

MED-4727 Part A

Safety Data Sheet

According to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878
Revision Date: 08/08/2024 Date of Issue: 19/09/2014

Version: 4.0

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

1.1. Product Identifier

Product Form Mixture
Product Name MED-4727 Part A
Synonyms Silicone Elastomer

1.2. Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

1.2.1. Relevant Identified Uses

Use of the Substance/Mixture For professional use only

1.2.2. Uses Advised Against

Uses Advised Against No additional information available

1.3. Details of the Supplier of the Safety Data Sheet

NuSil Technology Europe
1198 Avenue Maurice Donat
Le Natura Bt. 2
06250 Mougins
France
+33 4 92 96 93 31
productstewardship@avantorsciencesgcc.com
www.nusil.com

1.4. Emergency Telephone Number

Emergency Number +1 703-527-3887 CHEMTREC (International and Maritime)
800-424-9300 CHEMTREC (in US)
+(44)-870-8200418
+(353)-19014670

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

Classification According to Regulation (EC) No. 1272/2008

Aquatic Chronic 3 H412

Full text of hazard classes, H-statements: see section 16

2.2. Label Elements

Labelling According to Regulation (EC) No. 1272/2008 [CLP]

Signal Word (CLP) -
Hazard Statements (CLP) H412 - Harmful to aquatic life with long lasting effects.
Precautionary Statements (CLP) P273 - Avoid release to the environment.
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

2.3. Other Hazards

Other Hazards Not Contributing to the Classification Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

Octamethylcyclotetrasiloxane (556-67-2)	This substance meets the PBT criteria of REACH regulation, annex XIII This substance meets the vPvB criteria of REACH regulation, annex XIII
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Decamethylcyclopentasiloxane (541-02-6)	This substance meets the vPvB criteria of REACH regulation, annex XIII
Dodecamethylcyclohexasiloxane (540-97-6)	This substance meets the vPvB criteria of REACH regulation, annex XIII

The substance/mixture does not contain substance(s) equal to or greater than 0.1% by weight that are present in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product Identifier	%	Classification According to Regulation (EC) No. 1272/2008
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica* substance with national workplace exposure limit(s) (AT, CZ, DE, EE, FI, GB, IE, LV, SI, NO, CH)	(CAS-No.) 68909-20-6 (EC-No.) 272-697-1 (EC Index-No.) 014-052-00-7 (REACH-no) 01-2119379499-16 (synthetic amorphous silica); 01-2119438176-38 (hexamethyldisilazane)	10 - 30	STOT RE 2, H373
Octamethylcyclotetrasiloxane substance listed as REACH Candidate (Octamethylcyclotetrasiloxane (D4))	(CAS-No.) 556-67-2 (EC-No.) 209-136-7 (EC Index-No.) 014-018-00-1	< 0,25	Flam. Liq. 3, H226 Repr. 2, H361f Aquatic Chronic 1, H410 (M=10)
Decamethylcyclopentasiloxane substance listed as REACH Candidate (Decamethylcyclopentasiloxane (D5))	(CAS-No.) 541-02-6 (EC-No.) 208-764-9	< 0,25	Not classified
Dodecamethylcyclohexasiloxane substance listed as REACH Candidate (Dodecamethylcyclohexasiloxane (D6))	(CAS-No.) 540-97-6 (EC-No.) 208-762-8	< 0,25	Not classified

Full text of H-statements: see section 16

*This hazard applies to silica in dust form. There is no exposure to dust as the substance is bound within the matrix of the product.

SECTION 4: FIRST AID MEASURES

4.1. Description of First-aid Measures

First-Aid Measures General	Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
First-Aid Measures After Inhalation	When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.
First-Aid Measures After Skin Contact	Remove contaminated clothing. Drench affected area with water for at least 5 minutes. Obtain medical attention if irritation develops or persists.
First-Aid Measures After Eye Contact	Rinse cautiously with water for at least 5 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if irritation develops or persists.
First-Aid Measures After Ingestion	Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

Symptoms/Effects	Not expected to present a significant hazard under anticipated conditions of normal use.
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Symptoms/Effects After Inhalation	Prolonged exposure may cause irritation.
Symptoms/Effects After Skin Contact	Prolonged exposure may cause skin irritation.
Symptoms/Effects After Eye Contact	May cause slight irritation to eyes.
Symptoms/Effects After Ingestion	Ingestion may cause adverse effects.
Chronic Symptoms	None expected under normal conditions of use.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media	Water spray, fog, carbon dioxide (CO ₂), alcohol-resistant foam, or dry chemical.
Unsuitable Extinguishing Media	Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard	Not considered flammable but may burn at high temperatures.
Explosion Hazard	Product is not explosive.
Reactivity	Hazardous reactions will not occur under normal conditions.
Hazardous Combustion Products	Carbon oxides (CO, CO ₂). Formaldehyde. Nitrogen oxides. Silicon oxides. Oxides of platinum.

5.3. Advice for Firefighters

Precautionary Measures Fire	Exercise caution when fighting any chemical fire.
Firefighting Instructions	Use water spray or fog for cooling exposed containers.
Protection During Firefighting	Do not enter fire area without proper protective equipment, including respiratory protection.
Other Information	Do not allow run-off from fire fighting to enter drains or water courses.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures	Avoid prolonged contact with eyes, skin and clothing. Avoid breathing (vapour, mist, spray).
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6.1.1. For Non-Emergency Personnel

Protective Equipment	Use appropriate personal protective equipment (PPE).
Emergency Procedures	Evacuate unnecessary personnel.

6.1.2. For Emergency Responders

Protective Equipment	Equip cleanup crew with proper protection.
Emergency Procedures	Ventilate area. Upon arrival at the scene, a first responder is expected to recognise the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit.

6.2. Environmental Precautions

Prevent entry to sewers and public waters. Avoid release to the environment.

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6.3. Methods and Materials for Containment and Cleaning Up

For Containment	Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.
Methods for Cleaning Up	Contact competent authorities after a spill. Absorb and/or contain spill with inert material. Clean up spills immediately and dispose of waste safely. Transfer spilled material to a suitable container for disposal.

6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Additional Hazards When Processed	Will decompose above 150 °C (> 300 °F) releasing formaldehyde vapours.
Precautions for Safe Handling	Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid prolonged contact with eyes, skin and clothing. Avoid breathing vapours, mist, spray.
Hygiene Measures	Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures	Comply with applicable regulations.
Storage Conditions	Store in accordance with applicable national storage class systems. Keep/Store away from extremely high or low temperatures, direct sunlight, ignition sources, incompatible materials. Keep container closed when not in use. Store in a dry, cool place.
Incompatible Materials	Strong acids, strong bases, strong oxidisers.

7.3. Specific End Use(s)

For professional use only.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

Please see section 16 for the legal basis of limit value information in section 8.1, including the national legislation or provision which gives rise to a given limit.

Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica (68909-20-6)		
Austria	OEL TWA (Legal Basis:BGBl. II Nr. 254/2018)	4 mg/m ³ (also Silica manufactured through wet process-inhalable fraction)
Czech Republic	OEL TWA (Legal Basis:Reg. 41/2020)	0,1 mg/m ³ (respirable fraction) 4 mg/m ³
Estonia	OEL TWA (Legal Basis:Regulation No. 105)	2 mg/m ³ (amorphous-respirable dust)
Finland	OEL TWA (Legal Basis:HTP-ARVOT 2020)	5 mg/m ³ (Silicon dioxide, amorphous)
Germany	OEL TWA (Legal Basis:TRGS 900)	4 mg/m ³ (the risk of damage to the embryo or fetus can be excluded when AGW and BGW values are observed-inhalable fraction)
Ireland	OEL TWA (Legal Basis:2020 COP)	6 mg/m ³ (total inhalable dust) 2,4 mg/m ³ (respirable dust)
Ireland	OEL STEL (Legal Basis:2020 COP)	18 mg/m ³ (calculated-respirable dust) 7,2 mg/m ³ (calculated-respirable dust)
Latvia	OEL TWA (Legal Basis:Reg. No. 325)	1 mg/m ³
Norway	OEL TWA (Legal Basis:FOR-2020-04-06-695)	1,5 mg/m ³ (respirable dust)

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Norway	OEL STEL (Legal Basis:FOR-2020-04-06-695)	3 mg/m ³ (value calculated-respirable dust)
Slovenia	OEL TWA (Legal Basis:No. 79/19)	4 mg/m ³ (inhalable fraction, gel)
Switzerland	OEL TWA (Legal Basis:OLVSNAIF)	4 mg/m ³ (including Silica, amorphous-inhalable dust)

8.2. Exposure Controls

Appropriate Engineering Controls

Suitable eye/body wash equipment should be available in the vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

Personal Protective Equipment

Gloves. Protective goggles. Protective clothing. Insufficient ventilation: wear respiratory protection. Personal protective equipment should be chosen in accordance with Regulation (EU) 2016/425, CEN standards, and in discussion with the supplier of the protective equipment.



