

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

- 1.1 Product identifier:** R PRO 30 - Comp.A (Base)
Other means of identification:
Not relevant
- 1.2 Relevant identified uses of the substance or mixture and uses advised against:**
Relevant uses (Consumer use): Gum
Uses advised against: All uses not specified in this section or in section 7.3
- 1.3 Details of the supplier of the safety data sheet:**
Reschimica srl
Via F.Borromini, 50
50028 Tavarnelle Val di Pesa - Toscana - Italia
Phone: 0558071454 - Fax: 0558071661
reachsds@reschimica.com
<https://www.reschimica.com/it/>
- 1.4 Emergency telephone number:** CAV "Osp. Pediatrico Bambino Gesù" 06 68593726
Az. Osp. Univ. Foggia 800183459
Az. Osp. "A. Cardarelli" 081 7472901
CAV Policlinico "Umberto I" 06-49978000
CAV Policlinico "A. Gemelli" 06-3054343
Az. Osp. "Careggi" U.O. Tossicologia Medica 055-7947819
CAV Centro Nazionale di Informazione Tossicologica 0382-24444
Osp. Niguarda Ca' Granda 02-66101029
Azienda Ospedaliera Papa Giovanni XXII 800883300
Azienda Ospedaliera Integrata Verona, 800011858

SECTION 2: HAZARDS IDENTIFICATION

- The product has been classified in accordance with the information contained in the suppliers' SDS and the additional information from tests carried out by said suppliers
- 2.1 Classification of the substance or mixture:**
This product contains crystalline silica but due to its liquid state it prevents particles within the size range of the breathable fraction from becoming airborne, therefore, the hazard classification linked to it does not apply to the breathable crystalline silica fraction (STOT RE).
CLP Regulation (EC) No 1272/2008:
The product is not classified as hazardous according to CLP Regulation (EC) No 1272/2008.
- 2.2 Label elements:**
CLP Regulation (EC) No 1272/2008:
Hazard statements:
Not relevant
Precautionary statements:
Not relevant
Supplementary information:
EUH210: Safety data sheet available on request.
- 2.3 Other hazards:**
Product does not meet PBT/vPvB criteria
Endocrine-disrupting properties: The product does not meet the criteria.
Exposure to respirable crystalline free silica and processed silanamine is not expected during normal use of this product. For more information see section 11






SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

- 3.1 Substance:**
Not relevant
- 3.2 Mixture:**
Chemical description: Silicone-based blend
Components:

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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS (continued)

In accordance with Annex II of Regulation (EC) No 1907/2006 (point 3), the product contains:

Identification	Chemical name/Classification		Concentration
CAS: 68909-20-6 EC: 272-697-1 Index: 014-052-00-7 REACH: Not relevant	Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica⁽¹⁾	ATP ATP18	10 - <25%
	Regulation 1272/2008	STOT RE 2: H373; EUH066 - Warning 	
CAS: 14464-46-1 EC: 238-455-4 Index: Not relevant REACH: Not relevant	Cristobalite (RCS > 10 %)⁽¹⁾	Self-classified	5 - <10%
	Regulation 1272/2008	STOT RE 1: H372 - Danger 	
CAS: 556-67-2 EC: 209-136-7 Index: 014-018-00-1 REACH: 01-2119529238-36-XXXX	Octamethylcyclotetrasiloxane⁽²⁾	Self-classified	0.01 - <0.1%
	Regulation 1272/2008	Aquatic Chronic 1: H410; Flam. Liq. 3: H226; Repr. 2: H361f - Warning   	

⁽¹⁾ Substances presenting a health or environmental hazard which meet criteria laid down in Regulation (EU) No. 2020/878

⁽²⁾ Voluntarily-listed substance failing to meet any of the criteria set out in Regulation (EU) No. 2020/878

To obtain more information on the hazards of the substances consult sections 11, 12 and 16.

Other information:

Identification	M-factor	
	Octamethylcyclotetrasiloxane CAS: 556-67-2 EC: 209-136-7	Acute
	Chronic	10

Due to the physical characteristics of the product there is no danger of aspiration deriving from the contained cristobalite.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures:

The symptoms resulting from intoxication can appear after exposure, therefore, in case of doubt, seek medical attention for direct exposure to the chemical product or persistent discomfort, showing the SDS of this product.

By inhalation:

This product is not classified as hazardous through inhalation. However, in case of intoxication symptoms it is recommended to remove the person affected from the area of exposure, provide clean air and keep at rest. Request medical attention if symptoms persist.

By skin contact:

Remove contaminated clothing and footwear, rinse skin or shower the person affected if appropriate with plenty of cold water and neutral soap. In serious cases see a doctor. If the product causes burns or freezing, clothing should not be removed as this could worsen the injury caused if it is stuck to the skin. If blisters form on the skin, these should never be burst as this will increase the risk of infection.

By eye contact:

Rinse eyes thoroughly with water for at least 15 minutes. If the injured person uses contact lenses, these should be removed unless they are stuck to the eyes, in which case removal could cause further damage. In all cases, after cleaning, a doctor should be consulted as quickly as possible with the SDS for the product.

By ingestion/aspiration:

In case of consumption, seek immediate medical assistance showing the SDS for the product.

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

Acute and delayed effects are indicated in sections 2 and 11.

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

Not relevant

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media:

Suitable extinguishing media:

Product is non-flammable under normal conditions of storage, handling and use. In the case of combustion as a result of improper handling, storage or use preferably use polyvalent powder extinguishers (ABC powder), in accordance with the Regulation on fire protection systems.

Unsuitable extinguishing media:

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SECTION 5: FIREFIGHTING MEASURES (continued)

Non-applicable

5.2 Special hazards arising from the substance or mixture:

As a result of combustion or thermal decomposition reactive sub-products are created that can become highly toxic and, consequently, can present a serious health risk.

5.3 Advice for firefighters:

Depending on the magnitude of the fire it may be necessary to use full protective clothing and Self Contained Breathing Apparatus. Minimum emergency facilities and equipment should be available (fire blankets, portable first aid kit,...)

Additional provisions:

Act in accordance with the Internal Emergency Plan and the Information Sheets on actions to take after an accident or other emergencies. Eliminate all sources of ignition. In case of fire, cool the storage containers and tanks for products susceptible to combustion, explosion or BLEVE as a result of high temperatures. Avoid spillage of the products used to extinguish the fire into an aqueous medium.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures:

For non-emergency personnel:

Isolate leaks provided that there is no additional risk for the people performing this task. Evacuate the area and keep out those without protection. Personal protection equipment must be used against potential contact with the spilled product (See section 8). Above all prevent the formation of any vapour-air flammable mixtures, through either ventilation or the use of an inert medium. Remove any source of ignition. Eliminate electrostatic charges by interconnecting all the conductive surfaces on which static electricity could form, and also ensuring that all surfaces are connected to the ground.

