



Version 2.15			S Number:)59-00017	Date of last issue: 23.03.2020 Date of first issue: 17.10.2014
SECTIO	ON 1. PRODUCT AND CO	MPA	NY IDENTIFICAT	ION
Pro	oduct name	:	Montelukast Tab	let Formulation
Ма	nufacturer or supplier's	detai	ils	
Co	mpany	:	Organon & Co.	
Ad	dress	:	30 Hudson Stree Jersey City, New	rt, 33nd floor Jersey, U.S.A 07302
Те	lephone	:	551-430-6000	
En	nergency telephone numbe	er :	215-631-6999	
E-i	mail address	:	EHSSTEWARD	@organon.com
Re	commended use of the c	hem	ical and restriction	ons on use
Re	commended 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 -< 60
Montelukast	151767-02-1	< 10
Magnesium stearate	557-04-0	< 10
Titanium dioxide	13463-67-7	< 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.



Version 2.15	Revision Date: 02.10.2020	SDS Number: 23059-00017	Date of last issue: 23.03.2020 Date of first issue: 17.10.2014
lf inha	aled	: If inhaled, rer Get medical a	nove to fresh air. attention.
In cas	se of skin contact	: Wash with wa Get medical a	ater and soap. attention if symptoms occur.
In cas	se of eye contact		se well with water. attention if irritation develops and persists.
lf swa	allowed	Get medical a	DO NOT induce vomiting. attention if symptoms occur. thoroughly with water.
and e delay	important symptoms iffects, both acute and ed ction of first-aiders	the skin. Dust contact : First Aid resp	dust can cause mechanical irritation or drying of with the eyes can lead to mechanical irritation. onders should pay attention to self-protection,
Notes	s to physician	when the pot	ecommended personal protective equipment ential for exposure exists (see section 8). matically and supportively.

SECTION 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 prod- ucts	:	Carbon oxides Metal oxides
Specific extinguishing meth- ods	:	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. Evacuate area.
Special protective equipment for firefighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- tive equipment and emer- gency procedures	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal pro- tective 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	:	Sweep up or vacuum up spillage and collect in suitable con-



Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
2.15	02.10.2020	23059-00017	Date of first issue: 17.10.2014
contai	nment and cleaning up	Avoid dispersal of with compressed Dust deposits sh es, as these may leased into the a Local or national posal of this mat employed in the mine which regu Sections 13 and	of dust in the air (i.e., clearing dust surfaces

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 Advice on safe handling	::	Use only with adequate ventilation. 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 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.
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.
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

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type	Control parame-	Basis
		(Form of	ters / Permissible	



Version 2.15	Revision Date: 02.10.2020	SDS Number: 23059-00017	2 410 01 140	t issue: 23.03.2020 t issue: 17.10.2014	
			exposure)	concentration	
Cellul	lose	9004-34-6	TWA	10 mg/m3	AU OEL
			ation: This value	is for inhalable dust	containing no
			TWA	10 mg/m3	ACGIH
Monte	elukast	151767-02-1	TWA	40 µg/m3 (OEB 3)	Internal
			Wipe limit	400 µg/100 cm ²	Internal
Magn	nesium stearate	557-04-0	TWA	10 mg/m3	AU OEL
			ation: This value < 1% crystalline	is for inhalable dust silica	containing no
			TWA (Inhal- able particu- late matter)	10 mg/m3	ACGIH
			TWA (Res- pirable par- ticulate mat- ter)	3 mg/m3	ACGIH
Titani	ium dioxide	13463-67-7	TWA	10 mg/m3	AU OEL
			ation: This value	is for inhalable dust silica	containing no
			TWA	10 mg/m3 (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 con- tainment devices). Minimize open handling.
Personal protective equipment	
Respiratory protection :	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection.
Filter type : Hand protection	Particulates type
Material :	Chemical-resistant gloves
Remarks:Eye protection:Skin and body protection:	Consider double gloving. 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. 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.

