

Grazoprevir Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
4.3	28.09.2024	443813-00023	Date of first issue: 07.01.2016

SECTION 1: Identification of the substance/mixture and of the company/undertaking

: EHSDATASTEWARD@msd.com

1.1 Product identifier Trade name	:	Grazoprevir Formulation
1.2 Relevant identified uses of t	he s	ubstance or mixture and uses advised against
Use of the Sub- stance/Mixture	:	Pharmaceutical
Recommended restrictions on use	:	Not applicable
1.3 Details of the supplier of the	e safe	ety data sheet
Company	:	MSD Kilsheelan Clonmel Tipperary, IE
Telephone	:	353-51-601000

1.4 Emergency telephone number

E-mail address of person

responsible for the SDS

+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Specific target organ toxicity - repeated exposure, Category 2

H373: May cause damage to organs through prolonged or repeated exposure.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms	:	
Signal word	:	Warning
Hazard statements	:	H373 May cause damage to organs through prolonged or repeated exposure.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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Preca	utionary statements	: P260 Respo P314	Do not bre onse:	athe dust. al advice/ attention if you feel unwell.

Hazardous components which must be listed on the label: Grazoprevir

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

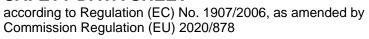
Dust contact with the eyes can lead to mechanical irritation. May form explosive dust-air mixture during processing, handling or other means.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Grazoprevir	1350462-55-3	STOT RE 2; H373 (Liver, Testis)	>= 10 - < 20
Sodium n-dodecyl sulfate	151-21-3 205-788-1	Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Dam. 1; H318 Aquatic Chronic 3; H412 specific concentra- tion limit Eye Irrit. 2; H319 10 - < 20 % Eye Dam. 1; H318 >= 20 %	>= 1 - < 2,5





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			Acute toxicity esti- mate	
			Acute oral toxicity: 1.200 mg/kg	

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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.		
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).		
If inhaled	:	If inhaled, remove to fresh air. Get medical attention if symptoms occur.		
In case of skin contact	:	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.		
4.2 Most important symptoms a	nd e	effects, both acute and delayed		
Symptoms	:	Headache Gastrointestinal discomfort		
Risks	:	May cause damage to organs through prolonged or repeated exposure.		
		Dust contact with the eyes can lead to mechanical irritation.		
4.3 Indication of any immediate	me	dical attention and special treatment needed		
Treatment	:	Treat symptomatically and supportively.		



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SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	None known.

5.2 Special hazards arising from the substance or mixture

5.2 Special hazarus ansing nom	une	
Specific hazards during fire- fighting	:	Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.
Hazardous combustion prod- ucts	:	Carbon oxides Nitrogen oxides (NOx) Metal oxides Chlorine compounds Sulphur oxides
5.3 Advice for firefighters		
Special protective equipment for firefighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.
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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures Personal precautions Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

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 	
	cannot be contained.	



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6.3 Methods and material for containment and cleaning up

Methods for cleaning up	: Sweep up or vacuum up spillage and collect in suitable con-
Methods for cleaning up	tainer for disposal.
	Avoid dispersal of dust in the air (i.e., clearing dust surfaces
	with compressed air).
	1 ,
	Dust deposits should not be allowed to accumulate on surfac-
	es, as these may form an explosive mixture if they are re-
	leased into the atmosphere in sufficient concentration.
	Local or national regulations may apply to releases and dis-
	posal of this material, as well as those materials and items
	•
	employed in the cleanup of releases. You will need to deter-
	mine which regulations are applicable.
	Sections 13 and 15 of this SDS provide information regarding
	certain local or national requirements.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures	: Static electricity may accumulate and ignite suspended dust causing an explosion.
	Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
Local/Total ventilation	: Use only with adequate ventilation.
Advice on safe handling	: Do not get on skin or clothing.
-	Do not breathe dust.
	Do not swallow.
	Avoid contact with eyes.
	Handle in accordance with good industrial hygiene and safety
	practice, based on the results of the workplace exposure as- sessment
	Minimize dust generation and accumulation.
	Keep container closed when not in use.
	Keep away from heat and sources of ignition.
	Take precautionary measures against static discharges.
	Take care to prevent spills, waste and minimize release to the environment.
Hygiene measures	: If exposure to chemical is likely during typical use, provide eye
	flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contami- nated clothing before re-use.
	The effective operation of a facility should include review of engineering controls, proper personal protective equipment,
	appropriate degowning and decontamination procedures,
	industrial hygiene monitoring, medical surveillance and the use of administrative controls.
7.2 Conditions for safe storage, in	ncluding any incompatibilities

Requirements for storage
areas and containers:Keep in properly labelled containers. Store in accordance with
the particular national regulations.



