SAFETY DATA SHEET

Based upon Regulation (EC) No 1907/2006, as amended by Regulation (EU) No 2020/878



ROCK

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

1.1. Product identifier

Product name : ROCK

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

Sealing compound

1.2.2 Uses advised against

No uses advised against

1.3. Details of the supplier of the safety data sheet

Supplier of the safety data sheet

TEC7*

Industrielaan 5B

B-2250 Olen

2 +32 14 85 97 37

4 +32 14 85 97 38

info@tec7.be

*TEC7 is a registered trademark of Novatech International N.V.

Manufacturer of the product

Novatech International N.V.

Industrielaan 5B

B-2250 Olen

2 +32 14 85 97 37

4 +32 14 85 97 38 info@novatech.be

1.4. Emergency telephone number

24h/24h (Telephone advice: English, French, German, Dutch) :

+32 14 58 45 45 (BIG)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Not classified as dangerous according to the criteria of Regulation (EC) No 1272/2008

2.2. Label elements

Not classified as dangerous according to the criteria of Regulation (EC) No 1272/2008 $\,$

Supplemental information

EUH208 Contains: butan-2-one O,O',O"-(methylsilylidyne)trioxime; 2-butanone oxime. May produce an allergic reaction.

EUH211 Warning! Hazardous respirable droplets may be formed when sprayed. Do not breathe spray or mist.

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	M-factors and ATE
titanium dioxide; [in powder form containing 1 % or more of particles with aerodynamic diameter \leq 10 μ m] 01-2119489379-17	13463-67-7 236-675-5	C≥1%	Carc. 2; H351	(1)(2)	Constituent	

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ROCK							
butan-2-one O,O',O"-(methylsilylidyne)trioxime	22984-54-9 245-366-4	0.1% <c<1%< th=""><th>Skin Sens. 1; H317 Skin Irrit. 2; H315 Eye Irrit. 2; H319</th><th>(1)(10)</th><th>Constituent</th><th></th></c<1%<>	Skin Sens. 1; H317 Skin Irrit. 2; H315 Eye Irrit. 2; H319	(1)(10)	Constituent		
2-butanone oxime	96-29-7 202-496-6	0.1% <c<1%< td=""><td>Carc. 2; H351 Skin Sens. 1; H317 Acute Tox. 4; H312 Eye Dam. 1; H318</td><td>(1)(10)</td><td></td><td>ATE oral: 100 mg/kg ATE dermal: 1100 mg/kg</td></c<1%<>	Carc. 2; H351 Skin Sens. 1; H317 Acute Tox. 4; H312 Eye Dam. 1; H318	(1)(10)		ATE oral: 100 mg/kg ATE dermal: 1100 mg/kg	

- (1) For H- and EUH-statements in full: see section 16
- (2) Substance with a Community workplace exposure limit
- (10) Subject to restrictions of Annex XVII of Regulation (EC) No. 1907/2006

SECTION 4: First aid measures

4.1. Description of first aid measures

General:

Observe (own) safety. If possible, approach victim and check vital functions. In case of injury and/or intoxication, call the European emergency number 112. Treat symptoms starting with most life-threatening injuries and disorders. Keep victim under observation, possibility of delayed symptoms.

After inhalation:

Remove victim into fresh air. In case of respiratory problems, consult a doctor/medical service.

After skin contact:

If possible, wipe up/dry remove chemical. Then rinse/shower immediately with (lukewarm) water. If irritation persists, consult a doctor/medical service.

After eye contact:

Rinse immediately with (lukewarm) water. Remove contact lenses, if present and easy to do. Continue rinsing. If irritation persists, consult a doctor/medical service.

After ingestion:

Rinse mouth with water. If you feel unwell, consult a doctor/medical service. Do not wait for symptoms to occur to consult Poison Center.

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

${\bf 5.1.1}\ Suitable\ extinguishing\ media:}$

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 nitrous vapours.

5.3. Advice for firefighters

5.3.1 Instructions:

No specific fire-fighting instructions required.

5.3.2 Special protective equipment for fire-fighters:

Gloves (EN 374). Protective clothing (EN 14605 or EN 13034). Heat/fire exposure: self-contained breathing 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 section 8.2

6.1.2 Protective equipment for emergency responders

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

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Suitable protective clothing

See section 8.2

6.2. Environmental precautions

Contain released product.

6.3. Methods and material for containment and cleaning up

Solid spill: cover with absorbent material. Scoop solid spill into closing containers. Clean contaminated surfaces with an excess of water. Wash clothing and equipment after handling.

6.4. Reference to other sections

See section 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 strict hygiene. Keep container tightly closed.

7.2. Conditions for safe storage, including any incompatibilities

7.2.1 Safe storage requirements:

Meet the legal requirements. Store in a cool area. Store in a dry area. Keep container in a well-ventilated place.

7.2.2 Keep away from:

Heat sources, water/moisture.

