SILICONE RUBBER - SILICONE RUBBER

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Safety Data Sheet

According to Annex II to REACH - Regulation (EU) 2020/878 and to Annex II to UK REACH

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

1.1. Product identifier

Silicone Rubber Code: Product name SILICONE RUBBER Chemical name and synonym Silicone Rubber

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

Silicone rubber compounds for centrifugal casting and pear wax Intended use

1.3. Details of the supplier of the safety data sheet

Name Nicem spa Full address via Togliatti 38 District and Country 20030 Senago (MI)

Italia

Tel. 02.990901 Fax 02.99090333

e-mail address of the competent person

responsible for the Safety Data Sheet ivan.conti@nicem.eu

1.4. Emergency telephone number

For urgent inquiries refer to Centro Antiveleni Ospedale Niguarda- Milano 02.66101029

Centro Antiveleni Azienda Ospedaliera S.G Battisti - Torino 011.6637637 Centro Antiveleni Azienda Ospedaliera Careggi- Firenze 055.4277238

Centro Antiveleni Policlinico A. Gemelli - Roma 06.3054343

Centro Antiveleni Università degli Studi La Sapienza- Roma 06.49970698 Centro Antiveleni Azienda OspedalieraA. Cardarelli .- Napoli 081.7472870 Servizio Antiveleni Istituto Scentifico G. Gaslini- Genova 010.5636245 Servizio Antiveleni Università degli Studi - Padova 049.82750783 Centro Nazionale Imform. Tossic. Fond. S. Maugeri - Pavia 0382.24444

Azienda Ospedaliera Papa Giovanni XXIII - Bergamo

SECTION 2. Hazards identification

2.1. Classification of the substance or mixture

The product is not classified as dangerous pursuant to the provisions of Regulation (EC) 1272/2008 (CLP) (and subsequent amendments and adjustments).

Hazard classification and indication:

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2.2. Label elements

Free of labeling as it does not present a hazard to human health by inhalation, ingestion or contact with skin or to the aquatic environment in the form in which they are placed on the market, in accordance with Regulation (EC) 1272/2008 - Annex I - 1.3.4.

Hazard pictograms:

Signal words: Warning

Precautionary statements:

P501 Dispose of contents / container to . . .

P102 Keep out of reach of children.

P101 If medical advice is needed, have product container or label at hand.

P273 Avoid release to the environment.

P391 Collect spillage.

P314 Get medical advice / attention if you feel unwell.

Contains:

2.3. Other hazards

On the basis of available data, the product does not contain any PBT or vPvB in percentage ≥ than 0,1%.

The product contains substances with endocrine disrupting properties in concentration ≥ 0,1%:

Ottametilciclotetrasilossano

SECTION 3. Composition/information on ingredients

3.2. Mixtures

Contains:

Identification x = Conc. % Classification (EC) 1272/2008 (CLP)

QUARTZ

INDEX - $34 \le x < 36$ STOT RE 2 H373

EC 238-878-4 CAS 14808-60-7

REACH Reg. esente secondo

l'allegato V7

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Dodecamethylcyclohexasiloxane

INDEX - $0.5 \le x < 0.6$

EC 208-762-8 CAS 540-97-6

REACH Reg. 01-2119517435-42-

0001

Ottametilciclotetrasilossano

INDEX 014-018-00-1 0,5 ≤ x < 0,6 Flam. Liq. 3 H226, Repr. 2 H361f, Aquatic Acute 1 H400 M=10, Aquatic

Chronic 1 H410 M=10

EC 209-136-7 CAS 556-67-2

REACH Reg. 01-2119529238-36-

0001

Decamethylcycolentasiloxa

INDEX - $0.2 \le x < 0.4$

EC 208-764-9 CAS 541-02-6

REACH Reg. 01-2119511367-43-

0002

The full wording of hazard (H) phrases is given in section 16 of the sheet.

SECTION 4. First aid measures

4.1. Description of first aid measures

EYES: Remove contact lenses, if present. Wash immediately with plenty of water for at least 15 minutes, opening the eyelids fully. If problem persists, seek medical advice.