SAFETY DATA SHEET



Version 2.15	Revision Date: 02.10.2020		S Number: 059-00017	Date of last issue: 23.03.2020 Date of first issue: 17.10.2014
SECTION	I 9. PHYSICAL AND CHI	EMIC		8
Арре	earance	:	tablet	
Colo	ur	:	coloured	
Odou	ır	:	odourless	
Odou	ur Threshold	:	No data available	9
pН		:	No data available	9
Melti	ng point/freezing point	:	No data available	9
Initia range	l boiling point and boiling e	:	No data available	
Flash	n point	:	Not applicable	
Evap	poration rate	:	No data available	9
Flam	mability (solid, gas)	:	May form explosi dling or other me	ive dust-air mixture during processing, han- ans.
Flam	mability (liquids)	:	No data available	9
	er explosion limit / Upper nability limit	:	No data available	9
	er explosion limit / Lower nability limit	:	No data available	9
Vapo	our pressure	:	No data available	9
Relat	tive vapour density	:	No data available	9
Relat	tive density	:	No data available	9
Dens	sity	:	No data available	9
	bility(ies) /ater solubility	:	No data available	
	tion coefficient: n-	:	No data available	9
	nol/water -ignition temperature	:	No data available	2
Deco	omposition temperature	:	No data available	9
Visco V	osity iscosity, kinematic	:	No data available	
Explo	osive properties	:	Not explosive	



ersion .15	Revision Date: 02.10.2020		S Number:)59-00017	Date of last issue: 23.03.2020 Date of first issue: 17.10.2014			
Oxidi	izing properties	:	The substance	or mixture is not classified as oxidizing.			
Molecular weight		: No data available					
Partio	cle size	:	No data availa	ble			
ECTION	I 10. STABILITY AND RE	EAC	ΤΙVITY				
	nical stability ibility of hazardous reac-	:	Stable under n May form explo dling or other r	as a reactivity hazard. ormal conditions. osive dust-air mixture during processing, han neans. strong oxidizing agents.			
Conc	litions to avoid	:	Heat, flames a Avoid dust forr				
	npatible materials ardous decomposition ucts	:	Oxidizing ager				
ECTION	I 11. TOXICOLOGICAL I	NFC	RMATION				
Ехро	osure routes	:	Inhalation Skin contact Ingestion Eye contact				
	e toxicity classified based on availa	blo	nformation				
	ponents:						
Cellu	llose:						
•••••	llose: e oral toxicity	:	LD50 (Rat): > 5	,000 mg/kg			
Acute			LD50 (Rat): > 5 LC50 (Rat): > 5 Exposure time: Test atmosphere	.8 mg/l 4 h			
Acute	e oral toxicity		LC50 (Rat): > 5 Exposure time:	.8 mg/l 4 h e: dust/mist			
Acute Acute Acute	e oral toxicity e inhalation toxicity	:	LC50 (Rat): > 5 Exposure time: Test atmospher	.8 mg/l 4 h e: dust/mist			
Acute Acute Acute	e oral toxicity e inhalation toxicity e dermal toxicity	:	LC50 (Rat): > 5 Exposure time: Test atmospher	.8 mg/l 4 h e: dust/mist > 2,000 mg/kg			
Acute Acute Acute	e oral toxicity e inhalation toxicity e dermal toxicity telukast:	:	LC50 (Rat): > 5 Exposure time: Test atmospher LD50 (Rabbit):	.8 mg/l 4 h e: dust/mist > 2,000 mg/kg ,000 mg/kg			
Acute Acute Acute Mont Acute	e oral toxicity e inhalation toxicity e dermal toxicity telukast:	:	LC50 (Rat): > 5 Exposure time: Test atmospher LD50 (Rabbit): LD50 (Rat): > 5	.8 mg/l 4 h e: dust/mist > 2,000 mg/kg ,000 mg/kg > 5,000 mg/kg			
Acute Acute Acute Mont Acute	e oral toxicity e inhalation toxicity e dermal toxicity telukast: e oral toxicity	:	LC50 (Rat): > 5 Exposure time: Test atmospher LD50 (Rabbit): LD50 (Rat): > 5 LD50 (Mouse):	.8 mg/l 4 h e: dust/mist > 2,000 mg/kg ,000 mg/kg > 5,000 mg/kg ata available			
Acute Acute Acute Acute Acute Acute	e oral toxicity e inhalation toxicity e dermal toxicity telukast: e oral toxicity e inhalation toxicity	:	LC50 (Rat): > 5 Exposure time: Test atmospher LD50 (Rabbit): LD50 (Rat): > 5 LD50 (Mouse): Remarks: No da	.8 mg/l 4 h e: dust/mist > 2,000 mg/kg ,000 mg/kg > 5,000 mg/kg ata available			



