

SAFETY DATA SHEET

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

CREMOR CETOMACROGOLIS PH 5 FTM-TMF

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

1.1. Product identifier

Product name : CREMOR CETOMACROGOLIS PH 5 FTM-TMF

Synonyms : CREME AU CETOMACROGOL TAMPONNEE FTM; GEBUFFERDE CETOMACROGOLCRÈME TMF

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	
Eye Irrit.	category 2	H319: Causes serious eye irritation.	
Aquatic Chronic	category 3	H412: Harmful to aquatic life with long lasting effects.	

2.2. Label elements

Signal word



H-statements	
H319	Causes serious eye irritation.
H412	Harmful to aquatic life with long lasting effects.
P-statements	

P101 If medical advice is needed, have product container or label at hand.
P102 Keep out of reach of children.

Neer out of reach of children.

Warning

P280 Wear eye protection

Created by: Brandweerinformatiecentrum voor gevaarlijke stoffen vzw (BIG)

P264 Wash hands thoroughly after handling.
P273 Avoid release to the environment.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.

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Continue rinsing.

P337 + P313 If eye irritation persists: Get medical advice/attention.

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

2.3. Other hazards

http://www.big.be

No other hazards known

Technische Schoolstraat 43 A, B-2440 Geel

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134-17915-677-en

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	112-72-1 204-000-3	C<0.18 %	Eye Irrit. 2; H319 Aquatic Chronic 1; H410	(1)	Constituent
white mineral oil (petroleum) 01-2119487078-27	8042-47-5 232-455-8	C=6 %		(2)	Constituent
alcohols, C16-18, ethoxylated (EO 20)	68439-49-6	C=1.8 %	Acute Tox. 4; H302 Eye Dam. 1; H318 Aquatic Acute 1; H400 Aquatic Chronic 2; H411	(1)	Constituent

⁽¹⁾ For H-statements in full: 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 eye contact:

Rinse immediately with plenty of 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:

Irritation of the eye tissue.

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 (not alcohol-resistant).

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 phosphorus 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). Safety glasses (EN166). Protective clothing (EN 14605 or EN 13034). Heat/fire exposure: compressed air apparatus (EN 136 + EN 137).

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⁽²⁾ Substance with a Community workplace exposure limit

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). Safety glasses (EN166). 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.

6.3. Methods and material for containment and cleaning up

Scoop solid spill into closing containers. Carefully collect the spill/leftovers. Clean contaminated surfaces with a soap solution. 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.

Belgium

Huiles minérales (brouillards)	Time-weighted average exposure limit 8 h	5 mg/m³
	Short time value	10 mg/m ³
The Netherlands		
Olienevel (minerale olie) Time-weighted average exposure limit 8 h (Public occupational exposure 5 limit value)		sure 5 mg/m³
Germany		
Weißes Mineralöl (Erdöl)	Time-weighted average exposure limit 8 h (TRGS 900)	5 mg/m³
USA (TLV-ACGIH)		
Mineral oil, pure, highly and severely refined Time-weighted average exposure limit 8 h (TLV - Adopted Value) 5		5 mg/m³ (I)

(I): Inhalable fraction

b) National biological limit values

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

8.1.2 Sampling methods

If applicable and available it will be listed below.

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

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tetradecanol

Effect level (DNEL/DMEL)	Туре	Value	Remark
DNEL	Long-term systemic effects inhalation	313 mg/m ³	
	Long-term local effects inhalation	178 mg/m³	
	Long-term systemic effects dermal	89 mg/kg bw/day	

white mineral oil (petroleum)

Effect level (DNEL/DMEL)	Туре	Value	Remark
DNEL	Long-term systemic effects inhalation	160 mg/m³	
	Long-term systemic effects dermal	220 mg/kg hw/day	

DNEL/DMEL - General population tetradecanol

Effect level (DNEL/DMEL)	Туре	Value	Remark
DNEL	Long-term systemic effects inhalation	77 mg/m³	
	Long-term systemic effects dermal	44.4 mg/kg bw/day	
	Long-term systemic effects oral	44.4 mg/kg bw/day	

white mineral oil (petroleum)

Effect level (DNEL/DMEL)	Туре	Value	Remark
DNEL	Long-term systemic effects inhalation	35 mg/m ³	
	Long-term systemic effects dermal	93 mg/kg bw/day	
	Long-term systemic effects oral	40 mg/kg bw/day	

PNEC tetradecanol

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	

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).

c) Eye protection:

Safety glasses (EN166).

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	50000 mPa.s - 250000 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	

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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	4.5 - 5.5

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. Acid reaction.