Materials for Protective Clothing

Chemically resistant materials and fabrics.

Hand Protection

Wear protective gloves.

Eye Protection

Chemical goggles or safety glasses.

Skin and Body Protection

Wear suitable protective clothing.

Respiratory Protection

In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection. If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn.

Other Information

When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State	Liquid
Colour, Appearance	Colourless
Odour	Odourless
Odour Threshold	No data available
pH	No data available
Evaporation Rate	No data available
Melting Point	No data available
Freezing Point	No data available
Boiling Point	No data available
Flash Point	> 135 °C (275 °F)
Auto-Ignition Temperature	No data available
Decomposition Temperature	No data available
Flammability	Not applicable
Vapour Pressure	No data available
Relative Vapour Density At 20 °C	No data available
Relative Density	> 1 (water = 1)
Solubility	No data available
Partition Coefficient n-Octanol/Water	No data available
Viscosity	No data available
Explosive Properties	No data available
Oxidising Properties	No data available

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Explosive Limits	No data available
Particle Aspect Ratio	Not applicable
Particle Aggregation State	Not applicable
Particle Agglomeration State	Not applicable
Particle Specific Surface Area	Not applicable
Particle Dustiness	Not applicable

9.2. Other Information

VOC content	< 1%
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SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

Hazardous reactions will not occur under normal conditions.

10.2. Chemical Stability

Stable under recommended handling and storage conditions (see section 7).

10.3. Possibility of Hazardous Reactions

Hazardous polymerisation will not occur.

10.4. Conditions to Avoid

Direct sunlight, extremely high or low temperatures, and incompatible materials.

10.5. Incompatible Materials

Strong acids, strong bases, strong oxidisers.

10.6. Hazardous Decomposition Products

Thermal decomposition may produce: Carbon oxides (CO, CO₂). Nitrogen oxides. Oxides of platinum. Silicon oxides. Will decompose above 150 °C (> 300 °F) releasing formaldehyde vapours. Formaldehyde is a potential carcinogen and can act as a potential skin and respiratory sensitiser. Formaldehyde can also cause respiratory and eye irritation.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information On Hazard Classes As Defined In Regulation (EC) No 1272/2008

Likely Routes of Exposure	Dermal; Eye contact; Ingestion; Inhalation
Acute Toxicity (Oral)	Not classified (Based on available data, the classification criteria are not met)
Acute Toxicity (Dermal)	Not classified (Based on available data, the classification criteria are not met)
Acute Toxicity (Inhalation)	Not classified (Based on available data, the classification criteria are not met)

Octamethylcyclotetrasiloxane (556-67-2)	
LD50 Oral Rat	> 4800 mg/kg (No mortality)
LD50 Dermal Rat	> 2375 mg/kg
LD50 Dermal Rabbit	> 2,5 ml/kg (No mortality)
LC50 Inhalation Rat	36 mg/l/4h
Decamethylcyclopentasiloxane (541-02-6)	
LD50 Oral Rat	> 5000 mg/kg (Species: Sprague-Dawley)
LD50 Dermal Rabbit	> 2000 mg/kg (Species: New Zealand White) No deaths reported
LC50 Inhalation Rat	8,67 mg/l/4h
LC50 Inhalation Rat	8,67 mg/l/4h (Species: Fischer)
ATE CLP (vapours)	8,67 mg/l/4h
Dodecamethylcyclohexasiloxane (540-97-6)	
LD50 Oral Rat	> 50 g/kg
LD50 Dermal Rat	> 2000 mg/kg (No deaths)

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Skin Corrosion/Irritation	Not classified (Based on available data, the classification criteria are not met)
Eye Damage/Irritation	Not classified (Based on available data, the classification criteria are not met)
Respiratory or Skin Sensitization	Not classified (Based on available data, the classification criteria are not met)
Germ Cell Mutagenicity	Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	Not classified (Based on available data, the classification criteria are not met)
Reproductive Toxicity	Not classified (Based on available data, the classification criteria are not met)
Specific Target Organ Toxicity (Single Exposure)	Not classified (Based on available data, the classification criteria are not met)
Specific Target Organ Toxicity (Repeated Exposure)	Not classified (Based on available data, the classification criteria are not met)
Aspiration Hazard	Not classified (Based on available data, the classification criteria are not met)
Symptoms/Injuries After Inhalation	Prolonged exposure may cause irritation.
Symptoms/Injuries After Skin Contact	Prolonged exposure may cause skin irritation.
Symptoms/Injuries After Eye Contact	May cause slight irritation to eyes.
Symptoms/Injuries After Ingestion	Ingestion may cause adverse effects.
Chronic Symptoms	None expected under normal conditions of use.

11.2. Information On Other Hazards

Based on available data this substance/the substances in this mixture not listed below do(es) not have endocrine disrupting properties with respect to humans as it does not meet the criteria set out in section A of Regulation (EU) No 2017/2100 and/or the criteria set out in Regulation (EU) 2018/605, or the substance(s) are not required to be disclosed.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Hazardous To The Aquatic Environment, Short-Term (Acute)	Not classified (Based on available data, the classification criteria are not met)
Hazardous To The Aquatic Environment, Long-Term (Chronic)	Harmful to aquatic life with long lasting effects.

Octamethylcyclotetrasiloxane (556-67-2)	
LC50 Fish	> 22 µg/l
NOEC chronic Fish	0,0044 mg/l

12.2. Persistence and Degradability

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Persistence and Degradability	May cause long-term adverse effects in the environment.

12.3. Bioaccumulative Potential

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Bioaccumulative Potential	Not established.

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SECTION 15: REGULATORY INFORMATION

15.1. Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

15.1.1. EU-Regulations

15.1.1.1. REACH Annex XVII Information

Contains no REACH substances with Annex XVII restrictions

15.1.1.2. REACH Candidate List Information

Contains a substance on the REACH candidate list in concentration $\geq 0.1\%$ or with a lower specific limit: Octamethylcyclotetrasiloxane (D4) (EC 209-136-7, CAS 556-67-2), Decamethylcyclopentasiloxane (D5) (EC 208-764-9, CAS 541-02-6), Dodecamethylcyclohexasiloxane (D6) (EC 208-762-8, CAS 540-97-6)

15.1.1.3. POP (2019/1021) - Persistent Organic Pollutants Information

Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

15.1.1.4. PIC Regulation EU (649/2012) - Export and Import of Hazardous Chemicals Information

Contains no substance subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

15.1.1.5. REACH Annex XIV Information

Contains no REACH Annex XIV substances

15.1.1.6. Substances Depleting the Ozone layer (1005/2009) Information

No additional information available

15.1.1.7. EC Inventory Information

No additional information available

15.1.1.8. Other Information

No additional information available

15.1.2. National Regulations

No additional information available

15.1.3. International Inventory Lists

No additional information available

15.2. Chemical Safety Assessment

No chemical safety assessment has been carried out

SECTION 16: OTHER INFORMATION

Date of Preparation or Latest Revision 08/08/2024

Data Sources

Information and data obtained and used in the authoring of this safety data sheet could come from database subscriptions, official government regulatory body websites, product/ingredient manufacturer or supplier specific information, and/or resources that include substance specific data and classifications according to GHS or their subsequent adoption of GHS.

