

EU - SAFETY DATA SHEET

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

Revision Date: 07.11.2023
Supersedes Date: 24.10.2021

Version: 10.0
Replaces version: 9.0



Hinrisil Hydro – component A

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

1.1 Product identifier:

Commercial product name: Hinrisil Hydro – component A
Duplicating silicone

UFI: GE3J-5UHQ-H116-TF18

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

Supplier: ERNST HINRICHS Dental GmbH
Street / mailbox: Borsigstr. 1
Country code. / postal code / city: D - 38644 Goslar
Phone: Tel.: +49 (0) 5321 - 5 06 24
Fax: Fax: +49 (0) 5321 - 5 08 81
E-mail / Website: info@hinrichs-dental.de - www.hinrichs-dental.de

1.4 Emergency telephone number:

ERNST HINRICHS Dental GmbH: +49 (0) 53 21 / 37 79 - 0 (Mo-Fr 8:00-16:00)

SECTION 2: Hazards identification

2.1 Classification according to Regulation (EC) No 1272/2008:

The product has been classified according to the legislation in force.

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

Health Hazards

STOT RE 1 H372 Causes damage to the respiratory system through prolonged or repeated exposure.
Route of exposure: Inhalation.

2.2 Label Elements

Supplemental label information:

EUH210: Safety data sheet available on request.

2.3 Other hazards:

Physical Hazards: No data available.

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Health Hazards:

Inhalation: No data available.

Eye contact: No data available.

Skin Contact: No data available.

Ingestion: No data available.

Other Health Effects: No data available.

Environmental hazards: No data available.

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: No other information noted.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

General information: Mixture of organosiloxanes, additives.

Dangerous components:

Chemical name	Concentration*	Type	CAS-No.	EC No.	Notes
Cristobalite	20 - <50%	Component	14464-46-1	238-455-4	STOT RE 1 H372; #
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	10 - <20%	Component	68909-20-6	272-697-1	STOT RE 2 H373; EUH066;
Octamethylcyclotetrasiloxane	0,01 - <0,079%	Impurities	556-67-2	209-136-7	Flam. Liq. 3 H226; Repr. 2 H361f; Aquatic Chronic 1 H410; Aquatic Toxicity (Chronic): 10; #; ##; 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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The full text for all H-statements is displayed in section 16

SECTION 4: First aid measures

General:

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

4.1 Description of first aid measures:

After 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.

After skin contact:

Remove contaminated clothing and shoes. Wash skin with soap and water. Get medical attention if symptoms occur. Wash contaminated clothing before reuse.

After 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.

After swallowing:

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.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media:

Water spray, foam, dry powder or carbon dioxide.

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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:

Protective equipment:

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 fire-fighters:

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

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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:

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.

7.3 Specific end use(s):

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

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SECTION 8: Exposure controls/personal protection

8.1 Control Parameters

Occupational Exposure Limits:

Quartz/cristobalite: When encapsulated in a polymer, is not expected to pose a health hazard when processed under normal conditions of use.

Designation of material	Type	Exposure Limit Values	Source	Remarks
Cristobalite	TWA	0,1 mg/m ³	EU OELIII 12.2017	Respirable fraction and dust
	AGW	4 mg/m ³	TRGS 900 03.2015	If the AGW and BGW values are complied with, there should be no risk of reproductive damage (see Number 2.7). Inhalable fraction.
	AGW	0,3 mg/m ³	TRGS 900 03.2015	If the AGW and BGW values are complied with, there should be no risk of reproductive damage (see Number 2.7). Respirable fraction.
	STEL CL	-	TRGS 900 10.2020	Category II: substances with a resorptive effect. Inhalable fraction.
	AGW	1,25 mg/m ³	TRGS 900 04.2021	If the AGW and BGW values are complied with, there should be no risk of reproductive damage (see Number 2.7). Respirable fraction.
octamethylcyclotetrasiloxane	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

Personal protective equipment

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.

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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.

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.

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

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Colour:	White
Odour:	Odourless
pH-Value:	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 1,2 kg/dm ³ (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 5 000 mm ² /s (20 °C)
Particle characteristics:	Not applicable.
9.2 Other information:	
Dynamic viscosity:	5 000 - 7 000 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

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Not relevant.

