

	Revision Date: 09.04.2021		S Number: 74875-00005	Date of last issue: 10.10.2020 Date of first issue: 08.07.2019	
SECTION 1.	PRODUCT AND CO	MPA	NY IDENTIFICAT	ION	
Product	name	:	Loratadine / Mor	ntelukast Formulation	
Manufac	turer or supplier's	detai	ils		
Compan	у	:	Organon & Co.		
Address	Address		30 Hudson Stree Jersey City, New	et, 33nd floor v Jersey, U.S.A 07302	
Telephor	Telephone		551-430-6000		
Emergency telephone		:	215-631-6999		
E-mail a	ddress	:	EHSSTEWARD	@organon.com	
	nended use of the c			ons on use	
Recomm	Recommended use		Pharmaceutical		
ECTION 2.	HAZARDS IDENTIF	ICAT	ION		
GHS Cla	ssification				
Reprodu	ctive toxicity	:	: Category 2		
Short-ter hazard	m (acute) aquatic	:	: Category 2		
Long-ter hazard	Long-term (chronic) aquatic hazard		Category 2		

GHS label elements

GHS label elements Hazard pictograms	:	
Signal Word	:	Warning
Hazard Statements	:	H361f Suspected of damaging fertility. H411 Toxic to aquatic life with long lasting effects.
Precautionary Statements	:	Prevention: P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. P273 Avoid release to the environment. P280 Wear protective gloves/ protective clothing/ eye protec- tion/ face protection.

Response:



Version 1.4	Revision Date: 09.04.2021	SDS Number: 4574875-00005	Date of last issue: 10.10.2020 Date of first issue: 08.07.2019			
		P308 + P313 II attention. P391 Collect sj	exposed or concerned: Get medical advice/			
	Storage: P405 Store locked up.					
		Disposal: P501 Dispose disposal plant.	P501 Dispose of contents/ container to an approved waste			
Othe	r hazards which do r	ot result in classifica	tion			
Dust contact with the eyes can lead to mechanical irritation. Contact with dust can cause mechanical irritation or drying of the skin. May form combustible dust concentrations in air during processing, handling or other means.						
SECTION	3. COMPOSITION/IN	FORMATION ON ING	REDIENTS			
Subs	tance / Mixture	: Mixture				

Components

Chemical name	CAS-No.	Concentration (% w/w)
Cellulose	9004-34-6	>= 30 -< 50
Montelukast	151767-02-1	>= 5 -< 10
Loratadine	79794-75-5	>= 5 -< 10

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	:	In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.
In case of eye contact	:	
If swallowed	:	If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	:	Suspected of damaging fertility. Contact with dust can cause mechanical irritation or drying of the skin.
Protection of first-aiders	:	Dust contact with the eyes can lead to mechanical irritation. 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.

SAFETY DATA SHEET



Loratadine / Montelukast Formulation

Versi 1.4	ion	Revision Date: 09.04.2021		9S Number: 74875-00005	Date of last issue: 10.10.2020 Date of first issue: 08.07.2019	
SEC	TION 5	. FIRE-FIGHTING ME	ASL	IRES		
:	Suitable extinguishing media		:	: Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical		
	Unsuita media	ble extinguishing	:	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.		
	Hazard ucts	ous combustion prod-	:	Carbon 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.		
	Special protective equipment for fire-fighters		:		e, wear self-contained breathing apparatus. ective equipment.	
SEC	TION 6	. ACCIDENTAL RELE	AS	EMEASURES		
t	tive equ	al precautions, protec- upment and emer- procedures	:	Follow safe handl	ective equipment. ing advice (see section 7) and personal ent recommendations (see section 8).	
	Enviror	mental precautions	:	Retain and dispos	akage or spillage if safe to do so. se of contaminated wash water. should be advised if significant spillages	
		ls and materials for ment and cleaning up	:	container for disp Avoid dispersal of with compressed Dust deposits sho surfaces, as these released into the Local or national	dust in the air (i.e., clearing dust surfaces	

employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

- Technical measures
- : Static electricity may accumulate and ignite suspended dust



