



Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
8.0	2024/04/06	1563968-00016	Date of first issue: 2017/04/18

### **1. PRODUCT AND COMPANY IDENTIFICATION**

Chemical product name	:	Ezetimibe Granules Formulation
Supplier's company name, a	ddr	ess and phone number
Company name of supplier	:	Organon & Co.
Address	:	30 Hudson Street, 33nd floor Jersey City, New Jersey, U.S.A 07302
Telephone	:	+1-551-430-6000
E-mail address	:	EHSSTEWARD@organon.com
Emergency telephone number	:	+1-215-631-6999

#### Recommended use of the chemical and restrictions on use

Recommended use	:	Pharmaceutical
Restrictions on use	:	Not applicable

### 2. HAZARDS IDENTIFICATION

GHS classification of chemic Long-term (chronic) aquatic hazard		oroduct Category 2
GHS label elements		
Hazard pictograms	:	¥2
Signal word	:	None
Hazard statements	:	H411 Toxic to aquatic life with long lasting effects.
Precautionary statements	:	Prevention:
		P273 Avoid release to the environment.
		Response:
		P391 Collect spillage.
		<b>Disposal:</b> P501 Dispose of contents/ container to an approved waste disposal plant.



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

Important symptoms and out- :	:	Dust contact with the eyes can lead to mechanical irritation.
lines of the emergency as-		May form explosive dust-air mixture during processing, han-
sumed		dling or other means.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
Cellulose	9004-34-6	>= 20 - < 30	
Ezetimibe	163222-33-1	>= 2.5 - < 10	
Sodium n-dodecyl sulfate	151-21-3	2	2-1679

### 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
If inhaled	:	advice. 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	:	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.
Specific hazards during fire-	:	Exposure to combustion products may be a hazard to health.



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fightir Haza ucts	ng Irdous combustion prod-	:	Carbon oxides Nitrogen oxides Fluorine compou Metal oxides Sulphur oxides	· · · ·
ods Spec	ific extinguishing meth- ial protective equipment efighters	:	cumstances and Use water spray Remove undam so. Evacuate area. In the event of fi	ng measures that are appropriate to local cir- the surrounding environment. to cool unopened containers. aged containers from fire area if it is safe to do re, wear self-contained breathing apparatus. otective equipment.
6. ACCID	ENTAL RELEASE MEAS	SUF	RES	
tive e	onal precautions, protec- equipment and emer- y procedures	:	Follow safe hand	otective equipment. dling advice (see section 7) and personal pro- nt recommendations (see section 8).
Envir	onmental precautions	:	Prevent further I Retain and dispo	the environment. eakage or spillage if safe to do so. ose of contaminated wash water. should be advised if significant spillages ined.
	ods and materials for ainment and cleaning up	:	tainer for dispos Avoid dispersal with compressed Dust deposits sh es, as these may leased into the a Local or nationa posal of this mat employed in the mine which regu Sections 13 and	of dust in the air (i.e., clearing dust surfaces
7. HANDL	ING AND STORAGE			
Hand Tech	<b>lling</b> nical measures	:	Static electricity	may accumulate and ignite suspended dust

	•	Claire electricity may accumulate and ignite edepended duct
		causing an explosion.
		Provide adequate precautions, such as electrical grounding
		and bonding, or inert atmospheres.
Local/Total ventilation	:	Use only with adequate ventilation.





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Advice on safe handling Avoidance of contact Hygiene measures		<ul> <li>practice, based sessment</li> <li>Minimize dust g</li> <li>Keep container</li> <li>Keep away fror</li> <li>Take precaution</li> <li>Take care to pr</li> <li>environment.</li> <li>Oxidizing agent</li> <li>If exposure to c</li> <li>flushing system</li> <li>place.</li> </ul>	dust. 
Stora	0.00	wash contamir	ated clothing before re-use.
	itions for safe storage	· Keen in proper	y labelled containers.
Conu	mons for sale storage		ance with the particular national regulations.
Mater	rials to avoid		th the following product types:
Packa	aging material	: Unsuitable mat	erial: None known.

