



Vers 3.10		Revision Date: 06.04.2024		S Number: 3956-00016	Date of last issue: 30.09.2023 Date of first issue: 18.04.2017
SEC	TION 1 Produc	: IDENTIFICATION t name	:	Ezetimibe Granu	les Formulation
	Manufa	acturer or supplier's d	letai	ls	
	Compa		:	Organon & Co.	
	Addres	S	:	30 Hudson Stree Jersey City, New	t, 33nd floor Jersey, U.S.A 07302
	Telepho	one	:	+1-551-430-6000	)
	Emerge	ency telephone number	· :	+1-215-631-6999	)
	E-mail	address	:	EHSSTEWARD	⊉organon.com
	Recom	mended use of the ch mended use tions on use		<b>cal and restrictic</b> Pharmaceutical Not applicable	ons on use

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

#### **GHS Classification**

Not a hazardous substance or mixture.

#### **GHS** label elements

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required

#### Other hazards which do not result in classification

Dust contact with the eyes can lead to mechanical irritation. May form explosive dust-air mixture during processing, handling or other means.

#### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)
Cellulose	9004-34-6	>= 10 -< 30
Ezetimibe	163222-33-1	< 10
Sodium n-dodecyl sulfate	151-21-3	>= 1 -< 3

### **SECTION 4. FIRST AID MEASURES**

General advice

: In the case of accident or if you feel unwell, seek medical advice immediately.



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		When sympton advice.	ns persist or in all cases of doubt seek medical
lf inha	aled	: If inhaled, remo	ove to fresh air. tention if symptoms occur.
In cas	se of skin contact	: In case of cont Remove conta Get medical at Wash clothing	act, immediately flush skin with plenty of water minated clothing and shoes. tention.
In cas	se of eye contact	: If in eyes, rinse Get medical at	e well with water. tention if irritation develops and persists.
lf swa	llowed	: If swallowed, D Get medical at	O NOT induce vomiting. tention if symptoms occur. toroughly with water.
	important symptoms ffects, both acute and ed		ith the eyes can lead to mechanical irritation.
Prote	ction of first-aiders	and use the re- when the poter	nders should pay attention to self-protection, commended personal protective equipment ntial for exposure exists (see section 8).
Notes	to physician	: Treat symptom	atically and supportively.

#### ECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire- fighting	:	Exposure to combustion products may be a hazard to health.
Hazardous combustion prod- ucts	:	Carbon oxides Nitrogen oxides (NOx) Fluorine compounds Metal oxides Sulphur oxides
Specific extinguishing meth- ods	:	Use extinguishing measures that are appropriate to local cir- cumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for firefighters Hazchem Code	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment. 2Z

### SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- :	Use personal protective equipment.
tive equipment and emer-	Follow safe handling advice (see section 7) and personal pro-
gency procedures	tective equipment recommendations (see section 8).



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Environmental precautions		:	: Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.			
	Methods and materials for containment 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 posal of this mate employed in the c mine which regula Sections 13 and 1	dust in the air (i.e., clearing dust surfaces		

### SECTION 7. HANDLING AND STORAGE

Technical measures	<ul> <li>Static electricity may accumulate and ignite suspended dust causing an explosion.</li> <li>Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.</li> </ul>
Local/Total ventilation Advice on safe handling	<ul> <li>Use only with adequate ventilation.</li> <li>Do not get on skin or clothing.</li> <li>Do not breathe dust.</li> <li>Do not swallow.</li> <li>Avoid contact with eyes.</li> <li>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment</li> </ul>
Hygiene measures	<ul> <li>Minimize dust generation and accumulation.</li> <li>Keep container closed when not in use.</li> <li>Keep away from heat and sources of ignition.</li> <li>Take precautionary measures against static discharges.</li> <li>Take care to prevent spills, waste and minimize release to the environment.</li> <li>If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.</li> </ul>
Conditions for safe storage Materials to avoid	<ul> <li>When using do not eat, drink or smoke.</li> <li>Wash contaminated clothing before re-use.</li> <li>Keep in properly labelled containers.</li> <li>Store in accordance with the particular national regulations.</li> <li>Do not store with the following product types: Strong oxidizing agents</li> </ul>



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### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis		
Cellulose	9004-34-6	TWA	10 mg/m3	AU OEL		
Celidiose	3004-34-0	TWA	10 mg/m3	ACGIH		
Ezetimibe	163222-33-1		25 µg/m3 (OEB 3)	Internal		
LZeumbe	103222-33-1	Wipe limit	250 µg/100 cm <sup>2</sup>	Internal		
Engineering measures	Minimize wo Apply meas Ensure that dust collecto signed in a r	Ensure adequate ventilation, especially in confined areas. Minimize workplace exposure concentrations. Apply measures to prevent dust explosions. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are de- signed in a manner to prevent the escape of dust into the				
Personal protective equip	· ·	.e., there is no le	akage from the equipn	nent).		
Respiratory protection Filter type Hand protection	sure assess ommended	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-re	Chemical-resistant gloves				
Remarks	on the conc stance and determined applications chemicals o glove manuf end of work	: Choose gloves to protect hands against chemicals depen on the concentration and quantity of the hazardous sub- stance and specific to place of work. Breakthrough time is determined for the product. Change gloves often! For spe applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.				
Eye protection		Wear the following personal protective equipment: Safety goggles				
<b>.</b>	Skin and body protection : Skin should be washed after contact.					

#### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: granular
Colour	: white
Odour	: No data available
Odour Threshold	: No data available
рН	: No data available





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	Melting	point/freezing point	:	No data available	
	Initial be range	oiling point and boiling	:	No data available	3
	Flash p	oint	:	Not applicable	
	Evapora	ation rate	:	No data available	)
	Flamma	ability (solid, gas)	:	May form explosi dling or other me	ve dust-air mixture during processing, han- ans.
	Flamma	ability (liquids)	:	No data available	)
		explosion limit / Upper bility limit	:	No data available	
		explosion limit / Lower bility limit	:	No data available	
	Vapour	pressure	:	No data available	)
	Relative	e vapour density	:	No data available	9
	Density	,	:	No data available	)
	Solubili Wat	ty(ies) er solubility	:	No data available	)
		n coefficient: n-	:	No data available	)
	octanol Auto-ig	nition temperature	:	No data available	
	Decom	position temperature	:	No data available	
	Viscosi Visc	ty :osity, kinematic	:	No data available	)
	Explosi	ve properties	:	Not explosive	
	Oxidizir	ng properties	:	The substance o	r mixture is not classified as oxidizing.
	Molecu	lar weight	:	No data available	)
	Particle Particle	e characteristics size	:	No data available	

### SECTION 10. STABILITY AND REACTIVITY





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	tivity nical stability ibility of hazardous reac-	:	Stable under no May form explose dling or other me	sive dust-air mixture during processing, han-
Cond	litions to avoid	:	Heat, flames an Avoid dust form	
	npatible materials Irdous decomposition ucts	:	Oxidizing agents	
SECTION	11. TOXICOLOGICAL I	NFO	ORMATION	
Ехро	sure routes	:	Inhalation Skin contact Ingestion Eye contact	
	<b>e toxicity</b> classified based on availa	ble	information.	
	<u>Product:</u> Acute oral toxicity <u>Components:</u>		Acute toxicity est Method: Calculat	timate: > 2,000 mg/kg tion method
<u>Com</u>				
Cellu	llose:			
Acute	e oral toxicity	:	LD50 (Rat): > 5,0	000 mg/kg
Acute	e inhalation toxicity	:	LC50 (Rat): > 5.8 Exposure time: 4 Test atmosphere	h
Acute	e dermal toxicity	:	LD50 (Rabbit): >	2,000 mg/kg
Ezeti	mibe:			
Acute	e oral toxicity	:	LD50 (Rat): > 5,0	000 mg/kg
			LD50 (Mouse): >	5,000 mg/kg
			LD50 (Dog): > 3,	000 mg/kg
Acute	e inhalation toxicity	:	Remarks: No dat	ta available
Acute	e dermal toxicity	:	Remarks: No dat	ta available
	e toxicity (other routes of nistration)	:	LD50 (Rat): > 2,0 Application Route	000 mg/kg e: Intraperitoneal
			LD50 (Mouse): >	1,000 - < 2,000 mg/kg



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### **Ezetimibe Granules Formulation**

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			Application Route	e: Intraperitoneal
5/	dium n-dodocyl sulfato:			
	odium n-dodecyl sulfate: cute oral toxicity		LD50 (Rat): 1,200	) ma/ka
		•	Method: OECD T	
Ad	cute dermal toxicity	:		00 mg/kg est Guideline 402 on data from similar materials
SI	kin corrosion/irritation			
-	ot classified based on availa	able	information.	
<u>C</u>	omponents:			
Ez	etimibe:			
	becies	:	Rabbit	
R	esult	-	No skin irritation	
So	odium n-dodecyl sulfate:			
	oecies esult	÷	Rabbit Skin irritation	
	-5011	•	Skin initation	
	erious eye damage/eye irri			
	ot classified based on availa	able	information.	
<u>C</u>	omponents:			
	etimibe:		Data	
	becies esult	:	Rabbit No eye irritation	
	odium n-dodecyl sulfate:		<b>D</b> 11 %	
	becies esult	:	Rabbit Irreversible effect	s on the eve
	ethod	:	OECD Test Guide	
Re	espiratory or skin sensitis	atio	on	
-	kin sensitisation			
	ot classified based on availa	able	information.	
	espiratory sensitisation ot classified based on availa	hle	information	
	omponents:		mornation.	
	etimibe:			
C4				

