

Vers 3.3	sion	Revision Date: 09.04.2021	00	S Number: 37796-00009	Date of last issue: 10.10.2020 Date of first issue: 18.04.2017			
1. PRODUCT AND COMPANY IDE			ENT	IFICATION				
	Produc	t name	:	Ezetimibe Granu	Ezetimibe Granules Formulation			
	Manufa	acturer or supplier's d	etai	ls				
	Compa	ny	:	Organon & Co.				
	Addres	S	:	30 Hudson Stree Jersey City, New	t, 33nd floor Jersey, U.S.A 07302			
	Telepho	one	:	551-430-6000				
	Emerge	ency telephone number	:	215-631-6999				
	E-mail	address	:	EHSSTEWARD	@organon.com			
		mended use of the ch mended use		ical and restriction	ons on use			

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification Skin corrosion/irritation	:	Category 3
Long-term (chronic) aquatic hazard	:	Category 2
GHS label elements		
Hazard pictograms	:	¥_2
Signal word	:	Warning
Hazard statements	:	H316 Causes mild skin irritation. H411 Toxic to aquatic life with long lasting effects.
Precautionary statements	:	Prevention: P273 Avoid release to the environment.
		Response: P332 + P317 If skin irritation occurs: Get medical help. P391 Collect spillage.



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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. May form explosive dust-air mixture 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	>= 20 - < 30
Ezetimibe	163222-33-1	>= 5 - < 10
Sodium n-dodecyl sulfate	151-21-3	>= 1 - < 2.5

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.
In case of skin contact	:	Get medical attention if symptoms occur. In case of contact, immediately flush skin with 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 if symptoms occur. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	:	Causes mild skin irritation. 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		
Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	None known.



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Specific hazards during fire- fighting Hazardous combustion prod- ucts		:	Exposure to combustion products may be a hazard to healt Carbon oxides Nitrogen oxides (NOx) Fluorine compounds Sulphur oxides Metal oxides	
ods Spe	cific extinguishing meth- cial protective equipment irefighters	:	cumstances and Use water spray f Remove undama so. Evacuate area. In the event of fire	y measures that are appropriate to local cir- the surrounding environment. o cool unopened containers. ged containers from fire area if it is safe to do e, wear self-contained breathing apparatus. tective equipment.
	DENTAL RELEASE MEA	SUI		
tive	sonal precautions, protec- equipment and emer- cy procedures	:	Follow safe hand	tective equipment. ing advice (see section 7) and personal pro- recommendations (see section 8).
Env	ironmental precautions	:	Retain and dispose	akage or spillage if safe to do so. se of contaminated wash water. should be advised if significant spillages
	nods and materials for ainment and cleaning up	:	tainer for disposa Avoid dispersal o with compressed Dust deposits sho es, as these may leased into the at Local or national posal of this mate employed in the o mine which regula Sections 13 and	f 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 and bonding, or inert atmospheres.
Local/Total ventilation Advice on safe handling	:	Use only with adequate ventilation. Do not get on skin or clothing. Do not breathe dust. Do not swallow. Avoid contact with eyes.



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Cor	ditions for safe storage	practice, based sessment Minimize dust g Keep container Keep away from Take precaution Take care to pre environment.	dance with good industrial hygiene and safety on the results of the workplace exposure as- eneration and accumulation. closed when not in use. In heat and sources of ignition. hary measures against static discharges. event spills, waste and minimize release to the
Cor	iditions for safe storage		y labelled containers. ance with the particular national regulations.
Mat	erials to avoid		h the following product types:

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	ACGIH
Ezetimibe	163222-33-1	TWA	25 µg/m3 (OEB 3)	Internal
		Wipe limit	250 µg/100 cm ²	Internal

Engineering measures :	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 work area (i.e., there is no leakage from the equipment).
Personal protective equipmen	t
Respiratory protection :	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection.
Filter type : Hand protection	Particulates type
Material :	Chemical-resistant gloves
Remarks :	Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous sub- stance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special 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
Skin and body protection : Hygiene measures :	Skin should be washed after contact. If exposure to chemical is likely during typical use, provide eye