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work en-
vironment

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Reference concentration / Permissible con- centration	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 <sup>2</sup>	Internal

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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 equipment	
Despiratory protection	If a deguate least exhaust ventilation is not evailable or evan

Respiratory protection :		If adequate local exhaust ventilation is not available or expo-
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	ter type protection		sment demonstrates exposures outside the rec- I guidelines, use respiratory protection. s type
Ma	aterial	: Chemical-r	esistant gloves
Re	emarks	on the con stance and determined application chemicals	oves to protect hands against chemicals depending centration and quantity of the hazardous sub- specific to place of work. Breakthrough time is not I for the product. Change gloves often! For special s, we recommend clarifying the resistance to of the aforementioned protective gloves with the ufacturer. Wash hands before breaks and at the kday.
Eye p	protection	: Wear the f	bllowing personal protective equipment:
Skin a	and body protection	Safety gog : Skin shoul	gies d be washed after contact.
9. PHYSIC	CAL AND CHEMICAL	PROPERTIES	
Physi	cal state	: granular	
Colou	ır	: white	
Odou	r	: No data a	vailable
Odou	r Threshold	: No data a	vailable

Melting point/freezing point	:	No data available
Menning point/neezing point	•	

Boiling point, initial boiling	:	No data available
point and boiling range		

- Flammability (solid, gas) : May form explosive dust-air mixture during processing, handling or other means.
- Flammability (liquids) : No data available

Lower explosion limit and uppe Upper explosion limit / Up- per flammability limit		
Lower explosion limit / Lower flammability limit	:	No data available
Flash point	:	Not applicable
Decomposition temperature	:	No data available
рН	:	No data available
Evaporation rate	:	No data available





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Auto	-ignition temperature	:	No data available	9
Visco V	osity iscosity, kinematic	:	No data available	9
	bility(ies) /ater solubility	:	No data available	9
	tion coefficient: n- nol/water	:	No data available	9
Vapo	our pressure	:	No data available	9
	sity and / or relative dens ensity	ity :	No data available	9
Rela	tive vapour density	:	No data available	9
Expl	osive properties	:	Not explosive	
Oxid	izing properties	:	The substance o	r mixture is not classified as oxidizing.
Mole	cular weight	:	No data available	9
	cle characteristics article size	:	No data available	9

### **10. STABILITY AND REACTIVITY**

Reactivity Chemical stability Possibility of hazardous reac- tions	:	Not classified as a reactivity hazard. Stable under normal conditions. May form explosive dust-air mixture during processing, han- dling 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



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	e toxicity lassified based on availa	ble	information.	
	e oral toxicity	:	Acute toxicity estine Method: Calculation	mate: > 2,000 mg/kg on method
Com	oonents:			
Cellu	lose:			
Acute	oral toxicity	:	LD50 (Rat): > 5,00	00 mg/kg
Acute	inhalation toxicity	:	LC50 (Rat): > 5.8 Exposure time: 4 Test atmosphere:	h
Acute	e dermal toxicity	:	LD50 (Rabbit): > 2	2,000 mg/kg
Ezeti	mibe:			
Acute	oral toxicity	:	LD50 (Rat): > 5,00	00 mg/kg
			LD50 (Mouse): >	5,000 mg/kg
			LD50 (Dog): > 3,0	000 mg/kg
Acute	inhalation toxicity	:	Remarks: No data	a available
Acute	e dermal toxicity	:	Remarks: No data	a available
	toxicity (other routes of nistration)	:	LD50 (Rat): > 2,00 Application Route	
			LD50 (Mouse): > Application Route	1,000 - < 2,000 mg/kg : Intraperitoneal
II Sodiu	um n-dodecyl sulfate:			
	e oral toxicity	:	LD50 (Rat): 1,200 Method: OECD Te	
Acute	e dermal toxicity	:	LD50 (Rat): > 2,00 Method: OECD Te Remarks: Based o	
Skin (	corrosion/irritation			
	lassified based on availa	ble	information.	
<u>Com</u>	oonents:			
Ezeti	mibe:			
Speci	es	:	Rabbit	

