

EG-MATERIAL SAFETY DATA SHEET

According to Regulation (EC) No. 1907/2006 (REACH) Article 31, Annex II as amended.



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Version: 9.0

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Hinrisil KL - component A

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

1.1 Product identifier:

Commercial product name: Hinrisil KL – component A
Duplicating silicone
This substance/ mixture contains nanoforms

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

Identified uses: Moulding diverse objects.
Uses advised against: None known.

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier: ERNST HINRICHS Dental GmbH
Street / mailbox: Borsigstr. 1
Country code. / postal code / city: D - 38644 Goslar
Phone: 0 53 21 / 5 06 24
Fax: 0 53 21 / 5 08 81
E-mail / Website: info@hinrichs-dental.de / www.hinrichs-dental.de
Further information obtainable from: ERNST HINRICHS Dental GmbH

1.4 Emergency telephone number

ERNST HINRICHS Dental GmbH: +49 (0) 53 21 / 5 06 24 (Mon-Fri. 8 a.m. – 4 p.m.)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture: The product has been classified according to the legislation in force.

Classification according to Regulation (EC) No 1272/2008 as amended.

Health Hazards:

Specific Target Organ Toxicity - Repeated Exposure Category 2 H373: May cause damage to organs through prolonged or repeated exposure. (Target Organs: Lung)

2.2 Label Elements:

Supplemental label information: EUH210: Safety data sheet available on request.
EUH066: Repeated exposure may cause skin dryness or cracking.

2.3 Other hazards:

Physical Hazards: No specific recommendations.

Health Hazards:

Inhalation: Surface treated silica: When encapsulated in a polymer, is not expected to pose a health hazard when processed under normal conditions of use. Although classified according to EC criteria, this product is exempt from labelling according to article 23 and Annex 1 (section 1.3.4.1) of regulation (CE) n°1272/2008.

Eye contact: No specific symptoms noted.

Skin Contact: Repeated exposure may cause skin dryness or cracking.

Ingestion: No specific symptoms noted.

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Other Health Effects:	No other information noted.
Environmental Hazards:	No hazard identified as the maximum bioavailable concentration of Octamethylcyclotetrasiloxane (D4) is lower than the classification cut-off value (see Section 12 of this SDS).
Results of PBT and vPvB assessment:	This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.
Endocrine Disruption - Health:	The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
Endocrine Disruption - Environment:	The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
Other hazards:	No other information noted.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

General information: Mixture of organosiloxanes, additives.

Hazardous Component(s):

Chemical name	Concentration *	Type	CAS-No.	EC No.	REACH Registration No.	Notes
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	20 - <50%	Component	68909-20-6	272-697-1	Exempt	
octamethylcyclotetrasiloxane; [D4]	0,01 - <0,079%	Impurities	556-67-2	209-136-7	Not relevant.	# ## PBT, vPvB

* All concentrations are percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

This substance has workplace exposure limit(s).

This substance is listed as SVHC.

PBT: persistent, bioaccumulative and toxic substance.

vPvB: very persistent and very bioaccumulative substance.

ED: Endocrine Disruptor

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Classification:

Chemical name	Classification	Specific concentration limit: / ATE / M-Factor:	Notes
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	STOT RE 2 H373; EUH066;		
octamethylcyclotetrasiloxane; [D4]	Flam. Liq. 3 H226; Repr. 2 H361f; Aquatic Chronic 1 H410;	Aquatic Toxicity (Chronic): 10	

The full text for all H-statements is displayed in section 16.

Particle characteristics:

Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica

Assessment:	This substance/ mixture contains nanoforms ;
Particle Size:	1 - 100 nm

SECTION 4: First aid measures

General information:

Move into fresh air and keep at rest. Take off contaminated clothing and wash it before reuse. Get medical attention if symptoms occur.

4.1 Description of first aid measures:

Inhalation:

In case of inhalation: Move person into fresh air and keep at rest. Get medical attention immediately. If breathing is difficult, trained personnel should give oxygen. If breathing stops, provide artificial respiration.

Skin Contact:

Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Wash skin with soap and water. Get medical attention immediately. Contaminated clothing to be placed in closed container until disposal or decontamination. Wash contaminated clothing before reuse.

Eye contact:

In the event of contact with the eyes, rinse thoroughly with clean water for at least 15 minutes. Get medical attention if symptoms occur.

Ingestion:

Do not induce vomiting. Rinse mouth thoroughly with water. Get medical attention if symptoms occur.

Personal Protection for First-aid Responders:

First Aid responders should pay attention to self-protection and use the recommended protective clothing (chemical resistant gloves, splash protection). Refer to sections 5 and 8 for information on emergency procedures and protective equipment.

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

Any important symptoms and effects are described in Section 11 (Toxicological information) of this SDS.

4.3 Indication of any immediate medical attention and special treatment needed: Notes to the physician:

No specific recommendations.
Show this Safety Data Sheet to the attending physician.

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SECTION 5: Firefighting measures

- 5.1 Extinguishing media**
- Suitable extinguishing media:** Water spray, foam, dry powder or carbon dioxide.
- Unsuitable extinguishing media:** Avoid water in straight hose stream; will scatter and spread fire.
- 5.2 Special hazards arising from the substance or mixture:** Product will burn under fire conditions. Thermal decomposition or combustion may liberate carbon oxides, silicon oxides and other toxic gases or vapours.
- 5.3 Advice for firefighters:**
- Special protective equipment for firefighters:** Use standard firefighting procedures and consider the hazards of other involved materials. Remove undamaged containers from fire area if it is safe to do so. Evacuate to a safe location and contact the emergency services. Water spray should be used to cool containers. Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.
- Special protective equipment for firefighters:** Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

SECTION 6: Accidental release measures

- 6.1 Personal precautions, protective equipment and emergency procedures:** Personnel not required or not equipped with personal protection should be evacuated from the area. Caution: Contaminated surfaces may be slippery. Follow safe handling advice and personal protective equipment recommendations. Avoid contact with eyes, skin, and clothing. Provide good ventilation. Avoid inhalation of vapours, mists or dusts. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Prevent further leakage or spillage if safe to do so. Alert the Health, Safety & Environmental department of spill.
- 6.2 Environmental Precautions:** Do not release into the environment. Do not discharge into drains, water courses or onto the ground. Collect spillage. Use containment for a large spill. Notify relevant authorities if this material is released to the environment.
- 6.3 Methods and material for containment and cleaning up:** Access to contaminated area only to authorized people. Absorb with sand or other inert absorbent. Shovel up and place in a container for salvage or disposal. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Never return the spilled product to its original container for reuse. Containers with collected spillage must be properly labelled with correct contents and hazard symbol. Container must be kept tightly closed. To clean the floor and all objects contaminated by this material, use an appropriate solvent (see § 9). Flush area with plenty of water. Ensure that waste and contaminated materials are collected and removed from the work area as soon as possible in a suitably labelled

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container. Dispose of residue in accordance with regulations in force.

6.4 Reference to other sections:

Please observe the important information mentioned in the other sections. In particular, information on exposure controls/personal protection and disposal considerations can be found under sections 8 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Precautions:

Avoid inhalation of vapours/aerosols/dusts and contact with skin and eyes. Provide adequate ventilation, including appropriate local extraction, to ensure that the defined occupational exposure limit is not exceeded. If ventilation is insufficient, suitable respiratory protection must be provided. See Section 8 of the SDS for Personal Protective Equipment. Provide eyewash station and safety shower and ensure that their location are labelled conspicuously. Limit the quantities of product in the work area to those which are necessary for the work in hand. Handle in accordance with good industrial hygiene and safety practices. Handle and open container with care. Protect from contamination. Do not mix with incompatible materials. For further information, refer to section 10: "Stability and Reactivity". Take care to prevent spills, waste and minimize release to the environment. In case of spills, beware of slippery floors and surfaces.

Hygiene measures:

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. Contaminated work clothing should not be allowed out of the workplace.

7.2 Conditions for safe storage, including any incompatibilities:

Store in accordance with local/regional/national regulations. Avoid discharge into drains, water courses or onto the ground. Provide impermeable soil. Store in a dry place. Store in a well-ventilated place. Keep container tightly closed. Keep in properly labelled containers. Keep above the chemical's freezing point. Protect against physical damage and/or friction. Store away from incompatible materials. For further information, refer to section 10: "Stability and Reactivity".