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			place. When using do no	and safety showers close to the working ot eat, drink or smoke. ed clothing before re-use.
9. PHYSIC	AL AND CHEMICAL PI	ROP	ERTIES	
Appea	arance	:	granular	
Colou	r	:	white	
Odou	r	:	No data available	9
Odou	r Threshold	:	No data available	9
pН		:	No data available	9
Meltin	g point/freezing point	:	No data available	9
Initial range	boiling point and boiling	:	No data available	9
Flash	point	:	Not applicable	
Evapo	pration rate	:	No data available	e
Flamn	nability (solid, gas)	:	May form explosi dling or other me	ive dust-air mixture during processing, han-
Flamr	nability (liquids)	:	No data available	9
	r explosion limit / Upper ability limit	:	No data available	2
	r explosion limit / Lower ability limit	:	No data available	9
Vapou	ur pressure	:	No data available	9
Relati	ve vapour density	:	No data available	9
Densi	ty	:	No data available	e
	ility(ies) ater solubility	:	No data available	e
	on coefficient: n-	:	No data available	e
	ol/water gnition temperature	:	No data available	e
Decor	mposition temperature	:	No data available	e
Viscos Vis	sity scosity, kinematic	:	No data available	9

SAFETY DATA SHEET



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Exp	osive properties	:	Not explosive				
Oxic	lizing properties	:	: The substance or mixture is not classified as oxidizing.				
Mole	ecular weight	:	: No data available				
Part	icle size	:	No data available				
10. STA	BILITY AND REACTIVITY	,					
Che	ctivity mical stability sibility of hazardous reac- s	:	Stable under nor May form explos dling or other me	ive dust-air mixture during processing, han-			
Con	ditions to avoid	:	Heat, flames and				
Haz	mpatible materials ardous decomposition lucts	:	Avoid dust formation.Oxidizing agentsNo hazardous decomposition products are known.				
11. TOXI	COLOGICAL INFORMAT		١				
	Information on likely routes of exposure		Inhalation Skin contact Ingestion Eye contact				
	Acute toxicity Not classified based on availab		information.				
Pro	Product:						
Acu	e oral toxicity	:	Acute toxicity esti Method: Calculati	mate: > 5,000 mg/kg on method			
<u>Con</u>	nponents:						
Cell	ulose:						
Acu	e oral toxicity	:	LD50 (Rat): > 5,0	00 mg/kg			
Acu	e inhalation toxicity	:	LC50 (Rat): > 5.8 Exposure time: 4 Test atmosphere:	h			
Acu	e dermal toxicity	:	LD50 (Rabbit): > 2	2,000 mg/kg			
Eze	timibe:						
Acu	e oral toxicity	:	LD50 (Rat): > 5,0	00 mg/kg			
			LD50 (Mouse): >	5,000 mg/kg			
			LD50 (Dog): > 3,0)00 mg/kg			
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SAFETY DATA SHEET



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Acute	inhalation toxicity	:	Remarks: No dat	a available
Acute	dermal toxicity	:	Remarks: No data	a available
	toxicity (other routes of istration)	:	LD50 (Rat): > 2,0 Application Route	
			LD50 (Mouse): > Application Route	1,000 - < 2,000 mg/kg e: Intraperitoneal
Sodiu	Im n-dodecyl sulfate:			
Acute	oral toxicity	:	LD50 (Rat): 1,200 Method: OECD T	
Acute	dermal toxicity	:		00 mg/kg est Guideline 402 on data from similar materials
-	corrosion/irritation es mild skin irritation.			
Comp	oonents:			
Ezetir	nibe:			
Specie Resul		:	Rabbit No skin irritation	
Sodiu	Im n-dodecyl sulfate:			
Specie	es	:	Rabbit	
Resul	t	:	Skin irritation	
	us eye damage/eye irri assified based on availa			
Comp	oonents:			
Ezetir				
Specie Resul		:	Rabbit No eye irritation	
Sodiu	Im n-dodecyl sulfate:			
Specie	es	:	Rabbit	
Metho Resul		:	OECD Test Guide Irreversible effect	
Respi	ratory or skin sensitis	atic	n	
Skin s	sensitisation			
Not cl	assified based on availa	ble	information.	