Version 1.4	Revision Date: 09.04.2021	SDS Number: 4574875-00005	Date of last issue: 10.10.2020 Date of first issue: 08.07.2019			
	Total ventilation on safe handling	and bonding, or i Use only with add Do not breathe d Do not swallow. Avoid contact wit Avoid prolonged Handle in accord practice, based of assessment Minimize dust ge Keep container c Keep away from Take precautiona	e precautions, such as electrical grounding nert atmospheres. equate ventilation. ust.			
Conditions for safe storage : Keep in properly labeled containers. Store locked up.						
Materi	als to avoid	: Do not store with	Store in accordance with the particular national regulations. Do not store with the following product types: Strong oxidizing agents			

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Cellulose	9004-34-6	CMP	10 mg/m ³	AR OEL
	Further inform	Further information: Irritation		
		TWA	10 mg/m ³	ACGIH
Montelukast	151767-02-1	TWA	40 µg/m3 (OEB 3)	Internal
		Wipe limit	400 µg/100 cm ²	Internal
Loratadine	79794-75-5	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 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 Hand protection	: Particulates type					



Version 1.4	Revision Date: 09.04.2021	SDS Number: 4574875-00005	Date of last issue: 10.10.2020 Date of first issue: 08.07.2019			
Ma	aterial	: Chemical-resi	stant gloves			
Remarks Eye protection		: Wear safety g If the work env mists or aeros Wear a facesh	 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 			
Skin and body protection		: Work uniform Additional boo task being per disposable su Use appropria	Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.			
Hygiene measures		: If exposure to eye flushing s working place When using d Wash contam The effective of engineering co appropriate de industrial hygi	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.			

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	tablet
Color	:	No data available
Odor	:	No data available
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	:	Not applicable
Flammability (solid, gas)	:	May form combustible dust concentrations in air during proce- ssing, handling or other means.
Flammability (liquids)	:	Not applicable
Upper explosion limit / Upper flammability limit	:	No data available

SAFETY DATA SHEET



Loratadine / Montelukast Formulation

Vers 1.4	sion	Revision Date: 09.04.2021		S Number: 4875-00005	Date of last issue: 10.10.2020 Date of first issue: 08.07.2019
	Lower explosion limit / Lower flammability limit Vapor pressure		:	No data available	
			:	Not applicable	
	Relative	e vapor density	:	Not applicable	
	Relative	e density	:	No data available)
	Density	,	:	No data available)
	Solubili Wat	ty(ies) er solubility	:	No data available	
	Partition coefficient: n- octanol/water Autoignition temperature Decomposition temperature		:	Not applicable	
			:	No data available)
			:	No data available)
	Viscosi Visc	ty osity, kinematic	:	Not applicable	
	Explosi	ve properties	:	Not explosive	
	Oxidizir	ng properties	:	The substance of	r mixture is not classified as oxidizing.
	Molecu	lar weight	:	No data available	
	Particle	size	:	No data available)

SECTION 10. STABILITY AND REACTIVITY

Reactivity Chemical stability Possibility of hazardous reac- tions	::	Not classified as a reactivity hazard. Stable under normal conditions. May form combustible dust concentrations in air during processing, handling or other means. Can react with strong oxidizing agents.
Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
Incompatible materials	:	5 5
Hazardous decomposition products	:	No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of	:	Inhalation
exposure		Skin contact
		Ingestion
		Eye contact

Acute toxicity

Not classified based on available information.



Version 1.4	Revision Date: 09.04.2021	SDS Number: 4574875-00005	Date of last issue: 10.10.2020 Date of first issue: 08.07.2019		
<u>Co</u>	mponents:				
Ce	llulose:				
Ac	ute oral toxicity	: LD50 (Rat): > 5	5.000 mg/kg		
Ac	ute inhalation toxicity	Exposure time:	LC50 (Rat): > 5,8 mg/l Exposure time: 4 h Test atmosphere: dust/mist		
Ac	ute dermal toxicity	: LD50 (Rabbit):	> 2.000 mg/kg		
Мс	ontelukast:				
Ac	ute oral toxicity	: LD50 (Rat): > 5	5.000 mg/kg		
		LD50 (Mouse):	> 5.000 mg/kg		
Ac	ute inhalation toxicity	: Remarks: No d	lata available		
Ac	ute dermal toxicity	: Remarks: No d	lata available		
Lo	ratadine:				
Ac	ute oral toxicity	: LD50 (Rat): > 5	5.000 mg/kg		
Ac	ute inhalation toxicity	: LC50 (Rat): > 0 Exposure time: Test atmosphe Assessment: T tion toxicity	:1h		

Skin corrosion/irritation

Not classified based on available information.