SKIN: Remove contaminated clothing. Wash immediately with plenty of water. If irritation persists, get medical advice/attention. Wash contaminated clothing before using it again.

INHALATION: Remove to open air. In the event of breathing difficulties, get medical advice/attention immediately.

INGESTION: Get medical advice/attention. Induce vomiting only if indicated by the doctor. Never give anything by mouth to an unconscious person, unless authorised by a doctor.

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

Specific information on symptoms and effects caused by the product are unknown.

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

Information not available

SECTION 5. Firefighting measures

5.1. Extinguishing media

SUITABLE EXTINGUISHING EQUIPMENT

The extinguishing equipment should be of the conventional kind: carbon dioxide, foam, powder and water spray.

UNSUITABLE EXTINGUISHING EQUIPMENT

None in particular.

5.2. Special hazards arising from the substance or mixture

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HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE Do not breathe combustion products.

5.3. Advice for firefighters

GENERAL INFORMATION

Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.

SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS

Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

SECTION 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

If there are no contraindications, spray powder with water to prevent the formation of dust.

Wear suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. These indications apply for both processing staff and those involved in emergency procedures.

6.2. Environmental precautions

The product must not penetrate into the sewer system or come into contact with surface water or ground water.

6.3. Methods and material for containment and cleaning up

Collect the leaked product and place it in containers for recovery or disposal. If there are no contraindications, use jets of water to eliminate product residues.

Make sure the leakage site is well aired. Evaluate the compatibility of the container to be used, by checking section 10. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

6.4. Reference to other sections

Any information on personal protection and disposal is given in sections 8 and 13.

SECTION 7. Handling and storage

7.1. Precautions for safe handling

Before handling the product, consult all the other sections of this material safety data sheet. Avoid leakage of the product into the environment. Do not eat, drink or smoke during use. Remove any contaminated clothes and personal protective equipment before entering places in which people eat.

7.2. Conditions for safe storage, including any incompatibilities

Store only in the original container. Store the containers sealed, in a well ventilated place, away from direct sunlight. Keep containers away from any incompatible materials, see section 10 for details.

7.3. Specific end use(s)

Information not available

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SECTION 8. Exposure controls/personal protection

8.1. Control parameters

OEL EU

Regulatory references:

Valeurs limites d'exposition professionnelle aux agents chimiques en France. ED 984 - INRS

Italia Decreto Legislativo 9 Aprile 2008, n.81

PRT Portugal Decreto-Lei n.º 1/2021 de 6 de janeiro, valores-limite de exposição profissional indicativos para os agentes

químicos. Decreto-Lei n.º 35/2020 de 13 de julho, proteção dos trabalhadores contra os riscos ligados à

exposição durante o trabalho a agentes cancerígenos ou mutagénicos
Directive (EU) 2022/431; Directive (EU) 2019/1831; Directive (EU) 2019/130; Directive (EU) 2019/983;

Directive (EU) 2017/2398; Directive (EU) 2017/164; Directive 2009/161/EU; Directive 2006/15/EC; Directive

2004/37/EC; Directive 2000/39/EC; Directive 98/24/EC; Directive 91/322/EEC.

TLV-ACGIH

QUARTZ							
Threshold Limit Value							
Туре	Country			STEL/15min		Remarks /	
						Observations	
		mg/m3	ppm	mg/m3	ppm		
VLEP	FRA	0,1				RESP	
VLEP	ITA	0,1				RESP	
VLE	PRT	0,025				RESP	
OEL	EU	0,1				RESP	
TLV-ACGIH		0.025				RESP	

Legend:

ΕU

(C) = CEILING; INHAL = Inhalable Fraction; RESP = Respirable Fraction; THORA = Thoracic Fraction.

8.2. Exposure controls

As the use of adequate technical equipment must always take priority over personal protective equipment, make sure that the workplace is well aired through effective local aspiration.

When choosing personal protective equipment, ask your chemical substance supplier for advice.