Packaging frequently used at our sites:

Polyethylene. Plastic lined steel drum.

Lagerklasse:

Es liegen keine Daten vor.

Storage Class:

No data available.

7.3 Specific end use(s):

No specific recommendations. See the technical data sheet on this product for further information.

SECTION 8: Exposure controls/personal protection

8.1 Control Parameters:

Occupational Exposure Limits:

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octamethylcyclotetrasiloxane; [D4]

Type	Exposure Limit Values	Source	Date	Remarks
TWA	10 ppm 120 mg/m ³	WEEL		

Monitoring methods:

Ensure workers' exposure monitoring in accordance with national and European regulations in force, in particular Directives 98/24/EC and 2004/37/EC.

8.2 Exposure controls: Appropriate engineering controls:

Use engineering controls to reduce air contamination to permissible exposure level. The level of protection and types of controls necessary will vary depending upon potential exposure conditions. Engineering controls are always preferable to personal protective equipment. Control measures to consider: Provide adequate ventilation. In case of inadequate ventilation: Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. Provide eyewash station and safety shower.

Individual protection measures, such as personal protective equipment:

Avoid inhalation of vapours/aerosols/dusts and contact with skin and eyes. Personal protective equipment should be chosen according to applicable standards, adapted to the conditions of use of the product and in discussion with the supplier of the personal protective equipment.

Eye/face protection:

Safety Glasses with side shields.

Skin protection: Hand Protection:

This recommendation is valid only for the product named in this safety data sheet supplied by us, and only for the indicated intended use purposes. In case this product will be mixed with other substances, you need to contact a supplier of CE approved protective gloves in order to determine the appropriate gloves.

Prolonged or repeated contact:

Material: Nitrile.
Glove thickness: 1,25 mm
Guideline: EN374-3

Short contact:

Material: Nitrile / Neoprene
Glove thickness: 0,198 mm
Guideline: EN374-3

Skin and Body Protection:

Wear appropriate clothing to prevent any possibility of skin contact. Isolate contaminated clothing and wash before reuse. In case of splashes: Wear apron or special protective clothing.

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Respiratory Protection:

If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn. Use the following CE approved air-purifying respirator: Breathing apparatus with combined filter type ABEK. Wear respiratory protection with combination filter (dust and gas filter) during operations leading to the formation of dust/aerosols.

Environmental Controls:

See sections 7 and 13 of the Safety Data Sheet.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance:

Physical state:

Liquid

Form:

Viscous

Colour:

White

Odour:

Odourless

pH:

By definition, pH measurement consists in the determination of hydrogen ions concentration in solution, generally aqueous. Silicones products are hydrophobic and therefore, not soluble in water. By consequence, it is not possible to measure the pH value.

Melting point/freezing point:

No data available.

Boiling Point:

No data available.

Flash Point:

> 200 °C (Closed cup according to method ASTM D56.)

Flammability:

No data available.

Flammability Limit - Upper (%):

No data available.

Flammability Limit - Lower (%):

No data available.

Vapour pressure:

< 0,1 hPa (20 °C)

Relative vapour density:

No data available.

Evaporation Rate:

No data available.

Density:

Approximate 1,05 kg/dm³ (20 °C)

Solubility(ies):

Solubility in Water:

Practically Insoluble

Solubility (other):

Diethylether: Miscible (in all proportions).
Chlorinated solvents: Miscible (in all proportions).
Aromatic hydrocarbons: Miscible (in all proportions).
Aliphatic hydrocarbons: Miscible (in all proportions).
Acetone: Very slightly soluble
Ethanol: Very slightly soluble

Partition coefficient (n-octanol/water):

No data available.

Self Ignition Temperature:

> 400 °C

Decomposition Temperature:

> 200 °C

Kinematic viscosity:

Approximate 4 800 mm²/s (20 °C)

Particle characteristics:

Not applicable.

9.2 Other information:

Dynamic viscosity:

Approximate 5 000 mPa.s

Oxidizing properties:

According to the data on the components

Not considered as oxidizing.

(evaluation by structure-activity relationship)

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SECTION 10: Stability and reactivity

10.1 Reactivity:	Not relevant.
10.2 Chemical Stability:	Material is stable under normal conditions.
10.3 Possibility of hazardous Reactions:	No data available.
10.4 Conditions to Avoid:	No special precautions.
10.5 Incompatible Materials:	Strong oxidizing agents.
10.6 Hazardous Decomposition Products:	Thermal decomposition or combustion may liberate carbon oxides and other toxic gases or vapours. Amorphous silica.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008:

Acute Toxicity:

Oral:

Not classified for acute toxicity based on available data.

Dermal:

Not classified for acute toxicity based on available data.

Inhalation:

Not classified for acute toxicity based on available data.

Repeated Dose Toxicity:

Based on our knowledge of the composition information:

Based on our knowledge of the composition information:
OCTAMETHYLCYCLOTETRASILOXANE; [D4] (556-67-2):
NOAEL: 1,82 mg/l ; LOAEL: 8,5 mg/l ; (Rat ; Female, Male ;
Inhalation - vapour) ; Target Organ(s): Kidney ; Method:
Similar to OECD 453 ; Chronic exposure.
NOAEL: 960 mg/kg ; (Rabbit ; Female, Male ; Dermal) ; No
treatment-related adverse effects observed ; Method: Similar
to OECD 410 ; Subacute exposure.

Skin Corrosion/Irritation:

Based on our knowledge of the composition information:

SILANAMINE, 1,1,1-TRIMETHYL-N-(TRIMETHYLSILYL)-,
HYDROLYSIS PRODUCTS WITH SILICA (68909-20-6):
Repeated exposure may cause skin dryness or cracking.
OCTAMETHYLCYCLOTETRASILOXANE; [D4] (556-67-2):
An Expert Judgment stated that no classification is necessary
based on present knowledge. Not irritating (Rabbit) ; Method:
Similar to OECD 404

Serious Eye Damage/Eye Irritation:

Based on our knowledge of the composition information:

OCTAMETHYLCYCLOTETRASILOXANE; [D4] (556-67-2):
An Expert Judgment stated that no classification is necessary
based on present knowledge. Not irritating (Rabbit) ; Method:
OECD 405

Respiratory or Skin Sensitisation:

Based on our knowledge of the composition information:

OCTAMETHYLCYCLOTETRASILOXANE; [D4] (556-67-2):
Skin sensitization: Not a skin sensitizer. (Guinea Pig) ;
Method: OECD 406

Germ Cell Mutagenicity:

In vitro: Based on our knowledge of the composition information:

OCTAMETHYLCYCLOTETRASILOXANE; [D4] (556-67-2):

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In vivo: Based on our knowledge of the composition information:

Bacterial reverse mutation test: No mutagenic effect. (Salmonella typhimurium ; with and without metabolic activation) ; Method: OECD 471

In vitro gene mutations test on mammalian cells: No mutagenic effect. (Mouse lymphoma cells ; with and without metabolic activation) ; Method: Similar to OECD 476

In vitro mammalian chromosomal aberration test: No clastogenic effect. (Chinese hamster ovary cells ; with and without metabolic activation) ; Method: Similar to OECD 473

OCTAMETHYLCYCLOTETRASILOXANE; [D4] (556-67-2): Mammalian bone marrow chromosomal aberration test: negative (Rat ; Female, Male ; Inhalation) ; Method: Similar to OECD 475

Rodent dominant Lethal test: negative (Rat ; Female, Male ; Gavage (Oral)) ; Method: Similar to OECD 478

Carcinogenicity: Based on our knowledge of the composition information:

OCTAMETHYLCYCLOTETRASILOXANE; [D4] (556-67-2): Not classified

No effects expected. NOAEC: $\geq 8,492$ mg/l (Rat ; Female, Male ; Inhalation - vapour) ; Method: Similar to OECD 453 ; Chronic exposure.

Reproductive Toxicity: Fertility: Based on our knowledge of the composition information:

OCTAMETHYLCYCLOTETRASILOXANE; [D4] (556-67-2): Suspected of damaging fertility.