### Test Ty Specie

libe.		
уре	:	Maximisation Test
es	:	Guinea pig





ersion .10	Revision Date: 06.04.2024		S Number: 63956-00016	Date of last issue: 30.09.2023 Date of first issue: 18.04.2017
Result		:	negative	
Sodiu	m n-dodecyl sulfate:			
Test T Expos Specie Result Remai	ure routes es	:	Maximisation Te Skin contact Guinea pig negative Based on data fi	rom similar materials
Chron	ic toxicity			
Germ	cell mutagenicity			
	assified based on avail onents:	lable	information.	
Cellul				
	oxicity in vitro	:	Test Type: Bacte Result: negative	erial reverse mutation assay (AMES)
			Test Type: In vit Result: negative	ro mammalian cell gene mutation test
Genot	oxicity in vivo	:	Test Type: Mam cytogenetic assa Species: Mouse Application Rout Result: negative	te: Ingestion
Ezetin	nibe:			
Genote	oxicity in vitro	:		erial reverse mutation assay (AMES) tion: with and without metabolic activation
				mosomal aberration man lymphocytes
Genot	oxicity in vivo	:	Test Type: Micro Species: Mouse Cell type: Bone Application Rout Result: negative	marrow te: Oral
Sodiu	m n-dodecyl sulfate:			
	oxicity in vitro	:		erial reverse mutation assay (AMES) Test Guideline 471
				ro mammalian cell gene mutation test



ersion 10	Revision Date: 06.04.2024	SDS Number:Date of last issue: 30.09.20231563956-00016Date of first issue: 18.04.2017	
		Result: negative	
Geno	otoxicity in vivo	: Test Type: Rodent dominant lethal test (germ cell) (in Species: Mouse Application Route: Ingestion Result: negative	vivo)
	inogenicity lassified based on ava	ilable information	
	ponents:		
Cellu Spec	l <b>lose:</b>	: Rat	
	cation Route	: Ingestion	
	sure time	: 72 weeks	
Resu	It	: negative	
Ezeti	mibe:		
Spec		: Rat, female	
	cation Route sure time	: oral (feed) : 104 weeks	
Resu		: negative	
Spec		: Rat, male	
	cation Route sure time	: oral (feed) : 104 weeks	
Resu		: negative	
Spec	ies	: Mouse	
	cation Route	: oral (feed)	
Expo Resu	sure time It	: 104 weeks : negative	
Sodi	um n-dodecyl sulfate		
Spec	-	: : Rat	
Appli	cation Route	: Ingestion	
Expo Meth	sure time	: 2 Years : OECD Test Guideline 453	
Resu		: negative	
Rema	arks	: Based on data from similar materials	
Repr	oductive toxicity		
-	lassified based on ava	ilable information.	
<u>Com</u>	ponents:		
Cellu	lose:		
Effec	ts on fertility	: Test Type: One-generation reproduction toxicity study Species: Rat	
Effec	ts on fertility		



ersion 10	Revision Date: 06.04.2024	-	S Number: 63956-00016	Date of last issue: 30.09.2023 Date of first issue: 18.04.2017
			Application Rout Result: negative	
Effect ment	s on foetal develop-	:	Test Type: Fertil Species: Rat Application Rout Result: negative	ity/early embryonic development e: Ingestion
Ezetir	nibe:			
Effect	s on fertility	:	Species: Rat, m Fertility: NOAEL	ity/early embryonic development ale and female : > 1,000 mg/kg body weight ts on fertility, No fetotoxicity
Effect ment	s on foetal develop-	:	Test Type: Deve Species: Rat Application Rout Developmental Result: No adve	e: Oral Foxicity: NOAEL: > 1,000 mg/kg body weigł
			Test Type: Deve Species: Rabbit Application Rout Developmental Result: No adve	e: Oral Foxicity: NOAEL: > 1,000 mg/kg body weigł
Sodiu	Im n-dodecyl sulfate:			
Effect	s on fertility	:	Species: Rat Application Rout Method: OECD Result: negative	Test Guideline 416
Effect ment	s on foetal develop-	:	Species: Rat Application Rout Result: negative	

### STOT - single exposure

Not classified based on available information.

### STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity

### **Components:**

Cellulose:



### **Ezetimibe Granules Formulation**

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Spec NOA	EL	:	Rat >= 9,000 mg/kg	
	cation Route sure time	:	Ingestion 90 Days	
Spec NOA Appli	EL cation Route sure time	: : : : : : : : : : : : : : : : : : : :	Dog 1,000 mg/kg Oral 90 d No significant ac	dverse effects were reported
	EL cation Route sure time	:	Rat 1,500 mg/kg Oral 90 d No significant ac	dverse effects were reported
	EL cation Route sure time	:	Mouse 500 mg/kg Oral 90 d No significant ac	dverse effects were reported
	EL cation Route sure time	:	Dog 300 mg/kg Oral 1 yr No significant ac	dverse effects were reported
	um n-dodecyl sulfate	:		
	EL cation Route sure time	:	Rat 488 mg/kg Ingestion 90 Days Based on data fr	rom similar materials
-	ration toxicity lassified based on ava	ailable	information.	
•				