For emergency responders:

Wear protective equipment. Keep unprotected persons away. See section 8.

6.2 Environmental precautions:

It is recommended to avoid environmental spillage of both the product and its container.

6.3 Methods and material for containment and cleaning up:

It is recommended:

Prevent the entrance of product in drains, sewers or watercourses. Absorb the spill using sand or inert absorbent and move it to a safe place. Do not absorb in sawdust or other combustible absorbents. Collect the product in appropriate containers and manage it according to current legislation.

Spillages in water or sea:

Small spillages:

Contain spillage using barriers or similar equipment. Use suitable absorbents for collection and treat the waste in accordance with current regulations.

Large spillages:

If possible, contain spillage in open water using barriers or similar equipment. If this is not possible, try to control its spread and collect the product with suitable mechanical means. Always consult experts before using dispersants and make sure you have the necessary approvals if they are to be used. Treat the waste according to current regulations.

6.4 Reference to other sections:

See sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling:

A.- General precautions for safe use

Comply with the current legislation concerning the prevention of industrial risks with regards manually handling weights. Maintain order, cleanliness and dispose of using safe methods (section 6).

B.- Technical recommendations for the prevention of fires and explosions

Avoid the evaporation of the product as it contains flammable substances, which could form flammable vapour/air mixtures in the presence of sources of ignition. Control sources of ignition (mobile phones, sparks,...) and transfer at slow speeds to avoid the creation of electrostatic charges. Consult section 10 for conditions and materials that should be avoided.

C.- Technical recommendations on general occupational hygiene

Do not eat or drink during the process, washing hands afterwards with suitable cleaning products.

D.- Technical recommendations to prevent environmental risks

It is recommended to have absorbent material available at close proximity to the product (See subsection 6.3)

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SECTION 7: HANDLING AND STORAGE (continued)

7.2 Conditions for safe storage, including any incompatibilities:

A.- Specific storage requirements

Minimum Temp.:	5 °C
Maximum Temp.:	30 °C
Maximum time:	6 Months

B.- General conditions for storage

Avoid sources of heat, radiation, static electricity and contact with food. For additional information see subsection 10.5

7.3 Specific end use(s):

Except for the instructions already specified it is not necessary to provide any special recommendation regarding the uses of this product.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters:

Substances whose occupational exposure limits have to be monitored in the workplace (European OEL, not country-specific legislation):

Directive (EU) 2000/39, Directive 2004/37/EC, Directive (EU) 2006/15, Directive (EU) 2009/161, Directive (EU) 2017/164, Directive (EU) 2019/1831:

Identification	Occupational exposure limits	
	IOELV (8h)	IOELV (STEL)
Cristobalite (RCS > 10 %) CAS: 14464-46-1 EC: 238-455-4		0,1 mg/m ³

DNEL (Workers):

Identification		Short exposure		Long exposure	
		Systemic	Local	Systemic	Local
Octamethylcyclotetrasiloxane CAS: 556-67-2 EC: 209-136-7	Oral	Not relevant	Not relevant	Not relevant	Not relevant
	Dermal	Not relevant	Not relevant	Not relevant	Not relevant
	Inhalation	Not relevant	Not relevant	73 mg/m ³	73 mg/m ³

DNEL (General population):

Identification		Short exposure		Long exposure	
		Systemic	Local	Systemic	Local
Octamethylcyclotetrasiloxane CAS: 556-67-2 EC: 209-136-7	Oral	Not relevant	Not relevant	3,7 mg/kg	Not relevant
	Dermal	Not relevant	Not relevant	Not relevant	Not relevant
	Inhalation	Not relevant	Not relevant	13 mg/m ³	13 mg/m ³

PNEC:

Identification		PNEC	
		Systemic	Local
Octamethylcyclotetrasiloxane CAS: 556-67-2 EC: 209-136-7	STP	10 mg/L	Fresh water
	Soil	0,54 mg/kg	Marine water
	Intermittent	Not relevant	Sediment (Fresh water)
	Oral	0,041 g/kg	Sediment (Marine water)

8.2 Exposure controls:

A.- Individual protection measures, such as personal protective equipment

As a preventative measure it is recommended to use basic Personal Protective Equipment, with the corresponding <<CE marking>> in accordance with Regulation (EU) 2016/425. For more information on Personal Protective Equipment (storage, use, cleaning, maintenance, class of protection,...) consult the information leaflet provided by the manufacturer. For more information see subsection 7.1. All information contained herein is a recommendation which needs some specification from the labour risk prevention services as it is not known whether the company has additional measures at its disposal.

B.- Respiratory protection

If the working conditions and/or safety measures adopted do not allow keeping the airborne concentration of the product below the exposure limits (if any) or at acceptable levels (if no exposure limits exist), suitable respiratory protection equipment chosen by a qualified professional should be used.

C.- Specific protection for the hands

Not relevant

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)

D.- Eye and face protection

Not relevant

E.- Body protection

Not relevant

F.- Additional emergency measures

It is advised to implement additional emergency equipments in workplaces that are particularly exposed to the product or in situations where risk assessments highlight the necessity of such equipments.

It is not necessary to take additional emergency measures.

Environmental exposure controls:

To comply with environmental protection regulations, it is recommended to prevent any spillage of the product and its container. For more detailed information, please refer to subsection 7.1.D.

Volatile organic compounds:

With regard to Directive 2010/75/EU, this product has the following characteristics:

V.O.C. (Supply):	0,09 % weight
V.O.C. density at 20 °C:	0,99 kg/m ³ (0,99 g/L)
Average carbon number:	8
Average molecular weight:	296,6 g/mol

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties:

For complete information see the product datasheet.

Appearance:

Physical state at 20 °C:	Liquid
Appearance:	Not relevant *
Colour:	Not relevant *
Odour:	Odourless
Odour threshold:	Not relevant *

Volatility:

Boiling point at atmospheric pressure:	175 °C
Vapour pressure at 20 °C:	90 Pa
Vapour pressure at 50 °C:	721,86 Pa (0,72 kPa)
Evaporation rate at 20 °C:	Not relevant *

Product description:

Density at 20 °C:	1101,4 kg/m ³
Relative density at 20 °C:	1,101
Dynamic viscosity at 20 °C:	7,69 mPa·s
Kinematic viscosity at 20 °C:	6,98 mm ² /s
Kinematic viscosity at 40 °C:	Not relevant *
Concentration:	Not relevant *
pH:	Not relevant *
Vapour density at 20 °C:	Not relevant *
Partition coefficient n-octanol/water 20 °C:	Not relevant *
Solubility in water at 20 °C:	Not relevant *
Solubility properties:	Not relevant *
Decomposition temperature:	Not relevant *

*Not relevant due to the nature of the product, not providing information property of its hazards.

