1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name: Montelukast Granules 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

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Montelukast</td>
<td>Concentration (% w/w)</td>
</tr>
<tr>
<td>Montelukast</td>
<td>&gt;= 0.1 - &lt; 1</td>
</tr>
</tbody>
</table>

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.
## 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  
| 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 | Wear self-contained breathing apparatus for firefighting if necessary.  
|                             | Use personal protective equipment.  

## 6. ACCIDENTAL RELEASE MEASURES

| Personal precautions, protective equipment and emergency procedures | 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.

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.
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: Oxidizing agents

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.

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>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>

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, 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: powder

Colour: No data available

Odour: No data available

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: No data available

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
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 |
## Respiratory or skin sensitisation

### Skin sensitisation
Not classified based on available information.

### Respiratory sensitisation
Not classified based on available information.

## Components:

### Montelukast:

<table>
<thead>
<tr>
<th>Remarks</th>
<th>No data available</th>
</tr>
</thead>
</table>

## 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:

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

- 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
SAFETY DATA SHEET

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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:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 Years</td>
</tr>
<tr>
<td>Dose</td>
<td>200 mg/kg body weight</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>92 weeks</td>
</tr>
<tr>
<td>Dose</td>
<td>100 mg/kg body weight</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

Components:

Montelukast:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
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<tr>
<td>Exposure time</td>
<td>2 Years</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>92 weeks</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

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

**Components:**

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

12. ECOLOGICAL INFORMATION

**Ecotoxicity**

**Components:**

<table>
<thead>
<tr>
<th>Product</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Montelukast:</td>
<td></td>
</tr>
<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>
</tr>
<tr>
<td></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>
</tr>
<tr>
<td></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>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Toxicity to fish (Chronic toxicity)</td>
<td>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</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET
Montelukast Granules Formulation

Version 3.0  Revision Date: 2020/03/23  SDS Number: 23004-00018  Date of last issue: 2019/09/13  Date of first issue: 2014/10/17

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

Persistence and degradability

Components:

Montelukast:
Biodegradability: Result: not rapidly degradable  
Biodegradation: 0 %  
Exposure time: 28 d

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

Bioaccumulative potential

Components:

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

Mobility in soil  
No data available

Hazardous to the ozone layer  
Not applicable

Other adverse effects  
No data available

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
Not applicable

Substances Subject to be Indicated Names
Not applicable

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

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

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format: yyyy/mm/dd

Full text of other abbreviations:

AICS - Australian Inventory of Chemical Substances; 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 Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their usage.
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.

JP / EN