

Safety Data Sheet

According to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878 Revision Date: 24/04/2024 Date of Issue: 06/06/2014

Version: 6.0

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

#### 1.1. Product Identifier

Product Form Mixture

Product Name MED-4050 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 and 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 Exposure may aggravate those with pre-existing eye, skin, or to the Classification respiratory conditions.

	respiratory conditions.
Dodecamethylcyclohexasiloxane (540-97-6)	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

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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

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
Dodecamethylcyclohexasiloxane substance listed as REACH Candidate	(CAS-No.) 540-97-6 (EC-No.) 208-762-8	< 1	Not classified
Decamethylcyclopentasiloxane substance listed as REACH Candidate	(CAS-No.) 541-02-6 (EC-No.) 208-764-9	< 1	Not classified
Octamethylcyclotetrasiloxane substance listed as REACH Candidate	(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)

Full text of H-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 Inhalation	When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.
First-Aid Measures After Skin	Remove contaminated clothing. Drench affected area with

Contact 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. Rinse mouth. Do NOT induce vomiting. Obtain medical

Ingestion 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.

Symptoms/Effects After Prolonged exposure may cause irritation.

Inhalation

First-Aid Measures After

Symptoms/Effects After Skin Prolonged exposure may cause skin irritation.

Contact

Symptoms/Effects After Eye May cause slight irritation to eyes.

Contact

Symptoms/Effects After Ingestion may cause adverse effects.

Ingestion

Chronic Symptoms None expected under normal conditions of use.

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#### 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 Unsuitable Extinguishing Media Use extinguishing media appropriate for surrounding fire. Do not use a heavy water stream. Use of heavy stream of water may spread fire. Application of water stream to hot product may cause frothing and increase fire intensity.

#### 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. Oxides of platinum.

Products Silicon oxides.

5.3. Advice for Firefighters

Precautionary Measures Fire Firefighting Instructions

Protection During Firefighting

Exercise caution when fighting any chemical fire.

Use water spray or fog for cooling exposed containers.

Do not enter fire area without proper protective equipment,

including respiratory protection.

#### **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).

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 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. Ventilate area.

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

Absorb and/or contain spill with inert material. 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.

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#### **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 Avoid breathing vapours, mist, spray. Avoid contact with skin,

eyes and clothing. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and

when leaving work.

Hygiene Measures Wash hands and other exposed areas with mild soap and

water before eating, drinking, or smoking and again when leaving work. 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.

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.

#### 8.2. Exposure Controls

Appropriate Engineering Suitable eye/body wash equipment should be available in the

Controls vicinity of any potential exposure. Ensure adequate ventilation,

especially in confined areas. Ensure all national/local

regulations are observed.

Personal Protective Equipment Gloves. Protective clothing. Protective goggles. 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.

Chemically resistant materials and fabrics.







Materials for Protective Clothing

Hand Protection Wear protective gloves. Eye Protection Chemical safety goggles.

Skin and Body Protection Wear suitable protective clothing.

Respiratory Protection 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.

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#### 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 рΗ 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

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

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, CO<sub>2</sub>). 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.

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#### 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)

Not classified (Based on available data, the classification Acute Toxicity (Dermal)

criteria are not met)

Acute Toxicity (Inhalation) Not classified (Based on available data, the classification

criteria are not met)

Dodecamethylcyclohexasiloxane (540-97-6)	
LD50 Oral Rat	> 50 g/kg (Source: NLM_CIP)
LD50 Dermal Rat	> 2000 mg/kg (No deaths)
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
Octamethylcyclotetrasiloxane (556-67-2)	
LD50 Oral Rat	> 4800 mg/kg (No mortality)
LD50 Dermal Rat	> 2375 mg/kg (Source: ECHA)
LD50 Dermal Rabbit	> 2,5 ml/kg (No mortality)
LC50 Inhalation Rat	36 mg/l/4h

Skin Corrosion/Irritation Not classified (Based on available data, the classification

criteria are not met)

Not classified (Based on available data, the classification Eye Damage/Irritation

criteria are not met)

Not classified (Based on available data, the classification Respiratory or Skin Sensitisation

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 may cause adverse effects.

