

Safety Data Sheet

According to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830
Revision date: 20/12/2019 Date of issue: 18/03/2014

Version: 3.0

SECTION 1: Identification of the Substance/mixture and of the Company/Undertaking

1.1. Product Identifier

Product form Mixture
Product Name MED-4520
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

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
ehs@nusil.com
www.nusil.com

1.4. Emergency Telephone Number

Emergency Number : 800-424-9300 CHEMTREC (in US); +1 703-527-3887 CHEMTREC
(International and Maritime)
+(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 [CLP]

Not classified

2.2. Label Elements

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

EUH-statements EUH210 - Safety data sheet available on request.

2.3. Other Hazards

Contains vPvB substances $\geq 0.1\%$ assessed in accordance with REACH Annex XIII

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

SECTION 3: Composition/Information on Ingredients

3.1. Substances

Not applicable

3.2. Mixture

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Name	Product Identifier	%	Classification According to Regulation (EC) No. 1272/2008 [CLP]
Siloxanes and Silicones, dimethyl, methyl hydrogen	(CAS-No.) 68037-59-2	< 5	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335
Dodecamethylcyclohexasiloxane	(CAS-No.) 540-97-6 (EC-No.) 208-762-8	< 1	Not classified

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 Contact	Remove contaminated clothing. Drench affected area with water for at least 5 minutes. Obtain medical attention if irritation develops or persists.
First-Aid Measures After Eye Contact	Rinse cautiously with water for at least 5 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if irritation develops or persists.
First-Aid Measures After Ingestion	Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

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

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

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

SECTION 5: Firefighting Measures

5.1. Extinguishing Media

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

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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.

5.3. Advice for Firefighters

Precautionary Measures Fire	Exercise caution when fighting any chemical fire.
Firefighting Instructions	Use water spray or fog for cooling exposed containers.
Protection During Firefighting	Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental Release Measures

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

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

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

6.1.2. For Emergency Responders

Protective Equipment	Equip cleanup crew with proper protection.
Emergency Procedures	Ventilate area. Upon arrival at the scene, a first responder is expected to recognize 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.

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

Precautions for Safe Handling	Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid prolonged contact with eyes, skin and clothing. Avoid breathing vapours, mist, spray.
Hygiene Measures	Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures	Comply with applicable regulations.
Storage Conditions	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.

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Incompatible Materials Strong acids, strong bases, strong oxidizers.

7.3. Specific End Use(S)

For extrusion, transfer and compression molding and calendaring. For professional use only

SECTION 8: Exposure Controls/Personal Protection

8.1. Control Parameters

No additional information available

8.2. Exposure Controls

Appropriate Engineering Controls

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

Personal Protective Equipment

Gloves. Protective clothing. Protective goggles.



Materials for Protective Clothing

Chemically resistant materials and fabrics.

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.

SECTION 9: Physical and Chemical Hazards

9.1. Information on Basic Physical and Chemical Properties

Physical State	Gum
Colour	Colourless
Odour	Odourless
Odour Threshold	No data available
pH	No data available
Evaporation Rate	No data available
Melting Point	No data available
Freezing Point	No data available
Boiling Point	No data available
Flash Point	> 135 °C (275 °F)
Auto-Ignition Temperature	No data available
Decomposition Temperature	No data available
Flammability (Solid, Gas)	Not applicable
Vapour Pressure	No data available
Relative Vapour Density At 20 °C	No data available
Relative Density	1.10 (water=1)
Solubility	No data available
Partition Coefficient n-Octanol/Water	No data available

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Viscosity, Kinematic	No data available
Viscosity, Dynamic	No data available
Explosive Properties	No data available
Oxidising Properties	No data available
Explosive Limits	No data available

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 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 oxidizers.

10.6. Hazardous Decomposition Products

Carbon oxides (CO, CO₂). 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 sensitizer. Formaldehyde can also cause respiratory and eye irritation.

SECTION 11: Toxicological Information

11.1. Information On Toxicological Effects

Acute Toxicity Not classified (Based on available data, the classification criteria are not met)

Dodecamethylcyclohexasiloxane (540-97-6)	
LD50 Oral Rat	> 50 g/kg
Skin Corrosion/Irritation	Not classified (Based on available data, the classification criteria are not met)
Eye Damage/Irritation	Not classified (Based on available data, the classification criteria are not met)
Respiratory or Skin Sensitization	Not classified (Based on available data, the classification criteria are not met)
Germ Cell Mutagenicity	Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	Not classified (Based on available data, the classification criteria are not met)
Reproductive Toxicity	Not classified (Based on available data, the classification criteria are not met)
Specific Target Organ Toxicity (Single Exposure)	Not classified (Based on available data, the classification criteria are not met)
Specific Target Organ Toxicity (Repeated Exposure)	Not classified (Based on available data, the classification criteria are not met)

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Aspiration Hazard

Not classified (Based on available data, the classification criteria are not met)

SECTION 12: Ecological Information

12.1. Toxicity

Ecology - General Not classified.

12.2. Persistence and Degradability

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Persistence and Degradability	Not established.

12.3. Bioaccumulative Potential

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Bioaccumulative potential	Not established.