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ersion .0	Revision Date: 2024/04/06	SDS Number: 1563968-00016	Date of last issue: 2023/09/30 Date of first issue: 2017/04/18	
Resu	lt	: No skin irritatio	n	
Sodiu	um n-dodecyl sulfate	:		
Speci	-	: Rabbit		
Resu		: Skin irritation		
Serio	ous eye damage/eye i	rritation		
Not c	lassified based on ava	ilable information.		
<u>Com</u>	ponents:			
Ezeti	mibe:			
Speci	ies	: Rabbit		
Resu		: No eye irritatio	n	
Sodiu	um n-dodecyl sulfate	:		
Speci		: Rabbit		
Resu Metho		: Irreversible eff : OECD Test Gu	ects on the eye	
Resp	iratory or skin sensit	isation		
-	sensitisation			
Not cl	lassified based on ava	ilable information.		
Resp	iratory sensitisation			
-	lassified based on ava	ilable information.		
<u>Com</u>	ponents:			
Ezeti	mibe:			
Test	Туре	: Maximisation 7	est	
Speci	ies	: Guinea pig		
Resu	lt	: negative		
Sodiu	um n-dodecyl sulfate	:		
Test		: Maximisation	est	
Expos Speci	sure routes	: Skin contact		
Resu	-	: Guinea pig : negative		
Rema			from similar materials	
Germ	cell mutagenicity			
Not c	lassified based on ava	ilable information.		
<u>Com</u>	ponents:			
Cellu	lose:			
	toxicity in vitro	: Test Type: Bad	cterial reverse mutation assay (AMES)	



rsion )	Revision Date: 2024/04/06		lumber: 68-00016	Date of last issue: 2023/09/30 Date of first issue: 2017/04/18
II		То	st Type: In vi	tro mammalian cell gene mutation test
			sult: negative	
Genot	oxicity in vivo	cyt Sp Ap	st Type: Man ogenetic ass ecies: Mouse plication Rou sult: negative	te: Ingestion
Ezetin	nibe:			
Genot	oxicity in vitro	Me		erial reverse mutation assay (AMES) ation: with and without metabolic activation
		Te		omosomal aberration uman lymphocytes e
Genot	oxicity in vivo	Sp Ce Ap	st Type: Micr ecies: Mouse Il type: Bone plication Rou sult: negative	marrow te: Oral
Sodiu	m n-dodecyl sulfate	:		
	oxicity in vitro	: Te Me		erial reverse mutation assay (AMES) Test Guideline 471 e
			st Type: In vi sult: negative	tro mammalian cell gene mutation test
Genot	oxicity in vivo	Sp Ap	st Type: Rod ecies: Mouse plication Rou sult: negative	te: Ingestion

Not classified based on available information.

### Components:

Cellulose:		
Species	:	Rat
Application Route	:	Ingestion
Exposure time	:	72 weeks
Result	:	negative