7.2.3 Suitable packaging material:

Synthetic material, metal,

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 Titane (dioxyde de)

France		
Titane (dioxyde de), en Ti	Time-weighted average exposure limit 8 h (VL: Valeur non réglementaire indicative)	10 mg/m³
Germany		
Butanonoxim	Time-weighted average exposure limit 8 h (TRGS 900)	0.3 ppm
	Time-weighted average exposure limit 8 h (TRGS 900)	1 mg/m ³
UK		
Titanium dioxide respirable	Time-weighted average exposure limit 8 h (Workplace exposure limit (EH40/2005))	4 mg/m³
Titanium dioxide total inhalable	Time-weighted average exposure limit 8 h (Workplace exposure limit (EH40/2005))	10 mg/m³
USA (TLV-ACGIH)		
Titanium dioxide	Time-weighted average exposure limit 8 h (TLV - Adopted Value)	10 mg/m ³

Time-weighted average exposure limit 8 h

10 mg/m³

b) National biological limit values

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

USA (BEI-ACGIH)

Methemoglobin inducers	Blood: during or end of shift	5 % of hemoglobin	Background, Nonspecific
(Methemoglobin)			

8.1.2 Sampling methods

Product name	Test	Number
TiO2	NIOSH	7302
TiO2	NIOSH	7304

$\bf 8.1.3$ 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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butan-2-one O,O',O"-(methylsilylidyne)trioxime

Effect level (DNEL/DMEL)	Туре	Value	Remark
DNEL	Long-term systemic effects inhalation	1.02 mg/m ³	
	Long-term systemic effects dermal	0.145 mg/kg bw/day	

2-butanone oxime

Effect level (DNEL/DMEL)	Туре	Value	Remark
DNEL	Long-term systemic effects inhalation	28 μg/m³	
	Long-term local effects inhalation	0.9 mg/m ³	
	Long-term systemic effects dermal	4 μg/kg bw/day	

<u>DNEL/DMEL - General population</u> butan-2-one O,O',O''-(methylsilylidyne)trioxime

Effect level (DNEL/DMEL)	Туре	Value	Remark
DNEL	Long-term systemic effects inhalation	0.25 mg/m³	
	Long-term systemic effects dermal	0.072 mg/kg bw/day	
	Long-term systemic effects oral	0.072 mg/kg bw/day	

2-butanone oxime

Effect level (DNEL/DMEL)	Туре	Value	Remark
DNEL	Long-term systemic effects inhalation	4.82 μg/m³	
	Long-term local effects inhalation	0.43 mg/m³	
	Long-term systemic effects oral	1.6 μg/kg bw/day	

<u>PNEC</u> butan-2-one O,O',O''-(methylsilylidyne)trioxime

Compartments	Value	Remark	
Fresh water	0.018 mg/l		
Marine water	0.002 mg/l		
STP	3.9 mg/l		
Fresh water sediment	557.543 mg/kg sediment dw		
Marine water sediment	55.754 mg/kg sediment dw		
Soil	65.63 mg/kg soil dw		
Oral	3.22 mg/kg food		

2-butanone oxime

Compartments	Value	Remark
Fresh water	0.256 mg/l	
Marine water	0.026 mg/l	
Fresh water (intermittent releases)	0.118 mg/l	
Marine water (intermittent releases)	0.012 mg/l	
STP	177 mg/l	
Fresh water sediment	1.012 mg/kg sediment dw	
Marine water sediment	0.101 mg/kg sediment dw	
Soil	0.052 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. Carry operations in the open/under local exhaust/ventilation or with respiratory protection.

8.2.2 Individual protection measures, such as personal protective equipment

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

a) Respiratory protection:

Respiratory protection not required in normal conditions. Mist formation: aerosol mask with filter type P3.

b) Hand protection:

Protective gloves against chemicals (EN 374).

Materials	Measured breakthrough time	Thickness	Protection index	Remark		
butyl rubber		≥ 0.7 mm		Good resistance		
viton		≥ 0.7 mm		Good resistance		
nitrile rubber		≥ 0.7 mm		Good resistance		

c) Eye protection:

Safety glasses (EN 166).

d) Skin protection:

Protective clothing (EN 14605 or EN 13034).

8.2.3 Environmental exposure controls:

See sections 6.2, 6.3 and 13

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SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical form	Paste
Viscosity	Viscous
Odour	Characteristic odour
Odour threshold	No data available in the literature
Colour	Variable in colour, depending on the composition
Particle size	Not applicable (mixture)
Explosion limits	No data available in the literature
Flammability	Not classified as flammable
Log Kow	Not applicable (mixture)
Dynamic viscosity	No data available in the literature
Kinematic viscosity	No data available in the literature
Melting point	No data available in the literature
Boiling point	No data available in the literature
Relative vapour density	Not applicable
Vapour pressure	No data available in the literature
Solubility	Water ; insoluble
Relative density	1;20°C
Absolute density	1000 kg/m³ ; 20 °C
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
рН	Not applicable (non-soluble in water)

9.2. Other information

No data available

SECTION 10: Stability and reactivity

10.1. Reactivity

Heating increases the fire hazard.

10.2. Chemical stability

Stable under normal conditions.

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

Water/moisture.

10.6. Hazardous decomposition products

Upon combustion: formation of CO, CO2 and small quantities of nitrous vapours.