Fertility study 2 generations: NOAEL (parent): 3,64 mg/l ; NOAEL (F1): 3,64 mg/l ; NOAEL (F2): None. (Rat ; Female, Male ; Inhalation) ; Method: Similar to OECD 416 ; Effects on fertility

Teratogenicity: Based on our knowledge of the composition information:

OCTAMETHYLCYCLOTETRASILOXANE; [D4] (556-67-2): NOAEL (terato): $> 8,492$ mg/l ; NOAEL (mater): 3,64 mg/l (Rat ; Inhalation - vapour) ; Method: Similar to OECD 414 ; The product is not considered to be toxic for development. NOAEL (terato): $> 6,066$ mg/l ; NOAEL (mater): 3,64 mg/l (Rabbit ; Inhalation - vapour) ; Method: Similar to OECD 414 ; The product is not considered to be toxic for development.

Specific Target Organ Toxicity - Single Exposure:

Based on our knowledge of the composition information:

OCTAMETHYLCYCLOTETRASILOXANE; [D4] (556-67-2): Based on available data, the classification criteria are not met.

Specific Target Organ Toxicity - Repeated Exposure:

Based on our knowledge of the composition information: May cause damage to organs through prolonged or repeated exposure.

SILANAMINE, 1,1,1-TRIMETHYL-N-(TRIMETHYLSILYL)-, HYDROLYSIS PRODUCTS WITH SILICA (68909-20-6): Causes damage to organs through prolonged or repeated exposure. Inhalation: Target Organ(s): Lungs

OCTAMETHYLCYCLOTETRASILOXANE; [D4] (556-67-2): Based on available data, the classification criteria are not met.

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Aspiration Hazard:

Based on our knowledge of the composition information:

OCTAMETHYLCYCLOTETRASILOXANE; [D4] (556-67-2):
Based on available data, the classification criteria are not met.

11.2 Information on other hazards:

Endocrine disrupting properties:

No data available.

SECTION 12: Ecological information

General information:

The maximum concentration of Octamethylcyclotetrasiloxane (D4) leachable from the product is below the established no-effect threshold (<0.0079 mg/l) for aquatic organisms.

12.1 Toxicity:

Acute toxicity:

Fish: Based on our knowledge of the composition information:

OCTAMETHYLCYCLOTETRASILOXANE; [D4] (556-67-2):
LC 50 (Oncorhynchus mykiss; 96 h ; Flow through) : > 0,022 mg/l ; Method: According to a standardised method.

Aquatic Invertebrates: Based on our knowledge of the composition information:

OCTAMETHYLCYCLOTETRASILOXANE; [D4] (556-67-2):
EC 50 (Water flea (Daphnia magna); 48 h ; Flow through) : > 0,015 mg/l ; Method: According to a standardised method.

Aquatic plants: Based on our knowledge of the composition information:

OCTAMETHYLCYCLOTETRASILOXANE; [D4] (556-67-2):
ErC50 (Algae (Pseudokirchneriella subcapitata); 96 h) : > 0,022 mg/l ; Method: According to a standardised method.
ErC10 (Algae (Pseudokirchneriella subcapitata); 96 h) : >= 0,022 mg/l ; Method: According to a standardised method.

Toxicity to microorganisms: Based on our knowledge of the composition information:

OCTAMETHYLCYCLOTETRASILOXANE; [D4] (556-67-2):
EC 50 (3 h) : > 10 000 mg/l

Chronic Toxicity:

Fish: Based on our knowledge of the composition information:

OCTAMETHYLCYCLOTETRASILOXANE; [D4] (556-67-2):
NOEC (Oncorhynchus mykiss; 93 d ; Flow through) : >= 0,0044 mg/l ; Method: According to a standardised method.

Aquatic Invertebrates: Based on our knowledge of the composition information:

OCTAMETHYLCYCLOTETRASILOXANE; [D4] (556-67-2):
NOEC (Water flea (Daphnia magna); 21 d ; Flow through) : >= 0,015 mg/l ; Method: According to a standardised method.

12.2 Persistence and Degradability:

Biodegradation: Based on our knowledge of the composition information:

OCTAMETHYLCYCLOTETRASILOXANE; [D4] (556-67-2):
3,7 % (activated sludge and sewage, soil ; 28 d) ; Method: OECD 310 ; The product is not considered to be readily biodegradable.

BOD/COD Ratio:

No data available.

12.3 Bioaccumulative Potential:

Bioconcentration Factor (BCF): Based on our knowledge of the composition information:

OCTAMETHYLCYCLOTETRASILOXANE; [D4] (556-67-2):
Bioconcentration Factor (BCF): 14 900 (Fathead Minnow) ; Method: OECD 305 ; Not bioaccumulable based on the depuration rate constant

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Partition coefficient (n-octanol/water):
Based on our knowledge of the composition information:

OCTAMETHYLCYCLOTETRASILOXANE; [D4] (556-67-2):
Log Kow: 5,10

12.4 Mobility in Soil:

No data available.

12.5 Results of PBT and vPvB assessment:
Based on our knowledge of the composition information:

OCTAMETHYLCYCLOTETRASILOXANE; [D4] (556-67-2):
Meets PBT (persistent/bioaccumulative/toxic) criteria.
(REACH (1907/2006) Ax XIII)
Meets vPvB criteria (REACH (1907/2006) Ax XIII)

12.6 Endocrine disrupting properties:

No data available.

12.7 Other adverse effects:

No data available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Do not empty into drains. The user's attention is drawn to the possible existence of local regulations regarding disposal. Please observe the important information mentioned in the other sections. In particular, information on hazards identification and product stability and reactivity under sections 2 and 10.

Disposal methods:

Dispose of waste at an appropriate treatment and disposal facility in accordance with applicable laws and regulations, and product characteristics at time of disposal. Incinerate in suitable combustion chamber.

Contaminated Packaging:

Contaminated packages should be as empty as possible. Recycle following cleaning or dispose of at an authorised site. Packaging that cannot be cleaned should be disposed of in the same way as the product it contained.

Waste code:

The waste code of the European Waste Catalogue (EWC) cannot be determined for this product, as its determination depends on how the material is used by the end-users. The waste code has to be determined within the EU in agreement with the waste-disposal operator.

SECTION 14: Transport information

ADR:

Not regulated.

ADN:

Not regulated.

RID:

Not regulated.

IMDG / IMO

Not regulated.

IATA:

Not regulated.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
EU Regulations:

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Regulation 1005/2009/EC on substances that deplete the ozone layer, Annex I, Controlled Substances:

None present or none present in regulated quantities.

Regulation 1005/2009/EC on substances that deplete the ozone layer, Annex II, New Substances:

None present or none present in regulated quantities.

EU. Regulation 2019/1021/EU on persistent organic pollutants (POPs) (recast), as amended:

None present or none present in regulated quantities.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 1 as amended:

None present or none present in regulated quantities.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 2 as amended:

None present or none present in regulated quantities.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 3 as amended:

None present or none present in regulated quantities.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex V as amended:

None present or none present in regulated quantities.

EU. Directive 2010/75/EU on Industrial Emissions (IPPC), Annex II, L 334/17:

Chemical name	CAS-No.
octamethylcyclotetrasiloxane; [D4]	556-67-2

EU. REACH Annex XIV, Substances Subject to Authorization:

None present or none present in regulated quantities.

EU. REACH Candidate List of Substances of Very High Concern for Authorization (SVHC):

Chemical name	CAS-No.	Concentration	Additional Information
octamethylcyclotetrasiloxane; [D4]	556-67-2	0,01 - 0,079%	very Persistent and very Bioaccumulative (vPvB) Persistent, Bioaccumulative and Toxic (PBT)

Regulation (EC) No. 1907/2006 Annex XVII Substances subject to restriction on marketing and use:

Chemical name	CAS-No.	Entry No:	Concentration:
octamethylcyclotetrasiloxane; [D4]	556-67-2	70	0,01 - 0,079%

Directive 98/24/EC on the protection of workers from the risks related to chemical agents at work:

Chemical name	CAS-No.	Concentration
octamethylcyclotetrasiloxane; [D4]	556-67-2	0,01 - 0,079%

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EU. Regulation No. 166/2006 PRTR (Pollutant Release and Transfer Registry), Annex II: Pollutants:

None present or none present in regulated quantities.

EU. Directive 2012/18/EU (SEVESO III) on major accident hazards involving dangerous substances, Annex I:

Not applicable

National Regulations: Wassergefährdungs-klasse (WGK):

WGK 1: schwach wassergefährdend. Einstufung nach AwSV

Water Hazard Class (WGK):

WGK 1: slightly water-endangering. Classification according to AwSV

15.2 Chemical safety assessment:

Surface treated silica: When encapsulated in a polymer, is not expected to pose a health hazard when processed under normal conditions of use. For safe use information, please refer to section 8 of this SDS.

