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Safety Data Sheet Complies with Annex II of REACH - Regulation (EU) 2020/878

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

1.1. Product identifier

Code: RPC7228RP1701 Product name Sarpol RP17 - Part A UFI code: CS00-H08A-W00N-M3SN

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

Intended use **Anti-wear coatings**

1.3. Details of the supplier of the safety data sheet

Name SARO Srl

Via G. Di Vittorio, 5 Full address District and Country 20020 Arconate (MI)

Italy

tel. 0331453794

e-mail address of the competent person

responsible for the Safety Data Sheet amministrazione@sa.ro.it

1.4. Emergency telephone number

For urgent inquiries refer to IRELAND: National Poisons Information Centre (NPIC): +353 1 8092166

MALTA: Medicines & poisons info Office 112

SECTION 2. Identification of hazards

2.1. Classification of the substance or mixture

The product is classified as hazardous under the provisions of Regulation (EC) 1272/2008 (CLP) (as amended and adapted). The product therefore requires a safety data sheet in accordance with the provisions of Regulation (EU) 2020/878. Additional information concerning health and/or environmental hazards can be found in sections 11 and 12 of this sheet.

Classification and hazard statements:

Chemical and physical hazards: the product is not classified for this hazard class

Health hazards: The product causes severe eye and skin irritation. The product may cause an allergic skin reaction.

Environmental hazards: The product is toxic to aquatic organisms with long-lasting effects.

Eye irritation, category 2 Causes severe eye irritation. H319 Skin irritation, category 2 H315 Causes skin irritation.

Skin sensitisation, category 1 H317 It may cause an allergic skin reaction.

Dangerous for the aquatic environment, chronic toxicity, Toxic to aquatic organisms with long-lasting effects. H411

category 2

2.2 Label Elements

Hazard labelling in accordance with Regulation (EC) 1272/2008 (CLP) and subsequent amendments and adjustments.

Hazard pictograms:





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Signal words:

Hazard statements:

H319 Causes severe eye irritation. H315 Causes skin irritation.

H317 It may cause an allergic skin reaction.

Attention

Toxic to aquatic organisms with long-lasting effects. H411

Caution! Dangerous respirable droplets may be formed in the event of vaporisation. Do not breathe vapours or mists. EUH211

Precautionary statements:

P280 Wear protective gloves and protect your eyes and your face.

Do not disperse in the environment. P273

P391 Collect the spilled material.

P261 Avoid breathing fumes, gases, mist and vapours. P333+P313 In case of skin irritation or rash: consult a doctor. P337+P313 If eye irritation persists, consult a doctor.

Contains:

2,2-bis-[4-(2,3-epoxypropoxy)phenyl]-propane
Reaction mass of 2,2'-[methylenebis(2,1-phenylenoxymethylene)]bis(oxirane) and 2-({2-[4-(oxiran- 2-

ylmethoxy)benzyl]phenoxy}methyl)oxirane

2.3. Other hazards

According to the available data, the product does not contain PBT or vPvB substances in percentage ≥ 0.1 %. The product does not contain substances with endocrine-disrupting properties in concentrations ≥ 0.1%.

SECTION 3. Composition/information on ingredients

3.2. Mixtures

Contains:

Identification	Concentration%	Classification (EC) 1272/2008 (CLP)	Specific concentration limits
1			1272/2008 (CLP)

2,2-bis-[4-(2,3-

epoxypropoxy)phenyl]-propane

INDEX 603-073-00-2 20-25* Eye Irrit. 2 H319, Skin Irrit. 2 H315: ≥ 5%, Skin Irrit, 2 H315. Eye Irrit. 2 H319: ≥ 5%.

Skin Sens. 1 H317, Aquatic Chronic 2 H411

EC 216-823-5 CAS 1675-54-3

Reaction mass of 2,2'-[methylenebis(2,1-

phenyleneoxymethylene)]bis(oxira ne) and 2,2'-[methylenebis(4,1phenyleneoxymethylene)]bis(oxira ne) and 2-({ 2-[4-(oxiran- 2ylmethoxy)benzyl]phenoxy}

methyl)oxirane

INDEX -20-25* Skin Irrit, 2 H315. Not applicable

Skin Sens. 1 H317, Aquatic Chronic 2 H411

EC 701-263-0

CAS -

REACH Reg. 01-2119454392-40-

Titanium dioxide; [in powder form containing ≥ 1 % particles with an aerodynamic diameter ≤ 10 µm].

INDEX 022-006-00-2 5-10*

Carc. 2 H351, Not applicable

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Classification note according to Annex VI of the CLP Regulation: 10, V, W

Not applicable

EC 236-675-5

CAS 13463-67-7

REACH Reg. 01-2119489379-17-

XXXX

Octamethylcyclotetrasiloxane

INDEX 014-018-00-1 0.05-0.1* Flam. Liq. 3 H226,

Repr. 2 H361f.

Aquatic Chronic 1 H410 M=10

EC 209-136-7

CAS 556-67-2

REACH Reg. 01-2119529238-36-

Upper value of range excluded

The full text of the hazard statements (H) is given in section 16 of the sheet.

SECTION 4. First Aid Measures

4.1. Description of first aid measures

EYES: Remove any contact lenses. Wash immediately with plenty of water for at least 15-30 minutes, opening the eyelids wide. Consult a doctor if the problem persists.

SKIN: Remove contaminated clothing. Wash immediately with plenty of water. If irritation persists, consult a doctor. Wash contaminated clothing before re-use

INHALATION: Move the subject to fresh air. If breathing is difficult, call a doctor immediately.

INGESTION: Seek medical advice immediately. Induce vomiting only as directed by a doctor. Do not administer anything by mouth if the subject is unconscious and unless authorised by a doctor.

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

No specific information is known about symptoms and effects caused by the product.