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Ezeti	mibe:			
Speci			at, female	
	cation Route		al (feed)	
	sure time		4 weeks	
Resu	π	: ne	gative	
Speci	es	: Ra	at, male	
	cation Route		al (feed)	
	sure time		4 weeks	
Resu	lt	: ne	gative	
Speci	es	: M	ouse	
	cation Route	: or	al (feed)	
Expos	sure time	: 10	4 weeks	
Resu	lt	: ne	gative	
Sodiı	um n-dodecyl sulfate	:		
Speci	-	: Ra	at	
	cation Route	: Ing	gestion	
Expos	sure time	: 2	Years	
Metho			ECD Test Gui	deline 453
Resu			gative	
Rema	arks	: Ba	ased on data i	rom similar materials
Ronr	oductive toxicity			
-	lassified based on ava	ilahle info	rmation	
			initiation.	
Com	oonents:			
<u>Com</u> Cellu				
Cellu				generation reproduction toxicity study
Cellu	lose:	Sp	ecies: Rat	
Cellu	lose:	Sp Ap	pecies: Rat	te: Ingestion
Cellu	lose:	Sp Ap	ecies: Rat	te: Ingestion
Cellu Effect	lose: ts on fertility	Sp Ap Re	pecies: Rat oplication Rou esult: negative	te: Ingestion
Cellu Effect	lose:	Sp Ap Re	pecies: Rat oplication Rou esult: negative	te: Ingestion
Cellu Effect	lose: ts on fertility	Sp Ap Re : Te Sp Ap	ecies: Rat oplication Rou esult: negative est Type: Ferti- pecies: Rat oplication Rou	te: Ingestion lity/early embryonic development te: Ingestion
Cellu Effect	lose: ts on fertility	Sp Ap Re : Te Sp Ap	pecies: Rat oplication Rou esult: negative est Type: Ferti pecies: Rat	te: Ingestion lity/early embryonic development te: Ingestion
Cellu Effect	lose: ts on fertility ts on foetal develop-	Sp Ap Re : Te Sp Ap	ecies: Rat oplication Rou esult: negative est Type: Ferti- pecies: Rat oplication Rou	te: Ingestion lity/early embryonic development te: Ingestion
Cellu Effect Effect ment	lose: ts on fertility ts on foetal develop- mibe:	Sp Ap Re : Te Sp Ap Re	becies: Rat oplication Rou esult: negative est Type: Ferti becies: Rat oplication Rou esult: negative	te: Ingestion lity/early embryonic development te: Ingestion
Cellu Effect Effect ment	lose: ts on fertility ts on foetal develop-	Sp Ap Re : Te Sp Ap Re : Te	eccies: Rat oplication Rou esult: negative est Type: Ferti opcies: Rat oplication Rou esult: negative est Type: Ferti	te: Ingestion lity/early embryonic development te: Ingestion
Cellu Effect Effect ment	lose: ts on fertility ts on foetal develop- mibe:	Sp Ap Re : Te Sp Re : Te Sp Fe	eccies: Rat oplication Rou esult: negative est Type: Ferti- peccies: Rat oplication Rou esult: negative est Type: Ferti- peccies: Rat, m ertility: NOAEL	te: Ingestion lity/early embryonic development te: Ingestion lity/early embryonic development ale and female .: > 1,000 mg/kg body weight
Cellu Effect Effect ment	lose: ts on fertility ts on foetal develop- mibe:	Sp Ap Re : Te Sp Re : Te Sp Fe	eccies: Rat oplication Rou esult: negative est Type: Ferti- peccies: Rat oplication Rou esult: negative est Type: Ferti- peccies: Rat, m ertility: NOAEL	te: Ingestion lity/early embryonic development te: Ingestion lity/early embryonic development ale and female
Cellu Effect Effect ment Ezetin Effect	lose: ts on fertility ts on foetal develop- mibe: ts on fertility	Sp Ap Re : Te Sp Re : Te Sp Fe Re	ecies: Rat oplication Rou esult: negative est Type: Ferti- pecies: Rat oplication Rou esult: negative est Type: Ferti- pecies: Rat, m ertility: NOAEL esult: No effect	te: Ingestion lity/early embryonic development te: Ingestion lity/early embryonic development ale and female .: > 1,000 mg/kg body weight tts on fertility, No fetotoxicity
Cellu Effect Effect ment Ezetin Effect	lose: ts on fertility ts on foetal develop- mibe:	Sp Ap Re : Te Sp Re : Te Re Re : Te	eccies: Rat oplication Rou esult: negative est Type: Ferti- peccies: Rat oplication Rou esult: negative est Type: Ferti- peccies: Rat, m ertility: NOAEL	te: Ingestion lity/early embryonic development te: Ingestion lity/early embryonic development ale and female .: > 1,000 mg/kg body weight tts on fertility, No fetotoxicity
Cellu Effect Effect ment Ezetin Effect	lose: ts on fertility ts on foetal develop- mibe: ts on fertility	Sp Ap Re : Te Sp Re : Te Re : Te Sp Ap	ecies: Rat oplication Rou esult: negative est Type: Ferti- pecies: Rat oplication Rou esult: negative est Type: Ferti- pecies: Rat, me ertility: NOAEL esult: No effec- est Type: Deve- pecies: Rat oplication Rou	te: Ingestion lity/early embryonic development te: Ingestion lity/early embryonic development ale and female .: > 1,000 mg/kg body weight tts on fertility, No fetotoxicity



