

SAFETY DATA SHEET

Based upon Regulation (EC) No 1907/2006, as amended by Regulation (EU) No 2015/830

CREMOR HYDROPHILICUS ANIONICUS FTM-TMF

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

1.1. Product identifier

Product name : CREMOR HYDROPHILICUS ANIONICUS FTM-TMF

Synonyms : ANIONISCHE HYDROFIELE CREME TMF; CREME HYDROPHILE ANIONIQUE FTM

Registration number REACH : Not applicable (mixture)

Product type REACH : Mixture

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1 Relevant identified uses

This raw material is purchased by a pharmacist and after distribution will be delivered to the patient as such or processed in a magistral or officinal preparation

External use

1.2.2 Uses advised against

No uses advised against known

1.3. Details of the supplier of the safety data sheet

Supplier of the safety data sheet

Pannoc NV/SA Lammerdries-oost 23 B-2250 Olen ☎ +32 14 21 70 18 info@pannoc.eu

1.4. Emergency telephone number

During business hours, 8:00-16:30 (CET): +32 14 21 70 18

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classified as dangerous according to the criteria of Regulation (EC) No 1272/2008

Class	Category	Hazard statements	
Aquatic Chronic	category 3	H412: Harmful to aquatic life with long lasting effects.	

2.2. Label elements

Signal word No signal word

H-statements

H412 Harmful to aquatic life with long lasting effects.

P-statements

P273 Avoid release to the environment.

P501 Dispose of contents/container in accordance with local/regional/national/international regulation.

2.3. Other hazards

No other hazards known

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name REACH Registration No	CAS No EC No	Conc. (C)	Classification according to CLP	Note	Remark
tetradecanol	112-72-1	C<0.375 %	Eye Irrit. 2; H319	(1)	Constituent
	204-000-3		Aquatic Chronic 1; H410		
dodecan-1-ol	112-53-8	C≤0.195 %	Eye Irrit. 2; H319	(1)	Constituent
	203-982-0		Aquatic Acute 1; H400		
			Aquatic Chronic 2; H411		

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Technische Schoolstraat 43 A, B-2440 Geel

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g	, ,	56-81-5 200-289-5	C=5 %		(2)	Constituent
- 1	, ,				(1)(8)	Constituent
Ic	01-2119489463-28	287-809-4		Eye Dam. 1; H318		
				Skin Irrit. 2; H315		
				Aquatic Chronic 3; H412		

- (1) For H-statements in full: see heading 16
- (2) Substance with a Community workplace exposure limit
- (8) Specific concentration limits, see heading 16

SECTION 4: First aid measures

4.1. Description of first aid measures

General:

If you feel unwell, seek medical advice.

After inhalation:

Remove the victim into fresh air. Respiratory problems: consult a doctor/medical service.

After skin contact:

Rinse with water. Do not apply (chemical) neutralizing agents without medical advice. Take victim to a doctor if irritation persists.

After eve contact:

Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing. Do not apply (chemical) neutralizing agents without medical advice. Take victim to an ophthalmologist if irritation persists.

After ingestion:

Rinse mouth with water. Do not apply (chemical) neutralizing agents without medical advice. Consult a doctor/medical service if you feel unwell.

4.2. Most important symptoms and effects, both acute and delayed

4.2.1 Acute symptoms

After inhalation:

No effects known.

After skin contact:

No effects known.

After eye contact:

No effects known.

After ingestion:

No effects known.

4.2.2 Delayed symptoms

No effects known.

4.3. Indication of any immediate medical attention and special treatment needed

If applicable and available it will be listed below.

SECTION 5: Firefighting measures

5.1. Extinguishing media

5.1.1 Suitable extinguishing media:

Small fire: Quick-acting ABC powder extinguisher, Quick-acting BC powder extinguisher, Quick-acting class B foam extinguisher, Quick-acting CO2 extinguisher. Major fire: Class B foam (alcohol-resistant), Water spray if puddle cannot expand.

5.1.2 Unsuitable extinguishing media:

 $Small\ fire:\ Water\ (quick-acting\ extinguisher,\ reel);\ risk\ of\ puddle\ expansion.$

Major fire: Water; risk of puddle expansion.

5.2. Special hazards arising from the substance or mixture

Upon combustion: formation of CO, CO2 and small quantities of sulphur oxides.

5.3. Advice for firefighters

5.3.1 Instructions:

Take account of environmentally hazardous firefighting water. Use water moderately and if possible collect or contain it.

5.3.2 Special protective equipment for fire-fighters:

Gloves (EN 374). Protective clothing (EN 14605 or EN 13034). Heat/fire exposure: compressed air apparatus (EN 136 + EN 137).

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

No naked flames.

6.1.1 Protective equipment for non-emergency personnel

See heading 8.2

6.1.2 Protective equipment for emergency responders

Gloves (EN 374). Protective clothing (EN 14605 or EN 13034).