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

Treat symptomatically. Consult a doctor.

SECTION 5. Fire-fighting measures

5.1. Extinguishing media

SUITABLE EXTINGUISHING EQUIPMENT

The extinguishing media are the traditional ones: carbon dioxide, foam, powder and water mist.

UNSUITABLE EXTINGUISHING EQUIPMENT

None in particular.

5.2. Special hazards arising from the substance or mixture

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE

Avoid breathing in combustion products, especially COx and titanium compounds.

5.3. Recommendations for firefighters

GENERAL INFORMATION

Cool containers with jets of water to prevent decomposition of the product and the development of substances potentially hazardous to health. Always wear full fire protection equipment. Collect extinguishing water, which must not be discharged into the sewage system. Dispose of contaminated extinguishing water and fire residue in accordance with current regulations.

EQUIPMENT

Normal fire-fighting clothing, such as an open-circuit self-contained breathing apparatus (EN 137), flame-resistant suit (EN469), flame-resistant gloves (EN 659) and firefighter's boots (HO A29 or A30).

SECTION 6. Accidental Release Measures

6.1. Personal precautions, protective equipment and emergency procedures FOR NON-EMERGENCY PERSONNEL

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Alert personnel responsible coordinating the response to such emergencies. Move away from the area affected by the accident if you are not in possession of the personal protective equipment listed in section 8.

FOR EMERGENCY RESPONDERS

Evacuate personnel not suitably equipped deal with the emergency. to Wear suitable protective clothing and equipment, as set out in section 8 of the safety data sheet, to prevent any contamination of the skin, eyes and personal clothing. Stop leak if safe to

Do not permit workers to access the area affected by the accident until safe conditions have been restored. Ventilate the areas affected.

6.2. Environmental Precautions

Prevent the product from entering sewers, surface water and groundwater.

6.3 Methods and materials for containment and remediation

Collect the leaked product into a suitable container. Assess the compatibility of the container to be used with the product, checking section 10. Absorb the remainder with inert absorbent material (e.g. vermiculite, diatomaceous earth, sand, kieselguhr, zeolites, activated carbon, aluminium/silica gel). Ensure sufficient ventilation of the site affected by the leak. Disposal of the contaminated material must be carried out in accordance with the provisions of section 13.

6.4. Reference to other sections

Information on personal protection and disposal can be found in sections 8 and 13.

SECTION 7. Handling and Storage

7.1. Precautions for safe handling

Handle the product after consulting all other sections of this safety data sheet. Avoid dispersing the product in the environment. Do not eat, drink or smoke during use. Remove contaminated clothing and protective equipment before entering eating areas.

7.2. Conditions for safe storage, including any incompatibilities

Store only in the original container. Keep containers closed, in a well-ventilated place, out of direct sunlight. Keep containers away from any incompatible materials, e.g. acids, bases and strong oxidants, see section 10.

7.3. Specific end use(s)

There are no particular end uses other than the identified relevant uses listed in Section 1.2 of this safety data sheet.

SECTION 8. Exposure controls/personal protection

8.1. Control Parameters

Regulatory references:

TI V-ACGIH ACGIH 2024

The product does not contain any substances for which there are Community Occupational Exposure Limits (OELs) or National Occupational Exposure Limits (VLEPs) that require declaration in this section.

For the substances mentioned in this section, DNEL/PNEC values are also given (although the relevant REACH registration numbers are not available for these substances) in order to pass on as much information as possible to enable the identification and application of appropriate risk management

Titanium dioxide: [in powder form containing ≥ 1 % particles with an aerodynamic diameter ≤ 10 um].

Туре	Status	TWA/8h		STEL/15min	STEL/15min		Critical effects
		mg/m3	ppm	mg/m3	ppm		
TLV-ACGIH		2,5					Fine particles
TLV-ACGIH		0,2				RESPIR, A3	Irritation of the lower respiratory tract pneumoconiosis
Health - Derived No-	-Effect Level - DNEL	/ DMEL			Effects on		

Health - Derived No-Effect	Level - DNEL / I	DMEL							
	Effects on				Effects on				
	consumers				workers				
Exhibition Street	A quito local	A outo avatamia	Chronio local	Chronio	A quita Ional	Aguto	Chronio local	Chronio	