Ezetimibe:

Components:

Not applicable

### Experience with human exposure

### Components:

Ezetimibe:



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Inges	tion	:		idache, Nausea, Vomiting, Diarrhoea, flatu- ain, upper respiratory tract infection, Back
ECTION	12. ECOLOGICAL INFO	ORN	IATION	
Ecoto	oxicity			
Com	ponents:			
<b>Cellu</b> Toxic	<b>lose:</b> ity to fish	:	LC50 (Orvzias I	atipes (Japanese medaka)): > 100 mg/l
	,		Exposure time:	
Ezeti	mibe:			
Toxic	ity to fish	:	Exposure time: Method: OECD	les promelas (fathead minnow)): > 0.125 m 96 h Test Guideline 203 xicity at the limit of solubility
	ity to daphnia and other tic invertebrates	:	Exposure time: Method: OECD	magna (Water flea)): > 4 mg/l 48 h Test Guideline 202 xicity at the limit of solubility
Toxic plants	ity to algae/aquatic	:	0.317 mg/l Exposure time: Method: OECD	irchneriella subcapitata (green algae)): > 96 h Test Guideline 201 xicity at the limit of solubility
			mg/l Exposure time: Method: OECD	kirchneriella subcapitata (green algae)): 0.3 96 h Test Guideline 201 xicity at the limit of solubility
Toxic icity)	ity to fish (Chronic tox-	:	Exposure time:	ales promelas (fathead minnow)): 0.051 mg 33 d Test Guideline 210
			Exposure time:	don variegatus (sheepshead minnow)): 4 m 7 d xicity at the limit of solubility
	ity to daphnia and other tic invertebrates (Chron- icity)	:	Exposure time:	a magna (Water flea)): 0.282 mg/l 21 d xicity at the limit of solubility
Toxic	ity to microorganisms	:	EC50: > 4.4 mg	/I



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	<b>m n-dodecyl sulfate:</b> y to fish	:	LC50 (Pimephale Exposure time: 9	es promelas (fathead minnow)): 29 mg/l 6 h
	y to daphnia and other c invertebrates	:	EC50 (Ceriodaph Exposure time: 4	nnia dubia (water flea)): 5.55 mg/l 8 h
Toxicit plants	y to algae/aquatic	:	ErC50 (Desmode Exposure time: 7	esmus subspicatus (green algae)): > 120 mg 2 h
			NOEC (Desmode Exposure time: 7	esmus subspicatus (green algae)): 30 mg/l 2 h
Toxicit icity)	y to fish (Chronic tox-	:	NOEC (Pimephal mg/l Exposure time: 4	les promelas (fathead minnow)): >= 1.357 2 d
aquatio	y to daphnia and other c invertebrates (Chron-	:	NOEC (Ceriodap Exposure time: 7	hnia dubia (water flea)): 0.88 mg/l d
ic toxic Toxicit	ity) y to microorganisms	:	EC50: 135 mg/l Exposure time: 3	h
Persis	tence and degradabili	ity		
Comp	onents:			
<b>Cellul</b> Biodeg	<b>ose:</b> gradability	:	Result: Readily b	iodegradable.
<b>Ezetim</b> Biodeg	<b>nibe:</b> gradability	:	Result: Not readi Biodegradation: Exposure time: 2	6.8 %
Stabilit	y in water	:	Hydrolysis: 50 % Method: OECD T	(4.5 d) Test Guideline 111

Sodium n-dodecyl sulfate:





