

Version 3.0	Revision Date: 06.04.2024	-	S Number: 74882-00012	Date of last issue: 30.09.2023 Date of first issue: 08.07.2019	
Section 1	: Identification				
Prod	uct identifier	:	Loratadine / Mo	ontelukast Formulation	
	mmended use of the cl mmended use	hem :	Pharmaceutica		
Restrictions on use		:	Not applicable		
	ifacturer or supplier's o	deta	ils		
Comp	bany	:	Organon & Co.		
Address		:	30 Hudson Stro Jersey City, Ne	eet, 33nd floor ew Jersey, U.S.A 07302	
Telep	Telephone : +1-551-430-6000		00		
Emergency telephone number : +1-2		+1-215-631-69	99		
E-mail address		:	: EHSSTEWARD@organon.com		
ection 2	: Hazard identification				
Class	sification of the substa	nce	or mixture		
Repro	oductive toxicity	:	Category 2		
Long- hazar	-term (chronic) aquatic <sup>-</sup> d	:	Category 2		
GHS	Label elements, includ	ing	precautionary s	statements	
Haza	rd pictograms	:		¥	
Signa	al word	:	: Warning		
Haza	rd statements	:		ed of damaging fertility. aquatic life with long lasting effects.	
Preca	autionary statements	:	Prevention:		
			P201 Obtain s		

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection/ hearing protection.



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#### **Response:**

P308 + P313 IF exposed or concerned: Get medical advice/ attention. P391 Collect spillage.

#### Storage:

P405 Store locked up.

#### Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

#### 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 combustible dust concentrations in air 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	>= 1 -< 10
Loratadine	79794-75-5	>= 3 -< 10

#### Section 4: First-aid measures

Description of necessary first-aid measures					
General advice	<ul> <li>In the case of accident or if you feel unwell, seek medical advice immediately.</li> <li>When symptoms persist or in all cases of doubt seek medical advice.</li> </ul>				
If inhaled	: If inhaled, remove to fresh air. Get medical attention.				
In case of skin contact	<ul> <li>In case of contact, immediately flush skin with soap and plenty of water.</li> <li>Remove contaminated clothing and shoes.</li> <li>Get medical attention.</li> <li>Wash clothing before reuse.</li> <li>Thoroughly clean shoes before reuse.</li> </ul>				
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. Rinse mouth thoroughly with water.				
Most important symptoms and effects, both acute and delayed					

Risks	:	Suspected of damaging fertility.
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Pro	otection of first-aiders	:	the skin. Dust contact with First Aid responde and use the recor	can cause mechanical irritation or drying of the eyes can lead to mechanical irritation. ers should pay attention to self-protection, nmended personal protective equipment Il for exposure exists (see section 8).
	lication of any immediate	me		d special treatment needed cally and supportively.
	5: Fire-fighting measure	S	Treat Symptomati	
		•		
	inguishing media itable extinguishing media	:	Water spray Alcohol-resistant Carbon dioxide (C Dry chemical	
Un me	suitable extinguishing dia	:	None known.	
Sp	ecial hazards arising from	n the	e substance or m	ixture
Sp	ecific hazards during fire- nting	:	Avoid generating concentrations, an potential dust exp	dust; fine dust dispersed in air in sufficient nd in the presence of an ignition source is a
Ha uct	zardous combustion prod- s	:	Carbon oxides Metal oxides	
Sp	ecial protective actions for	or fir	e-fighters	
Spo	ecial protective equipment firefighters ecific extinguishing meth-		In the event of fire Use personal prot Use extinguishing cumstances and t Use water spray t	e, wear self-contained breathing apparatus. tective equipment. I measures that are appropriate to local cir- the surrounding environment. In cool unopened containers. Iged containers from fire area if it is safe to do
Section	6: Accidental release me	easu	res	
	al precautions, protective rsonal precautions		Use personal prot Follow safe handl	rgency procedures tective equipment. ing advice (see section 7) and personal pro- t recommendations (see section 8).
	nmental precautions vironmental precautions	:	Retain and dispos	akage or spillage if safe to do so. se of contaminated wash water. should be advised if significant spillages



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### Loratadine / Montelukast Formulation

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### Methods and materials for containment and cleaning up

Methods for cleaning up	<ul> <li>Sweep up or vacuum up spillage and collect in suitable container for disposal.</li> <li>Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).</li> <li>Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are re-</li> </ul>
	leased into the atmosphere in sufficient concentration.
	Local or national regulations may apply to releases and dis-
	posal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter-
	mine which regulations are applicable.
	Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

### Section 7: Handling and storage

### Precautions for safe handling

recoulding for sale handling	
Technical measures :	Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
Local/Total ventilation : 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, in	cluding any incompatibilities
Conditions for safe storage :	Keep in properly labelled containers. Store locked up.