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-	iratory sensitisation			
Not c	lassified based on avail	able	information.	
Com	ponents:			
Ezeti	mibe:			
Test		:	Maximisation Tes	t
Spec Resu		:	Guinea pig negative	
Sodi	um n-dodecyl sulfate:			
Test		:	Maximisation Tes	t
Expo Spec	sure routes	÷	Skin contact	
Resu			Guinea pig negative	
Rema		:		om similar materials
	n cell mutagenicity			
Not c	lassified based on avail	able	information.	
Com	ponents:			
Cellu	lose:			
Geno	toxicity in vitro	:	Test Type: Bacter Result: negative	rial reverse mutation assay (AMES)
			Test Type: In vitro Result: negative	o mammalian cell gene mutation test
Geno	toxicity in vivo	:	Test Type: Mamn cytogenetic assay Species: Mouse	nalian erythrocyte micronucleus test (in vivo /)
			Application Route Result: negative	: Ingestion
Ezeti	mibe:			
	toxicity in vitro	:		rial reverse mutation assay (AMES) on: with and without metabolic activation
			Test Type: Chron Test system: Hun Result: negative	nosomal aberration nan lymphocytes
Geno	toxicity in vivo	:	Test Type: Micror Species: Mouse Cell type: Bone m Application Route Result: negative	arrow
Sodi	um n-dodecyl sulfate:			
	otoxicity in vitro	:	Test Type: Bacter Method: OECD T	rial reverse mutation assay (AMES) est Guideline 471



rsion 3	Revision Date: 09.04.2021	SDS Number: 1567796-00009	Date of last issue: 10.10.2020 Date of first issue: 18.04.2017
		Result: negativ	e
		Test Type: In v Result: negativ	itro mammalian cell gene mutation test e
Genot	toxicity in vivo	: Test Type: Roo Species: Mous Application Ro Result: negativ	ute: Ingestion
	nogenicity		
	assified based on ava	ailable information.	
Comp	oonents:		
Cellu			
Speci		: Rat	
	cation Route	: Ingestion : 72 weeks	
Resul	sure time t	: negative	
i tesui	·	. negative	
Ezetir	mibe:		
Speci		: Rat, female	
	cation Route	: oral (feed)	
	sure time	: 104 weeks	
Resul	t	: negative	
Speci	es	: Rat, male	
	cation Route	: oral (feed)	
	sure time	: 104 weeks	
Resul	t	: negative	
Speci		: Mouse	
	cation Route	: oral (feed)	
Expos Resul	sure time	: 104 weeks : negative	
ivesui	t i	. negative	
Sodiu	Im n-dodecyl sulfate):	
Speci		: Rat	
	cation Route	: Ingestion	
Expos Metho	sure time	: 2 Years : OECD Test Gu	videline 452
Resul		: negative	
Rema			from similar materials
-	oductive toxicity		
Not cl	assified based on ava	ailable information.	
Comp	<u>oonents:</u>		