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

Exposure levels must be kept as low as possible to avoid significant build-up in the organism. Manage personal protective equipment so as to guarantee maximum protection (e.g. reduction in replacement times).

HAND PROTECTION

In the case of prolonged contact with the product, protect the hands with penetration-resistant work gloves (see standard EN 374).

Work glove material must be chosen according to the use process and the products that may form. Latex gloves may cause sensitivity reactions.

SKIN PROTECTION

Wear category II professional long-sleeved overalls and safety footwear (see Regulation 2016/425 and standard EN ISO 20344). Wash body with soap and water after removing protective clothing.

EYE PROTECTION

Wear airtight protective goggles (see standard EN 166).

RESPIRATORY PROTECTION

None required, unless indicated otherwise in the chemical risk assessment.

ENVIRONMENTAL EXPOSURE CONTROLS

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The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.

Product residues must not be indiscriminately disposed of with waste water or by dumping in waterways.

SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties Value Information

Appearance solid

Colour Manca la traduzione (C01 101) <======

(*)<<Error>>Manca la traduzione (C01 101)

not available

Odour characteristic

Melting point / freezing point > 500 °C
Initial boiling point not available
Flammability not flammable
Lower explosive limit not available
Upper explosive limit not available
Flash point not available
Auto-ignition temperature not available

pH not available
Kinematic viscosity not available
Solubility insoluble
Partition coefficient: n-octanol/water not available
Vapour pressure not available

Density and/or relative density 1,40

Relative vapour density not available
Particle characteristics not available

9.2. Other information

Decomposition temperature

9.2.1. Information with regard to physical hazard classes

Information not available

9.2.2. Other safety characteristics

Total solids (250°C / 482°F) 98,75 %

SECTION 10. Stability and reactivity

10.1. Reactivity

There are no particular risks of reaction with other substances in normal conditions of use.

Revision nr. 16 Nicem spa Dated 19/03/2024 Printed on 19/03/2024 SILICONE RUBBER - SILICONE RUBBER Page n. 7/14 Replaced revision:15 (Dated: 09/06/2023) 10.2. Chemical stability The product is stable in normal conditions of use and storage. 10.3. Possibility of hazardous reactions No hazardous reactions are foreseeable in normal conditions of use and storage. 10.4. Conditions to avoid None in particular. However the usual precautions used for chemical products should be respected. 10.5. Incompatible materials Information not available 10.6. Hazardous decomposition products Information not available **SECTION 11. Toxicological information** In the absence of experimental data for the product itself, health hazards are evaluated according to the properties of the substances it contains, using the criteria specified in the applicable regulation for classification. It is therefore necessary to take into account the concentration of the individual hazardous substances indicated in section 3, to evaluate the toxicological effects of exposure to the product. 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008 Metabolism, toxicokinetics, mechanism of action and other information Information not available Information on likely routes of exposure Information not available Delayed and immediate effects as well as chronic effects from short and long-term exposure Information not available

Interactive effects

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Information not available

ACUTE TOXICITY

ATE (Inhalation) of the mixture:

ATE (Oral) of the mixture:

Not classified (no significant component)

Not classified (no significant component)

ATE (Dermal) of the mixture:

Not classified (no significant component)

Manca la traduzione (WZ00060) <======(*)

 LD50 (Dermal):
 > 2400 mg/kg

 LD50 (Oral):
 > 2000 mg/kg

 LC50 (Inhalation mists/powders):
 36 mg/l/4h

Manca la traduzione (WZ00064) <======(*)

LD50 (Dermal): > 2400 mg/kg LD50 (Oral): > 2000 mg/kg

Manca la traduzione (WZ00063) <======(*)

LD50 (Dermal): > 2400 mg/kg LD50 (Oral): > 2000 mg/kg

SKIN CORROSION / IRRITATION

Does not meet the classification criteria for this hazard class

SERIOUS EYE DAMAGE / IRRITATION

Does not meet the classification criteria for this hazard class

RESPIRATORY OR SKIN SENSITISATION

Does not meet the classification criteria for this hazard class

GERM CELL MUTAGENICITY

Does not meet the classification criteria for this hazard class

CARCINOGENICITY

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Does not meet the classification criteria for this hazard class