Ingestion

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

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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 Not classified (Based on available data, the classification

Environment, Short–Term criteria are not met)

(Acute)

Hazardous To The Aquatic Harmful 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

#### 12.2. Persistence and Degradability

MED-4050 Part A		
	Persistence and Degradability	Not established.

#### 12.3. Bioaccumulative Potential

12.0. Diodecomolarive i oremial	
MED-4050 Part A	
Bioaccumulative Potential	Not established.
Dodecamethylcyclohexasiloxane (540-97-6)	
Partition coefficient n-octanol/water (Log Pow)	8,87 at 23,6 °C
Decamethylcyclopentasiloxane (541-02-6)	
Partition coefficient n-octanol/water (Log Pow)	8,023 at 25,3 °C
Octamethylcyclotetrasiloxane (556-67-2)	
BCF Fish	12400
Partition coefficient n-octanol/water (Log Pow)	6,488 at 25,1 °C

#### 12.4. Mobility in Soil

No additional information available

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

Component	
Dodecamethylcyclohexasiloxane (540-97-6)	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 PBT criteria of REACH regulation, annex XIII This substance meets the vPvB criteria of REACH regulation, annex XIII
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

#### 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 Adverse Effects None known.

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, territorial, provincial, and international

regulations.

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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

#### 14.1. UN Number or ID Number

Not regulated for transport

#### 14.2. UN Proper Shipping Name

Not regulated for transport

#### 14.3. Transport Hazard Class

Not regulated for transport

#### 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 substance(s) listed on the REACH Candidate List in concentrations ≥ 0.1 % or SCL: Dodecamethylcyclohexasiloxane (EC 208-762-8, CAS 540-97-6), Decamethylcyclopentasiloxane (EC 208-764-9, CAS 541-02-6), Octamethylcyclotetrasiloxane (EC 209-136-7, CAS 556-67-2)

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

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

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

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

#### 15.1.1.5. REACH Annex XIV Information

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

#### 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

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#### 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

Data Sources

24/04/2024

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

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#### 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
H226	Flammable liquid and vapour.
H361f	Suspected of damaging fertility.
H410	Very toxic to aquatic life with long lasting effects.
H412	Harmful 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 3 Calculation method

#### Indication of Changes

Section	Change	Date Changed	Version
1	Language modified	24/04/2024	6.0
2	Classification modified; Language modified	24/04/2024	6.0
3	Data modified; Language modified	24/04/2024	6.0
4	Language modified	24/04/2024	6.0
5	Language modified	24/04/2024	6.0
6	Language modified	24/04/2024	6.0
7	Language modified	24/04/2024	6.0
8	Language modified	24/04/2024	6.0
9	Data modified	24/04/2024	6.0
10	Language modified	24/04/2024	6.0
11	Data modified; Language modified	24/04/2024	6.0
12	Data modified; Language modified	24/04/2024	6.0
13	Language modified	24/04/2024	6.0
14	Language modified	24/04/2024	6.0
15	Language modified	24/04/2024	6.0
16	Language modified	24/04/2024	6.0

#### **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 - 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

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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 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

#### Glossary of Data Source Abbreviations

ATSDR: Agency for Toxic Substances and Disease Registry (U.S. Department of Health and Human Services)

AU\_WES: Australia WES

CHEMVIEW: ChemView (U.S. Environmental Protection Agency) EC\_RAR: European Commission Renewal Assessment Report EC\_SCOEL: European Commission Scientific Committee on

Occupational Exposure Limits

ECETOC: European Centre for Ecotoxicology and Toxicology of

Chemicals Reports

ECHA\_API: European Chemicals Agency API ECHA\_RAC: ECHA Committee for Risk Assessment

EFSA: European Food Safety Authority EPA: U.S. Environmental Protection Agency

EPA\_AEGL: Acute Exposure Guideline Levels (U.S. Environmental Protection Agency)