: Test Type: One-generation reproduction toxicity study



Effects on foetal development Species: Rat Application Route: Ingestion Result: negative Effects on foetal development Species: Rat Application Route: Ingestion Result: negative Ezetimibe: E Effects on fertility : Test Type: Fertility/early embryonic development Species: Rat, male and female Fertility: NoAEL: > 1,000 mg/kg body weight Result: No effects on fertility. Effects on foetal develop- ment : Test Type: Development Species: Rat Application Route: Oral Developmental Toxicity: NOAEL: > 1,000 mg/kg body weight Result: No adverse effects Sodium n-dodecyl sulfate: E Effects on fertility : Test Type: Two-generation reproduction toxicity study Species: Rati Application Route: Oral Developmental Toxicity: NOAEL: > 1,000 mg/kg body weight Result: No adverse effects Sodium n-dodecyl sulfate: : Effects on fertility : Test Type: Two-generation reproduction toxicity study Species: Rati Application Route: Ingestion Method: OECD Test Guideline 416 Result: negative Remarks: Based on data from similar materials Effects on foetal develop- ment : Test Type: Embryo-foetal development Species: Rati Application Route: Ingestion Result: negative Remarks: Based on data from similar materials Stort - single exposure Not classified based on available information. : Stort - repeated develop- ment : Stort - single	rsion B	Revision Date: 09.04.2021	SDS Number: 1567796-00009	Date of last issue: 10.10.2020 Date of first issue: 18.04.2017
ment Species: Rat Application Route: Ingestion Result: negative Ezetimibe: Effects on fertility Elfects on fertility : Test Type: Fertility/early embryonic development Species: Rat, male and female Fertility: NOAEL:> 1,000 mg/kg body weight Result: No affects on fertility, No fetotoxicity Effects on foetal develop- ment : Test Type: Development Species: Rat Application Route: Oral Developmental Toxicity: NOAEL:> 1,000 mg/kg body weight Result: No adverse effects Sodium n-dodecyl sulfate: : Test Type: Development Species: Rat Application Route: Oral Developmental Toxicity: NOAEL:> 1,000 mg/kg body weight Result: No adverse effects Sodium n-dodecyl sulfate: : Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Ingestion Method: OECD Test Guideline 416 Result: negative Remarks: Based on data from similar materials Effects on foetal develop- ment : Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials STOT - single exposure Not classified based on available information. STOT - repeated exposure Not classified based on available information. STOT - repeated dose toxicity : Components: Cellulose: : Species Species : Rat			Application F	Route: Ingestion
Effects on fertility : Test Type: Fertility/learly embryonic development Species: Rat, male and female Fertility: NOAEL: > 1,000 mg/kg body weight Result: No affects on fertility, No fetotoxicity Effects on foetal development ment : Test Type: Development Species: Rat Application Route: Oral Developmental Toxicity: NOAEL: > 1,000 mg/kg body weight Result: No adverse effects Sodium n-dodecyl sulfate: Effects on fertility Effects on fertility : Test Type: Development Species: Rat Application Route: Oral Developmental Toxicity: NOAEL: > 1,000 mg/kg body weight Result: No adverse effects Sodium n-dodecyl sulfate: Effects on fertility Effects on fertility : Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Ingestion Method: OECD Test Guideline 416 Result: negative Remarks: Based on data from similar materials Effects on foetal develop- ment : Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Method: OECD Test Guideline 416 Result: negative Remarks: Based on data from similar materials STOT - single exposure Not classified based on available information. STOT - repeated exposure Not classified based on available information. Repeated dose toxicity Components: Cellulose: Species Species Species Result: negative Remarks: Based on data from similar m		s on foetal develop-	Species: Rat Application F	t Route: Ingestion
Species: Rat, male and female Fertility: NOAEL: > 1,000 mg/kg body weight Result: No effects on fertility, No fetotoxicity Effects on foetal develop- ment : Test Type: Development Species: Rat Application Route: Oral Developmental Toxicity: NOAEL: > 1,000 mg/kg body weight Result: No adverse effects Sodium n-dodecyl sulfate: : Test Type: Development Species: Rabbit Application Route: Oral Developmental Toxicity: NOAEL: > 1,000 mg/kg body weight Result: No adverse effects Sodium n-dodecyl sulfate: : Effects on fertility : Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Ingestion Method: OECD Test Guideline 416 Result: negative Remarks: Based on data from similar materials Effects on foetal develop- ment : Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials STOT - single exposure : Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials STOT - single exposure : Not classified based on available information. STOT - repeated exposure : Not classified based on available information. Repeated dose toxicity : Components: Cellulose: : Species Species : Rat	Ezetir	nibe:		
ment Species: Rat Application Route: Oral Developmental Toxicity: NOAEL: > 1,000 mg/kg body weight Result: No adverse effects Test Type: Development Species: Rabbit Application Route: Oral Developmental Toxicity: NOAEL: > 1,000 mg/kg body weight Result: No adverse effects Sodium n-dodecyl sulfate: Effects on fertility : Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Ingestion Method: OECD Test Guideline 416 Result: negative Remarks: Based on data from similar materials Effects on foetal develop- ment : Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials STOT - single exposure : Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials STOT - single exposure : Result: negative Remarks: Based on data from similar materials STOT - single exposure : Not classified based on available information. STOT - single dased on available information. : Repeated dose toxicity Components: : Cellulose: Species Species : Rat	Effect	s on fertility	Species: Rat Fertility: NO/	t, male and female AEL: > 1,000 mg/kg body weight
Species: Rabbit Application Route: Oral Developmental Toxicity: NOAEL: > 1,000 mg/kg body weigh Result: No adverse effects Sodium n-dodecyl sulfate: Effects on fertility : Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Ingestion Method: OECD Test Guideline 416 Result: negative Remarks: Based on data from similar materials Effects on foetal develop- ment : Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials STOT - single exposure Not classified based on available information. STOT - repeated exposure Not classified based on available information. Repeated dose toxicity Components: Cellulose: Species Species: x Repeated x<		s on foetal develop-	Species: Rat Application F Developmen	t Route: Oral htal Toxicity: NOAEL: > 1,000 mg/kg body weigh
Effects on fertility : Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Ingestion Method: OECD Test Guideline 416 Result: negative Remarks: Based on data from similar materials Effects on foetal develop- ment : Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials STOT - single exposure Not classified based on available information. Repeated dose toxicity Components: Cellulose: Species Species : Rat			Species: Ral Application F Developmen	bbit Route: Oral htal Toxicity: NOAEL: > 1,000 mg/kg body weigh
Species: Rat Application Route: Ingestion Method: OECD Test Guideline 416 Result: negative Remarks: Based on data from similar materials Remarks: Based on data from similar materials Effects on foetal develop- : Test Type: Embryo-foetal development ment Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials STOT - single exposure Remarks: Based on data from similar materials Not classified based on available information. STOT - repeated exposure Not classified based on available information. Repeated dose toxicity Components: Cellulose: Species : Repeate : Species :	Sodiu	Im n-dodecyl sulfate:		
ment Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials STOT - single exposure Remarks: Based on data from similar materials Not classified based on available information. STOT - repeated exposure Not classified based on available information. Repeated dose toxicity Components: Cellulose: Species : Rat	Effect	s on fertility	Species: Rat Application F Method: OE(Result: nega	t Route: Ingestion CD Test Guideline 416 Itive
Not classified based on available information. STOT - repeated exposure Not classified based on available information. Repeated dose toxicity Components: Cellulose: Species : Rat		s on foetal develop-	Species: Rat Application F Result: nega	t Route: Ingestion itive
STOT - repeated exposure Not classified based on available information. Repeated dose toxicity Components: Cellulose: Species : Rat		• •		
Not classified based on available information. Repeated dose toxicity Components: Cellulose: Species : Rat				
Repeated dose toxicity <u>Components:</u> Cellulose: Species : Rat				
Components: Cellulose: Species : Rat				
Cellulose: Species : Rat	-	-		
Species : Rat				
	Speci	es		j/kg