Suitable protective clothing

See heading 8.2

6.2. Environmental precautions

Contain released product. Dam up the liquid spill. Prevent soil and water pollution. Prevent spreading in sewers.

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6.3. Methods and material for containment and cleaning up

Scoop solid spill into closing containers. Contaminated surfaces: clean (treat). Carefully collect the spill/leftovers. Take collected spill to manufacturer/competent authority. Wash clothing and equipment after handling.

6.4. Reference to other sections

See heading 13.

SECTION 7: Handling and storage

The information in this section is a general description. If applicable and available, exposure scenarios are attached in annex. Always use the relevant exposure scenarios that correspond to your identified use.

7.1. Precautions for safe handling

Keep away from naked flames/heat. Observe normal hygiene standards. Do not discharge the waste into the drain. Keep container tightly closed.

7.2. Conditions for safe storage, including any incompatibilities

7.2.1 Safe storage requirements:

Storage temperature: 15 °C - 25 °C. Store in a dark area. Meet the legal requirements.

7.2.2 Keep away from:

Heat sources.

7.2.3 Suitable packaging material:

Polypropylene.

7.2.4 Non suitable packaging material:

No data available

7.3. Specific end use(s)

If applicable and available, exposure scenarios are attached in annex. See information supplied by the manufacturer.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 Occupational exposure

a) Occupational exposure limit values

If limit values are applicable and available these will be listed below.

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cérine (brouillard) Time-weighted average exposure limit 8 h		10 mg/m ³
France		
Glycérine (aérosols de)	Time-weighted average exposure limit 8 h (VL: Valeur non réglementaire indicative)	10 mg/m ³
Germany		
Glycerin	Time-weighted average exposure limit 8 h (TRGS 900)	200 mg/m ³
UK		
UK		

b) National biological limit values

If limit values are applicable and available these will be listed below.

8.1.2 Sampling methods

Product name	Test	Number
Glycerin Mist (Particulates)	NIOSH	0600

8.1.3 Applicable limit values when using the substance or mixture as intended

If limit values are applicable and available these will be listed below.

8.1.4 Threshold values

DNEL/DMEL - Workers

tetradecanol

Effect level (DNEL/DMEL)	Туре	Value	Remark
DNEL	Long-term systemic effects inhalation	313 mg/m³	
	Long-term local effects inhalation	178 mg/m³	
	Long-term systemic effects dermal	89 mg/kg bw/day	

dodecan-1-ol

Effect level (DNEL/DMEL)	Туре	Value	Remark
DNEL	Long-term systemic effects inhalation	313 mg/m³	
	Long-term local effects dermal	155 mg/m³	
	Long-term systemic effects dermal	89 mg/kg bw/day	

glycerol

Effect level (DNEL/DMEL) Type		Value	Remark
DNEL Long-t	-term local effects inhalation	56 mg/m³	

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	esters, sodium salts

Effect level (DNEL/DMEL)	Туре	Value	Remark
DNEL	Long-term systemic effects inhalation	285 mg/m ³	
	Long-term systemic effects dermal	4060 mg/kg hw/day	

DNEL/DMEL - General population

tetradecanol

Effect level (DNEL/DMEL)	Туре	Value	Remark
DNEL	Long-term systemic effects inhalation	77 mg/m ³	
	Long-term systemic effects dermal	44.4 mg/kg bw/day	
	Long-term systemic effects oral	44.4 mg/kg bw/day	

dodecan-1-ol

Effect level (DNEL/DMEL)	Туре	Value	Remark
DNEL	Long-term systemic effects inhalation	77 mg/m³	
	Long-term systemic effects dermal	44.5 mg/kg bw/day	
	Long-term systemic effects oral	44.5 mg/m ³	

glycerol

Effect level (DNEL/DMEL)	Туре	Value	Remark
DNEL	Long-term local effects inhalation	33 mg/m ³	
	Long-term systemic effects oral	229 mg/kg bw/day	

sulfuric acid, mono C12-14-alkyl esters, sodium salts

Effect level (DNEL/DMEL)	Туре	Value	Remark
DNEL	Long-term systemic effects inhalation	85 mg/m³	
	Long-term systemic effects dermal	2440 mg/kg bw/day	
	Long-term systemic effects oral	24 mg/kg bw/day	