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES (continued)

Melting point/freezing point:	Not relevant *
Flammability:	
Flash Point:	Non Flammable (>60 °C)
Flammability (solid, gas):	Not relevant *
Autoignition temperature:	400 °C
Lower flammability limit:	Not relevant *
Upper flammability limit:	Not relevant *
Particle characteristics:	
Median equivalent diameter:	Not relevant *

9.2 Other information:

Information with regard to physical hazard classes:

Explosive properties:	Not relevant *
Oxidising properties:	Not relevant *
Corrosive to metals:	Not relevant *
Heat of combustion:	Not relevant *
Aerosols-total percentage (by mass) of flammable components:	Not relevant *

Other safety characteristics:

Surface tension at 20 °C:	Not relevant *
Refraction index:	Not relevant *

*Not relevant due to the nature of the product, not providing information property of its hazards.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity:

No hazardous reactions are expected because the product is stable under recommended storage conditions. See section 7 from Safety Data Sheet.

10.2 Chemical stability:

Chemically stable under the indicated conditions of storage, handling and use.

10.3 Possibility of hazardous reactions:

Under the specified conditions, hazardous reactions that lead to excessive temperatures or pressure are not expected.

10.4 Conditions to avoid:

Applicable for handling and storage at room temperature:

Shock and friction	Contact with air	Increase in temperature	Sunlight	Humidity
Not applicable	Not applicable	Precaution	Precaution	Not applicable

10.5 Incompatible materials:

Acids	Water	Oxidising materials	Combustible materials	Others
Avoid strong acids	Not applicable	Avoid direct impact	Not applicable	Avoid alkalis or strong bases

10.6 Hazardous decomposition products:

See subsection 10.3, 10.4 and 10.5 to find out the specific decomposition products. Depending on the decomposition conditions, complex mixtures of chemical substances can be released: carbon dioxide (CO₂), carbon monoxide and other organic compounds.

SECTION 11: TOXICOLOGICAL INFORMATION

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

The product has been classified in accordance with the information contained in the suppliers' SDS and the additional information from tests carried out by said suppliers

Dangerous health implications:

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SECTION 11: TOXICOLOGICAL INFORMATION (continued)

In case of exposure that is repetitive, prolonged or at concentrations higher than the recommended occupational exposure limits, adverse effects on health may result, depending on the means of exposure:

A- Ingestion (acute effect):

- Acute toxicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for consumption. For more information see section 3
- Corrosivity/Irritability: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

B- Inhalation (acute effect):

- Acute toxicity : Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for inhalation. For more information see section 3.
- Corrosivity/Irritability: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

C- Contact with the skin and the eyes (acute effect):

- Contact with the skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for skin contact. For more information see section 3.
- Contact with the eyes: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

D- CMR effects (carcinogenicity, mutagenicity and toxicity to reproduction):

- Carcinogenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for the effects mentioned. For more information see section 3.
IARC: Cristobalite (RCS > 10 %) (1: Carcinogenic to humans)
- Mutagenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.
- Reproductive toxicity: Based on available data, the classification criteria are not met. However, it does contain substances classified as hazardous for this effect. For more information see section 3.

E- Sensitizing effects:

- Respiratory: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous with sensitising effects. For more information see section 3.
- Skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

F- Specific target organ toxicity (STOT) - single exposure:

Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

G- Specific target organ toxicity (STOT)-repeated exposure:

- Specific target organ toxicity (STOT)-repeated exposure: Based on available data, the classification criteria are not met. However, it contains substances classified as hazardous for inhalation. For more information see section 3.
- Skin: Based on available data, the classification criteria are not met. However, it does contain substances which are classified as dangerous due to repetitive exposure. For more information see section 3.

H- Aspiration hazard:

Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

Other information:

For the classification of health hazards (Part 3), the route of exposure, information on mechanisms and metabolism studies are useful in determining the significance of an effect on humans. If such information raises doubts as to its relevance to humans, no matter how well-founded and high-quality the data are, a lower classification may be justified. When there is scientific evidence that the mechanism or mode of action is not relevant for humans, the substance or mixture shall not be classified" (Annex I, Section 1.1.5, Regulation EC 1272/2008).

Monitoring for possible inhalation exposure conducted in-house according to industrial hygiene regulations for paste and fluid products revealed exposure levels to crystalline free silica (respirable fraction) and treated silanamine below the method's limit of quantification, therefore exposure is not expected during the use indicated in section 1.2 for this specific product.

However, actual levels of dust present in the workplace must be obtained by monitoring as required by worker health and safety regulations

Specific toxicology information on the substances:

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SECTION 11: TOXICOLOGICAL INFORMATION (continued)

Identification	Acute toxicity		Genus
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica CAS: 68909-20-6 EC: 272-697-1	LD50 oral	>2000 mg/kg	
	LD50 dermal	>2000 mg/kg	
	LC50 inhalation vapour	>20 mg/L	
Cristobalite (RCS > 10 %) CAS: 14464-46-1 EC: 238-455-4	LD50 oral	>2000 mg/kg	
	LD50 dermal	>2000 mg/kg	
	LC50 inhalation dust	>5 mg/L	
Octamethylcyclotetrasiloxane CAS: 556-67-2 EC: 209-136-7	LD50 oral	61440 mg/kg	Rat
	LD50 dermal	10000 mg/kg	Rabbit
	LC50 inhalation vapour	>20 mg/L	

11.2 Information on other hazards:

Endocrine disrupting properties

Endocrine-disrupting properties: The product does not meet the criteria.

Other information

Not relevant

SECTION 12: ECOLOGICAL INFORMATION

Based on available data, the classification criteria are not met. However, it does contain substances classified as hazardous for this effect. For more information see section 3.