Inventory Status:

Australia Industrial Chem. Act (AIC):

On or in compliance with the inventory.

Canada DSL Inventory List:

On or in compliance with the inventory.

China Inv. Existing Chemical Substances:

On or in compliance with the inventory.

Japan (ENCS) List:

Q (quantity restricted)

Korea Existing Chemicals Inv. (KECI):

On or in compliance with the inventory.

New Zealand Inventory of Chemicals:

On or in compliance with the inventory.

Philippines PICCS:

On or in compliance with the inventory.

Taiwan Chemical Substance Inventory:

On or in compliance with the inventory.

US TSCA Inventory:

On or in compliance with the inventory.

Thailand DIW Existing Chemical Inv. List:

On or in compliance with the inventory.

Vietnam National Chemical Inventory:

On or in compliance with the inventory.

EINECS, ELINCS or NLP:

On or in compliance with the inventory.

SECTION 16: Other information

Revision Information:

SECTION 2:

Modification:

Hazard(s) identification

SECTION 3:

Modification:

Composition/information on ingredients

SECTION 15:

Modification:

Regulatory information

Abbreviations and acronyms:

CLP: Regulation No. 1272/2008.

PBT: persistent, bioaccumulative and toxic substance.

vPvB: very persistent and very bioaccumulative substance.

NOAEL: No Observable Adverse Effect Level

LOAEL: Lowest Observable Adverse Effect Level

ED: Endocrine Disruptor

SVHC: Listed on the Candidate List of substances of very high concern (SVHC)

Wording of the H-statements in section 2 and 3:

EUH066 Repeated exposure may cause skin dryness or cracking.

EUH210 Safety data sheet available on request.

H226 Flammable liquid and vapour.

H361f Suspected of damaging fertility.

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

H410 Very toxic to aquatic life with long lasting effects.

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Issue Date:

06.10.2023

Disclaimer:

The information given is based on data available for the material, the components of the material, and similar materials. The information is believed to be correct. It is given in good faith. This information should be used to make an independent determination of the methods to safeguard workers and the environment

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Hinrisil KL - component B

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

1.1 Product identifier:

Commercial product name: Hinrisil KL - component B
Duplicating silicone
This substance/ mixture contains nanoforms

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

Identified uses: Moulding diverse objects.
Uses advised against: None known.

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier: ERNST HINRICHS Dental GmbH
Street / mailbox: Borsigstr. 1
Country code. / postal code / city: D - 38644 Goslar
Phone: 0 53 21 / 5 06 24
Fax: 0 53 21 / 5 08 81
E-mail / Website: info@hinrichs-dental.de / www.hinrichs-dental.de
Further information obtainable from: ERNST HINRICHS Dental GmbH

1.4 Emergency telephone number

ERNST HINRICHS Dental GmbH: +49 (0) 53 21 / 5 06 24 (Mon-Fri. 8 a.m. – 4 p.m.)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture: The product has been classified according to the legislation in force.

Classification according to Regulation (EC) No 1272/2008 as amended.

Health Hazards:

Specific Target Organ Toxicity - Repeated Exposure Category 2 H373: May cause damage to organs through prolonged or repeated exposure. (Target Organs: Lung)

2.2 Label Elements:

Supplemental label information: EUH210: Safety data sheet available on request.
EUH066: Repeated exposure may cause skin dryness or cracking.

2.3 Other hazards:

Physical Hazards: No specific recommendations.

Health Hazards:

Inhalation: Surface treated silica: When encapsulated in a polymer, is not expected to pose a health hazard when processed under normal conditions of use. Although classified according to EC criteria, this product is exempt from labelling according to article 23 and Annex 1 (section 1.3.4.1) of regulation (CE) n°1272/2008.

Eye contact: No specific symptoms noted.

Skin Contact: Repeated exposure may cause skin dryness or cracking.

Ingestion: No specific symptoms noted.

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Other Health Effects:	No other information noted.
Environmental hazards:	No hazard identified as the maximum bioavailable concentration of Octamethylcyclotetrasiloxane (D4) is lower than the classification cut-off value (see Section 12 of this SDS).
Results of PBT and vPvB assessment:	This substance/mixture contains components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB).
Endocrine Disruption - Health:	The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
Endocrine Disruption - Environment:	The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
Other hazards:	Chemical compounds containing silicon - hydrogen bonds (SiH). This product may generate hydrogen gas. For further information, refer to section 10: "Stability and Reactivity".

SECTION 3: Composition/information on ingredients

3.2 Mixtures

General information: Mixture of organosiloxanes, additives.

Hazardous Component(s):

Chemical name	Concentration*	Type	CAS-No.	EC No.	REACH Registration No.	Notes
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	20 - <50%	Component	68909-20-6	272-697-1	Exempt	
Dodecamethylcyclohexasiloxane	0,1 - <1%	Impurities	540-97-6	208-762-8	Not relevant.	## vPvB
Decamethylcyclopentasiloxane	0,1 - <1%	Impurities	541-02-6	208-764-9	Not relevant.	## vPvB

* All concentrations are percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

This substance has workplace exposure limit(s).

This substance is listed as SVHC.

PBT: persistent, bioaccumulative and toxic substance.

vPvB: very persistent and very bioaccumulative substance.

ED: Endocrine Disruptor

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Classification

Chemical name	Classification	Specific concentration limit: / ATE / M-Factor:	Notes
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	STOT RE 2 H373; EUH066;		
Dodecamethylcyclohexasiloxane	None known.		
Decamethylcyclopentasiloxane	None known.		
octamethylcyclotetrasiloxane; [D4]	Flam. Liq. 3 H226; Repr. 2 H361f; Aquatic Chronic 1 H410;	Aquatic Toxicity (Chronic): 10	

The full text for all H-statements is displayed in section 16.

Particle characteristics:

Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica

Assessment:	This substance/ mixture contains nanoforms ;
Particle Size:	1 - 100 nm

SECTION 4: First aid measures

General information:

Move into fresh air and keep at rest. Take off contaminated clothing and wash it before reuse. Get medical attention if symptoms occur.

4.1 Description of first aid measures:

Inhalation:

In case of inhalation: Move person into fresh air and keep at rest. Get medical attention immediately. If breathing is difficult, trained personnel should give oxygen. If breathing stops, provide artificial respiration.

Skin Contact:

Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Wash skin with soap and water. Get medical attention immediately. Contaminated clothing to be placed in closed container until disposal or decontamination. Wash contaminated clothing before reuse.

Eye contact:

In the event of contact with the eyes, rinse thoroughly with clean water for at least 15 minutes. Get medical attention if symptoms occur.

Ingestion:

Do not induce vomiting. Rinse mouth thoroughly with water. Get medical attention if symptoms occur.

Personal Protection for First-aid Responders:

First Aid responders should pay attention to self-protection and use the recommended protective clothing (chemical resistant gloves, splash protection). Refer to sections 5 and 8 for information on emergency procedures and protective equipment.

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

Any important symptoms and effects are described in Section 11 (Toxicological information) of this SDS.

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

Notes to the physician:

No specific recommendations.

Show this Safety Data Sheet to the attending physician.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media:

Alcohol resistant foam. Carbon dioxide (CO₂). Dry sand. Water spray.

Unsuitable extinguishing media:

Alkaline powders. Do not use water jet as an extinguisher, as this will spread the fire. For further information, refer to section 10: "Stability and Reactivity".

5.2 Special hazards arising from the substance or mixture:

Product will burn under fire conditions. This product may generate hydrogen gas. Vapours may form explosive mixtures with air. For further information, refer to section 10: "Stability and Reactivity". Thermal decomposition or combustion may liberate carbon oxides, silicon oxides and other toxic gases or vapours.

5.3 Advice for firefighters: Special firefighting procedures:

Use standard firefighting procedures and consider the hazards of other involved materials. Remove undamaged containers from fire area if it is safe to do so. Evacuate to a safe location and contact the emergency services. Water spray should be used to cool containers. Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

Special protective equipment for firefighters:

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures:

Personnel not required or not equipped with personal protection should be evacuated from the area. Caution: Contaminated surfaces may be slippery. Follow safe handling advice and personal protective equipment recommendations. Avoid contact with eyes, skin, and clothing. Provide good ventilation. Avoid inhalation of vapours, mists or dusts. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Remove all possible sources of ignition in the surrounding area. Avoid sparks, flames, heat and smoking. Keep away from Alkalis and caustic products. Prevent further leakage or spillage if safe to do so. Alert the Health, Safety & Environmental department of spill.