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nalation			210 µg/m³	systemic		systemic	1.25 mg/m ³	systemic
-bis-[4-(2,3-epoxyprodicted concentration of no	poxy)phenyl]-properties on the environment	ment - PNEC						
ference value in fresh wate	er			0,006	mg	/I		
ference value in seawater				0,001	mg	/I		
shwater sediment reference	ce value			0,341	mg	/kg		
erence value for sediment	s in seawater			0,034	mg	/kg		
ference value for water, int	ermittent release			0,018	mg	/I		
ference value for STP micr	oorganisms			10	mg	/I		
ference value for the food	chain (secondary pois	oning)		11	mg	/kg		
ference value for the terres	strial compartment			0,065	mg	/kg		
ealth - Derived No-Effe	Effects on consumers	DMEL			Effects on workers			
hibition Street	Acute local	Acute systemic	Chronic local	Chronic systemic	Acute local	Acute systemic	Chronic local	Chronic systemic
al				0.5 mg/kg		Systematic		Systemic
alation				0.87 mg/m3				4.93 mg/m
rmica				89.3 µg/kg				0.75 mg/kg
				bw/d				bw/d
dicted concentration of no	effect on the environr	ment - PNEC		1,5	hā/	I		
edicted concentration of no ference value in fresh wate	effect on the environr	ment - PNEC		1,5				
edicted concentration of no eference value in fresh water eference value in seawater	effect on the environr	ment - PNEC			μg/			
edicted concentration of no oference value in fresh water oference value in seawater eshwater sediment reference	effect on the environment	ment - PNEC		1,5 0,15	μg/	1		
edicted concentration of no ference value in fresh water ference value in seawater eshwater sediment reference ference value for sediment	effect on the environment cer ce value s in seawater	ment - PNEC		1,5 0,15 3	μg/	l /kg sed dw /kg sed dw		
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edicted concentration of no ofference value in fresh water ofference value in seawater eshwater sediment reference value for sediment ofference value for STP microference value for the food ofference value for the food of	effect on the environment er ce value s in seawater coorganisms chain (secondary pois			1,5 0,15 3 0,3	mg mg mg	/kg sed dw /kg sed dw /l		
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edicted concentration of no ference value in fresh water ference value in seawater eshwater sediment reference ference value for sediment ference value for STP micr ference value for the food of ference value for the terresealth - Derived No-Effernibition Street	effect on the environment er value s in seawater corganisms chain (secondary pois strial compartment ect Level - DNEL / Effects on consumers	oning) DMEL	Chronic local	1,5 0,15 3 0,3 10 41 0,54 Chronic systemic 3.7 mg/kg	mg mg mg	/kg sed dw /kg sed dw // /kg food /kg soil	Chronic local	Chronic
edicted concentration of no ference value in fresh water ference value in seawater eshwater sediment reference value for sediment ference value for STP microference value for the food of ference value for the terrest ference value ference value ference value for the terrest ference value ference v	effect on the environment er value s in seawater corganisms chain (secondary pois strial compartment ect Level - DNEL / Effects on consumers	oning) DMEL	Chronic local	1,5 0,15 3 0,3 10 41 0,54	mg mg mg	/kg sed dw /kg sed dw // /kg food /kg soil	Chronic local	
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Reference value for the terrestrial compartment

0,237

ma/ka/d

Health - Derived No-E	Effect Level - DNEL /	DMEL						
	Effects on				Effects on			
	consumers				workers			
Exhibition Street	Acute local	Acute systemic	Chronic local	Chronic systemic	Acute local	Acute systemic	Chronic local	Chronic systemic
Oral				6.25 mg/kg bw/d				
Inhalation				8.7 mg/m3				29.39 mg/m3
Dermica				62.5 mg/kg bw/d			8.3 µg/cm2	104.15 mg/kg bw/d

Legend:

(C) = CEILING; INALAB = Inhalable Fraction; RESPIR = Breathable Fraction; TORAC = Thoracic Fraction.

VND = hazard identified but no DNEL/PNEC available; NEA = no exposure expected; NPI = no hazard identified; LOW = low hazard; MED = medium hazard; HIGH = high hazard.

8.2. Exposure controls

Since the use of appropriate technical measures should always take priority over personal protective equipment, ensure good ventilation in the workplace through effective local exhaust ventilation.

When choosing personal protective equipment, seek advice from your chemical suppliers if necessary.

Personal protective equipment must be CE marked, showing that it complies with applicable standards.

HAND PROTECTION

Protect hands with category III work gloves, at least type B, that protect against aromatic hydrocarbons (class F) and heterocyclic and ether compounds (class H). Recommended material PVA and related. For the final choice of work glove material (ref. standard EN 374), the following must be considered: compatibility, degradation, breakage time and permeation.

In the case of preparations, the resistance of work gloves to chemicals must be checked before use as it cannot be predicted. Gloves have a wear time that depends on the duration and mode of use.

SKIN PROTECTION

Wear long-sleeved work clothes and category III occupational safety footwear (ref. Reg. (EU) 2016/425 and EN ISO 20344). Wash with soap and water after removing protective clothing.

EYE PROTECTION

It is advisable to wear protective goggles preferably airtight (ref. standard EN ISO 16321). Provide emergency shower with visocular tray.

RESPIRATORY PROTECTION

The use of respiratory protective equipment is necessary if the technical measures taken are not sufficient to limit the worker's exposure to the threshold values taken into consideration. It is advisable to wear a mask with a type A filter, the class (1, 2 or 3) of which should be chosen in relation to the limit concentration of use. (ref. standard EN 14387). It is recommended the use of a type P filtering facemask whose class (1, 2 or 3) and actual need, will have to be defined according to the outcome of the risk assessment (ref. standard EN 149).

In the event that the substance in question is odourless or its odour threshold is above the relevant TLV-TWA and in the event of an emergency, wear an open-circuit self-contained breathing apparatus (ref. standard EN 137) or a supplied-air respirator (ref. standard EN 138). For the correct choice of respiratory protective device, refer to EN 529.

ENVIRONMENTAL EXPOSURE CONTROLS

Emissions from production processes, including those from ventilation equipment, should be controlled in order to comply with environmental protection regulations.

Product residues must not be discharged unchecked into drains or watercourses.

SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

PropertiesValueInformationAppearanceLiquid

Colour white

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The product is not soluble in water

The product is a mixture

Odour delicate Melting or freezing point not available > 300 °C Initial boiling point Flammability non-flammable not available Lower explosive limit Upper explosive limit not available Flash point 200 °C

Auto-ignition temperature not available Decomposition temperature not available

not applicable

Kinematic viscosity >20,5

Solubility insoluble in water

Partition coefficient: n-octanol/water not applicable

Vapour pressure 44 mBar

Density and/or relative density 1.82 G/cmc

Relative vapour density >1

Particle characteristics not applicable The product is liquid

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Information not available

9.2.2. Other safety features Information not available

SECTION 10. Stability and reactivity

10.1. Reactivity

There are no particular risk of reaction with other substances under normal conditions of use.

Octamethylcyclotetrasiloxane Air-sensitive.

10.2. Chemical stability

The product is stable under normal conditions of use and storage.

10.3. Possibility of dangerous reactions

Under normal use and storage conditions, no hazardous reactions are to be expected.