Other Information

According to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

Full Text of H-statements:

Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1
Aquatic Chronic 3	Hazardous to the aquatic environment — Chronic Hazard, Category 3
Flam. Liq. 3	Flammable liquids, Category 3
Repr. 2	Reproductive toxicity, Category 2
STOT RE 2	Specific target organ toxicity – Repeated exposure, Category 2
H226	Flammable liquid and vapour.
H361f	Suspected of damaging fertility.

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H373	May cause damage to organs through prolonged or repeated exposure.
H410	Very toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.

Classification and Procedure Used to Derive the Classification for Mixtures According to Regulation (EC) 1272/2008 [CLP]:

Aquatic Chronic 3	Calculation method
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Indication of Changes

Section	Change	Date Changed	Version
1	Language modified	08/08/2024	4.0
2	Classification modified; Language modified	08/08/2024	4.0
3	Data modified	08/08/2024	4.0
4	Language modified	08/08/2024	4.0
5	Language modified	08/08/2024	4.0
6	Language modified	08/08/2024	4.0
7	Language modified	08/08/2024	4.0
8	Data modified; Language modified	08/08/2024	4.0
9	Data modified	08/08/2024	4.0
10	Language modified	08/08/2024	4.0
11	Data modified; Language modified	08/08/2024	4.0
12	Data modified; Language modified	08/08/2024	4.0
14	Classification modified	08/08/2024	4.0
15	Language modified	08/08/2024	4.0
16	Language modified	08/08/2024	4.0

Abbreviations and Acronyms

ACGIH – American Conference of Governmental Industrial Hygienists

ADN – European Agreement Concerning the International Carriage of Dangerous Goods by Inland Waterways

ADR - European Agreement Concerning the International Carriage of Dangerous Goods by Road

ATE - Acute Toxicity Estimate

BCF - Bioconcentration Factor

BEI - Biological Exposure Indices (BEI)

BOD – Biochemical Oxygen Demand

CAS No. - Chemical Abstracts Service Number

CLP – Classification, Labeling and Packaging Regulation (EC) No 1272/2008

COD – Chemical Oxygen Demand

EC – European Community

EC50 - Median Effective Concentration

EEC – European Economic Community

EINECS – European Inventory of Existing Commercial Chemical Substances

EmS-No. (Fire) - IMDG Emergency Schedule Fire

EmS-No. (Spillage) - IMDG Emergency Schedule Spillage

EU – European Union

ErC50 - EC50 in Terms of Reduction Growth Rate

GHS – Globally Harmonized System of Classification and Labeling of Chemicals

IARC - International Agency for Research on Cancer

IATA - International Air Transport Association

IBC Code - International Bulk Chemical Code

IMDG - International Maritime Dangerous Goods

IPRV - Ilgalaikio Poveikio Ribinis Dydis

IOELV – Indicative Occupational Exposure Limit Value

LC50 - Median Lethal Concentration

LD50 - Median Lethal Dose

LOAEL - Lowest Observed Adverse Effect Level

LOEC - Lowest-Observed-Effect Concentration

Log K_{oc} - Soil Organic Carbon-water Partitioning Coefficient

Log K_{ow} - Octanol/water Partition Coefficient

Log Pow - Ratio of the equilibrium concentration (C) of a dissolved substance in a two-phase system consisting of two largely immiscible solvents, in this case octanol and water

MAK – Maximum Workplace Concentration/Maximum Permissible Concentration

MARPOL - International Convention for the Prevention of Pollution

NDS - Najwyższe Dopuszczalne Stezenie

NDSch - Najwyższe Dopuszczalne Stezenie Chwilowe

NDSP - Najwyższe Dopuszczalne Stezenie Pulapowe

NOAEL - No-Observed Adverse Effect Level

NOEC - No-Observed Effect Concentration

NRD - Nevirsytinas Ribinis Dydis

NTP – National Toxicology Program

OEL - Occupational Exposure Limits

PBT - Persistent, Bioaccumulative and Toxic

PEL - Permissible Exposure Limit

pH – Potential Hydrogen

REACH – Registration, Evaluation, Authorisation, and Restriction of Chemicals

RID – Regulations Concerning the International Carriage of Dangerous Goods by Rail

SADT - Self Accelerating Decomposition Temperature

SDS - Safety Data Sheet

STEL - Short Term Exposure Limit

STOT - Specific Target Organ Toxicity

TA-Luft - Technische Anleitung zur Reinhaltung der Luft

TEL TRK – Technical Guidance Concentrations

ThOD – Theoretical Oxygen Demand

TLM - Median Tolerance Limit

TLV - Threshold Limit Value

TPRD - Trumpalaikio Poveikio Ribinis Dydis

TRGS 510 - Technische Regel für Gefahrstoffe 510 - Lagerung von Gefahrstoffen in ortsbeweglichen Behältern

TRGS 552 – Technische Regeln für Gefahrstoffe - N-Nitrosamine

TRGS 900 - Technische Regel für Gefahrstoffe 900 –

Arbeitsplatzgrenzwerte

TRGS 903 - Technische Regel für Gefahrstoffe 903 - Biologische

Grenzwerte

TSCA - Toxic Substances Control Act

TWA - Time Weighted Average

VOC – Volatile Organic Compounds

VLA-EC - Valor Límite Ambiental Exposición de Corta Duración

VLA-ED - Valor Límite Ambiental Exposición Diaria

VLE – Valeur Limite D'exposition

VME – Valeur Limite De Moyenne Exposition

vPvB - Very Persistent and Very Bioaccumulative

WEL – Workplace Exposure Limit

WGK - Wassergefährdungsklasse

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Limit Value Legal Basis*

*Includes the below and any related regulations/provisions, and subsequent amendments

EU - 2019/1831 EU in accor. with 98/24/EC - Directive 2019/1831/EU of October 24, 2019 establishing a fifth list of indicative occupational exposure limit values pursuant to Council Directive 98/24/EC, and amending Commission Directives 2000/39/EC.

EU - 2019/1243/EU, and 98/24/EC - Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work and amendment Regulation (EU) 2019/1243.

Austria - BGBl. II Nr. 254/2018 - Ordinance on Limit Values for Workplace Substances and on Carcinogens from the Federal Ministry of Economics and Labour, Published in 2003, Appendix 1: Substance List, Published through: Ministry of Economics and Labour of the Republic of Austria amended through the Government Gazette II (BGBl. II) No 119/2004 & BGBl. II No. 242/2006, BGBl. II No. 243/2007, lastly changed through BGBl. I Nr. 51/2011), BGBl. II Nr. 186/2015, BGBl. II Nr. 288/2017 amended by BGBl. II Nr. 254/2018.

Austria - BLV BGBl. II Nr. 254/2018 - Ordinance on health monitoring at the workplace 2008, published through BGBl. II Nr. 224/2007 by Austria Minister for Labor and Social Affairs, Lastly changed through BGBl. II Nr. 254/2018

Belgium - Royal Decree 21/01/2020 - Royal decree amending title 1 relating to chemical agents in Book VI of the code of well-being at work, with regard to the list of limit values of exposure to chemical agents and title 2 relating to carcinogens, mutagens and reprotoxics of Book VI of the code of well-being at work (1)

Bulgaria - Reg. No. 13/10 - Regulation No. 13 of December 30, 2003 on the Protection of Workers from Hazards Related to Exposure to Chemical Agents at Work Labor Code, Annex No.1 Limit values of chemical agents in the air of the working environment, and Annex № 2 Biological limit values of chemical agents and their metabolites (bio markers of exposure) or bio markers of effect Amended by: 71/2006, 67/2007, 2/2012, 46/2015, 73/2018, 5/2020), and Regulation No.10 of September 26, 2003 on the Protection of Workers from the Risks Associated with Exposure to Carcinogens and Mutagens at Work Annex No.1 Occupational Exposure Limits, Amended by: 8/2004, 46/2015, 5/2020

Croatia - OG No. 91/2018 - Regulation on the Protection of Workers from Exposure to Hazardous Chemicals at Work, the Limit Values of Exposure and the Biological Limit Values. Official Gazette No. 91 of October 12, 2018

Cyprus - KDP 16/2019 - Government of Cyprus Cabinet of Ministers Regulation 268/2001 - Safety and Health in the Working Environment (Chemical Substances) Article 38, As amended by Regulation 16/2019 and Cabinet of Ministers Regulation 153/2001 - Safety and Health in the Working Environment (Chemical Substances-Carcinogens), as amended by Regulation 493/2004 - Safety and Health in the Working Environment (Chemical Substances - Carcinogens) AND Law 47(I) 2000 - Occupational Health and Safety (Asbestos), as amended by Decree 316/2006.