EPA\_FIFRA: Federal Insecticide, Fungicide, and Rodenticide Act Reregistration Eligibility Decision (U.S. Environmental Protection Agency)

EPA\_HPV: High Production Volume Chemicals (U.S. Environmental Protection Agency)

EPA\_TRED: Risk Assessment for Tolerance Reassessment Eligibility Decision (U.S. Environmental Protection Agency)

EU\_CLH: European Union Harmonised Classification and Labelling Proposal

EU\_RAR: European Union Risk Assessment Report

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

5000 10000 5 10 11 10050

FOOD\_JOURN: Food Research Journal (1956)

IARC: The International Agency for Research on Cancer IDLH: National Institute for Occupational Health and Safety

Immediately Dangerous to Life or Health Value Profiles

IUCLID: International Uniform Chemical Information Database

JAPAN\_GHS: Japan GHS Basis for Classification Data

JP J-CHECK: Japan J-Check

KR\_NIER: South Korea National Institute of Environmental Research Evaluations

NICNAS: Australia National Industrial Chemicals Notification and Assessment Scheme

NIOSH: National Institute for Occupational Health and Safety (U.S. Department of Health and Human Services)

NLM\_CIP: National Library of Medicine ChemID plus database NLM\_HSDB: National Library of Medicine Hazardous Substance Data Bank

NLM\_PUBMED: National Library of Medicine PubMed database NTP: National Toxicology Program

NZ\_CCID: New Zealand Chemical Classification and Information Database

OECD\_EHSP: Environment, Health, and Safety Publication (Organisation for Economic Co-operation and Development) OECD\_SIDS: Screening Information Data Sets (Organisation for Economic Co-operation and Development)

WHO: World Health Organization

#### 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 Greece - PWHSE - Occ

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:

**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

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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

**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.

Finance HTP-ARYOT 2020 - Concentrations Known to be

**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

**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 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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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.

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Version: 5.0

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

#### 1.1. Product Identifier

Product Form Mixture

Product Name MED-4050 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

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Le Natura Bt. 2 06250 Mougins

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productstewardship@avantorsciencesgcc.com

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#### 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

Aguatic Chronic 3 H412

Full text of hazard classes and 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 Exposure may aggravate those with pre-existing eye, skin, or

to the Classification respiratory conditions.

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

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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

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
Siloxanes and Silicones, dimethyl, methyl hydrogen	(CAS-No.) 68037-59-2	< 5	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335
Decamethylcyclopentasiloxane substance listed as REACH Candidate	(CAS-No.) 541-02-6 (EC-No.) 208-764-9	< 1	Not classified
Dodecamethylcyclohexasiloxane substance listed as REACH Candidate	(CAS-No.) 540-97-6 (EC-No.) 208-762-8	< 1	Not classified
Octamethylcyclotetrasiloxane substance listed as REACH Candidate	(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)

Full text of H-statements: see section 16

#### **SECTION 4: FIRST AID MEASURES**

First-Aid Measures General

#### 4.1. Description of First-aid Measures

	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
First-Aid Measures After Skin	persists. Remove contaminated clothing. Immediately drench affected

Contact area with water for at least 15 minutes. Obtain medical

attention if irritation develops or persists.

diffiliation develops of persists.

First-Aid Measures After Eye

Contact

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

Obtain medical attention if irritation develops or persists. Rinse mouth. Do NOT induce vomiting. Obtain medical

Never give anything by mouth to an unconscious person. If you

Ingestion 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.

Symptoms/Effects After

First-Aid Measures After

Inhalation

Prolonged exposure may cause irritation.

Symptoms/Effects After Skin

Contact

Prolonged exposure may cause skin irritation.

COMMON (FIG.

Symptoms/Effects After Eye

Contact

May cause slight irritation to eyes.

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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 Unsuitable Extinguishing Media Use extinguishing media appropriate for surrounding fire. Do not use a heavy water stream. Use of heavy stream of water may spread fire. Application of water stream to hot product may cause frothing and increase fire intensity.