sion 5	Revision Date: 02.10.2020	SDS Numbe 23059-0001			
		icity			
			s: Based on data from similar materials		
Acute	dermal toxicity		abbit): > 2,000 mg/kg s: Based on data from similar materials		
Titani	um dioxide:				
Acute	oral toxicity	: LD50 (R	at): > 5,000 mg/kg		
Acute inhalation toxicity		Exposur Test atm Assessn	LC50 (Rat): > 6.82 mg/l Exposure time: 4 h Test atmosphere: dust/mist Assessment: The substance or mixture has no acute inhala- tion toxicity		
_	corrosion/irritation assified based on ava	ailable informatio	on.		
<u>Comp</u>	oonents:				
Monte	elukast:				
Speci Resul		: Rabbit : Mild skir	rritation		
Magn	esium stearate:				
Speci		: Rabbit			
Resul Rema		: No skin	irritation n data from similar materials		
Rema	115	. Daseu u	n data nom sinniar materiais		
Titani	um dioxide:				
Speci		: Rabbit			
Resul	t	: No skin	irritation		
	us eye damage/eye				
	assified based on ava	allable informatio	bri.		
Comp	oonents:				
	elukast:				
Speci Resul		: Rabbit : Severe i	ritation		
Resul	t	: Severe i	mation		
Magn	esium stearate:				
Speci		: Rabbit			
Resul		: No eye i	rritation		
Rema	rks	: Based o	n data from similar materials		
Titani	um dioxide:				
		D.L.L.Y			
Speci	es	: Rabbit			



5	Revision Date: 02.10.2020	SDS Number: 23059-00017	Date of last issue: 23.03.2020 Date of first issue: 17.10.2014
Respi	ratory or skin sens	itisation	
Skin s	sensitisation		
Not cla	assified based on av	ailable information.	
Resni	ratory sensitisatior	1	
-	assified based on av		
<u>Comp</u>	oonents:		
Monte	elukast:		
Rema	rks	: No data avai	lable
Magn	esium stearate:		
Test T	vpe	: Maximisatior	n Test
	sure routes	: Skin contact	
Specie	es	: Guinea pig	
Metho	od	: OECD Test	Guideline 406
Resul		: negative	
Rema	rks	: Based on da	ta from similar materials
Titani	um dioxide:		
Test T	уре	: Local lymph	node assay (LLNA)
Expos	sure routes	: Skin contact	
Specie		: Mouse	
Resul	t	: negative	
Chror	nic toxicity		
	-		
Germ	cell mutagenicity	ailable information	
Germ Not cla	cell mutagenicity assified based on av	ailable information.	
Germ Not cla <u>Comp</u>	cell mutagenicity assified based on av ponents:	ailable information.	
Germ Not cla <u>Comp</u> Cellul	cell mutagenicity assified based on av ponents: lose:		
Germ Not cla <u>Comp</u> Cellul	cell mutagenicity assified based on av ponents:		acterial reverse mutation assay (AMES) tive
Germ Not cla <u>Comp</u> Cellul	cell mutagenicity assified based on av ponents: lose:	: Test Type: B Result: nega Test Type: Ir	tive n vitro mammalian cell gene mutation test
Germ Not cla <u>Comp</u> Cellul	cell mutagenicity assified based on av ponents: lose:	: Test Type: B Result: nega	tive n vitro mammalian cell gene mutation test
Germ Not cla <u>Comp</u> Cellul Genot	cell mutagenicity assified based on av ponents: lose:	: Test Type: B Result: nega Test Type: Ir Result: nega	tive n vitro mammalian cell gene mutation test tive
Germ Not cla <u>Comp</u> Cellul Genot	cell mutagenicity assified based on av <u>ponents:</u> lose: toxicity in vitro	: Test Type: B Result: nega Test Type: Ir Result: nega : Test Type: M cytogenetic a	tive n vitro mammalian cell gene mutation test tive fammalian erythrocyte micronucleus test (in viv assay)
Germ Not cla <u>Comp</u> Cellul Genot	cell mutagenicity assified based on av <u>ponents:</u> lose: toxicity in vitro	: Test Type: B Result: nega Test Type: Ir Result: nega : Test Type: M cytogenetic a Species: Mo	tive n vitro mammalian cell gene mutation test tive fammalian erythrocyte micronucleus test (in viv assay) use
Germ Not cla <u>Comp</u> Cellul Genot	cell mutagenicity assified based on av <u>ponents:</u> lose: toxicity in vitro	 Test Type: B Result: nega Test Type: Ir Result: nega Test Type: N cytogenetic a Species: Mo Application F 	tive n vitro mammalian cell gene mutation test tive fammalian erythrocyte micronucleus test (in viv assay) use Route: Ingestion
Germ Not cla <u>Comp</u> Cellul Genot	cell mutagenicity assified based on av <u>ponents:</u> lose: toxicity in vitro	: Test Type: B Result: nega Test Type: Ir Result: nega : Test Type: M cytogenetic a Species: Mo	tive n vitro mammalian cell gene mutation test tive fammalian erythrocyte micronucleus test (in viv assay) use Route: Ingestion
Germ Not cla Comp Cellul Genot	cell mutagenicity assified based on av <u>ponents:</u> lose: toxicity in vitro	 Test Type: B Result: nega Test Type: Ir Result: nega Test Type: N cytogenetic a Species: Mo Application F 	tive n vitro mammalian cell gene mutation test tive fammalian erythrocyte micronucleus test (in viv assay) use Route: Ingestion
Genot	cell mutagenicity assified based on av <u>conents:</u> lose: coxicity in vitro	 Test Type: B Result: nega Test Type: Ir Result: nega Test Type: N cytogenetic a Species: Mo Application F Result: nega Test Type: B 	tive n vitro mammalian cell gene mutation test tive fammalian erythrocyte micronucleus test (in viv assay) use Route: Ingestion tive
Genot	cell mutagenicity assified based on av <u>ponents:</u> lose: toxicity in vitro	 Test Type: B Result: nega Test Type: Ir Result: nega Test Type: N cytogenetic a Species: Mo Application F Result: nega 	tive n vitro mammalian cell gene mutation test tive fammalian erythrocyte micronucleus test (in vive assay) use Route: Ingestion tive
Genot	cell mutagenicity assified based on av <u>ponents:</u> lose: toxicity in vitro	 Test Type: B Result: nega Test Type: Ir Result: nega Test Type: N cytogenetic a Species: Mo Application F Result: nega Test Type: B Result: nega 	tive n vitro mammalian cell gene mutation test tive Mammalian erythrocyte micronucleus test (in vive assay) use Route: Ingestion tive
Genot	cell mutagenicity assified based on av <u>ponents:</u> lose: toxicity in vitro	 Test Type: B Result: nega Test Type: Ir Result: nega Test Type: N cytogenetic a Species: Mo Application F Result: nega Test Type: B Result: nega Test Type: Ir 	tive n vitro mammalian cell gene mutation test tive fammalian erythrocyte micronucleus test (in viv assay) use Route: Ingestion tive



