of the chemical and restrictions on use
Recommended use : Pharmaceutical

2. HAZARDS IDENTIFICATION

GHS classification of chemical product
Not a hazardous substance or mixture according to the Globally Harmonised System (GHS).

GHS label elements
Not a hazardous substance or mixture according to the Globally Harmonised System (GHS).

Other hazards which do not result in classification
Important symptoms and outlines of the emergency assumed : Dust contact with the eyes can lead to mechanical irritation. Contact with dust can cause mechanical irritation or drying of the skin. May form explosive dust-air mixture during processing, handling or other means.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 30 - &lt; 40</td>
<td></td>
</tr>
<tr>
<td>Montelukast</td>
<td>151767-02-1</td>
<td>&gt;= 1 - &lt; 10</td>
<td></td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>&gt;= 1 - &lt; 10</td>
<td>2-611</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>&gt;= 0.1 - &lt; 1</td>
<td>1-558, 5-5225</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES
SAFETY DATA SHEET
Montelukast Tablet Formulation

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: Wash with water and soap. Get medical attention if symptoms occur.
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 if symptoms occur. Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed: Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation.
Protection of first-aiders: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician: Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media: None known.
Specific hazards during firefighting: 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
Metal oxides

Specific extinguishing methods: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.

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

6. ACCIDENTAL RELEASE MEASURES

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

Environmental precautions: Avoid release to the environment. Prevent further leakage or spillage if safe to do so.
SAFETY DATA SHEET
Montelukast Tablet Formulation

Version: 4.1  Revision Date: 2020/10/02  SDS Number: 23082-00017  Date of last issue: 2020/03/23
Date of first issue: 2014/10/17

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.

7. HANDLING AND STORAGE

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

Local/Total ventilation:
- Use only with adequate ventilation.

Advice on safe handling:
- Do not breathe dust.
- Do not swallow.
- Avoid contact with eyes.
- Avoid prolonged or repeated contact with skin.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
- Minimize dust generation and accumulation.
- Keep container closed when not in use.
- Keep away from heat and sources of ignition.
- Take precautionary measures against static discharges.
- Take care to prevent spills, waste and minimize release to the environment.

Avoidance of contact:
Hygiene measures:
- Oxidizing agents

- 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.

Storage
Conditions for safe storage:
- Keep in properly labelled containers.
- Store in accordance with the particular national regulations.
Materials to avoid: Do not store with the following product types: Strong oxidizing agents

Packaging material: Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

<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>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) Internal</td>
<td></td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>Wipe limit</td>
<td>400 µg/100 cm² Internal</td>
<td>Internal</td>
</tr>
<tr>
<td>Montelukast</td>
<td></td>
<td>TWA (Inhalable particulate matter)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Montelukast</td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>3 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>OEL-M (Respirable dust)</td>
<td>1 mg/m³ (Titanium)</td>
<td>JP OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>OEL-M (Total dust)</td>
<td>4 mg/m³ (Titanium)</td>
<td>JSOH</td>
</tr>
</tbody>
</table>

Further information: Class 2 Dust

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: Chemical-resistant gloves

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: tablet
Colour: coloured
Odour: odourless
Odour Threshold: No data available
Melting point/freezing point: No data available
Boiling point, initial boiling point and boiling range: No data available
Flammability (solid, gas): May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids): No data available
Lower explosion limit and upper explosion limit / flammability limit
Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
Flash point: Not applicable
Decomposition temperature: No data available
pH: No data available
Evaporation rate: No data available
Auto-ignition temperature: No data available
Viscosity
Viscosity, kinematic: No data available
Solubility(ies)
Water solubility: No data available
Partition coefficient: n-
octanol/water

Vapour pressure : No data available

Density and / or relative density
Relative density : No data available
Density : No data available
Relative vapour density : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : No data available

Particle characteristics
Particle size : No data available

10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions
May form explosive dust-air mixture during processing, handling or other means.
Can react with strong oxidizing agents.