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Mater	rials to avoid		ance with the particular national regulations. h the following product types: g agents

### Section 8: Exposure controls/personal protection

### **Control parameters**

#### **Occupational Exposure Limits**

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Cellulose	9004-34-6	PEL (long term)	10 mg/m3	SG OEL
		TWA	10 mg/m3	ACGIH
Montelukast	151767-02-1	TWA	40 µg/m3 (OEB 3)	Internal
		Wipe limit	400 µg/100 cm <sup>2</sup>	Internal
Loratadine	79794-75-5	TWA	40 µg/m3 (OEB 3)	Internal
		Wipe limit	400 µg/100 cm <sup>2</sup>	Internal

Appropriate engineering control 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.
Individual protection measure	es	, such as personal protective equipment (PPE)
	:	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 protection	:	Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, dis- posable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.
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

: Chemical-resistant gloves



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Re	emarks	:	Consider double	gloving.
Section 9:	Physical and chemica	l pro	operties	
Appea	arance	:	tablet	
Colou	ır	:	No data available	e
Odou	r	:	No data available	e
Odou	r Threshold	:	No data available	e
рН		:	No data available	e
Meltir	ng point/freezing point	:	No data available	e
Initial range	boiling point and boiling	:	No data available	e
Flash	point	:	Not applicable	
Evapo	pration rate	:	Not applicable	
Flamr	nability (solid, gas)	:		istible dust concentrations in air during pro- g or other means.
Flamr	mability (liquids)	:	Not applicable	
	r explosion limit / Upper nability limit	:	No data available	e
	r explosion limit / Lower nability limit	:	No data available	e
Vapo	ur pressure	:	Not applicable	
Relati	ve vapour density	:	Not applicable	
Relati	ve density	:	No data available	e
Densi	ty	:	No data available	e
	ility(ies) ater solubility	:	No data available	e
	ion coefficient: n-	:	Not applicable	
	ol/water ignition temperature	:	No data available	e
Deco	mposition temperature	:	No data available	e
Visco	sity			