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 phosphorus oxides.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

11.1.1 Test results

Acute toxicity

CREMOR CETOMACROGOLIS PH 5 FTM-TMF

No (test)data on the mixture available

Judgement is based on the relevant ingredients

tetradecanol

Parameter	Method	Value	Exposure time			Remark
					determination	
LD50	OECD 401	> 2000 mg/kg bw		Rat (male /	Experimental value	
				female)		
LD50		8000 mg/kg bw	24 h	Rabbit (male /	Experimental value	
				female)		
LC50		> 1.5 mg/l air	1 h	Rat (male /	Experimental value	
				female)	· .	
	LD50 LD50	LD50 OECD 401 LD50	LD50 OECD 401 > 2000 mg/kg bw LD50 8000 mg/kg bw	LD50 OECD 401 > 2000 mg/kg bw LD50 8000 mg/kg bw 24 h	LD50 OECD 401 > 2000 mg/kg bw Rat (male / female) LD50 8000 mg/kg bw 24 h Rabbit (male / female) LC50 > 1.5 mg/l air 1 h Rat (male /	DECD 401 > 2000 mg/kg bw Rat (male / female) Experimental value

Route of exposure	Parameter	Method	Value	Exposure time	Species	Value	Remark
						determination	
Oral	LD50	Equivalent to OECD	> 5000 mg/kg bw		Rat (male /	Read-across	
		401			female)		
Dermal	LD50	Equivalent to OECD	> 2000 mg/kg bw	24 h	Rabbit (male /	Read-across	
		402			female)		
Inhalation	LC50	Equivalent to OECD	> 5 mg/l air	4 h	Rat (male /	Read-across	
		403	_		female)		

alc	llcohols, C16-18, ethoxylated (EO 20)										
	Route of exposure	Parameter	Method	Value	Exposure time	Species	Value	Remark			
							determination				
	Oral	LD50		300 mg/kg - 2000			Experimental value				
				mg/kg							

Conclusion

Not classified for acute toxicity

Corrosion/irritation

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No (test)data on the mixture available

Classification is based on the relevant ingredients

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

white mineral oil (petroleum)

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

alcohols, C16-18, ethoxylated (EO 20)

Route of exposure	Result	Method	Exposure time	Time point	 Value determination	Remark
Eye	Serious eye				Literature study	
	damage;					
	category 1					ļ

Conclusion

Causes serious eye irritation.

Not classified as irritating to the skin

Not classified as irritating to the respiratory system

Respiratory or skin sensitisation

CREMOR CETOMACROGOLIS PH 5 FTM-TMF

No (test)data on the mixture available

Judgement is based on the relevant ingredients

tetradecanol

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

white mineral oil (petroleum)

Route of exposure	Result	Method	Exposure time	Observation time	Species	Value determination	Remark
				point			
Skin	Not sensitizing	Equivalent to OECD 406		48 hours	Guinea pig (male)	Experimental value	

Conclusion

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

Specific target organ toxicity

CREMOR CETOMACROGOLIS PH 5 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

white mineral oil (petroleum)

Route of exposure	Parameter	Method	Value	Organ	Effect	Exposure time	Species	Value
								determination
Oral	NOEL	Equivalent to	> 20000 ppm			90 day(s)	Rat (male /	Experimental
		OECD 408					female)	value
Skin	NOAEL	Equivalent to	> 2000			13 weeks (daily)	Rat (male /	Experimental
		OECD 411					female)	value
Inhalation (mist)	NOEL	Equivalent to	50 mg/m³ air			4 weeks (6h / day, 5	Rat (male /	Experimental
		OECD 412				days / week)	female)	value

Conclusion

Not classified for subchronic toxicity

Mutagenicity (in vitro)

CREMOR CETOMACROGOLIS PH 5 FTM-TMF

No (test)data on the mixture available

Judgement is based on the relevant ingredients

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

white mineral oil (petroleum)

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

Mutagenicity (in vivo)

CREMOR CETOMACROGOLIS PH 5 FTM-TMF

No (test)data on the mixture available

Judgement is based on the relevant ingredients

tetradecanol

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

white mineral oil (petroleum)

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

Conclusion

Not classified for mutagenic or genotoxic toxicity

Carcinogenicity

CREMOR CETOMACROGOLIS PH 5 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

white mineral oil (petroleum)

	the contraction of							
Route of	Parameter	Method	Value	Exposure time	Species	Effect	Organ	Value
exposure								determination
Oral	NOAEL	OECD 453	> 1200 mg/kg	24 month(s)	Rat (male /			Experimental
			bw/day		female)			value

Conclusion

Not classified for carcinogenicity

Reproductive toxicity

CREMOR CETOMACROGOLIS PH 5 FTM-TMF

No (test)data on the mixture available

Judgement is based on the relevant ingredients

tetradecanol

	Parameter	Method	Value	Exposure time	Species	Effect	- 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
it and all to to be	NOAEL (P)		1243 mg/kg bw/day	13 week(s)	Rat (female)	No effect		Read-across

white mineral oil (petroleum)

	Parameter	Method	Value	Exposure time	Species	Effect	- 0	Value determination
Developmental toxicity	NOAEL	Equivalent to OECD 414	> 5 ml/kg	20 day(s) - 40 day(s)	Rat	No effect		Experimental value

Conclusion

Not classified for reprotoxic or developmental toxicity

Toxicity other effects

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Chronic effects from short and long-term exposure

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No effects known.