Czech Republic - Reg. 41/2020 - Regulation 41/2020 amending Regulation 361/2007 of Coll. establishing Occupation Exposure Limits as amended

Czech Republic - Decree No. 107/2013 - Decree No. 107/2013 Coll., amending Decree No. 432/2003 Coll., laying down the conditions for the application of the work into categories, limit values for the parameters of biological exposure tests, collection of biological material conditions for the implementation of biological exposure tests and requirements for reporting work with asbestos and biological agents

Denmark - BEK No. 698 of 28/05/2020 - Order on Limit Values for Substances and Materials, The Statutory Order No. 507 of May 17, 2011, Appendix 1 - Limits for air pollution, etc. and Appendix 3 - Biological Exposure Values, Amended by: No. 986 of October 11, 2012, No. 655 of May 31, 2018, No. 1458 December 13, 2019, No. 698 of May 28, 2020

Estonia - Regulation No. 105 - Health and Safety Requirements for the Use of Dangerous Chemicals and Materials Containing Them

Greece - PWHSE - Occupational Exposure Limits - Protection of workers' health and safety from exposure to certain chemical substances during the workday, (latest amendment 82/2018) and Occupation Exposure Limits - Protection of workers' health and safety from exposure to certain carcinogenic and mutagenic chemical substances (latest amendment 26/2020), and Presidential Decree 212/2006 - Protection of workers that are exposed to asbestos.

Hungary - Decree 05/2020 - 5/2020. (II. 6.) ITM decree on the protection of the health and safety of workers from the risks related to chemical agents

Ireland - 2020 COP - 2020 Code of Practice for the Chemical Agents Regulations, Schedule 1

Italy - Decree 81 - Title IX, Annex XLIII and XXXVIII, Professional Exposure Limits and Annex XXXIX Mandatory Biological Limit Values and Health Monitoring, Article 1, Law 123 of August 3, 2007, Legislative Decree 81 of April 9, 2008, Last amended: January 2020

Italy - IMDFN1 - Ministerial Decree of August 20, 1999 Final Note (1)

Latvia - Reg. No. 325 - Cabinet of Ministers Regulation No. 325 - Labour Protection Requirements when Coming in Contact with Chemical Substances at Workplaces, Amended by Cabinet of Ministers Regulation No. 92, 163, 407 and No. 11.

Lithuania - HN 23:2011 - Lithuanian Hygiene Standard HN 23:2011 Occupational Exposure Limit Values, Amended by Order V-695/A1-272.

Luxembourg - A-N 684 - Grand-Ducal Regulation of 20 July 2018 amending the Grand-Ducal Regulation of 14 November 2016 concerning the protection of the safety and health of employees against the risks associated with chemical agents in the workplace. Official journal of the Grand-Duke of Luxembourg, A-N°684 of 2018

Malta - MOSHAA Ch. 424 - Malta Occupational Health and Safety Authority Act: Chapter 424 as amended by: Legal Notice 353, 53, 198, and 57.

Netherlands- OWCR LV - Occupational Working Conditions Regulation, Limit Values for substances harmful to health, Annex XVIII, Updated from August 1, 2020.

Norway - FOR-2020-04-060695 - Regulations concerning action and limit values for physical and chemical agents in the working environment and classified biological agents, FOR-2011-12-06-1358, Updated by: FOR-2020-04-06-695, FOR-2020-03-23-402, FOR-2018-12-20-2186, FOR-2018-08-21-1255, FOR-2017-12-20-2353.

Poland - Dz. U. 2020 Nr. 61 - Regulation of the Minister of Family, Labor and Social Policy of June 12, 2018 on the Highest Allowable Concentrations and Intensities of Factors Harmful to Health in the Work Environment Dz.U. 2018 Nr. 1286 of June 12, 2018, Annex 1 - List of values of the highest permissible chemical concentrations and dust factors harmful to health in the work environment, amended by: Dz. U. 2020 Nr. 61.

Portugal - Portuguese Norm NP 1796:2014 - Occupational exposure limits and biological exposure indices to chemical agents. Table 1 - Occupational exposure limits and biological exposure indices to chemical agents (OELs), Law Decree 35/2020.

Romania - Gov. Dec. No 1.218 - Governmental Decision No. 1.218 from 06/09/2006 on the minimum health and safety requirements for protection of workers from the risks related to exposure to chemical agents, Annex No. 1 Mandatory National Occupational Exposure Limit Values for Chemical Agents. Amended by Decision no. 157, 584, 359, and 1.

Slovakia - Gov. Decree 33/2018 - Government Decree of Slovak Republic 33/2018 on January 17, 2018 amending Government Decree of Slovak Republic 355/2006 about protection of health of employees when working with chemical agents

Slovenia - No. 79/19 - Regulation for protection of workers against risks related to carcinogenic or mutagenic substances exposure. Annex III - Classification and binding levels of carcinogenic or mutagenic substances for occupational

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and Occupational Exposure Limits to Chemical Agents
Government of the Republic, Regulation No. 105 of 20 March
2001, Amended 17 October 2019, and 17 January, 2020.

Finland - HTP-ARVOT 2020 - Concentrations Known to be
Hazardous, 654/2020 OEL values 2020 Publications of Ministry of
Social Affairs and Health 2020:24 Annexes1, 2 and 3.

France - INRS ED 984 - Occupational Exposure Limit Values to
Chemical Agents in France Published 2016 by the INRS National
Institute of Research and Safety Health and safety of work,
revised, updated by: Decree 2016-344, JORF No 0119, and
Decree 2019-1487.

France - Decree 2009-1570 - Decree 2009-1570 of December 15,
2009, relative to the control of chemical risk on workplaces.

Germany - TRGS 900 - Occupational Exposure Limits, Technical
Rules for Dangerous Substances, latest amendment March, 2020

Germany - TRGS 903 - Biological Threshold Limits (BGW-Values),
Technical Rules for Dangerous Substances, latest amendment
March, 2020

Gibraltar - LN. 2018/131 - Factories (Control of Chemical Agents
at Work) Regulations 2003 LN. 2003/035, amended by LN.
2008/035, LN. 2008/050, LN. 2012/021, LN. 2015/143, LN. 2018/181.

exposure. The Official Journal of the Republic of Slovenia, No.
101/2005. Amended by 38/15, 79/19. Regulation for protection of
workers against risks related to exposure to chemical substances
at the workplace. Republic of Slovenia, No. 100/2001 . Annex I -
List of Binding Occupational Exposure Limit Values. Amended by
39/05, 53/07, 102/10, 38/15, 78/18, 78/19

Spain - AFS 2018:1 - NATIONAL INSTITUTE FOR HEALTH AND SAFETY
AT WORK. Occupational exposure limits for chemical agents in
Spain. Tables 1 and 3. Latest edition Feb. 2019

Sweden - AFS 2018:1 - Statute Book of the Swedish Work
Environment Authority, AFS 2018:1

The Swedish Work Environment Authority's Ordinance and
General Guidance on Hygienic Limit Values

Switzerland - OLVSNAIF - Occupational Limit Values 2020 Swiss
National Accident Insurance Fund. List of Biological Limit Values
(BAT-Werte) and List of MAK Values.