SECTION 11: Toxicological information

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

11.1.1 Test results

Acute toxicity

No (test)data on the mixture available

Judgement is based on the relevant ingredients $\underline{titanium\ dioxide;}\ [\underline{in\ powder\ form\ containing\ 1\ \%\ or\ more\ of\ particles\ with\ aerodynamic\ diameter\ \le\ 10\ \mu m]}$

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						Data waiving	
Inhalation (dust)	LC50	OECD 403	> 5.09 mg/l	4 h	Rat (male)	Experimental value	

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butan-2-one O,O',O"-(methylsilylidyne)trioxime

Route of exposure	Parameter	Method	Value	Exposure time	Species	Value	Remark
						determination	
Oral	LD50	OECD 401	2463 mg/kg bw		Rat (male /	Experimental value	
					female)		
Dermal	LD50	OECD 402	> 2000 mg/kg bw	24 h	Rat (male /	Experimental value	
					female)		
Inhalation						Data waiving	

2-butanone oxime

Route of exposure	Parameter	Method	Value	Exposure time	Species	Value	Remark
						determination	
Oral	LD50	Equivalent to OECD 401	2326 mg/kg bw		Rat (male)	Experimental value	
Dermal	LD50	Equivalent to OECD 402	> 1000 mg/kg bw	24 h	Rabbit (male / female)	Experimental value	
Inhalation (vapours)	LC50	Equivalent to OECD 403	> 4.83 mg/l air	4 h	Rat (male / female)	Experimental value	

Conclusion

Not classified for acute toxicity

Corrosion/irritation

<u>ROCK</u>

No (test)data on the mixture available

Judgement is based on the relevant ingredients titanium dioxide; [in powder form containing 1 % or more of particles with aerodynamic diameter \leq 10 μ m]

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

butan-2-one O,O',O"-(methylsilylidyne)trioxime

Route of exposure	Result	Method	Exposure time	Time point	Species	Value	Remark
						determination	
Еуе	Irritating	Equivalent to OECD 405		24; 48; 72 hours		Experimental value	
Skin	Irritating; category 2					Literature study	

2-butanone oxime

Route of exposure	Result	Method	Exposure time	Time point	Species	Value	Remark
						determination	
Eye	Serious eye	Equivalent to			Rabbit	Experimental	Single treatment
	damage	OECD 405				value	
Skin	Irritating	Equivalent to EPA	4 h	1; 24; 48; 72 hours	Rabbit	Experimental	
		OPPTS 870.2500				value	

Classification of this substance according to Annex VI is debatable as it does not correspond to the conclusion from the test

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

<u>ROCK</u>

No (test)data on the mixture available

Judgement is based on the relevant ingredients

 $\underline{titanium\ dioxide; [in\ powder\ form\ containing\ 1\ \%\ or\ more\ of\ particles\ with\ aerodynamic\ diameter\ \le\ 10\ \mu m]}$

Route of exposure	Result	Method	Exposure time	Observation time	Species	Value determination I	Remark
				point			
Skin		Equivalent to OECD 429			Mouse (female)	Experimental value	
Inhalation (dust)	Not sensitizing				Mouse (female)	Experimental value	

butan-2-one O,O',O''-(methylsilylidyne)trioxime

Route of exposure	Result	Method	 Observation time point	Species	Value determination	Remark
Skin	Sensitizing	Equivalent to OECD 406		Guinea pig (female)	Experimental value	

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2-butanone oxime

R	Route of exposure	Result	Method	 Observation time point	Species	Value determination	Remark
S	Skin		Equivalent to OECD 406		Guinea pig (female)	Experimental value	

Conclusion

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

Specific target organ toxicity

ROCK

No (test)data on the mixture available

Judgement is based on the relevant ingredients titanium dioxide; [in powder form containing 1 % or more of particles with aerodynamic diameter \leq 10 µm]

Route of exposure	Parameter	Method	Value	Organ	Effect	Exposure time	- •	Value determination
Oral (stomach	NOAEL	OECD 408	> 1000 mg/kg		No effect	90 day(s)		Experimental
tube)			bw/day				female)	value
Dermal								Data waiving

butan-2-one O,O',O"-(methylsilylidyne)trioxime

Route of exposure	Parameter	Method	Value	Organ	Effect	Exposure time		Value determination
Oral (stomach tube)	NOEL	Subacute toxicity test	4 mg/kg bw/day	Blood	No effect	1 '''	Rat (male / female)	Experimental value
Oral (drinking water)	NOAEL	Equivalent to OECD 408	25 mg/kg bw/day - 30 mg/kg bw/day	Blood	No effect		l - ' ' ' ' '	Experimental value

Classification of this substance is debatable as it does not correspond to the conclusion from the test

