

# **Montelukast Tablet Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
5.2	06.04.2024	23084-00024	Date of first issue: 17.10.2014

#### SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Restrictions on use : Not applicable

Product name	:	Montelukast Tablet Formulation		
Manufacturer or supplier's	deta	ails		
Company name of supplier	:	Organon & Co.		
Address	:	Avenida 16 de Septiembre No. 301		
		Xaltocan - Xochimilco Mexico 16090		
Telephone	:	+52 55 57284444		
Emergency telephone	:	1-215-631-6999		
E-mail address	:	EHSSTEWARD@organon.com		
Recommended use of the chemical and restrictions on use				
Recommended use	:	Pharmaceutical		

#### **SECTION 2. HAZARDS IDENTIFICATION**

GHS Classification 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/ face protection.
		Response: P308 + P313 IF exposed or concerned: Get medical advice/ attention.
		<b>Storage:</b> P405 Store locked up.
		<b>Disposal:</b> P501 Dispose of contents/ container to an approved waste disposal plant.



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#### 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	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. 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 (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 prod-	:	Carbon oxides



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	ucts			Metal oxides		
	Specific ods	c extinguishing meth-	:	Use extinguishing measures that are appropriate to local cir- cumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so.		
	Special for fire-	protective equipment fighters	:	Evacuate area. In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.		
SEC	CTION 6	ACCIDENTAL RELE	AS	E MEASURES		
	tive equ	al precautions, protec- upment and emer- procedures	:		ective equipment. ng advice (see section 7) and personal ent recommendations (see section 8).	
	Environ	mental precautions	:	<ul> <li>Avoid release to the environment.</li> <li>Prevent further leakage or spillage if safe to do so.</li> <li>Retain and dispose of contaminated wash water.</li> <li>Local authorities should be advised if significant spillages cannot be contained.</li> </ul>		
		ls and materials for ment 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 surface with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they a 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 ite employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regard 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.



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	lygiene measures	<ul> <li>Take precaution</li> <li>Take care to previous environment.</li> <li>If exposure to flushing system place.</li> <li>When using do Wash contaming</li> <li>The effective of engineering consigneering consig</li></ul>	m heat and sources of ignition. onary measures against static discharges. revent spills, waste and minimize release to the chemical is likely during typical use, provide eye ns and safety showers close to the working o not eat, drink or smoke. nated clothing before re-use. operation of a facility should include review of ontrols, proper personal protective equipment, egowning and decontamination procedures, ene monitoring, medical surveillance and the strative controls.
	Conditions for safe storage	Store in accord	rly labeled containers. dance with the particular national regulations.
N	laterials to avoid	: Do not store w Strong oxidizir	ith the following product types: ng agents

#### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

:

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Cellulose	9004-34-6	VLE-PPT	10 mg/m³	NOM-010- STPS-2014
		TWA	10 mg/m <sup>3</sup>	ACGIH
Montelukast	151767-02-1	TWA	40 µg/m3 (OEB 3)	Internal
		Wipe limit	400 µg/100 cm <sup>2</sup>	Internal
Magnesium stearate	557-04-0	VLE-PPT	10 mg/m <sup>3</sup>	NOM-010- STPS-2014
		TWA (Inhalable particulate matter)	10 mg/m³	ACGIH
		TWA (Respirable particulate matter)	3 mg/m <sup>3</sup>	ACGIH
Titanium dioxide	13463-67-7	VLE-PPT	10 mg/m <sup>3</sup>	NOM-010- STPS-2014

#### Ingredients with workplace control parameters

**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



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Respiratory protection Filter type Hand protection		exposure asse	cal exhaust ventilation is not available or essment demonstrates exposures outside the guidelines, use respiratory protection. pe
Material		: Chemical-resis	stant gloves
	emarks rotection	<ul> <li>Consider double gloving.</li> <li>Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty cond mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is potential for direct contact to the face with dusts, mists aerosols.</li> </ul>	
Skin and body protection		Additional bod task being per disposable sui	or laboratory coat. y garments should be used based upon the formed (e.g., sleevelets, apron, gauntlets, ts) to avoid exposed skin surfaces. te degowning techniques to remove potentially clothing.