### SAFETY DATA SHEET



Viscosity, kinematic       :       Not applicable         Explosive properties       :       Not explosive         Oxidizing properties       :       The substance or mixture is not classified as oxidizing.         Molecular weight       :       No data available         Particle characteristics       Particle characteristics       Particle size         Particle size       :       No data available         Section 10: Stability and reactivity       :       Not classified as a reactivity hazard.         Chemical stability       :       Stable under normal conditions.         Possibility of hazardous reac       :       May form combustible dust concentrations in air during processing handling or other means. Can react with strong oxidizing agents. Avoid dust formation. Incompatible materials       :         Hazardous decomposition       :       No hazardous decomposition products are known. products         Section 11: Toxicological information       Skin contact Ingestion Eye contact         Acute toxicity       :       LD50 (Rat): > 5,000 mg/kg         Acute oral toxicity       :       LD50 (Rat): > 5,000 mg/kg	Version 3.0	Revision Date: 06.04.2024		S Number: 74882-00012	Date of last issue: 30.09.2023 Date of first issue: 08.07.2019	
Explosive properties       : Not explosive         Oxidizing properties       : The substance or mixture is not classified as oxidizing.         Molecular weight       : No data available         Particle characteristics       : No data available         Section 10: Stability and reactivity       : Not classified as a reactivity hazard.         Chemical stability       : Stable under normal conditions.         Possibility of hazardous reactions       : May form combustible dust concentrations in air during processing in anding or other means.         Conditions to avoid       : Heat, flames and sparks. Avoid dust formation.         Incompatible materials       : Oxidizing gents         Hazardous decomposition       : No hazardous decomposition products are known. products         Section 11: Toxicological information       : Skin contact Ingestion Eye contact         Acute toxicity       : LD50 (Rat): > 5,000 mg/kg         Acute oral toxicity       : LC50 (Rat): > 5,000 mg/kg         Acute dermal toxicity       : LD50 (Rat): > 2,000 mg/kg         Mortelukas:       : LD50 (Rat): > 5,000 mg/kg         Mortelukas:       : LD50 (Rat): > 5,000 mg/kg						
Oxidizing properties       : The substance or mixture is not classified as oxidizing.         Molecular weight       : No data available         Particle characteristics       : No data available         Section 10: Stability and reactivity       : Not classified as a reactivity hazard.         Chemical stability       : Stable under normal conditions.         Possibility of hazardous reac- tions       : May form combustible dust concentrations in air during pro- cessing, handling or other means.         Conditions to avoid       : Heat, flames and sparks. Avoid dust formation.         Incompatible materials       : Oxidizing agents         Hazardous decomposition products       : No hazardous decomposition products are known. products         Section 11: Toxicological information       Skin contact Ingestion Eye contact         Information on likely routes of : skin contact Ingestion Eye contact       Inhalation Skin contact         Moteluase:       :         Acute toxicity       :         Not classified based on available information.         Components:       :         Cellulose:         Acute inhalation toxicity       :         LD50 (Rat): > 5.8 mg/l Exposure ima: 4 here at atmosphere: dust/mist         Acute dermal toxicity       :         LD50 (Rat): > 2,000 mg/kg         Montelukase:       : <td< td=""><td>V</td><td>iscosity, kinematic</td><td>:</td><td>Not applicable</td><td></td></td<>	V	iscosity, kinematic	:	Not applicable		
Molecular weight       :       No data available         Particle characteristics       Particle size       :       No data available         Section 10: Stability and reactivity       :       Not classified as a reactivity hazard.         Chemical stability       :       Stable under normal conditions.         Possibility of hazardous reactivity       :       Stable under normal conditions.         Possibility of hazardous reactivity       :       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       :       Oxidizing agents         Hazardous decomposition       :       No hazardous decomposition products are known. products         Section 11: Toxicological information       :       Skin contact Ingestion Eye contact         Mote classified based on available information.       :       Components:         Cellulose:       :       LO50 (Rat): > 5,000 mg/kg         Acute oral toxicity       :       LD50 (Rat): > 2,000 mg/kg         Acute dermal toxicity       :       LD50 (Rat): > 2,000 mg/kg         Montelukast:       :       LD50 (Rat): > 5,000 mg/kg	Expl	osive properties	:	Not explosive		
Particle characteristics       Farticle size       : No data available         Section 10: Stability and reactivity       : Not classified as a reactivity hazard.         Chemical stability       :: Stable under normal conditions.         Possibility of hazardous reactivity       : May form combustible dust concentrations in air during processing, handling or other means.         Conditions to avoid       : Heat, flames and sparks.         Avoid dust formation.       : Oxidizing agents         Hazardous decomposition       : No hazardous decomposition products are known.         products       : Oxidizing agents         Section 11: Toxicological information       : No hazardous decomposition products are known.         Information on likely routes of : Inhalation exposure       : Skin contact lingestion Eye contact         Most classified based on available information.       : Components:         Cellulose:       : LD50 (Rat): > 5,000 mg/kg         Acute oral toxicity       : LD50 (Rat): > 2,000 mg/kg         Acute dermal toxicity       : LD50 (Rat): > 2,000 mg/kg         Montelukast:       : LD50 (Rat): > 5,000 mg/kg	Oxic	lizing properties	:	The substance o	r mixture is not classified as oxidizing.	