)	Revision Date: 2024/04/06	SDS Number: 1563968-00016	Date of last issue: 2023/09/30 Date of first issue: 2017/04/18
II		Result: No adv	erse effects
		Test Type: Dev Species: Rabbi	
		Application Rou	ute: Oral Toxicity: NOAEL: > 1,000 mg/kg body weight
Sodiu	um n-dodecyl sulfate:	:	
Effect	ts on fertility	Species: Rat Application Rou Method: OECD	Test Guideline 416
		Result: negativ Remarks: Base	e ed on data from similar materials
Effect ment	ts on foetal develop-	Species: Rat Application Rot	
		Result: negativ Remarks: Base	e d on data from similar materials
	- single exposure		
Not c	lassified based on avai		
Not c STOT			
Not c <b>STOT</b> Not c	lassified based on avai		
Not cl STOT Not cl Repe	lassified based on avai		
Not cl STOT Not cl Repe	lassified based on avai - repeated exposure lassified based on avai ated dose toxicity ponents:		
Not cl STOT Not cl Repe <u>Com</u> Cellu	lassified based on avai - repeated exposure lassified based on avai ated dose toxicity ponents: lose: les	lable information.	
Not cl STOT Not cl Repe Com Cellu Speci NOA	lassified based on avai - repeated exposure lassified based on avai ated dose toxicity ponents: lose: les EL	lable information. : Rat : >= 9,000 mg/kg	3
Not cl STOT Not cl Repe <u>Com</u> Cellu Speci NOAE Applio	lassified based on avai - repeated exposure lassified based on avai ated dose toxicity ponents: lose: les	lable information.	3
Not cl STOT Not cl Repe Com Cellu Speci NOAE Applic Expos	lassified based on avai <b>- repeated exposure</b> lassified based on avai <b>ated dose toxicity</b> <b>bonents:</b> <b>lose:</b> les EL cation Route	lable information. : Rat : >= 9,000 mg/kg : Ingestion	9
Not cl STOT Not cl Repe <u>Comj</u> Cellu Speci NOAE Applic Expos	lassified based on avai <b>- repeated exposure</b> lassified based on avai <b>ated dose toxicity</b> <b>bonents:</b> <b>lose:</b> EL cation Route sure time <b>mibe:</b> les	Rat Solution: Rat Solution Solut	)
Not cl STOT Not cl Repe Com Cellu Speci NOAE Expose Ezeti Speci NOAE	lassified based on avail <b>- repeated exposure</b> lassified based on avail <b>ated dose toxicity</b> <b>bonents:</b> <b>lose:</b> les EL cation Route sure time <b>mibe:</b> les EL	Rat Rat Page 2,000 mg/kg Ingestion Solution Dog 1,000 mg/kg	
Not cl STOT Not cl Repe Com Cellu Speci NOAE Applic Expose Ezeti NOAE Applic	lassified based on avail <b>- repeated exposure</b> lassified based on avail <b>ated dose toxicity</b> <b>bonents:</b> <b>lose:</b> les EL cation Route sure time <b>mibe:</b> les EL cation Route	Rat Rat >= 9,000 mg/kg Ingestion 90 Days Dog 1,000 mg/kg Oral	
Not cl STOT Not cl Repe Com Cellu Speci NOAE Applic Expose Ezeti NOAE Applic	lassified based on avail <b>- repeated exposure</b> lassified based on availated dose toxicity <b>bonents:</b> <b>lose:</b> les EL cation Route sure time <b>mibe:</b> les EL cation Route sure time	Rat Rat >= 9,000 mg/kg Ingestion 90 Days Dog 1,000 mg/kg Oral 90 d	adverse effects were reported
Not cl STOT Not cl Repe Com Cellu Speci NOAE Applic Expos Speci NOAE Applic Expos	lassified based on avail <b>r - repeated exposure</b> lassified based on avail <b>ated dose toxicity</b> <b>bonents:</b> <b>lose:</b> les EL cation Route sure time <b>mibe:</b> les EL cation Route sure time arks	Rat Rat >= 9,000 mg/kg Ingestion 90 Days Dog 1,000 mg/kg Oral 90 d	
Not cl STOT Not cl Repe <u>Comj</u> Cellu Speci NOAE Applic Expos Rema	lassified based on avail <b>r - repeated exposure</b> lassified based on avail <b>ated dose toxicity</b> <b>ponents:</b> <b>lose:</b> les EL cation Route sure time <b>mibe:</b> les EL cation Route sure time arks EL cation Route sure time arks	Rat E Rat E >= 9,000 mg/kg E Ingestion E 00 Days E 00 Days E 00 d E 00	
Not cl STOT Not cl Repe <u>Comj</u> Cellu Speci NOAE Applic Expos Rema Speci NOAE	lassified based on avai <b>r - repeated exposure</b> lassified based on avai <b>ated dose toxicity</b> <b>bonents:</b> <b>lose:</b> les EL cation Route sure time <b>mibe:</b> les EL cation Route sure time arks es EL cation Route sure time arks	Rat E Rat E >= 9,000 mg/kg E Ingestion E 00 Days E 00 Days E 00 d E 00	
Not cl STOT Not cl Repe <u>Comj</u> Cellu Speci NOAE Applic Expos Rema Speci NOAE	lassified based on avai <b>r - repeated exposure</b> lassified based on avai <b>ated dose toxicity</b> <b>bonents:</b> <b>lose:</b> les EL cation Route sure time <b>mibe:</b> les EL cation Route sure time arks les EL cation Route sure time arks	<ul> <li>Rat</li> <li>&gt;= 9,000 mg/kg</li> <li>Ingestion</li> <li>90 Days</li> <li>Cral</li> <li>90 d</li> <li>No significant a</li> <li>Rat</li> <li>1,500 mg/kg</li> <li>Oral</li> <li>90 d</li> </ul>	