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NuSil EU GHS SDS (2020/878)

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Revision Date: 08/08/2024 Date of Issue: 19/09/2014

Version: 4.0

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

1.1. Product Identifier

Product Form Mixture
Product Name MED-4727 Part B
Synonyms Silicone Elastomer

1.2. Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

1.2.1. Relevant Identified Uses

Use of the Substance/Mixture For professional use only

1.2.2. Uses Advised Against

Uses Advised Against No additional information available

1.3. Details of the Supplier of the Safety Data Sheet

NuSil Technology Europe
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800-424-9300 CHEMTREC (in US)
+(44)-870-8200418
+(353)-19014670

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

Classification According to Regulation (EC) No. 1272/2008

Aquatic Chronic 3 H412

Full text of hazard classes, H-statements: see section 16

2.2. Label Elements

Labelling According to Regulation (EC) No. 1272/2008 [CLP]

Signal Word (CLP) -
Hazard Statements (CLP) H412 - Harmful to aquatic life with long lasting effects.
Precautionary Statements (CLP) P273 - Avoid release to the environment.
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

2.3. Other Hazards

Other Hazards Not Contributing to the Classification Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

Octamethylcyclotetrasiloxane (556-67-2)	This substance meets the PBT criteria of REACH regulation, annex XIII This substance meets the vPvB criteria of REACH regulation, annex XIII
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Decamethylcyclopentasiloxane (541-02-6)	This substance meets the vPvB criteria of REACH regulation, annex XIII
Dodecamethylcyclohexasiloxane (540-97-6)	This substance meets the vPvB criteria of REACH regulation, annex XIII

The substance/mixture does not contain substance(s) equal to or greater than 0.1% by weight that are present in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product Identifier	%	Classification According to Regulation (EC) No. 1272/2008
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica* substance with national workplace exposure limit(s) (AT, CZ, DE, EE, FI, GB, IE, LV, SI, NO, CH)	(CAS-No.) 68909-20-6 (EC-No.) 272-697-1 (EC Index-No.) 014-052-00-7 (REACH-no) 01-2119379499-16 (synthetic amorphous silica); 01-2119438176-38 (hexamethyldisilazane)	10 - 30	STOT RE 2, H373
Siloxanes and Silicones, dimethyl, methyl hydrogen	(CAS-No.) 68037-59-2	< 5	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335
Octamethylcyclotetrasiloxane substance listed as REACH Candidate (Octamethylcyclotetrasiloxane (D4))	(CAS-No.) 556-67-2 (EC-No.) 209-136-7 (EC Index-No.) 014-018-00-1	< 0,25	Flam. Liq. 3, H226 Repr. 2, H361f Aquatic Chronic 1, H410 (M=10)
Decamethylcyclopentasiloxane substance listed as REACH Candidate (Decamethylcyclopentasiloxane (D5))	(CAS-No.) 541-02-6 (EC-No.) 208-764-9	< 0,25	Not classified
Dodecamethylcyclohexasiloxane substance listed as REACH Candidate (Dodecamethylcyclohexasiloxane (D6))	(CAS-No.) 540-97-6 (EC-No.) 208-762-8	< 0,25	Not classified

Full text of H-statements: see section 16

*This hazard applies to silica in dust form. There is no exposure to dust as the substance is bound within the matrix of the product.

SECTION 4: FIRST AID MEASURES

4.1. Description of First-aid Measures

First-Aid Measures General	Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
First-Aid Measures After Inhalation	When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.
First-Aid Measures After Skin Contact	Remove contaminated clothing. Drench affected area with water for at least 5 minutes. Obtain medical attention if irritation develops or persists.
First-Aid Measures After Eye Contact	Rinse cautiously with water for at least 5 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if irritation develops or persists.
First-Aid Measures After Ingestion	Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

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4.2. Most Important Symptoms and Effects Both Acute and Delayed

Symptoms/Effects	Not expected to present a significant hazard under anticipated conditions of normal use.
Symptoms/Effects After Inhalation	Prolonged exposure may cause irritation.
Symptoms/Effects After Skin Contact	Prolonged exposure may cause skin irritation.
Symptoms/Effects After Eye Contact	May cause slight irritation to eyes.
Symptoms/Effects After Ingestion	Ingestion may cause adverse effects.
Chronic Symptoms	None expected under normal conditions of use.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media	Water spray, fog, carbon dioxide (CO ₂), alcohol-resistant foam, or dry chemical.
Unsuitable Extinguishing Media	Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard	Not considered flammable but may burn at high temperatures.
Explosion Hazard	Product is not explosive.
Reactivity	Hazardous reactions will not occur under normal conditions.
Hazardous Combustion Products	Carbon oxides (CO, CO ₂). Formaldehyde. Nitrogen oxides. Silicon oxides. Oxides of platinum.

5.3. Advice for Firefighters

Precautionary Measures Fire	Exercise caution when fighting any chemical fire.
Firefighting Instructions	Use water spray or fog for cooling exposed containers.
Protection During Firefighting	Do not enter fire area without proper protective equipment, including respiratory protection.
Other Information	Do not allow run-off from fire fighting to enter drains or water courses.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures	Avoid prolonged contact with eyes, skin and clothing. Avoid breathing (vapour, mist, spray).
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6.1.1. For Non-Emergency Personnel

Protective Equipment	Use appropriate personal protective equipment (PPE).
Emergency Procedures	Evacuate unnecessary personnel.

6.1.2. For Emergency Responders

Protective Equipment	Equip cleanup crew with proper protection.
Emergency Procedures	Ventilate area. Upon arrival at the scene, a first responder is expected to recognise the presence of dangerous goods, protect oneself and the public, secure the area, and call for

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the assistance of trained personnel as soon as conditions permit.

6.2. Environmental Precautions

Prevent entry to sewers and public waters. Avoid release to the environment.

6.3. Methods and Materials for Containment and Cleaning Up

For Containment

Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

Methods for Cleaning Up

Contact competent authorities after a spill. Absorb and/or contain spill with inert material. Clean up spills immediately and dispose of waste safely. Transfer spilled material to a suitable container for disposal.

6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Additional Hazards When Processed

Will decompose above 150 °C (> 300 °F) releasing formaldehyde vapours.

Precautions for Safe Handling

Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid prolonged contact with eyes, skin and clothing. Avoid breathing vapours, mist, spray.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures

Comply with applicable regulations.

Storage Conditions

Store in accordance with applicable national storage class systems. Keep/Store away from extremely high or low temperatures, direct sunlight, ignition sources, incompatible materials. Keep container closed when not in use. Store in a dry, cool place.

Incompatible Materials

Strong acids, strong bases, strong oxidisers.

7.3. Specific End Use(s)

For professional use only.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

Please see section 16 for the legal basis of limit value information in section 8.1, including the national legislation or provision which gives rise to a given limit.

Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica (68909-20-6)		
Austria	OEL TWA (Legal Basis:BGBl. II Nr. 254/2018)	4 mg/m ³ (also Silica manufactured through wet process-inhalable fraction)
Czech Republic	OEL TWA (Legal Basis:Reg. 41/2020)	0,1 mg/m ³ (respirable fraction) 4 mg/m ³
Estonia	OEL TWA (Legal Basis:Regulation No. 105)	2 mg/m ³ (amorphous-respirable dust)
Finland	OEL TWA (Legal Basis:HTP-ARVOT 2020)	5 mg/m ³ (Silicon dioxide, amorphous)
Germany	OEL TWA (Legal Basis:TRGS 900)	4 mg/m ³ (the risk of damage to the embryo or fetus can be excluded when AGW and BGW values are observed-inhalable fraction)

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Ireland	OEL TWA (Legal Basis:2020 COP)	6 mg/m ³ (total inhalable dust) 2,4 mg/m ³ (respirable dust)
Ireland	OEL STEL (Legal Basis:2020 COP)	18 mg/m ³ (calculated-respirable dust) 7,2 mg/m ³ (calculated-respirable dust)
Latvia	OEL TWA (Legal Basis:Reg. No. 325)	1 mg/m ³
Norway	OEL TWA (Legal Basis:FOR-2020-04-06-695)	1,5 mg/m ³ (respirable dust)
Norway	OEL STEL (Legal Basis:FOR-2020-04-06-695)	3 mg/m ³ (value calculated-respirable dust)
Slovenia	OEL TWA (Legal Basis:No. 79/19)	4 mg/m ³ (inhalable fraction, gel)
Switzerland	OEL TWA (Legal Basis:OLVSNAIF)	4 mg/m ³ (including Silica, amorphous-inhalable dust)

8.2. Exposure Controls

Appropriate Engineering Controls

Suitable eye/body wash equipment should be available in the vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

Personal Protective Equipment

Gloves. Protective goggles. Protective clothing. Insufficient ventilation: wear respiratory protection. Personal protective equipment should be chosen in accordance with Regulation (EU) 2016/425, CEN standards, and in discussion with the supplier of the protective equipment.