PNEC tetradecanol

tetradecanor		
Compartments	Value	Remark
Fresh water	0.001 mg/l	
Marine water	0 mg/l	
Fresh water sediment	2.14 mg/kg sediment dw	
Marine water sediment	0.214 mg/kg sediment dw	
Soil	0.428 mg/kg soil dw	

dodecan-1-ol

Compartments	Value	Remark
Fresh water	0.001 mg/l	
Marine water	0 mg/l	
Fresh water sediment	0.666 mg/kg sediment dw	
Marine water sediment	0.067 mg/kg sediment dw	
Soil	0.132 mg/kg soil dw	

glycerol

Compartments	Value	Remark
Fresh water	0.885 mg/l	
Marine water	0.088 mg/l	
Aqua (intermittent releases)	8.85 mg/l	
STP	1000 mg/l	
Fresh water sediment	3.3 mg/kg sediment dw	
Marine water sediment	0.33 mg/kg sediment dw	
Soil	0.141 mg/kg soil dw	
ulfuria acid mana C12 14 alloul actors codium calta	•	•

sulfuric acid. mono C12-14-alkyl esters, sodium salts

munic dela, mono eta 14 dikyi esters, sodiam satis					
Compartments	Value	Remark			
Fresh water	0.131 mg/l				
Salt water	0.013 mg/l				
Fresh water (intermittent releases)	0.036 mg/l				
STP	1.35 mg/l				
Fresh water sediment	4.61 mg/kg sediment dw				
Marine water sediment	0.461 mg/kg sediment dw				
Soil	0.846 mg/kg soil dw				

8.1.5 Control banding

If applicable and available it will be listed below.

8.2. Exposure controls

The information in this section is a general description. If applicable and available, exposure scenarios are attached in annex. Always use the relevant exposure scenarios that correspond to your identified use.

8.2.1 Appropriate engineering controls

Keep away from naked flames/heat.

8.2.2 Individual protection measures, such as personal protective equipment

Observe normal hygiene standards. Do not eat, drink or smoke during work.

a) Respiratory protection:

Respiratory protection not required in normal conditions.

b) Hand protection:

Protective gloves against chemicals (EN 374).

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c) Eye protection:

Eye protection not required in normal conditions.

d) Skin protection:

Protective clothing (EN 14605 or EN 13034).

8.2.3 Environmental exposure controls:

See headings 6.2, 6.3 and 13

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical form	Paste
	Homogeneous ointment
Odour	No data available on odour
Odour threshold	No data available in the literature
Colour	White
Particle size	No data available in the literature
Explosion limits	No data available in the literature
Flammability	Not classified as flammable
Log Kow	Not applicable (mixture)
Dynamic viscosity	100000 mPa.s - 300000 mPa.s ; room temperature
Kinematic viscosity	No data available in the literature
Melting point	No data available in the literature
Boiling point	No data available
Evaporation rate	No data available
Relative vapour density	No data available in the literature
Vapour pressure	No data available in the literature
Solubility	No data available in the literature
Relative density	No data available in the literature
Decomposition temperature	No data available in the literature
Auto-ignition temperature	No data available in the literature
Flash point	No data available in the literature
Explosive properties	No chemical group associated with explosive properties
Oxidising properties	No chemical group associated with oxidising properties
рН	6.0 - 8.0

9.2. Other information

Surface tension	No data available in the literature
Absolute density	No data available in the literature

SECTION 10: Stability and reactivity

10.1. Reactivity

Heating increases the fire hazard.

10.2. Chemical stability

No data available.

10.3. Possibility of hazardous reactions

No data available.

10.4. Conditions to avoid

Precautionary measures

Keep away from naked flames/heat.

10.5. Incompatible materials

No data available.

10.6. Hazardous decomposition products

Upon combustion: formation of CO, CO2 and small quantities of sulphur oxides.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

11.1.1 Test results

Acute toxicity

CREMOR HYDROPHILICUS ANIONICUS FTM-TMF

No (test)data on the mixture available

Judgement is based on the relevant ingredients

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tetrac	lecanol

Route of exposure	Parameter	Method	Value	Exposure time	Species	Value	Remark
						determination	
Oral	LD50	OECD 401	> 2000 mg/kg bw		Rat (male / female)	Experimental value	
Dermal	LD50		8000 mg/kg bw		Rabbit (male / female)	Experimental value	
Inhalation (vapours)	LC50		> 1.5 mg/l air	1 h	Rat (male / female)	Experimental value	

glycerol

Route of exposure	Parameter	Method	Value	Exposure time	Species	Value	Remark
						determination	
Oral	LD50	OECD 401	27200 mg/kg		Rat (female)	Experimental value	
Dermal	LD50		56750 mg/kg	4 day(s)	Guinea pig (male / female)	Experimental value	
Inhalation (vapours)	LC50	OECD 403	> 2.75 mg/l	4 h	,,	Converted value	
Inhalation						Expert judgement	Not classified

sulfuric acid, mono C12-14-alkyl esters, sodium salts

Route of exposure	Parameter	Method	Value	Exposure time	Species	Value	Remark
						determination	
Oral	LD50	EU Method B.1 tris	500 mg/kg bw -		Rat (male /	Experimental value	
			2000 mg/kg bw		female)		
Dermal	LD50	OECD 402	> 2000 mg/kg bw	24 h	Rat (male /	Read-across	
					female)		
Inhalation						Data waiving	