Particle size       : No data available         Section 10: Stability and reactivity         Reactivity       : Stable under normal conditions.         Possibility of hazardous reac- tions       : May form combustible dust concentrations in air during pro- cessing, handling or other means. Can react with strong oxidizing agents.         Conditions to avoid       : Heat, flames and sparks. Avoid dust formation.         Incompatible materials       : Oxidizing agents         Hazardous decomposition       : No hazardous decomposition products are known.         Products       : No hazardous decomposition products are known.         Section 11: Toxicological information exposure       : Inhalation Skin contact Ingestion Eye contact         Acute toxicity       : LD50 (Rat): > 5,000 mg/kg         Acute oral toxicity       : LD50 (Rat): > 2,000 mg/kg         Acute dermal toxicity       : LD50 (Rat): > 2,000 mg/kg         Acute dermal toxicity       : LD50 (Rat): > 5,000 mg/kg	Mole	ecular weight	:	No data available	9	
Reactivity       :       Not classified as a reactivity hazard.         Chemical stability       :       Stable under normal conditions.         Possibility of hazardous reactions       :       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       :       Oxidizing agents         Hazardous decomposition       :       No hazardous decomposition products are known.         products       :       No hazardous decomposition products are known.         Section 11: Toxicological information       :       Inhalation Skin contact Ingestion Eye contact         Acute toxicity       :       Inhalation       Skin contact Ingestion Eye contact         Acute toxicity       :       LD50 (Rat): > 5,000 mg/kg         Acute oral toxicity       :       LD50 (Rat): > 5.8 mg/l Exposure time: 4 h Test atmosphere: dust/mist         Acute dermal toxicity       :       LD50 (Rabbit): > 2,000 mg/kg         Montelukast:        LD50 (Rat): > 5,000 mg/kg			:	No data available	9	
Chemical stability       :       Stable under normal conditions.         Possibility of hazardous reac- tions       :       May form combustible dust concentrations in air during pro- cessing, handling or other means. Can react with strong oxidizing agents.         Conditions to avoid       :       Heat, flames and sparks. Avoid dust formation.         Incompatible materials Hazardous decomposition products       :       Oxidizing agents         Section 11: Toxicological information       :       Inhalation Skin contact Ingestion Eye contact         Information on likely routes of exposure       :       Inhalation Skin contact Ingestion Eye contact         Acute toxicity       :       LD50 (Rat): > 5,000 mg/kg         Acute inhalation toxicity       :       LD50 (Rat): > 2,000 mg/kg         Acute dermal toxicity       :       LD50 (Rat): > 2,000 mg/kg         Acute oral toxicity       :       LD50 (Rat): > 2,000 mg/kg         Acute oral toxicity       :       LD50 (Rat): > 2,000 mg/kg	Section	10: Stability and reactivi	ty			
Avoid dust formation.         Incompatible materials       :       Oxidizing agents         Hazardous decomposition       :       No hazardous decomposition products are known.         products       :       No hazardous decomposition products are known.         Section 11: Toxicological information       :       No hazardous decomposition products are known.         Information on likely routes of exposure       :       Inhalation skin contact Ingestion Eye contact         Acute toxicity       Not classified based on available information.       :         Components:       :       Cellulose:         Acute oral toxicity       :       LD50 (Rat): > 5,000 mg/kg         Acute inhalation toxicity       :       LC50 (Rat): > 5.8 mg/l Exposure time: 4 h Test atmosphere: dust/mist         Acute dermal toxicity       :       LD50 (Rabit): > 2,000 mg/kg         Montelukast:       :       LD50 (Rat): > 5,000 mg/kg	Che Poss	mical stability sibility of hazardous reac-	:	Stable under nor May form combu cessing, handling	mal conditions. stible dust concentrations in air during pro- g or other means.	
Information on likely routes of : Inhalation exposure Skin contact Ingestion Eye contact Acute toxicity Not classified based on available information. Components: Cellulose: Acute oral toxicity : LD50 (Rat): > 5,000 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 Montelukast: Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg	Inco Haza	mpatible materials ardous decomposition	:	Avoid dust formation. Oxidizing agents		
exposureSkin contact Ingestion Eye contactAcute toxicityEye contactNot classified based on available information.Components:Cellulose:LD50 (Rat): > 5,000 mg/kgAcute oral toxicity:LC50 (Rat): > 5.8 mg/l Exposure time: 4 h Test atmosphere: dust/mistAcute dermal toxicity:LD50 (Rabit): > 2,000 mg/kgMontelukast:LD50 (Rat): > 5,000 mg/kg	Section	11: Toxicological inform	atio	'n		
Not classified based on available information.         Components:         Cellulose:         Acute oral toxicity       :         LD50 (Rat): > 5,000 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         Montelukast:         Acute oral toxicity       :         LD50 (Rat): > 5,000 mg/kg		•	:	Skin contact Ingestion		
Cellulose:         Acute oral toxicity       : LD50 (Rat): > 5,000 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         Montelukast:       Acute oral toxicity       : LD50 (Rat): > 5,000 mg/kg		-	ble	information.		
Acute oral toxicity:LD50 (Rat): > 5,000 mg/kgAcute inhalation toxicity:LC50 (Rat): > 5.8 mg/l Exposure time: 4 h Test atmosphere: dust/mistAcute dermal toxicity:LD50 (Rabbit): > 2,000 mg/kgMontelukast: Acute oral toxicity:LD50 (Rat): > 5,000 mg/kg	Con	nponents:				
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         Montelukast:       Acute oral toxicity       :       LD50 (Rat): > 5,000 mg/kg	Cell	ulose:				
Exposure time: 4 h         Test atmosphere: dust/mist         Acute dermal toxicity       :         LD50 (Rabbit): > 2,000 mg/kg         Montelukast:         Acute oral toxicity       :         LD50 (Rat): > 5,000 mg/kg	Acut	te oral toxicity	:	LD50 (Rat): > 5,0	00 mg/kg	
Montelukast: Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg	Acut	te inhalation toxicity	:	Exposure time: 4	h	
Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg	Acut	te dermal toxicity	:	LD50 (Rabbit): > 2	2,000 mg/kg	
Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg	II Mon	itelukast:				
LD50 (Mouse): > 5,000 mg/kg			:	LD50 (Rat): > 5,0	00 mg/kg	
				LD50 (Mouse): >	5,000 mg/kg	