	Biodegradation: 95 % Exposure time: 28 d Method: OECD Test Guideline 301B Species: Lepomis macrochirus (Bluegill sunfish) Bioconcentration factor (BCF): 173 Exposure time: 97 d Method: OECD Test Guideline 305 log Pow: 4.36 log Pow: 0.83 log Pow: 0.83 Method: OECD Test Guideline 106 <b>EXTIONS</b> Do not dispose of waste into sewer. Dispose of in accordance with local regulations. Empty containers should be taken to an approved waste han dling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.	Biodegradation: 95 %         Exposure time: 28 d         Method: OECD Test Guideline 301B         Bioaccumulative potential         Components:         Ezetimibe:         Bioaccumulation       : Species: Lepomis macrochirus (Bluegill sunfish) Bioconcentration factor (BCF): 173 Exposure time: 97 d Method: OECD Test Guideline 305         Partition coefficient: n- octanol/water       : log Pow: 4.36         Sodium n-dodecyl sulfate:       : Partition coefficient: n- octanol/water         Mobility in soil       : Components:         Ezetimibe:       : Distribution among environ- mental compartments         Distribution among environ- mental compartments       : log Koc: 4.35 Method: OECD Test Guideline 106         Other adverse effects No data available       : Do not dispose of waste into sewer. Dispose of in accordance with local regulations. Contaminated packaging	ersion 10	Revision Date: 06.04.2024	-	0S Number: 63956-00016	Date of last issue: 30.09.2023 Date of first issue: 18.04.2017
Biodegradation: 95 % Exposure time: 28 d Method: OECD Test Guideline 301B         Bioaccumulative potential         Components:         Ezetimibe:         Bioaccumulation       : Species: Lepomis macrochirus (Bluegill sunfish) Bioconcentration factor (BCF): 173 Exposure time: 97 d Method: OECD Test Guideline 305         Partition coefficient: n- octanol/water       : log Pow: 4.36         Sodium n-dodecyl sulfate:         Partition coefficient: n- octanol/water       : log Pow: 0.83         Components:         Ezetimibe:         Distribution among environ- mental compartments       : log Koc: 4.35 Method: OECD Test Guideline 106         Other adverse effects No data available       : log Koc: 4.35 Method: OECD Test Guideline 106         ETION 13. DISPOSAL CONSIDERATIONS       Disposal methods         Waste from residues       : Do not dispose of waste into sewer. Dispose of in accordance with local regulations. Contaminated packaging	Biodegradation: 95 % Exposure time: 28 d Method: OECD Test Guideline 301B Species: Lepomis macrochirus (Bluegill sunfish) Bioconcentration factor (BCF): 173 Exposure time: 97 d Method: OECD Test Guideline 305 log Pow: 4.36 log Pow: 0.83 log Pow: 0.83 Method: OECD Test Guideline 106 <b>EXTIONS</b> Do not dispose of waste into sewer. Dispose of in accordance with local regulations. Empty containers should be taken to an approved waste har dling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.	Biodegradation: 95 %         Exposure time: 28 d         Method: OECD Test Guideline 301B         Bioaccumulative potential         Components:         Ezetimibe:         Bioaccumulation       : Species: Lepomis macrochirus (Bluegill sunfish) Bioconcentration factor (BCF): 173 Exposure time: 97 d Method: OECD Test Guideline 305         Partition coefficient: n- octanol/water       : log Pow: 4.36         Sodium n-dodecyl sulfate:         Partition coefficient: n- octanol/water       : log Pow: 0.83         Mobility in soil       Components:         Ezetimibe:       Distribution among environ- mental compartments       : log Koc: 4.35 Method: OECD Test Guideline 106         Other adverse effects No data available       ECTION 13. DISPOSAL CONSIDERATIONS         Disposal methods       : Do not dispose of waste into sewer. Dispose of in accordance with local regulations. Contaminated packaging         Waste from residues       : Do not dispose of as unused product.					
Biodegradation: 95 % Exposure time: 28 d Method: OECD Test Guideline 301B         Bioaccumulative potential         Components:         Ezetimibe:         Bioaccumulation       : Species: Lepomis macrochirus (Bluegill sunfish) Bioconcentration factor (BCF): 173 Exposure time: 97 d Method: OECD Test Guideline 305         Partition coefficient: n- octanol/water       : log Pow: 4.36         Sodium n-dodecyl sulfate:         Partition coefficient: n- octanol/water       : log Pow: 0.83         Mobility in soil         Components:         Ezetimibe:         Distribution among environ- mental compartments       : log Koc: 4.35 Method: OECD Test Guideline 106         Other adverse effects No data available       : Method: OECD Test Guideline 106         Cottor adverse effects       : Do not dispose of waste into sewer. Dispose of in accordance with local regulations. Contaminated packaging	Biodegradation: 95 % Exposure time: 28 d Method: OECD Test Guideline 301B Species: Lepomis macrochirus (Bluegill sunfish) Bioconcentration factor (BCF): 173 Exposure time: 97 d Method: OECD Test Guideline 305 log Pow: 4.36 log Pow: 0.83 log Pow: 0.83 Method: OECD Test Guideline 106 <b>EXTIONS</b> Do not dispose of waste into sewer. Dispose of in accordance with local regulations. Empty containers should be taken to an approved waste har dling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.	Biodegradation: 95 %         Exposure time: 28 d         Method: OECD Test Guideline 301B         Bioaccumulative potential         Components:         Ezetimibe:         Bioaccumulation       : Species: Lepomis macrochirus (Bluegill sunfish) Bioconcentration factor (BCF): 173 Exposure time: 97 d Method: OECD Test Guideline 305         Partition coefficient: n- octanol/water       : log Pow: 4.36         Sodium n-dodecyl sulfate:         Partition coefficient: n- octanol/water       : log Pow: 0.83         Mobility in soil       Components:         Ezetimibe:       : Distribution among environ- mental compartments       : log Koc: 4.35 Method: OECD Test Guideline 106         Other adverse effects No data available       : Do not dispose of waste into sewer. Dispose of in accordance with local regulations. Contaminated packaging       : Do not dispose of waste into sewer. Dispose of a sunused product. If not otherwise specified: Dispose of as unused product.	Biode	egradability		Result: Readily	biodegradable
