

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

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.

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 : No special precautions are necessary for first aid responders.

Notes to physician : Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

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

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.

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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. |

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8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Threshold limit value and permissible exposure limits for each component in the work environment**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Montelukast	151767-02-1	TWA	40 µg/m ³ (OEB 3)	Internal
		Wipe limit	400 µg/100 cm ²	Internal

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

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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	:	No data available
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	:	No data available
Viscosity, kinematic	:	No data available
Solubility(ies)	:	No data available
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Vapour pressure	:	No data available
Density and / or relative density	:	No data available
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	:	No data available
Particle size	:	No data available

10. STABILITY AND REACTIVITY

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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
- 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

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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
 Result: negative

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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:

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

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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.

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Experience with human exposure**Product:**

Skin contact : Remarks: May irritate skin.
 Eye contact : Symptoms: Severe irritation
 Ingestion : Symptoms: upper respiratory tract infection, pharyngitis, Headache, Cough, Abdominal pain, Diarrhoea, Fever

Components:**Montelukast:**

Skin contact : Remarks: May irritate skin.
 Eye contact : Symptoms: Severe irritation
 Ingestion : Symptoms: upper respiratory tract infection, pharyngitis, Headache, Cough, Abdominal pain, Diarrhoea, Fever

12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****Montelukast:**

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

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

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

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

Toxicity to fish (Chronic toxicity) : 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

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	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
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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.

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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

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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

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16. OTHER INFORMATION**Further information**

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

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

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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.

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