The product has been classified in accordance with the information contained in the suppliers' SDS and the additional information from tests carried out by said suppliers

12.1 Toxicity:

Acute toxicity:

Identification	Concentration		Species	Genus
Octamethylcyclotetrasiloxane CAS: 556-67-2 EC: 209-136-7	LC50	0,022 mg/L (96 h)	Oncorhynchus mykiss	Fish
	EC50	0,015 mg/L (48 h)	Daphnia magna	Crustacean
	EC50	0,022 mg/L (96 h)	Pseudokirchneriella subcapitata	Algae

Chronic toxicity:

Identification	Concentration		Species	Genus
Octamethylcyclotetrasiloxane CAS: 556-67-2 EC: 209-136-7	NOEC	>0.01 - 0.1 mg/L		Fish
	NOEC	>0.01 - 0.1 mg/L		Crustacean

12.2 Persistence and degradability:

Substance-specific information:

Identification	Degradability		Biodegradability	
	Octamethylcyclotetrasiloxane CAS: 556-67-2 EC: 209-136-7	BOD5	Not relevant	Concentration
	COD	Not relevant	Period	29 days
	BOD5/COD	Not relevant	% Biodegradable	4 %

12.3 Bioaccumulative potential:

Substance-specific information:

Identification	Bioaccumulation potential	
Octamethylcyclotetrasiloxane CAS: 556-67-2 EC: 209-136-7	BCF	12400
	Pow Log	6.5
	Potential	Very High

12.4 Mobility in soil:

Identification	Absorption/desorption		Volatility	
Octamethylcyclotetrasiloxane CAS: 556-67-2 EC: 209-136-7	Koc	16600	Henry	1200000 Pa·m ³ /mol
	Conclusion	Immobile	Dry soil	Yes
	Surface tension	1,819E-2 N/m (25 °C)	Moist soil	Yes

12.5 Results of PBT and vPvB assessment:

Product does not meet PBT/vPvB criteria

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SECTION 12: ECOLOGICAL INFORMATION (continued)

12.6 Endocrine disrupting properties:

Endocrine-disrupting properties: The product does not meet the criteria.

12.7 Other adverse effects:

Not described

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods:

Type of waste (Regulation (EU) No 1357/2014):

HP5 Specific Target Organ Toxicity (STOT)/Aspiration Toxicity

Waste management (disposal and evaluation):

Consult the authorized waste service manager on the assessment and disposal operations in accordance with Annex 1 and Annex 2 (Directive 2008/98/EC). As under 15 01 (2014/955/EC) of the code and in case the container has been in direct contact with the product, it will be processed the same way as the actual product. Otherwise, it will be processed as non-hazardous residue. Waste should not be disposed of to drains. See paragraph 6.2.

Regulations related to waste management:

In accordance with Annex II of Regulation (EC) No 1907/2006 (REACH) the community or state provisions related to waste management are stated

Community legislation: Directive 2008/98/EC, 2014/955/EU, Regulation (EU) No 1357/2014

SECTION 14: TRANSPORT INFORMATION

This product is not regulated for transport (ADR/RID,IMDG,IATA)

SECTION 15: REGULATORY INFORMATION

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

- Article 95, REGULATION (EU) No 528/2012: *Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica (68909-20-6) - PT: (18)*
- Candidate substances for authorisation under the Regulation (EC) No 1907/2006 (REACH): *Octamethylcyclotetrasiloxane (556-67-2)*
- Regulation (EU) 2019/1021 on persistent organic pollutants: Not relevant
- Regulation (EU) No 2024/590, about substances that deplete the ozone layer: Not relevant
- REGULATION (EU) No 649/2012, in relation to the import and export of hazardous chemical products: Not relevant
- Substances included in Annex XIV of REACH ("Authorisation List") and sunset date: Not relevant

Seveso III:

Not relevant

Limitations to commercialisation and the use of certain dangerous substances and mixtures (Annex XVII REACH, etc)

:

Laboral exposure to respirable crystalline silica must be controlled in accordance with Directive (EU) 2022/431, of the European Parliament and of the Council, of March 9, 2022, amending Directive 2004/37/EC, relating to the protection of workers against risks related to exposure to carcinogens or mutagens during work.

Specific provisions in terms of protecting people or the environment:

It is recommended to use the information included in this safety data sheet as a basis for conducting workplace-specific risk assessments in order to establish the necessary risk prevention measures for the handling, use, storage and disposal of this product.

Other legislation:

The product could be affected by sectorial legislation

15.2 Chemical safety assessment:

The supplier has not carried out evaluation of chemical safety.

SECTION 16: OTHER INFORMATION

Legislation related to safety data sheets:

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SECTION 16: OTHER INFORMATION (continued)

The SDS shall be supplied in an official language of the country where the product is placed on the market. This safety data sheet has been designed in accordance with ANNEX II-Guide to the compilation of safety data sheets of Regulation (EC) No 1907/2006 (COMMISSION REGULATION (EU) 2020/878).

Modifications related to the previous Safety Data Sheet which concerns the ways of managing risks.:

Not relevant

Texts of the legislative phrases mentioned in section 3:

The phrases indicated do not refer to the product itself; they are present merely for informative purposes and refer to the individual components which appear in section 3

CLP Regulation (EC) No 1272/2008:

Aquatic Chronic 1: H410 - Very toxic to aquatic life with long lasting effects.

Flam. Liq. 3: H226 - Flammable liquid and vapour.

Repr. 2: H361f - Suspected of damaging fertility.

STOT RE 1: H372 - Causes damage to organs through prolonged or repeated exposure (Inhalation).

STOT RE 2: H373 - May cause damage to organs through prolonged or repeated exposure (Inhalation).

Advice related to training:

Training is recommended in order to prevent industrial risks for staff using this product and to facilitate their comprehension and interpretation of this safety data sheet, as well as the label on the product.

Principal bibliographical sources:

<http://echa.europa.eu>

<http://eur-lex.europa.eu>

Abbreviations and acronyms:

ADR: European agreement concerning the international carriage of dangerous goods by road

IMDG: International maritime dangerous goods code

IATA: International Air Transport Association

ICAO: International Civil Aviation Organisation

COD: Chemical Oxygen Demand

BOD5: 5day biochemical oxygen demand

BCF: Bioconcentration factor

LD50: Lethal Dose 50

LC50: Lethal Concentration 50

EC50: Effective concentration 50

LogPOW: Octanolwater partition coefficient

Koc: Partition coefficient of organic carbon

UFI: unique formula identifier

IARC: International Agency for Research on Cancer

The information contained in this safety data sheet is based on sources, technical knowledge and current legislation at European and state level, without being able to guarantee its accuracy. This information cannot be considered a guarantee of the properties of the product, it is simply a description of the security requirements. The occupational methodology and conditions for users of this product are not within our awareness or control, and it is ultimately the responsibility of the user to take the necessary measures to obtain the legal requirements concerning the manipulation, storage, use and disposal of chemical products. The information on this safety data sheet only refers to this product, which should not be used for needs other than those specified.