Method: OECD Test Guideline 301B         Bioaccumulative potential         Components:         Ezetimibe:         Bioaccumulation       : Species: Lepomis macrochirus (Bluegill sunfish) Bioconcentration factor (BCF): 173 Exposure time: 97 d Method: OECD Test Guideline 305         Partition coefficient: n- octanol/water       : log Pow: 4.36         Sodium n-dodecyl sulfate:       : Partition coefficient: n- octanol/water         Partition coefficient: n- octanol/water       : log Pow: 0.83         Mobility in soil       : Components:         Ezetimibe:       : Distribution among environ- mental compartments         Distribution among environ- mental compartments       : log Koc: 4.35 Method: OECD Test Guideline 106         Other adverse effects No data available       : Do not dispose of waste into sewer. Disposed in accordance with local regulations. Contaminated packaging	Method: OECD Test Guideline 301B Species: Lepomis macrochirus (Bluegill sunfish) Bioconcentration factor (BCF): 173 Exposure time: 97 d Method: OECD Test Guideline 305 log Pow: 4.36 log Pow: 0.83 log Koc: 4.35 Method: OECD Test Guideline 106 RATIONS Do not dispose of waste into sewer. Dispose of in accordance with local regulations. Empty containers should be taken to an approved waste har dling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.	Method: OECD Test Guideline 301B         Bioaccumulative potential         Components:         Ezetimibe:         Bioaccumulation       : Species: Lepomis macrochirus (Bluegill sunfish) Bioconcentration factor (BCF): 173 Exposure time: 97 d Method: OECD Test Guideline 305         Partition coefficient: n- octanol/water       : log Pow: 4.36         Sodium n-dodecyl sulfate:       : Partition coefficient: n- octanol/water         Mobility in soil       : Components:         Ezetimibe:       : Distribution among environ- mental compartments         Other adverse effects No data available       : Do not dispose of waste into sewer. Disposal methods         Waste from residues       : Do not dispose of in accordance with local regulations. Contaminated packaging         Contaminated packaging       : Empty containers should be taken to an approved waste ding site for recycling or dispose of a sunused product.	Diode	gradubility	•	Biodegradation:	95 %
Components:         Ezetimibe:         Bioaccumulation       : Species: Lepomis macrochirus (Bluegill sunfish) Bioconcentration factor (BCF): 173 Exposure time: 97 d Method: OECD Test Guideline 305         Partition coefficient: n- octanol/water       : log Pow: 4.36         Sodium n-dodecyl sulfate:       : Partition coefficient: n- octanol/water         Partition coefficient: n- octanol/water       : log Pow: 0.83         Mobility in soil       : Components:         Ezetimibe:       : Distribution among environ- mental compartments         Distribution among environ- mental compartments       : log Koc: 4.35 Method: OECD Test Guideline 106         Other adverse effects No data available       : Do not dispose of waste into sewer. Disposal methods         Waste from residues       : Do not dispose of waste into sewer. Dispose of in accordance with local regulations.         Contaminated packaging       : Empty containers should be taken to an approved waste	Bioconcentration factor (BCF): 173 Exposure time: 97 d Method: OECD Test Guideline 305 log Pow: 4.36 log Pow: 0.83 log Koc: 4.35 Method: OECD Test Guideline 106 <b>RATIONS</b> Do not dispose of waste into sewer. Dispose of in accordance with local regulations. Empty containers should be taken to an approved waste har dling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.	Components:       Ezetimibe:         Bioaccumulation       : Species: Lepomis macrochirus (Bluegill sunfish) Bioconcentration factor (BCF): 173 Exposure time: 97 d Method: OECD Test Guideline 305         Partition coefficient: n- octanol/water       : log Pow: 4.36         Sodium n-dodecyl sulfate:       : Partition coefficient: n- octanol/water         Partition coefficient: n- octanol/water       : log Pow: 0.83         Mobility in soil       : Components:         Ezetimibe:       : Distribution among environ- mental compartments       : log Koc: 4.35 Method: OECD Test Guideline 106         Other adverse effects No data available       : Do not dispose of waste into sewer. Disposel methods         Waste from residues       : Do not dispose of waste into sewer. Dispose of in accordance with local regulations.         Contaminated packaging       : Empty containers should be taken to an approved waste dling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.					
Ezetimibe:         Bioaccumulation       : Species: Lepomis macrochirus (Bluegill sunfish) Bioconcentration factor (BCF): 173 Exposure time: 97 d Method: OECD Test Guideline 305         Partition coefficient: n-       : log Pow: 4.36         octanol/water       Sodium n-dodecyl sulfate:         Partition coefficient: n-       : log Pow: 0.83         octanol/water       Mobility in soil         Components:       Ezetimibe:         Distribution among environ- mental compartments       : log Koc: 4.35 Method: OECD Test Guideline 106         Other adverse effects No data available       Method: OECD Test Guideline 106         Ezetinon t3. DISPOSAL CONSIDERATIONS       Disposal methods         Waste from residues       : Do not dispose of waste into sewer. Dispose of in accordance with local regulations.         Contaminated packaging       : Empty containers should be taken to an approved waste	Bioconcentration factor (BCF): 173 Exposure time: 97 d Method: OECD Test Guideline 305 log Pow: 4.36 log Pow: 0.83 log Koc: 4.35 Method: OECD Test Guideline 106 RATIONS Do not dispose of waste into sewer. Dispose of in accordance with local regulations. Empty containers should be taken to an approved waste har dling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.	Ezetimibe:         Bioaccumulation       :       Species: Lepomis macrochirus (Bluegill sunfish) Bioconcentration factor (BCF): 173 Exposure time: 97 d Method: OECD Test Guideline 305         Partition coefficient: n-       :       log Pow: 4.36         octanol/water       Sodium n-dodecyl sulfate:         Partition coefficient: n-       :       log Pow: 0.83         octanol/water       .       log Pow: 0.83         Mobility in soil       .       .         Components:       .       .         Ezetimibe:       .       .         Distribution among environ- mental compartments       :       log Koc: 4.35 Method: OECD Test Guideline 106         Other adverse effects No data available       .       .       .         EzetION 13. DISPOSAL CONSIDERATIONS       .       .         Disposal methods       .       .       .         Waste from residues       :       .       Do not dispose of waste into sewer. Dispose of in accordance with local regulations.         Contaminated packaging       :       Empty containers should be taken to an approved waste ding site for recycling or disposal. If not otherwise specified: Dispose of as unused product.	Bioad	ccumulative potential			
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octanol/water       Mobility in soil         Components:       Ezetimibe:         Distribution among environ- mental compartments       : log Koc: 4.35         Other adverse effects       Method: OECD Test Guideline 106         Other adverse effects       No data available         CCTION 13. DISPOSAL CONSIDERATIONS         Disposal methods         Waste from residues       : Do not dispose of waste into sewer. Dispose of in accordance with local regulations.         Contaminated packaging       : Empty containers should be taken to an approved waste	log Koc: 4.35 Method: OECD Test Guideline 106 RATIONS Do not dispose of waste into sewer. Dispose of in accordance with local regulations. Empty containers should be taken to an approved waste har dling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.	octanol/water       Very Containers should be taken to an approved waste dling site for recycling or disposal.         Mobility in soil       Components:         Ezetimibe:       Distribution among environments         Distribution among environments       : log Koc: 4.35         Method: OECD Test Guideline 106         Other adverse effects         No data available         CCTION 13. DISPOSAL CONSIDERATIONS	Sodiu	um n-dodecyl sulfate:			