Conclusion

Not classified for acute toxicity

Corrosion/irritation

CREMOR HYDROPHILICUS ANIONICUS FTM-TMF

No (test)data on the mixture available

Judgement is based on the relevant ingredients

tetradecanol

Route of exposure	Result	Method	Exposure time	Time point	Species	Value	Remark
						determination	
Eye	Irritating	OECD 405		1; 24; 48; 72 hours		Experimental value	Single treatment
Skin	Not irritating	Equivalent to OECD 404	4 h	1; 24; 48; 72 hours		Experimental value	

dodecan-1-ol

Route of exposure	Result	Method	Exposure time	Time point	 Value determination	Remark
Eye	Irritating	Equivalent to OECD 405	24 h	24 hours	l '	Single treatment without rinsing

glycerol

Route of exposure	Result	Method	Exposure time	Time point	Species	Value	Remark
						determination	
Eye	Not irritating			1; 24; 72 hours		Experimental value	Single treatment
Skin	Not irritating	OECD 404	24 h			Experimental value	

sulfuric acid, mono C12-14-alkyl esters, sodium salts

Route of exposure	Result	Method	Exposure time	Time point		Value determination	Remark
Eye	Irritating	Equivalent to OECD 405		24; 48; 72 hours	Rabbit		30% aqueous solution
Eye	Serious eye damage; category 1					Expert judgement	Pure substance
Skin	Irritating	Equivalent to OECD 404	24 h	24; 72 hours	Rabbit	Read-across	

Conclusion

Not classified as irritating to the skin

Not classified as irritating to the eyes

Not classified as irritating to the respiratory system

Respiratory or skin sensitisation

CREMOR HYDROPHILICUS ANIONICUS FTM-TMF

No (test)data on the mixture available

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Judgement is based on the relevant ingredients

tetradecanol

Route of exposure	Result	Method	 Observation time point	Species	Value determination	Remark
Skin	Not sensitizing	OECD 406	24; 48 hours	Guinea pig (female)	Experimental value	

glycerol

Route of exposure	Result	Method	Exposure time	Observation time point	Species	Value determination	Remark
Skin	Not sensitizing	Human observation			Human	Experimental value	

sulfuric acid, mono C12-14-alkyl esters, sodium salts

Route of exposure	Result	Method	 Observation time point	Species	Value determination	Remark
Skin		Guinea pig maximisation test		Guinea pig	Read-across	

Conclusion

Not classified as sensitizing for skin Not classified as sensitizing for inhalation

Specific target organ toxicity

CREMOR HYDROPHILICUS ANIONICUS FTM-TMF

No (test)data on the mixture available

Judgement is based on the relevant ingredients

tetradecanol

Route of exposure	Parameter	Method	Value	Organ	Effect	Exposure time	- •	Value determination
Oral (diet)	NOAEL		> 4567 mg/kg bw		No effect	13 week(s)	Rat (female)	Read-across
Oral (diet)	NOAEL		> 4257 mg/kg bw		No effect	13 week(s)	Rat (male)	Read-across

glycerol

Route of exposure	Parameter	Method	Value	Organ	Effect	Exposure time		Value determination
Oral (diet)	NOAEL	Equivalent to OECD 452	8000 mg/kg bw/day - 10000 mg/kg bw/day		No effect	2 year(s)	Rat (male / female)	Experimental value
Dermal	NOEL	Subchronic toxicity test	5040 mg/kg bw/day		No effect	45 weeks (8h / day, 5 days / week)	Rabbit	Experimental value
Inhalation (aerosol)	NOAEL	Equivalent to OECD 413	167 mg/m³ air	Respiratory tract	No effect	13 weeks (6h / day, 5 days / week)	Rat (male / female)	Experimental value

sulfuric acid, mono C12-14-alkyl esters, sodium salts

Route of exposure	Parameter	Method	Value	Organ	Effect	Exposure time	Species	Value
								determination
Oral (diet)	_	Equivalent to OECD 408	470 mg/kg bw/day - 506 mg/kg bw/day		No effect	13 weeks (7 days / week)	Rat (male / female)	Read-across
Dermal	NOAEL	Equivalent to OECD 411	400 mg/kg bw			13 weeks (2 times / week)		Experimental value

Conclusion

Not classified for subchronic toxicity

Mutagenicity (in vitro)

CREMOR HYDROPHILICUS ANIONICUS FTM-TMF

No (test)data on the mixture available

Judgement is based on the relevant ingredients

<u>tetradecanol</u>

Result	Method	Test substrate	Effect	Value determination	Remark
Negative with metabolic	OECD 471	Bacteria (S.typhimurium)		Experimental value	
activation, negative					
without metabolic					
activation					

glycerol

Result	Method	Test substrate	Effect	Value determination	Remark
Negative with metabolic	Equivalent to OECD 471	Bacteria (S.typhimurium)	No effect	Experimental value	
activation, negative					
without metabolic					
activation					

