

Version 1.4	Revision Date: 2021/04/09		S Number: 4876-00005	Date of last issue: 2020/10/10 Date of first issue: 2019/07/08
1. PROD	UCT AND COMPANY IDE	ENT	FICATION	
Proc	duct name	:	Loratadine / Mon	telukast Formulation
	nufacturer or supplier's d	letai :	<b>ls</b> Organon & Co.	
Add	ress	:	JL Raya Pandaaı Pandaan, Jawa T	
Tele	ephone	:	551-430-6000	
Eme	ergency telephone number	· :	215-631-6999	
E-m	ail address	:	EHSSTEWARD@	⊉organon.com
	commended use of the ch ommended use	nemi :	cal and restrictic Pharmaceutical	ons on use
2. HAZA	RDS IDENTIFICATION			
	S Classification	:	Category 2	
Lon haz	g-term (chronic) aquatic ard	:	Category 2	
	<b>5 label elements</b> ard pictograms	:		
Sigr	nal word	:	Warning	▼
Haz	ard statements	:		l of damaging fertility. uatic life with long lasting effects.
Prec	cautionary statements	:	P202 Do not han and understood. P273 Avoid relea P280 Wear prote tion/ face protection <b>Response:</b>	exposed or concerned: Get medical advice/



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#### 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.

#### 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
Loratadine	79794-75-5	>= 3 -< 10

#### 4. FIRST AID MEASURES

General advice	:	In the case of accident or if you feel unwell, seek medical ad- vice 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 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	:	Suspected of damaging fertility. Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation.
Protection of first-aiders	:	First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
Notes to physician	:	Treat symptomatically and supportively.

**5. FIREFIGHTING MEASURES** 

### SAFETY DATA SHEET



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S	Suitable extinguishing media Unsuitable extinguishing media		:	<ul> <li>Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical</li> <li>None known.</li> </ul>		
			:			
	Specific hazards during fire- fighting		:	concentrations, an potential dust exp	dust; fine dust dispersed in air in sufficient nd in the presence of an ignition source is a losion hazard. pustion products may be a hazard to health.	
	lazardo icts	ous combustion prod-	:	Carbon oxides		
	Specific ods	extinguishing meth-	:	cumstances and t Use water spray t Remove undamag so.	measures that are appropriate to local cir- he surrounding environment. o cool unopened containers. ged containers from fire area if it is safe to do	
	Special or firefi	protective equipment ghters	:	Evacuate area. In the event of fire Use personal prot	e, wear self-contained breathing apparatus. ective equipment.	
6. AC	CIDEN	TAL RELEASE MEAS	SUR	ES		
tiv	ve equ	al precautions, protec- ipment and emer- rocedures	:		ective equipment. ing advice (see section 7) and personal pro- recommendations (see section 8).	
E	Inviron	mental precautions	:	Retain and dispos	akage or spillage if safe to do so. e of contaminated wash water. should be advised if significant spillages	
		s and materials for ment and cleaning up	:	tainer for disposal Avoid dispersal of with compressed Dust deposits sho es, as these may leased into the att Local or national to posal of this mate employed in the c mine which regula Sections 13 and 1	dust in the air (i.e., clearing dust surfaces	

#### 7. HANDLING AND STORAGE

Technical measures	: Static electricity may accumulate and ignite suspended dust
	causing an explosion.
	Provide adequate precautions, such as electrical grounding



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	I/Total ventilation ce on safe handling	<ul> <li>Use only with a</li> <li>Do not breathe</li> <li>Do not swallow.</li> <li>Avoid contact w</li> <li>Avoid prolonged</li> <li>Handle in accor</li> <li>practice, based</li> <li>sessment</li> <li>Minimize dust g</li> <li>Keep container</li> <li>Keep away from</li> <li>Take precautior</li> </ul>	
Cond	ditions for safe storage		y labelled containers.
Mate	rials to avoid	Store in accord	ance with the particular national regulations. h the following product types:

#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

-			-	
Components	CAS-No.	Value type	Control parame-	Basis
		(Form of	ters / Permissible	
		exposure)	concentration	
Cellulose	9004-34-6	NAB	10 mg/m3	ID 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

### Components with workplace control parameters

Engineering measures	<ul> <li>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.</li> </ul>
Personal protective equipme	ent

### Personal protective equip

Respiratory protection Filter type Hand protection		If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection. Particulates type
Material	:	Chemical-resistant gloves
Remarks	:	Consider double gloving.



