Montelukast Granules Formulation

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

1.1 Product identifier
   Trade name : Montelukast Granules Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
   Use of the Substance/Mixture : Pharmaceutical

1.3 Details of the supplier of the safety data sheet
   Company : Organon & Co.
   30 Hudson Street, 33nd floor
   07302 Jersey City, New Jersey, U.S.A
   Telephone : 551-430-6000
   E-mail address of person responsible for the SDS : EHSSTEWARD@organon.com

1.4 Emergency telephone number
   215-631-6999

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
   Classification (REGULATION (EC) No 1272/2008) : Not a hazardous substance or mixture.

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008) : Not a hazardous substance or mixture.

2.3 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 explosive dust-air mixture during processing, handling or other means.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
</table>

1 / 15
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Montelukast Granules Formulation

Version 2.15  Revision Date: 23.03.2020  SDS Number: 23000-00018  Date of last issue: 13.09.2019
Date of first issue: 17.10.2014

| Montelukast          | 151767-02-1 | Eye Irrit. 2; H319 | >= 0.1 - < 1 |

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

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

Protection of first-aiders: No special precautions are necessary for first aid responders.

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

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.

4.2 Most important symptoms and effects, both acute and delayed

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

4.3 Indication of any immediate medical attention and special treatment needed

Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

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

Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-: Avoid generating dust; fine dust dispersed in air in sufficient
fighting 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

5.3 Advice for firefighters

Special protective equipment for firefighters: Wear self-contained breathing apparatus for firefighting if necessary. Use personal protective equipment.

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

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions: Follow safe handling advice and personal protective equipment recommendations.

6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up: Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.
Montelukast Granules Formulation

SECTION 7: Handling and storage

7.1 Precautions for safe 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.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
- Minimize dust generation and accumulation.
- Keep container closed when not in use.
- Keep away from heat and sources of ignition.
- Take precautionary measures against static discharges.
- Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures:
- If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.
- The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

7.2 Conditions for safe storage, including any incompatibilities

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

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

7.3 Specific end use(s)

Specific use(s):
- No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

**Occupational Exposure Limits**

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<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>
</tbody>
</table>
8.2 Exposure controls

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

Personal protective equipment

Eye 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 face shield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Hand protection

Material : Chemical-resistant gloves
Remarks : Consider double gloving.

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

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Equipment should conform to I.S. EN 143

Filter type : Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance : powder
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 : No data available
Flammability (solid, gas) : May form explosive dust-air mixture during processing, handling or other means.
Montelukast Granules Formulation

Upper explosion limit / Upper flammability limit: No data available

Lower explosion limit / Lower flammability limit: No data available

Vapour pressure: No data available

Relative vapour 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
  Auto-ignition 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.

9.2 Other information

Flammability (liquids): No data available

Molecular weight: No data available

Particle size: No data available

SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
Hazardous reactions: May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.

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

10.5 Incompatible materials
Materials to avoid: Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects
Information on likely routes of exposure:
- Inhalation
- Skin contact
- Ingestion
- Eye contact

Acute toxicity
Not classified based on available information.

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

Acute inhalation toxicity: Remarks: No data available

Acute dermal toxicity: Remarks: No data available

Skin corrosion/irritation
Not classified based on available information.

Components:
Montelukast:
Species: Rabbit
Result: Mild skin irritation

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

Components:
Montelukast:
Species: Rabbit
Result: Severe irritation
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Montelukast Granules Formulation

Version: 2.15  Revision Date: 23.03.2020  SDS Number: 23000-00018  Date of last issue: 13.09.2019
Date of first issue: 17.10.2014

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

Germ cell mutagenicity
Not classified based on available information.

Product:

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

Components:

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

Test Type: In vitro mammalian cell gene mutation test
Test system: Chinese hamster fibroblasts
Result: negative

Test Type: Chromosomal aberration
Test system: Chinese hamster ovary cells
Result: negative

Test Type: Alkaline elution assay
Test system: rat hepatocytes
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Montelukast Granules Formulation

Result: negative

Genotoxicity in vivo
Test Type: Chromosomal aberration
Species: Mouse
Cell type: Bone marrow
Application Route: Oral
Result: negative

Carcinogenicity
Not classified based on available information.

Product:
Species: Rat
Application Route: Oral
Exposure time: 2 Years
Dose: 200 mg/kg body weight
Result: negative

Species: Mouse
Application Route: Oral
Exposure time: 92 weeks
Dose: 100 mg/kg body weight
Result: negative

Components:

Montelukast:
Species: Rat
Application Route: Oral
Exposure time: 2 Years
Result: negative

Species: Mouse
Application Route: Oral
Exposure time: 92 weeks
Result: negative

Reproductive toxicity
Not classified based on available information.

Product:
Effects on fertility
Test Type: Fertility
Species: Rat, male
Application Route: Oral
Fertility: NOAEL Parent: 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 Parent: 200 mg/kg body weight
Symptoms: Reduced fertility
Montelukast Granules Formulation

**Components:**

**Montelukast:**

**Effects on fertility**

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

- **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

**STOT - single exposure**

Not classified based on available information.