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sulfuric acid, mono C12-14-alkyl esters, sodium salts

Result	Method	Test substrate Effect		Value determination	Remark
Negative	OECD 471	Bacteria (S.typhimurium)		Experimental value	
Negative	Equivalent to OECD 476	Mouse (lymphoma L5178Y		Experimental value	
		cells)			

Mutagenicity (in vivo)

CREMOR HYDROPHILICUS ANIONICUS FTM-TMF

No (test)data on the mixture available

Judgement is based on the relevant ingredients

<u>tetradecanol</u>

Result	Method	Exposure time	Test substrate	Organ	Value determination
Negative	Equivalent to OECD		Mouse (male / female)	Bone marrow	Read-across
	474				

sulfuric acid, mono C12-14-alkyl esters, sodium salts

Result	Method	Exposure time	Test substrate	Organ	Value determination
Negative	Equivalent to OECD		Rat (male / female)	Bone marrow	Read-across
	475				

Conclusion

Not classified for mutagenic or genotoxic toxicity

Carcinogenicity

CREMOR HYDROPHILICUS ANIONICUS FTM-TMF

No (test)data on the mixture available

Judgement is based on the relevant ingredients

tetradecanol

Route of	Parameter	Method	Value	Exposure time	Species	Effect	Organ	Value
exposure								determination
Intraperitone				5 day(s)	Mouse	No carcinogenic		Experimental
al						effect		value

glycerol

Route of	Parameter	Method	Value	Exposure time	Species	Effect	Organ	Value
exposure								determination
Oral		Carcinogenic		2 year(s)	Rat (male /	No carcinogenic		Experimental
		toxicity study			female)	effect		value

sulfuric acid, mono C12-14-alkyl esters, sodium salts

Route of	Parameter	Method	Value	Exposure time	Species	Effect	Organ	Value
exposure								determination
Oral	NOEL	Equivalent to	> 1125 mg/kg	104 weeks (7 days /	Rat (male /	No carcinogenic		Read-across
		OECD 453	bw/day	week)	female)	effect		

Conclusion

Not classified for carcinogenicity

Reproductive toxicity

CREMOR HYDROPHILICUS ANIONICUS FTM-TMF

No (test)data on the mixture available $\,$

Judgement is based on the relevant ingredients

tetradecanol

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	Parameter	Method	Value	Exposure time	Species	Effect	1 0	Value determination
Developmental toxicity	NOAEL	Equivalent to OECD 422	2000 mg/kg bw/day	41 day(s) - 54 day(s)	Rat (male / female)	No effect		Read-across
Maternal toxicity	NOAEL	Equivalent to OECD 422	2000 mg/kg bw/day	41 day(s) - 54 day(s)	Rat (female)	No effect		Read-across
Effects on fertility	NOAEL (P)		1127 mg/kg bw/day	13 week(s)	Rat (male)	No effect		Read-across
	NOAEL (P)		1243 mg/kg bw/day	13 week(s)	Rat (female)	No effect		Read-across

glycerol

	Parameter	Method	Value	Exposure time	Species	Effect	- 0-	Value determination
Developmental toxicity	NOAEL	Equivalent to OECD 414	1310 mg/kg bw/day	6 days (gestation, daily) - 15 days (gestation, daily)	Rat	No effect	Foetus	Experimental value
Maternal toxicity	NOAEL	Equivalent to OECD 414	1310 mg/kg bw/day	6 days (gestation, daily) - 15 days (gestation, daily)	Rat (female)	No effect		Experimental value
Effects on fertility	Dose level		2000 mg/kg bw/day	8 weeks (daily) - 12 weeks (daily)	Rat (male / female)	No effect		Experimental value

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sulfuric acid, mono C12-14-alkyl esters, sodium salts

	Parameter	Method	Value	Exposure time	Species	Effect	- 0.	Value determination
Developmental toxicity	NOEL	Equivalent to OECD 414	250 mg/kg bw/day	10 days (1x / day)	Rat	No effect		Experimental value
Maternal toxicity	NOEL	Equivalent to OECD 414	250 mg/kg bw/day	10 days (1x / day)	Rat	No effect		Experimental value

Conclusion

Not classified for reprotoxic or developmental toxicity

Toxicity other effects

CREMOR HYDROPHILICUS ANIONICUS FTM-TMF

No (test)data on the mixture available

Chronic effects from short and long-term exposure

CREMOR HYDROPHILICUS ANIONICUS FTM-TMF

No effects known.