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Advice	e on common storage	:	Do not store with Strong oxidizing	the following product types: agents
-	i c end use(s) fic use(s)	:	No data available	

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Dust

5 mg/m3 Value type (Form of exposure): TWA (respirable dust) Basis: FOR-2011-12-06-1358

10 mg/m3 Value type (Form of exposure): TWA (total dust) Basis: FOR-2011-12-06-1358

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Grazoprevir	1350462- 55-3	TWA	85 μg/m3 (OEB 3)	Internal
		Wipe limit	850 μg/100 cm²	Internal

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006

Substance name	End Use	Exposure routes	Potential health ef- fects	Value
Sodium chloride	Workers	Inhalation	Long-term systemic effects	2068,62 mg/m3
	Workers	Inhalation	Acute systemic ef- fects	2068,62 mg/m3
	Workers	Skin contact	Long-term systemic effects	295,52 mg/kg bw/day
	Workers	Skin contact	Acute systemic ef- fects	295,52 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	443,28 mg/m3
	Consumers	Inhalation	Acute systemic ef- fects	443,28 mg/m3
	Consumers	Skin contact	Long-term systemic effects	126,65 mg/kg bw/day
	Consumers	Skin contact	Acute systemic ef- fects	126,65 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	126,65 mg/kg bw/day
	Consumers	Ingestion	Acute systemic ef- fects	126,65 mg/kg bw/day



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Sodiu sulfat	um n-dodecyl æ	Workers	Inhalatio	n Long-term systemic effects	285 mg/m3
		Workers	Skin con	tact Long-term systemic effects	4060 mg/kg bw/day
		Consumers	Inhalatio	n Long-term systemic effects	85 mg/m3
		Consumers	Skin con	tact Long-term systemic effects	2440 mg/kg bw/day
		Consumers	Ingestion	h Long-term systemic effects	24 mg/kg bw/day

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006

Substance name	Environmental Compartment	Value
Sodium chloride	Fresh water	5 mg/l
	Sewage treatment plant	500 mg/l
	Soil	4,86 mg/kg dry weight (d.w.)
Sodium n-dodecyl sulfate	Fresh water	0,176 mg/l
	Marine water	0,018 mg/l
	Sewage treatment plant	1,35 mg/l
	Fresh water sediment	6,97 mg/kg dry weight (d.w.)
	Marine sediment	0,697 mg/kg dry weight (d.w.)
	Soil	1,29 mg/kg dry weight (d.w.)

8.2 Exposure controls

Engineering measures

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).

Minimize open handling.

Personal protective equipment

Eye/face protection	:	Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Hand protection		
Material	:	Chemical-resistant gloves
Remarks Skin and body protection	:	Consider double gloving. Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.



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Respi	iratory protection	contaminate : If adequate sure assess ommended	iate degowning techniques to remove potentially d clothing. local exhaust ventilation is not available or expo- ment demonstrates exposures outside the rec- guidelines, use respiratory protection. should conform to NS EN 143
Fil	ter type	: Particulates	

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	:	powder
Colour	:	No data available
Odour	:	No data available
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, han- dling or other means.
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point	:	Not applicable
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
рН	:	No data available
Viscosity Viscosity, kinematic	:	Not applicable
Solubility(ies) Water solubility	:	No data available



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		on coefficient: n- l/water	:	Not applicable	
	Vapou	r pressure	:	Not applicable	
	Relativ	ve density	:	No data available	e
	Densit	у	:	No data available	e
	Relativ	ve vapour density	:	Not applicable	
		e characteristics ticle size	:	No data availabl	e
9.2 Other information		nformation			
	Explos	sives	:	Not explosive	
	Oxidiz	ing properties	:	The substance of	r mixture is not classified as oxidizing.
	Evapo	ration rate	:	Not applicable	