Components:

Montelukast:

	Rabbit Mild skin irritation
--	--------------------------------

Loratadine:

Species	:	Rabbit
Result	:	No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Montelukast:

Species	:	Rabbit
Result	:	Severe irritation



ersion 1	Revision Date: 09.04.2021	-	S Number: 74875-00005	Date of last issue: 10.10.2020 Date of first issue: 08.07.2019
Lorat	adine:			
Speci	es		Rabbit	
Resul			No eye irritation	
	-	-		
Respi	iratory or skin sens	sitizatio	n	
-	sensitization			
Not cl	assified based on av	vailable	information.	
Respi	iratory sensitizatio	n		
Not cl	assified based on av	vailable	information.	
<u>Comp</u>	oonents:			
Monte	elukast:			
Rema	arks	:	No data availabl	e
Lorat	adine:			
Test 1	Гуре	:	Maximization Te	st
	es of exposure		Dermal	
Speci		:	Guinea pig	
	ssment	:		skin sensitization.
Resul	lt	:	negative	
Not cl	a cell mutagenicity lassified based on av conents:	vailable	information.	
Not cl <u>Comp</u>	assified based on av	vailable	information.	
Not cl <u>Comr</u> Cellul	lassified based on av ponents: lose:	vailable		
Not cl <u>Comr</u> Cellul	assified based on av	vailable i	Test Type: Bacto	erial reverse mutation assay (AMES)
Not cl <u>Comr</u> Cellul	lassified based on av ponents: lose:	vailable i		erial reverse mutation assay (AMES)
Not cl <u>Comr</u> Cellul	lassified based on av ponents: lose:	vailable :	Test Type: Bacto Result: negative Test Type: In vit	ro mammalian cell gene mutation test
Not cl <u>Comr</u> Cellul	lassified based on av ponents: lose:	vailable :	Test Type: Bacto Result: negative	ro mammalian cell gene mutation test
Not cl <u>Comr</u> Cellul Genot	lassified based on av <u>ponents:</u> lose: toxicity in vitro	vailable i :	Test Type: Bacta Result: negative Test Type: In vit Result: negative	ro mammalian cell gene mutation test
Not cl <u>Comr</u> Cellul Genot	lassified based on av ponents: lose:	vailable : :	Test Type: Bacta Result: negative Test Type: In vit Result: negative Test Type: Mam	ro mammalian cell gene mutation test malian erythrocyte micronucleus test (in vivo
Not cl <u>Comr</u> Cellul Genot	lassified based on av <u>ponents:</u> lose: toxicity in vitro	vailable : :	Test Type: Bacta Result: negative Test Type: In vit Result: negative Test Type: Mam cytogenetic assa	ro mammalian cell gene mutation test malian erythrocyte micronucleus test (in vivo
Not cl <u>Comr</u> Cellul Genot	lassified based on av <u>ponents:</u> lose: toxicity in vitro	vailable : :	Test Type: Bacta Result: negative Test Type: In vit Result: negative Test Type: Mam	ro mammalian cell gene mutation test malian erythrocyte micronucleus test (in vivo ay)
Not cl <u>Comr</u> Cellul Genot	lassified based on av <u>ponents:</u> lose: toxicity in vitro	vailable : :	Test Type: Bacto Result: negative Test Type: In vit Result: negative Test Type: Mam cytogenetic assa Species: Mouse	ro mammalian cell gene mutation test malian erythrocyte micronucleus test (in vivo ay) re: Ingestion
Not cl <u>Comp</u> Cellul Genot	lassified based on av <u>ponents:</u> lose: toxicity in vitro	vailable : :	Test Type: Bactor Result: negative Test Type: In vit Result: negative Test Type: Mam cytogenetic assa Species: Mouse Application Rout	ro mammalian cell gene mutation test malian erythrocyte micronucleus test (in vivo ay) re: Ingestion
Not cl <u>Comp</u> Cellul Genot	lassified based on av <u>ponents:</u> lose: toxicity in vitro toxicity in vivo	vailable i :	Test Type: Bacte Result: negative Test Type: In vit Result: negative Test Type: Mam cytogenetic assa Species: Mouse Application Rout Result: negative	ro mammalian cell gene mutation test malian erythrocyte micronucleus test (in vivo ay) re: Ingestion