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rsion	Revision Date: 06.04.2024		S Number: 74882-00012	Date of last issue: 30.09.2023 Date of first issue: 08.07.2019
Acute	inhalation toxicity	:	Remarks: No da	ata available
Acute	dermal toxicity	:	Remarks: No da	ata available
Lorat	adine:			
Acute	oral toxicity	:	LD50 (Rat): > 5	,000 mg/kg
Acute inhalation toxicity		:	LC50 (Rat): > 0 Exposure time: Test atmospher Assessment: Th tion toxicity	1 h
-	corrosion/irritation assified based on ava	ailable	information.	
	oonents:			
Monte	elukast:			
Speci Resul		:	Rabbit Mild skin irritatio	on
Lorat	adine:			
Speci Resul	es	:	Rabbit No skin irritatior	1
Serio	us eye damage/eye	irritati	on	
	assified based on ava			
<u>Comp</u>	oonents:			
	elukast:			
Speci Resul		:	Rabbit Severe irritatior	1
	adine:			
Speci Resul		:	Rabbit No eye irritatior	1
Resp	iratory or skin sensi	tisatio	'n	
	sensitisation assified based on ava	ailable	information.	
Resp	iratory sensitisation			



rsion )	Revision Date: 06.04.2024	SDS Number: 4574882-0001	Date of last issue: 30.09.2023 Date of first issue: 08.07.2019
Com	e e no méri		
	oonents:		
	elukast:	NI 17	
Rema	arks	: No data av	allable
Lorat	adine:		
Test		: Maximisatio	on Test
	sure routes	: Dermal	
Speci Asses	ssment	: Guinea pig	ause skin sensitisation.
Resu		: negative	
Germ	cell mutagenicity		
	lassified based on ava	able information.	
<u>Com</u>	oonents:		
Cellu	lose:		
Geno	toxicity in vitro	: Test Type: Result: neg	Bacterial reverse mutation assay (AMES) ative
		Test Type: Result: neg	In vitro mammalian cell gene mutation test ative
Geno	toxicity in vivo	cytogenetic Species: M	ouse Route: Ingestion
Mont	elukast:		
Geno	toxicity in vitro	: Test Type: Result: neg	Bacterial reverse mutation assay (AMES) ative
			In vitro mammalian cell gene mutation test n: Chinese hamster fibroblasts jative
			Chromosomal aberration n: Chinese hamster ovary cells jative
			Alkaline elution assay n: rat hepatocytes jative
Geno	toxicity in vivo		Chromosomal aberration ouse