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions	:	May form explosive dust-air mixture during processing, han- dling or other means. Can react with strong oxidizing agents.
10.4 Conditions to avoid		
Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
10.5 Incompatible materials		
Materials to avoid	:	Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of	:	Inhalation
exposure		Skin contact

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rsion	Revision Date: 28.09.2024		S Number: 3813-00023	Date of last issue: 06.04.2024 Date of first issue: 07.01.2016
			Ingestion Eye contact	
Acute	e toxicity			
Not cl	lassified based on av	ailable	information.	
<u>Produ</u>	uct:			
Acute	oral toxicity	:	Acute toxicity e Method: Calcul	stimate: > 2.000 mg/kg ation method
<u>Comp</u>	oonents:			
Grazo	oprevir:			
Acute	oral toxicity	:	LD50 (Rat): > 2	2.000 mg/kg
Sodiu	um n-dodecyl sulfat	e:		
Acute	oral toxicity	:	LD50 (Rat): 1.2 Method: OECD	200 mg/kg 9 Test Guideline 401
Acute	e dermal toxicity	:	LD50 (Rat): > 2 Method: OECD	Test Guideline 402
			Remarks: Base	ed on data from similar materials
Skin	corrosion/irritation		Remarks: Base	ed on data from similar materials
_	corrosion/irritation lassified based on av	ailable		ed on data from similar materials
Not cl		ailable		ed on data from similar materials
Not cl	assified based on av	ailable		ed on data from similar materials
Not cl	lassified based on av ponents: pprevir:	ailable :	information.	
Not cl <u>Comp</u> Grazo Resul	lassified based on av ponents: pprevir: It	:	information.	
Not cl <u>Comp</u> Grazo Resul	lassified based on av ponents: pprevir: It um n-dodecyl sulfat	:	information.	
Not cl Comp Grazo Resul Sodiu	lassified based on av <u>conents:</u> pprevir: It um n-dodecyl sulfat es	:	information. No skin irritatio	
Not cl Comp Grazo Resul Sodiu Speci Resul	lassified based on av <u>conents:</u> pprevir: It um n-dodecyl sulfat es It	: e: :	information. No skin irritatio Rabbit Skin irritation	
Not cl Comp Grazo Resul Sodiu Speci Resul	lassified based on av <u>conents:</u> pprevir: It um n-dodecyl sulfat es	e: : : :	information. No skin irritatio Rabbit Skin irritation on	
Not cl Comp Grazo Resul Sodiu Speci Resul Serio Not cl	lassified based on av <u>conents:</u> pprevir: It um n-dodecyl sulfat es It us eye damage/eye	e: : : :	information. No skin irritatio Rabbit Skin irritation on	
Not cl Comp Grazo Resul Sodiu Speci Resul Serio Not cl <u>Comp</u>	lassified based on av <u>conents:</u> pprevir: It um n-dodecyl sulfat es It us eye damage/eye lassified based on av	e: : : :	information. No skin irritatio Rabbit Skin irritation on	
Not cl Comp Grazo Resul Sodiu Speci Resul Serio Not cl <u>Comp</u>	lassified based on av <u>conents:</u> pprevir: It um n-dodecyl sulfat es It us eye damage/eye lassified based on av <u>conents:</u> pprevir:	e: : : :	information. No skin irritatio Rabbit Skin irritation on	
Not cl Comp Grazo Resul Sodiu Speci Resul Serio Not cl Comp Grazo	lassified based on av <u>conents:</u> pprevir: It um n-dodecyl sulfat es It us eye damage/eye lassified based on av <u>conents:</u> pprevir: es	e: : : :	information. No skin irritatio Rabbit Skin irritation on information.	n
Not cl Comp Grazo Resul Sodiu Speci Resul Serio Not cl Comp Grazo Speci Resul	lassified based on av <u>conents:</u> pprevir: It um n-dodecyl sulfat es It us eye damage/eye lassified based on av <u>conents:</u> pprevir: es	e: irritatio ailable	information. No skin irritatio Rabbit Skin irritation on information. Bovine cornea	n
Not cl Comp Grazo Resul Sodiu Speci Resul Serio Not cl Comp Grazo Speci Resul	lassified based on av <u>conents:</u> pprevir: It um n-dodecyl sulfat es It us eye damage/eye lassified based on av <u>conents:</u> pprevir: es It um n-dodecyl sulfat	e: irritatio ailable	information. No skin irritatio Rabbit Skin irritation on information. Bovine cornea	n
Not cl Comp Grazo Resul Sodiu Speci Resul Serio Not cl Comp Grazo Speci Resul	lassified based on av <u>conents:</u> previr: It um n-dodecyl sulfat es It us eye damage/eye lassified based on av <u>conents:</u> previr: es It um n-dodecyl sulfat es od	e: irritatio ailable	information. No skin irritatio Rabbit Skin irritation on information. Bovine cornea No eye irritation	n n