6.2 Environmental Precautions:

Do not release into the environment. Do not discharge into drains, water courses or onto the ground. Collect spillage. Use containment for a large spill. Notify relevant authorities if this material is released to the environment.

6.3 Methods and material for containment and cleaning up:

Access to contaminated area only to authorized people. Absorb with sand or other inert absorbent. Shovel up and place in a container for salvage or disposal. Materials in contact with water, moisture, acids or bases have the

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potential to generate hydrogen gas. Use clean non-sparking tools to collect absorbed material. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Recovered material should be stored in a vented container. Never return the spilled product to its original container for reuse. Containers with collected spillage must be properly labelled with correct contents and hazard symbol. Container must be kept tightly closed. To clean the floor and all objects contaminated by this material, use an appropriate solvent (see § 9). Flush area with plenty of water. Ensure that waste and contaminated materials are collected and removed from the work area as soon as possible in a suitably labelled container. Dispose of residue in accordance with regulations in force.

6.4 Reference to other sections:

Please observe the important information mentioned in the other sections. In particular, information on exposure controls/personal protection and disposal considerations can be found under sections 8 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling Precautions:

This product may generate hydrogen gas. Keep away from ignition source. Empty container after use should be stored in separate area, and be disposed after degassing completely. Take precautionary measures against static discharges. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres. Read and follow manufacturer's recommendations. Avoid inhalation of vapours/aerosols/dusts and contact with skin and eyes. Use mechanical ventilation in case of handling which causes formation of vapours. If ventilation is insufficient, suitable respiratory protection must be provided. See Section 8 of the SDS for Personal Protective Equipment. Provide eyewash station and safety shower and ensure that their location are labelled conspicuously. Limit the quantities of product in the work area to those which are necessary for the work in hand. Handle in accordance with good industrial hygiene and safety practices. Handle and open container with care. Protect from contamination. Do not mix with incompatible materials. For further information, refer to section 10: "Stability and Reactivity". Take care to prevent spills, waste and minimize release to the environment. In case of spills, beware of slippery floors and surfaces.

Hygiene measures:

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. Contaminated work clothing should not be allowed out of the workplace.

7.2 Conditions for safe storage, including any incompatibilities:

Store in accordance with local/regional/national regulations. Avoid discharge into drains, water courses or onto the

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ground. Provide impermeable soil. Store in a cool, dry place with adequate ventilation. Keep away from incompatible materials, open flames, and high temperatures. For further information, refer to section 10: "Stability and Reactivity". Store in original tightly closed container, equipped with a degassing device. Product may evolve minute quantities of flammable hydrogen gas which can accumulate. Adequately ventilate to maintain vapours well below flammability limits and exposure guidelines. Do not repackage. Clogged container vents may increase pressure build up. Keep in properly labelled containers. Keep above the chemical's freezing point. Protect against physical damage and/or friction.

Packaging frequently used at our sites: Polyethylene. Steel drums coated with epoxy-resin.

Lagerklasse: Es liegen keine Daten vor.

Storage Class: No data available.

7.3 Specific end use(s): No specific recommendations. See the technical data sheet on this product for further information.

SECTION 8: Exposure controls/personal protection

8.1 Control Parameters:

Occupational Exposure Limits:
octamethylcyclotetrasiloxane; [D4]

Type	Exposure Limit Values	Source	Date	Remarks
TWA	10 ppm 120 mg/m ³	WEEL		

Monitoring methods: Ensure workers' exposure monitoring in accordance with national and European regulations in force, in particular Directives 98/24/EC and 2004/37/EC.

8.2 Exposure controls: Appropriate engineering controls:

Use engineering controls to reduce air contamination to permissible exposure level. The level of protection and types of controls necessary will vary depending upon potential exposure conditions. Engineering controls are always preferable to personal protective equipment. Control measures to consider: Provide adequate ventilation. In case of inadequate ventilation: Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. Provide eyewash station and safety shower.

Individual protection measures, such as personal protective equipment:

Avoid inhalation of vapours/aerosols/dusts and contact with skin and eyes. Personal protective equipment should be chosen according to applicable standards, adapted to the conditions of use of the product and in discussion with the supplier of the personal protective equipment.

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Eyeface protection:	Safety glasses with side shields
Hand Protection:	<p>This recommendation is valid only for the product named in this safety data sheet supplied by us, and only for the indicated intended use purposes. In case this product will be mixed with other substances, you need to contact a supplier of CE approved protective gloves in order to determine the appropriate gloves.</p> <p>Prolonged or repeated contact: Material: Nitrile. Glove thickness: 1,25 mm Guideline: EN374-3</p> <p>Short contact: Material: Nitrile / Neoprene Glove thickness: 0,198 mm Guideline: EN374-3</p>
Skin and Body Protection:	Wear appropriate clothing to prevent any possibility of skin contact. Isolate contaminated clothing and wash before reuse. In case of splashes: Wear apron or special protective clothing.
Respiratory Protection:	If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn. Use the following CE approved air-purifying respirator: Breathing apparatus with combined filter type ABEK. Wear respiratory protection with combination filter (dust and gas filter) during operations leading to the formation of dust/aerosols.
Environmental Controls:	See sections 7 and 13 of the Safety Data Sheet.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state:	Liquid
Form:	Viscous
Colour:	Pink
Odour:	Odourless
pH:	By definition, pH measurement consists in the determination of hydrogen ions concentration in solution, generally aqueous. Silicones products are hydrophobic and therefore, not soluble in water. By consequence, it is not possible to measure the pH value.
Melting point/freezing point:	No data available.
Boiling Point:	No data available.
Flash Point:	> 200 °C (Closed cup according to method ASTM D56.)
Flammability:	No data available.
Flammability Limit - Upper (%):	74 %(V) Hydrogen.
Flammability Limit - Lower (%):	4 %(V) Hydrogen.
Vapour pressure:	< 0,1 hPa (20 °C)

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Relative vapour density:	No data available.
Evaporation Rate:	No data available.
Density:	Approximate 1,05 kg/dm ³ (20 °C)
Solubility(ies):	Practically Insoluble
Solubility in Water:	Diethylether: Miscible (in all proportions).
Solubility (other):	Aliphatic hydrocarbons: Miscible (in all proportions). Aromatic hydrocarbons: Miscible (in all proportions). Chlorinated solvents: Miscible (in all proportions). Acetone: Very slightly soluble Ethanol: Very slightly soluble
Partition coefficient (n-octanol/water):	No data available.
Self Ignition Temperature:	500 °C Hydrogen.
Decomposition Temperature:	> 200 °C
Kinematic viscosity:	Approximate 5 000 mm ² /s (20 °C)
Particle characteristics:	Not applicable.

9.2 Other information:	
Dynamic viscosity:	Approximate 4 000 mPa.s
Oxidizing properties:	According to the data on the components Not considered as oxidizing. (evaluation by structure-activity relationship)

SECTION 10: Stability and reactivity

10.1 Reactivity:	No other information noted.
10.2 Chemical Stability:	Material is stable under normal conditions.
10.3 Possibility of hazardous reactions:	This product may generate hydrogen gas.
10.4 Conditions to avoid:	No other information noted.
10.5 Incompatible Materials:	A fire or explosion hazard arises because highly flammable gas (hydrogen) is released when it is in contact with: Strong oxidizing agents. Alkalis and caustic products. Chemical compounds with mobile hydrogen, in the presence of metal salts and complexes.
10.6 Hazardous Decomposition Products:	Thermal decomposition or combustion may liberate carbon oxides and other toxic gases or vapours. Amorphous silica. Quantity of hydrogen potentially released (l/kg of product): <7

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008:	
Acute Toxicity:	
Oral:	Not classified for acute toxicity based on available data.
Dermal:	Not classified for acute toxicity based on available data.
Inhalation:	Not classified for acute toxicity based on available data.
Repeated dose toxicity:	
Based on our knowledge of the composition information:	DODECAMETHYLCYCLOHEXASILOXANE (540-97-6):

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NOAEL: 1 000 mg/kg ; (Rat ; Female, Male ; Oral) ; Method: OECD 422 ; Subacute exposure.