REPRODUCTIVE TOXICITY

Does not meet the classification criteria for this hazard class

STOT - SINGLE EXPOSURE

Does not meet the classification criteria for this hazard class

STOT - REPEATED EXPOSURE

May cause damage to organs

ASPIRATION HAZARD

Does not meet the classification criteria for this hazard class

11.2. Information on other hazards

Based on the available data, the product contains the following endocrine disruptors in concentrations of 0.1% or greater by weight that may have endocrine disrupting effects on humans and cause adverse effects on the exposed individual or his or her progeny:

Manca la traduzione (WZ00060) <======(*)

SECTION 12. Ecological information

This product is dangerous for the environment and is toxic for aquatic organisms. In the long term, it have negative effects on acquatic environment. **12.1. Toxicity**

Manca la traduzione (WZ00060) <=====

(*)<<Error>>Manca la traduzione (WZ00060)

LC50 - for Fish
EC50 - for Crustacea
Chronic NOEC for Fish

> 0,022 mg/l/96h

> 0,015 mg/l/48h

> 0,0079 mg/l

12.2. Persistence and degradability

Information not available

12.3. Bioaccumulative potential

Information not available

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Information not available

12.5. Results of PBT and vPvB assessment

On the basis of available data, the product does not contain any PBT or vPvB in percentage ≥ than 0,1%.

12.6. Endocrine disrupting properties

Based on the available data, the product does not contain substances listed in the main European lists of potential or suspected endocrine disruptors with environmental effects under evaluation.

12.7. Other adverse effects

Information not available

SECTION 13. Disposal considerations

13.1. Waste treatment methods

Reuse, when possible. Product residues should be considered special hazardous waste. The hazard level of waste containing this product should be evaluated according to applicable regulations.

Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.

CONTAMINATED PACKAGING

Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

SECTION 14. Transport information

The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

14.1. UN number or ID number

not applicable

14.2. UN proper shipping name

not applicable

14.3. Transport hazard class(es)

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not applicable

14.4. Packing group

not applicable

14.5. Environmental hazards

not applicable

14.6. Special precautions for user

not applicable

14.7. Maritime transport in bulk according to IMO instruments

Information not relevant

SECTION 15. Regulatory information

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

Seveso Category - Directive 2012/18/EU: E2

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006

<u>Product</u>

Point 40

Contained substance

Point 75

Point 70 Manca la traduzione (WZ00060) REACH Reg.: 01-2119529238-36-

001 <======= (*)<<Error>>Manca la traduzione (WZ00060) REACH Reg.: 01-2119529238-36-0001

Point 70 Manca la traduzione (WZ00063)

REACH Reg.: 01-2119511367-43-0002 <======= (*)<<Error>>Manca la traduzione (WZ00063) REACH Reg.: 01-2119511367-43-0002

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

not applicable

Substances in Candidate List (Art. 59 REACH)

Manca la traduzione (WZ00060) <======(*)

REACH Reg.: 01-2119529238-36-0001

Manca la traduzione (WZ00064) <======(*)

REACH Reg.: 01-2119517435-42-0001

Manca la traduzione (WZ00063) <======(*)

REACH Reg.: 01-2119511367-43-0002

Substances subject to authorisation (Annex XIV REACH)

None

Substances subject to exportation reporting pursuant to Regulation (EU) 649/2012:

None

Substances subject to the Rotterdam Convention:

None

Substances subject to the Stockholm Convention:

None

Healthcare controls

Workers exposed to this chemical agent must not undergo health checks, provided that available risk-assessment data prove that the risks related to the workers' health and safety are modest and that the 98/24/EC directive is respected.

15.2. Chemical safety assessment

A chemical safety assessment has not been performed for the preparation/for the substances indicated in section 3.