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

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

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

### Magnesium stearate:
- **Acute oral toxicity:** LD50 (Rat): > 2,000 mg/kg  
  Method: OECD Test Guideline 423  
  Assessment: The substance or mixture has no acute oral toxicity  
  Remarks: Based on data from similar materials
- **Acute dermal toxicity:** LD50 (Rabbit): > 2,000 mg/kg  
  Remarks: Based on data from similar materials

### Titanium dioxide:
- **Acute oral toxicity:** LD50 (Rat): > 5,000 mg/kg
- **Acute inhalation toxicity:** LC50 (Rat): > 6.82 mg/l  
  Exposure time: 4 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

#### Magnesium stearate:
- **Species:** Rabbit  
  **Result:** No skin irritation  
  **Remarks:** Based on data from similar materials

#### Titanium dioxide:
- **Species:** Rabbit  
  **Result:** No skin irritation

### Serious eye damage/eye irritation
Not classified based on available information.
Components:

Montelukast:
Species: Rabbit
Result: Severe irritation

Magnesium stearate:
Species: Rabbit
Result: No eye irritation
Remarks: Based on data from similar materials

Titanium dioxide:
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

Magnesium stearate:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative
Remarks: Based on data from similar materials

Titanium dioxide:
Test Type: Local lymph node assay (LLNA)
Exposure routes: Skin contact
Species: Mouse
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
### Montelukast Tablet Formulation

<table>
<thead>
<tr>
<th>Montelukast:</th>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Result: negative</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Test Type: In vitro mammalian cell gene mutation test</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Test system: Chinese hamster fibroblasts</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Test Type: Chromosomal aberration</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Test system: Chinese hamster ovary cells</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Test Type: Alkaline elution assay</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Test system: rat hepatocytes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Magnesium stearate:</th>
<th>Genotoxicity in vitro</th>
<th>Test Type: In vitro mammalian cell gene mutation test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Result: negative</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Test Type: Chromosome aberration test in vitro</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 473</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Test Type: Bacterial reverse mutation assay (AMES)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Titanium dioxide:</th>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Result: negative</td>
<td></td>
</tr>
</tbody>
</table>

|                     | Genotoxicity in vivo  | Test Type: In vivo micronucleus test             |
|                     | Species: Mouse        |                                                  |
|                     | Result: negative      |                                                  |

**Remarks:** Based on data from similar materials
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

Titanium dioxide:
Species: Rat
Application Route: Inhalation (dust/mist/fume)
Exposure time: 2 Years
Method: OECD Test Guideline 453
Result: positive
Remarks: The mechanism or mode of action may not be relevant in humans.

Carcinogenicity - Assessment: Limited evidence of carcinogenicity in inhalation studies with animals.

Reproductive toxicity
Not classified based on available information.

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

Magnesium stearate:
Effects on fertility:
Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 422
Result: negative
Remarks: Based on data from similar materials

Effects on foetal development:
Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

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

**Magnesium stearate:**
Species: Rat
NOAEL: > 100 mg/kg
Application Route: Ingestion
Exposure time: 90 Days
Remarks: Based on data from similar materials

**Titanium dioxide:**
Species: Rat
NOAEL: 24,000 mg/kg
Application Route: Ingestion
Exposure time: 28 Days
Species: Rat
NOAEL: 10 mg/m3
Application Route: inhalation (dust/mist/fume)
Exposure time: 2 yr

**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

12. ECOLOGICAL INFORMATION

**Ecotoxicity**

**Components:**

**Cellulose:**
## Montelukast Tablet Formulation

| Toxicity to fish | LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l  
| Exposition time: 48 h  
| Remarks: Based on data from similar materials |

### Montelukast:

#### Toxicity to fish

| LC50 (Pimephales promelas (fathead minnow)): > 0.0778 mg/l  
| Exposition 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  
| Exposition 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  
| Exposition time: 72 h  
| Method: OECD Test Guideline 201  
| Remarks: No toxicity at the limit of solubility  

| EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l  
| Exposition 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  
| Exposition 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  
| Exposition time: 7 d  
| Method: OECD Test Guideline 210  
| 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  
| Exposition time: 21 d  
| Remarks: No toxicity at the limit of solubility |

#### Toxicity to microorganisms

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

### Magnesium stearate:

#### Toxicity to fish

| LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l  
| Exposition time: 48 h  
| Method: DIN 38412  
| Remarks: Based on data from similar materials |

#### Toxicity to daphnia and other aquatic invertebrates

<p>| EL50 (Daphnia magna (Water flea)): &gt; 1 mg/l |</p>
<table>
<thead>
<tr>
<th>aquatic invertebrates</th>
<th>Exposure time: 47 h</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test substance:</td>
<td>Water Accommodated Fraction</td>
</tr>
<tr>
<td>Remarks:</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>No toxicity at the limit of solubility</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicty to algae/aquatic plants</th>
<th>EL50 (Pseudokirchneriella subcapitata (green algae)): &gt; 1 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time:</td>
<td>72 h</td>
</tr>
<tr>
<td>Test substance:</td>
<td>Water Accommodated Fraction</td>
</tr>
<tr>
<td>Method:</td>
<td>OECD Test Guideline 201</td>
</tr>
<tr>
<td>Remarks:</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>No toxicity at the limit of solubility</td>
<td></td>
</tr>
</tbody>
</table>

| NOELR (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l |
| Exposure time: 72 h |
| Test substance: Water Accommodated Fraction |
| Method: OECD Test Guideline 201 |
| Remarks: Based on data from similar materials |

