

SAFETY DATA SHEET



Montelukast Tablet Formulation



Version 4.11 Revision Date: 02.10.2020 SDS Number: 23056-00017 Date of last issue: 23.03.2020
Date of first issue: 17.10.2014

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Montelukast Tablet Formulation

Manufacturer or supplier's details

Company : 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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Not a hazardous substance or mixture.

GHS label elements

Not a hazardous substance or mixture.

Other hazards which do not result in classification

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 | CAS-No. | Concentration (% w/w) |
|--------------------|-------------|-----------------------|
| Cellulose | 9004-34-6 | >= 30 -< 50 |
| Montelukast | 151767-02-1 | >= 5 -< 10 |
| Magnesium stearate | 557-04-0 | >= 1 -< 5 |
| Titanium dioxide | 13463-67-7 | >= 0,1 -< 1 |

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.

Montelukast Tablet Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 23.03.2020 |
| 4.11 | 02.10.2020 | 23056-00017 | Date of first issue: 17.10.2014 |

| | | |
|---|---|---|
| In case of skin contact | : | Get medical attention. Wash with water and soap. |
| In case of eye contact | : | Get medical attention if symptoms occur. If in eyes, rinse well with water. |
| If swallowed | : | Get medical attention if irritation develops and persists. If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water. |
| Most important symptoms and effects, both acute and delayed | : | Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation. |
| Protection of first-aiders | : | First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8). |
| Notes to physician | : | Treat symptomatically and supportively. |

SECTION 5. FIRE-FIGHTING MEASURES

| | | |
|--|---|---|
| Suitable extinguishing media | : | Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) Dry chemical |
| 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. |

Montelukast Tablet Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 23.03.2020 |
| 4.11 | 02.10.2020 | 23056-00017 | Date of first issue: 17.10.2014 |

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

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 | CMP | 10 mg/m ³ | AR OEL |
| | Further information: Irritation | | | |
| | | TWA | 10 mg/m ³ | ACGIH |
| Montelukast | 151767-02-1 | TWA | 40 µg/m ³ (OEB 3) | Internal |
| | | Wipe limit | 400 µg/100 cm ² | Internal |
| Magnesium stearate | 557-04-0 | CMP | 10 mg/m ³ | AR OEL |
| | Further information: A4 - Not classifiable as a human carcinogen, Irritation | | | |
| | | TWA | 10 mg/m ³ | ACGIH |

SAFETY DATA SHEET



Montelukast Tablet Formulation



Version 4.11 Revision Date: 02.10.2020 SDS Number: 23056-00017 Date of last issue: 23.03.2020
 Date of first issue: 17.10.2014

| | | | | |
|------------------|--|-------------------------------------|---|--------|
| | | (Inhalable particulate matter) | | |
| | | TWA (Respirable particulate matter) | 3 mg/m ³ | ACGIH |
| Titanium dioxide | 13463-67-7 | CMP | 10 mg/m ³ | AR OEL |
| | Further information: A4 - Not classifiable as a human carcinogen, lung | | | |
| | | TWA | 10 mg/m ³ (Titanium dioxide) | ACGIH |

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.

SAFETY DATA SHEET



Montelukast Tablet Formulation



Version 4.11 Revision Date: 02.10.2020 SDS Number: 23056-00017 Date of last issue: 23.03.2020
Date of first issue: 17.10.2014

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 |
| 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 |

Montelukast Tablet Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 23.03.2020 |
| 4.11 | 02.10.2020 | 23056-00017 | Date of first issue: 17.10.2014 |

| | | |
|----------------------|---|--|
| 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. 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 tox- |
|---------------------|---|---|

Montelukast Tablet Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 23.03.2020 |
| 4.11 | 02.10.2020 | 23056-00017 | Date of first issue: 17.10.2014 |

icity
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

Montelukast Tablet Formulation

Version 4.11 Revision Date: 02.10.2020 SDS Number: 23056-00017 Date of last issue: 23.03.2020
Date of first issue: 17.10.2014

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

Montelukast Tablet Formulation

Version 4.11 Revision Date: 02.10.2020 SDS Number: 23056-00017 Date of last issue: 23.03.2020
Date of first issue: 17.10.2014

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

Not classified based on available information.

Components:**Cellulose:**

Species : Rat
Application Route : Ingestion
Exposure time : 72 weeks
Result : negative

Montelukast:

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

Montelukast Tablet Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 23.03.2020 |
| 4.11 | 02.10.2020 | 23056-00017 | Date of first issue: 17.10.2014 |

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

Titanium dioxide:

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

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

Reproductive toxicity

Not classified based on available information.

Components:**Cellulose:**

Effects on fertility : Test Type: One-generation reproduction toxicity study
 Species: Rat
 Application Route: Ingestion
 Result: negative

Effects on 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

Montelukast Tablet Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 23.03.2020 |
| 4.11 | 02.10.2020 | 23056-00017 | Date of first issue: 17.10.2014 |

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

Montelukast Tablet Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 23.03.2020 |
| 4.11 | 02.10.2020 | 23056-00017 | Date of first issue: 17.10.2014 |

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 : EC50 (*Daphnia magna* (Water flea)): > 0,0675 mg/l
 aquatic invertebrates : Exposure time: 48 h
 Method: OECD Test Guideline 202
 Remarks: No toxicity at the limit of solubility.

Toxicity to algae/aquatic : NOEC (*Pseudokirchneriella subcapitata* (green algae)): 100
 plants : mg/l
 Exposure time: 72 h

Montelukast Tablet Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 23.03.2020 |
| 4.11 | 02.10.2020 | 23056-00017 | Date of first issue: 17.10.2014 |

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) : 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

Montelukast Tablet Formulation

Version 4.11 Revision Date: 02.10.2020 SDS Number: 23056-00017 Date of last issue: 23.03.2020
Date of first issue: 17.10.2014

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

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

SAFETY DATA SHEET



Montelukast Tablet Formulation



Version 4.11 Revision Date: 02.10.2020 SDS Number: 23056-00017 Date of last issue: 23.03.2020
Date of first issue: 17.10.2014

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.

SECTION 15. REGULATORY INFORMATION

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

Argentina. Carcinogenic Substances and Agents Registry. : Not applicable

Control of precursors and essential chemicals for the preparation of drugs. : Not applicable

International Regulations

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

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Further information

SAFETY DATA SHEET



Montelukast Tablet Formulation



| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 23.03.2020 |
| 4.11 | 02.10.2020 | 23056-00017 | Date of first issue: 17.10.2014 |

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/>

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
AR OEL : Argentina. Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average
AR OEL / CMP : TLV (Threshold Limit Value)

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

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.

AR / Z8