<u>Octamethylcyclotetrasiloxane</u>

Vapours can form explosive mixtures with air if heated above its flash point.

10.4. Conditions to be avoided

None in particular. However, observe the usual precautions with chemicals.

Octamethylcyclotetrasiloxane

Heating (GESTIS, 2017). Free Flames (IPCS, 2002). Mist formation (IPCS, 2002).

10.5. Incompatible materials

Acids, bases and strong oxidants

10.6. Hazardous decomposition products

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Gases and vapours potentially harmful to health, in particular COx and titanium compounds, can be released by thermal decomposition.

SECTION 11. Toxicological information

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

In the absence of experimental toxicological data on the product itself, the possible health hazards of the product were assessed on the basis of the properties of the substances contained, according to the criteria laid down in the relevant classification regulations.

Therefore, consider the concentration of any individual hazardous substances mentioned in Section 3 to assess the toxicological effects of exposure to the product.

Metabolism, kinetics, mechanism of action and other information

Octamethylcyclotetrasiloxane

The substance is only 10% absorbed orally and inhaled. By the dermal route absorption is minimal

for the volatility of the substance.

In volunteers exposed by inhalation, a rapid elimination of 24% of the absorbed substance is observed. The plasma clearance is rapid and non-linear. Metabolites are present even 24 h after exposure and are eliminated in the urine. They are dimethylsilanediol, methylsilanetriol and trimethyldisiloxane-1.3.3-triol.

In animal studies it is distributed in all tissues with preference for the respiratory tract and adipose tissue. It is eliminated with a half-life of 68 h in plasma, 154 h in skin and 273 h in testicles.

Following skin exposure, despite its lipophilic properties, no accumulation is observed in the tissue adipose. Only a small amount is found in the epidermis and dermis.

The substance is cleaved and demethylated with the formation of two main metabolites: dimethylsilanediol and methylsilanetriol.

Following oral exposure, elimination is faecal.

Following inhalation exposure, elimination is predominantly with exhaled air and urine, to a lesser extent with faeces. (INRS, 2008)

In rat studies, the substance was shown to induce hepatic microsomal enzymes, similar to the phenobarbital (HSDB, 2017).

Information on likely routes of exposure

Caution! Dangerous respirable droplets may be formed in the event of vaporisation. Do not breathe vapours or mists.

Octamethylcyclotetrasiloxane

The main potential exposure routes are expected to be inhalation and skin contact in the workers exposed to the production and use of the substance. The potential exposure of the population general can occur by inhalation in contaminated environments and by skin contact with products cosmetics and care products containing the substance. Further exposure may be due to ingestion of drinks containing the substance.

Immediate, delayed and chronic effects from short- and long-term exposures

Octamethylcyclotetrasiloxane

No pulmonary and/or biological effects were observed in a study on inhalation volunteers (INRS, 2008).

No symptoms of acute toxicity were observed in animal studies (NICNAS, 2018).

No human data are available in long-term studies.

In long-term studies performed on animals by the oral, dermal and inhalation routes, there was no evidence of relevant alterations.

In the rat, following inhalation, a reversible weight gain and enzyme induction are observed and not accompanied by other symptoms of hepatotoxicity (NICNAS, 2018).

Interactive effects

Information not available

ACUTE TOXICITY

Based on the available data and considering the classification criteria of Annex I, Part 3 of Regulation (EC) 1272/2008 as amended , the product is not classified for this hazard class

ATE (Inhalation) of the mixture:

ATE (Oral) of the mixture:

ATE (Oral) of the mixture:

ATE (Dermal) of the mixture:

Not classified (no relevant components)

Not classified (no relevant components)

Titanium dioxide; [in powder form containing ≥ 1 % particles with an aerodynamic diameter ≤ 10 μm].

LD50 (Oral): > 5000 mg/kg Rat, OECD Guideline 425 (Acute Oral Toxicity: Up-and-Down)

LC50 (inhalation mists/dust): 3.43 mg/l/4h Rat

2,2-bis-[4-(2,3-epoxypropoxy)phenyl]-propane

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LD50 (Dermal): 23.032 mg/kg Rabbit LD50 (Oral): 19800 mg/kg Rat

<u>Octamethylcyclotetrasiloxane</u>

LD50 (Dermal): > 2000 mg/kg bw Rat > 4800 mg/kg bw Rat LD50 (Oral): 36 mg/l/4h Rat LC50 (inhalation mists/dust):

Reaction mass of 2,2'-[methylenebis(2,1-phenyleneoxymethylene)]bis(oxirane) and 2,2'-[methylenebis(4,1-phenyleneoxymethylene)]bis(oxirane) and 2-(\par{

2-[4-[4-(oxirane-2-ylmethoxy)benzyl]phenoxy}methyl)oxirane

LD50 (Dermal): > 2000 mg/kg rat LD50 (Oral): > 5000 mg/kg rat

SKIN CORROSION / SKIN IRRITATION

Based on available data and considering the classification criteria provided in Table 3.2.3 of Annex I of Regulation (EC) 1272/2008 as amended, the product is classified as Skin irrit. 2, H315

Octamethylcyclotetrasiloxane

It has no irritating power.

Available information indicates an anti-irritant effect of the substance (NICNAS, 2018).

In a study on skin irritation in white New Zealand rabbits (6, sex not specified) [conducted according to guidelines similar to OECD TG 404 (not GLP)], 0.5 ml of pure substance was applied to the intact and abraded skin. No skin reactions were observed. The desquamation observed on the skin abraded was fully recovered within 72 hours (no further details available) (NICNAS, 2018).

In another study, the pure substance was applied to intact and abraded skin of the ear and abdomen of rabbits New Zealand (4, gender not specified). Negligible skin reactions were observed following applications on undamaged skin while mild irritation was observed following three applications on skin abraded (no further details available) (Johnson et al., 2011 in NICNAS, 2018).

