

according to GB/T 16483 and GB/T 17519

Montelukast Granules Formulation

Versi 2.14	••••	Revision Date: 2019/09/13		S Number: 993-00017	Date of last issue: 2019/04/24 Date of first issue: 2014/10/17			
1. PR	1. PRODUCT AND COMPANY IDENTIFICATION							
Product name		:	Montelukast Gra	nules Formulation				
I	Manufa	acturer or supplier's d	letai	ls				
(Compa	ny	:	Organon & Co.				
	Addres	S	:	30 Hudson Stree Jersey City, New	t, 33nd floor Jersey, U.S.A 07302			
-	Telephone		:	551-430-6000				
I	Emergency telephone number		r:	215-631-6999				
I	E-mail a	address	:	EHSSTEWARD	@organon.com			
I	Recommended use of the chemical and restrictions on use							

: Pharmaceutical

2. HAZARDS IDENTIFICATION

Recommended use

Emergency Overview

Appearance Colour Odour	: powder : No data available : No data available	
Not a hazardous subs	ce or mixture.	

GHS Classification

Not a hazardous substance or mixture.

GHS label elements

Not a hazardous substance or mixture.

Physical and chemical hazards

Not classified based on available information.

Health hazards

Not classified based on available information.

Environmental hazards

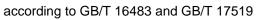
Not classified based on available information.

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

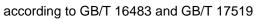




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Com	ponents					
Cher	nical name			CAS-No.	Concentration (% w/w)	
Mont	telukast			151767-02-1	>= 0.1 -< 1	
FIRST	AID MEASURES					
Gene	eral advice	:	vice immediat	ely.	I feel unwell, seek medical ad-	
lf inh	aled	:		nove to fresh air. Ittention if sympto	ms occur	
In ca	se of skin contact	:	Wash with wa			
In ca	se of eye contact	:	If in eyes, rins	e well with water.		
lf swa	allowed	:	If swallowed, Get medical a	DO NOT induce v ttention if sympto	vomiting. ms occur.	
and e delay Prote	important symptoms effects, both acute and yed ection of first-aiders s to physician	:	 Rinse mouth thoroughly with water. Contact with dust can cause mechanical irritation or drying o the skin. Dust contact with the eyes can lead to mechanical irritation. No special precautions are necessary for first aid responders Treat symptomatically and supportively. 			
FIREFI	GHTING MEASURES					
	able extinguishing media	:	Water spray Alcohol-resist Carbon dioxic Dry chemical			
medi	uitable extinguishing	:	None known.			
	ific hazards during fire-	:	 Avoid generating dust; fine dust dispersed in air in sufficien concentrations, and in the presence of an ignition source is potential dust explosion hazard. Exposure to combustion products may be a hazard to healt Carbon oxides 			
Haza ucts	ardous combustion prod-	:				
Spec ods	ific extinguishing meth-	:	cumstances a Use water spi Remove unda so.	nd the surroundir ay to cool unoper maged container	5	
	cial protective equipment refighters	:	essary.		apparatus for firefighting if nec- nent.	

6. ACCIDENTAL RELEASE MEASURES





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Personal precautions, protec- tive equipment and emer- gency procedures		:	Follow safe handling advice and personal protective equip- ment 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		:	tainer for disposal Avoid dispersal of with compressed a Dust deposits sho es, as these may fi leased into the atr Local or national r posal of this mater employed in the cl mine which regula Sections 13 and 1	dust in the air (i.e., clearing dust surfaces	

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 as- sessment 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
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.

SAFETY DATA SHEET according to GB/T 16483 and GB/T 17519





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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Montelukast	151767-02-1	TWA	40 µg/m3 (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 con- tainment devices). Minimize open handling.
Personal protective equipmen	t
Respiratory protection:Filter type:Eye/face protection:	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection. Particulates type 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, dis- posable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.
Hand protection	
Material :	Chemical-resistant gloves
Remarks : Hygiene measures :	Consider double gloving. If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the work- ing 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

according to GB/T 16483 and GB/T 17519



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	Appear	ance	:	powder	
	Colour		:	No data available)
	Odour		:	No data available)
	Odour ⁻	Threshold	:	No data available)
	рН		:	No data available)
	Melting	point/freezing point	:	No data available)
		oiling point and boiling	:	No data available)
	range Flash p	oint	:	Not applicable	
	Evapora	ation rate	:	No data available	
	Flamma	ability (solid, gas)	:	May form explosi dling or other me	ve dust-air mixture during processing, han- ans.
	Flamma	ability (liquids)	:	No data available)
		explosion limit / Upper bility limit	:	No data available	
		explosion limit / Lower bility limit	:	No data available	
	Vapour	pressure	:	No data available)
	Relative	e vapour density	:	No data available)
	Relative	e density	:	No data available)
	Density	,	:	No data available	9
	Solubili Wat	ty(ies) er solubility	:	No data available	9
	Partition octanol	n coefficient: n-	:	No data available	9
		nition temperature	:	No data available	
	Decom	position temperature	:	No data available	9
	Viscosi Visc	ty osity, kinematic	:	No data available	9
	Explosi	ve properties	:	Not explosive	
	Oxidizir	ng properties	:	The substance of	r mixture is not classified as oxidizing.

