

R PRO TECH 45 - Comp. A (Base)

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

1.1 Product identifier: R PRO TECH 45 - Comp. A (Base)

Inert

CAS: Non-applicable

EC: Non-applicable

Index: Non-applicable

REACH: Non-applicable

Other means of identification:

Non-applicable

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

Relevant uses: Silicon rubber. For professional users/industrial user only. 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 S.R.L.
Via F.Borromini, 50
50028 Tavarnelle Val di Pesa - Toscana - Italia
Phone: 0558071454 - Fax: 0558071661
info@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:

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:

Non-applicable

Precautionary statements:

Non-applicable

Supplementary information:

EUH210: Safety data sheet available on request.

2.3 Other hazards:

Product fails to meet PBT/vPvB criteria
Endocrine-disrupting properties: The product fails to meet the criteria.

*** Changes with regards to the previous version*

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substance:

Chemical description: Mixture based on silicones

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R PRO TECH 45 - Comp. A (Base)

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS (continued)

Components:

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

Identification	Chemical name/Classification	Concentration
CAS: Non-applicable EC: Non-applicable Index: Non-applicable REACH: Non-applicable	Inert ¹ Regulation 1272/2008 Not classified	76 - <100 %
CAS: 556-67-2 EC: 209-136-7 Index: 014-018-00-1 REACH: 01-2119529238-36-XXXX	Octamethylcyclotetrasiloxane ² Regulation 1272/2008 Aquatic Chronic 1: H410; Repr. 2: H361f - Warning	ATP ATP15 0,1 - <0,5 %

¹ Main component

² Substances presenting a health or environmental hazard which meet criteria laid down 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 1 Chronic 10

3.2 Mixture:

Non-applicable

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 does not contain substances classified as hazardous for inhalation, however, in case of symptoms of intoxication remove the person affected from the exposure area and provide with fresh air. Seek medical attention if the symptoms get worse or persist.

By skin contact:

In case of contact it is recommended to clean the affected area thoroughly with water and neutral soap. In case of changes to the skin (stinging, redness, rashes, blisters,...), seek medical advice with this Safety Data Sheet

By eye contact:

This product does not contain substances classified as hazardous for eye contact. Rinse eyes thoroughly for at least 15 minutes with lukewarm water, ensuring that the person affected does not rub or close their eyes.

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:

Non-applicable

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

5.2 Special hazards arising from the substance or mixture:

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SECTION 5: FIREFIGHTING MEASURES (continued)

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 (SCBA). Minimum emergency facilities and equipment should be available (fire blankets, portable first aid kit,...) in accordance with Directive 89/654/EC.

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. Personal protection equipment must be used against potential contact with the spilt product (See section 8). Evacuate the area and keep out those who do not have protection.

For emergency responders:

See section 8.

6.2 Environmental precautions:

Avoid spillage into the aquatic environment as it contains substances potentially dangerous for this. Contain the product absorbed in hermetically sealed containers. In the case of serious spillage into the aquatic environment notify the relevant authority.

6.3 Methods and material for containment and cleaning up:

It is recommended:

Absorb the spillage using sand or inert absorbent and move it to a safe place. Do not absorb in sawdust or other combustible absorbents. For any concern related to disposal consult section 13.

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 destroy using safe methods (section 6).

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

Product is non-flammable under normal conditions of storage, handling and use. It is recommended to transfer at slow speeds to avoid the generation of electrostatic charges that can affect flammable products. Consult section 10 for information on 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:

A.- Technical measures for storage

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

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SECTION 7: HANDLING AND STORAGE (continued)

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):

There are no applicable occupational exposure limits for the substances contained in the product

DNEL (Workers):

Identification		Short exposure		Long exposure	
		Systemic	Local	Systemic	Local
Octamethylcyclotetrasiloxane CAS: 556-67-2 EC: 209-136-7	Oral	Non-applicable	Non-applicable	Non-applicable	Non-applicable
	Dermal	Non-applicable	Non-applicable	Non-applicable	Non-applicable
	Inhalation	Non-applicable	Non-applicable	73 mg/m³	73 mg/m³

DNEL (General population):

Identification		Short exposure		Long exposure	
		Systemic	Local	Systemic	Local
Octamethylcyclotetrasiloxane CAS: 556-67-2 EC: 209-136-7	Oral	Non-applicable	Non-applicable	3,7 mg/kg	Non-applicable
	Dermal	Non-applicable	Non-applicable	Non-applicable	Non-applicable
	Inhalation	Non-applicable	Non-applicable	13 mg/m³	13 mg/m³

PNEC:

Identification					
Octamethylcyclotetrasiloxane CAS: 556-67-2 EC: 209-136-7	STP	10 mg/L	Fresh water	0,0015 mg/L	
	Soil	0,54 mg/kg	Marine water	0,00015 mg/L	
	Intermittent	Non-applicable	Sediment (Fresh water)	3 mg/kg	
	Oral	0,041 g/kg	Sediment (Marine water)	0,3 mg/kg	

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

The use of protection equipment will be necessary if a mist forms or if the occupational exposure limits are exceeded.