- END OF SAFETY DATA SHEET -

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

- 1.1 Product identifier:** R PRO 30 - Comp.B (Catalyst)
- Other means of identification:**
Not relevant
- 1.2 Relevant identified uses of the substance or mixture and uses advised against:**
Relevant uses (Consumer use): Gum
Uses advised against: All uses not specified in this section or in section 7.3
- 1.3 Details of the supplier of the safety data sheet:**
Reschimica srl
Via F.Borromini, 50
50028 Tavarnelle Val di Pesa - Toscana - Italia
Phone: 0558071454 - Fax: 0558071661
reachsds@reschimica.com
<https://www.reschimica.com/it/>
- 1.4 Emergency telephone number:** CAV "Osp. Pediatrico Bambino Gesù" 06 68593726
Az. Osp. Univ. Foggia 800183459
Az. Osp. "A. Cardarelli" 081 7472901
CAV Policlinico "Umberto I" 06-49978000
CAV Policlinico "A. Gemelli" 06-3054343
Az. Osp. "Careggi" U.O. Tossicologia Medica 055-7947819
CAV Centro Nazionale di Informazione Tossicologica 0382-24444
Osp. Niguarda Ca' Granda 02-66101029
Azienda Ospedaliera Papa Giovanni XXII 800883300
Azienda Ospedaliera Integrata Verona, 800011858

SECTION 2: HAZARDS IDENTIFICATION






- 2.1 Classification of the substance or mixture:**
This product contains crystalline silica but due to its liquid state it prevents particles within the size range of the breathable fraction from becoming airborne, therefore, the hazard classification linked to it does not apply to the breathable crystalline silica fraction (STOT RE).
CLP Regulation (EC) No 1272/2008:
The product is not classified as hazardous according to CLP Regulation (EC) No 1272/2008.
- 2.2 Label elements:**
CLP Regulation (EC) No 1272/2008:
Hazard statements:
Not relevant
Precautionary statements:
Not relevant
Supplementary information:
EUH210: Safety data sheet available on request.
- 2.3 Other hazards:**
Product does not meet PBT/vPvB criteria
Endocrine-disrupting properties: The product does not meet the criteria.
Exposure to respirable crystalline free silica and processed silanamine is not expected during normal use of this product. For more information see section 11

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

- 3.1 Substance:**
Not relevant
- 3.2 Mixture:**
Chemical description: Silicone-based blend
Components:
In accordance with Annex II of Regulation (EC) No 1907/2006 (point 3), the product contains:

- CONTINUED ON NEXT PAGE -

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS (continued)

Identification	Chemical name/Classification	Concentration
CAS: 14464-46-1 EC: 238-455-4 Index: Not relevant REACH: Not relevant	Cristobalite (RCS > 10 %) ⁽¹⁾ Self-classified	10 - <25%
	Regulation 1272/2008 STOT RE 1: H372 - Danger 	
CAS: 68909-20-6 EC: 272-697-1 Index: 014-052-00-7 REACH: Not relevant	Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica ⁽¹⁾ ATP ATP18	10 - <25%
	Regulation 1272/2008 STOT RE 2: H373; EUH066 - Warning 	
CAS: 556-67-2 EC: 209-136-7 Index: 014-018-00-1 REACH: 01-2119529238-36-XXXX	Octamethylcyclotetrasiloxane ⁽²⁾ Self-classified	0.01 - <0.1%
	Regulation 1272/2008 Aquatic Chronic 1: H410; Flam. Liq. 3: H226; Repr. 2: H361f - Warning   	

⁽¹⁾ Substances presenting a health or environmental hazard which meet criteria laid down in Regulation (EU) No. 2020/878

⁽²⁾ Voluntarily-listed substance failing to meet any of the criteria set out in Regulation (EU) No. 2020/878

To obtain more information on the hazards of the substances consult sections 11, 12 and 16.

Other information:

Identification	M-factor	
	Octamethylcyclotetrasiloxane CAS: 556-67-2 EC: 209-136-7	Acute
	Chronic	10

Due to the physical characteristics of the product there is no danger of aspiration deriving from the contained cristobalite.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures:

The symptoms resulting from intoxication can appear after exposure, therefore, in case of doubt, seek medical attention for direct exposure to the chemical product or persistent discomfort, showing the SDS of this product.

By inhalation:

This product is not classified as hazardous through inhalation. However, in case of intoxication symptoms it is recommended to remove the person affected from the area of exposure, provide clean air and keep at rest. Request medical attention if symptoms persist.

By skin contact:

Remove contaminated clothing and footwear, rinse skin or shower the person affected if appropriate with plenty of cold water and neutral soap. In serious cases see a doctor. If the product causes burns or freezing, clothing should not be removed as this could worsen the injury caused if it is stuck to the skin. If blisters form on the skin, these should never be burst as this will increase the risk of infection.

By eye contact:

Rinse eyes thoroughly with water for at least 15 minutes. If the injured person uses contact lenses, these should be removed unless they are stuck to the eyes, in which case removal could cause further damage. In all cases, after cleaning, a doctor should be consulted as quickly as possible with the SDS for the product.

By ingestion/aspiration:

In case of consumption, seek immediate medical assistance showing the SDS for the product.

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

Acute and delayed effects are indicated in sections 2 and 11.

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

Not relevant

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media:

Suitable extinguishing media:

Product is non-flammable under normal conditions of storage, handling and use. In the case of combustion as a result of improper handling, storage or use preferably use polyvalent powder extinguishers (ABC powder), in accordance with the Regulation on fire protection systems.

Unsuitable extinguishing media:

Non-applicable

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SECTION 5: FIREFIGHTING MEASURES (continued)

5.2 Special hazards arising from the substance or mixture:

As a result of combustion or thermal decomposition reactive sub-products are created that can become highly toxic and, consequently, can present a serious health risk.

5.3 Advice for firefighters:

Depending on the magnitude of the fire it may be necessary to use full protective clothing and Self Contained Breathing Apparatus. Minimum emergency facilities and equipment should be available (fire blankets, portable first aid kit,...)

Additional provisions:

Act in accordance with the Internal Emergency Plan and the Information Sheets on actions to take after an accident or other emergencies. Eliminate all sources of ignition. In case of fire, cool the storage containers and tanks for products susceptible to combustion, explosion or BLEVE as a result of high temperatures. Avoid spillage of the products used to extinguish the fire into an aqueous medium.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures:

For non-emergency personnel:

Isolate leaks provided that there is no additional risk for the people performing this task. Evacuate the area and keep out those without protection. Personal protection equipment must be used against potential contact with the spilt product (See section 8). Above all prevent the formation of any vapour-air flammable mixtures, through either ventilation or the use of an inert medium. Remove any source of ignition. Eliminate electrostatic charges by interconnecting all the conductive surfaces on which static electricity could form, and also ensuring that all surfaces are connected to the ground.