according to GB/T 16483 and GB/T 17519

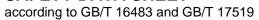


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Mole	cular weight	:	No data availal	ble			
Particle size		:	No data available				
10. STAB	ILITY AND REACTIVITY	,					
Cher	ctivity nical stability ibility of hazardous reac-	:	Stable under n May form explo dling or other n	as a reactivity hazard. ormal conditions. osive dust-air mixture during processing, han- neans. strong oxidizing agents.			
Cond	ditions to avoid	:	Heat, flames a				
Haza	Incompatible materials Hazardous decomposition products		Avoid dust formation.Oxidizing agentsNo hazardous decomposition products are known.				
11. TOXI		101	I				
Expo	osure routes	:	Inhalation Skin contact Ingestion Eye contact				
	e toxicity classified based on availa	ble	information.				
NOU							
	ponents:						
<u>Com</u> Mon		:	LD50 (Rat): > 5	,000 mg/kg			
<u>Com</u> Mon	ponents: telukast:	:	LD50 (Rat): > 5 LD50 (Mouse):				
<u>Com</u> Mon Acut	ponents: telukast:			> 5,000 mg/kg			
<u>Com</u> Mon Acut	ponents: telukast: e oral toxicity	:	LD50 (Mouse):	> 5,000 mg/kg ata available			
Com Mon Acut Acut Acut	ponents: telukast: e oral toxicity e inhalation toxicity	:	LD50 (Mouse): Remarks: No da Remarks: No da	> 5,000 mg/kg ata available			
Com Mon Acut Acut Acut Skin Not o	aponents: telukast: e oral toxicity e inhalation toxicity e dermal toxicity corrosion/irritation	:	LD50 (Mouse): Remarks: No da Remarks: No da	> 5,000 mg/kg ata available			

Serious eye damage/eye irritation

Not classified based on available information.





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<u>Comp</u>	oonents:						
Monte	elukast:						
	Species :		Rabbit				
Result :		:	Severe irritatio	on			
Resp	iratory or skin sens	itisatio	n				
-	sensitisation lassified based on ava	ailable i	nformation.				
Resp	iratory sensitisation	1					
Not cl	assified based on av	ailable i	nformation.				
Comp	ponents:						
	elukast:						
Rema	arks	:	No data availa	ble			
	cell mutagenicity						
Not cl	assified based on av	ailable i	nformation.				
Produ							
Geno	toxicity in vitro	•	Test Type: Ba Result: negati	cterial reverse mutation assay (AMES) ve			
				vitro mammalian cell gene mutation test Chinese hamster fibroblasts ve			
				romosomal aberration Chinese hamster ovary cells ve			
				aline elution assay at hepatocytes ve			
Geno	toxicity in vivo	:	Test Type: Ch Species: Mous Cell type: Bon Application Ro Result: negati	e marrow bute: Oral			
Comp	oonents:						
Monte	elukast:						
Geno	toxicity in vitro	:	Test Type: Ba Result: negati	cterial reverse mutation assay (AMES) ve			
				vitro mammalian cell gene mutation test Chinese hamster fibroblasts ve			
			7/4				

according to GB/T 16483 and GB/T 17519

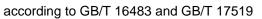


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		Test system: C Result: negativ	aline elution assay It hepatocytes
Genc	otoxicity in vivo	: Test Type: Chr Species: Mous Cell type: Bone Application Rou Result: negativ	e marrow ute: Oral
	inogenicity classified based on ava	ilable information.	
	ies cation Route sure time lt	: Rat : Oral : 2 Years : 200 mg/kg bod : negative : Mouse	y weight
Appli	cation Route sure time	: Oral : 92 weeks : 100 mg/kg bod : negative	y weight
	ponents:		
Spec Appli	cation Route sure time	: Rat : Oral : 2 Years : negative	
	cation Route sure time	: Mouse : Oral : 92 weeks : negative	
-	oductive toxicity classified based on ava	ilable information.	
<u>Prod</u> Effec	l <u>uct:</u> ts on fertility	: Test Type: Fert Species: Rat, n	nale
		Application Rou Fertility: NOAE	ute: Oral L Parent: 800 mg/kg body weight