Not cl <u>Comp</u> Cellul Genot	assified based on av <u>ponents:</u> lose: toxicity in vitro	vailable : :	Test Type: Bacte Result: negative Test Type: In vit Result: negative Test Type: Mam cytogenetic assa Species: Mouse Application Rout Result: negative	ro mammalian cell gene mutation test malian erythrocyte micronucleus test (in vivo ay) ee: Ingestion erial reverse mutation assay (AMES)
Not cl <u>Comp</u> Cellul Genot	lassified based on av <u>ponents:</u> lose: toxicity in vitro toxicity in vivo	vailable i : :	Test Type: Bacta Result: negative Test Type: In vit Result: negative Test Type: Mam cytogenetic assa Species: Mouse Application Rout Result: negative	ro mammalian cell gene mutation test malian erythrocyte micronucleus test (in vivo ay) ee: Ingestion erial reverse mutation assay (AMES)
Not cl <u>Comp</u> Cellul Genot	lassified based on av <u>ponents:</u> lose: toxicity in vitro toxicity in vivo	vailable : :	Test Type: Bacta Result: negative Test Type: In vit Result: negative Test Type: Mam cytogenetic assa Species: Mouse Application Rout Result: negative Test Type: Bacta Result: negative Test Type: In vit	ro mammalian cell gene mutation test malian erythrocyte micronucleus test (in vivo ay) ee: Ingestion erial reverse mutation assay (AMES) ro mammalian cell gene mutation test
Not cl <u>Comp</u> Cellul Genot	lassified based on av <u>ponents:</u> lose: toxicity in vitro toxicity in vivo	vailable : :	Test Type: Bacta Result: negative Test Type: In vit Result: negative Test Type: Mam cytogenetic assa Species: Mouse Application Rout Result: negative Test Type: Bacta Result: negative Test Type: In vit	ro mammalian cell gene mutation test malian erythrocyte micronucleus test (in vivo ay) re: Ingestion erial reverse mutation assay (AMES) ro mammalian cell gene mutation test inese hamster fibroblasts
Not cl <u>Comp</u> Cellul Genot	lassified based on av <u>ponents:</u> lose: toxicity in vitro toxicity in vivo	vailable : :	Test Type: Bacta Result: negative Test Type: In vit Result: negative Test Type: Mam cytogenetic assa Species: Mouse Application Rout Result: negative Test Type: Bacta Result: negative Test Type: In vit Test Type: In vit Test system: Ch Result: negative	ro mammalian cell gene mutation test malian erythrocyte micronucleus test (in vivo ay) e: Ingestion erial reverse mutation assay (AMES) ro mammalian cell gene mutation test inese hamster fibroblasts
Not cl <u>Comp</u> Cellul Genot	lassified based on av <u>ponents:</u> lose: toxicity in vitro toxicity in vivo	vailable : :	Test Type: Bacta Result: negative Test Type: In vit Result: negative Test Type: Mam cytogenetic assa Species: Mouse Application Rout Result: negative Test Type: Bacta Result: negative Test Type: In vit Test system: Ch Result: negative Test Type: Chro	ro mammalian cell gene mutation test malian erythrocyte micronucleus test (in vivo ay) e: Ingestion erial reverse mutation assay (AMES) ro mammalian cell gene mutation test inese hamster fibroblasts mosomal aberration
Not cl <u>Comp</u> Cellul Genot	lassified based on av <u>ponents:</u> lose: toxicity in vitro toxicity in vivo	vailable : :	Test Type: Bacta Result: negative Test Type: In vit Result: negative Test Type: Mam cytogenetic assa Species: Mouse Application Rout Result: negative Test Type: Bacta Result: negative Test Type: In vit Test system: Ch Result: negative Test Type: Chro	ro mammalian cell gene mutation test malian erythrocyte micronucleus test (in vivo ay) ee: Ingestion erial reverse mutation assay (AMES) ro mammalian cell gene mutation test inese hamster fibroblasts mosomal aberration inese hamster ovary cells