C.- Specific protection for the hands

Non-applicable

D.- Eye and face protection

Non-applicable

E.- Body protection

Non-applicable

F.- Additional emergency measures

It is not necessary to take additional emergency measures.

Environmental exposure controls:

In accordance with the community legislation for the protection of the environment it is recommended to avoid environmental spillage of both the product and its container. For additional information see subsection 7.1.D

Volatile organic compounds:

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

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)

V.O.C. (Supply):	0,44 % weight
V.O.C. density at 20 °C:	4,44 kg/m ³ (4,44 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:	Transparent
Colour:	According to the markings on the package
Odour:	Odourless
Odour threshold:	Non-applicable *

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:	Non-applicable *

Product description:

Density at 20 °C:	999,8 kg/m ³
Relative density at 20 °C:	1
Dynamic viscosity at 20 °C:	7,67 cP
Kinematic viscosity at 20 °C:	7,67 mm ² /s
Kinematic viscosity at 40 °C:	Non-applicable *
Concentration:	Non-applicable *
pH:	Non-applicable *
Vapour density at 20 °C:	Non-applicable *
Partition coefficient n-octanol/water 20 °C:	Non-applicable *
Solubility in water at 20 °C:	Non-applicable *
Solubility properties:	Non-applicable *
Decomposition temperature:	Non-applicable *
Melting point/freezing point:	Non-applicable *

Flammability:

Flash Point:	Non Flammable (>60 °C)
Flammability (solid, gas):	Non-applicable *
Autoignition temperature:	400 °C
Lower flammability limit:	Non-applicable *
Upper flammability limit:	Non-applicable *

Particle characteristics:

Median equivalent diameter:	Non-applicable
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9.2 Other information:

Information with regard to physical hazard classes:

Explosive properties:	Non-applicable *
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*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)

Oxidising properties:	Non-applicable *
Corrosive to metals:	Non-applicable *
Heat of combustion:	Non-applicable *
Aerosols-total percentage (by mass) of flammable components:	Non-applicable *
Other safety characteristics:	
Surface tension at 20 °C:	Non-applicable *
Refraction index:	Non-applicable *

*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.

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	Not applicable	Not applicable	Not applicable

10.5 Incompatible materials:

Acids	Water	Oxidising materials	Combustible materials	Others
Avoid strong acids	Not applicable	Not applicable	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:

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):

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SECTION 11: TOXICOLOGICAL INFORMATION (continued)

- 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: Non-applicable
- 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, as it does not contain substances classified as hazardous for this effect. 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.

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:

Non-applicable

Specific toxicology information on the substances:

Identification	Acute toxicity		Genus
Inert	LD50 oral	>2000 mg/kg	
CAS: Non-applicable	LD50 dermal	>2000 mg/kg	
EC: Non-applicable	LC50 inhalation	Non-applicable	
Octamethylcyclotetrasiloxane	LD50 oral	>2000 mg/kg	
CAS: 556-67-2	LD50 dermal	>2000 mg/kg	
EC: 209-136-7	LC50 inhalation	>20 mg/L	

11.2 Information on other hazards:

Endocrine disrupting properties

Endocrine-disrupting properties: The product fails to meet the criteria.