SECTION 12: Ecological information

12.1. Toxicity

CREMOR CETOMACROGOLIS PH 5 FTM-TMF

No (test)data on the mixture available

Classification of the mixture is based on the relevant ingredients

tetradecanol

	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	

white mineral oil (petroleum)

	Parameter	Method	Value	Duration	Species		Fresh/salt water	Value determination
Acute toxicity fishes	LL50	OECD 203	> 100 mg/l	96 h	Oncorhynchus mykiss	Static system	Fresh water	Experimental value; Nominal concentration
Acute toxicity crustacea	LL50	OECD 202	> 100 mg/l	48 h	Daphnia magna	Static system	Fresh water	Experimental value; Locomotor effect
Toxicity algae and other aquatic plants	NOEL	OECD 201	≥ 100 mg/l	72 h	Pseudokirchneri ella subcapitata	Static system	Fresh water	Weight of evidence; Growth rate

alcohols, C16-18, ethoxylated (EO 20)

	Parameter	Method	Value	Duration	Species		Fresh/salt water	Value determination
Acute toxicity crustacea	EL50	OECD 202	0.32 mg/l	48 h	Daphnia magna	Static system		Similar product; Nominal concentration
Toxicity algae and other aquatic plants	EL50	OECD 201	0.56 mg/l	72 h	Pseudokirchneri ella subcapitata			Similar product; Growth rate
Long-term toxicity aquatic crustacea	NOEC		0.0542 mg/l	21 day(s)	Daphnia magna			Calculated value

$\underline{\textbf{Conclusion}}$

Harmful to aquatic life with long lasting effects.

12.2. Persistence and degradability

tetradecanol

Biodegradation 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 /cm ³	Calculated value

Biodegradation soil

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

white mineral oil (petroleum)

Biodegradation water

achidation water				
Method	Value	Duration	Value determination	
OECD 301F: Manometric Respirometry Test	31 %; GLP	28 day(s)	Read-across	

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alcohols, C16-18, ethoxylated (EO 20)

Biodegradation water

Method	Value	Duration	Value determination
OECD 301B: CO2 Evolution Test	90 % - 100 %	28 day(s)	Experimental value

Conclusion

Contains non readily biodegradable component(s)

12.3. Bioaccumulative potential

CREMOR CETOMACROGOLIS PH 5 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

white mineral oil (petroleum)

Log Kow

Method	Remark	Value	Temperature	Value determination
	No data available			

alcohols, C16-18, ethoxylated (EO 20)

BCF fishes

Parameter	Method	Value	Duration	Species	Value determination
BCF		387.5	72 day(s)	Pimephales promelas	Similar product

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

alcohols, C16-18, ethoxylated (EO 20)

(10b) NOC			
rameter	Method	Value	Value determination
Koc	SRC PCKOCWIN v2.0	5.215	Calculated value

Conclusion

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

Contains component(s) with potential for mobility in the soil

12.5. Results of PBT and vPvB assessment

Due to insufficient data no statement can be made whether the component(s) fulfil(s) the criteria of PBT and vPvB according to Annex XIII of Regulation (EC) No 1907/2006.

12.6. Other adverse effects

CREMOR CETOMACROGOLIS PH 5 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)

white mineral oil (petroleum)

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

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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.

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).

SECTION 14: Transport information

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

14.	I.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				
	Annex 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)

white mineral oil (petroleum)

Parameter	Parametric value	Note	Reference
Pesticides	0.1 μg/l		Listed in Annex I, Part B, of Directive 98/83/EC on the quality of water intended for human consumption.
Pesticides — Total	0.5 μg/l		Listed in Annex I, Part B, of Directive 98/83/EC on the quality of water intended for human consumption.

National legislation Belgium

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No data available

National legislation The Netherlands
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Waterbezwaarlijkheid Z (1); Algemene Beoordelingsmethodiek (ABM)

National legislation France
CREMOR CETOMACROGOLIS PH 5 FTM-TMF

No data available

National legislation Germany

CREMOR CETOMACROGOLIS PH 5 FTM-TMF

	WGK	1; Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen (AwSV) - 18. April 2017	
<u>tetradecanol</u>			
	TA-Luft	5.2.5/I	
white mineral oil (petroleum)			
	TA-Luft	5.2.5	

National legislation United Kingdom
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No data available

Other relevant data CREMOR CETOMACROGOLIS PH 5 FTM-TMF

No data available

white mineral oil (petroleum)

TLV - Carcinogen Mineral oil, pure, highly and severely refined; A4

15.2. Chemical safety assessment

No chemical safety assessment has been conducted for the mixture.

SECTION 16: Other information

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

H302 Harmful if swallowed.

H318 Causes serious eye damage.

H319 Causes serious eve 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 Effect Concentration 50 % EC50

FrC50 EC50 in terms of reduction of growth rate

Lethal Concentration 50 % LC50

LD50 Lethal Dose 50 %

No Observed Adverse Effect Level NOAEL NOEC No Observed Effect Concentration

Organisation for Economic Co-operation and Development OECD

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

vPvB very Persistent & very Bioaccumulative

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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