SEVERE EYE DAMAGE/EYE IRRITATION

Based on available data and considering the classification criteria provided in Table 3.3.3 of Annex I of Regulation (EC) 1272/2008 as amended, the product is classified as Eye irrit. 2, H319

Octamethylcyclotetrasiloxane
It has no irritant power (NICNAS, 2018).

RESPIRATORY OR SKIN SENSITISATION

Based on the available data and considering the classification criteria of Annex I, Part 3 of Regulation (EC) 1272/2008 as amended, the product is classified as Skin Sens. 1, H317

<u>Octamethylcyclotetrasiloxane</u>

It has no sensitising power (NICNAS, 2018).

The substance did not induce skin sensitisation when tested in maximisation tests on guinea pigs (GPMT) (NICNAS, 2018).

GERM CELL MUTAGENICITY

Based on available data and considering the classification criteria of Annex I, Part 3 of Regulation (EC) 1272/2008 as amended, the product is not classified for this hazard class.

CARCINOGENICITY

Based on available data and considering the classification criteria of Annex I, Part 3 of Regulation (EC) 1272/2008 as amended, the product is not classified for this hazard class.

<u>Octamethylcyclotetrasiloxane</u>

Based on the available data, the substance did not show any carcinogenic power (NICNAS, 2018).

REPRODUCTIVE TOXICITY

Based on available data and considering the classification criteria of Annex I, Part 3 of Regulation (EC) 1272/2008 as amended, the product is not classified for this hazard class.

Harmful effects on sexual function and fertility

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<u>Octamethylcyclotetrasiloxane</u>

There is no evidence that the substance causes toxicity in male rats.

In female rats, high concentrations (700 ppm for 6h/day) cause an increase in the duration of the ovarian cycle, a reduction in the corpora luteum and slight histological changes of the uterus, vagina and mammary glands. After mating, a reduction in the number of implantation sites is observed,

the average number of litters per litter, the average life span of newborns and an increase in the pre- and post-implantation losses.

The effects on fertility only occur if females are exposed during the entire period (from 3 days before mating until the 3rd day of gestation) and are reversible at the end of exposure.

The effects are due to a reduction in the serum peak of LH resulting in delayed ovulation.

Data indicate that the substance has mild oestrogenic activity.

The relevance of these findings for humans is uncertain (NICNAS, 2018).

Harmful effects on offspring development

Octamethylcyclotetrasiloxane

In studies conducted by the inhalation route, there is no evidence that the substance causes developmental toxicity in the exposed rats and rabbits (NICNAS, 2018).

SPECIFIC TARGET ORGAN TOXICITY (STOT) - SINGLE EXPOSURE

Based on available data and considering the classification criteria of Annex I, Part 3 of Regulation (EC) 1272/2008 as amended, the product is not classified for this hazard class.

<u>Octamethylcyclotetrasiloxane</u>

No pulmonary and/or biological effects were observed in a study on inhalation volunteers (INRS, 2008).

No symptoms of acute toxicity were observed in animal studies (NICNAS, 2018).

SPECIFIC TARGET ORGAN TOXICITY (STOT) - REPEATED EXPOSURE

Based on available data and considering the classification criteria of Annex I, Part 3 of Regulation (EC) 1272/2008 as amended, the product is not classified for this hazard class.

Octamethylcyclotetrasiloxane

No human data are available.

In animal studies, performed by the oral, dermal and inhalation routes, no relevant alterations were found.

In the rat, following inhalation, a reversible weight gain and enzyme induction are observed and

not accompanied by other symptoms of hepatotoxicity (NICNAS, 2018).

DANGER IN THE EVENT OF ASPIRATION

Based on available data and considering the classification criteria of Annex I, Part 3 of Regulation (EC) 1272/2008 as amended, the product is not classified for this hazard class.

11.2. Information on other hazards

According to the available data, the product does not contain any substances listed in the main European lists of potential or suspected endocrine disruptors with effects on human health under evaluation.

SECTION 12. Ecological Information

12.1. Toxicity

Based on the assessment of the classification of components and the classification provisions of Annex I, Part 4 of Regulation (EC) 1272/2008 as amended, the mixture is classified as dangerous for the environment with long-term effects *Aq. Chronic 2, H411*.

Titanium dioxide; [in powder form containing

≥ 1 % particles with an aerodynamic diameter

≤ 10 µm].

EC50 - Crustaceans

> 100 mg/l/48h Daphnia Magna

NOEC Chronic Crustaceans

> 10 mg/l 21 days - Daphnia Magna

2,2-bis-[4-(2,3-epoxypropoxy)phenyl]-

propane

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LC50 - Fish 1.5 mg/l/96h Oncorhynchus mykiss

EC50 - Crustaceans 1.1 mg/l/48h Daphnia magna

EC50 - Algae / Aquatic Plants 9.1 mg/l/72h Scenedesmus capricornutum

NOEC Chronic Crustaceans 0.3 mg/l Daphnia magna, 21 days

Octamethylcyclotetrasiloxane

LC50 - Fish > 22 µg/l/96h Oncorhynchus mykiss

EC50 - Crustaceans > 15 µg/l/48h Daphnia magna

NOEC Chronic Fish > 4.4 µg/l Oncorhynchus mykiss, 93 days NOEC Chronic Crustaceans > 15 µg/l Daphnia magna - 21days

Reaction mass of 2,2'-[methylenebis(2,1phenyleneoxymethylene)]bis(oxirane) and

2,2'-[methylenebis(4,1-

phenyleneoxymethylene)]bis(oxirane) and 2-({2-[4-(oxiran- 2-ylmethoxy)benzyl]phenoxy}

methyl)oxirane

LC50 - Fish 2.54 mg/l/96h

12.2. Persistence and degradability

Octamethylcyclotetrasiloxane
Octamethylcyclotetrasiloxane does not biodegrade in water or organic sediments under aerobic conditions (HSDB, 2017).