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	cation Route sure time	: Ingestion : 90 Days
Ezetir	nibe:	
	EL cation Route sure time	 Dog 1,000 mg/kg Oral 90 d No significant adverse effects were reported
	EL cation Route sure time	 Rat 1,500 mg/kg Oral 90 d No significant adverse effects were reported
	EL cation Route sure time	 Mouse 500 mg/kg Oral 90 d No significant adverse effects were reported
	EL cation Route sure time	 Dog 300 mg/kg Oral 1 yr No significant adverse effects were reported
Speci NOAE Applic	EL cation Route sure time	 Rat 488 mg/kg Ingestion 90 Days Based on data from similar materials
-	ation toxicity assified based on avai	able information.
Comp	oonents:	
Ezetir Not ap	mibe: oplicable	
Expe	rience with human ex	oosure
Comp	oonents:	
Ezetir	nibe:	
Ingest	tion	: Symptoms: Headache, Nausea, Vomiting, Diarrhoea, flatu- lence, muscle pain, upper respiratory tract infection, Back pain, joint pain



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12. ECOL	OGICAL INFORMATION	N		
Ecot	oxicity			
<u>Com</u>	ponents:			
Cellu	llose:			
Toxic	to fish	:	Exposure time: 4	atipes (Japanese medaka)): > 100 mg/l 48 h I on data from similar materials
Ezeti	mibe:			
Τοχία	sity to fish	:	Exposure time: 9 Method: OECD	es promelas (fathead minnow)): > 0.125 mg/l 96 h Test Guideline 203 kicity at the limit of solubility
	tity to daphnia and other tic invertebrates	:	Exposure time: 4 Method: OECD	magna (Water flea)): > 4 mg/l 48 h Test Guideline 202 kicity at the limit of solubility
Toxic plant	sity to algae/aquatic s	:	0.317 mg/l Exposure time: 9 Method: OECD	irchneriella subcapitata (green algae)): > 96 h Test Guideline 201 kicity at the limit of solubility
			mg/l Exposure time: 9 Method: OECD	kirchneriella subcapitata (green algae)): 0.317 96 h Test Guideline 201 kicity at the limit of solubility
Τοχία	ity to microorganisms	:		3 h
Toxic icity)	to fish (Chronic tox-	:		
			NOEC: 4 mg/l Exposure time: 7 Species: Cyprind	7 d odon variegatus (sheepshead minnow)