<table>
<thead>
<tr>
<th>Toxicity to microorganisms</th>
<th>EC10 (Pseudomonas putida): &gt; 100 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time:</td>
<td>16 h</td>
</tr>
<tr>
<td>Test substance:</td>
<td>Water Accommodated Fraction</td>
</tr>
<tr>
<td>Method:</td>
<td>OECD Test Guideline 201</td>
</tr>
<tr>
<td>Remarks:</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Titanium dioxide:**

<table>
<thead>
<tr>
<th>Toxicity to fish</th>
<th>LC50 (Oncorhynchus mykiss (rainbow trout)): &gt; 100 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time:</td>
<td>96 h</td>
</tr>
<tr>
<td>Method:</td>
<td>OECD Test Guideline 203</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to daphnia and other aquatic invertebrates</th>
<th>EC50 (Daphnia magna (Water flea)): &gt; 100 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time:</td>
<td>48 h</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to algae/aquatic plants</th>
<th>EC50 (Skeletonema costatum (marine diatom)): &gt; 10,000 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time:</td>
<td>72 h</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to microorganisms</th>
<th>EC50: &gt; 1,000 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time:</td>
<td>3 h</td>
</tr>
<tr>
<td>Method:</td>
<td>OECD Test Guideline 209</td>
</tr>
</tbody>
</table>

**Persistence and degradability**

**Components:**

**Cellulose:**

| Biodegradability | Result: Readily biodegradable. |

**Montelukast:**

<table>
<thead>
<tr>
<th>Biodegradability</th>
<th>Result: not rapidly degradable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biodegradation:</td>
<td>0 %</td>
</tr>
<tr>
<td>Exposure time:</td>
<td>28 d</td>
</tr>
</tbody>
</table>
Stability in water          : Hydrolysis: 50 % (21.7 h)

**Magnesium stearate:**

**Biodegradability**          : Result: Not biodegradable
    Remarks: Based on data from similar materials

**Bioaccumulative potential**

**Components:**

**Montelukast:**

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

**Magnesium stearate:**

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

**Mobility in soil**

No data available

**Hazardous to the ozone layer**

Not applicable

**Other adverse effects**

No data available

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**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.

---

**14. TRANSPORT INFORMATION**

**International Regulations**

**UNRTDG**

Not regulated as a dangerous good

**IATA-DGR**

Not regulated as a dangerous good

**IMDG-Code**

Not regulated as a dangerous good

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

Not applicable for product as supplied.

**National Regulations**

Refer to section 15 for specific national regulation.
15. REGULATORY INFORMATION

Related Regulations

Fire Service Law
Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law
Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture
Not applicable

Harmful Substances Required Permission for Manufacture
Not applicable

Substances Prevented From Impairment of Health
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity
Not applicable

Substances Subject to be Notified Names
Article 57-2 (Enforcement Order Table 9)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium stearate</td>
<td>327</td>
<td>&gt;=1 - &lt;10</td>
</tr>
<tr>
<td>Titanium(IV) oxide</td>
<td>191</td>
<td>&gt;=0.1 - &lt;1</td>
</tr>
</tbody>
</table>

Substances Subject to be Indicated Names
Article 57 (Enforcement Order Article 18)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium stearate</td>
<td>327</td>
</tr>
</tbody>
</table>

Ordinance on Prevention of Hazards Due to Specified Chemical Substances
Not applicable

Ordinance on Prevention of Lead Poisoning
Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning
Not applicable

Ordinance on Prevention of Organic Solvent Poisoning
Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)
Not applicable
Poisonous and Deleterious Substances Control Law
Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof
Not applicable

High Pressure Gas Safety Act
Not applicable

Explosive Control Law
Not applicable

Vessel Safety Law
Not regulated as a dangerous good

Aviation Law
Not regulated as a dangerous good

Marine Pollution and Sea Disaster Prevention etc Law
Bulk transportation : Not classified as noxious liquid substance
Pack transportation : Not classified as marine pollutant

Narcotics and Psychotropics Control Act
Narcotic or Psychotropic Raw Material (Export / Import Permission)
Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
Not applicable

Waste Disposal and Public Cleansing Law
Industrial waste

The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

16. OTHER INFORMATION

Further information
Date format : yyyy/mm/dd

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
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.

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