NOAEL: 0,0182 mg/l ; (Rat ; Female, Male ; Inhalation - vapour) ; Method: OECD 413 ; Subchronic exposure.

DECAMETHYLCYCLOPENTASILOXANE (541-02-6):

An Expert Judgment stated that no classification is necessary based on present knowledge. NOAEL: 1 000 mg/kg ; (Rat ; Female, Male ; 90 d ; Oral) ; No treatment-related adverse effects observed ; Method: OECD 408

NOAEL: 2,42 mg/l ; (Rat ; Female, Male ; 2 yr ; Inhalation - vapour) ; No treatment-related adverse effects observed ; Method: OECD 453

NOAEL: 1 600 mg/kg ; (Rat ; Female, Male ; 28 d ; Dermal) ; No treatment-related adverse effects observed ; Method: OECD 410

OCTAMETHYLCYCLOTETRASILOXANE; [D4] (556-67-2):
NOAEL: 1,82 mg/l ; LOAEL: 8,5 mg/l ; (Rat ; Female, Male ; Inhalation - vapour) ; Target Organ(s): Kidney ; Method: Similar to OECD 453 ; Chronic exposure.

NOAEL: 960 mg/kg ; (Rabbit ; Female, Male ; Dermal) ; No treatment-related adverse effects observed ; Method: Similar to OECD 410 ; Subacute exposure.

Skin Corrosion/Irritation:

Based on our knowledge of the composition information:

SILANAMINE, 1,1,1-TRIMETHYL-N-(TRIMETHYLSILYL)-, HYDROLYSIS PRODUCTS WITH SILICA (68909-20-6):
Repeated exposure may cause skin dryness or cracking.

DODECAMETHYLCYCLOHEXASILOXANE (540-97-6):
Not irritating (Rabbit) ; Method: OECD 404

DECAMETHYLCYCLOPENTASILOXANE (541-02-6):
Not Classified Not irritating (Rabbit ; 24 h) ; Method: OECD 404

OCTAMETHYLCYCLOTETRASILOXANE; [D4] (556-67-2):
An Expert Judgment stated that no classification is necessary based on present knowledge. Not irritating (Rabbit) ; Method: Similar to OECD 404

Serious Eye Damage/Eye Irritation:

Based on our knowledge of the composition information:

DODECAMETHYLCYCLOHEXASILOXANE (540-97-6):
Not irritating (Rabbit) ; Method: OECD 405

DECAMETHYLCYCLOPENTASILOXANE (541-02-6):
Not Classified Not irritating (Rabbit) ; Method: OECD 405

OCTAMETHYLCYCLOTETRASILOXANE; [D4] (556-67-2):
An Expert Judgment stated that no classification is necessary based on present knowledge. Not irritating (Rabbit) ; Method: OECD 405

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Respiratory or Skin Sensitization:

Based on our knowledge of the composition information:

DODECAMETHYLCYCLOHEXASILOXANE (540-97-6):
Skin sensitization: Not a skin sensitizer. (Guinea Pig) ;
Method: OECD 406

DECAMETHYLCYCLOPENTASILOXANE (541-02-6):
Skin sensitization: Not a skin sensitizer. ; Not a skin sensitizer. (Mouse) ; Method: OECD 429

OCTAMETHYLCYCLOTETRASILOXANE; [D4] (556-67-2):
Skin sensitization: Not a skin sensitizer. (Guinea Pig) ;
Method: OECD 406

Germ Cell Mutagenicity:

In vitro: Based on our knowledge of the composition information:

DODECAMETHYLCYCLOHEXASILOXANE (540-97-6):
Bacterial reverse mutation test: No mutagenic effect. (Salmonella typhimurium and Escherichia coli ; with and without metabolic activation) ; Method: OECD 471
In vitro gene mutations test on mammalian cells: No mutagenic effect. (Mouse lymphoma cells ; with and without metabolic activation) ; Method: OECD 476

DECAMETHYLCYCLOPENTASILOXANE (541-02-6):
Bacterial reverse mutation test: No mutagenic components identified. (Salmonella typhimurium and Escherichia coli ; with and without metabolic activation) ; Method: OECD 471
In vitro gene mutations test on mammalian cells: No mutagenic components identified. (Mouse lymphoma cells ; with and without metabolic activation) ; Method: OECD 476
Chromosomal aberration: No clastogenic effect. (Chinese hamster lung cells ; with and without metabolic activation) ; Method: OECD 473

OCTAMETHYLCYCLOTETRASILOXANE; [D4] (556-67-2):
Bacterial reverse mutation test: No mutagenic effect. (Salmonella typhimurium ; with and without metabolic activation) ; Method: OECD 471
In vitro gene mutations test on mammalian cells: No mutagenic effect. (Mouse lymphoma cells ; with and without metabolic activation) ; Method: Similar to OECD 476
In vitro mammalian chromosomal aberration test: No clastogenic effect. (Chinese hamster ovary cells ; with and without metabolic activation) ; Method: Similar to OECD 473

In vivo: Based on our knowledge of the composition information:

DODECAMETHYLCYCLOHEXASILOXANE (540-97-6):
Mammalian erythrocyte micronucleus test: No mutagenic effect. (Mouse ; Intraperitoneal) ; Method: OECD 474

DECAMETHYLCYCLOPENTASILOXANE (541-02-6):
Mammalian erythrocyte micronucleus test: negative (Rat ; Female, Male ; Inhalation) ; Method: OECD 474
Unscheduled DNA Synthesis (UDS) Test with mammalian liver cells in vivo: negative (Rat ; Female, Male ; Inhalation) ; Method: OECD 486

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OCTAMETHYLCYCLOTETRASILOXANE; [D4] (556-67-2):
Mammalian bone marrow chromosomal aberration test:
negative (Rat ; Female, Male ; Inhalation) ; Method: Similar
to OECD 475
Rodent dominant Lethal test: negative (Rat ; Female, Male ;
Gavage (Oral)) ; Method: Similar to OECD 478

Carcinogenicity: **Based on our knowledge of the composition** **information:**

DECAMETHYLCYCLOPENTASILOXANE (541-02-6):
Not classified
The product is not considered to be carcinogenic. NOAEC:
>= 2,42 mg/l (Rat ; Female, Male ; 24 months ; Inhalation -
vapour) ; Method: Similar to OECD 453 ; No carcinogenic
effects relevant to humans.

OCTAMETHYLCYCLOTETRASILOXANE; [D4] (556-67-2):
Not classified
No effects expected. NOAEC: >= 8,492 mg/l (Rat ; Female,
Male ; Inhalation - vapour) ; Method: Similar to OECD 453 ;
Chronic exposure.

Reproductive toxicity: **Fertility: Based on our knowledge of the** **composition information:**

DODECAMETHYLCYCLOHEXASILOXANE (540-97-6):
Not classified
Reproduction/developmental toxicity screening test: NOAEL
(parent): >= 1 000 mg/kg ; NOAEL (F1): >= 1 000 mg/kg ;
NOAEL (F2): None. (Rat ; Female, Male ; Gavage (Oral)) ;
Method: OECD 422 ; The product is not considered to affect
fertility.

DECAMETHYLCYCLOPENTASILOXANE (541-02-6):
Not classified
Fertility study 2 generations: NOAEL (parent): > 2,496 mg/l ;
NOAEL (F1): > 2,496 mg/l ; NOAEL (F2): None. (Rat ;
Female, Male ; Inhalation - vapour) ; Method: OECD 416 ;
No adverse effect observed.

OCTAMETHYLCYCLOTETRASILOXANE; [D4] (556-67-2):
Suspected of damaging fertility.
Fertility study 2 generations: NOAEL (parent): 3,64 mg/l ;
NOAEL (F1): 3,64 mg/l ; NOAEL (F2): None. (Rat ; Female,
Male ; Inhalation) ; Method: Similar to OECD 416 ; Effects on
fertility

Teratogenicity: Based on our knowledge of **the composition information:**

DODECAMETHYLCYCLOHEXASILOXANE (540-97-6):
Not classified
NOAEL (terato): >= 1 000 mg/kg ; NOAEL (mater): >= 1 000
mg/kg (Rabbit ; Gavage (Oral)) ; Method: OECD 414
NOAEL (terato): >= 1 000 mg/kg ; NOAEL (mater): >= 1 000
mg/kg (Rat ; Gavage (Oral)) ; Method: OECD 414

DECAMETHYLCYCLOPENTASILOXANE (541-02-6):
Not classified

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NOAEL (terato): > 2 427 mg/l ; NOAEL (mater): > 2 427 mg/l (Rat ; Inhalation) ; Method: OECD 414 ; No adverse effect observed.