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			Remarks: No toxi	city at the limit of solubility
	ty to daphnia and other c invertebrates (Chron- city)	:		
M-Fac toxicity	tor (Chronic aquatic /)	:	1	
Sodiu	m n-dodecyl sulfate:			
Toxicit	ty to fish	:	LC50 (Pimephale Exposure time: 9	s promelas (fathead minnow)): 29 mg/l 5 h
	ty to daphnia and other c invertebrates	:	EC50 (Ceriodaph Exposure time: 4	nia dubia (water flea)): 5.55 mg/l 3 h
Toxicit plants	ty to algae/aquatic	:	ErC50(Desmode mg/l Exposure time: 72	esmus subspicatus (green algae)): > 120 2 h
			NOEC (Desmode Exposure time: 7	esmus subspicatus (green algae)): 30 mg/ 2 h
Toxicit	ty to microorganisms	:	EC50: 135 mg/l Exposure time: 3	h
Toxicit icity)	ty to fish (Chronic tox-	:	NOEC: >= 1.357 Exposure time: 4 Species: Pimepha	
	ty to daphnia and other c invertebrates (Chron- city)	:	NOEC: 0.88 mg/l Exposure time: 7 Species: Cerioda	d phnia dubia (water flea)
Persis	stence and degradabili	ity		
<u>Comp</u>	onents:			
Cellul Biodeç	ose: gradability	:	Result: Readily b	odegradable.
Ezetin	nibe:			
Biode	gradability	:	Result: Not readil Biodegradation: Exposure time: 2	6.8 %
Stabili	ty in water	:	Hydrolysis: 50 % Method: OECD T	
Sodiu	m n-dodecyl sulfate: gradability		Result: Readily b	adagradabla



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			Biodegradation: Exposure time: 2 Method: OECD	
Bioad	cumulative potential			
<u>Com</u>	oonents:			
Ezeti	mibe:			
Bioac	cumulation	:	Exposure time: 9 Bioconcentration	is macrochirus (Bluegill sunfish) 97 d n factor (BCF): 173 Fest Guideline 305
	ion coefficient: n- ol/water	:	log Pow: 4.36	
Sodiı	um n-dodecyl sulfate:			
Partiti	ion coefficient: n- ol/water	:	log Pow: 0.83	
Mobi	lity in soil			
<u>Com</u>	oonents:			
Ezeti	mibe:			
	oution among environ- al compartments	:	- 3	Test Guideline 106
	r adverse effects ata available			
13. DISPO	SAL CONSIDERATION	١S		
Dispo	osal methods			
			Dianaga of in ag	
Waste	e from residues aminated packaging	:	Empty container dling site for rec	cordance with local regulations. s should be taken to an approved waste har /cling or disposal. specified: Dispose of as unused product.
Waste Conta		: : 	Empty container dling site for rec	s should be taken to an approved waste har /cling or disposal.
Waste Conta	aminated packaging	: : 	Empty container dling site for rec	s should be taken to an approved waste har /cling or disposal.
Waste Conta	aminated packaging SPORT INFORMATION national Regulations	: : I	Empty container dling site for rec If not otherwise	s should be taken to an approved waste har /cling or disposal.
Waste Conta 14. TRANS Interr UNR UN no	aminated packaging SPORT INFORMATION national Regulations	: : I	Empty container dling site for rec If not otherwise	s should be taken to an approved waste har /cling or disposal.



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I	ATA-D	GR			
ι	UN/ID N	No.	:	UN 3077	
F	Proper	shipping name	:	Environmentally h (Ezetimibe)	azardous substance, solid, n.o.s.
(Class		:	9	
F	Packing	g group	:	III	
	Labels		:	Miscellaneous	
	Packing aircraft)	g instruction (cargo	:	956	
	Packing ger airc	g instruction (passen- raft)	:	956	
Ē	Environ	mentally hazardous	:	yes	
I	MDG-0	Code			
ι	UN nun	nber	:	UN 3077	
F	Proper	shipping name	:	ENVIRONMENTA N.O.S. (Ezetimibe)	ALLY HAZARDOUS SUBSTANCE, SOLID,
(Class		:	9	
F	Packing	g group	:	III	
_	Labels		:	9	
	EmS C		:	F-A, S-F	
Ν	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.

15. REGULATORY INFORMATION

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

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	eChem Portal search results and European Chemicals Agen-
Sheet	cy, http://echa.europa.eu/



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Date format		: dd.mm.yyyy		
Full t	ext of other abbrevia	ations		
ACGI	Н	: USA. ACGIH T	hreshold Limit Values (TLV)	
ACGI	H / TWA	: 8-hour, time-w	eighted average	

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response: ELx - Loading rate associated with x% response: EmS - Emergency Schedule: ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose): MARPOL - International Convention for the Prevention of Pollution from Ships: n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration: NO(A)EL - No Observed (Adverse) Effect Level: NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for 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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