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	tablet
Color	:	colored
Odor	:	odorless
Odor Threshold	:	No data available
рН	:	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



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	Relative	e vapor density	:	No data available	9
	Relative density		:	No data available	9
	Density		:	No data available	9
	Solubili Wat	ty(ies) er solubility	:	No data available	9
		n coefficient: n-	:	No data available	9
	octanol. Autoign	ition temperature	:	No data available	9
	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 o	r mixture is not classified as oxidizing.
	Molecu	lar weight	:	No data available	9
	Particle Particle	characteristics size	:	No data available	9

### SECTION 10. STABILITY AND REACTIVITY

Chemical stability Possibility of hazardous reac- tions	<ul> <li>May form explosive dust-air mixture during processing, handling or other means.</li> <li>Can react with strong oxidizing agents.</li> </ul>
Conditions to avoid Incompatible materials Hazardous decomposition products	<ul> <li>Heat, flames and sparks.</li> <li>Avoid dust formation.</li> <li>Oxidizing agents</li> <li>No hazardous decomposition products are known.</li> </ul>

### SECTION 11. TOXICOLOGICAL INFORMATION

#### Information on likely routes of exposure

Inhalation Skin contact Ingestion Eye contact

#### Acute toxicity

Not classified based on available information.



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<u>Comp</u>	onents:				
Cellul	ose:				
Acute	oral toxicity	:	LD50 (Rat): > 5,0	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		
Monte	lukast:				
Acute	oral toxicity	:	LD50 (Rat): > 5,0	000 mg/kg	
			LD50 (Mouse): >	5,000 mg/kg	
Acute	inhalation toxicity	:	Remarks: No dat	a available	
Acute	dermal toxicity	:	Remarks: No dat	a available	
Magno	esium stearate:				
-	oral toxicity	:	Assessment: The icity	000 mg/kg Test Guideline 423 e substance or mixture has no acute oral to on data from similar materials	
Acute	dermal toxicity	:	LD50 (Rabbit): > 2,000 mg/kg Remarks: Based on data from similar materials		
Titani	um dioxide:				
Acute	oral toxicity	:	LD50 (Rat): > 5,0	000 mg/kg	
Acute	inhalation toxicity	:	LC50 (Rat): > 6.8 Exposure time: 4 Test atmosphere Assessment: The tion toxicity	h	
Skin d	orrosion/irritation				
Not cla	assified based on ava	ilable	information.		
<u>Comp</u>	onents:				
Monte	lukast:				
Specie Result		:	Rabbit Mild skin irritatior	1	
Magno	esium stearate:				
Specie Result		:	Rabbit No skin irritation		
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Rema	irks	:	Based on data f	rom similar materials
Titani	ium dioxide:			
Speci	es	•	Rabbit	
Resul		:	No skin irritation	
	us eye damage/eye			
	assified based on ava	ailable	information.	
	<u>oonents:</u>			
Monte	elukast:			
Speci		:	Rabbit	
Resul	t	:	Severe irritation	
Magn	esium stearate:			
Speci		:	Rabbit	
Resul		:	No eye irritation	
Rema	irks	:	Based on data f	rom similar materials
Titani	ium dioxide:			
Speci		:	Rabbit	
Resul	t	:	No eye irritation	
Resp	iratory or skin sensi	itizatio	n	
-	sensitization			
-	sensitization assified based on ava	ailable	information.	
Not cl			information.	
Not cl <b>Resp</b>	assified based on ava	1		
Not cl <b>Resp</b> Not cl	assified based on avaination	1		
Not cl Respi Not cl <u>Comp</u>	assified based on avainatory sensitization assified based on avainatory conents: elukast:	1	information.	
Not cl Resp Not cl <u>Comp</u>	assified based on avainatory sensitization assified based on avainatory conents: elukast:	1		e
Not cl Respi Not cl <u>Comp</u> Monto Rema	assified based on avainatory sensitization assified based on avaination conents: elukast: arks esium stearate:	1	information. No data availabl	
Not cl Respi Not cl Comp Monte Rema Magn Test	assified based on avainatory sensitization assified based on avaination assified based on avaination advants: alukast: a	1	information. No data availab Maximization Te	
Not cl Respi Not cl Comp Monto Rema Magn Test 1 Route	assified based on avainatory sensitization assified based on avaination assified based on avaination assignments: assignments	1	information. No data availab Maximization Te Skin contact	
Not cl Respi Not cl Comp Monto Rema Magn Test T Route Speci	assified based on avainatory sensitization assified based on avaination assified based on avaination assified based on avaination assignments: elukast: arks esium stearate: Type as of exposure es	1	information. No data availab Maximization Te Skin contact Guinea pig	est
Not cl Respi Not cl Comp Monto Rema Magn Test T Route Speci Metho	assified based on avainatory sensitization assified based on avainatory conents: elukast: arks esium stearate: Type es of exposure es od	1	information. No data availabl Maximization Te Skin contact Guinea pig OECD Test Guin	est
Not cl Respi Not cl Comp Monto Rema Magn Test T Route Speci Metho Resul	assified based on avainatory sensitization assified based on avainatory sensitization assified based on avainator conents: elukast: arks esium stearate: Type es of exposure es od t	1	information. No data availabl Maximization Te Skin contact Guinea pig OECD Test Guin negative	est deline 406
Not cl Respi Not cl Comp Monto Rema Magn Test T Route Speci Metho	assified based on avainatory sensitization assified based on avainatory sensitization assified based on avainator conents: elukast: arks esium stearate: Type es of exposure es od t	1	information. No data availabl Maximization Te Skin contact Guinea pig OECD Test Guin negative	est
Not cl Respi Not cl Comp Monto Rema Magn Test T Route Speci Metho Resul Rema	assified based on avainatory sensitization assified based on avainatory sensitization assified based on avainator conents: elukast: elukast: arks esium stearate: Type es of exposure es od t t urks	1	information. No data availabl Maximization Te Skin contact Guinea pig OECD Test Gui negative Based on data f	est deline 406 rom similar materials
Not cl Respi Not cl Comp Monto Rema Magn Test T Route Speci Metho Resul Rema Titani Test T	assified based on avainatory sensitization assified based on avainatory sensitization assified based on avainator conents: elukast: elukast: arks esium stearate: Type es of exposure es od t t urks fum dioxide: Type	1	information. No data availabl Maximization Te Skin contact Guinea pig OECD Test Gui negative Based on data f	est deline 406 rom similar materials
Not cl Respi Not cl Comr Monto Rema Magn Test T Route Speci Metho Resul Rema Titani Test T Route	assified based on avainatory sensitization assified based on avainatory sensitization assified based on avainator ponents: elukast: aurks esium stearate: Type es of exposure es bod t t turks fum dioxide: Type es of exposure	1	information. No data availabl Maximization Te Skin contact Guinea pig OECD Test Gui negative Based on data f Local lymph noo Skin contact	est deline 406 rom similar materials
Not cl Respi Not cl Comp Monto Rema Magn Test T Route Speci Metho Resul Rema Titani Test T	assified based on availation assified based on availation assignments a	1	information. No data availabl Maximization Te Skin contact Guinea pig OECD Test Gui negative Based on data f	est deline 406 rom similar materials