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Eye protection		<ul> <li>Wear safety glasses with side shields or goggles.</li> <li>If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.</li> <li>Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.</li> </ul>				
Skin and body protection		<ul> <li>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.</li> </ul>				
Hygiene measures		eye flushing syst ing place. When using do r Wash contamina The effective ope engineering cont appropriate dego	emical is likely during typical use, provide tems and safety showers close to the work- not eat, drink or smoke. ted clothing before re-use. eration of a facility should include review of trols, proper personal protective equipment, pwning and decontamination procedures, e monitoring, medical surveillance and the ative controls.			

#### 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	tablet
Colour	:	No data available
Odour	:	No data available
Odour 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 pro- cessing, handling or other means.
Flammability (liquids)	:	Not applicable
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available

### SAFETY DATA SHEET



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Vap	oour pressure	:	Not applicable	
Rel	ative vapour density	:	Not applicable	
Rel	ative density	:	No data available	
Der	nsity	:	No data available	
	ubility(ies) Water solubility	:	No data available	
	tition coefficient: n-	:	Not applicable	
	anol/water o-ignition temperature	:	No data available	
Dec	composition temperature	:	No data available	
	cosity Viscosity, kinematic	:	Not applicable	
Exp	plosive properties	:	Not explosive	
Oxi	dizing properties	:	The substance o	mixture is not classified as oxidizing.
Mol	lecular weight	:	No data available	
Par	ticle size	:	No data available	
10. STA	BILITY AND REACTIVIT	Y		
	activity emical stability		Not classified as Stable under nor	a reactivity hazard. nal 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 No hazardous decomposition products are known.

### 11. TOXICOLOGICAL INFORMATION

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

#### Acute toxicity

Not classified based on available information.



### Loratadine / Montelukast Formulation

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	Compo	onents:			
	Cellulo	ose:			
	Acute of	oral toxicity	:	LD50 (Rat): > 5,0	00 mg/kg
	Acute i	nhalation toxicity	:	LC50 (Rat): > 5.8 Exposure time: 4 Test atmosphere:	h
	Acute of	dermal toxicity	:	LD50 (Rabbit): >	2,000 mg/kg
	Monte	lukast:			
	Acute of	oral toxicity	:	LD50 (Rat): > 5,0	00 mg/kg
				LD50 (Mouse): >	5,000 mg/kg
	Acute i	nhalation toxicity	:	Remarks: No data	a available
	Acute of	dermal toxicity	:	Remarks: No data	a available
	Lorata	dine:			
	Acute of	oral toxicity	:	LD50 (Rat): > 5,0	00 mg/kg
	Acute i	nhalation toxicity	:	LC50 (Rat): > 0.0 Exposure time: 1 Test atmosphere: Assessment: The tion toxicity	h

#### 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



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Lorat	adine:			
Speci	es	:	Rabbit	
Resul	lt	:	No eye irritation	
Resp	iratory or skin sens	sitisatio	n	
-	sensitisation			
Not cl	assified based on av	/ailable	information.	
-	iratory sensitisation assified based on av		information.	
<u>Comp</u>	oonents:			
Monte	elukast:			
Rema	arks	:	No data available	9
Lorat	adine:			
Test		:	Maximisation Te	st
	sure routes	:	Dermal	
Speci		:	Guinea pig	
Resul	ssment	:	negative	skin sensitisation.
Genn	cell mutagenicity			
Not cl	assified based on av	/ailable	information.	
Not cl	assified based on av	vailable	information.	
Not cl <u>Comp</u> Cellu	assified based on av	vailable :		erial reverse mutation assay (AMES)
Not cl <u>Comp</u> Cellu	lassified based on av ponents: lose:		Test Type: Bacte Result: negative	erial reverse mutation assay (AMES) ro mammalian cell gene mutation test
Not cl <u>Com</u> Cellu Geno	lassified based on av ponents: lose:		Test Type: Bacte Result: negative Test Type: In vitr Result: negative	ro mammalian cell gene mutation test malian erythrocyte micronucleus test (in vivo y)
Not cl <u>Com</u> Cellu Geno	lassified based on av <u>ponents:</u> lose: toxicity in vitro		Test Type: Bacte Result: negative Test Type: In vitr Result: negative Test Type: Mami cytogenetic assa Species: Mouse Application Rout	ro mammalian cell gene mutation test malian erythrocyte micronucleus test (in vivo y)
Not cl <u>Comp</u> Cellu Geno Geno	lassified based on av		Test Type: Bacte Result: negative Test Type: In vitr 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 y)
Not cl <u>Comp</u> Cellu Geno Geno	lassified based on av <u>ponents:</u> lose: toxicity in vitro toxicity in vivo		Test Type: Bacte Result: negative Test Type: In vitr Result: negative Test Type: Mami cytogenetic assa Species: Mouse Application Rout Result: negative Test Type: Bacte Result: negative Test Type: In vitr	ro mammalian cell gene mutation test malian erythrocyte micronucleus test (in vivo y) e: Ingestion