SECTION 12: Ecological information

12.1. Toxicity

CREMOR HYDROPHILICUS ANIONICUS FTM-TMF

No (test)data on the mixture available

Classification of the mixture is based on the relevant ingredients

<u>tetradecanol</u>

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	Parameter	Method	Value	Duration	Species		Fresh/salt water	Value determination
Acute toxicity fishes	LC50	OECD 203	> 1 mg/l	96 h	Oncorhynchus mykiss	Semi-static system	Fresh water	Experimental value
Acute toxicity crustacea	EC50	OECD 202	3.2 mg/l	48 h	Daphnia magna	Semi-static system	Fresh water	Experimental value
Toxicity algae and other aquatic plants	EL50	Equivalent to OECD 201	> 10 mg/l	96 h	Desmodesmus subspicatus	Static system	Fresh water	Experimental value
Long-term toxicity fish	NOEC	OECD 210	0.26 mg/l	33 day(s)	Pimephales promelas	Flow- through system	Fresh water	Experimental value
Long-term toxicity aquatic crustacea	NOEC	OECD 211	1.6 μg/l	21 day(s)	Daphnia magna	Semi-static system	Fresh water	Experimental value

	Parameter	Method	Value	Duration	Species	Value determination
Toxicity soil macro-organisms	EC50	OECD 207	> 1000 mg/kg soil	72 h	Caenorhabditis	Experimental value
			dw		elegans	

d	od	eca	n-:	<u>1-ol</u>	

	Parameter	Method	Value	Duration	Species		Fresh/salt water	Value determination
Acute toxicity fishes	LC50	US EPA	1.01 mg/l	96 h	Pimephales promelas	Flow- through system	Fresh water	Experimental value
Acute toxicity crustacea	EC50	OECD 202	0.765 mg/l	48 h	Daphnia magna	Static system	Fresh water	Experimental value; GLP
Toxicity algae and other aquatic plants	ErC50	OECD 201	0.66 mg/l	72 h	Desmodesmus subspicatus	Static system	Fresh water	Experimental value; GLP
Long-term toxicity aquatic crustacea	NOEC	OECD 211	0.014 mg/l	21 day(s)	Daphnia magna	Semi-static system	Fresh water	Experimental value; GLP

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CETOL								
	Parameter	Method	Value	Duration	Species		Fresh/salt water	Value determination
Acute toxicity fishes	LC50		54000 mg/l	96 h	Salmo gairdneri	Static system	Fresh water	Experimental value; Lethal
Acute toxicity crustacea	EC50		> 10000 mg/l	24 h	Daphnia magna	Static system	Fresh water	Experimental value; Locomotor effect
Toxicity algae and other aquatic plants	EC0		> 10000 mg/l	8 day(s)	Scenedesmus quadricauda	Static system	Fresh water	Experimental value; Turbid water
Long-term toxicity fish								Data waiving
Long-term toxicity aquatic crustacea								Data waiving
Toxicity aquatic micro- organisms	Toxicity threshold		> 10000 mg/l	16 h	Pseudomonas putida	Static system	Fresh water	Experimental value; Growth

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sulfuric acid, mono C12-14-alkyl esters, sodium salts

	Parameter	Method	Value	Duration	Species		Fresh/salt water	Value determination
Acute toxicity fishes	LC50	OECD 203	3.6 mg/l	96 h	Oncorhynchus mykiss	Semi-static system	Fresh water	Experimental value; GLP
Acute toxicity crustacea	EC50	EU Method	4.7 mg/l	48 h	Daphnia magna	Static system	Fresh water	Experimental value; GLP
Toxicity algae and other aquatic plants	NOEC	EU Method C.3	0.6 mg/l	72 h	Desmodesmus subspicatus	Static system	Fresh water	Experimental value; Growth rate
Long-term toxicity fish	NOEC		≥ 1.367 mg/l	42 day(s)	Pimephales promelas	Flow- through system	Fresh water	Read-across; Growth
Long-term toxicity aquatic crustacea	NOEC	Other	0.14 mg/l	21 day(s)	Daphnia magna	Static system	Fresh water	Weight of evidence; Lethal

Conclusion

Harmful to aquatic life with long lasting effects.

12.2. Persistence and degradability

 $\underline{\mathsf{tetradecanol}}$

Biodegradation water

loughdudion water					
Method	Value	Duration	Value determination		
ISO 10708	92 %	28 day(s)	Experimental value		

Phototransformation air (DT50 air)

Method	Value	Conc. OH-radicals	Value determination
AOPWIN v1.91	18.3 h	500000 /cm³	Calculated value