Other information

Non-applicable

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R PRO TECH 45 - Comp. A (Base)

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity:

Acute toxicity:

Identification	Concentration	Species	Genus
Octamethylcyclotetrasiloxane	LC50 500 mg/L (96 h)	Brachydanio rerio	Fish
CAS: 556-67-2	EC50 Non-applicable		
EC: 209-136-7	EC50 Non-applicable		

Chronic toxicity:

Identification	Concentration	Species	Genus
Octamethylcyclotetrasiloxane	NOEC 0,0044 mg/L	Oncorhynchus mykiss	Fish
CAS: 556-67-2 EC: 209-136-7	NOEC 0,015 mg/L	Daphnia magna	Crustacean

12.2 Persistence and degradability:

Not available

12.3 Bioaccumulative potential:

Identification	Bioaccumulation potential
Octamethylcyclotetrasiloxane	BCF 12400
CAS: 556-67-2	Pow Log 4.45
EC: 209-136-7	Potential Very High

12.4 Mobility in soil:

Identification	Absorption/desorption	Volatility
Octamethylcyclotetrasiloxane	Koc Non-applicable	Henry Non-applicable
CAS: 556-67-2	Conclusion Non-applicable	Dry soil Non-applicable
EC: 209-136-7	Surface tension 1,819E-2 N/m (25 °C)	Moist soil Non-applicable

12.5 Results of PBT and vPvB assessment:

Product fails to meet PBT/vPvB criteria

12.6 Endocrine disrupting properties:

Endocrine-disrupting properties: The product fails to 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):

Non-applicable

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-dangerous 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

Transport of dangerous goods by land:

With regard to ADR 2021 and RID 2021:

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R PRO TECH 45 - Comp. A (Base)

SECTION 14: TRANSPORT INFORMATION (continued)

- 14.1 UN number or ID number:** Non-applicable
14.2 UN proper shipping name: Non-applicable
14.3 Transport hazard class(es): Non-applicable
 Labels: Non-applicable
14.4 Packing group: Non-applicable
14.5 Environmental hazards: No
14.6 Special precautions for user
 Special regulations: Non-applicable
 Tunnel restriction code: Non-applicable
 Physico-Chemical properties: see section 9
 Limited quantities: Non-applicable
14.7 Maritime transport in bulk according to IMO instruments: Non-applicable



Transport of dangerous goods by sea:

With regard to IMDG 39-18:

-   **14.1 UN number or ID number:** UN3082
14.2 UN proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Octamethylcyclotetrasiloxane)
14.3 Transport hazard class(es): 9
 Labels: 9
14.4 Packing group: III
14.5 Marine pollutant: Yes
14.6 Special precautions for user
 Special regulations: 335, 969, 274
 EmS Codes: F-A, S-F
 Physico-Chemical properties: see section 9
 Limited quantities: 5 L
 Segregation group: Non-applicable
14.7 Maritime transport in bulk according to IMO instruments: Non-applicable

Transport of dangerous goods by air:

With regard to IATA/ICAO 2022:

-   **14.1 UN number or ID number:** UN3082
14.2 UN proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Octamethylcyclotetrasiloxane)
14.3 Transport hazard class(es): 9
 Labels: 9
14.4 Packing group: III
14.5 Environmental hazards: Yes
14.6 Special precautions for user
 Physico-Chemical properties: see section 9
14.7 Maritime transport in bulk according to IMO instruments: Non-applicable

SECTION 15: REGULATORY INFORMATION

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

Candidate substances for authorisation under the Regulation (EC) No 1907/2006 (REACH): Octamethylcyclotetrasiloxane

Substances included in Annex XIV of REACH ("Authorisation List") and sunset date: Non-applicable

Regulation (EC) No 1005/2009, about substances that deplete the ozone layer: Non-applicable

Article 95, REGULATION (EU) No 528/2012: Non-applicable

REGULATION (EU) No 649/2012, in relation to the import and export of hazardous chemical products: Non-applicable

Seveso III:

Non-applicable

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

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R PRO TECH 45 - Comp. A (Base)

SECTION 15: REGULATORY INFORMATION (continued)

Contains Octamethylcyclotetrasiloxane. 1. | Shall not be placed on the market in wash-off cosmetic products in a concentration equal to or greater than 0,1 % by weight of either substance, after 31 January 2020. | 2. | For the purposes of this entry, "wash-off cosmetic products" means cosmetic products as defined in Article 2(1)(a) of Regulation (EC) No 1223/2009 that, under normal conditions of use, are washed off with water after application.'

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.:

CLP Regulation (EC) No 1272/2008 (SECTION 2, SECTION 16):

· Supplementary information

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.

Repr. 2: H361f - Suspected of damaging fertility.