rsion	Revision Date: 09.04.2021		OS Number: 74875-00005	Date of last issue: 10.10.2020 Date of first issue: 08.07.2019
			Test Type: Alka Test system: rat Result: negative	
Genot	toxicity in vivo	:	Test Type: Chro Species: Mouse Cell type: Bone Application Rou Result: negative	marrow te: Oral
Lorata	adine:			
Genot	toxicity in vitro	:	Test Type: Bact Result: negative	erial reverse mutation assay (AMES)
			Test Type: In vit Result: negative	ro mammalian cell gene mutation test
			Test Type: Chro Result: negative	pmosome aberration test in vitro
				damage and repair, unscheduled DNA syn- alian cells (in vitro)
Genot	toxicity in vivo	:	Test Type: Micro Species: Mouse Cell type: Bone Application Rou Result: negative	marrow te: Oral
	cell mutagenicity -	:	Weight of evider cell mutagen.	nce does not support classification as a germ
Not cl	nogenicity assified based on ava ponents:	iilable	information.	
Cellul				
	ation Route	:	Rat Ingestion	
Expos Resul	sure time t	:	72 weeks negative	
Monte	elukast:			
Specie		:	Rat Oral	
	ation Route		Orai 2 Years	
Resul		:	negative	
Specie		:	Mouse	
Applic	ation Route	:	Oral	



rsion	Revision Date: 09.04.2021		S Number: 74875-00005	Date of last issue: 10.10.2020 Date of first issue: 08.07.2019
Expos	ure time	:	92 weeks	
Result	t	:	negative	
Lorata	adine:			
Specie	es	:	Rat	
	ation Route	:	Oral	
	ure time	:	2 Years	
LOAE		:	10 mg/kg body v	veight
Result	t	:	positive	-
Specie		:	Monkey	
	ation Route	:	Oral	
	ure time	:	17 Months	
NOAE	-	:	40 mg/kg body v	veight
Result	t	:	negative	
Repro	oductive toxicity			
Suspe	ected of damaging fertilit	v.		
•	onents:	,		
Cellul	ose:			
	s on fertility	:	Test Type: One-	generation reproduction toxicity study
			Species: Rat	
			Application Rout	e: Ingestion
			Result: negative	-
Effects	s on fetal development	:		ity/early embryonic development
			Species: Rat	- Les estes
			Application Rout	e: Ingestion
			Result: negative	
Monte	elukast:			
Effects	s on fertility	:	Test Type: Fertil	
			Species: Rat, ma	
			Application Rout	
				: 800 mg/kg body weight
			Result: Animal te	esting did not show any effects on fertility.
			Test Type: Fertil	ity
			Species: Rat, fei	
			Application Rout	e: Oral
				200 mg/kg body weight
			Symptoms: Red	uced fertility
			Test Type: Fertil	
			Species: Rat, fer	
			Application Rout	
				: 100 mg/kg body weight
			Symptoms: Red	uced tertility

Loratadine:

SAFETY DATA SHEET



ersion 1	Revision Date: 09.04.2021	SDS Number:Date of last issue: 10.10.20204574875-00005Date of first issue: 08.07.2019
Effect	s on fertility	: Species: Rat, male Application Route: Oral Fertility: LOAEL: 64 mg/kg body weight Result: Effects on fertility.
Effect	s on fetal development	 Species: Rat Application Route: Oral Developmental Toxicity: LOAEL: 48 mg/kg body weight Result: Embryo-fetal toxicity.
		Species: Rabbit Application Route: Oral Developmental Toxicity: LOAEL: 48 mg/kg body weight Result: Embryo-fetal toxicity.
		Species: Rat Application Route: Oral Developmental Toxicity: LOAEL: 12 mg/kg body weight
Repro sessn	oductive toxicity - As- nent	: Some evidence of adverse effects on sexual function and fertility, based on animal experiments.
Not cl STOT	-single exposure assified based on availa -repeated exposure assified based on availa	
	ated dose toxicity	
-	oonents:	
Cellu Speci NOAE Applic	lose: es	 Rat >= 9.000 mg/kg Ingestion 90 Days
Speci NOAE Applic	EL cation Route sure time	 Monkey, male and female 150 - 300 mg/kg Oral 53 Weeks No significant adverse effects were reported
	EL cation Route sure time	 Rat 50 mg/kg Oral 53 Weeks No significant adverse effects were reported
Speci NOAE Applic		: Mouse : 50 mg/kg : Oral



.4	Revision Date: 09.04.2021	SDS Number: 4574875-00005	Date of last issue: 10.10.2020 Date of first issue: 08.07.2019
	sure time	: 14 Weeks	
Rema	arks	: No significan	t adverse effects were reported
Lorat	adine:		
Speci		: Rat	
NOAEL		: 4 mg/kg	
LOAE		: 8 mg/kg	
	cation Route	: Oral	
	sure time et Organs	: 180 Days : Central nervo	ous system
Rema			f limited toxicological significance.
Spec	es	: Monkey	
NOAI		: 0,4 mg/kg	
LOAE		: 4 mg/kg	
	cation Route	: Oral	
	sure time	: 180 Days	aug augtam
Rema	et Organs	: Central nerve	f limited toxicological significance.
Mont Skin d	oonents: elukast:		ay irritate skin.
Inges	ontact	: Symptoms: S : Symptoms: u	Severe irritation upper respiratory tract infection, pharyngitis, cough, Abdominal pain, Diarrhea, Fever
Inges	ontact	: Symptoms: S : Symptoms: u	
Inges	iontact tion	: Symptoms: S : Symptoms: U Headache, C	upper respiratory tract infection, pharyngitis, Cough, Abdominal pain, Diarrhea, Fever
Inges Lorat	iontact tion	: Symptoms: S : Symptoms: U Headache, C : Symptoms: F	upper respiratory tract infection, pharyngitis,
Inges Lorat Inges ECTION	iontact tion adine: tion	: Symptoms: S : Symptoms: U Headache, C : Symptoms: F	upper respiratory tract infection, pharyngitis, Cough, Abdominal pain, Diarrhea, Fever
Inges Lorat Inges ECTION Ecoto	iontact tion tion 12. ECOLOGICAL IN	: Symptoms: S : Symptoms: U Headache, C : Symptoms: F	upper respiratory tract infection, pharyngitis, Cough, Abdominal pain, Diarrhea, Fever
Inges Lorat Inges ECTION Ecoto	iontact tion adine: tion 12. ECOLOGICAL IN posicity ponents:	: Symptoms: S : Symptoms: U Headache, C : Symptoms: F	upper respiratory tract infection, pharyngitis, Cough, Abdominal pain, Diarrhea, Fever
Inges Lorat Inges ECTION Ecoto <u>Com</u> Cellu	iontact tion adine: tion 12. ECOLOGICAL IN posicity ponents:	: Symptoms: S : Symptoms: U Headache, C : Symptoms: F NFORMATION : LC50 (Oryzia Exposure tim	apper respiratory tract infection, pharyngitis, Cough, Abdominal pain, Diarrhea, Fever Fatigue, Headache, dry mouth, Nausea
Inges Lorat Inges ECTION Ecoto Com Cellu Toxic	iontact tion 12. ECOLOGICAL IN poxicity ponents: lose:	: Symptoms: S : Symptoms: U Headache, C : Symptoms: F NFORMATION : LC50 (Oryzia Exposure tim	apper respiratory tract infection, pharyngitis, Cough, Abdominal pain, Diarrhea, Fever Fatigue, Headache, dry mouth, Nausea