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Speci NOAI Applie Expos	EL cation Route sure time	: Mouse : 500 mg/kg : Oral : 90 d : No significar	t adverse effects were reported
Speci NOAI Applie Expo Rema	EL cation Route sure time	: Dog : 300 mg/kg : Oral : 1 yr : No significar	t adverse effects were reported
Sodiu	um n-dodecyl sulfate	:	
Speci NOAI Applie Expos Rema	EL cation Route sure time	: Rat : 488 mg/kg : Ingestion : 90 Days : Based on da	ta from similar materials
Not c <u>Com</u>	r <b>ation toxicity</b> lassified based on ava ponents: mibe:	ilable information.	
	pplicable		
-	rience with human e	xposure	
	<u>ponents:</u> mibe:		
Inges			Headache, Nausea, Vomiting, Diarrhoea, flatu- e pain, upper respiratory tract infection, Back in
12. ECOL	OGICAL INFORMATI	ON	
Ecoto	oxicity		
<u>Com</u>	ponents:		
<b>Cellu</b> Toxic	<b>lose:</b> ity to fish	Exposure tim	as latipes (Japanese medaka)): > 100 mg/l ne: 48 h ased on data from similar materials
	mibe:		
Toxic	ity to fish	: LC50 (Pimer	phales promelas (fathead minnow)): > 0.125 mg/l
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rsion )	Revision Date: 2024/04/06	-	9S Number: 63968-00016	Date of last issue: 2023/09/30 Date of first issue: 2017/04/18
	ty to daphnia and other c invertebrates	:	Remarks: No tox	est Guideline 203 icity at the limit of solubility nagna (Water flea)): > 4 mg/l
			Method: OECD T	est Guideline 202 icity at the limit of solubility
Toxici plants	ty to algae/aquatic	:	0.317 mg/l Exposure time: 9 Method: OECD T	rchneriella subcapitata (green algae)): > 6 h Test Guideline 201 icity at the limit of solubility
			mg/l Exposure time: 9 Method: OECD T	irchneriella subcapitata (green algae)): 0.3′ 6 h Test Guideline 201 icity at the limit of solubility
Toxici icity)	ty to fish (Chronic tox-	:	Exposure time: 3	les promelas (fathead minnow)): 0.051 mg/ 3 d <sup>-</sup> est Guideline 210
			Exposure time: 7	on variegatus (sheepshead minnow)): 4 mg d icity at the limit of solubility
	ty to daphnia and other c invertebrates (Chron- city)	:	Exposure time: 2	magna (Water flea)): 0.282 mg/l 1 d icity at the limit of solubility
	ctor (Chronic aquatic	:	1	
toxicit <u>;</u> Toxici	y) ty to microorganisms	:		h
	I <b>m n-dodecyl sulfate:</b> ty to fish	:	LC50 (Pimephale Exposure time: 9	es promelas (fathead minnow)): 29 mg/l 6 h
Toxici	ty to daphnia and other	:	EC50 (Ceriodaph	nnia dubia (water flea)): 5.55 mg/l