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Lorata	adine:		
Genot	oxicity in vitro	: Test Type: Bac Result: negative	terial reverse mutation assay (AMES) e
		Test Type: In vi Result: negative	tro mammalian cell gene mutation test e
		Test Type: Chro Result: negative	omosome aberration test in vitro e
			A damage and repair, unscheduled DNA syn nalian cells (in vitro) e
Genot	oxicity in vivo	: Test Type: Micr Species: Mouse Cell type: Bone Application Rou Result: negative	e marrow ute: Oral
Germ	cell mutagenicity -	: Weight of evide	ence does not support classification as a ge
	sment	cell mutagen.	
Asses Carcin Not cla	sment nogenicity assified based on ava ponents:	-	
Asses Carcin Not cla	n <b>ogenicity</b> assified based on ava ponents:	-	
Asses Carcin Not cla <u>Comp</u> Cellul	nogenicity assified based on ava ponents: ose:	-	
Asses Carcin Not cla <u>Comp</u> Cellul Specie Applic	nogenicity assified based on ava <u>conents:</u> ose: es ation Route	ailable information.	
Asses Carcin Not cla <u>Comp</u> Cellul Specie Applic Expos	nogenicity assified based on ava <u>conents:</u> ose: es ation Route ure time	ailable information. : Rat : Ingestion : 72 weeks	
Asses Carcin Not cla <u>Comp</u> Cellul Specie Applic	nogenicity assified based on ava <u>conents:</u> ose: es ation Route ure time	ailable information. : Rat : Ingestion	
Asses Carcin Not cla <u>Comp</u> Cellul Specie Applic Expos Result	nogenicity assified based on ava <u>conents:</u> ose: es ation Route ure time	ailable information. : Rat : Ingestion : 72 weeks	
Asses Carcin Not cla <u>Comp</u> Cellul Specia Applic Expos Result Monte	nogenicity assified based on ava ponents: ose: es ation Route sure time t	ailable information. : Rat : Ingestion : 72 weeks	
Asses Carcin Not cla <u>Comp</u> Cellul Specie Applic Expos Result Monte	nogenicity assified based on ava ponents: ose: es ation Route sure time t	ailable information. : Rat : Ingestion : 72 weeks : negative	
Asses Carcin Not cla <u>Comp</u> Cellul Specia Applic Expos Result Monte Applic Expos	nogenicity assified based on ava <u>conents:</u> ose: es ation Route ture time t elukast: es ation Route aure time	ailable information. : Rat : Ingestion : 72 weeks : negative : Rat : Oral : 2 Years	
Asses Carcin Not cla <u>Comp</u> Cellul Specia Applic Expos Result Monte Applic	nogenicity assified based on ava <u>conents:</u> ose: es ation Route ture time t elukast: es ation Route aure time	ailable information. : Rat : Ingestion : 72 weeks : negative : Rat : Oral	
Asses Carcin Not cla <u>Comp</u> Cellul Specie Applic Expos Result Monte Specie Applic Expos Result	nogenicity assified based on ava <u>conents:</u> ose: es ation Route ture time t elukast: es ation Route sure time t	ailable information. : Rat : Ingestion : 72 weeks : negative : Rat : Oral : 2 Years : negative : Mouse	
Asses Carcin Not cla <u>Comp</u> Cellul Specie Applic Expos Result Monte Applic Expos Result Specie Applic Expos	nogenicity assified based on ava <u>conents:</u> ose: es ation Route ure time t elukast: es ation Route ure time t es ation Route	ailable information. : Rat : Ingestion : 72 weeks : negative : Rat : Oral : 2 Years : negative : Mouse : Oral	
Asses Carcin Not cla <u>Comp</u> Cellul Specie Applic Expos Result Monte Applic Expos Result Specie Applic Expos	nogenicity assified based on ava ponents: ose: es ation Route ture time t es ation Route ture time t es ation Route ture time t	ailable information. : Rat : Ingestion : 72 weeks : negative : Rat : Oral : 2 Years : negative : Mouse	
Asses Carcin Not cla <u>Comp</u> Cellul Specie Applic Expos Result Specie Applic Expos Result	nogenicity assified based on avaination conents: ose: es ation Route ture time t elukast: es ation Route ture time t es ation Route ture time t	ailable information. : Rat : Ingestion : 72 weeks : negative : Rat : Oral : 2 Years : negative : Mouse : Oral : Oral : 2 Years : negative	
Asses Carcin Not cla <u>Comp</u> Cellul Specia Applic Expos Result Specia Applic Expos Result Specia Applic Expos Result Specia Applic Expos Result Specia Applic Expos Result	nogenicity assified based on avaination conents: ose: es ation Route dure time t elukast: es ation Route dure time t es ation Route dure time t adine: es	ailable information. : Rat : Ingestion : 72 weeks : negative : Rat : Oral : 2 Years : negative : Mouse : Oral : Oral : 2 Years : negative	
Asses Carcin Not cla <u>Comp</u> Cellul Specia Applic Expos Result Specia Applic Expos Result Specia Applic Expos Result Lorata Specia	nogenicity assified based on avaination conents: ose: es ation Route cure time t elukast: es ation Route cure time t es ation Route cure time t adine:	ailable information. : Rat : Ingestion : 72 weeks : negative : Rat : Oral : 2 Years : negative : Mouse : Oral : 92 weeks : negative	



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LOAEL Result		: 10 mg/kg body : positive	weight
Species Applica Exposu NOAEL Result	tion Route ire time	: Monkey : Oral : 17 Months : 40 mg/kg body : negative	weight
-	<b>Juctive toxicity</b> sted of damaging ferti	lity.	
Compo	onents:		
Cellulo	se:		
Effects	on fertility	: Test Type: One Species: Rat Application Rou Result: negative	
Effects ment	on foetal develop-	: Test Type: Ferti Species: Rat Application Rou Result: negative	
Montel	ukast:		
	on fertility		ale
		Test Type: Ferti Species: Rat, fe Application Rou Fertility: LOAEL Symptoms: Red	male te: Oral : 200 mg/kg body weight
		Test Type: Ferti Species: Rat, fe Application Rou Fertility: NOAEL Symptoms: Rec	male te: Oral .: 100 mg/kg body weight
Lorata	dine:		
	on fertility	: Species: Rat, m Application Rou Fertility: LOAEL Result: Effects o	te: Oral : 64 mg/kg body weight
Effects	on foetal develop-	: Species: Rat	