ersion 2	Revision Date: 06.04.2024	SDS Number: 23084-00024	Date of last issue: 26.09.2023 Date of first issue: 17.10.2014
	cell mutagenicity assified based on av	ailable information.	
Comp	oonents:		
Cellu	lose:		
Geno	toxicity in vitro	: Test Type: Bad Result: negativ	cterial reverse mutation assay (AMES) /e
		Test Type: In v Result: negativ	ritro mammalian cell gene mutation test re
Genot	toxicity in vivo	: Test Type: Ma cytogenetic as Species: Mous Application Ro Result: negativ	te ute: Ingestion
Monte	elukast:		
Genot	toxicity in vitro	: Test Type: Bao Result: negativ	cterial reverse mutation assay (AMES) re
			ritro mammalian cell gene mutation test Chinese hamster fibroblasts re
			romosomal aberration Chinese hamster ovary cells re
		Test Type: Alk Test system: ra Result: negativ	
Genot	toxicity in vivo	: Test Type: Chi Species: Mous Cell type: Bone Application Ro Result: negativ	e marrow ute: Oral
Mean			
-	esium stearate: toxicity in vitro	Result: negativ	ritro mammalian cell gene mutation test re ed on data from similar materials
		Test Type: Chi Method: OECI	romosome aberration test in vitro D Test Guideline 473
		Result: negativ Remarks: Base	ed on data from similar materials
		Result: negativ	cterial reverse mutation assay (AMES) re ed on data from similar materials