rsion	Revision Date: 2021/04/09		S Number: 74876-00005	Date of last issue: 2020/10/10 Date of first issue: 2019/07/08
			Test Type: Alkal Test system: rat Result: negative	
Geno	toxicity in vivo	:	Test Type: Chro Species: Mouse Cell type: Bone Application Rout Result: negative	marrow ie: Oral
Lorat	adine:			
Geno	toxicity in vitro	:	Test Type: Bactor Result: negative	erial reverse mutation assay (AMES)
			Test Type: In vit Result: negative	ro mammalian cell gene mutation test
			Test Type: Chro Result: negative	mosome aberration test in vitro
				damage and repair, unscheduled DNA syn- alian cells (in vitro)
Geno	toxicity in vivo	:	Test Type: Micro Species: Mouse Cell type: Bone Application Rout Result: negative	marrow e: Oral
	cell mutagenicity -	:	Weight of evider cell mutagen.	nce does not support classification as a gern
Not cl	nogenicity assified based on ava ponents:	ailable	information.	
Cellu			<b>D</b> (	
	cation Route sure time		Rat Ingestion 72 weeks negative	
Monte	elukast:			
	cation Route sure time	:	Rat Oral 2 Years negative	



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Expos	ure time	: 92 weeks	
Result		: negative	
Lorata	adine:		
Specie	es	: Rat	
Applic	ation Route	: Oral	
Expos	ure time	: 2 Years	
LOAEI	L	: 10 mg/kg body weight	
Result		: positive	
Specie		: Monkey	
	ation Route	: Oral	
	ure time	: 17 Months	
NOAE		: 40 mg/kg body weight	
Result		: negative	
Repro	ductive toxicity		
Suspe	cted of damaging fert	ity.	
<u>Comp</u>	onents:		
Cellul			
Effects	s on fertility	: Test Type: One-genera Species: Rat Application Route: Inge Result: negative	ation reproduction toxicity study
Effects	s on foetal develop-		y embryonic development
ment		Species: Rat	
		Application Route: Inge	estion
		Result: negative	
Monte	lukast:		
Effects	s on fertility	: Test Type: Fertility	
		Species: Rat, male	
		Application Route: Oral	
		Fertility: NOAEL: 800 m	
		Result: Animal testing o	did not show any effects on fertility.
		Test Type: Fertility	
		Species: Rat, female	
		Application Route: Oral	
		Fertility: LOAEL: 200 m	
		Symptoms: Reduced fe	ertility
		Test Type: Fertility	
		Species: Rat, female	
		Application Route: Oral	
		Fertility: NOAEL: 100 m Symptoms: Reduced fe	

### Loratadine:



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Effect	ts on fertility	<ul> <li>Species: Rat, male Application Route: Oral Fertility: LOAEL: 64 mg/kg body weight Result: Effects on fertility</li> </ul>
Effect ment	ts on foetal develop-	<ul> <li>Species: Rat Application Route: Oral Developmental Toxicity: LOAEL: 48 mg/kg body weight Result: Embryo-foetal toxicity</li> </ul>
		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
Repro sessr	oductive toxicity - As- nent	: Some evidence of adverse effects on sexual function an fertility, based on animal experiments.
STO	lassified based on avai Γ <b>- repeated exposure</b> lassified based on avai	
Repe	ated dose toxicity	
<u>Com</u>	ponents:	
	ies	: Rat : >= 9,000 mg/kg : Ingestion : 90 Days
Mont	elukast:	
	EL cation Route sure time	<ul> <li>Monkey, male and female</li> <li>150 - 300 mg/kg</li> <li>Oral</li> <li>53 Weeks</li> <li>No significant adverse effects were reported</li> </ul>
	EL cation Route sure time	<ul> <li>Rat</li> <li>50 mg/kg</li> <li>Oral</li> <li>53 Weeks</li> <li>No significant adverse effects were reported</li> </ul>
Speci NOAI		: Mouse : 50 mg/kg