2-butanone oxime

Route of exposure	Parameter	Method	Value	Organ	Effect	Exposure time		Value determination
Oral (drinking water)	NOAEL	EPA OPPTS 870.3100	25 mg/kg bw/day - 30 mg/kg bw/day	Blood	No effect	13 week(s)	Rat (male / female)	Experimental value
Oral (stomach tube)	NOAEL	EPA OTS 798.6050	125 mg/kg bw/day	Central nervous system	No effect	13 weeks (5 days / week)	Rat (male / female)	Experimental value
Oral (stomach tube)	LOAEL	EPA OTS 798.6050	40 mg/kg bw/day	Blood	Change in the haemogramm e/blood composition	13 weeks (5 days / week)	Rat (male / female)	Experimental value
Dermal								Data waiving
Inhalation (vapours)	NOAEC	Equivalent to OECD 412	90 mg/m³ air	Blood		4 weeks (6h / day, 5 days / week)	Rat (male / female)	Experimental value

Conclusion

Not classified for subchronic toxicity

Mutagenicity (in vitro)

<u>ROCK</u>

No (test)data on the mixture available

Judgement is based on the relevant ingredients

 $\underline{\text{titanium dioxide; [in powder form containing 1 \% or more of particles with aerodynamic diameter} \leq 10 \ \mu\text{m}]$

Result	Method	Test substrate	Effect	Value determination	Remark
Negative with metabolic activation, negative without metabolic activation	OECD 473	Chinese hamster ovary (CHO)		Experimental value	
Negative with metabolic activation, negative without metabolic activation	OECD 471	Bacteria (S.typhimurium)		Experimental value	

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butan-2-one O,O',O''-(methylsilylidyne)trioxime

Result	Method	Test substrate	Effect	Value determination	Remark
Negative with metabolic activation, negative without metabolic activation	Equivalent to OECD 476	CHL/IU cells	No effect	Experimental value	
Positive with metabolic activation, positive without metabolic activation	Equivalent to OECD 476	Mouse (lymphoma L5178Y cells)	No effect	Read-across	
Negative with metabolic activation, negative without metabolic activation	Equivalent to OECD 473	Chinese hamster ovary (CHO)	No effect	Experimental value	

2-butanone oxime

Result	Method	Test substrate	Effect	Value determination	Remark
Ambiguous	Equivalent to OECD 476	Mouse (lymphoma L5178Y cells)		Experimental value	
Negative with metabolic activation, negative without metabolic activation	OECD 471	Bacteria (S.typhimurium)		Experimental value	
Negative with metabolic activation, negative without metabolic activation	OECD 482	Rat liver cells		Experimental value	

Mutagenicity (in vivo)

<u>ROCK</u>

No (test)data on the mixture available

Judgement is based on the relevant ingredients

 $\underline{titanium\ dioxide; [in\ powder\ form\ containing\ 1\ \%\ or\ more\ of\ particles\ with\ aerodynamic\ diameter\ \le\ 10\ \mu m]}$

Result	Method	Exposure time	Test substrate	Organ	Value determination
Negative (Oral (stomach tube))	OECD 474		Mouse (male / female)		Experimental value

butan-2-one O,O',O''-(methylsilylidyne)trioxime

Result	Method	Exposure time	Test substrate	Organ	Value determination
Negative (Oral (drinking water))	Equivalent to OECD	13 weeks (daily)	Mouse (male / female)		Experimental value
	474				
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2-butanone oxime

Result	Method	Exposure time	Test substrate	Organ	Value determination
Negative (Oral (diet))	Equivalent to OECD 477	3 day(s)	Drosophila melanogaster (male)		Experimental value
Negative (Oral (stomach tube))	Equivalent to OECD 475		Rat (male / female)		Experimental value

Conclusion

Not classified for mutagenic or genotoxic toxicity

Carcinogenicity

ROCK

No (test)data on the mixture available

Judgement is based on the relevant ingredients

The classification as a carcinogen by inhalation applies only to mixtures in powder form containing 1 % or more of titanium dioxide which is in the form of or incorporated in particles with aerodynamic diameter $\leq 10 \ \mu m$.

 $\underline{\text{titanium dioxide; [in powder form containing 1 \% or more of particles with aerodynamic diameter } \leq 10 \ \mu\text{m}]}$

Route of	Parameter	Method	Value	Exposure time	Species	Effect	Organ	Value determination
exposure								
Inhalation (dust)	NOAEC	OECD 453	, , , , , , , , , , , , , , , , , , ,	104 weeks (6h / day, 5 days / week)	Rat (male / female)	No carcinogenic effect	Lungs	Experimental value
Oral (diet)	NOEL	Carcinogenic toxicity study	50000 ppm	103 weeks (7 days / week)	Rat (male / female)	No carcinogenic effect		Experimental value

2-butanone oxime

Route of	Parameter	Method	Value	Exposure time	Species	Effect	Organ	Value determination			
exposure											
Inhalation	LOAEC	EPA OTS	54 mg/m³ air	26 weeks (6h / day,	Rat (male)	Neoplastic		Experimental value			
(vapours)		798.3300		5 days / week)		effects					

Conclusion

Not classified for carcinogenicity

Reproductive toxicity

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<u>ROCK</u>

No (test)data on the mixture available

Judgement is based on the relevant ingredients

 $\underline{titanium\ dioxide; [in\ powder\ form\ containing\ 1\ \%\ or\ more\ of\ particles\ with\ aerodynamic\ diameter\ \le\ 10\ \mu m]}$