For emergency responders:

Wear protective equipment. Keep unprotected persons away. See section 8.

6.2 Environmental precautions:

It is recommended to avoid environmental spillage of both the product and its container.

6.3 Methods and material for containment and cleaning up:

It is recommended:

Prevent the entrance of product in drains, sewers or watercourses. Absorb the spill using sand or inert absorbent and move it to a safe place. Do not absorb in sawdust or other combustible absorbents. Collect the product in appropriate containers and manage it according to current legislation.

Spillages in water or sea:

Small spillages:

Contain spillage using barriers or similar equipment. Use suitable absorbents for collection and treat the waste in accordance with current regulations.

Large spillages:

If possible, contain spillage in open water using barriers or similar equipment. If this is not possible, try to control its spread and collect the product with suitable mechanical means. Always consult experts before using dispersants and make sure you have the necessary approvals if they are to be used. Treat the waste according to current regulations.

6.4 Reference to other sections:

See sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling:

A.- General precautions for safe use

Comply with the current legislation concerning the prevention of industrial risks with regards manually handling weights. Maintain order, cleanliness and dispose of using safe methods (section 6).

B.- Technical recommendations for the prevention of fires and explosions

Avoid the evaporation of the product as it contains flammable substances, which could form flammable vapour/air mixtures in the presence of sources of ignition. Control sources of ignition (mobile phones, sparks,...) and transfer at slow speeds to avoid the creation of electrostatic charges. Consult section 10 for conditions and materials that should be avoided.

C.- Technical recommendations on general occupational hygiene

Do not eat or drink during the process, washing hands afterwards with suitable cleaning products.

D.- Technical recommendations to prevent environmental risks

It is recommended to have absorbent material available at close proximity to the product (See subsection 6.3)

7.2 Conditions for safe storage, including any incompatibilities:

- CONTINUED ON NEXT PAGE -

SECTION 7: HANDLING AND STORAGE (continued)

A.- Specific storage requirements

Minimum Temp.:	5 °C
Maximum Temp.:	30 °C
Maximum time:	6 Months

B.- General conditions for storage

Avoid sources of heat, radiation, static electricity and contact with food. For additional information see subsection 10.5

7.3 Specific end use(s):

Except for the instructions already specified it is not necessary to provide any special recommendation regarding the uses of this product.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters:

Substances whose occupational exposure limits have to be monitored in the workplace (European OEL, not country-specific legislation):

Directive (EU) 2000/39, Directive 2004/37/EC, Directive (EU) 2006/15, Directive (EU) 2009/161, Directive (EU) 2017/164, Directive (EU) 2019/1831:

Identification	Occupational exposure limits	
	IOELV (8h)	IOELV (STEL)
Cristobalite (RCS > 10 %) CAS: 14464-46-1 EC: 238-455-4		0,1 mg/m ³

DNEL (Workers):

Identification		Short exposure		Long exposure	
		Systemic	Local	Systemic	Local
Octamethylcyclotetrasiloxane CAS: 556-67-2 EC: 209-136-7	Oral	Not relevant	Not relevant	Not relevant	Not relevant
	Dermal	Not relevant	Not relevant	Not relevant	Not relevant
	Inhalation	Not relevant	Not relevant	73 mg/m ³	73 mg/m ³

DNEL (General population):

Identification		Short exposure		Long exposure	
		Systemic	Local	Systemic	Local
Octamethylcyclotetrasiloxane CAS: 556-67-2 EC: 209-136-7	Oral	Not relevant	Not relevant	3,7 mg/kg	Not relevant
	Dermal	Not relevant	Not relevant	Not relevant	Not relevant
	Inhalation	Not relevant	Not relevant	13 mg/m ³	13 mg/m ³

PNEC:

Identification		PNEC	
		Systemic	Local
Octamethylcyclotetrasiloxane CAS: 556-67-2 EC: 209-136-7	STP	10 mg/L	Fresh water
	Soil	0,54 mg/kg	Marine water
	Intermittent	Not relevant	Sediment (Fresh water)
	Oral	0,041 g/kg	Sediment (Marine water)

8.2 Exposure controls:

A.- Individual protection measures, such as personal protective equipment

As a preventative measure it is recommended to use basic Personal Protective Equipment, with the corresponding <<CE marking>> in accordance with Regulation (EU) 2016/425. For more information on Personal Protective Equipment (storage, use, cleaning, maintenance, class of protection,...) consult the information leaflet provided by the manufacturer. For more information see subsection 7.1. All information contained herein is a recommendation which needs some specification from the labour risk prevention services as it is not known whether the company has additional measures at its disposal.

B.- Respiratory protection

If the working conditions and/or safety measures adopted do not allow keeping the airborne concentration of the product below the exposure limits (if any) or at acceptable levels (if no exposure limits exist), suitable respiratory protection equipment chosen by a qualified professional should be used.

C.- Specific protection for the hands

Not relevant

D.- Eye and face protection

- CONTINUED ON NEXT PAGE -

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)

Not relevant

E.- Body protection

Not relevant

F.- Additional emergency measures

It is advised to implement additional emergency equipments in workplaces that are particularly exposed to the product or in situations where risk assessments highlight the necessity of such equipments.

It is not necessary to take additional emergency measures.

Environmental exposure controls:

To comply with environmental protection regulations, it is recommended to prevent any spillage of the product and its container. For more detailed information, please refer to subsection 7.1.D.

Volatile organic compounds:

With regard to Directive 2010/75/EU, this product has the following characteristics:

V.O.C. (Supply):	0,09 % weight
V.O.C. density at 20 °C:	1,11 kg/m ³ (1,11 g/L)
Average carbon number:	8
Average molecular weight:	296,6 g/mol

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties:

For complete information see the product datasheet.

Appearance:

Physical state at 20 °C:	Liquid
Appearance:	Not relevant *
Colour:	Not relevant *
Odour:	Odourless
Odour threshold:	Not relevant *

Volatility:

Boiling point at atmospheric pressure:	175 °C
Vapour pressure at 20 °C:	90 Pa
Vapour pressure at 50 °C:	721,86 Pa (0,72 kPa)
Evaporation rate at 20 °C:	Not relevant *

Product description:

Density at 20 °C:	1237,8 kg/m ³
Relative density at 20 °C:	1,238
Dynamic viscosity at 20 °C:	7,69 mPa·s
Kinematic viscosity at 20 °C:	6,21 mm ² /s
Kinematic viscosity at 40 °C:	Not relevant *
Concentration:	Not relevant *
pH:	Not relevant *
Vapour density at 20 °C:	Not relevant *
Partition coefficient n-octanol/water 20 °C:	Not relevant *
Solubility in water at 20 °C:	Not relevant *
Solubility properties:	Not relevant *
Decomposition temperature:	Not relevant *
Melting point/freezing point:	Not relevant *

*Not relevant due to the nature of the product, not providing information property of its hazards.