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Expos	sure time	: 14 Weeks	
Rema		: No significant	adverse effects were reported
Lorat	adine:		
Speci	es	: Rat	
NOAE		: 4 mg/kg	
LOAE		: 8 mg/kg	
	cation Route	: Oral	
	sure time et Organs	: 180 Days : Central nervo	ue evetom
Rema			limited toxicological significance.
Speci	es	: Monkey	
NOAE		: 0.4 mg/kg	
LOAE		: 4 mg/kg	
	cation Route	: Oral	
	sure time et Organs	: 180 Days : Central nervo	ue system
Rema			limited toxicological significance.
Not cl Expe Com	ation toxicity lassified based on av rience with human e ponents:		
Not cl Expe Comp Mont Skin c	lassified based on av rience with human e ponents: elukast: contact contact	: Remarks: Ma : Symptoms: S	y irritate skin. evere irritation pper respiratory tract infection, pharyngitis,
Not cl Expe Comj Mont Skin c Eye c Inges	lassified based on av rience with human e ponents: elukast: contact contact tion	: Remarks: Ma : Symptoms: S : Symptoms: u	evere irritation
Not cl Expe Comp Monte Skin c Eye c Inges	lassified based on av rience with human e ponents: elukast: contact contact tion	Exposure : Remarks: Ma : Symptoms: S : Symptoms: u Headache, C	evere irritation pper respiratory tract infection, pharyngitis, ough, Abdominal pain, Diarrhoea, Fever
Not cl Expe Comp Mont Skin c Eye c Inges Lorat Inges	lassified based on av rience with human e ponents: elukast: contact contact tion adine: tion	Exposure Remarks: Ma Symptoms: S Symptoms: u Headache, C Symptoms: F	evere irritation pper respiratory tract infection, pharyngitis,
Not cl Expe Comj Mont Skin c Eye c Inges Lorat Inges	lassified based on av rience with human of ponents: elukast: contact contact tion adine: tion OGICAL INFORMAT	Exposure Remarks: Ma Symptoms: S Symptoms: u Headache, C Symptoms: F	evere irritation pper respiratory tract infection, pharyngitis, ough, Abdominal pain, Diarrhoea, Fever
Not cl Expe Comj Mont Skin c Eye c Inges Lorat Inges	lassified based on av rience with human of ponents: elukast: contact contact tion adine: tion OGICAL INFORMAT	Exposure Remarks: Ma Symptoms: S Symptoms: u Headache, C Symptoms: F	evere irritation pper respiratory tract infection, pharyngitis, ough, Abdominal pain, Diarrhoea, Fever
Not cl Expe Comj Mont Skin c Eye c Inges Lorat Inges . ECOL Ecoto	lassified based on av rience with human of ponents: elukast: contact contact tion adine: tion OGICAL INFORMAT oxicity ponents:	Exposure Remarks: Ma Symptoms: S Symptoms: u Headache, C Symptoms: F	evere irritation pper respiratory tract infection, pharyngitis, ough, Abdominal pain, Diarrhoea, Fever
Not cl Expe Comj Mont Skin c Eye c Inges Lorat Inges	lassified based on av rience with human of ponents: elukast: contact contact tion adine: tion OGICAL INFORMAT oxicity ponents:	Exposure Remarks: Ma Symptoms: S Symptoms: u Headache, C Symptoms: F	evere irritation pper respiratory tract infection, pharyngitis, ough, Abdominal pain, Diarrhoea, Fever
Not cl Expe Comp Mont Skin c Eye c Inges Lorat Inges . ECOL Ecoto Comp Cellu	lassified based on av rience with human of ponents: elukast: contact contact tion adine: tion OGICAL INFORMAT oxicity ponents:	<ul> <li>Remarks: Ma</li> <li>Symptoms: S</li> <li>Symptoms: u Headache, C</li> <li>Symptoms: F</li> </ul>	evere irritation pper respiratory tract infection, pharyngitis, ough, Abdominal pain, Diarrhoea, Fever atigue, Headache, dry mouth, Nausea s latipes (Japanese medaka)): > 100 mg/l
Not cl Expe Comp Mont Skin c Eye c Inges Lorat Inges . ECOL Ecoto Comp Cellu Toxic	lassified based on av rience with human of ponents: elukast: contact contact tion adine: tion OGICAL INFORMAT ponents: lose:	<ul> <li>Remarks: Ma</li> <li>Symptoms: S</li> <li>Symptoms: u Headache, C</li> <li>Symptoms: F</li> </ul>	evere irritation pper respiratory tract infection, pharyngitis, ough, Abdominal pain, Diarrhoea, Fever atigue, Headache, dry mouth, Nausea s latipes (Japanese medaka)): > 100 mg/l e: 48 h