	Parameter	Method	Value	Exposure time	Species	Effect	- 0	Value determination
Developmental toxicity (Oral (stomach tube))	NOAEL	OECD 414	. 0, 0	2 weeks (7 days / week)	Rat	No effect	l	Experimental value
Maternal toxicity (Oral (stomach tube))	NOAEL	OECD 414	1000 mg/kg bw/day	2 weeks (7 days / week)	Rat	No effect	l	Experimental value

butan-2-one O,O',O"-(methylsilylidyne)trioxime

	Parameter	Method	Value	Exposure time	Species	Effect	- 0	Value determination
Developmental toxicity (Oral (stomach tube))	NOAEL	EPA OTS 798.4900	> 600 mg/kg bw/day	10 days (gestation, daily)	Rat	No effect		Experimental value
Maternal toxicity (Oral (stomach tube))	LOAEL	EPA OTS 798.4900	60 mg/kg bw/day	10 days (gestation, daily)	Rat	Spleen enlargement/af fection	l '	Experimental value
Effects on fertility (Oral (stomach tube))	NOAEL	Equivalent to OECD 416	> 200 mg/kg bw/day	13 weeks (5 days / week) - 19 weeks (5 days / week)	Rat (male / female)	No effect		Experimental value

2-butanone oxime

	Parameter	Method	Value	Exposure time	Species	Effect	- 0	Value determination
Developmental toxicity (Oral (stomach tube))	NOAEL (F1)	OECD 414	> 600 mg/kg bw/day	10 day(s)	Rat	No effect		Experimental value
Maternal toxicity (Oral (stomach tube))	LOAEL	OECD 414	60 mg/kg bw/day	10 days (gestation, daily)	Rat	Maternal toxicity		Experimental value
Effects on fertility (Oral (stomach tube))	NOAEL (F1)	EPA TSCA testing guidelines	10 mg/kg bw/day	≥ 200 day(s)	Rat (male / female)	No effect		Experimental value

Conclusion

Not classified for reprotoxic or developmental toxicity

Toxicity other effects

<u>ROCK</u>

No (test)data on the mixture available

Chronic effects from short and long-term exposure

<u>ROCK</u>

Skin rash/inflammation.

11.2. Information on other hazards

No evidence of endocrine disrupting properties

SECTION 12: Ecological information

12.1. Toxicity

ROCK

No (test)data on the mixture available

Judgement of the mixture is based on the relevant ingredients

 $\underline{titanium\ dioxide; [in\ powder\ form\ containing\ 1\ \%\ or\ more\ of\ particles\ with\ aerodynamic\ diameter\ \le\ 10\ \mu m]}$

	Parameter	Method	Value	Duration	Species	Test design	Fresh/salt	Value determination
							water	
Acute toxicity fishes	LC50		> 1000 mg/l		Pisces		Fresh water	
Acute toxicity crustacea	EC50		> 1000 mg/l		Invertebrata		Fresh water	
Toxicity algae and other	EC50	OECD 201	> 100 mg/l	72 h	Pseudokirchneri	Static	Fresh water	Experimental value;
aquatic plants					ella subcapitata	system		Growth rate
	NOEC	OECD 201	≥ 100 mg/l	72 h	Pseudokirchneri ella subcapitata	Static system	Fresh water	Experimental value; Growth rate

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	Parameter	Method	Value	Duration	Species	Test design	Fresh/salt water	Value determination
Acute toxicity fishes	LC50	OECD 203	> 100 mg/l	96 h	Oryzias latipes	Semi-static system	Fresh water	Experimental value; GLP
Acute toxicity crustacea	EC50	OECD 202	201 mg/l	48 h	Daphnia magna	Static system	Fresh water	Experimental value; Locomotor effect
Toxicity algae and other aquatic plants	ErC50	OECD 201	16 mg/l	72 h	Pseudokirchneri ella subcapitata	Static system	Fresh water	Experimental value; GLP
	NOEC	OECD 201	2.6 mg/l	72 h	Pseudokirchneri ella subcapitata	Static system	Fresh water	Experimental value; Growth rate
Long-term toxicity fish	NOEC	OECD 204	50 mg/l	14 day(s)	Oryzias latipes	Flow- through system	Fresh water	Experimental value; GLP
Long-term toxicity aquatic crustacea	NOEC	OECD 211	≥ 100 mg/l	21 day(s)	Daphnia magna	Semi-static system	Fresh water	Experimental value; GLP
Toxicity aquatic micro- organisms	EC50	OECD 209	> 300 mg/l	3 h	Activated sludge	Static system	Fresh water	Experimental value; GLP