Vers 1.4	sion	Revision Date: 09.04.2021		S Number: 74875-00005	Date of last issue: 10.10.2020 Date of first issue: 08.07.2019
		r to daphnia and other invertebrates	:	Exposure time: 48 Method: OECD Te	
	Toxicity plants	r to algae/aquatic	:	mg/l Exposure time: 72 Method: OECD Te	
				mg/l Exposure time: 72 Method: OECD Te	
	Toxicity icity)	to fish (Chronic tox-	:	Exposure time: 32 Method: OECD Te	
				mg/l Exposure time: 7	on variegatus (sheepshead minnow)): 0,0816 d city at the limit of solubility.
		to daphnia and other invertebrates (Chron- ty)	:	Exposure time: 21	nagna (Water flea)): 0,23 mg/l d city at the limit of solubility.
	Toxicity	to microorganisms	:	EC50: > 100 mg/l Exposure time: 3 Test Type: Respir Method: OECD Te Remarks: No toxic	ation inhibition
	Lorata	dine:			
	Toxicity		:	LC50 (Lepomis m Exposure time: 96 Method: OECD Te	
		to daphnia and other invertebrates	:	EC50 (Daphnia m Exposure time: 48 Method: OECD Te	
	Toxicity plants	v to algae/aquatic	:	EC50 (Pseudokiro mg/l Exposure time: 72 Method: OECD Te	
				NOEC (Pseudokir mg/l Exposure time: 72	chneriella subcapitata (green algae)): 0,053 ? h



Method: OECD Test Guideline 201 M-Factor (Acute aquatic tox-icity) : Toxicity to fish (Chronic tox-icity) : NOEC (Pimephales promelas (fathead minnow)): (Exposure time: 32 d Method: OECD Test Guideline 210) Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : M-Factor (Chronic aquatic ic toxicity) : M-Factor (Chronic aquatic is toxicity) : Toxicity to microorganisms : EC50: > 1.000 mg/l : Exposure time: 3 h : Test Type: Respiration inhibition Method: OECD Test Guideline 209 Persistence and degradability : Components: : Biodegradability : Result: not rapidly degradable. Montelukast: : Biodegradability : Result: not rapidly degradable Biodegr	
icity) Toxicity to fish (Chronic tox-icity) : NOEC (Pimephales promelas (fathead minnow)): C Exposure time: 32 d Method: OECD Test Guideline 210 Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0,078 mg/l Exposure time: 21 d Method: OECD Test Guideline 211 M-Factor (Chronic aquatic to toxicity) : 1 More active to microorganisms : EC50: > 1.000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209 Persistence and degradability Components: Cellulose: Biodegradability Biodegradability : Result: not rapidly degradable. Montelukast: : Result: not rapidly degradable Biodegradation: 0 % Exposure time: 28 d	
Toxicity to fish (Chronic tox- icity): NOEC (Pimephales promelas (fathead minnow)): C Exposure time: 32 d Method: OECD Test Guideline 210Toxicity to daphnia and other aquatic invertebrates (Chron- ic toxicity): NOEC (Daphnia magna (Water flea)): 0,078 mg/l Exposure time: 21 d Method: OECD Test Guideline 211M-Factor (Chronic aquatic toxicity): 1M-Factor (Chronic aquatic toxicity): EC50: > 1.000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209Persistence and degradabilityComponents:Cellulose: Biodegradability: Result: Readily biodegradable.Montelukast: Biodegradability: Result: not rapidly degradable Biodegradation: 0 % Exposure time: 28 d	
aquatic invertebrates (Chron- ic toxicity) Exposure time: 21 d Method: OECD Test Guideline 211 M-Factor (Chronic aquatic : 1 toxicity) 1 Toxicity to microorganisms : EC50: > 1.000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209 Persistence and degradability Components: Biodegradability Montelukast: Biodegradability Exposure time: 28 d),084 mg/
toxicity) Toxicity to microorganisms:EC50: > 1.000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209Persistence and degradability Components: Biodegradability:Cellulose: Biodegradability:Result: Readily biodegradable.Montelukast: Biodegradability:Biodegradability:Result: not rapidly degradable BiodegradabilityMontelukast: Biodegradability:Biodegradability:Result: not rapidly degradable Biodegradability	
Toxicity to microorganisms:EC50: > 1.000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209Persistence and degradabilityComponents:Cellulose:Biodegradability:Result: Readily biodegradable.Montelukast:Biodegradability:Result: not rapidly degradable BiodegradabilityEise State BiodegradabilityBiodegradability:Biodegradability::: <td></td>	
Components: Cellulose: Biodegradability : Result: Readily biodegradable. Montelukast: Biodegradability : Result: not rapidly degradable Biodegradable Exposure time: 28 d	
Cellulose: Biodegradability : Result: Readily biodegradable. Montelukast: Biodegradability : Result: not rapidly degradable Biodegradation: 0 % Exposure time: 28 d	
Biodegradability : Result: Readily biodegradable. Montelukast: Biodegradability Biodegradability : Result: not rapidly degradable Biodegradation: 0 % Exposure time: 28 d	
Biodegradability : Result: not rapidly degradable Biodegradation: 0 % Exposure time: 28 d	
Biodegradation: 0 % Exposure time: 28 d	
Stability in water : Hydrolysis: 50 %(21.7 h)	
Loratadine:	
Biodegradability : Result: not rapidly degradable Biodegradation: 50 % Exposure time: 20 d Method: OECD Test Guideline 314	
Stability in water : Degradation half life (DT50): 283 d	
Bioaccumulative potential	
Components:	
Montelukast: Partition coefficient: n- : log Pow: > 4,3 octanol/water	
Loratadine: Partition coefficient: n- : log Pow: 2,35 octanol/water	