12.4. Mobility in Soil

No additional information available

12.5. Results of PBT and vPvB assessment

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

12.6. 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, regional, national, and international regulations.
Ecology - Waste Materials 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
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. Transport in Bulk According to Annex II of MARPOL and The IBC Code

Not applicable

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SECTION 15: Regulatory Information

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

15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions

Contains a substance on the REACH candidate list in concentration $\geq 0.1\%$ or with a lower specific limit:

Dodecamethylcyclohexasiloxane (D6) (EC 208-762-8, CAS 540-97-6)

Contains no REACH Annex XIV substances

15.1.2. National Regulations

No additional information available

15.2. Chemical Safety Assessment

No chemical safety assessment has been carried out

SECTION 16: Other Information

Indication of Changes

Section	Section Header	Change	Date Changed
1	Identification of the Substance/mixture and of the Company/Undertaking	Modified	20/12/2019
2	Hazards identification	Modified	20/12/2019
3	Composition/information on ingredients	Modified	20/12/2019
10	Stability and reactivity	Modified	20/12/2019
11	Toxicological information	Modified	20/12/2019
15	Regulatory information	Modified	20/12/2019

Date of Preparation or Latest Revision 20/12/2019

Revision

Data Sources

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

Other Information

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Full Text of H- and EUH-statements:

Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Skin Irrit. 2	Skin corrosion/irritation, Category 2
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
EUH210	Safety data sheet available on request.

Abbreviations and Acronyms

ACGIH – American Conference of Governmental Industrial Hygienists
ADN – European Agreement Concerning the International Carriage of Dangerous

MARPOL - International Convention for the Prevention of Pollution
NDS - Najwyższe Dopuszczalne Stężenie

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Goods by Inland Waterways	NDSCh - Najwyższe Dopuszczalne Steżenie Chwilowe
ADR - European Agreement Concerning the International Carriage of Dangerous Goods by Road	NDSP - Najwyższe Dopuszczalne Steżenie Pulapowe
ATE - Acute Toxicity Estimate	NOAEL - No-Observed Adverse Effect Level
BCF - Bioconcentration Factor	NOEC - No-Observed Effect Concentration
BEI - Biological Exposure Indices (BEI)	NRD - Nevirsytinas Ribinis Dydis
BOD - Biochemical Oxygen Demand	NTP - National Toxicology Program
CAS No. - Chemical Abstracts Service Number	OEL - Occupational Exposure Limits
CLP - Classification, Labeling and Packaging Regulation (EC) No 1272/2008	PBT - Persistent, Bioaccumulative and Toxic
COD - Chemical Oxygen Demand	PEL - Permissible Exposure Limit
EC - European Community	pH - Potential Hydrogen
EC50 - Median Effective Concentration	REACH - Registration, Evaluation, Authorisation, and Restriction of Chemicals
EEC - European Economic Community	RID - Regulations Concerning the International Carriage of Dangerous Goods by Rail
EINECS - European Inventory of Existing Commercial Chemical Substances	SADT - Self Accelerating Decomposition Temperature
EmS-No. (Fire) - IMDG Emergency Schedule Fire	SDS - Safety Data Sheet
EmS-No. (Spillage) - IMDG Emergency Schedule Spillage	STEL - Short Term Exposure Limit
EU - European Union	TA-Luft - Technische Anleitung zur Reinhaltung der Luft
ErC50 - EC50 in Terms of Reduction Growth Rate	TEL TRK - Technical Guidance Concentrations
GHS - Globally Harmonized System of Classification and Labeling of Chemicals	ThOD - Theoretical Oxygen Demand
IARC - International Agency for Research on Cancer	TLM - Median Tolerance Limit
IATA - International Air Transport Association	TLV - Threshold Limit Value
IBC Code - International Bulk Chemical Code	TPRD - Trumpalaikio Poveikio Ribinis Dydis
IMDG - International Maritime Dangerous Goods	TRGS 510 - Technische Regel für Gefahrstoffe 510 - Lagerung von Gefahrstoffen in ortsbeweglichen Behältern
IPRV - Ilgaliaikio Poveikio Ribinis Dydis	TRGS 552 - Technische Regeln für Gefahrstoffe - N-Nitrosamine
IOELV - Indicative Occupational Exposure Limit Value	TRGS 900 - Technische Regel für Gefahrstoffe 900 - Arbeitsplatzgrenzwerte
LC50 - Median Lethal Concentration	TRGS 903 - Technische Regel für Gefahrstoffe 903 - Biologische Grenzwerte
LD50 - Median Lethal Dose	TSCA - Toxic Substances Control Act
LOAEL - Lowest Observed Adverse Effect Level	TWA - Time Weighted Average
LOEC - Lowest-Observed-Effect Concentration	VOC - Volatile Organic Compounds
Log Koc - Soil Organic Carbon-water Partitioning Coefficient	VLA-EC - Valor Límite Ambiental Exposición de Corta Duración
Log Kow - Octanol/water Partition Coefficient	VLA-ED - Valor Límite Ambiental Exposición Diaria
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	VLE - Valeur Limite D'exposition
MAK - Maximum Workplace Concentration/Maximum Permissible Concentration	VME - Valeur Limite De Moyenne Exposition
	vPvB - Very Persistent and Very Bioaccumulative
	WEL - Workplace Exposure Limit
	WGK - Wassergefährdungsklasse

Nusil EU GHS SDS

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Polymer Systems Technology Limited

Silicone Sales & Services UK - Ireland - Benelux

© 2022 - **Polymer Systems Technology Limited™**
Unit 2. Network 4. Cressex Business Park,
Lincoln Road, High Wycombe, Bucks. HP12 3RF

tel: +44 (0) 1494 446610

web: <https://www.silicone-polymers.com>

email: sales@silicone-polymers.co.uk