**STOT - repeated exposure**

Not classified based on available information.

**Repeated dose toxicity**

**Components:**

**Montelukast:**

- **Species:** Monkey, male and female
- **NOAEL:** 150 - 300 mg/kg
- **Application Route:** Oral
- **Exposure time:** 53 Weeks
- **Remarks:** No significant adverse effects were reported

- **Species:** Rat
- **NOAEL:** 50 mg/kg
- **Application Route:** Oral
- **Exposure time:** 53 Weeks
- **Remarks:** No significant adverse effects were reported

- **Species:** Mouse
- **NOAEL:** 50 mg/kg
- **Application Route:** Oral
- **Exposure time:** 14 Weeks
- **Remarks:** No significant adverse effects were reported

**Aspiration toxicity**

Not classified based on available information.
Experience with human exposure

**Product:**

<table>
<thead>
<tr>
<th>Type</th>
<th>Remarks</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin contact</td>
<td>Remarks: May irritate skin.</td>
<td></td>
</tr>
<tr>
<td>Eye contact</td>
<td>Symptoms: Severe irritation</td>
<td></td>
</tr>
<tr>
<td>Ingestion</td>
<td>Symptoms: upper respiratory tract infection, pharyngitis, headache, Cough, Abdominal pain, Diarrhoea, Fever</td>
<td></td>
</tr>
</tbody>
</table>

**Components:**

**Montelukast:**

<table>
<thead>
<tr>
<th>Type</th>
<th>Remarks</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin contact</td>
<td>Remarks: May irritate skin.</td>
<td></td>
</tr>
<tr>
<td>Eye contact</td>
<td>Symptoms: Severe irritation</td>
<td></td>
</tr>
<tr>
<td>Ingestion</td>
<td>Symptoms: upper respiratory tract infection, pharyngitis, headache, Cough, Abdominal pain, Diarrhoea, Fever</td>
<td></td>
</tr>
</tbody>
</table>

**SECTION 12: Ecological information**

**12.1 Toxicity**

**Components:**

**Montelukast:**

<table>
<thead>
<tr>
<th>Type</th>
<th>Remarks</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to fish</td>
<td>LC50 (Pimephales promelas (fathead minnow)): &gt; 0.0778 mg/l Exposure time: 96 h Method: OECD Test Guideline 203 Remarks: No toxicity at the limit of solubility</td>
<td></td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates</td>
<td>EC50 (Daphnia magna (Water flea)): &gt; 0.0675 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 Remarks: No toxicity at the limit of solubility</td>
<td></td>
</tr>
<tr>
<td>Toxicity to algae/aquatic plants</td>
<td>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</td>
<td></td>
</tr>
<tr>
<td></td>
<td>EC50 : &gt; 100 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: No toxicity at the limit of solubility</td>
<td></td>
</tr>
<tr>
<td>Toxicity to microorganisms</td>
<td>EC50 : &gt; 100 mg/l Exposure time: 3 h Method: OECD Test Guideline 209 Remarks: No toxicity at the limit of solubility</td>
<td></td>
</tr>
<tr>
<td>Toxicity to fish (Chronic toxicity)</td>
<td>NOEC: 0.073 mg/l Exposure time: 32 d Species: Pimephales promelas (fathead minnow)</td>
<td></td>
</tr>
</tbody>
</table>
Method: OECD Test Guideline 210
Remarks: No toxicity at the limit of solubility

NOEC: 0.0816 mg/l
Exposure time: 7 d
Species: Cyprinodon variegatus (sheepshead minnow)
Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) :
NOEC: 0.23 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Remarks: No toxicity at the limit of solubility

12.2 Persistence and degradability

Components:
Montelukast:
Biodegradability : Result: not rapidly degradable
Biodegradation: 0 %
Exposure time: 28 d
Stability in water : Hydrolysis: 50 % (21.7 h)

12.3 Bioaccumulative potential

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

12.4 Mobility in soil
No data available

12.5 Results of PBT and vPvB assessment
Not relevant

12.6 Other adverse effects
No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods
Product : Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. If not otherwise specified: Dispose of as unused product.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Montelukast Granules Formulation

SECTION 14: Transport information

14.1 UN number
Not regulated as a dangerous good

14.2 UN proper shipping name
Not regulated as a dangerous good

14.3 Transport hazard class(es)
Not regulated as a dangerous good

14.4 Packing group
Not regulated as a dangerous good

14.5 Environmental hazards
Not regulated as a dangerous good

14.6 Special precautions for user
Not applicable

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Not applicable

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable


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

AICS : not determined

DSL : not determined

IECSC : not determined
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Montelukast Granules Formulation

Version 2.15
Revision Date: 23.03.2020
SDS Number: 23000-00018

Date of last issue: 13.09.2019
Date of first issue: 17.10.2014

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Full text of H-statements
H319 : Causes serious eye irritation.

Full text of other abbreviations
Eye Irrit. : Eye irritation

Further information
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Montelukast Granules Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.15</td>
<td>23.03.2020</td>
<td>23000-00018</td>
<td>13.09.2019</td>
</tr>
</tbody>
</table>

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.

IE / EN