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Titani	ium dioxide:					
	toxicity in vitro	:	Test Type: Bact Result: negative	erial reverse mutation assay (AMES)		
Genotoxicity in vivo		:	: Test Type: In vivo micronucleus test Species: Mouse Result: negative			
Carci	nogenicity					
Suspe	ected of causing cance	er if in	haled.			
Com	oonents:					
Cellu	lose:					
Speci		:	Rat			
	cation Route	:	Ingestion			
	sure time	:	72 weeks			
Resul	t	:	negative			
Monte	elukast:					
Speci	es	:	Rat			
Applic	cation Route	:	Oral			
	sure time	:	2 Years			
Resul	t	:	negative			
Speci	es	:	Mouse			
Applic	cation Route	:	Oral			
	sure time	:	92 weeks			
Resul	t	:	negative			
Titan	ium dioxide:					
Speci	es	:	Rat			
	cation Route	:	inhalation (dust/	mist/fume)		
-	sure time	:	2 Years			
Metho Resul		÷	OECD Test Gui positive	deline 453		
Rema		:		or mode of action may not be relevant in h		
Rome		•	mans.	of mode of ability her be relevant in h		
	nogenicity - Assess-	:		e of carcinogenicity in inhalation studies wit		
ment			animals.			
Repro	oductive toxicity					
-	assified based on ava	ilable	information.			
<u>Comp</u>	oonents:					
Cellu	lose:					
Effect	s on fertility	:	Test Type: One- Species: Rat	generation reproduction toxicity study		
			Application Rout			

Application Route: Ingestion Result: negative



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Effects on fetal development		:	: Test Type: Fertility/early embryonic developmer Species: Rat Application Route: Ingestion Result: negative		
Monte	elukast:				
Effects on fertility		:		male oute: Oral EL: 800 mg/kg body weight al testing did not show any effects on fertility.	
			Species: Rat, Application Ro Fertility: LOA	female	
				female	
Magn	esium stearate:				
Effect	ts on fertility	:	reproduction/o Species: Rat Application Ro Method: OEC Result: negati	ombined repeated dose toxicity study with the developmental toxicity screening test oute: Ingestion D Test Guideline 422 ive sed on data from similar materials	
Effect	ts on fetal development	:	Species: Rat Application Re Result: negation	nbryo-fetal development oute: Ingestion ive sed on data from similar materials	
	<b>F-single exposure</b> lassified based on availa	able	information.		
	<b>F-repeated exposure</b> lassified based on availa	able	information.		
Repe	ated dose toxicity				

### Repeated dose toxicity

#### Components:

#### Cellulose:

Species	:	Rat
NOAEL	:	>= 9,000 mg/kg
Application Route	:	Ingestion



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Expos	sure time	: 90 Days	
Mont	elukast:		
Speci	es	: Monkey, m	ale and female
NOAE		: 150 - 300 ı	ng/kg
	cation Route	: Oral	
	sure time	: 53 Weeks	and a large offering and a second all
Rema	arks	: No signific	ant adverse effects were reported
Speci		: Rat	
NOAE		: 50 mg/kg	
	cation Route	: Oral	
Rema	sure time	: 53 Weeks	ant advarge offects were reported
Rema	IIKS	. No signific	ant adverse effects were reported
Speci	es	: Mouse	
NOAE		: 50 mg/kg	
	cation Route	: Oral	
	sure time	: 14 Weeks	
Rema	arks	: No signific	ant adverse effects were reported
Magn	esium stearate:		
Speci	es	: Rat	
NOAE		: > 100 mg/ł	kg
	cation Route	: Ingestion	
-	sure time	: 90 Days	
Rema	arks	: Based on o	data from similar materials
Titan	ium dioxide:		
Speci	es	: Rat	
NOAE		: 24,000 mg	/kg
	cation Route	: Ingestion	
Expos	sure time	: 28 Days	
Speci		: Rat	
NOAE		: 10 mg/m <sup>3</sup>	
	cation Route		(dust/mist/fume)
Expos	sure time	: 2 y	
Aspir	ation toxicity		
Not cl	assified based on av	ailable information.	
Ехре	rience with human e	exposure	
<u>Com</u>	oonents:		
Mont	elukast:		