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Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Grazoprevir:

Test Type	:	Local lymph node assay (LLNA)
Exposure routes	:	Dermal
Result	:	Not a skin sensitizer.

Sodium n-dodecyl sulfate:

:	Maximisation Test
:	Skin contact
:	Guinea pig
:	negative
:	Based on data from similar materials
	:

Germ cell mutagenicity

Not classified based on available information.

Components:

Grazoprevir:

Genotoxicity in vitro	Test Type: Bacterial reverse mutation assay (AMES) Result: negative
	Test Type: Chromosome aberration test in vitro Result: negative
Genotoxicity in vivo :	Test Type: In vivo micronucleus test Application Route: Oral Result: negative
Germ cell mutagenicity- As- : sessment	Weight of evidence does not support classification as a germ cell mutagen.
Sodium n-dodecyl sulfate:	
Genotoxicity in vitro :	Test Type: Bacterial reverse mutation assay (AMES) Method: OECD Test Guideline 471 Result: negative
	Test Type: In vitro mammalian cell gene mutation test Result: negative
Genotoxicity in vivo :	Test Type: Rodent dominant lethal test (germ cell) (in vivo) Species: Mouse Application Route: Ingestion

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Result: negative

Carcinogenicity

Not classified based on available information.

Components:

Sodium n-dodecyl sulfate:

Species :	Rat
Application Route :	Ingestion
Exposure time :	2 Years
Method :	OECD Test Guideline 453
Result :	negative
Remarks :	Based on data from similar materials

Reproductive toxicity

Not classified based on available information.

Components:

Grazoprevir:	
Effects on fertility :	Test Type: Fertility Species: Rat Application Route: Oral Fertility: NOAEL: 400 mg/kg body weight Result: negative
	Test Type: Multi-generation study Species: Rat Application Route: Oral Fertility: NOAEL: 400 mg/kg body weight Result: No effects on fertility, No effects on foetal development
Effects on foetal develop- : ment	Test Type: Embryo-foetal development Species: Rat Application Route: Oral Embryo-foetal toxicity: NOAEL: 200 mg/kg body weight Result: No effects on foetal development
	Test Type: Embryo-foetal development Species: Rabbit Application Route: Oral Embryo-foetal toxicity: NOAEL: 200 mg/kg body weight Result: No effects on foetal development
	Test Type: Embryo-foetal development Species: Rabbit Application Route: Intravenous Embryo-foetal toxicity: NOAEL: 100 mg/kg body weight Result: No effects on foetal development

Sodium n-dodecyl sulfate:



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Effect	s on fertility	Species: Rat Application Ro Method: OECE Result: negativ) Test Guideline 416
Effect ment	s on foetal develop-	Species: Rat Application Ro Result: negativ	•
стот	- single exposure		

Not classified based on available information.

STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

Components:

Grazoprevir:

Target Organs	:	Liver, Testis
Assessment	:	May cause damage to organs through prolonged or repeated
		exposure.