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

Product safety information sheet prepared in accordance with Article 32 of Regulation (EC) 1907/2006 (REACH); this document does not constitute a Safety Data Sheet under Article 31 of Regulation (EC) No. 1907/2006, as a Safety Data Sheet is not mandatory for this product.
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 -

R PRO TECH 45 - Comp. B (Catalyst)

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

1.1 Product identifier: R PRO TECH 45 - Comp. B (Catalyst)

Inert

CAS: Non-applicable

EC: Non-applicable

Index: Non-applicable

REACH: Non-applicable

Other means of identification:

Non-applicable

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

Relevant uses: Silicon rubber. For professional users/industrial user only. 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:

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Azienda Ospedaliera Integrata Verona, 800011858

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture:

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:

None

2.3 Other hazards:

Product fails to meet PBT/vPvB criteria

Endocrine-disrupting properties: The product fails to meet the criteria.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substance:

Chemical description: Mixture based on silicones

Components:

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

Identification	Chemical name/Classification	Concentration
CAS: Non-applicable EC: Non-applicable Index: Non-applicable REACH: Non-applicable	Inert Not classified	100 %
	Regulation 1272/2008	

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

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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS (continued)

3.2 Mixture:

Non-applicable

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures:

Consult a doctor in case of discomfort showing the SDS for the product.

By inhalation:

In case of symptoms, move the person affected into fresh air.

By skin contact:

In case of contact it is recommended to clean the affected area thoroughly with water and neutral soap. In case of changes to the skin (stinging, redness, rashes, blisters,...), seek medical advice with this Safety Data Sheet

By eye contact:

Rinse with water until the product has been eliminated. In case of problems, consult a doctor showing the SDS for the product.

By ingestion/aspiration:

In case of consumption in large quantities, it is recommended to seek medical assistance.

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:

Non-applicable

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media:

Suitable extinguishing media:

Product is non-flammable, with a low risk of fire due to the flammability characteristics of the product in normal conditions of storage, handling and use. In the case of the existence of sustained combustion as a result of improper handling, storage or use any type of extinguishing agent can be used (ABC Powder, water,...)

Unsuitable extinguishing media:

Non-applicable

5.2 Special hazards arising from the substance or mixture:

Due to its inflammable nature, the product does not present a fire risk under normal conditions of storage, handling and use.

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 (SCBA). Minimum emergency facilities and equipment should be available (fire blankets, portable first aid kit,...) in accordance with Directive 89/654/EC.

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.

For emergency responders:

See section 8.

6.2 Environmental precautions:

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SECTION 6: ACCIDENTAL RELEASE MEASURES (continued)

This product is not classified as hazardous to the environment. Keep product away from drains, surface and ground water.

6.3 Methods and material for containment and cleaning up:

It is recommended:

Absorb the spillage using sand or inert absorbent and move it to a safe place. Do not absorb in sawdust or other combustible absorbents. For any concern related to disposal consult section 13.

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 destroy using safe methods (section 6).

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

It is recommended to transfer at a slow speed to avoid the creation of electrostatic charges that could affect flammable products. 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 not necessary to take special measures to prevent environmental risks. For more information see subsection 6.2

7.2 Conditions for safe storage, including any incompatibilities:

A.- Technical measures for storage

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):

There are no applicable occupational exposure limits for the substances contained in the product

DNEL (Workers):

Non-applicable

DNEL (General population):

Non-applicable

PNEC:

Non-applicable

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.

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)

B.- Respiratory protection

The use of protection equipment will be necessary if a mist forms or if the occupational exposure limits are exceeded.

C.- Specific protection for the hands

Non-applicable

D.- Eye and face protection

Non-applicable

E.- Body protection

Non-applicable

F.- Additional emergency measures

It is not necessary to take additional emergency measures.

Environmental exposure controls:

In accordance with the community legislation for the protection of the environment it is recommended to avoid environmental spillage of both the product and its container. For additional information see 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 % weight
V.O.C. density at 20 °C:	0 kg/m ³ (0 g/L)
Average carbon number:	Non-applicable
Average molecular weight:	Non-applicable

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:	Transparent
Colour:	According to the markings on the package
Odour:	Odourless
Odour threshold:	Non-applicable *

Volatility:

Boiling point at atmospheric pressure:	Non-applicable *
Vapour pressure at 20 °C:	Non-applicable *
Vapour pressure at 50 °C:	Non-applicable *
Evaporation rate at 20 °C:	Non-applicable *

Product description:

Density at 20 °C:	1000 kg/m ³
Relative density at 20 °C:	1
Dynamic viscosity at 20 °C:	Non-applicable *
Kinematic viscosity at 20 °C:	Non-applicable *
Kinematic viscosity at 40 °C:	Non-applicable *
Concentration:	Non-applicable *
pH:	Non-applicable *
Vapour density at 20 °C:	Non-applicable *
Partition coefficient n-octanol/water 20 °C:	Non-applicable *