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



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ECTION	CTION 12. ECOLOGICAL INFORMATION							
Ecoto	oxicity							
<u>Comp</u>	oonents:							
Cellul	ose:							
Toxici	ty to fish	:	Exposure time: 48	ipes (Japanese medaka)): > 100 mg/l 3 h on data from similar materials				
Monte	elukast:							
Toxici	ty to fish	:	Exposure time: 96 Method: OECD To					
	ty to daphnia and other ic invertebrates	:	Exposure time: 48 Method: OECD Te					
Toxici plants	ty to algae/aquatic	:	mg/l Exposure time: 72 Method: OECD To					
			mg/l Exposure time: 72 Method: OECD To					
Toxici icity)	ty to fish (Chronic tox-	:	Exposure time: 32 Method: OECD Te					
			mg/l Exposure time: 7	on variegatus (sheepshead minnow)): 0.08 d city at the limit of solubility.				
	ty to daphnia and other ic invertebrates (Chron- city)		Exposure time: 21	nagna (Water flea)): 0.23 mg/l l d city at the limit of solubility.				
Toxici	ty to microorganisms	:	EC50: > 100 mg/l Exposure time: 3 Test Type: Respir Method: OECD To Remarks: No toxio	h ation inhibition				



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Magnes	sium stearate:			
-	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	
	to daphnia and other invertebrates	:	Exposure time: 47 Test substance: V Method: Directive	Vater Accommodated Fraction 67/548/EEC, Annex V, C.2. on data from similar materials
Toxicity plants	to algae/aquatic	:	mg/l Exposure time: 72 Test substance: V Method: OECD Te	Vater Accommodated Fraction est Guideline 201 on data from similar materials
			mg/l Exposure time: 72 Test substance: V Method: OECD Te	Vater Accommodated Fraction
Toxicity	to microorganisms	:	Exposure time: 16 Test substance: V	nas putida): > 100 mg/l 5 h Vater Accommodated Fraction on data from similar materials
Titaniu	m dioxide:			
Toxicity		:	LC50 (Oncorhync Exposure time: 96 Method: OECD Te	
	to daphnia and other invertebrates	:	EC50 (Daphnia m Exposure time: 48	agna (Water flea)): > 100 mg/l 3 h
Toxicity plants	to algae/aquatic	:	EC50 (Skeletoner Exposure time: 72	na costatum (marine diatom)): > 10,000 mg/l 2 h
Toxicity	to microorganisms	:	EC50: > 1,000 mg Exposure time: 3 Method: OECD Te	h
Persist	ence and degradabili	ity		
<u>Compo</u>	nents:			
Cellulo	se:			
Biodegr	adability	:	Result: Readily bi	odegradable.



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Mont	elukast:				
Biode	egradability	Biodegradation	Result: not rapidly degradable Biodegradation: 0 % Exposure time: 28 d		
Stabil	lity in water	: Hydrolysis: 5	Hydrolysis: 50 %(21.7 h)		
Magr	nesium stearate:				
Biode	egradability	: Result: Not b Remarks: Ba	iodegradable sed on data from similar materials		
Bioad	ccumulative potentia	I			
<u>Com</u>	ponents:				
Mont	elukast:				
	ion coefficient: n- ol/water	: log Pow: > 4.	3		
Magn	nesium stearate:				
	ion coefficient: n- ol/water	: log Pow: > 4			
Mobi	lity in soil				
No da	ata available				
Othe	r adverse effects				
Nia da	ata available				

#### SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods		
Waste from residues	:	Do not dispose of waste into sewer.
		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.



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stic regulation 002-SCT gulated as a dangero		
	ous good	
al precautions for upplicable	ıser	
15. REGULATORY I	INFORMATION	
v, health and enviro re	onmental regulations/	legislation specific for the substance or
tial chemical product	ts and machinery for	s, : Not applicable
gredients of this p	roduct are reported ir	1 the following inventories:
	: not determined	ł
	: not determined	ł
)	: not determined	Ł
	I5. REGULATORY I r, health and envirous re al Law for the contro- tial chemical product cing capsules, tablet re regredients of this p	IS. REGULATORY INFORMATION The second secon

Revision Date Date format	:	06.04.2024 dd.mm.yyyy			
Full text of other abbreviations					
ACGIH NOM-010-STPS-2014		USA. ACGIH Threshold Limit Values (TLV) Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting the Work Environment - Identification, Assessment and Con- trol - Appendix 1 Occupational Exposure Limits			
ACGIH / TWA NOM-010-STPS-2014 / VLE- PPT		8-hour, time-weighted average Time weighted average 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



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5.2	06.04.2024	23084-00024	Date of first issue: 17.10.2014

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; TECI - Thailand Existing Chemicals Inventory; 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/

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

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