Materials for Protective Clothing

Chemically resistant materials and fabrics.

Hand Protection

Wear protective gloves.

Eye Protection

Chemical goggles or safety glasses.

Skin and Body Protection

Wear suitable protective clothing.

Respiratory Protection

In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection. If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn.

Other Information

When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State	Liquid
Colour, Appearance	Colourless
Odour	Odourless
Odour Threshold	No data available
pH	No data available
Evaporation Rate	No data available
Melting Point	No data available
Freezing Point	No data available
Boiling Point	No data available
Flash Point	> 135 °C (275 °F)
Auto-Ignition Temperature	No data available
Decomposition Temperature	No data available
Flammability	Not applicable
Vapour Pressure	No data available
Relative Vapour Density At 20 °C	No data available
Relative Density	> 1 (water = 1)

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Solubility	No data available
Partition Coefficient n-Octanol/Water	No data available
Viscosity	No data available
Explosive Properties	No data available
Oxidising Properties	No data available
Explosive Limits	No data available
Particle Aspect Ratio	Not applicable
Particle Aggregation State	Not applicable
Particle Agglomeration State	Not applicable
Particle Specific Surface Area	Not applicable
Particle Dustiness	Not applicable

9.2. Other Information

VOC content < 1%

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

Contact with water, alcohols, acids or bases, and many metals or metallic compounds can liberate flammable Hydrogen gas which can form explosive mixtures in air.

10.2. Chemical Stability

Stable under recommended handling and storage conditions (see section 7).

10.3. Possibility of Hazardous Reactions

Hazardous polymerization will not occur. Evolved hydrogen gas is flammable and may form explosive mixtures with air.

10.4. Conditions to Avoid

Direct sunlight, extremely high or low temperatures, and incompatible materials.

10.5. Incompatible Materials

Alcohols. Metals. Strong acids, strong bases, strong oxidisers. Water.

10.6. Hazardous Decomposition Products

May produce explosive hydrogen gas on contact with incompatibilities or upon thermal decomposition. Thermal decomposition may produce: Carbon oxides (CO, CO₂). Nitrogen oxides. Silicon oxides. Will decompose above 150 °C (> 300 °F) releasing formaldehyde vapours. Formaldehyde is a potential carcinogen and can act as a potential skin and respiratory sensitiser. Formaldehyde can also cause respiratory and eye irritation.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information On Hazard Classes As Defined In Regulation (EC) No 1272/2008

Likely Routes of Exposure	Dermal; Eye contact; Ingestion; Inhalation
Acute Toxicity (Oral)	Not classified (Based on available data, the classification criteria are not met)
Acute Toxicity (Dermal)	Not classified (Based on available data, the classification criteria are not met)
Acute Toxicity (Inhalation)	Not classified (Based on available data, the classification criteria are not met)

Octamethylcyclotetrasiloxane (556-67-2)	
LD50 Oral Rat	> 4800 mg/kg (No mortality)
LD50 Dermal Rat	> 2375 mg/kg
LD50 Dermal Rabbit	> 2,5 ml/kg (No mortality)
LC50 Inhalation Rat	36 mg/l/4h

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Decamethylcyclopentasiloxane (541-02-6)	
LD50 Oral Rat	> 5000 mg/kg (Species: Sprague-Dawley)
LD50 Dermal Rabbit	> 2000 mg/kg (Species: New Zealand White) No deaths reported
LC50 Inhalation Rat	8,67 mg/l/4h
LC50 Inhalation Rat	8,67 mg/l/4h (Species: Fischer)
ATE CLP (vapours)	8,67 mg/l/4h

Dodecamethylcyclohexasiloxane (540-97-6)	
LD50 Oral Rat	> 50 g/kg
LD50 Dermal Rat	> 2000 mg/kg (No deaths)

Skin Corrosion/Irritation	Not classified (Based on available data, the classification criteria are not met)
Eye Damage/Irritation	Not classified (Based on available data, the classification criteria are not met)
Respiratory or Skin Sensitization	Not classified (Based on available data, the classification criteria are not met)
Germ Cell Mutagenicity	Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	Not classified (Based on available data, the classification criteria are not met)
Reproductive Toxicity	Not classified (Based on available data, the classification criteria are not met)
Specific Target Organ Toxicity (Single Exposure)	Not classified (Based on available data, the classification criteria are not met)
Specific Target Organ Toxicity (Repeated Exposure)	Not classified (Based on available data, the classification criteria are not met)
Aspiration Hazard	Not classified (Based on available data, the classification criteria are not met)
Symptoms/Injuries After Inhalation	Prolonged exposure may cause irritation.
Symptoms/Injuries After Skin Contact	Prolonged exposure may cause skin irritation.
Symptoms/Injuries After Eye Contact	May cause slight irritation to eyes.
Symptoms/Injuries After Ingestion	Ingestion may cause adverse effects.
Chronic Symptoms	None expected under normal conditions of use.

11.2. Information On Other Hazards

Based on available data this substance/the substances in this mixture not listed below do(es) not have endocrine disrupting properties with respect to humans as it does not meet the criteria set out in section A of Regulation (EU) No 2017/2100 and/or the criteria set out in Regulation (EU) 2018/605, or the substance(s) are not required to be disclosed.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Hazardous To The Aquatic Environment, Short-Term (Acute)	Not classified (Based on available data, the classification criteria are not met)
Hazardous To The Aquatic Environment, Long-Term (Chronic)	Harmful to aquatic life with long lasting effects.

Octamethylcyclotetrasiloxane (556-67-2)	
LC50 Fish	> 22 µg/l

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14.4. Packing Group

Not regulated for transport

14.5. Environmental Hazards

Not regulated for transport

14.6. Special Precautions For User

No additional information available

14.7. Maritime Transport in Bulk According to IMO instruments

Not applicable

SECTION 15: REGULATORY INFORMATION

15.1. Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

15.1.1. EU-Regulations

15.1.1.1. REACH Annex XVII Information

Contains no REACH substances with Annex XVII restrictions

15.1.1.2. REACH Candidate List Information

Contains a substance on the REACH candidate list in concentration $\geq 0.1\%$ or with a lower specific limit: Octamethylcyclotetrasiloxane (D4) (EC 209-136-7, CAS 556-67-2), Decamethylcyclopentasiloxane (D5) (EC 208-764-9, CAS 541-02-6), Dodecamethylcyclohexasiloxane (D6) (EC 208-762-8, CAS 540-97-6)

15.1.1.3. POP (2019/1021) - Persistent Organic Pollutants Information

Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

15.1.1.4. PIC Regulation EU (649/2012) - Export and Import of Hazardous Chemicals Information

Contains no substance subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

15.1.1.5. REACH Annex XIV Information

Contains no REACH Annex XIV substances

15.1.1.6. Substances Depleting the Ozone layer (1005/2009) Information

No additional information available

15.1.1.7. EC Inventory Information

No additional information available

15.1.1.8. Other Information

No additional information available

15.1.2. National Regulations

No additional information available

15.1.3. International Inventory Lists

No additional information available

15.2. Chemical Safety Assessment

No chemical safety assessment has been carried out

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SECTION 16: OTHER INFORMATION

Date of Preparation or Latest Revision 08/08/2024
Data Sources Information and data obtained and used in the authoring of this safety data sheet could come from database subscriptions, official government regulatory body websites, product/ingredient manufacturer or supplier specific information, and/or resources that include substance specific data and classifications according to GHS or their subsequent adoption of GHS.