## SAFETY DATA SHEET



rsion )	Revision Date: 2024/04/06		S Number: 63968-00016	Date of last issue: 2023/09/30 Date of first issue: 2017/04/18
aquati	c invertebrates		Exposure time: 4	8 h
	ty to algae/aquatic	:		esmus subspicatus (green algae)): > 120 m
			NOEC (Desmode Exposure time: 7	esmus subspicatus (green algae)): 30 mg/l 2 h
Toxicit icity)	ty to fish (Chronic tox-	:	NOEC (Pimepha mg/l Exposure time: 4	es promelas (fathead minnow)): >= 1.357 2 d
aquati	ty to daphnia and other c invertebrates (Chron-	:	NOEC (Ceriodap Exposure time: 7	hnia dubia (water flea)): 0.88 mg/l d
ic toxic Toxicit	ty to microorganisms	:	EC50: 135 mg/l Exposure time: 3	h
Persis	stence and degradabili	ty		
<u>Comp</u>	onents:			
Cellul				
Biode	gradability	:	Result: Readily b	iodegradable.
Ezetin				
Biodeç	gradability	:	Result: Not readi Biodegradation: Exposure time: 2	6.8 %
Stabili	ty in water	:	Hydrolysis: 50 % Method: OECD T	(4.5 d) est Guideline 111
II Sodiu	m n-dodecyl sulfate:			
	gradability	:	Result: Readily b Biodegradation: Exposure time: 2 Method: OECD T	95 %
Bioac	cumulative potential			
<u>Comp</u>	onents:			
Ezetin	nibe:			
Bioaco	cumulation	:	Bioconcentration Exposure time: 9	s macrochirus (Bluegill sunfish) factor (BCF): 173 7 d est Guideline 305
<b>11</b>	on coefficient: n-		log Pow: 4.36	



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Sodiu Partit octan Mobi	ool/water um n-dodecyl sulfate: ion coefficient: n- iol/water lity in soil ponents: mibe:	: log Pow: 0.83	
	bution among environ- al compartments	: log Koc: 4.35 Method: OECI	D Test Guideline 106
	rdous to the ozone lay pplicable	er	
	<b>r adverse effects</b> ata available		
13. DISPO	SAL CONSIDERATION	IS	
Dien	osal methods		
-	e from residues		accordance with local regulations. e of waste into sewer.
Conta	aminated packaging	: Empty contain dling site for re	ers should be taken to an approved waste han- ecycling or disposal. e specified: Dispose of as unused product.
14. TRAN	SPORT INFORMATION	I	
Inter	national Regulations		
Prope	umber er shipping name s ing group	: UN 3077 : ENVIRONMEI N.O.S. (Ezetimibe) : 9 : III : 9	NTALLY HAZARDOUS SUBSTANCE, SOLID,
Envir	onmentally hazardous	: yes	
UN/IE Prope	D No. er shipping name	(Ezetimibe)	lly hazardous substance, solid, n.o.s.
Label	ing group ls ing instruction (cargo	: 9 : III : Miscellaneous : 956	



