

Safety Data Sheet

According to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878 Revision date: 23/05/2022 Date of Issue: 20/12/2013

Version: 5.0

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

#### 1.1. Product Identifier

Product Form Mixture
Product Name MED3-4800

Synonyms Silcone 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 2 H411

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

# 2.2. Label Elements

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

Hazard Pictograms (CLP)

GH209

Signal Word (CLP)

Hazard Statements (CLP) H411 - Toxic to aquatic life with long lasting effects.

Precautionary Statements (CLP) P273 - Avoid release to the environment.

P391 - Collect spillage.

P501 - Dispose of contents/container in accordance with local,

regional, national and/or international regulation.

23/05/2022 EN (English) 1/12

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

#### 2.3. Other Hazards

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

|  | This substance meets the PBT criteria of REACH regulation, annex XIII This substance meets the vPvB criteria of REACH regulation, annex XIII |
|--|--|
| 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              |
|--|---|---------|--|
| Titanium dioxide<br>substance with a Union workplace<br>exposure limit                                       | (CAS-No.) 13463-67-7<br>(EC-No.) 236-675-5<br>(EC Index-No.) 022-006-00-2 | 45 - 55 | Not classified   |
| Octamethylcyclotetrasiloxane<br>substance listed as REACH Candidate<br>(Octamethylcyclotetrasiloxane (D4))   | (CAS-No.) 556-67-2<br>(EC-No.) 209-136-7<br>(EC Index-No.) 014-018-00-1   | < 2.5   | Flam. Liq. 3, H226<br>Repr. 2, H361f<br>Aquatic Chronic 1, H410 (M=10) |
| Decamethylcyclopentasiloxane<br>substance listed as REACH Candidate<br>Decamethylcyclopentasiloxane (D5))    | (CAS-No.) 541-02-6<br>(EC-No.) 208-764-9                                  | < 1     | Not classified   |
| Dodecamethylcyclohexasiloxane<br>substance listed as REACH Candidate<br>(Dodecamethylcyclohexasiloxane (D6)) | (CAS-No.) 540-97-6<br>(EC-No.) 208-762-8                                  | <1      | Not classified   |

Full text of H- and EUH-statements: see section 16

## **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 When symptoms occur: go into open air and ventilate

Inhalation suspected area. Obtain medical attention if breathing difficulty

persists.

First-Aid Measures After Skin

Contact

Remove contaminated clothing. Immediately drench affected

area with water for at least 15 minutes. Obtain medical

attention if irritation develops or persists.

First-Aid Measures After Eye

Contact

Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Obtain medical attention.

First-Aid Measures After Rinse r

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.

23/05/2022 EN (English) 2/12

Safety Data Sheet

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

Symptoms/Effects After Prolonged exposure may cause irritation.

Inhalation

Symptoms/Effects After Skin Prolonged exposure to liquid may cause a mild irritation.

Contact

Symptoms/Effects After Eye Prolonged exposure may cause slight irritation to eyes.

Contact

Symptoms/Effects After Ingestion may cause adverse effects.

Ingestion

Chronic Symptoms None known.

### 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, dry chemical, foam, carbon dioxide.

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 Carbon oxides (CO, CO<sub>2</sub>). Formaldehyde. Silicon oxides.

**Products** 

5.3. Advice for Firefighters

Precautionary Measures Fire Exercise caution when fighting any chemical fire.

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 breathing (vapour, mist, spray). Avoid contact with skin,

eyes and clothing.

#### 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.

23/05/2022 EN (English) 3/12

#### 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 Clean up spills immediately and dispose of waste safely.

Transfer spilled material to a suitable container for disposal.

Contact competent authorities after a spill.

#### 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 Will decompose above 150 °C (> 300 °F) releasing

Processed 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 breathing vapours, mist, spray. Avoid contact with

eyes, skin and clothing.

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 container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials. Store

locked up/in a secure area.