rsion 5	Revision Date: 02.10.2020	SDS Number:Date of last issue: 23.03.202023059-00017Date of first issue: 17.10.2014
		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
Geno	toxicity in vivo	: Test Type: Chromosomal aberration Species: Mouse Cell type: Bone marrow Application Route: Oral Result: negative
Magn	esium stearate:	
-	toxicity 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
Titan	ium dioxide:	
	toxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
Geno	toxicity in vivo	: Test Type: In vivo micronucleus test Species: Mouse Result: negative
	nogenicity	
	lassified based on av	ailable information.
Com	ponents:	
Cellu		
Speci Applio	es cation Route	: Rat : Ingestion
	sure time	: 72 weeks : negative
Mont	elukast:	
Speci		: Rat
Applie	cation Route	: Oral



Version 2.15	Revision Date: 02.10.2020	SDS Number: 23059-00017	Date of last issue: 23.03.2020 Date of first issue: 17.10.2014
Expos Result	ure time	: 2 Years : negative	
	ation Route sure time	: Mouse : Oral : 92 weeks : negative	
Titani	um dioxide:		
	ation Route sure time d	 Rat inhalation (dustring) 2 Years OECD Test Generation positive The mechanis mans. 	
Carcin ment	nogenicity - Assess-	: Limited evider animals.	ce of carcinogenicity in inhalation studies with
Not cla	oductive toxicity assified based on avai conents:	lable information.	
Cellul	ose:		
Effects	s on fertility	: Test Type: On Species: Rat Application Rc Result: negativ	
Effects ment	s on foetal develop-	: Test Type: Fe Species: Rat Application Ro Result: negativ	
Monte	elukast:		
Effects	s on fertility		male
		Test Type: Fer Species: Rat, Application Ro Fertility: LOAE Symptoms: Re	female bute: Oral iL: 200 mg/kg body weight
		Test Type: Fer Species: Rat, Application Ro Fertility: NOAE	female