It can biodegrade to dimethylsilanediol in the presence of activated sludge (HSDB, 2017).

In the atmosphere, it exists only in vapour phase according to the vapour pressure value (HSDB, 2017).

In the vapour phase it degrades by reaction with photochemically produced hydroxyl radicals, with an estimated time of half-life = 13 days (HSDB, 2017). Not susceptible to photolysis when exposed to direct solar radiation (HSDB, 2017).

In water, it can hydrolyse, generating dimethylsilanediol (HSDB, 2017).

Titanium dioxide; [in powder form containing

≥ 1 % particles with an aerodynamic diameter

≤ 10 µm].

Solubility in water < 0.001 mg/l

Degradability: data not available

Octamethylcyclotetrasiloxane NOT rapidly degradable

3.7 % after 28 days

12.3. Bioaccumulation potential

Octamethylcyclotetrasiloxane

Based on the estimated and reported value of BCF = 12400 a very high potential for bioaccumulation is expected in aquatic organisms (HSDB, 2017).

Octamethylcyclotetrasiloxane

BCF 14900 l/kg Aquatic species. BMF fish 0.47

12.4. Mobility in soil

Octamethylcyclotetrasiloxane

Based on a very high estimated and reported value of Koc = 14000, it is expected that octamethylcyclotetrasiloxane has no mobility in soil (HSDB, 2017). It can volatilise from the dry soil surface depending on the vapour pressure value (HSDB, 2017).

Volatilisation from moist soil and water surfaces is a process of significant magnitude based on the value of Henry's law constant (HSDB, 2017).

It adsorbs significantly to sediments and suspended solids based on the estimated Koc value (HSDB, 2017).

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12.5. Results of PBT and vPvB assessment

According to the available data, the product does not contain PBT or vPvB substances in a proportion ≥ 0.1%.

12.6 Endocrine-disrupting properties

According to the available data, the product does not contain any substances listed in the main European lists of potential or suspected endocrine disrupters with effects on the environment under evaluation.

12.7. Other adverse effects

Information not available

SECTION 13. Disposal considerations

13.1. Waste treatment methods

Reuse if possible. Product residues are to be regarded as special hazardous waste. The hazardousness of waste containing some of this product must be assessed in accordance with current legislation.

Disposal must be entrusted to an authorised waste management company, in compliance with national and possibly local regulations.

CONTAMINATED PACKAGING
Contaminated packaging must be sent for recovery or disposal in accordance with national waste management regulations.

SECTION 14. Transport information

14.1. ONU number or ID number

ADR / RID, IMDG, IATA: ONU 3082

ADR / RID: In accordance with Special Provision 375, this product, when is packed in receptacles of a capacity ≤ 5Kg or 5L, is not

submitted to ADR provisions.

IMDG: In accordance with Section 2.10.2.7 of IMDG Code, this product, when is packed in receptacles of a capacity ≤ 5Kg or

5L, is not submitted to IMDG Code provisions.

IATA: In accordance with SP A197, this product, when is packed in receptacles of a capacity ≤ 5Kg or 5L, is not submitted to

IATA dangerous goods regulations.

14.2. ONU proper shipping name

ADR / RID: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.(2,2-bis-[4-(2,3-epoxy)phenyl]-propane, Reaction

mass of 2,2'-[methylenebis(2,1-phenylphenoxymethylene)]bis(oxirane) and 2,2'-[methylenebis(4,1-

phenylphenoxymethylene)]bis(oxirane) and 2-({ 2-[4-(oxiran- 2-ylmethoxy)benzyl]phenoxy} methyl)oxirane)

IMDG: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.(2,2-bis-[4-(2,3-epoxy)phenyl]-propané, Reaction

mass of 2,2'-[methylenebis(2,1-phenylphenoxymethylene)]bis(oxirane) and 2,2'-[methylenebis(4,1-

phenylphenoxymethylene)]bis(oxirane) and 2-({ 2-[4-(oxiran- 2-ylmethoxy)benzyl]phenoxy} methyl)oxirane) ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.(2,2-bis-[4-(2,3-epoxy)phenyl]-propane, Reaction

mass of 2,2'-[methylenebis(2,1-phenylphenoxymethylene)]bis(oxirane) and 2,2'-[methylenebis(4,1-

phenylphenoxymethylene)]bis(oxirane) and 2-({ 2-[4-(oxiran- 2-ylmethoxy)benzyl]phenoxy} methyl)oxirane)

14.3. Transport hazard class(es)

IATA:

ADR / RID: Class: 9 Label: 9

IMDG: Class: 9 Label: 9

IATA: Class: 9 Label: 9



14.4. Packing group

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ADR / RID, IMDG, IATA: Ш

14.5. Environmental hazards

ADR / RID: NO IMDG: NO IATA: NO

14.6. Special precautions for user

ADR / RID: HIN - Kemler: 90 Limited Quantities: 5 Tunnel restriction code: (-)

Special provision: 274, 335, 375, 601

IMDG: EMS: F-A, S-F Limited Quantities: 5

IATA: Cargo: Maximum quantity: 450 Packaging instructions: 964

Passengers:

Maximum quantity: 450 Packaging instructions:

964

A97, A158,

A197, A215

14.7. Bulk Maritime Transport in accordance with IMO Acts

Not relevant information

SECTION 15. Regulatory Information

15.1. Safety, health and environmental laws and regulations specific to the substance or mixture

Special provision:

Seveso Category - Directive 2012/18/EU: E2

Biocides Regulation (Reg. (EU) 528/2012): not applicable

Detergents Regulation (Reg. (EC) 648/2004): not applicable

Dir. 2004/42/EC - VOC / Legislative Decree 161/2006: not applicable

Restrictions on the product or contained substances according to Annex XVII Regulation (EC) 1907/2006

Product Point

3 - 40

Substances contained

Point 75 Titanium dioxide; [in powder form containing ≥ 1 % particles with an

aerodynamic diameter ≤ 10 µm].