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	Toxicity to daphnia and other aquatic invertebrates Toxicity to algae/aquatic plants Toxicity to fish (Chronic tox- icity)		:	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		
			:	mg/l Exposure time: 72 Method: OECD Te		
				mg/l Exposure time: 72 Method: OECD Te		
			:	Exposure time: 32 Method: OECD Te		
				mg/l Exposure time: 7	on variegatus (sheepshead minnow)): 0.0816 d city at the limit of solubility	
		v to daphnia and other invertebrates (Chron- ity)	:	Exposure time: 21	nagna (Water flea)): 0.23 mg/l d city at the limit of solubility	
	Toxicity	v to microorganisms	:	EC50: > 100 mg/l Exposure time: 3 Test Type: Respir Method: OECD Te Remarks: No toxic	ation inhibition	
	Lorata	dine:				
	Toxicity to fish		:	LC50 (Lepomis m Exposure time: 96 Method: OECD Te		
		v to daphnia and other invertebrates	:	EC50 (Daphnia m Exposure time: 48 Method: OECD Te		
	Toxicity plants	∕ 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	



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			Method: OECD	Test Guideline 201
		:	1	
icity) Toxicity icity)	/ to fish (Chronic tox-	:	Exposure time: 3	ales promelas (fathead minnow)): 0.084 mg/ 32 d Test Guideline 210
	/ to daphnia and other invertebrates (Chron- ity)	:	Exposure time: 2	magna (Water flea)): 0.078 mg/l 21 d Test Guideline 211
M-Fact toxicity	or (Chronic aquatic	:	1	
	/ / to microorganisms	:	EC50: > 1,000 n Exposure time: 3 Test Type: Resp Method: OECD	3 ĥ
Persis	tence and degradabili	ity		
Compo	onents:			
<b>Celluic</b> Biodeg	<b>ose:</b> radability	:	Result: Readily I	piodegradable.
Montel	ukast:			
Biodeg	radability	:	Result: not rapid Biodegradation: Exposure time: 2	0 %
Stabilit	y in water	:	Hydrolysis: 50 %	b(21.7 h)
Lorata	dine:			
Biodeg	radability	:	Result: not rapid Biodegradation: Exposure time: 2 Method: OECD	50 %
Stabilit	y in water	:	Degradation half	<sup>-</sup> life (DT50): 283 d
Bioaco	cumulative potential			
Compo	onents:			
<b>Monte</b> l Partitio octano	n coefficient: n-	:	log Pow: > 4.3	
<b>Lorata</b> Partitio	<b>dine:</b> n coefficient: n-	:	log Pow: 2.35	



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Mobil	lity in soil						
Com	oonents:						
Distrik	adine: bution among environ- al compartments	: log Koc: 5.25 Method: OECE	: log Koc: 5.25 Method: OECD Test Guideline 106				
	r <b>adverse effects</b> ata available						
13. DISPO	SAL CONSIDERATION	IS					
Waste	osal methods e from residues aminated packaging	: Empty containe dling site for re	ccordance with local regulations. ers should be taken to an approved waste han- cycling or disposal. e specified: Dispose of as unused product.				
14. TRAN	SPORT INFORMATION						
Interr	national Regulations						
<b>UNR</b> T UN nu	_	: UN 3077 : ENVIRONMEN N.O.S. (Loratadine)	ITALLY HAZARDOUS SUBSTANCE, SOLID,				
Class Packi Label	ng group	: 9 : III : 9					
<b>IATA</b> UN/IE Prope		: UN 3077 : Environmentall (Loratadine)	y hazardous substance, solid, n.o.s.				
Label	ng group s ng instruction (cargo	: 9 : III : Miscellaneous : 956					
ger ai	ng instruction (passen- ircraft) onmentally hazardous	: 956					
<b>IMDG</b> UN ni	<b>G-Code</b> umber er shipping name	N.O.S.	ITALLY HAZARDOUS SUBSTANCE, SOLID,				
Label EmS	ng group s	(Loratadine) : 9 : III : 9 : F-A, S-F : yes					



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#### 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.

#### **15. REGULATORY INFORMATION**

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

: Not applicable

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health

Hazardous substances that must be registered

#### Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances

Hazardous substances approved for use	:	Not applicable
Prohibited substances	:	Not applicable
Restricted substances	:	Not applicable

# Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials

Type of Hazardous Materials Restricted to Import,	:	Not applicable
Distribution and Supervision		

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

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

#### **16. OTHER INFORMATION**

#### Further information

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



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Date fo	rmat	:	yyyy/mm/dd	
Full tex	kt of other abbreviation	ons		
ACGIH ID OEL		:	USA. ACGIH Threshold Limit Values (TLV) Indonesia. Occupational Exposure Limits	
ACGIH ID OEL		:	8-hour, time-weigl Long term exposu	

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 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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