Biodegradation soil

ſ	Method	Value	Duration	Value determination
(OECD 301D: Closed Bottle Test	87 %	28 day(s)	Experimental value

dodecan-1-ol

Biodegradation water

Method Value Duration V

IVIE	etnoa	Value	Duration	Value determination
OE	CD 301B: CO2 Evolution Test	87.5 %	28 day(s)	Experimental value

glycerol

Biodegradation water

Method	Value	Duration	Value determination
	94 %	24 h	Experimental value

sulfuric acid, mono C12-14-alkyl esters, sodium salts

Biodegradation water

Method	Value	Duration	Value determination
OECD 301D: Closed Bottle Test	90 % - 100 %; GLP	28 day(s)	Experimental value

Conclusion

Contains readily biodegradable component(s)

12.3. Bioaccumulative potential

CREMOR HYDROPHILICUS ANIONICUS FTM-TMF

Log Kow

Method	Remark	Value	Temperature	Value determination
	Not applicable (mixture)			

tetradecanol

BCF fishes

Parameter	Method	Value	Duration	Species	Value determination
BCF	BCFBAF v3.01	26		Pisces	QSAR

Log Kow

	Method	Remark	Value	Temperature	Value determination
	ASTM E1147			25 °C	Experimental value
doc	lecan-1-ol				

Log Kow

Method	Remark	Value	Temperature	Value determination
OECD 117			23 °C	Experimental value

glycerol

	W
LOg	KOW

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Method	Remark	Value	Temperature	Value determination
Equivalent to OECD 107		I-1 /5	25 °C	Experimental value

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sulfuric acid, mono C12-14-alkyl esters, sodium salts

Log Kow

Method	Remark	Value	Temperature	Value determination
OECD 123		0.78	22 °C	Experimental value

Conclusion

Contains bioaccumulative component(s)

12.4. Mobility in soil

tetradecanol

(log) Koc

Parameter	Method	Value	Value determination
log Koc	OECD 121	4.53	Experimental value

dodecan-1-ol

(log) Koc

Parameter	Method	Value	Value determination
log Koc	OECD 121	3.71	Experimental value

glycerol

Volatility (Henry's Law constant H)

Value	Method	Temperature	Remark	Value determination
0.000000006 atm m ³ /mol		25 °C		Calculated value

sulfuric acid, mono C12-14-alkyl esters, sodium salts

(log) Koc

Parameter	Method	Value	Value determination
log Koc	Other	3.13 - 3.19	Read-across

Percent distribution

Method	Fraction air	 Fraction sediment	Fraction soil	Fraction water	Value determination
Mackay level I	0.003 %			100 %	Calculated value

Conclusion

Contains component(s) that adsorb(s) into the soil

12.5. Results of PBT and vPvB assessment

Does not contain component(s) that meet(s) the criteria of PBT and/or vPvB as listed in Annex XIII of Regulation (EC) No 1907/2006.

12.6. Other adverse effects

CREMOR HYDROPHILICUS ANIONICUS FTM-TMF

Greenhouse gases

None of the known components is included in the list of fluorinated greenhouse gases (Regulation (EU) No 517/2014)

Ozone-depleting potential (ODP)

Not classified as dangerous for the ozone layer (Regulation (EC) No 1005/2009)

sulfuric acid, mono C12-14-alkyl esters, sodium salts

Groundwater

Groundwater pollutant

SECTION 13: Disposal considerations

The information in this section is a general description. If applicable and available, exposure scenarios are attached in annex. Always use the relevant exposure scenarios that correspond to your identified use.

13.1. Waste treatment methods

13.1.1 Provisions relating to waste

European Union

Hazardous waste according to Directive 2008/98/EC, as amended by Regulation (EU) No 1357/2014 and Regulation (EU) No 2017/997. Waste material code (Directive 2008/98/EC, Decision 2000/0532/EC).

07 05 04* (wastes from the MFSU of pharmaceuticals: other organic solvents, washing liquids and mother liquors). Depending on branch of industry and production process, also other waste codes may be applicable.

13.1.2 Disposal methods

Remove waste in accordance with local and/or national regulations. Hazardous waste shall not be mixed together with other waste. Different types of hazardous waste shall not be mixed together if this may entail a risk of pollution or create problems for the further management of the waste. Hazardous waste shall be managed responsibly. All entities that store, transport or handle hazardous waste shall take the necessary measures to prevent risks of pollution or damage to people or animals. Do not discharge into drains or the environment. Dispose of at authorized waste collection point.

13.1.3 Packaging/Container

European Union

Waste material code packaging (Directive 2008/98/EC).

15 01 10* (packaging containing residues of or contaminated by dangerous substances).