ersion 0	Revision Date: 06.04.2024	SDS Number:Date of last issue: 30.09.20234574882-00012Date of first issue: 08.07.2019
ment		Application Route: Oral Developmental Toxicity: LOAEL: 48 mg/kg body weight Result: Embryo-foetal toxicity
		Species: Rabbit Application Route: Oral Developmental Toxicity: LOAEL: 48 mg/kg body weight Result: Embryo-foetal toxicity
		Species: Rat Application Route: Oral Developmental Toxicity: LOAEL: 12 mg/kg body weight
Reproo sessm	ductive toxicity - As- ent	: Some evidence of adverse effects on sexual function and fertility, based on animal experiments.
	- single exposure	
	assified based on ava	
	assified based on ava	
Repea	ted dose toxicity	
Comp	onents:	
Cellulo	ose:	
Specie NOAE		: Rat
	L ation Route	: >= 9,000 mg/kg : Ingestion
	ure time	: 90 Days
Monte	lukast:	
Specie		: Monkey, male and female
NOAE	L ation Route	: 150 - 300 mg/kg : Oral
	ure time	: 53 Weeks
Remar		: No significant adverse effects were reported
Specie		: Rat
NOAE	L ation Route	: 50 mg/kg : Oral
	ure time	: 53 Weeks
Remar		: No significant adverse effects were reported
		: Mouse
Specie	5	
NOAE	L	: 50 mg/kg
NOAE Applica		: 50 mg/kg : Oral : 14 Weeks



Version 3.0	Revision Date: 06.04.2024	SDS Number: 4574882-00012	Date of last issue: 30.09.2023 Date of first issue: 08.07.2019
Speci NOAE LOAE Applic Expos Targe Rema Speci NOAE	EL EL cation Route sure time t Organs irks es EL	: Monkey : 0.4 mg/kg	ous system i limited toxicological significance.
Expos	cation Route sure time t Organs	: 4 mg/kg : Oral : 180 Days : Central nervo : Effects are of	ous system Iimited toxicological significance.
Not cl Expe	ation toxicity assified based on avail rience with human ex ponents:		
Skin o	elukast: contact ontact tion	: Symptoms: S : Symptoms: u	ly irritate skin. levere irritation pper respiratory tract infection, pharyngitis, ough, Abdominal pain, Diarrhoea, Fever
Lorat Ingest	adine: tion	: Symptoms: F	atigue, Headache, dry mouth, Nausea
Toxic	oonents:	ion	
	ity to fish	Exposure tim	s latipes (Japanese medaka)): > 100 mg/l e: 48 h sed on data from similar materials
	elukast: ty to fish	Exposure tim Method: OEC	hales promelas (fathead minnow)): > 0.0778 mg/l e: 96 h D Test Guideline 203 toxicity at the limit of solubility
Toxici	ty to daphnia and othe	r : EC50 (Daphr	nia magna (Water flea)): > 0.0675 mg/l

### SAFETY DATA SHEET



rsion	Revision Date: 06.04.2024		9S Number: 74882-00012	Date of last issue: 30.09.2023 Date of first issue: 08.07.2019
aquati	c invertebrates			48 h Test Guideline 202 kicity at the limit of solubility
Toxicit plants	ty to algae/aquatic	:	mg/l Exposure time: Method: OECD	kirchneriella subcapitata (green algae)): 100 72 h Test Guideline 201 kicity at the limit of solubility
			mg/l Exposure time: Method: OECD	irchneriella subcapitata (green algae)): > 10 72 h Test Guideline 201 kicity at the limit of solubility
Toxicit icity)	ty to fish (Chronic tox-	:	Exposure time: 3 Method: OECD	ales promelas (fathead minnow)): 0.073 mg/ 32 d Test Guideline 210 kicity at the limit of solubility
			mg/l Exposure time:	don variegatus (sheepshead minnow)): 0.08 7 d kicity at the limit of solubility
	ty to daphnia and other ic invertebrates (Chron- city)	:	Exposure time:	magna (Water flea)): 0.23 mg/l 21 d kicity at the limit of solubility
Toxicit	ty to microorganisms	:	Method: OECD	
Lorata	adine:			
Toxicit	ty to fish	:	Exposure time:	macrochirus (Bluegill sunfish)): 0.382 mg/l 96 h Test Guideline 203
	ty to daphnia and other c invertebrates	:	Exposure time:	magna (Water flea)): 0.83 mg/l 48 h Test Guideline 202
Toxicit plants	ty to algae/aquatic	:	mg/l Exposure time:	irchneriella subcapitata (green algae)): > 0.9 72 h Test Guideline 201
			NOEC (Pseudol mg/l	kirchneriella subcapitata (green algae)): 0.0