ersion 15	Revision Date: 02.10.2020	SDS Number: 23059-00017	Date of last issue: 23.03.2020 Date of first issue: 17.10.2014
		Symptoms: Re	educed fertility
Magn	esium stearate:		
Effect	ts on fertility	reproduction/c Species: Rat Application Ro Method: OEC Result: negati	D Test Guideline 422
Effect ment	ts on foetal develop-	Species: Rat Application Ro Result: negati	nbryo-foetal development oute: Ingestion ve ed on data from similar materials
	- single exposure		
Not cl	lassified based on ava	ilable information.	
	- repeated exposure lassified based on ava		
	ated dose toxicity		
<u>Com</u>	oonents:		
Cellu	lose:		
Speci		: Rat	
NOAE		: >= 9,000 mg/k	g
	cation Route sure time	: Ingestion : 90 Days	
Mont			
Speci	elukast:	: Monkey, male	and female
NOAE		: 150 - 300 mg/	
Applic	cation Route	: Oral	5
	sure time	: 53 Weeks	· · · · · · · · · · · · · · · · · · ·
Rema	nrko	: No significant	adverse effects were reported
	1172	0	
Speci	es	: Rat	
NOAE	es EL	: Rat : 50 mg/kg	
NOAE Applic	es EL cation Route	: Rat : 50 mg/kg : Oral	
NOAE Applic	es EL cation Route sure time	: Rat : 50 mg/kg : Oral : 53 Weeks	adverse effects were reported
NOAE Applic Expos	es EL cation Route sure time arks	: Rat : 50 mg/kg : Oral : 53 Weeks	adverse effects were reported
NOAE Applic Expos Rema Speci NOAE	es EL cation Route sure time arks es EL	: Rat : 50 mg/kg : Oral : 53 Weeks : No significant : Mouse : 50 mg/kg	adverse effects were reported
NOAE Applic Expos Rema Speci NOAE Applic	es EL cation Route sure time arks es	: Rat : 50 mg/kg : Oral : 53 Weeks : No significant : Mouse	adverse effects were reported

Magnesium stearate:



Version 2.15	Revision Date: 02.10.2020	SDS Number: 23059-00017	Date of last issue: 23.03.2020 Date of first issue: 17.10.2014		
	EL cation Route sure time	: Rat : > 100 mg/kg : Ingestion : 90 Days : Based on data	a from similar materials		
Spec NOA Appli Expo Spec NOA Appli	EL cation Route sure time ies	: Rat : 24,000 mg/kg : Ingestion : 28 Days : Rat : 10 mg/m3 : inhalation (dustion)	24,000 mg/kg Ingestion 28 Days Rat 10 mg/m3 inhalation (dust/mist/fume)		
Not c	ration toxicity lassified based on ava rience with human e				
	ponents:				
Skin	elukast: contact contact tion				

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity		
Components:		
Cellulose:		
Toxicity to fish	:	LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l Exposure time: 48 h
		Remarks: Based on data from similar materials
Montelukast:		
Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): > 0.0778 mg/l Exposure time: 96 h Method: OECD Test Guideline 203 Remarks: No toxicity at the limit of solubility
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 0.0675 mg/l Exposure time: 48 h
		Method: OECD Test Guideline 202 Remarks: No toxicity at the limit of solubility
Toxicity to algae/aquatic	:	NOEC (Pseudokirchneriella subcapitata (green algae)): 100



Version 2.15	Revision Date: 02.10.2020	SDS Number: 23059-00017	Date of last issue: 23.03.2020 Date of first issue: 17.10.2014	
plants			e: 72 h D Test Guideline 201 toxicity at the limit of solubility	
		mg/l Exposure time Method: OEC	okirchneriella subcapitata (green algae)): > 100 e: 72 h D Test Guideline 201 toxicity at the limit of solubility	
Toxici icity)	ty to fish (Chronic tox-	Exposure time Method: OEC	phales promelas (fathead minnow)): 0.073 mg/l e: 32 d D Test Guideline 210 toxicity at the limit of solubility	
		mg/l Exposure time	nodon variegatus (sheepshead minnow)): 0.0816 e: 7 d toxicity at the limit of solubility	
	ty to daphnia and other ic invertebrates (Chron- city)	Exposure time	NOEC (Daphnia magna (Water flea)): 0.23 mg/l Exposure time: 21 d Remarks: No toxicity at the limit of solubility	
Toxici	ty to microorganisms	Method: OEC		
Magn	esium stearate:			
Toxici	ty to fish	Exposure time Method: DIN 3		
	ty to daphnia and other ic invertebrates	Exposure time Test substand Method: Dired Remarks: Bas	a magna (Water flea)): > 1 mg/l e: 47 h ee: Water Accommodated Fraction stive 67/548/EEC, Annex V, C.2. sed on data from similar materials the limit of solubility	
Toxici plants	ty to algae/aquatic	mg/l Exposure time Test substanc Method: OEC Remarks: Bas No toxicity at t	okirchneriella subcapitata (green algae)): > 1 e: 72 h ce: Water Accommodated Fraction D Test Guideline 201 sed on data from similar materials the limit of solubility udokirchneriella subcapitata (green algae)): > 1	