NOAEL (terato): > 2 427 mg/l ; NOAEL (mater): > 2 427 mg/l (Rabbit ; Inhalation) ; Method: OECD 414 ; No adverse effect observed.

OCTAMETHYLCYCLOTETRASILOXANE; [D4] (556-67-2):
NOAEL (terato): > 8,492 mg/l ; NOAEL (mater): 3,64 mg/l (Rat ; Inhalation - vapour) ; Method: Similar to OECD 414 ; The product is not considered to be toxic for development.
NOAEL (terato): > 6,066 mg/l ; NOAEL (mater): 3,64 mg/l (Rabbit ; Inhalation - vapour) ; Method: Similar to OECD 414 ; The product is not considered to be toxic for development.

Specific Target Organ Toxicity - Single Exposure:

Based on our knowledge of the composition information:

DODECAMETHYLCYCLOHEXASILOXANE (540-97-6):
Based on available data, the classification criteria are not met.

DECAMETHYLCYCLOPENTASILOXANE (541-02-6):
Based on available data, the classification criteria are not met.

OCTAMETHYLCYCLOTETRASILOXANE; [D4] (556-67-2):
Based on available data, the classification criteria are not met.

Specific Target Organ Toxicity - Repeated Exposure:

Based on our knowledge of the composition information:

SILANAMINE, 1,1,1-TRIMETHYL-N-(TRIMETHYLSILYL)-, HYDROLYSIS PRODUCTS WITH SILICA (68909-20-6):
Causes damage to organs through prolonged or repeated exposure. Inhalation: Target Organ(s): Lungs

DODECAMETHYLCYCLOHEXASILOXANE (540-97-6):
Based on available data, the classification criteria are not met.

DECAMETHYLCYCLOPENTASILOXANE (541-02-6):
Based on available data, the classification criteria are not met.

OCTAMETHYLCYCLOTETRASILOXANE; [D4] (556-67-2):
Based on available data, the classification criteria are not met.

Aspiration Hazard:

Based on our knowledge of the composition information:

DODECAMETHYLCYCLOHEXASILOXANE (540-97-6):
Based on available data, the classification criteria are not met.

DECAMETHYLCYCLOPENTASILOXANE (541-02-6):
Not applicable

OCTAMETHYLCYCLOTETRASILOXANE; [D4] (556-67-2):

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Based on available data, the classification criteria are not met.

11.2 Information on other hazards: Endocrine disrupting properties:

No data available.

SECTION 12: Ecological information

General information:

The maximum concentration of Octamethylcyclotetrasiloxane (D4) leachable from the product is below the established no-effect threshold (<0.0079 mg/l) for aquatic organisms.

12.1 Toxicity:

Acute toxicity:

Fish: Based on our knowledge of the composition information:

DODECAMETHYLCYCLOHEXASILOXANE (540-97-6):
LC 50 (Oncorhynchus mykiss; 96 h ; Flow through) : > 0,016 mg/l ; Method: OECD 204 ; No toxicity at the limit of solubility

DECAMETHYLCYCLOPENTASILOXANE (541-02-6):
LC 50 (Oncorhynchus mykiss; 96 h ; Flow through) : > 0,016 mg/l ; Method: OECD 204
NOEC (Oncorhynchus mykiss; 96 h ; Flow through) : >= 0,016 mg/l ; Method: OECD 204

OCTAMETHYLCYCLOTETRASILILOXANE; [D4] (556-67-2):
LC 50 (Oncorhynchus mykiss; 96 h ; Flow through) : > 0,022 mg/l ; Method: According to a standardised method.

Aquatic Invertebrates: Based on our knowledge of the composition information:

DODECAMETHYLCYCLOHEXASILOXANE (540-97-6):
EC 50 (Water flea (Daphnia magna); 48 h ; Flow through) : > 0,0029 mg/l ; Method: OECD 202 ; No toxicity at the limit of solubility

DECAMETHYLCYCLOPENTASILOXANE (541-02-6):
EC 50 (Water flea (Daphnia magna); 48 h ; Flow through) : > 0,0029 mg/l ; Method: OECD 202
NOEC (Water flea (Daphnia magna); 48 h ; Flow through) : >= 0,0029 mg/l ; Method: OECD 202

OCTAMETHYLCYCLOTETRASILILOXANE; [D4] (556-67-2):
EC 50 (Water flea (Daphnia magna); 48 h ; Flow through) : > 0,015 mg/l ; Method: According to a standardised method.

Aquatic plants: Based on our knowledge of the composition information:

DODECAMETHYLCYCLOHEXASILOXANE (540-97-6):
NOEC (growth rate) (Algae (Pseudokirchneriella subcapitata); 72 h ; Static) : >= 0,002 mg/l ; Method: OECD 201 ; No toxicity at the limit of solubility
ErC50 (Algae (Pseudokirchneriella subcapitata); 72 h ; Static) : > 0,002 mg/l ; Method: OECD 201 ; No toxicity at the limit of solubility

DECAMETHYLCYCLOPENTASILOXANE (541-02-6):
EC 50 (Algae (Pseudokirchneriella subcapitata); 96 h ; Static) : > 0,012 mg/l ; Method: OECD 201
NOEC (Algae (Pseudokirchneriella subcapitata); 96 h ; Static) : >= 0,012 mg/l ; Method: OECD 201

OCTAMETHYLCYCLOTETRASILILOXANE; [D4] (556-67-2):

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ErC50 (Algae (*Pseudokirchneriella subcapitata*); 96 h) : > 0,022 mg/l ; Method: According to a standardised method.
ErC10 (Algae (*Pseudokirchneriella subcapitata*); 96 h) : >= 0,022 mg/l ; Method: According to a standardised method.

Toxicity to microorganisms: Based on our knowledge of the composition information:

OCTAMETHYLCYCLOTETRASILOXANE; [D4] (556-67-2):
EC 50 (3 h) : > 10 000 mg/l

Chronic Toxicity:

Fish: Based on our knowledge of the composition information:

DODECAMETHYLCYCLOHEXASILOXANE (540-97-6):
NOEC (*Oncorhynchus mykiss*; 90 d ; Flow through) : >= 0,014 mg/l ; Method: OECD 210 ; No toxicity at the limit of solubility

DECAMETHYLCYCLOPENTASILOXANE (541-02-6):
NOEC (*Oncorhynchus mykiss*; 90 d ; Flow through) : >= 0,014 mg/l ; Method: OECD 210

OCTAMETHYLCYCLOTETRASILOXANE; [D4] (556-67-2):
NOEC (*Oncorhynchus mykiss*; 93 d ; Flow through) : >= 0,0044 mg/l ; Method: According to a standardised method.

Aquatic Invertebrates: Based on our knowledge of the composition information:

DODECAMETHYLCYCLOHEXASILOXANE (540-97-6):
NOEC (Water flea (*Daphnia magna*); 21 d ; semi-static) : >= 0,0046 mg/l ; Method: OECD 211 ; No toxicity at the limit of solubility

DECAMETHYLCYCLOPENTASILOXANE (541-02-6):
NOEC (Water flea (*Daphnia magna*); 21 d ; semi-static) : >= 0,015 mg/l ; Method: OECD 211

OCTAMETHYLCYCLOTETRASILOXANE; [D4] (556-67-2):
NOEC (Water flea (*Daphnia magna*); 21 d ; Flow through) : >= 0,015 mg/l ; Method: According to a standardised method.

12.2 Persistence and Degradability:

Biodegradation: Based on our knowledge of the composition information:

DODECAMETHYLCYCLOHEXASILOXANE (540-97-6):
4,5 % (activated sludge, domestic, non-adapted ; 28 d) ;
Method: OECD 310 ; The product is not readily biodegradable.

DECAMETHYLCYCLOPENTASILOXANE (541-02-6):
0,14 % (28 d) ; The product is not readily biodegradable.

OCTAMETHYLCYCLOTETRASILOXANE; [D4] (556-67-2):
3,7 % (activated sludge and sewage, soil ; 28 d) ; Method: OECD 310 ; The product is not considered to be readily biodegradable.