Components:         Ezetimibe:         Distribution among environmental compartments       : log Koc: 4.35         Method: OECD Test Guideline 106         Other adverse effects         No data available         CTION 13. DISPOSAL CONSIDERATIONS         Disposal methods         Waste from residues       : Do not dispose of waste into sewer. Dispose of in accordance with local regulations.         Contaminated packaging       : Empty containers should be taken to an approved waste	Method: OECD Test Guideline 106 <b>RATIONS</b> Do not dispose of waste into sewer. Dispose of in accordance with local regulations. Empty containers should be taken to an approved waste har dling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.	Components:         Ezetimibe:         Distribution among environmental compartments         Method: OECD Test Guideline 106         Other adverse effects         No data available         CCTION 13. DISPOSAL CONSIDERATIONS         Disposal methods         Waste from residues       : Do not dispose of waste into sewer. Dispose of in accordance with local regulations.         Contaminated packaging       : Empty containers should be taken to an approved waste dling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.			:	log Pow: 0.83	
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Distribution among environmental compartments       : log Koc: 4.35         Method: OECD Test Guideline 106         Other adverse effects         No data available         ECTION 13. DISPOSAL CONSIDERATIONS         Disposal methods         Waste from residues       : Do not dispose of waste into sewer. Dispose of in accordance with local regulations.         Contaminated packaging       : Empty containers should be taken to an approved waste	Method: OECD Test Guideline 106 <b>RATIONS</b> Do not dispose of waste into sewer. Dispose of in accordance with local regulations. Empty containers should be taken to an approved waste har dling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.	Distribution among environmental compartments       : log Koc: 4.35         Method: OECD Test Guideline 106         Other adverse effects         No data available         ECTION 13. DISPOSAL CONSIDERATIONS         Disposal methods         Waste from residues       : Do not dispose of waste into sewer. Dispose of in accordance with local regulations.         Contaminated packaging       : Empty containers should be taken to an approved waste dling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.	<u>Com</u>	ponents:			
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CTION 13. DISPOSAL CONSIDERATIONS         Disposal methods         Waste from residues       : Do not dispose of waste into sewer. Dispose of in accordance with local regulations.         Contaminated packaging       : Empty containers should be taken to an approved waste	Do not dispose of waste into sewer. Dispose of in accordance with local regulations. Empty containers should be taken to an approved waste har dling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.	CTION 13. DISPOSAL CONSIDERATIONS         Disposal methods         Waste from residues       : Do not dispose of waste into sewer. Dispose of in accordance with local regulations.         Contaminated packaging       : Empty containers should be taken to an approved waste dling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.	Othe	r adverse effects			
Disposal methodsWaste from residues: Do not dispose of waste into sewer. Dispose of in accordance with local regulations.Contaminated packaging: Empty containers should be taken to an approved waste	Do not dispose of waste into sewer. Dispose of in accordance with local regulations. Empty containers should be taken to an approved waste har dling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.	Disposal methods         Waste from residues       : Do not dispose of waste into sewer. Dispose of in accordance with local regulations.         Contaminated packaging       : Empty containers should be taken to an approved waste dling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.	No da	ata available			
Waste from residues:Do not dispose of waste into sewer.Dispose of in accordance with local regulations.Contaminated packaging:Empty containers should be taken to an approved waste	Dispose of in accordance with local regulations. Empty containers should be taken to an approved waste har dling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.	<ul> <li>Waste from residues</li> <li>Contaminated packaging</li> <li>Do not dispose of waste into sewer. Dispose of in accordance with local regulations.</li> <li>Empty containers should be taken to an approved waste dling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.</li> </ul>		13. DISPOSAL CONSI	DER	ATIONS	
Waste from residues:Do not dispose of waste into sewer.Dispose of in accordance with local regulations.Contaminated packaging:Empty containers should be taken to an approved waste	Dispose of in accordance with local regulations. Empty containers should be taken to an approved waste har dling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.	<ul> <li>Waste from residues</li> <li>Contaminated packaging</li> <li>Do not dispose of waste into sewer. Dispose of in accordance with local regulations.</li> <li>Empty containers should be taken to an approved waste dling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.</li> </ul>					
Dispose of in accordance with local regulations. Contaminated packaging : Empty containers should be taken to an approved wa	Dispose of in accordance with local regulations. Empty containers should be taken to an approved waste har dling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.	Contaminated packaging Contaminated packaging Dispose of in accordance with local regulations. Empty containers should be taken to an approved waste dling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.	-				
Contaminated packaging : Empty containers should be taken to an approved wa	Empty containers should be taken to an approved waste har dling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.	Contaminated packaging : Empty containers should be taken to an approved waste dling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.	Waste	e from residues	:		
	If not otherwise specified: Dispose of as unused product.	dling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.	Conta	aminated packaging	:		
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IT NOT OTHERWISE SPECIFIED: DISPOSE OF AS UNUSED PROC	ΑΤΙΟΝ	ECTION 14. TRANSPORT INFORMATION				II NOT OTHERWISE	specified: Dispose of as unused product.