rsion 5	Revision Date: 02.10.2020		0S Number: 059-00017	Date of last issue: 23.03.2020 Date of first issue: 17.10.2014
			Method: OECD T	Vater Accommodated Fraction
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	
Titani	um dioxide:			
Toxici	ty to fish	:	LC50 (Oncorhync Exposure time: 96 Method: OECD T	
	ty to daphnia and other cinvertebrates	:	EC50 (Daphnia m Exposure time: 48	agna (Water flea)): > 100 mg/l 3 h
Toxici plants	ty to algae/aquatic	:	EC50 (Skeletoner Exposure time: 72	ma costatum (marine diatom)): > 10,000 mg 2 h
Toxici	ty to microorganisms	:	EC50: > 1,000 m Exposure time: 3 Method: OECD T	h
Persis	stence and degradabili	ity		
	-			
Comp	oonents:			
<u>Comp</u> Cellul				
Cellul		:	Result: Readily bi	odegradable.
Cellul Biode	ose:	:	Result: Readily bi	odegradable.
Cellul Biode Monte	ose: gradability	:	Result: Readily bi Result: not rapidly Biodegradation: (Exposure time: 28	v degradable) %
Cellul Biode Monte Biode	ose: gradability elukast:	:	Result: not rapidly Biodegradation: (/ degradable) % 3 d
Cellul Biode Monte Biode Stabili	ose: gradability elukast: gradability ity in water	:	Result: not rapidly Biodegradation: (Exposure time: 28	/ degradable) % 3 d
Cellul Biode Monte Biode Stabili	ose: gradability elukast: gradability	: :	Result: not rapidly Biodegradation: (Exposure time: 28 Hydrolysis: 50 %(Result: Not biode	/ degradable) % 3 d 21.7 h)
Cellul Biode Monte Biode Stabili Magn Biode	ose: gradability elukast: gradability ity in water esium stearate:	: :	Result: not rapidly Biodegradation: (Exposure time: 28 Hydrolysis: 50 %(Result: Not biode	y degradable) % 3 d 21.7 h) gradable
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Version 2.15	Revision Date: 02.10.2020	SDS Number: 23059-00017	Date of last issue: 23.03.2020 Date of first issue: 17.10.2014	
	on coefficient: n- ol/water	: log Pow: > 4		
	ity in soil ta available			
	adverse effects ta available			
SECTION	13. DISPOSAL CON	SIDERATIONS		
Dispo	osal methods			

Waste from residues	:	Dispose of in accordance with local regulations.
Contaminated packaging	: Empty containers should be taken to an approved wast	
		dling 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.

National Regulations

ADG

Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

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

Prohibition/Licensing Requirements

: There is no applicable prohibition, authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regulations.

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

AICS	:	not determined
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DSL : not determined



Versio 2.15	on	Revision Date: 02.10.2020		DS Number: 059-00017	Date of last issue: 23.03.2020 Date of first issue: 17.10.2014			
IECSC		:	not determined					
SECTION 16. OTHER INFORMATION								
F	urthe	r information						
S	Revision Date Sources of key data used to compile the Safety Data Sheet		:	02.10.2020 Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen- cy, http://echa.europa.eu/				
D	Date format		:	dd.mm.yyyy				
F	Full text of other abbreviations							
	ACGIH AU OE		:		eshold Limit Values (TLV) ace Exposure Standards for Airborne Con-			
		/ TWA L / TWA	:	8-hour, time-weig Exposure standa	hted average d - time weighted average			

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



Version	Revision Date:	SDS Number:
2.15	02.10.2020	23059-00017

Date of last issue: 23.03.2020 Date of first issue: 17.10.2014

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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