SECTION 16. Other information

Text of hazard (H) indications mentioned in section 2-3 of the sheet:

Flam. Liq. 3 Flammable liquid, category 3

Repr. 2 Reproductive toxicity, category 2

STOT RE 2 Specific target organ toxicity - repeated exposure, category 2

Aquatic Acute 1 Hazardous to the aquatic environment, acute toxicity, category 1

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Aquatic Chronic 1 Hazardous to the aquatic environment, chronic toxicity, category 1

Aquatic Chronic 2 Hazardous to the aquatic environment, chronic toxicity, category 2

H226 Flammable liquid and vapour. H361f Suspected of damaging fertility.

H373 May cause damage to organs through prolonged or repeated exposure.

H400 Very toxic to aquatic life.

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

LEGEND:

- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- ATE: Acute Toxicity Estimate
- CAS: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect) CE: Identifier in ESIS (European archive of existing substances)
- CLP: Regulation (EC) 1272/2008
- DNEL: Derived No Effect Level
- EmS: Emergency Schedule
- GHS: Globally Harmonized System of classification and labeling of chemicals
- IATA DGR: International Air Transport Association Dangerous Goods Regulation
- IC50: Immobilization Concentration 50%
- IMDG: International Maritime Code for dangerous goods
- IMO: International Maritime Organization
- INDEX: Identifier in Annex VI of CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent bioaccumulative and toxic as REACH Regulation
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PNEC: Predicted no effect concentration
- REACH: Regulation (EC) 1907/2006
- RID: Regulation concerning the international transport of dangerous goods by train
- TLV: Threshold Limit Value
- TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure.
- TWA: Time-weighted average exposure limit
- TWA STEL: Short-term exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very Persistent and very Bioaccumulative as for REACH Regulation
- WGK: Water hazard classes (German).

GENERAL BIBLIOGRAPHY

- 1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
- 2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
- 3. Regulation (EU) 2020/878 (II Annex of REACH Regulation)
- 4. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament 5. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
- 6. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
- 7. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament 8. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
- 9. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
- 10. Regulation (EÚ) 2015/1221 (VII Atp. CLP) of the European Parliament
- 11. Regulation (EU) 2016/918 (VIII Atp. CLP) of the European Parliament
- 12. Regulation (EU) 2016/1179 (IX Atp. CLP) 13. Regulation (EU) 2017/776 (X Atp. CLP)
- 14. Regulation (EU) 2018/669 (XI Atp. CLP)
- 15. Regulation (EU) 2019/521 (XII Atp. CLP)
- 16. Delegated Regulation (UE) 2018/1480 (XIII Atp. CLP)
- 17. Regulation (EU) 2019/1148
- 18. Delegated Regulation (UE) 2020/217 (XIV Atp. CLP)
- 19. Delegated Regulation (UE) 2020/1182 (XV Atp. CLP)

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20. Delegated Regulation (UE) 2021/643 (XVI Atp. CLP)

- 21. Delegated Regulation (UE) 2021/849 (XVII Atp. CLP)
- 22. Delegated Regulation (UE) 2022/692 (XVIII Atp. CLP)
- The Merck Index. 10th Edition
- Handling Chemical Safety
- INRS Fiche Toxicologique (toxicological sheet)
- Patty Industrial Hygiene and Toxicology
- N.I. Sax Dangerous properties of Industrial Materials-7, 1989 Edition
- IFA GESTIS website
- ECHA website
- Database of SDS models for chemicals Ministry of Health and ISS (Istituto Superiore di Sanità) Italy

Note for users:

The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.

This document must not be regarded as a guarantee on any specific product property.

The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

Provide appointed staff with adequate training on how to use chemical products.

CALCULATION METHODS FOR CLASSIFICATION

Chemical and physical hazards: Product classification derives from criteria established by the CLP Regulation, Annex I, Part 2. The data for evaluation of chemical-physical properties are reported in section 9.

Health hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 3, unless determined otherwise in Section 11.

Environmental hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 4, unless determined otherwise in Section 12.

Changes to previous review:

The following sections were modified:

09.