2-butanone oxime

	Parameter	Method	Value	Duration	Species	Test design	Fresh/salt water	Value determination
Acute toxicity fishes	LC50	OECD 203	> 100 mg/l	96 h	Oryzias latipes	Semi-static system	Fresh water	Experimental value; Nominal concentration
Acute toxicity crustacea	EC50	OECD 202	201 mg/l	48 h	Daphnia magna	Static system	Fresh water	Experimental value; Locomotor effect
Toxicity algae and other aquatic plants	ErC50	OECD 201	11.8 mg/l	72 h	Selenastrum capricornutum	Static system	Fresh water	Experimental value; Nominal concentration
	NOEC	OECD 201	2.56 mg/l	72 h	Selenastrum capricornutum	Static system	Fresh water	Experimental value; Growth rate
Long-term toxicity fish	NOEC	OECD 204	≥ 100 mg/l	14 day(s)	Oryzias latipes	Flow- through system	Fresh water	Experimental value; Lethal
Long-term toxicity aquatic crustacea	NOEC	OECD 211	≥ 100 mg/l	21 day(s)	Daphnia magna	Semi-static system	Fresh water	Experimental value; Reproduction
Toxicity aquatic micro- organisms	EC50		281 mg/l	17 h	Pseudomonas putida	Static system	Fresh water	Experimental value; Growth

Conclusion

Not classified as dangerous for the environment according to the criteria of Regulation (EC) No 1272/2008

12.2. Persistence and degradability

butan-2-one O,O',O"-(methylsilylidyne)trioxime

Biodegradation water

Method	Value	Duration	Value determination
OECD 301C	20 % - 28 %	28 day(s)	Experimental value
. 15.115		•	

Half-life water (t1/2 water)

	Method		Primary degradation/mineralisation	Value determination
	EU Method C.7	< 1 h; GLP	Primary degradation	Experimental value
. .				

2-butanone oxime

Biodegradation water

Method	Value	Duration	Value determination
Equivalent to OECD 301C	14.5 % - 27 %	21 day(s)	Experimental value

Conclusion

Water

Contains non readily biodegradable component(s)

12.3. Bioaccumulative potential

<u>ROCK</u>

Log Kow

Method	Remark	Value	Temperature	Value determination			
	Not applicable (mixture)						

 $\underline{titanium\ dioxide; [in\ powder\ form\ containing\ 1\ \%\ or\ more\ of\ particles\ with\ aerodynamic\ diameter\ \le\ 10\ \mu m]}$

Log Kow

Method	Remark	Value	Temperature	Value determination
	No data available			

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BCF fishes

Parameter	Method	Value	Duration	Species	Value determination
BCF		0.5 - 5.8	6 week(s)	Cyprinus carpio	Experimental value

Log Kow

Method	Remark	Value	Temperature	Value determination
		0.36		Experimental value

2-butanone oxime

BCF fishes

Parameter	Method	Value	Duration	Species	Value determination
BCF	OECD 305	0.5 - 5.8; GLP	42 day(s)	Cyprinus carpio	Experimental value

Log Kow

Method	Remark	Value	Temperature	Value determination
Equivalent to OECD 117		0.63		Experimental value

Conclusion

Does not contain bioaccumulative component(s)

12.4. Mobility in soil

butan-2-one O,O',O"-(methylsilylidyne)trioxime

(log) Koc

Parameter	Method	Value	Value determination
log Koc	SRC PCKOCWIN v2.0	5.481	Calculated value

2-butanone oxime

(log) Koc

Parameter	Method	Value	Value determination
log Koc		0.55	QSAR

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

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. Endocrine disrupting properties

No evidence of endocrine disrupting properties

12.7. Other adverse effects

ROCK

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)

Groundwater

Groundwater pollutant

2-butanone oxime

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

Can be considered as non 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).

08 04 10 (wastes from MFSU of adhesives and sealants (including waterproofing products): waste adhesives and sealants other than those mentioned in 08 04 09). Depending on branch of industry and production process, also other waste codes may be applicable.

13.1.2 Disposal methods

Dispose of the small quantities as household waste. Remove waste in accordance with local and/or national regulations. 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 01 (paper and cardboard packaging).

15 01 02 (plastic packaging).

15 01 04 (metallic packaging).

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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. Maritime transport in bulk according to IMO instruments	
	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
0.0 %	

REACH Annex XVII - Restriction

Contains component(s) subject to restrictions of Annex XVII of Regulation (EC) No 1907/2006: restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles.