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SECTION 14: Transport information

Road (ADR), Rail (RID), Inland waterways (ADN), Sea (IMDG/IMSBC), Air (ICAO-TI/IATA-DGR)

14.1. UN number	
Transport	Not subject
14.2. UN proper shipping name	
14.3. Transport hazard class(es)	
Hazard identification number	
Class	
Classification code	
14.4. Packing group	
Packing group	
Labels	
14.5. Environmental hazards	
Environmentally hazardous substance mark	no
14.6. Special precautions for user	
Special provisions	
Limited quantities	
14.7. Transport in bulk according to Annex II of Marpol and the IBC Code	
Anney II of MARPOL 73/78	Not applicable, based on available data

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture **European legislation:**

VOC content Directive 2010/75/EU

VOC content	Remark	
	No data available	

European drinking water standards (Directive 98/83/EC)

sulfuric acid, mono C12-14-alkyl esters, sodium salts

Parameter	Parametric value	Note Reference		
Sodium	200 mg/l		200 mg/l Listed in Annex I, Part C, of Directive 98/83/EC on the quality	
			water intended for human consumption.	

National legislation Belgium
CREMOR HYDROPHILICUS ANIONICUS FTM-TMF

No data available

National legislation The Netherlands

CREMOR HYDROPHILICUS ANIONICUS FTM-TMF

Waterbezwaarlijkheid A (3); Algemene Beoordelingsmethodiek (ABM)

National legislation France
CREMOR HYDROPHILICUS ANIONICUS FTM-TMF

No data available

National legislation Germany
CREMOR HYDROPHILICUS ANIONICUS FTM-TMF

	CREMON TITUROT TILLEGO ANTONICOS TAM TIMI				
	WGK	1; Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen (AwSV) - 18. April 2017			
<u>tetradecanol</u>					
	TA-Luft	5.2.5/I			
٤	glycerol				
	TA-Luft	5.2.5			
	TRGS900 - Risiko der	Glycerin; Y; Risiko der Fruchtschädigung braucht bei Einhaltung des Arbeitsplatzgrenzwertes und des biologischen			
	Fruchtschädigung	Grenzwertes nicht befürchtet zu werden			
<u>sulfuric acid, mono C12-14-alkyl esters, sodium salts</u>					
	TA 1f+	r 3 1			

National legislation United Kingdom
CREMOR HYDROPHILICUS ANIONICUS FTM-TMF

No data available

Other relevant data CREMOR HYDROPHILICUS ANIONICUS FTM-TMF

No data available

15.2. Chemical safety assessment

No chemical safety assessment has been conducted for the mixture.

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SECTION 16: Other information

Full text of any H-statements referred to under heading 3:

H302 Harmful if swallowed.

H315 Causes skin irritation.

H318 Causes serious eye damage.

H319 Causes serious eye irritation.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.
H411 Toxic to aquatic life with long lasting effects.
H412 Harmful to aquatic life with long lasting effects.

(*) INTERNAL CLASSIFICATION BY BIG

ADI Acceptable daily intake

AOEL Acceptable operator exposure level

CLP (EU-GHS) Classification, labelling and packaging (Globally Harmonised System in Europe)

DMEL Derived Minimal Effect Level
DNEL Derived No Effect Level
EC50 Effect Concentration 50 %

ErC50 EC50 in terms of reduction of growth rate

LC50 Lethal Concentration 50 %

LD50 Lethal Dose 50 %

NOAEL No Observed Adverse Effect Level NOEC No Observed Effect Concentration

OECD Organisation for Economic Co-operation and Development

PBT Persistent, Bioaccumulative & Toxic
PNEC Predicted No Effect Concentration
STP Sludge Treatment Process

vPvB very Persistent & very Bioaccumulative

M-factor

dodecan-1-ol 1 Acute BIG	G

Specific concentration limits CLP

sulfuric acid, mono C12-14-alkyl esters, sodium salts	10 % ≤ C < 20 %	Eye Irrit. 2; H319	ECHA
	C ≥ 20 %	Eye Dam. 1; H318	ECHA

The information in this safety data sheet is based on data and samples provided to BIG. The sheet was written to the best of our ability and according to the state of knowledge at that time. The safety data sheet only constitutes a guideline for the safe handling, use, consumption, storage, transport and disposal of the substances/preparations/mixtures mentioned under point 1. New safety data sheets are written from time to time. Only the most recent versions may be used. Unless indicated otherwise word for word on the safety data sheet, the information does not apply to substances/preparations/mixtures in purer form, mixed with other substances or in processes. The safety data sheet offers no quality specification for the substances/preparations/mixtures in question. Compliance with the instructions in this safety data sheet does not release the user from the obligation to take all measures dictated by common sense, regulations and recommendations or which are necessary and/or useful based on the real applicable circumstances. BIG does not guarantee the accuracy or exhaustiveness of the information provided and cannot be held liable for any changes by third parties. This safety data sheet is only to be used within the European Union, Switzerland, Iceland, Norway and Liechtenstein. Any use outside of this area is at your own risk. Use of this safety data sheet is subject to the licence and liability limiting conditions as stated in your BIG licence agreement or when this is failing the general conditions of BIG. All intellectual property rights to this sheet are the property of BIG and its distribution and reproduction are limited. Consult the mentioned agreement/conditions for details.

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