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.

| Titanium dia | Titanium dioxide (13463-67-7)                   |  |  |  |  |
|--------------|---|--|--|--|--|
| Austria      | OEL TWA (Legal Basis:BGBl. II Nr. 254/2018)     | 5 mg/m³ (alveolar dust, respirable fraction)                               |  |  |  |
| Austria      | OEL STEL (Legal Basis:BGBI. II Nr. 254/2018)    | 10 mg/m³ (alveolar dust, respirable fraction)                              |  |  |  |
| Belgium      | OEL TWA (Legal Basis:Royal Decree 21/01/2020)   | 10 mg/m³   |  |  |  |
| Bulgaria     | OEL TWA (Legal Basis:Reg. No. 13/10)            | 10 mg/m³ (respirable dust)   |  |  |  |
| Croatia      | OEL TWA (Legal Basis:OG No. 91/2018)            | 10 mg/m³ (total dust, inhalable particles) 4 mg/m³ (respirable dust)       |  |  |  |
| Denmark      | OEL TWA (Legal Basis:BEK No. 698 of 28/05/2020) | 6 mg/m³  |  |  |  |
| Estonia      | OEL TWA (Legal Basis:Regulation No. 105)        | 5 mg/m³  |  |  |  |
| France       | OEL TWA (Legal Basis:INRS ED 984)               | 10 mg/m³   |  |  |  |
| Germany      | OEL TWA (Legal Basis:TRGS 900)                  | 1,25 mg/m³ (respirable fraction (dust) 10 mg/m³ (inhalable fraction (dust) |  |  |  |
| Greece       | OEL TWA (Legal Basis:PWHSE)                     | 10 mg/m³ (inhalable fraction)<br>5 mg/m³ (respirable fraction)             |  |  |  |
| Ireland      | OEL TWA (Legal Basis:2020 COP)                  | 10 mg/m³ (total inhalable dust)<br>4 mg/m³ (respirable dust)               |  |  |  |
| Ireland      | OEL STEL (Legal Basis:2020 COP)                 | 30 mg/m³ (calculated-respirable dust)                                      |  |  |  |

23/05/2022 EN (English) 4/12

#### Safety Data Sheet

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

|             |   | 12 mg/m³ (calculated)  |
|-------------|---|--|
| USA ACGIH   | OEL TWA (Legal Basis:IMDFN1)  | 10 mg/m³   |
| Latvia      | OEL TWA (Legal Basis:Reg. No. 325)                                  | 10 mg/m³   |
| Lithuania   | OEL TWA (Legal Basis:HN 23:2011)                                    | 5 mg/m³  |
| Norway      | OEL TWA (Legal Basis:FOR-2020-04-06-695)                            | 5 mg/m³  |
| Norway      | OEL STEL (Legal Basis:FOR-2020-04-06-695)                           | 10 mg/m³ (value calculated)  |
| Poland      | OEL TWA (Legal Basis:Dz. U. 2020 Nr. 61)                            | 10 mg/m³ (the concentration of the respirable Crystalline silica fraction is determined simultaneously-inhalable fraction) |
| Portugal    | OEL TWA (Legal Basis:Portuguese Norm NP 1796:2014)                  | 10 mg/m³   |
| Portugal    | OEL Chemical Category (Legal Basis:Portuguese<br>Norm NP 1796:2014) | A4 - Not Classifiable as a Human Carcinogen  |
| Romania     | OEL TWA (Legal Basis:Gov. Dec. No 1.218)                            | 10 mg/m³   |
| Romania     | OEL STEL (Legal Basis:Gov. Dec. No 1.218)                           | 15 mg/m³   |
| Slovakia    | OEL TWA (Legal Basis:Gov. Decree 33/2018)                           | 5 mg/m³  |
| Spain       | OEL TWA (Legal Basis:OELCAIS)                                       | 10 mg/m³   |
| Sweden      | OEL TLV (Legal Basis:AFS 2018:1)                                    | 5 mg/m³ (total dust)   |
| Switzerland | OEL TWA (Legal Basis:OLVSNAIF)                                      | 3 mg/m³ (respirable dust)  |

#### 8.2. **Exposure Controls**

Appropriate Engineering Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Controls

Ensure adequate ventilation, especially in confined areas.

Ensure all national/local regulations are observed.

Personal Protective Equipment Gloves. Protective clothing. Protective goggles. 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

Hand Protection **Eve Protection** 

Skin and Body Protection **Respiratory Protection** 

Chemically resistant materials and fabrics.

Wear protective gloves. Chemical safety goggles.

Wear suitable protective clothing.

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

protection.

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 White paste Odour Odorless

Odour Threshold No data available

На 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)

23/05/2022 EN (English) 5/12

#### Safety Data Sheet

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

| According to Regulation (EC) No. 1907/2006 (REACH) with its amendment Reg | gulation (EU) 2020/878 |
|---|------------------------|
| Auto-Ignition Temperature   | No data available      |
|   | No data available      |
| Decomposition Temperature   | No data available      |
| Flammability (solid, gas)   | 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      |
| Explosive Limits  | Not applicable         |
| 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 < 5 %

#### **SECTION 10: STABILITY AND REACTIVITY**

# 10.1. Reactivity

Hazardous reactions will not occur under normal conditions.