Repeated dose toxicity

Components:

Grazoprevir:	
Species:NOAEL:Application Route:Exposure time:Remarks:	Rat 400 mg/kg Oral 30 Days No significant adverse effects were reported
Species:NOAEL:Application Route:Exposure time:Remarks:	Rat 400 mg/kg Oral 180 Days No significant adverse effects were reported
Species:NOAEL:LOAEL:Application Route:Exposure time:Target Organs:	Dog 15 mg/kg 100 mg/kg Oral 270 Days Liver, Blood, Bone marrow, gallbladder, spleen, Testis
Species : NOAEL : LOAEL :	Mouse 200 mg/kg 500 mg/kg

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Exposi	Application Route Exposure time Target Organs		Oral 90 Days Liver, Kidney, Blood		
NOAEI LOAEL Applica Exposi	Species NOAEL LOAEL Application Route Exposure time Target Organs				
Specie NOAEI Exposi Remar	L ure time	: Monkey : 10 mg/kg : 8 Days : No significan	t adverse effects were reported		
Sodiur	m n-dodecyl sulfate:				
Specie NOAEI Applica Exposi	Species NOAEL Application Route Exposure time Remarks		a from similar materials		
Aspira	tion toxicity				
-	ssified based on availa	able information.			
11.2 Inform	nation on other hazar	ds			
Endoc	rine disrupting prope	erties			
Produ	ct:				
	essment : The substance/mixture does not contain component ered to have endocrine disrupting properties accord REACH Article 57(f) or Commission Delegated regu (EU) 2017/2100 or Commission Regulation (EU) 20 levels of 0.1% or higher.		endocrine disrupting properties according to le 57(f) or Commission Delegated regulation 00 or Commission Regulation (EU) 2018/605 at		
Experi	ence with human exp	osure			
Comp	onents:				
-	Grazoprevir: Ingestion		leadache, Gastrointestinal disturbance		
SECTION	SECTION 12: Ecological information				
12.1 Toxici	ty				
Comp	onents:				
Grazo Toxicit	previr: y to fish	: LC50 (Cyprin	odon variegatus (sheepshead minnow)): > 10		

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		mg/l Exposure time: 96 Remarks: No toxic	S h city at the limit of solubility
Toxicity to daphnia and other aquatic invertebrates		Exposure time: 48 Method: OECD Te	
		LC50 (Americamy Exposure time: 96	
Toxicity to algae/aquatic plants	:	mg/l Exposure time: 72 Method: OECD To	
		mg/l Exposure time: 72 Method: OECD To	
Toxicity to microorganisms	:	EC50 : > 1.000 m Exposure time: 3 Test Type: Respir Method: OECD To	h ation inhibition
		NOEC : 1,3 mg/l Exposure time: 3 Test Type: Respir Method: OECD Te	ation inhibition
Toxicity to fish (Chronic tox- icity)	:	Method: OECD Te	ales promelas (fathead minnow)
Toxicity to daphnia and other aquatic invertebrates (Chron- ic toxicity)		NOEC: 5 mg/l Exposure time: 21 Species: Daphnia Method: OECD To	magna (Water flea)
Sodium n-dodecyl sulfate:			
Toxicity to fish	:	LC50 (Pimephales Exposure time: 96	s promelas (fathead minnow)): 29 mg/l ò h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Ceriodaphi Exposure time: 48	nia dubia (water flea)): 5,55 mg/l 3 h



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Toxicity to plants	Toxicity to algae/aquatic plants		ErC50 (Desmode Exposure time: 72	smus subspicatus (green algae)): > 120 mg/l 2 h	
			NOEC (Desmode Exposure time: 72	smus subspicatus (green algae)): 30 mg/l 2 h	
Toxicity to	Toxicity to microorganisms		EC50 : 135 mg/l Exposure time: 3 h		
Toxicity to icity)	o fish (Chronic tox-	:	NOEC: >= 1,357 Exposure time: 42 Species: Pimepha		
	o daphnia and other vertebrates (Chron-)	:	NOEC: 0,88 mg/l Exposure time: 7 Species: Cerioda	d phnia dubia (water flea)	
12.2 Persister	nce and degradabil	ity			
Compone	ents:				
Grazopre					
Biodegrad	Biodegradability		Result: Not readil Biodegradation: (Exposure time: 28	56 %	
Sodium r	n-dodecyl sulfate:				
Biodegrad	Biodegradability		Result: Readily biodegradable. Biodegradation: 95 % Exposure time: 28 d Method: OECD Test Guideline 301B		
12.3 Bioaccur	mulative potential				
Compone	ents:				
Grazopre	evir:				
Bioaccum	nulation	:		macrochirus (Bluegill sunfish) factor (BCF): 7,62	
Partition o	coefficient: n- ater	:	log Pow: 3,72		
	n-dodecyl sulfate: coefficient: n- ater	:	: log Pow: 0,83		
12.4 Mobility	12.4 Mobility in soil				
Compone	Components:				
Grazopre Distributio	evir: on among environ-	:	log Koc: 4,01		