and use of certain dangerous	substances, mixtures and articles.	
	Designation of the substance, of the group of substances or of the mixture	Conditions of restriction
butan-2-one O,O',O''-{methylsilylidyne} trioxime 2-butanone oxime	Liquid substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: (a) hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F; (b) hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10; (c) hazard class 4.1; (d) hazard class 5.1.	1. Shall not be used in: — ornamental articles intended to produce light or colour effects by means of different phases, for example in ornamental lamps and ashtrays, — tricks and jokes, — games for one or more participants, or any article intended to be used as such, even with ornamental aspects, 2. Articles not complying with paragraph 1 shall not be placed on the market. 3. Shall not be placed on the market if they contain a colouring agent, unless required for fiscal reasons, or perfume, or both, if they: — can be used as fuel in decorative oil lamps for supply to the general public, and, — present an aspiration hazard and are labelled with H304, 4. Decorative oil lamps for supply to the general public shall not be placed on the market unless they conform to the European Standard on Decorative oil lamps (EN 14059) adopted by the European Committee for Standardisation (CEN). 5. Without prejudice to the implementation of other Community provisions relating to the classification, packaging and labelling of dangerous substances and mixtures, suppliers shall ensure, before the placing on the market, that the following requirements are met: a) lamp oils, labelled with H304, intended for supply to the general public are visibly, legibly and indelibly marked as follows: "Keep lamps filled with this liquid out of the reach of children"; and, by 1 December 2010, "Just a sip of lamp oil — or even sucking the wick of lamps — may lead to life-threatening lung damage"; b) grill lighter fluids, labelled with H304, intended for supply to the general public are legibly and indelibly marked by 1 December 2010 as follows: "Just a sip of grill lighter may lead to life threatening lung damage"; c) lamp oils and grill lighters, labelled with H304, intended for supply to the general public are packaged in black opaque containers not exceeding 1 litre by 1 December 2010.
- 2-butanone oxime	Substances falling within one or more of the following points: (a) substances classified as any of the following in Part 3 of Annex VI to Regulation (EC) No 1272/2008: — carcinogen category 1A, 1B or 2, or germ cell mutagen category 1A, 1B or 2, but excluding any such substances classified due to effects only following exposure by inhalation — reproductive toxicant category 1A, 1B or 2 but excluding any such substances classified due to effects only following exposure by inhalation — skin sensitiser category 1, 1A or 1B — skin corrosive category 1, 1A, 1B or 1C or	1. Shall not be placed on the market in mixtures for use for tattooing purposes, and mixtures containing any such substances shall not be used for tattooing purposes, after 4 January 2022 if the substance or substances in question is or are present in the following circumstances: (a) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as carcinogen category 1A, 1B or 2, or germ cell mutagen category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight; (b) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as reproductive toxicant category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by weight; (c) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin sensitiser category 1, 1A or 1B, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by weight; (d) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin corrosive category 1, 1A, 1B or 1C or skin irritant category 2, or as

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skin irritant category 2

— serious eye damage category 1 or eye irritant category 2

(b) substances listed in Annex II to Regulation (EC) No 1223/2009 of the European Parliament and of the Council

(c) substances listed in Annex IV to Regulation (EC) No 1223/2009 for which a condition is specified in at least one of the columns g, h and i of the table in that Annex (d) substances listed in Appendix 13 to this Annex.

The ancillary requirements in paragraphs 7 and 8 of column 2 of this entry apply to all mixtures for use for tattooing purposes, whether or not they contain a substance falling within points (a) to (d) of this column of this entry.

serious eye damage category 1 or eye irritant category 2, the substance is present in the mixture in a concentration equal to or greater than:

- (i) 0,1 % by weight, if the substance is used solely as a pH regulator;
- (ii) 0,01 % by weight, in all other cases;
- (e) in the case of a substance listed in Annex II to Regulation (EC) No 1223/2009 (*), the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight;

(f) in the case of a substance for which a condition of one or more of the following kinds is specified in column g (Product type, Body parts) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight:

- (i) "Rinse-off products";
- (ii) "Not to be used in products applied on mucous membranes";
- (iii) "Not to be used in eye products";
- (g) in the case of a substance for which a condition is specified in column h (Maximum concentration in ready for use preparation) or column i (Other) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration, or in some other way, that does not accord with the condition specified in that column; (h) in the case of a substance listed in Appendix 13 to this Annex, the substance is present in
- (h) in the case of a substance listed in Appendix 13 to this Annex, the substance is present in the mixture in a concentration equal to or greater than the concentration limit specified for that substance in that Appendix.
- 2. For the purposes of this entry use of a mixture "for tattooing purposes" means injection or introduction of the mixture into a person's skin, mucous membrane or eyeball, by any process or procedure (including procedures commonly referred to as L 423/12 EN Official Journal of the European Union 15.12.2020 permanent make-up, cosmetic tattooing, microblading and micro-pigmentation), with the aim of making a mark or design on his or her body.
- 3. If a substance not listed in Appendix 13 falls within more than one of points (a) to (g) of paragraph 1, the strictest concentration limit laid down in the points in question shall apply to that substance. If a substance listed in Appendix 13 also falls within one or more of points (a) to (g) of paragraph 1, the concentration limit laid down in point (h) of paragraph 1 shall apply to that substance.
- 4. By way of derogation, paragraph 1 shall not apply to the following substances until 4 January 2023:
- (a) Pigment Blue 15:3 (CI 74160, EC No 205-685-1, CAS No 147-14-8);
- (b) Pigment Green 7 (CI 74260, EC No 215-524-7, CAS No 1328-53-6).
- 5.If Part 3 of Annex VI to Regulation (EC) No 1272/2008 is amended after 4 January 2021 to classify or re-classify a substance such that the substance then becomes caught by point (a), (b), (c) or (d) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the date of application of that new or revised classification is after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect on the date of application of that new or revised classification.
- 6. If Annex II or Annex IV to Regulation (EC) No 1223/2009 is amended after 4 January 2021 to list or change the listing of a substance such that the substance then becomes caught by point (e), (f) or (g) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the amendment takes effect after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect from the date falling 18 months after entry into force of the act by which that amendment was made.
- 7. Suppliers placing a mixture on the market for use for tattooing purposes shall ensure that, after 4 January 2022, the mixture is marked with the following information:
- (a) the statement "Mixture for use in tattoos or permanent make-up";
- (b) a reference number to uniquely identify the batch;
- (c) the list of ingredients in accordance with the nomenclature established in the glossary of common ingredient names pursuant to Article 33 of Regulation (EC) No 1223/2009, or in the absence of a common ingredient name, the IUPAC name. In the absence of a common ingredient name or IUPAC name, the CAS and EC number. Ingredients shall be listed in descending order by weight or volume of the ingredients at the time of formulation. "Ingredient" means any substance added during the process of formulation and present in the mixture for use for tattooing purposes. Impurities shall not be regarded as ingredients. If the name of a substance, used as ingredient within the meaning of this entry, is already required to be stated on the label in accordance with Regulation (EC) No 1272/2008, that ingredient does not need to be marked in accordance with this Regulation;
- (d) the additional statement "pH regulator" for substances falling under point (d)(i) of paragraph 1;
- (e) the statement "Contains nickel. Can cause allergic reactions." If the mixture contains nickel below the concentration limit specified in Appendix 13;
- (f) the statement "Contains chromium (VI). Can cause allergic reactions." if the mixture contains chromium (VI) below the concentration limit specified in Appendix 13; (g) safety instructions for use insofar as they are not already required to be stated on the label by Regulation (EC) No 1272/2008. The information shall be clearly visible, easily legible and marked in a way that is indelible.