Point 75 2,2-bis-[4-(2,3-epoxypropoxy)phenyl]-propane

Point 75 Octamethylcyclotetrasiloxane

Regulation (EU) 2019/1148 - on the marketing and use of explosives precursors

not applicable

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Candidate List Substances (Art. 59 REACH)

According to the available data, the product does not contain SVHC substances in a proportion ≥ 0.1 %.

Substances subject to authorisation (Annex XIV REACH)

None

Substances subject to export notification Regulation (EU) 649/2012:

None

Substances subject to the Rotterdam Convention:

None

Substances subject to the Stockholm Convention:

None

Healthcare controls

Workers exposed to this chemical agent hazardous to health must be subject to health surveillance carried out in accordance with the provisions of Article 41 of Legislative Decree 81 of 9 April 2008, unless the risk to the safety and health of the worker has been assessed as insignificant, in accordance with Article 224(2).

Classification for water pollution in Germany (AwSV, vom 18. April 2017)

WGK 3: Very dangerous for water

15.2. Chemical Safety Assessment

A chemical safety assessment was carried out for the following contained substances:

Titanium dioxide; [in powder form containing ≥ 1 % particles with an aerodynamic diameter ≤ 10 μm].

Octamethylcyclotetrasiloxane

Reaction mass of 2,2'-[methylenebis(2,1-phenyleneoxymethylene)]bis(oxirane) and phenyleneoxymethylene)]bis(oxirane) and 2-(\par{2-[4-[4-(oxirane-2-ylmethoxy)benzyl]phenoxy}methyl)oxirane

2,2'-[methylenebis(4,1-

SECTION 16. Other information

Text of the hazard statements (H) cited in sections 2-3 of the sheet:

Flam. Liq. 3 Flammable liquid, category 3
Carc. 2 Carcinogenicity, category 2

Repr. 2 Toxicity for reproduction, category 2

Eye Irrit. 2 Eye irritation, category 2
Skin Irrit. 2 Skin irritation, category 2
Skin Sens. 1 Skin sensitisation, category 1

Aquatic Chronic 1 Dangerous for the aquatic environment, chronic toxicity, category 1

Aquatic Chronic 2 Dangerous for the aquatic environment, chronic toxicity, category 2

H226Flammable liquids and vapours.H351Suspected of causing cancer.H361fSuspected of harming fertility.H319Causes severe eye irritation.

H315 Causes skin irritation.

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H317 It may cause an allergic skin reaction.

H410 Very toxic to aquatic organisms with long-lasting effects. H411 Toxic to aquatic organisms with long-lasting effects.

EUH211 Caution! Dangerous respirable droplets may be formed in the event of vaporisation.

Do not breathe vapours or mists.

Note 10 The classification as a carcinogen by inhalation only applies to mixtures in the form of

dust containing ≥ 1 % titanium dioxide in the form of, or incorporated into, particles

with an aerodynamic diameter ≤ 10 µm.

When the substance is to be placed on the market in the form of fibres (diameter < 3) Note V

> μm, length > 5 μm and aspect ratio ≥ 3:1) or particles meeting the WHO fibre criteria or in the form of particles with a modified surface chemistry, the hazardous properties must be assessed in accordance with Title II of this Regulation to determine whether a higher category (Carc. 1B or 1 A) and/or additional routes of exposure (oral or

dermal) should be applied

Note W It has been observed that the carcinogenic hazard of the substance arises when the

amount of respirable dust inhaled is such that the pulmonary mechanisms of particle

expulsion are significantly impaired.

This note is intended to describe the particular toxicity of the substance and does not

constitute a classification criterion under this Regulation

_EGEND:

ADR: European Agreement concerning the Transport of Dangerous Goods by Road

CAS: Chemical Abstract Service number

EC: Identification number in ESIS (European Substances Database)

CLP: Regulation (EC) 1272/2008

DNEL: Derived level without effect

EC50: Concentration affecting 50% of the test population

EmS: Emergency Schedule

GHS: Globally Harmonised System for the Classification and Labelling of Chemicals

IATA DGR: International Air Transport Association Dangerous Goods Regulations

IC50: 50 per cent immobilisation concentration of the test population

IMDG: International Maritime Dangerous Goods Code

IMO: International Maritime Organisation

INDEX: Identification number in Annex VI of the CLP

LC50: Lethal concentration 50%

LD50: Lethal dose 50%.

OEL: Occupational Exposure Level

PBT: Persistent, bioaccumulative and toxic

PEC: Predictable environmental concentration

PEL: Expected Exposure Level

PMT: Persistent, mobile and toxic

PNEC: Predictable no-effect concentration

REACH: Regulation (EC) 1907/2006

RID: Regulations for the International Carriage of Dangerous Goods by Rail

STA: Acute Toxicity Estimate

TLV: Threshold Limit Value

TLV CEILING: Concentration not to be exceeded at any time during work exposure.

TWA: Weighted Average Exposure Limit

TWA STEL: Short-term exposure limit

VOC: Volatile Organic Compound

vPvB: Very persistent and very bioaccumulative

vPvM: Very persistent and very mobile

WGK: Aquatic Hazard Class (Germany).

A1 = recognised human carcinogen.

A2 = suspected human carcinogen.

A3 = recognised animal carcinogen with unknown relevance in humans.

A4 = not classified as carcinogenic to humans.

A5 = not suspected of being carcinogenic to humans.