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	<b>_</b>				
	Packing ger airc	instruction (passen- raft)	•	956	
	Ĕnviron	mentally hazardous	:	yes	
	IMDG-0	Code			
	UN nun	nber	:	UN 3077	
	Proper	shipping name	:	ENVIRONMENTA N.O.S. (Ezetimibe)	LLY HAZARDOUS SUBSTANCE, SOLID,
	Class		:	9	
	Packing	group	:	111	
	Labels		:	9	
	EmS Co	ode	:	F-A, S-F	
	Marine	pollutant	:	yes	

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

Not applicable for product as supplied.

#### **National Regulations**

Refer to section 15 for specific national regulation.

#### 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.

ERG Code : 171

### **15. REGULATORY INFORMATION**

#### **Related Regulations**

#### Fire Service Law

Not applicable to dangerous materials / designated flammables.

#### **Chemical Substance Control Law**

Priority Assessment Chemical Substance

Chemical name	Number
Sodium alkyl(C=8-18) sulfate	214

#### Industrial Safety and Health Law

#### Harmful Substances Prohibited from Manufacture

Not applicable

#### Harmful Substances Required Permission for Manufacture

Not applicable

### **Substances Prevented From Impairment of Health**

Not applicable





ersion	Revision Date:	SDS Number:	Date of last issue: 2	023/09/30
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on Ex	isting Chemicals ha		having Mutagenicity -	Annex 2: Information
Circu	oplicable lar concerning Infor otified Substances h		having Mutagenicity	- Annex 1: Information
Not a	oplicable			
Subs	tances Subject to be	e Notified Names		
	e 57-2 (Enforcement (			
	nical name Im dodecyl sulphate		Concentration (%) >0 - <10	Remarks From April 1st, 2025
			20-210	1 1011 April 131, 2023
	tances Subject to be			
	e 57 (Enforcement Or nical name	del Anicle To)		Remarks
	Im dodecyl sulphate			From April 1st, 2025
Not a	ance on Prevention oplicable ance on Prevention	of Lead Poisoning of Tetraalkyl Lead Po	visoning	
	oplicable			
	ance on Prevention	of Organic Solvent P	oisoning	
Subs	cement Order of the tances) oplicable	e Industrial Safety and	I Health Law - Attache	d table 1 (Dangerous
-	-	us Substances Contro	allaw	
	oplicable			
Act o	n Confirmation, etc.		of Specific Chemical S the Management Ther	
Class	I Designated Chem	ical Substances		
Cher	nical name		ministration number	Concentration (%)
	um dodecyl sulfate	275		2.0
Sodiu High	Pressure Gas Safet	y Act		
Sodiu High		y Act		



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#### Vessel Safety Law

Miscellaneous dangerous substances and articles (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

#### **Aviation Law**

Miscellaneous dangerous substances and articles (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

#### Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Not classified as noxious liquid substance

Pack transportation

: Classified as marine pollutant

### Narcotics and Psychotropics Control Act

Narcotic or Psychotropic Raw Material (Export / Import Permission) Not applicable Specific Narcotic or Psychotropic Raw Material (Export / Import permission) Not applicable

### Waste Disposal and Public Cleansing Law

Industrial waste

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

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

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

In this SDS, if the concentration of substances subject to notification under the Industrial Safety and Health Law is indicated as a range, it includes cases where it is a trade secret.

#### 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/

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

	Date format	:	yyyy/mm/dd			
Full text of other abbreviations						
	ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)			
	ACGIH / TWA	:	8-hour, 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



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

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

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