BOD/COD Ratio:

No data available.

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12.3 Bioaccumulative potential:

Bioconcentration Factor (BCF): Based on our knowledge of the composition information:

DODECAMETHYLCYCLOHEXASILOXANE (540-97-6):
Bioconcentration Factor (BCF): 2 860 (Fathead Minnow ; 49 d) ; Method: OECD 305 ; Has the potential to bioaccumulate.

DECAMETHYLCYCLOPENTASILOXANE (541-02-6):
Bioconcentration Factor (BCF): 16 200 (Pimephales promelas) ; Method: OECD 305 ; The product is not bioaccumulating.

OCTAMETHYLCYCLOTETRASILOXANE; [D4] (556-67-2):
Bioconcentration Factor (BCF): 14 900 (Fathead Minnow) ; Method: OECD 305 ; Not bioaccumulable based on the depuration rate constant

Partition coefficient (n-octanol/water): Based on our knowledge of the composition information:

DODECAMETHYLCYCLOHEXASILOXANE (540-97-6):
Log Kow: 8,87 (23 °C)

DECAMETHYLCYCLOPENTASILOXANE (541-02-6):
Log Kow: 5,20
Log Kow: 8,02 (25,3 °C) ; Method: OECD 123

OCTAMETHYLCYCLOTETRASILOXANE; [D4] (556-67-2):
Log Kow: 5,10

12.4 Mobility in Soil:

No data available.

12.5 Results of PBT and vPvB assessment: Based on our knowledge of the composition information:

DODECAMETHYLCYCLOHEXASILOXANE (540-97-6):
Meets vPvB criteria (REACH (1907/2006) Ax XIII)

DECAMETHYLCYCLOPENTASILOXANE (541-02-6):
Meets vPvB criteria (REACH (1907/2006) Ax XIII)

OCTAMETHYLCYCLOTETRASILOXANE; [D4] (556-67-2):
Meets PBT (persistent/bioaccumulative/toxic) criteria.
(REACH (1907/2006) Ax XIII)
Meets vPvB criteria (REACH (1907/2006) Ax XIII)

12.6 Endocrine disrupting properties:

No data available.

12.7 Other adverse effects:

No data available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods:

Do not empty into drains. The user's attention is drawn to the possible existence of local regulations regarding disposal. Please observe the important information mentioned in the other sections. In particular, information on hazards identification and product stability and reactivity under sections 2 and 10.

Disposal methods:

Waste of this material should not be mixed with other waste. Provide measures such as vented bungs to ensure pressure relief in the waste container. Dispose of waste at an appropriate treatment and disposal facility in accordance

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with applicable laws and regulations, and product characteristics at time of disposal. Incinerate in suitable combustion chamber.

Contaminated Packaging:

Contaminated packages should be as empty as possible and equipped with a degassing device. Recycle following cleaning or dispose of at an authorised site. Packaging that cannot be cleaned should be disposed of in the same way as the product it contained.

Waste code:

The waste code of the European Waste Catalogue (EWC) cannot be determined for this product, as its determination depends on how the material is used by the end-users. The waste code has to be determined within the EU in agreement with the waste-disposal operator.

SECTION 14: Transport information

ADR:	Not regulated.
ADN:	Not regulated.
RID:	Not regulated.
IMDG / IMO:	Not regulated.
IATA:	Not regulated.
Other information:	Warning Packaging with a breathing/venting bung are FORBIDDEN for transport by air.

SECTION 15: Regulatory information

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

EU Regulations:

Regulation 1005/2009/EC on substances that deplete the ozone layer, Annex I, Controlled Substances: None present or none present in regulated quantities.

Regulation 1005/2009/EC on substances that deplete the ozone layer, Annex II, New Substances: None present or none present in regulated quantities.

EU. Regulation 2019/1021/EU on persistent organic pollutants (POPs) (recast), as amended: None present or none present in regulated quantities.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 1 as amended: None present or none present in regulated quantities.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 2 as amended: None present or none present in regulated quantities.

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Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 3 as amended: None present or none present in regulated quantities.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex V as amended: None present or none present in regulated quantities.

EU. Directive 2010/75/EU on Industrial Emissions (IPPC), Annex II, L 334/17:

Chemical name	CAS-No.
octamethylcyclotetrasiloxane; [D4]	556-67-2

EU. REACH Annex XIV, Substances Subject to Authorization: None present or none present in regulated quantities.

EU. REACH Annex XIV, Substances Subject to Authorization: None present or none present in regulated quantities.

EU. REACH Candidate List of Substances of Very High Concern for Authorization (SVHC):

Chemical name	CAS-No.	Concentration	Additional Information
Dodecamethylcyclohexasiloxane	540-97-6	0,1 - 1,0%	very Persistent and very Bioaccumulative (vPvB)
Decamethylcyclopentasiloxane	541-02-6	0,1 - 1,0%	very Persistent and very Bioaccumulative (vPvB)
octamethylcyclotetrasiloxane; [D4]	556-67-2	0,01 - 0,079%	very Persistent and very Bioaccumulative (vPvB) Persistent, Bioaccumulative and Toxic (PBT)

Regulation (EC) No. 1907/2006 Annex XVII Substances subject to restriction on marketing and use:

Chemical name	CAS-No.	Entry No:	Concentration:
Decamethylcyclopentasiloxane	541-02-6	70	70
octamethylcyclotetrasiloxane; [D4]	556-67-2	70	0,01 - 0,079%

Directive 98/24/EC on the protection of workers from the risks related to chemical agents at work:

Chemical name	CAS-No.	Concentration
octamethylcyclotetrasiloxane; [D4]	556-67-2	0,01 - 0,079%

EU. Regulation No. 166/2006 PRTR (Pollutant Release and Transfer Registry), Annex II: Pollutants: None present or none present in regulated quantities.

EU. Directive 2012/18/EU (SEVESO III) on major accident hazards involving dangerous substances, Annex I: Not applicable

National Regulations:

Wassergefährdungsklasse (WGK):

WGK 1: schwach wassergefährdend. Einstufung nach AwSV, Anlage 1 (5.2)

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Water Hazard Class (WGK):

WGK 1: slightly water-endangering. Classification according to AwSV, Appendix 1 (5.2)

15.2 Chemical safety assessment:

Surface treated silica: When encapsulated in a polymer, is not expected to pose a health hazard when processed under normal conditions of use. For safe use information, please refer to section 8 of this SDS.

Inventory Status:

Australia Industrial Chem. Act (AIC):	Not in compliance with the inventory.
Canada DSL Inventory List:	Not in compliance with the inventory.
Canada NDSL Inventory:	Not in compliance with the inventory.
Japan (ENCS) List:	Not in compliance with the inventory.
Korea Existing Chemicals Inv. (KECI):	Not in compliance with the inventory.
New Zealand Inventory of Chemicals:	On or in compliance with the inventory.
Philippines PICCS:	Not in compliance with the inventory.
Taiwan Chemical Substance Inventory:	On or in compliance with the inventory.
Thailand DIW Existing Chemical Inv. List:	Not in compliance with the inventory.
Vietnam National Chemical Inventory:	Not in compliance with the inventory.
EINECS, ELINCS or NLP:	On or in compliance with the inventory.

SECTION 16: Other information

Revision Information:

SECTION 2:	Modification:	Hazard(s) identification
SECTION 3:	Modification:	Composition/information on ingredients
SECTION 15:	Modification:	Regulatory information

Abbreviations and acronyms:

CLP:	Regulation No. 1272/2008.
PBT:	persistent, bioaccumulative and toxic substance.
vPvB:	very persistent and very bioaccumulative substance.
NOAEL:	No Observable Adverse Effect Level
LOAEL:	Lowest Observable Adverse Effect Level
ED:	Endocrine Disruptor
SVHC:	Listed on the Candidate List of substances of very high concern (SVHC)

Wording of the H-statements in section 2 and 3:

EUH066	Repeated exposure may cause skin dryness or cracking.
EUH210	Safety data sheet available on request.
H226	Flammable liquid and vapour.
H361f	Suspected of damaging fertility.
H373	May cause damage to organs through prolonged or repeated exposure.
H410	Very toxic to aquatic life with long lasting effects.

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Disclaimer:

The information given is based on data available for the material, the components of the material, and similar materials. The information is believed to be correct. It is given in good faith. This information should be used to make an independent determination of the methods to safeguard workers and the environment