

# SAFETY DATA SHEET



## Montelukast Tablet Formulation



Version 5.6      Revision Date: 04/09/2021      SDS Number: 23065-00018      Date of last issue: 10/02/2020  
Date of first issue: 10/17/2014

---

### SECTION 1. IDENTIFICATION

Product name : Montelukast Tablet Formulation  
Other means of identification : No data available

#### Manufacturer or supplier's details

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

#### Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical  
Restrictions on use : Not applicable


---

### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with the Hazardous Products Regulations

Carcinogenicity (Inhalation) : Category 2

#### GHS label elements

Hazard pictograms : 

Signal Word : Warning

Hazard Statements : 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 and face protection.  
**Response:**  
P308 + P313 IF exposed or concerned: Get medical attention.  
**Storage:**  
P405 Store locked up.  
**Disposal:**  
P501 Dispose of contents and container to an approved waste disposal plant.

## Montelukast Tablet Formulation

Version 5.6      Revision Date: 04/09/2021      SDS Number: 23065-00018      Date of last issue: 10/02/2020  
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.  
May form explosive dust-air mixture during processing, handling or other means.

**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Components**

Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
Cellulose	No data available	9004-34-6	$\geq 30 - < 60$ *
Montelukast	No data available	151767-02-1	$\geq 5 - < 10$ *
Magnesium stearate	Octadecanoic acid, magnesium salt (2:1)	557-04-0	$\geq 1 - < 5$ *
Titanium dioxide	Titanic anhydride	13463-67-7	$\geq 0.1 - < 1$ *

\* Actual concentration or concentration range 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 (CO<sub>2</sub>)  
Dry chemical

# SAFETY DATA SHEET



## Montelukast Tablet Formulation



Version 5.6      Revision Date: 04/09/2021      SDS Number: 23065-00018      Date of last issue: 10/02/2020  
Date of first issue: 10/17/2014

---

- Unsuitable extinguishing media : None known.
- Specific hazards during fire fighting : Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides  
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 fire-fighters : In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.
- 

### SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
- Environmental precautions : Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
- Methods and materials for containment and cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.
- 

### SECTION 7. HANDLING AND STORAGE

- Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
- Local/Total ventilation : Use only with adequate ventilation.
- Advice on safe handling : Do not breathe dust. Do not swallow.
-

# SAFETY DATA SHEET



## Montelukast Tablet Formulation



Version 5.6      Revision Date: 04/09/2021      SDS Number: 23065-00018      Date of last issue: 10/02/2020  
 Date of first issue: 10/17/2014

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

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Cellulose	9004-34-6	TWA	10 mg/m <sup>3</sup>	CA AB OEL
		TWA (Total dust)	10 mg/m <sup>3</sup>	CA BC OEL
		TWA (respirable dust fraction)	3 mg/m <sup>3</sup>	CA BC OEL
		TWAEV (total dust)	10 mg/m <sup>3</sup>	CA QC OEL
		TWA	10 mg/m <sup>3</sup>	ACGIH
Montelukast	151767-02-1	TWA	40 µg/m <sup>3</sup> (OEB 3)	Internal
		Wipe limit	400 µg/100 cm <sup>2</sup>	Internal
Magnesium stearate	557-04-0	TWA	10 mg/m <sup>3</sup>	CA AB OEL
		TWA	10 mg/m <sup>3</sup>	CA BC OEL
		TWA (Inhalable particulate matter)	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable particulate matter)	3 mg/m <sup>3</sup>	ACGIH
		TWA	10 mg/m <sup>3</sup>	ACGIH
Titanium dioxide	13463-67-7	TWA	10 mg/m <sup>3</sup>	CA AB OEL
		TWAEV (total dust)	10 mg/m <sup>3</sup>	CA QC OEL
		TWA (Total dust)	10 mg/m <sup>3</sup>	CA BC OEL
		TWA (respirable dust fraction)	3 mg/m <sup>3</sup>	CA BC OEL
		TWA	10 mg/m <sup>3</sup>	ACGIH

# SAFETY DATA SHEET



## Montelukast Tablet Formulation



Version 5.6      Revision Date: 04/09/2021      SDS Number: 23065-00018      Date of last issue: 10/02/2020  
Date of first issue: 10/17/2014

(Titanium dioxide)

**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.

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

# SAFETY DATA SHEET



## Montelukast Tablet Formulation



Version 5.6      Revision Date: 04/09/2021      SDS Number: 23065-00018      Date of last issue: 10/02/2020  
Date of first issue: 10/17/2014

---

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.