IBE = Substance with Biological Exposure Indicator.

GE<u>NERAL BIBLIOGRAPHY:</u>

- 1. Regulation (EC) 1907/2006 of the European Parliament (REACH)
- 2. Regulation (EC) 1272/2008 of the European Parliament (CLP)
- 3. Regulation (EU) 2020/878 (All. II REACH Regulation) 4. Regulation (EC) 790/2009 of the European Parliament (I Atp. CLP)

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- 5. Regulation (EU) 286/2011 of the European Parliament (II Atp. CLP)
- Regulation (EU) 618/2012 of the European Parliament (III Atp. CLP)
- 7. Regulation (EU) 487/2013 of the European Parliament (IV Atp. CLP)
- 8. Regulation (EU) 944/2013 of the European Parliament (V Atp. CLP)
- 9. Regulation (EU) 605/2014 of the European Parliament (VI Atp. CLP)
- 10. Regulation (EU) 2015/1221 of the European Parliament (VII Atp. CLP)
- 11. Regulation (EU) 2016/918 of the European Parliament (VIII Atp. CLP)
- 12. Regulation (EU) 2016/1179 (IX Atp. CLP) 13. Regulation (EU) 2017/776 (X Atp. CLP)
- 14. Regulation (EU) 2018/669 (XI Atp. CLP)
- 15. Regulation (EU) 2019/521 (XII Atp. CLP)
- 16. Delegated Regulation (EU) 2018/1480 (XIII Atp. CLP)
- 17. Regulation (EU) 2019/1148
- 18. Delegated Regulation (EU) 2020/217 (XIV Atp. CLP)
- 19. Delegated Regulation (EU) 2020/1182 (XV Atp. CLP)
- 20. Delegated Regulation (EU) 2021/643 (XVI Atp. CLP)
- 21. Delegated Regulation (EU) 2021/849 (XVII Atp. CLP)
- 22. Delegated Regulation (EU) 2022/692 (XVIII Atp. CLP)
- 23. Delegated Regulation (EU) 2023/707
- The Merck Index. 10th Edition
- Handling Chemical Safety
- INRS Fiche Toxicologique (toxicological sheet)
- Patty Industrial Hygiene and Toxicology
- N.I. Sax Dangerous properties of Industrial Materials-7, 1989 Edition
- IFA GESTIS website
- ECHA Agency Website
- Database of model SDSs of chemical substances Ministry of Health and Istituto Superiore di Sanità

CALCULATION METHODS

Chemical-physical hazards: The hazard was derived from the classification criteria of the CLP Regulation Annex I Part 2 as amended.

Health hazards were assessed using the calculation method laid down in Regulation (EC) 1272/2008 (CLP) as amended for the classification of mixtures when data exist on all or some of the components of the mixture:

Acute Tox: application of criteria Table 3.1.1. Annex I Part 3 of the CLP Regulation as amended.

Skin Corr. 1A/1B/1C H314: application of additivity formula criteria Table 3.2.3 Annex I Part 3 of the CLP Regulation

Skin Irrit 2 H315: application formula additivity criteria Table 3.2.3 Annex I Part 3 of the CLP Regulation

Eye Dam 1 H318: application of additivity formula criteria Table 3.3.3 Annex I Part 3 of the CLP Regulation

Eye Irrit. 2 H319: application of the formula of the criteria additivity Table 3.3.3 Annex I Part 3 of the CLP Regulation

Eye Irrit. 2 H319: Table 3.3.3 of Annex I, Part 3 of Regulation (EC) 1272/2008 (CLP) as amended.

Skin Sens 1A/1B/1 H317 Table 3.4.5 of Annex I, Part 3 of Regulation (EC) 1272/2008 (CLP) as amended.

Resp Sens 1A/1B/1 H334 Table 3.4.5 of Annex I, Part 3 of Regulation (EĆ) 1272/2008 (CLÉ) as amended.

Muta. 1A/1B, 2 H340 - H341: Table 3.5.2 Annex I Part 3 of the CLP Regulation as amended.

Carc 1A/1B, 2 H350 - H351: Table 3.6.2 Annex I Part 3 of the CLP Regulation as amended.

Repr 1A/1B, 2 H360 - H361: Table 3.7.2 Annex I Part 3 of the CLP Regulation as amended.

STOT SE 1, 2 H370 - 371: application of calculation methods - Table 3.8.3 of Annex I, Part 3 of Regulation (EC) 1272/2008 (CLP) as amended.

STOT SE 3 H336; Chap, 3.8.3.4.5 of Annex I, Part 3 of Regulation (EC) 1272/2008 (CLP) as amended.

STOT RE 1, 2 H372 - H373: Table 3.9.4 Annex I Part 3 of the CLP Regulation as amended.

Asp Tox 1 H304: application of criteria 3.10 Annex I Part 3 of the CLP Regulation as amended.

Environmental hazards were assessed using the calculation method laid down in Regulation (EC) 1272/2008 (CLP) as amended for the classification of mixtures when data exist on all or some of the components of the mixture:

toxicity to the aquatic environment acute effects: Table 4.1.1 of Annex I, Part 4 of Regulation (EC) 1272/2008 (CLP) as amended;

toxicity to the aquatic environment chronic effects: Table 4.1.2 of Annex I, Part 4 of Regulation (EC) 1272/2008 (CLP) as amended.

Note for users:

The information contained in this sheet is based on the knowledge available to us at the date of the last version. The user must ensure the suitability and completeness of the information in relation to the specific use of the product.

It should not be interpreted as a guarantee of any specific product properties.

Since the use of the product is not under our direct control, it is the user's responsibility to observe the applicable laws and regulations regarding hygiene and safety. We accept no liability for improper use.

Provide adequate training for personnel handling chemicals.

Sections changed from the previous version: ALL.