10.2 Chemical Stability

Stable.

10.3 Possibility of Hazardous Reactions:

No data available.

10.4 Conditions to Avoid

No other information noted.

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:

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

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Serious Eye Damage/Eye Irritation:

Based on our knowledge of the composition information:

necessary based on present knowledge. Not irritating (Rabbit) ; Method: Similar to OECD 404

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 Sensitization:

Based on our knowledge of the composition information:

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

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

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:

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 (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): Not classified

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

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:

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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:

CRISTOBALITE (14464-46-1): 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:

CRISTOBALITE (14464-46-1): Causes 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.

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

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

through) : > 0,015 mg/l ; Method: According to a standardised method.

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

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)

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12.6 Endocrine disruptive effect

No data available.

12.7 Other adverse effects

None known.

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:

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

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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.
Cristobalite	14464-46-1
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:
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Hinrisil Hydro – component A

octamethylcyclotetrasiloxane; [D4]	556-67-2	70	0,01 - <0,079%
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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:

Chemical name	CAS-No.	Concentration
Cristobalite	14464-46-1	20 - 30%

National Regulations:

Wassergefährdungs-klasse (WGK):

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

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: Quartz/cristobalite: 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 AICS:	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.
EINECS, ELINCS or NLP:	On or in compliance with the inventory.

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Hinrisil Hydro – component A

SECTION 16: Other information

Revision Information:

SECTION 2:

Modification:

Classification of the substance or mixture

SECTION 3:

Modification:

Composition/information on ingredients

SECTION 15:

Modification:

Regulatory information

Abbreviations and acronyms:

CLP: Regulation No. 1272/2008.

PBT PBT: persistent, bioaccumulative and toxic substance.

vPvB 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 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.

H372 Causes damage to organs through prolonged or repeated exposure.

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

H410 Very toxic to aquatic life with long lasting effects.

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 Hydro – component B

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

1.1 Product identifier:

Commercial product name: Hinrisil Hydro – component B
Duplicating silicone

UFI: QYKV-YQ93-C41V-Q1XF

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

Supplier: ERNST HINRICHS Dental GmbH
Street / mailbox: Borsigstr. 1
Country code. / postal code / city: D - 38644 Goslar
Phone: Tel.: +49 (0) 5321 - 5 06 24
Fax: Fax: +49 (0) 5321 - 5 08 81
E-mail / Website: info@hinrichs-dental.de - www.hinrichs-dental.de

1.4 Emergency telephone number:

ERNST HINRICHS Dental GmbH: +49 (0) 53 21 / 37 79 - 0 (Mo-Fr 8:00-16:00)

SECTION 2: Hazards identification

2.1 Classification according to Regulation (EC) No 1272/2008:

The product has been classified according to the legislation in force.

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

Health Hazards

STOT RE 1 H372 Causes damage to the respiratory system through prolonged or repeated exposure.
Route of exposure: Inhalation.

2.2 Label Elements

Supplemental label information:

EUH210: Safety data sheet available on request.

2.3 Other hazards:

Physical Hazards: No specific recommendations.

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Hinrisil Hydro – component B

Health Hazards:

Inhalation:

Cristobalite : 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:

No specific symptoms noted.

Ingestion:

No specific symptoms noted.

Other Health Effects:

No specific symptoms 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).

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Hinrisil Hydro – component B

SECTION 3: Composition/information on ingredients

3.2 Mixtures

General information:

Mixture of Polyorganosiloxanes, fillers, additives.

Dangerous components:

Chemical name	Concentration*	Type	CAS-No.	EC No.	Notes
Cristobalite	20 - <50%	Component	14464-46-1	238-455-4	STOT RE 1 H372; #
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	10 - <20%	Component	68909-20-6	272-697-1	STOT RE 2 H373; EUH066;
Octamethylcyclotetrasiloxane	0,01 - <0,079%	Impurities	556-67-2	209-136-7	Flam. Liq. 3 H226; Repr. 2 H361f; Aquatic Chronic 1 H410; Aquatic Toxicity (Chronic): 10; #, ##, 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

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

SECTION 4: First aid measures

General:

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

4.1 Description of first aid measures:

After 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.