*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)

Solubility in water at 20 °C:	Non-applicable *
Solubility properties:	Non-applicable *
Decomposition temperature:	Non-applicable *
Melting point/freezing point:	Non-applicable *
Flammability:	
Flash Point:	Non Flammable (>60 °C)
Flammability (solid, gas):	Non-applicable *
Autoignition temperature:	Non-applicable *
Lower flammability limit:	Non-applicable *
Upper flammability limit:	Non-applicable *

Particle characteristics:

Median equivalent diameter:	Non-applicable
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9.2 Other information:

Information with regard to physical hazard classes:

Explosive properties:	Non-applicable *
Oxidising properties:	Non-applicable *
Corrosive to metals:	Non-applicable *
Heat of combustion:	Non-applicable *
Aerosols-total percentage (by mass) of flammable components:	Non-applicable *

Other safety characteristics:

Surface tension at 20 °C:	Non-applicable *
Refraction index:	Non-applicable *

*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.

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	Not applicable	Not applicable	Not applicable

10.5 Incompatible materials:

Acids	Water	Oxidising materials	Combustible materials	Others
Avoid strong acids	Not applicable	Not applicable	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:

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SECTION 11: TOXICOLOGICAL INFORMATION (continued)

LD50 oral > 2000 mg/kg (rat)

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:

A- Ingestion (acute effect):

- Acute toxicity : Based on available data, the classification criteria are not met
- Corrosivity/Irritability: Based on available data, the classification criteria are not met

B- Inhalation (acute effect):

- Acute toxicity : Based on available data, the classification criteria are not met
- Corrosivity/Irritability: Based on available data, the classification criteria are not met

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

- Contact with the skin: Based on available data, the classification criteria are not met
- Contact with the eyes: Based on available data, the classification criteria are not met

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

- Carcinogenicity: Based on available data, the classification criteria are not met
IARC: Non-applicable
- Mutagenicity: Based on available data, the classification criteria are not met
- Reproductive toxicity: Based on available data, the classification criteria are not met

E- Sensitizing effects:

- Respiratory: Based on available data, the classification criteria are not met
- Skin: Based on available data, the classification criteria are not met

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

Based on available data, the classification criteria are not met

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
- Skin: Based on available data, the classification criteria are not met

H- Aspiration hazard:

Based on available data, the classification criteria are not met

Other information:

Non-applicable

Specific toxicology information on the substances:

Identification	Acute toxicity		Genus
Inert	LD50 oral	>2000 mg/kg	
CAS: Non-applicable	LD50 dermal	>2000 mg/kg	
EC: Non-applicable	LC50 inhalation	Non-applicable	

11.2 Information on other hazards:

Endocrine disrupting properties

Endocrine-disrupting properties: The product fails to meet the criteria.

Other information

Non-applicable

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SECTION 12: ECOLOGICAL INFORMATION

- 12.1 Toxicity:**
Not available
- 12.2 Persistence and degradability:**
Not available
- 12.3 Bioaccumulative potential:**
Not available
- 12.4 Mobility in soil:**
Not available
- 12.5 Results of PBT and vPvB assessment:**
Product fails to meet PBT/vPvB criteria
- 12.6 Endocrine disrupting properties:**
Endocrine-disrupting properties: The product fails to 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):
Non-applicable
- 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-dangerous 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:**
Candidate substances for authorisation under the Regulation (EC) No 1907/2006 (REACH): Non-applicable
Substances included in Annex XIV of REACH ("Authorisation List") and sunset date: Non-applicable
Regulation (EC) No 1005/2009, about substances that deplete the ozone layer: Non-applicable
Article 95, REGULATION (EU) No 528/2012: Non-applicable
REGULATION (EU) No 649/2012, in relation to the import and export of hazardous chemical products: Non-applicable
- Seveso III:**
Non-applicable
- Limitations to commercialisation and the use of certain dangerous substances and mixtures (Annex XVII REACH, etc)**
:
Non-applicable
- Specific provisions in terms of protecting people or the environment:**

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SECTION 15: REGULATORY INFORMATION (continued)

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.:

COMMISSION REGULATION (EU) 2020/878

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:

Non-applicable

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

Product safety information sheet prepared in accordance with Article 32 of Regulation (EC) 1907/2006 (REACH); this document does not constitute a Safety Data Sheet under Article 31 of Regulation (EC) No. 1907/2006, as a Safety Data Sheet is not mandatory for this product.
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 -