SAFETY DATA SHEET

Montelukast Tablet Formulation

SECTION 1. IDENTIFICATION

Product name: Montelukast Tablet Formulation

Manufacturer or supplier’s details
Company name of supplier: Merck & Co., Inc
Address: 2000 Galloping Hill Road
            Kenilworth - New Jersey - U.S.A. 07033
Telephone: 908-740-4000
Telefax: 908-735-1496
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASEWARD@merck.com

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

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with 29 CFR 1910.1200
Combustible dust

Carcinogenicity (Inhalation): Category 2

GHS label elements
Hazard pictograms: 

Signal Word: Warning

Hazard Statements: If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.
H351 Suspected of causing cancer if inhaled.

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.
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Version 7.1  Revision Date: 09/13/2019  SDS Number: 23093-00015  Date of last issue: 04/24/2019  Date of first issue: 10/17/2014

Other hazards
Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.

SECTION 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>
</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>Magnesium stearate</td>
<td>557-04-0</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>&gt;= 0.1 - &lt; 1</td>
</tr>
</tbody>
</table>

Actual concentration is withheld as a trade secret

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: 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: Suspected of causing cancer if inhaled.
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 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.

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 and personal protective equipment recommendations.

Environmental precautions:
Discharge into the environment must be avoided.
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.

**Conditions for safe storage:**  
Keep in properly labeled containers.  
Store in accordance with the particular national regulations.

**Materials to avoid:**  
Do not store with the following product types:  
Strong oxidizing agents

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### 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>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable)</td>
<td>5 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total)</td>
<td>10 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total dust)</td>
<td>15 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (respirable fraction)</td>
<td>5 mg/m³</td>
<td>OSHA Z-1</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>Magnesium stearate</td>
<td>557-04-0</td>
<td>TWA (Inhalable fraction)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable fraction)</td>
<td>3 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>TWA (total dust)</td>
<td>15 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Titanium dioxide)</td>
<td>10 mg/m³</td>
<td>ACGIH</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:**  
General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided
by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

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.

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : tablet
Color : colored
Odor : odorless
Odor 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 : No data available
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<thead>
<tr>
<th>Version</th>
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<td>7.1</td>
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<td>04/24/2019</td>
<td>10/17/2014</td>
</tr>
</tbody>
</table>

Flammability (solid, gas): May form explosive dust-air mixture during processing, handling or other means.

Flammability (liquids): No data available

Upper explosion limit / Upper flammability limit: No data available

Lower explosion limit / Lower flammability limit: No data available

Vapor pressure: No data available

Relative vapor density: No data available

Relative density: No data available

Density: No data available

Solubility(ies)
  Water solubility: No data available

Partition coefficient: n-octanol/water: No data available

Autoignition temperature: No data available

Decomposition temperature: No data available

Viscosity
  Viscosity, kinematic: No data available

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 explosive dust-air mixture during processing, handling or other means.
  Can react with strong oxidizing agents.

Conditions to avoid: Heat, flames and sparks.

Incompatible materials
  Avoid dust formation.
  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

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 sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:

Montelukast:
Remarks: No data available

Magnesium stearate:
Test Type: Maximization Test
Routes of exposure: 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)
Routes of exposure: 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
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

Magnesium stearate:
Genotoxicity in vitro: Test Type: In vitro mammalian cell gene mutation test
Result: negative
Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative
Remarks: Based on data from similar materials

Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Remarks: Based on data from similar materials

Titanium dioxide:
Genotoxicity in vitro:
Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

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

Carcinogenicity
Suspected of causing cancer if inhaled.

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.
IARC
Group 2B: Possibly carcinogenic to humans
Titanium dioxide 13463-67-7

OSHA
No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

NTP
No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

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 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

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 fetal development:
Test Type: Embryo-fetal 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 y

**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

**SECTION 12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

**Components:**

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

**Montelukast:**
Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 0.0778 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
Remarks: No toxicity at the limit of solubility.

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 0.0675 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: No toxicity at the limit of solubility.

Toxicity to algae/aquatic plants : NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility.

EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility.
### Toxicity to fish (Chronic toxicity)

<table>
<thead>
<tr>
<th>Substance</th>
<th>NOEC</th>
<th>Exposure Time</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Pimephales promelas (fathead minnow))</td>
<td>0.073 mg/l</td>
<td>32 d</td>
<td>OECD Test Guideline 210</td>
<td>No toxicity at the limit of solubility.</td>
</tr>
<tr>
<td>(Cyprinodon variegatus (sheephead minnow))</td>
<td>0.0816 mg/l</td>
<td>7 d</td>
<td>OECD Test Guideline 210</td>
<td>No toxicity at the limit of solubility.</td>
</tr>
</tbody>
</table>

### Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

<table>
<thead>
<tr>
<th>Substance</th>
<th>NOEC</th>
<th>Exposure Time</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Daphnia magna (Water flea))</td>
<td>0.23 mg/l</td>
<td>21 d</td>
<td>OECD Test Guideline 210</td>
<td>No toxicity at the limit of solubility.</td>
</tr>
</tbody>
</table>

### Toxicity to microorganisms

<table>
<thead>
<tr>
<th>Substance</th>
<th>EC50</th>
<th>Exposure Time</th>
<th>Test Type</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&gt; 100 mg/l</td>
<td>3 h</td>
<td>Respiration inhibition</td>
<td>OECD Test Guideline 209</td>
<td>No toxicity at the limit of solubility.</td>
</tr>
</tbody>
</table>

### Magnesium stearate:

<table>
<thead>
<tr>
<th>Substance</th>
<th>LC50</th>
<th>Exposure Time</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Leuciscus idus (Golden orfe))</td>
<td>&gt; 100 mg/l</td>
<td>48 h</td>
<td>DIN 38412</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Substance</th>
<th>EL50</th>
<th>Exposure Time</th>
<th>Test Substance</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Daphnia magna (Water flea))</td>
<td>&gt; 1 mg/l</td>
<td>47 h</td>
<td>Water Accommodated Fraction</td>
<td>Directive 67/548/EEC, Annex V, C.2.</td>
<td>Based on data from similar materials No toxicity at the limit of solubility.</td>
</tr>
</tbody>
</table>

### Toxicity to algae/aquatic plants

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

<table>
<thead>
<tr>
<th>Substance</th>
<th>NOELR</th>
<th>Exposure Time</th>
<th>Test Substance</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Pseudokirchneriella subcapitata (green algae))</td>
<td>&gt; 1 mg/l</td>
<td>72 h</td>
<td>Water Accommodated Fraction</td>
<td>OECD Test Guideline 201</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

### Toxicity to microorganisms

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

### Titanium dioxide:
### Toxicity to fish
- LC50 (Onchorhynchus mykiss (rainbow trout)): > 100 mg/l
- Exposure time: 96 h
- Method: OECD Test Guideline 203

### Toxicity to daphnia and other aquatic invertebrates
- EC50 (Daphnia magna (Water flea)): > 100 mg/l
- Exposure time: 48 h

### Toxicity to algae/aquatic plants
- EC50 (Skeletonema costatum (marine diatom)): > 10,000 mg/l
- Exposure time: 72 h

### Toxicity to microorganisms
- EC50: > 1,000 mg/l
- Exposure time: 3 h
- 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)

**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

**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
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.

Domestic regulation

49 CFR
Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know

CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards: Combustible dust
Carcinogenicity

SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>D-mannitol</td>
<td>69-65-8</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
</tr>
<tr>
<td>D-Glucose, 4-O-.beta-D-galactopyranosyl-, monohydrate</td>
<td>64044-51-5</td>
</tr>
</tbody>
</table>
Montelukast Tablet Formulation

Montelukast
Crocarmellose sodium
Hydroxypropyl cellulose

California Prop. 65
WARNING: This product can expose you to chemicals including Titanium dioxide, which is/are known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

California Permissible Exposure Limits for Chemical Contaminants

<table>
<thead>
<tr>
<th>Chemical</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
</tr>
</tbody>
</table>

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

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

SECTION 16. OTHER INFORMATION

Further information

NFPA 704:

<table>
<thead>
<tr>
<th>Flammability</th>
<th>Health</th>
<th>Special hazard</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

HMIS® IV:

<table>
<thead>
<tr>
<th>HEALTH</th>
<th>FLAMMABILITY</th>
<th>PHYSICAL HAZARD</th>
</tr>
</thead>
<tbody>
<tr>
<td>* 0</td>
<td>3</td>
<td>0</td>
</tr>
</tbody>
</table>

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL : USA. NIOSH Recommended Exposure Limits
OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
ACGIH / TWA : 8-hour, time-weighted average
NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA Z-1 / TWA : 8-hour time weighted average

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation,
SAFETY DATA SHEET

Montelukast Tablet Formulation

Sources of key data used to compile the Material Safety Data Sheet:

Revision Date: 09/13/2019

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.

US / Z8