The information shall be written in the official language(s) of the Member State(s) where the mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise. Where necessary because of the size of the package, the information listed in the first subparagraph, except for point (a), shall be included instead in the instructions for use. Before using a mixture for tattooing purposes, the person using the mixture shall provide the person undergoing the procedure with the information marked on the package or included in the instructions for use pursuant to this paragraph.

8. Mixtures that do not contain the statement "Mixture for use in tattoos or permanent make-up" shall not be used for tattooing purposes.

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9. This entry does not apply to substances that are gases at temperature of 20 °C and pressure of 101,3 kPa, or generate a vapour pressure of more than 300 kPa at temperature of 50 °C, with the exception of formaldehyde (CAS No 50-00-0, EC No 200-001-8). $10. \ This \ entry \ does \ not \ apply \ to \ the \ placing \ on \ the \ market \ of \ a \ mixture \ for \ use \ for \ tattooing$ purposes, or to the use of a mixture for tattooing purposes, when placed on the market exclusively as a medical device or an accessory to a medical device, within the meaning of Regulation (EU) 2017/745, or when used exclusively as a medical device or an accessory to a medical device, within the same meaning. Where the placing on the market or use may not be exclusively as a medical device or an accessory to a medical device, the requirements of Regulation (EU) 2017/745 and of this Regulation shall apply cumulatively.

National legislation Belgium

No data available

National legislation The Netherlands

<u>KOCK</u>		
Waterbezwaarlijk	heid	Z (1); Algemene Beoordelingsmethodiek (ABM)
2-butanone oxime		
SZW - Lijst van		butanonoxim; Listed in SZW-list of carcinogenic substances
kankerverwekken	de stoffen	

National legislation France

ROCK

No data available

 $\underline{titanium\ dioxide; [in\ powder\ form\ containing\ 1\ \%\ or\ more\ of\ particles\ with\ aerodynamic\ diameter\ \le\ 10\ \mu m]}$

Catégorie cancérogène	Titane (dioxyde de), en Ti; C2	
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National legislation Germany

WGK		
itanium dioxide; [in powder form		
TA-Luft		
outan-2-one 0,0',0"-(methylsilylight		
TA-Luft		
2-butanone oxime		
TA-Luft		
TRGS900 - Risiko der		
Fruchtschädigung		
Sensibilisierende Stoffe		
Hautresorptive Stoffe		
itanium dioxide; [in powder form TA-Luft Dutan-2-one O,O',O''-(methylsilylid TA-Luft 2-butanone oxime TA-Luft TRGS900 - Risiko der Fruchtschädigung Sensibilisierende Stoffe		

National legislation United Kingdom

ROCK

No data available

Other relevant data

ROCK

<u>titanium dioxide</u>; [in powder form containing 1 % or more of particles with aerodynamic diameter \leq 10 μ m]

	2B; Titanium dioxide
TLV - Carcinogen	Titanium dioxide; 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- and EUH-statements referred to under section 3:

H312 Harmful in contact with skin.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction. H318 Causes serious eye damage.

H319 Causes serious eye irritation.

H351 Suspected of causing cancer.

H351 Suspected of causing cancer if inhaled.

EUH208 Contains a sensitising substance. May produce an allergic reaction.

EUH211 Warning! Hazardous respirable droplets may be formed when sprayed. Do not breathe spray or mist.

INTERNAL CLASSIFICATION BY BIG

ADI Acceptable daily intake

AOEL Acceptable operator exposure level

ATE Acute Toxicity Estimate

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

DMEL Derived Minimal Effect Level

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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

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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