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES (continued)

Flammability:

Flash Point:	Non Flammable (>60 °C)
Flammability (solid, gas):	Not relevant *
Autoignition temperature:	400 °C
Lower flammability limit:	Not relevant *
Upper flammability limit:	Not relevant *

Particle characteristics:

Median equivalent diameter:	Not relevant *
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9.2 Other information:

Information with regard to physical hazard classes:

Explosive properties:	Not relevant *
Oxidising properties:	Not relevant *
Corrosive to metals:	Not relevant *
Heat of combustion:	Not relevant *
Aerosols-total percentage (by mass) of flammable components:	Not relevant *

Other safety characteristics:

Surface tension at 20 °C:	Not relevant *
Refraction index:	Not relevant *

*Not relevant due to the nature of the product, not providing information property of its hazards.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity:

No hazardous reactions are expected because the product is stable under recommended storage conditions. See section 7 from Safety Data Sheet.

10.2 Chemical stability:

Chemically stable under the indicated conditions of storage, handling and use.

10.3 Possibility of hazardous reactions:

Under the specified conditions, hazardous reactions that lead to excessive temperatures or pressure are not expected.

10.4 Conditions to avoid:

Applicable for handling and storage at room temperature:

Shock and friction	Contact with air	Increase in temperature	Sunlight	Humidity
Not applicable	Not applicable	Precaution	Precaution	Not applicable

10.5 Incompatible materials:

Acids	Water	Oxidising materials	Combustible materials	Others
Avoid strong acids	Not applicable	Avoid direct impact	Not applicable	Avoid alkalis or strong bases

10.6 Hazardous decomposition products:

See subsection 10.3, 10.4 and 10.5 to find out the specific decomposition products. Depending on the decomposition conditions, complex mixtures of chemical substances can be released: carbon dioxide (CO₂), carbon monoxide and other organic compounds.

SECTION 11: TOXICOLOGICAL INFORMATION

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

The experimental information related to the toxicological properties of the product itself is not available

Dangerous health implications:

In case of exposure that is repetitive, prolonged or at concentrations higher than the recommended occupational exposure limits, adverse effects on health may result, depending on the means of exposure:

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SECTION 11: TOXICOLOGICAL INFORMATION (continued)

A- Ingestion (acute effect):

- Acute toxicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for consumption. For more information see section 3
- Corrosivity/Irritability: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

B- Inhalation (acute effect):

- Acute toxicity : Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for inhalation. For more information see section 3.
- Corrosivity/Irritability: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

C- Contact with the skin and the eyes (acute effect):

- Contact with the skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for skin contact. For more information see section 3.
- Contact with the eyes: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

D- CMR effects (carcinogenicity, mutagenicity and toxicity to reproduction):

- Carcinogenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for the effects mentioned. For more information see section 3.
IARC: Cristobalite (RCS > 10 %) (1: Carcinogenic to humans)
- Mutagenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.
- Reproductive toxicity: Based on available data, the classification criteria are not met. However, it does contain substances classified as hazardous for this effect. For more information see section 3.

E- Sensitizing effects:

- Respiratory: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous with sensitising effects. For more information see section 3.
- Skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

F- Specific target organ toxicity (STOT) - single exposure:

Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

G- Specific target organ toxicity (STOT)-repeated exposure:

- Specific target organ toxicity (STOT)-repeated exposure: Based on available data, the classification criteria are not met. However, it contains substances classified as hazardous for inhalation. For more information see section 3.
- Skin: Based on available data, the classification criteria are not met. However, it does contain substances which are classified as dangerous due to repetitive exposure. For more information see section 3.

H- Aspiration hazard:

Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

Other information:

For the classification of health hazards (Part 3), the route of exposure, information on mechanisms and metabolism studies are useful in determining the significance of an effect on humans. If such information raises doubts as to its relevance to humans, no matter how well-founded and high-quality the data are, a lower classification may be justified. When there is scientific evidence that the mechanism or mode of action is not relevant for humans, the substance or mixture shall not be classified" (Annex I, Section 1.1.5, Regulation EC 1272/2008).

Monitoring for possible inhalation exposure conducted in-house according to industrial hygiene regulations for paste and fluid products revealed exposure levels to crystalline free silica (respirable fraction) and treated silanamine below the method's limit of quantification, therefore exposure is not expected during the use indicated in section 1.2 for this specific product.

However, actual levels of dust present in the workplace must be obtained by monitoring as required by worker health and safety regulations.

Specific toxicology information on the substances:

Identification	Acute toxicity		Genus
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica CAS: 68909-20-6 EC: 272-697-1	LD50 oral	>2000 mg/kg	
	LD50 dermal	>2000 mg/kg	
	LC50 inhalation vapour	>20 mg/L	

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SECTION 11: TOXICOLOGICAL INFORMATION (continued)

Identification	Acute toxicity		Genus
Cristobalite (RCS > 10 %) CAS: 14464-46-1 EC: 238-455-4	LD50 oral	>2000 mg/kg	
	LD50 dermal	>2000 mg/kg	
	LC50 inhalation dust	>5 mg/L	
Octamethylcyclotetrasiloxane CAS: 556-67-2 EC: 209-136-7	LD50 oral	61440 mg/kg	Rat
	LD50 dermal	10000 mg/kg	Rabbit
	LC50 inhalation vapour	>20 mg/L	

11.2 Information on other hazards:

Endocrine disrupting properties

Endocrine-disrupting properties: The product does not meet the criteria.

Other information

Not relevant

SECTION 12: ECOLOGICAL INFORMATION

The experimental information related to the eco-toxicological properties of the product itself is not available

Based on available data, the classification criteria are not met. However, it does contain substances classified as hazardous for this effect. For more information see section 3.