Version 3.10	Revision Date: 06.04.2024	SDS Number: 1563956-00016		Date of last issue: 30.09.2023 Date of first issue: 18.04.2017
Clas	S	:	9	
	king group	:		
Labe		:	9	
Envi	ronmentally hazardous	:	yes	
IATA	A-DGR			
	D No.	:	UN 3077	
Prop	er shipping name	:	Environmentally ł (Ezetimibe)	nazardous substance, solid, n.o.s.
Clas	S	:	9	
Pack	king group	:		
Labe		:	Miscellaneous	
Pack aircr	king instruction (cargo aft)	:	956	
	king instruction (passen-	:	956	
	ronmentally hazardous	:	yes	
IMD	G-Code			
	number	:	UN 3077	
-	er shipping name	:		ALLY HAZARDOUS SUBSTANCE, SOLID,
Clas	S	:	9	
Pack	king group	:		
Labe	els	:	9	
EmS	Code	:	F-A, S-F	
Mari	ne pollutant	:	yes	
Tran	sport in bulk according	n to		OI 73/78 and the IBC Code

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

Not applicable for product as supplied.

### National Regulations

ADG		
UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ezetimibe)
Class	:	9
Packing group	:	
Labels	:	9
Hazchem Code	:	2Z
Environmentally hazardous	:	yes

#### 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.



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#### SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mix- ture					
Therapeutic Goods (Poisons : Standard) Instrument	<b>`</b>	e the original publication to check for conditions or threshold limits that might			
Prohibition/Licensing Requireme	nts :	There is no applicable prohibition, authorisation and restricted use requirements, including for carcino- gens referred to in Schedule 10 of the model WHS Act and Regula- tions.			
The components of this product are reported in the following inventories:					
AICS :	not determined				
DSL :	not determined				

: not determined

#### **SECTION 16: ANY OTHER RELEVANT INFORMATION**

IECSC

Further information Revision Date Sources of key data used to compile the Safety Data Sheet	:	06.04.2024 Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen- cy, http://echa.europa.eu/			
Date format	:	dd.mm.yyyy			
Full text of other abbreviations					
ACGIH AU OEL	:	USA. ACGIH Threshold Limit Values (TLV) Australia. Workplace Exposure Standards for Airborne Con- taminants.			
ACGIH / TWA AU OEL / TWA	:	8-hour, time-weighted average Exposure standard - time weighted average			

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory con-



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centration; 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.

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