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mental compartments

12.5 Results of PBT and vPvB assessment

Product:

Assessment

: This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Product:

Assessment

: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product	 Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer.
Contaminated packaging	 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.

SECTION 14: Transport information

14.1 UN number or ID numberADN:ADR:Not regulated as a dangerous good:Not regulated as a dangerous good

RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
ΙΑΤΑ	:	Not regulated as a dangerous good
14.2 UN proper shipping name		
ADN	:	Not regulated as a dangerous good

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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ADR	2	:	Not regulated as	a dangerous good
RID		:	Not regulated as	a dangerous good
IMD	G	:	Not regulated as	a dangerous good
IATA	A	:	Not regulated as	a dangerous good
14.3 Trar	nsport hazard class(es	5)		
ADN	I	:	Not regulated as	a dangerous good
ADR	2	:	Not regulated as	a dangerous good
RID		:	Not regulated as	a dangerous good
IMD	G	:	Not regulated as	a dangerous good
ΙΑΤΑ	A	:	Not regulated as	a dangerous good
14.4 Pac	king group			
ADN	I	:	Not regulated as	a dangerous good
ADR	1	:	Not regulated as	a dangerous good
RID		:	Not regulated as	a dangerous good
IMD	G	:	Not regulated as	a dangerous good
ΙΑΤΑ	A (Cargo)	:	Not regulated as	a dangerous good
ΙΑΤΑ	A (Passenger)	:	Not regulated as	a dangerous good
-	ironmental hazards regulated as a dangero	us go	od	
-	cial precautions for us applicable	ser		
14.7 Mari	itime transport in bulk	acc	ording to IMO inst	ruments
Rem	arks	:	Not applicable for	product as supplied.
	N 15: Regulatory inf			uslation specific for the substance or mix-

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)	:	Not applicable
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).	:	Not applicable
REACH - List of substances subject to authorisation (Annex XIV)	:	Not applicable
Regulation (EC) on substances that deplete the ozone layer	:	Not applicable
Regulation (EU) 2019/1021 on persistent organic pollu- tants (recast)	:	Not applicable
Regulation (EU) No 649/2012 of the European Parlia- ment and the Council concerning the export and import	:	Not applicable

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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of dangerous chemicals

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

Not applicable

Other regulations:

Note the regulation on organization, leadership and participation, chapter 12 on the work of children and young people.

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

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

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information :		Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.				
Full text of H-Statements						
H302		Harmful if swallowed.				
H315	-	Causes skin irritation.				
H318	-	Causes serious eye damage.				
H373	÷	May cause damage to organs through prolonged or repeated				
		exposure if swallowed.				
H412	:	Harmful to aquatic life with long lasting effects.				
Full text of other abbreviat	Full text of other abbreviations					
Acute Tox.	:	Acute toxicity				
Aquatic Chronic	:	Long-term (chronic) aquatic hazard				
Eye Dam.	:	Serious eye damage				
Skin Irrit.	:	Skin irritation				
STOT RE	:	Specific target organ toxicity - repeated exposure				
FOR-2011-12-06-1358	:	Norway. Occupational Exposure limits				
FOR-2011-12-06-1358 /	:	Long term exposure limit				
TWA						
ADN Europeon Agreement concerning the International Carriage of Dengarous Coode by Island						

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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 as-



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sociated with x% growth rate response; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; 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

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/

Classification of the mixture:

STOT RE 2 H373

Classification procedure: Calculation method

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.

NO / EN