#### 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 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.

Hazardous Combustion Carbon oxides (CO, CO<sub>2</sub>). Explosive hydrogen gas.

Products Formaldehyde. Silicon oxides.

5.3. Advice for Firefighters

Precautionary Measures Fire Firefighting Instructions

Protection During Firefighting

Exercise caution when fighting any chemical fire.
Use water spray or fog for cooling exposed containers.
Do not enter fire area without proper protective equipment,

including respiratory protection.

#### **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).

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 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. Ventilate area.

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

Absorb and/or contain spill with inert material. Transfer spilled

material to a suitable container for disposal. Contact

competent authorities after a spill.

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#### 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 Avoid breathing vapours, mist, spray. Avoid contact with skin,

eyes and clothing. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and

when leaving work.

Hygiene Measures Wash hands and other exposed areas with mild soap and

water before eating, drinking, or smoking and again when leaving work. 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.

Incompatible Materials Alcohols. Metals. Strong acids, strong bases, strong oxidisers.

Water.

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.

#### 8.2. Exposure Controls

Appropriate Engineering

Controls

Personal Protective Equipment

Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Gloves. Protective clothing. Protective goggles. 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

Hand Protection
Eye Protection

Skin and Body Protection

Chemically resistant materials and fabrics.

Wear protective gloves. Chemical safety goggles.

Wear suitable protective clothing. Wash contaminated clothing

before reuse.

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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 No data available Hq **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

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 Not applicable Particle Aggregation State 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 polymerisation will not occur. Evolved hydrogen gas is flammable and may form explosive mixtures with air.

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#### 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, 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 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)

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 (Source: NLM_CIP)	
LD50 Dermal Rat	> 2000 mg/kg (No deaths)	
Octamethylcyclotetrasiloxane (556-67-2)		
LD50 Oral Rat	> 4800 mg/kg (No mortality)	
LD50 Dermal Rat	> 2375 mg/kg (Source: ECHA)	
LD50 Dermal Rabbit	> 2,5 ml/kg (No mortality)	
LC50 Inhalation Rat	36 mg/l/4h	

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 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)

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)

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Symptoms/Injuries After Prolonged exposure may cause irritation.

Inhalation

Symptoms/Injuries After Skin Prolonged exposure may cause skin irritation.

Contact

Symptoms/Injuries After Eye May cause slight irritation to eyes.

Contact

Symptoms/Injuries After Ingestion may cause adverse effects.

Ingestion

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 Not classified (Based on available data, the classification

Environment, Short–Term criteria are not met)

(Acute)

Hazardous To The Aquatic Harmful 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

#### 12.2. Persistence and Degradability

MED-4050 Part B	•
Persistence and Degradability	Not established.

#### 12.3. Bioaccumulative Potential

MED-4050 Part B		
Bioaccumulative Potential	Not established.	
Decamethylcyclopentasiloxane (541-02-6)		
Partition coefficient n-octanol/water (Log Pow)	8,023 at 25,3 °C	
Dodecamethylcyclohexasiloxane (540-97-6)		
Partition coefficient n-octanol/water (Log Pow)	8,87 at 23,6 °C	
Octamethylcyclotetrasiloxane (556-67-2)		
BCF Fish	12400	
Partition coefficient n-octanol/water (Log Pow)	6,488 at 25,1 °C	

#### 12.4. Mobility in Soil

No additional information available

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

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
Octamethylcyclotetrasiloxane (556-67-2)	This substance meets the PBT criteria of REACH regulation, annex XIII
	This substance meets the vPvB criteria of RFACH 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

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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 Dispo

Recommendations

Dispose of contents/container in accordance with local, regional, national, territorial, provincial, 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

#### 14.1. UN Number or ID Number

Not regulated for transport

#### 14.2. UN Proper Shipping Name

Not regulated for transport

#### 14.3. Transport Hazard Class(es)

Not regulated for transport

#### 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 substance(s) listed on the REACH Candidate List in concentrations ≥ 0.1 % or SCL: Decamethylcyclopentasiloxane (EC 208-764-9, CAS 541-02-6), Dodecamethylcyclohexasiloxane (EC 208-762-8, CAS 540-97-6), Octamethylcyclotetrasiloxane (EC 209-136-7, CAS 556-67-2)