Other Information According to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

Full Text of H-statements:

Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1
Aquatic Chronic 3	Hazardous to the aquatic environment — Chronic Hazard, Category 3
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Flam. Liq. 3	Flammable liquids, Category 3
Repr. 2	Reproductive toxicity, Category 2
Skin Irrit. 2	Skin corrosion/irritation, Category 2
STOT RE 2	Specific target organ toxicity – Repeated exposure, Category 2
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H226	Flammable liquid and vapour.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H361f	Suspected of damaging fertility.
H373	May cause damage to organs through prolonged or repeated exposure.
H410	Very toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.

Classification and Procedure Used to Derive the Classification for Mixtures According to Regulation (EC) 1272/2008 [CLP]:

Aquatic Chronic 3	Calculation method
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Indication of Changes

Section	Change	Date Changed	Version
1	Language modified	08/08/2024	4.0
2	Classification modified; Language modified	08/08/2024	4.0
3	Data modified	08/08/2024	4.0
4	Language modified	08/08/2024	4.0
5	Language modified	08/08/2024	4.0
6	Language modified	08/08/2024	4.0
7	Language modified	08/08/2024	4.0
8	Data modified; Language modified	08/08/2024	4.0
9	Data modified	08/08/2024	4.0
10	Language modified	08/08/2024	4.0
11	Data modified; Language modified	08/08/2024	4.0
12	Data modified; Language modified	08/08/2024	4.0
14	Classification modified	08/08/2024	4.0
15	Language modified	08/08/2024	4.0
16	Language modified	08/08/2024	4.0

Abbreviations and Acronyms

ACGIH – American Conference of Governmental Industrial Hygienists
ADN – European Agreement Concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR - European Agreement Concerning the International Carriage of Dangerous Goods by Road
ATE - Acute Toxicity Estimate
BCF - Bioconcentration Factor
BEI - Biological Exposure Indices (BEI)
BOD – Biochemical Oxygen Demand
CAS No. - Chemical Abstracts Service Number

NDS - Najwyższe Dopuszczalne Stezenie
NDSCh - Najwyższe Dopuszczalne Stezenie Chwilowe
NDSP - Najwyższe Dopuszczalne Stezenie Pulapowe
NOAEL - No-Observed Adverse Effect Level
NOEC - No-Observed Effect Concentration
NRD - Nevirsytinas Ribinis Dydis
NTP – National Toxicology Program
OEL - Occupational Exposure Limits
PBT - Persistent, Bioaccumulative and Toxic
PEL - Permissible Exposure Limit
pH – Potential Hydrogen

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CLP – Classification, Labeling and Packaging Regulation (EC) No 1272/2008	REACH – Registration, Evaluation, Authorisation, and Restriction of Chemicals
COD – Chemical Oxygen Demand	RID – Regulations Concerning the International Carriage of Dangerous Goods by Rail
EC – European Community	SADT – Self Accelerating Decomposition Temperature
EC50 - Median Effective Concentration	SDS - Safety Data Sheet
EEC – European Economic Community	STEL - Short Term Exposure Limit
EINECS – European Inventory of Existing Commercial Chemical Substances	STOT - Specific Target Organ Toxicity
EmS-No. (Fire) - IMDG Emergency Schedule Fire	TA-Luft - Technische Anleitung zur Reinhaltung der Luft
EmS-No. (Spillage) - IMDG Emergency Schedule Spillage	TEL TRK – Technical Guidance Concentrations
EU – European Union	ThOD – Theoretical Oxygen Demand
ErC50 - EC50 in Terms of Reduction Growth Rate	TLM - Median Tolerance Limit
GHS – Globally Harmonized System of Classification and Labeling of Chemicals	TLV - Threshold Limit Value
IARC - International Agency for Research on Cancer	TPRD - Trumpalaikio Poveikio Ribinis Dydis
IATA - International Air Transport Association	TRGS 510 - Technische Regel für Gefahrstoffe 510 - Lagerung von Gefahrstoffen in ortsbeweglichen Behältern
IBC Code - International Bulk Chemical Code	TRGS 552 – Technische Regeln für Gefahrstoffe - N-Nitrosamine
IMDG - International Maritime Dangerous Goods	TRGS 900 - Technische Regel für Gefahrstoffe 900 – Arbeitsplatzgrenzwerte
IPRV - Ilgalaikio Poveikio Ribinis Dydis	TRGS 903 - Technische Regel für Gefahrstoffe 903 - Biologische Grenzwerte
IOELV – Indicative Occupational Exposure Limit Value	TSCA - Toxic Substances Control Act
LC50 - Median Lethal Concentration	TWA - Time Weighted Average
LD50 - Median Lethal Dose	VOC – Volatile Organic Compounds
LOAEL - Lowest Observed Adverse Effect Level	VLA-EC - Valor Límite Ambiental Exposición de Corta Duración
LOEC - Lowest-Observed-Effect Concentration	VLA-ED - Valor Límite Ambiental Exposición Diaria
Log Koc - Soil Organic Carbon-water Partitioning Coefficient	VLE – Valeur Limite D'exposition
Log Kow - Octanol/water Partition Coefficient	VME – Valeur Limite De Moyenne Exposition
Log Pow - Ratio of the equilibrium concentration (C) of a dissolved substance in a two-phase system consisting of two largely immiscible solvents, in this case octanol and water	vPvB - Very Persistent and Very Bioaccumulative
MAK – Maximum Workplace Concentration/Maximum Permissible Concentration	WEL – Workplace Exposure Limit
MARPOL - International Convention for the Prevention of Pollution	WGK - Wassergefährdungsklasse

Limit Value Legal Basis*

*Includes the below and any related regulations/provisions, and subsequent amendments

EU - 2019/1831 EU in accor. with 98/24/EC - Directive 2019/1831/EU of October 24, 2019 establishing a fifth list of indicative occupational exposure limit values pursuant to Council Directive 98/24/EC, and amending Commission Directives 2000/39/EC.

EU - 2019/1243/EU, and 98/24/EC - Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work and amendment Regulation (EU) 2019/1243.

Austria - BGBl. II Nr. 254/2018 - Ordinance on Limit Values for Workplace Substances and on Carcinogens from the Federal Ministry of Economics and Labour, Published in 2003, Appendix 1: Substance List, Published through: Ministry of Economics and Labour of the Republic of Austria amended through the Government Gazette II (BGBl. II) No 119/2004) & BGBl. II No. 242/2006, BGBl. II No. 243/2007, lastly changed through BGBl. I Nr. 51/2011), BGBl. II Nr. 186/2015, BGBl. II Nr. 288/2017 amended by BGBl. II Nr. 254/2018.

Austria - BLV BGBl. II Nr. 254/2018 - Ordinance on health monitoring at the workplace 2008, published through BGBl. II Nr. 224/2007 by Austria Minister for Labor and Social Affairs, Lastly changed through BGBl. II Nr. 254/2018

Belgium - Royal Decree 21/01/2020 - Royal decree amending title 1 relating to chemical agents in Book VI of the code of well-being at work, with regard to the list of limit values of exposure to chemical agents and title 2 relating to carcinogens, mutagens and reprotoxics of Book VI of the code of well-being at work (1)

Bulgaria - Reg. No. 13/10 - Regulation No. 13 of December 30, 2003 on the Protection of Workers from Hazards Related to Exposure to Chemical Agents at Work Labor Code, Annex No.1 Limit values of chemical agents in the air of the working environment, and Annex № 2 Biological limit values of chemical agents and their metabolites (bio markers of exposure) or bio markers of effect Amended by: 71/2006, 67/2007, 2/2012, 46/2015, 73/2018, 5/2020), and Regulation No.10 of September 26, 2003 on the Protection of Workers from the Risks Associated with Exposure to Carcinogens

Greece - PWHSE - Occupational Exposure Limits - Protection of workers' health and safety from exposure to certain chemical substances during the workday, (latest amendment 82/2018) and Occupation Exposure Limits - Protection of workers' health and safety from exposure to certain carcinogenic and mutagenic chemical substances (latest amendment 26/2020), and Presidential Decree 212/2006 - Protection of workers that are exposed to asbestos.