#### 10.2. Chemical Stability

Stable at normal conditions.

# 10.3. Possibility of Hazardous Reactions

Hazardous polymerization 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 generates: Carbon oxides (CO, CO<sub>2</sub>). 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 Inhalation

Ingestion Dermal Eye contact

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)

23/05/2022 EN (English) 6/12

# Safety Data Sheet

| According to Regulation | (EC) No. 1907/2 | 2006 (REACH) with | its amendment Reaul- | ation (EU) 2020/878 |
|-------------------------|-----------------|-------------------|----------------------|---------------------|

| According to Regulation (EC) No. 1907/2006 (REACH) with its of | amendment Regulation (EU) 2020/878  |
|--|---|
| 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  |
| Dodecamethylcyclohexasiloxane (540-97-6)                       |   |
| LD50 Oral Rat  | > 50 g/kg   |
| LD50 Dermal Rat  | > 2000 mg/kg (No deaths)  |
| Titanium dioxide (13463-67-7)                                  |   |
| LD50 Oral Rat  | > 10000 mg/kg   |
| LC50 Inhalation Rat  | 5,09 mg/l/4h  |
| Skin Corrosion/Irritation                                      | Not classified (Based on available data, the classification   |
| Eye Damage/Irritation  | criteria are not met) Not classified (Based on available data, the classification criteria are not met) |
| Respiratory or Skin Sensitisation                              | 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)                       |
| Titanium dioxide (13463-67-7)                                  |   |
| IARC Group   | 2B  |
| 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                                 | Not classified (Based on available data, the classification   |
| (Repeated Exposure)  | 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<br>Contact                        | Prolonged exposure to liquid may cause a mild irritation.   |
| Symptoms/Injuries After Eye<br>Contact                         | Prolonged exposure may cause slight irritation to eyes.   |
| Symptoms/Injuries After Ingestion                              | Ingestion may cause adverse effects.  |
| Chronic Symptoms   | None known.   |

# 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.

23/05/2022 EN (English) 7/12

# **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

Toxic to aquatic life with long lasting effects.

Environment, Long-Term

(Chronic)

| Octamethylcyclotetrasiloxane (556-67-2)   |  |
|---|--|
| LC50 Fish > 22 µg/l   |  |
| NOEC chronic Fish 0,0044 mg/l   |  |
| Titanium dioxide (13463-67-7)   |  |
| LC50 Fish > 1000 ml/l (Exposure Time: 96h - Species: Pimephales promelas (static) |  |

#### 12.2. Persistence and Degradability

|   | MED3-4800                     | •   |
|---|-------------------------------|---|
| ĺ | Persistence and Degradability | May cause long-term adverse effects in the environment. |

# 12.3. Bioaccumulative Potential

| MED3-4800  |                  |
|--|------------------|
| Bioaccumulative Potential                              | Not established. |
| Octamethylcyclotetrasiloxane (556-67-2) BCF Fish 12400 |                  |
|  |                  |

#### 12.4. Mobility in Soil

No additional information available

#### 12.5. Results of PBT and vPvB Assessment

|  | 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 |
|--|---|--|
| Decamethylcyclopentasiloxane (541-02-6)  This substance meets the vPvB criteria of REA                         |   | 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 XI |   | This substance meets the vPvB criteria of REACH regulation, annex XIII   |

## 12.6. Endocrine Disrupting Properties

Based on available data this substance/the substances in this mixture not listed below do(es) not have endocrine disrupting properties with respect to non-target organisms as it does not meet the criteria set out in section B 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.

#### 12.7. Other Adverse Effects

Other Information Avoid release to the environment.

#### SECTION 13: DISPOSAL CONSIDERATIONS

#### 13.1. Waste Treatment Methods

Product/Packaging Disposal Dispose of contents/container in accordance with local,

Recommendations regional, national, and international regulations.

Ecology - Waste Materials

This material is hazardous to the aquatic environment. Keep out of sewers and waterways. Avoid release to the environment.