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

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

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## **15.1.1.4. PIC Regulation EU (649/2012) - Export and Import of Hazardous Chemicals Information** Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and

import of hazardous chemicals)

#### 15.1.1.5. REACH Annex XIV Information

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

#### 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

Data Sources

24/04/2024

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
H226	Flammable liquid and vapour.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H361f	Suspected of damaging fertility.
H410	Very toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.
Repr. 2	Reproductive toxicity, Category 2
Skin Irrit. 2	Skin corrosion/irritation, Category 2
STOT SE 3	Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation

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	24/04/2024	5.0
2	Classification modified; Language modified	24/04/2024	5.0
3	Data modified; Language modified	24/04/2024	5.0
4	Language modified	24/04/2024	5.0
5	Language modified	24/04/2024	5.0
6	Language modified	24/04/2024	5.0
7	Language modified	24/04/2024	5.0
8	Language modified	24/04/2024	5.0
9	Data modified	24/04/2024	5.0
10	Language modified	24/04/2024	5.0
11	Data modified; Language modified	24/04/2024	5.0
12	Data modified; Language modified	24/04/2024	5.0
13	Language modified	24/04/2024	5.0
14	Language modified	24/04/2024	5.0
15	Language modified	24/04/2024	5.0
16	Language modified	24/04/2024	5.0

#### **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 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

#### Glossary of Data Source Abbreviations

ATSDR: Agency for Toxic Substances and Disease Registry (U.S. Department of Health and Human Services)

AU\_WES: Australia WES

CHEMVIEW: ChemView (U.S. Environmental Protection Agency) EC\_RAR: European Commission Renewal Assessment Report

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 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

FOOD\_JOURN: Food Research Journal (1956)

IARC: The International Agency for Research on Cancer IDLH: National Institute for Occupational Health and Safety Immediately Dangerous to Life or Health Value Profiles IUCLID: International Uniform Chemical Information Database

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EC\_SCOEL: European Commission Scientific Committee on

Occupational Exposure Limits

ECETOC: European Centre for Ecotoxicology and Toxicology of

Chemicals Reports

ECHA\_API: European Chemicals Agency API ECHA\_RAC: ECHA Committee for Risk Assessment

EFSA: European Food Safety Authority EPA: U.S. Environmental Protection Agency

EPA\_AEGL: Acute Exposure Guideline Levels (U.S. Environmental

Protection Agency)

EPA\_FIFRA: Federal Insecticide, Fungicide, and Rodenticide Act Reregistration Eligibility Decision (U.S. Environmental Protection Agency)

EPA\_HPV: High Production Volume Chemicals (U.S. Environmental Protection Agency)

EPA\_TRED: Risk Assessment for Tolerance Reassessment Eligibility Decision (U.S. Environmental Protection Agency)

EU\_CLH: European Union Harmonised Classification and Labelling Proposal

EU\_RAR: European Union Risk Assessment Report

#### 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

JAPAN\_GHS: Japan GHS Basis for Classification Data

JP\_J-CHECK: Japan J-Check

KR\_NIER: South Korea National Institute of Environmental Research Evaluations

NICNAS: Australia National Industrial Chemicals Notification and Assessment Scheme

NIOSH: National Institute for Occupational Health and Safety (U.S. Department of Health and Human Services)

NLM\_CIP: National Library of Medicine ChemID plus database NLM\_HSDB: National Library of Medicine Hazardous Substance Data Bank

NLM\_PUBMED: National Library of Medicine PubMed database NTP: National Toxicology Program

 $NZ\_CCID$ : New Zealand Chemical Classification and Information Database

OECD\_EHSP: Environment, Health, and Safety Publication (Organisation for Economic Co-operation and Development) OECD\_SIDS: Screening Information Data Sets (Organisation for Economic Co-operation and Development)

WHO: World Health Organization

**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

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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.

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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