Hungary - Decree 05/2020 - 5/2020. (II. 6.) ITM decree on the protection of the health and safety of workers from the risks related to chemical agents

Ireland - 2020 COP - 2020 Code of Practice for the Chemical Agents Regulations, Schedule 1

Italy - Decree 81 - Title IX, Annex XLIII and XXXVIII, Professional Exposure Limits and Annex XXXIX Mandatory Biological Limit Values and Health Monitoring, Article 1, Law 123 of August 3, 2007, Legislative Decree 81 of April 9, 2008, Last amended: January 2020

Italy - IMDFN1 - Ministerial Decree of August 20, 1999 Final Note (1)

Latvia - Reg. No. 325 - Cabinet of Ministers Regulation No. 325 - Labour Protection Requirements when Coming in Contact with Chemical Substances at Workplaces, Amended by Cabinet of Ministers Regulation No. 92, 163, 407 and No. 11.

Lithuania - HN 23:2011 - Lithuanian Hygiene Standard HN 23:2011 Occupational Exposure Limit Values, Amended by Order V-695/A1-272.

Luxembourg - A-N 684 - Grand-Ducal Regulation of 20 July 2018 amending the Grand-Ducal Regulation of 14 November 2016 concerning the protection of the safety and health of employees against the risks associated with chemical agents in the workplace. Official journal of the Grand-Duke of Luxembourg, A-N°684 of 2018

Malta - MOSHAA Ch. 424 - Malta Occupational Health and Safety Authority Act: Chapter 424 as amended by: Legal Notice 353, 53, 198, and 57.

Netherlands- OWCRV - Occupational Working Conditions

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and Mutagens at Work Annex No.1 Occupational Exposure Limits, Amended by: 8/2004, 46/2015, 5/2020

Croatia - OG No. 91/2018 - Regulation on the Protection of Workers from Exposure to Hazardous Chemicals at Work, the Limit Values of Exposure and the Biological Limit Values. Official Gazette No. 91 of October 12, 2018

Cyprus - KDP 16/2019 - Government of Cyprus Cabinet of Ministers Regulation 268/2001 - Safety and Health in the Working Environment (Chemical Substances) Article 38, As amended by Regulation 16/2019 and Cabinet of Ministers Regulation 153/2001 - Safety and Health in the Working Environment (Chemical Substances-Carcinogens), as amended by Regulation 493/2004 - Safety and Health in the Working Environment (Chemical Substances - Carcinogens) AND Law 47(I) 2000 - Occupational Health and Safety (Asbestos), as amended by Decree 316/2006.

Czech Republic - Reg. 41/2020 - Regulation 41/2020 amending Regulation 361/2007 of Coll. establishing Occupation Exposure Limits as amended

Czech Republic - Decree No. 107/2013 - Decree No. 107/2013 Coll., amending Decree No. 432/2003 Coll., laying down the conditions for the application of the work into categories, limit values for the parameters of biological exposure tests, collection of biological material conditions for the implementation of biological exposure tests and requirements for reporting work with asbestos and biological agents

Denmark - BEK No. 698 of 28/05/2020 - Order on Limit Values for Substances and Materials, The Statutory Order No. 507 of May 17, 2011, Appendix 1 - Limits for air pollution, etc. and Appendix 3 - Biological Exposure Values, Amended by: No. 986 of October 11, 2012, No. 655 of May 31, 2018, No. 1458 December 13, 2019, No. 698 of May 28, 2020

Estonia - Regulation No. 105 - Health and Safety Requirements for the Use of Dangerous Chemicals and Materials Containing Them and Occupational Exposure Limits to Chemical Agents Government of the Republic, Regulation No. 105 of 20 March 2001, Amended 17 October 2019, and 17 January, 2020.

Finland - HTP-ARVOT 2020 - Concentrations Known to be Hazardous, 654/2020 OEL values 2020 Publications of Ministry of Social Affairs and Health 2020:24 Annexes1, 2 and 3.

France - INRS ED 984 - Occupational Exposure Limit Values to Chemical Agents in France Published 2016 by the INRS National Institute of Research and Safety Health and safety of work, revised, updated by: Decree 2016-344, JORF No 0119, and Decree 2019-1487.

France - Decree 2009-1570 - Decree 2009-1570 of December 15, 2009, relative to the control of chemical risk on workplaces.

Germany - TRGS 900 - Occupational Exposure Limits, Technical Rules for Dangerous Substances, latest amendment March, 2020

Germany - TRGS 903 - Biological Threshold Limits (BGW-Values), Technical Rules for Dangerous Substances, latest amendment March, 2020

Gibraltar - LN. 2018/131 - Factories (Control of Chemical Agents at Work) Regulations 2003 LN. 2003/035, amended by LN. 2008/035, LN. 2008/050, LN. 2012/021, LN. 2015/143, LN. 2018/181.

Regulation, Limit Values for substances harmful to health, Annex XVIII, Updated from August 1, 2020.

Norway - FOR-2020-04-060695 - Regulations concerning action and limit values for physical and chemical agents in the working environment and classified biological agents, FOR-2011-12-06-1358, Updated by: FOR-2020-04-06-695, FOR-2020-03-23-402, FOR-2018-12-20-2186, FOR-2018-08-21-1255, FOR-2017-12-20-2353.

Poland - Dz. U. 2020 Nr. 61 - Regulation of the Minister of Family, Labor and Social Policy of June 12, 2018 on the Highest Allowable Concentrations and Intensities of Factors Harmful to Health in the Work Environment Dz.U. 2018 Nr. 1286 of June 12, 2018, Annex 1 - List of values of the highest permissible chemical concentrations and dust factors harmful to health in the work environment, amended by: Dz. U. 2020 Nr. 61.

Portugal - Portuguese Norm NP 1796:2014 - Occupational exposure limits and biological exposure indices to chemical agents. Table 1 - Occupational exposure limits and biological exposure indices to chemical agents (OELs), Law Decree 35/2020.

Romania - Gov. Dec. No 1.218 - Governmental Decision No. 1.218 from 06/09/2006 on the minimum health and safety requirements for protection of workers from the risks related to exposure to chemical agents, Annex No. 1 Mandatory National Occupational Exposure Limit Values for Chemical Agents. Amended by Decision no. 157, 584, 359, and 1.

Slovakia - Gov. Decree 33/2018 - Government Decree of Slovak Republic 33/2018 on January 17, 2018 amending Government Decree of Slovak Republic 355/2006 about protection of health of employees when working with chemical agents

Slovenia - No. 79/19 - Regulation for protection of workers against risks related to carcinogenic or mutagenic substances exposure. Annex III - Classification and binding levels of carcinogenic or mutagenic substances for occupational exposure. The Official Journal of the Republic of Slovenia, No. 101/2005. Amended by 38/15, 79/19. Regulation for protection of workers against risks related to exposure to chemical substances at the workplace. Republic of Slovenia, No. 100/2001 . Annex I - List of Binding Occupational Exposure Limit Values. Amended by 39/05, 53/07, 102/10, 38/15, 78/18, 78/19

Spain - AFS 2018:1 - NATIONAL INSTITUTE FOR HEALTH AND SAFETY AT WORK. Occupational exposure limits for chemical agents in Spain. Tables 1 and 3. Latest edition Feb. 2019

Sweden - AFS 2018:1 - Statute Book of the Swedish Work Environment Authority, AFS 2018:1 The Swedish Work Environment Authority's Ordinance and General Guidance on Hygienic Limit Values

Switzerland - OLVSNAIF - Occupational Limit Values 2020 Swiss National Accident Insurance Fund. List of Biological Limit Values (BAT-Werte) and List of MAK Values.

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