12.1 Toxicity:

Acute toxicity:

Identification	Concentration	Species	Genus
Octamethylcyclotetrasiloxane CAS: 556-67-2 EC: 209-136-7	LC50	0,022 mg/L (96 h)	Oncorhynchus mykiss
	EC50	0,015 mg/L (48 h)	Daphnia magna
	EC50	0,022 mg/L (96 h)	Pseudokirchneriella subcapitata

Chronic toxicity:

Identification	Concentration	Species	Genus
Octamethylcyclotetrasiloxane CAS: 556-67-2 EC: 209-136-7	NOEC	>0.01 - 0.1 mg/L	Fish
	NOEC	>0.01 - 0.1 mg/L	Crustacean

12.2 Persistence and degradability:

Substance-specific information:

Identification	Degradability		Biodegradability	
	Octamethylcyclotetrasiloxane CAS: 556-67-2 EC: 209-136-7	BOD5	Not relevant	Concentration
	COD	Not relevant	Period	29 days
	BOD5/COD	Not relevant	% Biodegradable	4 %

12.3 Bioaccumulative potential:

Substance-specific information:

Identification	Bioaccumulation potential	
Octamethylcyclotetrasiloxane CAS: 556-67-2 EC: 209-136-7	BCF	12400
	Pow Log	6.5
	Potential	Very High

12.4 Mobility in soil:

Identification	Absorption/desorption		Volatility	
Octamethylcyclotetrasiloxane CAS: 556-67-2 EC: 209-136-7	Koc	16600	Henry	1200000 Pa·m ³ /mol
	Conclusion	Immobile	Dry soil	Yes
	Surface tension	1,819E-2 N/m (25 °C)	Moist soil	Yes

12.5 Results of PBT and vPvB assessment:

Product does not meet PBT/vPvB criteria

12.6 Endocrine disrupting properties:

Endocrine-disrupting properties: The product does not meet the criteria.

12.7 Other adverse effects:

- CONTINUED ON NEXT PAGE -

SECTION 12: ECOLOGICAL INFORMATION (continued)

Not described

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods:

Type of waste (Regulation (EU) No 1357/2014):

HP5 Specific Target Organ Toxicity (STOT)/Aspiration Toxicity

Waste management (disposal and evaluation):

Consult the authorized waste service manager on the assessment and disposal operations in accordance with Annex 1 and Annex 2 (Directive 2008/98/EC). As under 15 01 (2014/955/EC) of the code and in case the container has been in direct contact with the product, it will be processed the same way as the actual product. Otherwise, it will be processed as non-hazardous residue. Waste should not be disposed of to drains. See paragraph 6.2.

Regulations related to waste management:

In accordance with Annex II of Regulation (EC) No 1907/2006 (REACH) the community or state provisions related to waste management are stated

Community legislation: Directive 2008/98/EC, 2014/955/EU, Regulation (EU) No 1357/2014

SECTION 14: TRANSPORT INFORMATION

This product is not regulated for transport (ADR/RID,IMDG,IATA)

SECTION 15: REGULATORY INFORMATION

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

- Article 95, REGULATION (EU) No 528/2012: *Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica (68909-20-6) - PT: (18)*
- Candidate substances for authorisation under the Regulation (EC) No 1907/2006 (REACH): *Octamethylcyclotetrasiloxane (556-67-2)*
- Regulation (EU) 2019/1021 on persistent organic pollutants: Not relevant
- Regulation (EU) No 2024/590, about substances that deplete the ozone layer: Not relevant
- REGULATION (EU) No 649/2012, in relation to the import and export of hazardous chemical products: Not relevant
- Substances included in Annex XIV of REACH ("Authorisation List") and sunset date: Not relevant

Seveso III:

Not relevant

Limitations to commercialisation and the use of certain dangerous substances and mixtures (Annex XVII REACH, etc)

:

Laboral exposure to respirable crystalline silica must be controlled in accordance with Directive (EU) 2022/431, of the European Parliament and of the Council, of March 9, 2022, amending Directive 2004/37/EC, relating to the protection of workers against risks related to exposure to carcinogens or mutagens during work.

Specific provisions in terms of protecting people or the environment:

It is recommended to use the information included in this safety data sheet as a basis for conducting workplace-specific risk assessments in order to establish the necessary risk prevention measures for the handling, use, storage and disposal of this product.

Other legislation:

The product could be affected by sectorial legislation

15.2 Chemical safety assessment:

The supplier has not carried out evaluation of chemical safety.

SECTION 16: OTHER INFORMATION

Legislation related to safety data sheets:

The SDS shall be supplied in an official language of the country where the product is placed on the market. This safety data sheet has been designed in accordance with ANNEX II-Guide to the compilation of safety data sheets of Regulation (EC) No 1907/2006 (COMMISSION REGULATION (EU) 2020/878).

Modifications related to the previous Safety Data Sheet which concerns the ways of managing risks.:

Not relevant

- CONTINUED ON NEXT PAGE -

SECTION 16: OTHER INFORMATION (continued)

Texts of the legislative phrases mentioned in section 3:

The phrases indicated do not refer to the product itself; they are present merely for informative purposes and refer to the individual components which appear in section 3

CLP Regulation (EC) No 1272/2008:

Aquatic Chronic 1: H410 - Very toxic to aquatic life with long lasting effects.

Flam. Liq. 3: H226 - Flammable liquid and vapour.

Repr. 2: H361f - Suspected of damaging fertility.

STOT RE 1: H372 - Causes damage to organs through prolonged or repeated exposure (Inhalation).

STOT RE 2: H373 - May cause damage to organs through prolonged or repeated exposure (Inhalation).

Advice related to training:

Training is recommended in order to prevent industrial risks for staff using this product and to facilitate their comprehension and interpretation of this safety data sheet, as well as the label on the product.

Principal bibliographical sources:

<http://echa.europa.eu>

<http://eur-lex.europa.eu>

Abbreviations and acronyms:

ADR: European agreement concerning the international carriage of dangerous goods by road

IMDG: International maritime dangerous goods code

IATA: International Air Transport Association

ICAO: International Civil Aviation Organisation

COD: Chemical Oxygen Demand

BOD5: 5day biochemical oxygen demand

BCF: Bioconcentration factor

LD50: Lethal Dose 50

LC50: Lethal Concentration 50

EC50: Effective concentration 50

LogPOW: Octanolwater partition coefficient

Koc: Partition coefficient of organic carbon

UFI: unique formula identifier

IARC: International Agency for Research on Cancer

The information contained in this safety data sheet is based on sources, technical knowledge and current legislation at European and state level, without being able to guarantee its accuracy. This information cannot be considered a guarantee of the properties of the product, it is simply a description of the security requirements. The occupational methodology and conditions for users of this product are not within our awareness or control, and it is ultimately the responsibility of the user to take the necessary measures to obtain the legal requirements concerning the manipulation, storage, use and disposal of chemical products. The information on this safety data sheet only refers to this product, which should not be used for needs other than those specified.

- END OF SAFETY DATA SHEET -