Vers 1.4			SDS Numbe 4574875-00		Date of last issue: 10.10.2020 Date of first issue: 08.07.2019	
Mobility in soil						
	Compo	onents:				
		dine: ution among environ- compartments	: log Koc: 5,25 Method: OECD Test Guideline 106			
		r adverse effects ata available				
SEC	TION 1	3. DISPOSAL CONSI	DERATIONS			
	Disposal methodsWaste from residues Contaminated packaging: Dispose of in accordance with local regulations. : Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.				should be taken to an approved waste ecycling or disposal.	
SEC	TION 1	4. TRANSPORT INFO	RMATION			
	Interna	ational Regulations				
UNRTDG UN number : UN 3077 Proper shipping name : ENVIRONMENTALLY HAZARDOUS S N.O.S. (Loratadine)			LLY HAZARDOUS SUBSTANCE, SOLID,			
Class : 9 Packing group : III Labels : 9 IATA-DGR UN/ID No. : UN 3077 Proper shipping name : Environmentally hazardous substance, soli (Loratadine)						
			azardous substance, solid, n.o.s.			
	Labels Packin aircraft		: 9 : III : Miscellar : 956 : 956	neous		
	Packing instruction (passen- : 956 ger aircraft) Environmentally hazardous : yes					
	IMDG- UN nur Proper	G-Code umber : UN 3077 er shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLIE N.O.S. (Loratadine)			LLY HAZARDOUS SUBSTANCE, SOLID,	
	Labels EmS C	g group ode pollutant	: 9 : III : 9 : F-A, S-F : yes			



Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
1.4	09.04.2021	4574875-00005	Date of first issue: 08.07.2019

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture					
Argentina. Carcinogenic Substances and Agents : Not applicable Registry.					
Control of precursors and essential chemicals for the : Not applicable preparation of drugs.					
International Regulations					
The ingredients of this product are reported in the following inventories:					
AICS	: not determined				
DSL	: not determined				
IECSC	: not determined				

SECTION 16. OTHER INFORMATION

Further information

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

Full text of other abbreviations

ACGIH AR OEL	JSA. ACGIH Threshold Limit Values (TLV) Argentina. Occupational Exposure Limits	
	8-hour, time-weighted average TLV (Threshold Limit Value)	

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA



Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
1.4	09.04.2021	4574875-00005	Date of first issue: 08.07.2019

- 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 specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

AR / Z8