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.

## Montelukast Tablet Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10/02/2020
5.6	04/09/2021	23065-00018	Date of first issue: 10/17/2014

---

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.

---

**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
---------------------	---	---------------------------

## Montelukast Tablet Formulation

Version 5.6      Revision Date: 04/09/2021      SDS Number: 23065-00018      Date of last issue: 10/02/2020  
Date of first issue: 10/17/2014

---

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.



## Montelukast Tablet Formulation

Version 5.6      Revision Date: 04/09/2021      SDS Number: 23065-00018      Date of last issue: 10/02/2020  
 Date of first issue: 10/17/2014

---

**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

## Montelukast Tablet Formulation

Version 5.6      Revision Date: 04/09/2021      SDS Number: 23065-00018      Date of last issue: 10/02/2020  
Date of first issue: 10/17/2014

---

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

## Montelukast Tablet Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10/02/2020
5.6	04/09/2021	23065-00018	Date of first issue: 10/17/2014

---

**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 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

## Montelukast Tablet Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10/02/2020
5.6	04/09/2021	23065-00018	Date of first issue: 10/17/2014

---

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 :  $\geq 9,000$  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

## Montelukast Tablet Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10/02/2020
5.6	04/09/2021	23065-00018	Date of first issue: 10/17/2014

---

NOAEL	:	24,000 mg/kg
Application Route	:	Ingestion
Exposure time	:	28 Days
Species	:	Rat
NOAEL	:	10 mg/m <sup>3</sup>
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
--	---	--

## Montelukast Tablet Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10/02/2020
5.6	04/09/2021	23065-00018	Date of first issue: 10/17/2014

---

Remarks: No toxicity at the limit of solubility.

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 0.073 mg/l  
 Exposure time: 32 d  
 Method: OECD Test Guideline 210  
 Remarks: No toxicity at the limit of solubility.

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

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

Toxicity to microorganisms : EC50: > 100 mg/l  
 Exposure time: 3 h  
 Test Type: Respiration inhibition  
 Method: OECD Test Guideline 209  
 Remarks: No toxicity at the limit of solubility.

**Magnesium stearate:**

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

Toxicity to daphnia and other aquatic invertebrates : EL50 (Daphnia magna (Water flea)): > 1 mg/l  
 Exposure time: 47 h  
 Test substance: Water Accommodated Fraction  
 Method: Directive 67/548/EEC, Annex V, C.2.  
 Remarks: Based on data from similar materials  
 No toxicity at the limit of solubility.

Toxicity to algae/aquatic plants : EL50 (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  
 No toxicity at the limit of solubility.

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

Toxicity to microorganisms : EC10 (Pseudomonas putida): > 100 mg/l  
 Exposure time: 16 h  
 Test substance: Water Accommodated Fraction  
 Remarks: Based on data from similar materials

## Montelukast Tablet Formulation

Version 5.6      Revision Date: 04/09/2021      SDS Number: 23065-00018      Date of last issue: 10/02/2020  
Date of first issue: 10/17/2014

---

**Titanium dioxide:**

- Toxicity to fish : LC50 (Oncorhynchus 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

## Montelukast Tablet Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10/02/2020
5.6	04/09/2021	23065-00018	Date of first issue: 10/17/2014

---

### 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

##### TDG

Not regulated as a dangerous good

---

### SECTION 15. REGULATORY INFORMATION

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

AICS : not determined

DSL : not determined

IECSC : not determined

---

### SECTION 16. OTHER INFORMATION

#### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
CA AB OEL : Canada. Alberta, Occupational Health and Safety Code (table 2: OEL)  
CA BC OEL : Canada. British Columbia OEL  
CA QC OEL : Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants  
ACGIH / TWA : 8-hour, time-weighted average  
CA AB OEL / TWA : 8-hour Occupational exposure limit  
CA BC OEL / TWA : 8-hour time weighted average  
CA QC OEL / TWA EV : Time-weighted average exposure value

---



# SAFETY DATA SHEET



## Montelukast Tablet Formulation



Version	Revision Date:	SDS Number:	Date of last issue: 10/02/2020
5.6	04/09/2021	23065-00018	Date of first issue: 10/17/2014

---

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical 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

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Revision Date : 04/09/2021  
Date format : mm/dd/yyyy

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.

CA / Z8