rsion )	Revision Date: 06.04.2024	-	0S Number: 74882-00012	Date of last issue: 30.09.2023 Date of first issue: 08.07.2019
			Exposure time: 7 Method: OECD 1	2 h Test Guideline 201
M-Fac icity)	ctor (Acute aquatic tox-	:	1	
	ty to fish (Chronic tox-	:	Exposure time: 3	les promelas (fathead minnow)): 0.084 mg 2 d Fest Guideline 210
	ty to daphnia and other ic invertebrates (Chron- city)	:	Exposure time: 2	magna (Water flea)): 0.078 mg/l 1 d Fest Guideline 211
	ctor (Chronic aquatic	:	1	
	toxicity) Toxicity to microorganisms		EC50: > 1,000 m Exposure time: 3 Test Type: Resp Method: OECD T	h
Persi	stence and degradabili	ity		
<u>Comp</u>	oonents:			
<b>Cellu</b> Biode	<b>lose:</b> gradability	:	Result: Readily b	viodegradable.
	elukast: gradability	:	Result: not rapid Biodegradation: Exposure time: 2	0%
Stabil	ity in water	:	Hydrolysis: 50 %	(21.7 h)
Lorat	adine:			
	gradability	:	Result: not rapid Biodegradation: Exposure time: 2 Method: OECD	50 %
Stabil	ity in water	:	Degradation half	life (DT50): 283 d
Bioad	cumulative potential			
<u>Comp</u>	oonents:			
Partiti	e <b>lukast:</b> on coefficient: n- ol/water	:	log Pow: > 4.3	
Lorat	- <b>P</b>			



ersion .0	Revision Date: 06.04.2024		S Number: 74882-00012	Date of last issue: 30.09.2023 Date of first issue: 08.07.2019
octan	on coefficient: n- ol/water <b>ity in soil</b>	:	log Pow: 2.35	
Lorat Distrik	oonents: adine: pution among environ- al compartments	:	log Koc: 5.25 Method: OECD 1	est Guideline 106
•	adverse effects ta available			
Section 13	3: Disposal considerat	ions	5	
Waste	esal methods from residues minated packaging	:	Dispose of in acc Empty containers	f waste into sewer. ordance with local regulations. s should be taken to an approved waste han- cling or disposal.
Section 14	I: Transport information	on	If not otherwise s	pecified: Dispose of as unused product.
Intern	ational Regulations			
<b>UNRT</b> UN nu UN pr		:	UN 3077 ENVIRONMENT	ALLY HAZARDOUS SUBSTANCE, SOLID,
	oper shipping name	•	N.O.S.	
Packi Label	oper shipping name port hazard class(es) ng group	:	N.O.S. (Loratadine) 9 III 9 yes	
Packin Labels Enviro <b>IATA-</b> UN/ID	oper shipping name port hazard class(es) ng group s onmental hazards <b>DGR</b> No.	:	(Loratadine) 9 III 9 yes UN 3077	
Packii Labels Enviro <b>IATA-</b> UN/ID UN pr	oper shipping name port hazard class(es) ng group s onmental hazards <b>DGR</b> No. oper shipping name	· · · ·	(Loratadine) 9 III 9 yes UN 3077 Environmentally (Loratadine)	hazardous substance, solid, n.o.s.
Packii Labels Enviro <b>IATA-</b> UN/ID UN pr Trans Packii Labels	oper shipping name port hazard class(es) ng group sommental hazards <b>DGR</b> No. oper shipping name port hazard class(es) ng group		(Loratadine) 9 III 9 yes UN 3077 Environmentally	hazardous substance, solid, n.o.s.
Packii Labels Enviro <b>IATA-</b> UN/ID UN pr Trans Packii Labels Packii aircra Packii ger ai	oper shipping name port hazard class(es) ng group sommental hazards <b>DGR</b> No. oper shipping name port hazard class(es) ng group song instruction (cargo ft) ng instruction (passen-		(Loratadine) 9 III 9 yes UN 3077 Environmentally (Loratadine) 9 III Miscellaneous	hazardous substance, solid, n.o.s.



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		N.O.S.
		(Loratadine)
Transport hazard class(es)	:	9
Packing group	:	111
Labels	:	9
EmS Code	:	F-A, S-F
Marine pollutant	:	yes

### Transport in bulk according to IMO instruments

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 specific for the product in question

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations. Environmental Protection and Management Act and : Not applicable

Environmental Protection and Management (Hazard- ous Substances) Regulations	•	
Fine Opfath (Detrologues and Flagence bla Materiale)		

Fire Safety (Petroleum and Flammable Materials) : Not applicable Regulations

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

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

#### Section 16: Other information

Revision Date	:	06.04.2024
Further information Sources of key data used to compile the Safety Data Sheet	:	Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen- cy, http://echa.europa.eu/

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format



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#### Full text of other abbreviations

ACGIH SG OEL		USA. ACGIH Threshold Limit Values (TLV) Singapore. Workplace Safety and Health (General Provisions) Regulations - First Schedule Permissible Exposure Limits of Toxic Substances.
ACGIH / TWA SG OEL / PEL (long term)	:	8-hour, time-weighted average Permissible Exposure Level (PEL) Long Term

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: 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

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

SG / EN