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		Result: Animal testing did not show any effects on fertility.			
			female		
Com	ponents:				
Mont	elukast:				
	ts on fertility	Result: Anima Test Type: Fe Species: Rat, Application Ro Fertility: LOAE	male bute: Oral EL: 800 mg/kg body weight I testing did not show any effects on fertility. rtility female		
			female		
	Γ - single exposure lassified based on ava	ailable information.			
STO	Γ - repeated exposur	A			
	lassified based on av				
	ated dose toxicity				
-	ponents:				
Mont	elukast:				
Spec NOAI Applie	ies EL cation Route sure time	: Monkey, male : 150 - 300 mg/ : Oral : 53 Weeks : No significant			
	EL cation Route sure time	: Rat : 50 mg/kg : Oral : 53 Weeks : No significant	adverse effects were reported		
Spec NOAI		: Mouse : 50 mg/kg			
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rsion I4	Revision Date: 2019/09/13		993-00017	Date of last issue: 2019/04/24 Date of first issue: 2014/10/17		
Application Route Exposure time Remarks		 Oral 14 Weeks No significant adverse effects were reported 				
-	ation toxicity assified based on availa	ble	information.			
Expe	rience with human exp	osu	ire			
	contact ontact	:				
<u>Comp</u>	oonents:					
Skin c	elukast: contact ontact cion	:				
	oxicity ponents:					
<u>Comp</u>	oonents:					
<u>Comr</u> Monte	-	:	Exposure time: 90 Method: OECD T			
<u>Comr</u> Monte Toxici Toxici	oonents: elukast:	:	Exposure time: 90 Method: OECD T Remarks: No toxi EC50 (Daphnia m Exposure time: 44 Method: OECD T	est Guideline 203 city at the limit of solubility nagna (Water flea)): > 0.0675 mg/l		
<u>Comr</u> Monte Toxici Toxici aquat	bonents: elukast: ty to fish ty to daphnia and other ic invertebrates ty to algae/aquatic	:	Exposure time: 90 Method: OECD T Remarks: No toxi EC50 (Daphnia m Exposure time: 44 Method: OECD T Remarks: No toxi NOEC (Pseudoki mg/l Exposure time: 72 Method: OECD T	6 h est Guideline 203 city at the limit of solubility hagna (Water flea)): > 0.0675 mg/l 8 h est Guideline 202 city at the limit of solubility rchneriella subcapitata (green algae)): 100 2 h		
Comp Monte Toxici Toxici aquat	bonents: elukast: ty to fish ty to daphnia and other ic invertebrates ty to algae/aquatic	: :	Exposure time: 90 Method: OECD T Remarks: No toxi EC50 (Daphnia m Exposure time: 44 Method: OECD T Remarks: No toxi NOEC (Pseudokin mg/l Exposure time: 72 Method: OECD T Remarks: No toxi EC50 (Pseudokin mg/l Exposure time: 72 Method: OECD T	5 h est Guideline 203 city at the limit of solubility hagna (Water flea)): > 0.0675 mg/l 3 h est Guideline 202 city at the limit of solubility rchneriella subcapitata (green algae)): 100 2 h est Guideline 201 city at the limit of solubility chneriella subcapitata (green algae)): > 100 2 h		

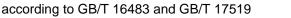
Disposal methods

according to GB/T 16483 and GB/T 17519



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				est Guideline 210 city at the limit of solubility		
			mg/l Exposure time: 7	on variegatus (sheepshead minnow)): 0.081 d city at the limit of solubility		
	ty to daphnia and other ic invertebrates (Chron- city)	:	Exposure time: 2	nagna (Water flea)): 0.23 mg/l 1 d city 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 			
Persis	stence and degradabili	ity				
<u>Comp</u>	oonents:					
Monte	elukast:					
Biode	gradability	:	Result: not rapidly Biodegradation: Exposure time: 2	D %		
Stabili	ty in water	:	Hydrolysis: 50 %	21.7 h)		
Bioac	cumulative potential					
<u>Comp</u>	oonents:					
Monte	elukast:					
	on coefficient: n- pl/water	:	log Pow: > 4.3			
	ity in soil ta available					
	adverse effects ta available					

Waste from residues Contaminated packaging	:	Dispose of in accordance with local regulations. Empty containers should be taken to an approved waste han- dling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.
		in not otherwise specifica. Dispose of as unased 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

GB 6944/12268 Not regulated as a dangerous good

Special precautions for user

Not applicable

15. REGULATORY INFORMATION

National regulatory information Law on the Prevention and Control of Occupational Diseases

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	:	Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/
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



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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

Disclaimer

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.

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