#### **SECTION 14: TRANSPORT INFORMATION**

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

In accordance with ADR / RID / IMDG / IATA / ADN

23/05/2022 EN (English) 8/12

Safety Data Sheet

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

| ADR                          | IMDG               | IATA               | ADN               | RID               |  |
|------------------------------|--------------------|--------------------|-------------------|-------------------|--|
| 14.1. UN Number or ID Number |                    |                    |                   |                   |  |
| UN 3082                      | UN 3082            | UN 3082            | UN 3082           | UN 3082           |  |
| 14.2. UN Proper S            | hipping Name       |                    |                   |                   |  |
| ENVIRONMENTALL               | ENVIRONMENTALL     | Environmentally    | ENVIRONMENTALL    | ENVIRONMENTALL    |  |
| Y HAZARDOUS                  | y hazardous        | hazardous          | y hazardous       | Y HAZARDOUS       |  |
| SUBSTANCE,                   | SUBSTANCE,         | substance, liquid, | SUBSTANCE,        | SUBSTANCE,        |  |
| LIQUID, N.O.S.               | LIQUID, N.O.S.     | n.o.s.             | LIQUID, N.O.S.    | LIQUID, N.O.S.    |  |
| (Octamethylcycl              | (Octamethylcycl    | (Octamethylcycl    | (Octamethylcycl   | (Octamethylcycl   |  |
| otetrasiloxane)              | otetrasiloxane)    | otetrasiloxane)    | otetrasiloxane)   | otetrasiloxane)   |  |
| 14.3. Transport H            | azard Class        |                    |                   |                   |  |
| 9                            | 9                  | 9                  | 9                 | 9                 |  |
|                              |                    |                    | <i>₹</i> ₩,       |                   |  |
| 9                            | 9/                 | 9                  | 9                 | 9                 |  |
| 14.4. Packing Gr             | oup                |                    |                   |                   |  |
| III                          | III                | III                | III               | III               |  |
| 14.5. Environmental Hazards  |                    |                    |                   |                   |  |
| Dangerous for the            | Dangerous for the  | Dangerous for the  | Dangerous for the | Dangerous for the |  |
| environment : Yes            | environment : Yes  | environment : Yes  | environment : Yes | environment : Yes |  |
|                              | Marine pollutant : |                    |                   |                   |  |
|                              | Yes                |                    |                   |                   |  |

# 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 ≥ 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

Safety Data Sheet

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

#### 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

# 15.2. Chemical Safety Assessment

No chemical safety assessment has been carried out

#### **SECTION 16: OTHER INFORMATION**

Date of Preparation or Latest Revision

Data Sources

23/05/2022

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. According to Regulation (EC) No. 1907/2006 (REACH)

with its amendment Regulation (EU) 2020/878

# Other Information

#### Full Text of H- and EUH-statements:

| Aquatic Chronic 1 | Hazardous to the aquatic environment — Chronic Hazard, Category 1 |
|-------------------|---|
| Aquatic Chronic 2 | Hazardous to the aquatic environment — Chronic Hazard, Category 2 |
| Flam. Liq. 3      | Flammable liquids, Category 3                                     |
| H226              | Flammable liquid and vapour.                                      |
| H361f             | Suspected of damaging fertility.                                  |
| H410              | Very toxic to aquatic life with long lasting effects.             |
| H411              | Toxic to aquatic life with long lasting effects.                  |
| Repr. 2           | Reproductive toxicity, Category 2                                 |

Classification and Procedure Used to Derive the Classification for Mixtures According to Regulation (EC) 1272/2008 [CLP]: Aquatic Chronic 2 Calculation method

#### Indication of Changes

No additional information available

#### 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

NDS - Najwyzsze Dopuszczalne Stezenie

NDSCh - Najwyzsze Dopuszczalne Stezenie Chwilowe

NDSP - Najwyzsze 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

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

23/05/2022 EN (English) 10/12

#### Safety Data Sheet

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

IBC Code - International Bulk Chemical Code IMDG - International Maritime Dangerous Goods

IPRV - Ilgalaikio Poveikio Ribinis Dydis

IFRV - IIGUIGIKIO FOVEIKIO KIDII IIS DYGIS

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 Koc - Soil Organic Carbon-water Partitioning Coefficient

Log Kow - 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

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

# Limit Value Legal Basis\*

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

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 - BGBI. 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) & BGBI. II No. 242/2006, BGBI. II No. 243/2007, lastly changed through BGBI. I Nr. 51/2011), BGBI. II Nr. 186/2015, BGBI. II Nr. 288/2017 amended by BGBI. II Nr. 254/2018.

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

**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- OWCRLV** - 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

23/05/2022 EN (English) 11/12

#### Safety Data Sheet

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

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.

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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Nusil EU GHS SDS (2020/878)

23/05/2022 EN (English) 12/12



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