After skin contact:

Remove contaminated clothing and shoes. Wash skin with soap and water. Get medical attention if symptoms occur. Wash contaminated clothing before reuse.

After 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.

After swallowing:

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

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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.

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:

Protective equipment:

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 fire-fighters:

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

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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. 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 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.

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SECTION 7: Handling and storage

7.1 Precautions for safe handling:

inhalation of vapours/aerosols/dusts and contact with skin and eyes. Provide adequate ventilation, including piate local extraction, to ensure that the defined occupational exposure limit is not exceeded. If ventilation is cient, suitable respiratory protection must be provided. See Section 8 of the SDS for Personal Protective ment. Provide eyewash station and safety shower and ensure that their location are labelled conspicuously. he quantities of product in the work area to those which are necessary for the work in hand. Handle in dance with good industrial hygiene and safety practices. Handle and open container with care. Protect from mination. Do not mix with incompatible materials. For further information, refer to section 10: "Stability and ivity". Take care to prevent spills, waste and minimize release to the environment. In case of spills, beware perly 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. Steel drums coated with epoxy-resin.

Lagerklasse:

Es liegen keine Daten vor.

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:

Quartz/cristobalite: When encapsulated in a polymer, is not expected to pose a health hazard when processed under normal conditions of use.

Designation of material	Type	Exposure Limit Values	Source	Remarks
Cristobalite	TWA	0,1 mg/m ³	EU OELIII 12.2017	Respirable fraction and dust
Cristobalite	AGW	4 mg/m ³	TRGS 900 03.2015	If the AGW and BGW values are complied with, there should be no risk of reproductive damage (see Number 2.7). Inhalable fraction.

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Cristobalite	AGW	0,3 mg/m ³	TRGS 900 03.2015	If the AGW and BGW values are complied with, there should be no risk of reproductive damage (see Number 2.7). Respirable fraction.
Cristobalite	STEL CL	-	TRGS 900 10.2020	Category II: substances with a resorptive effect. Inhalable fraction.
Cristobalite	AGW	1,25 mg/m ³	TRGS 900 04.2021	If the AGW and BGW values are complied with, there should be no risk of reproductive damage (see Number 2.7). Respirable fraction.
octamethylcyclotetrasiloxane	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

Personal protective equipment

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.

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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.

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: White

Odour: Odourless

pH-Value: 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.

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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 1,2 kg/dm ³ (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 5 000 mm ² /s (20 °C)
Particle characteristics:	Not applicable.
9.2 Other information:	
Dynamic viscosity:	Approximate 6 000 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.

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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): <3

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:

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

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Respiratory or Skin Sensitization:

Based on our knowledge of the composition information:

necessary based on present knowledge. Not irritating (Rabbit) ; Method: OECD 405

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

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

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:

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 (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): Not classified

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

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:

CRISTOBALITE (14464-46-1): Based on available data, the classification criteria are not met.

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Specific Target Organ Toxicity - Repeated Exposure:

Based on our knowledge of the composition information:

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

CRISTOBALITE (14464-46-1): Causes 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.

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.

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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

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)

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12.6 Endocrine disruptive effect

No data available.

12.7 Other adverse effects

None known.

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. 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:

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

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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.
Cristobalite	14464-46-1
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)

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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%

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

Chemical name	CAS-No.	Concentration
Cristobalite	14464-46-1	20 - 30%

National Regulations:

Wassergefährdungs-klasse (WGK):

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

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: Quartz/cristobalite: 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.
China Inv. Existing Chemical Substances:	On or in compliance with the inventory.
Japan (ENCS) List:	On or 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:	On or in compliance with the inventory.
Taiwan Chemical Substance Inventory:	On or in compliance with the inventory.
US TSCA Inventory:	Not in compliance with the inventory.
EINECS, ELINCS or NLP:	On or in compliance with the inventory.

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SECTION 16: Other information

Revision Information:

SECTION 3:

Modification:

Composition/information on ingredients

SECTION 15:

Modification:

Regulatory information

Abbreviations and acronyms:

CLP:	Regulation No. 1272/2008.
PBT	PBT: persistent, bioaccumulative and toxic substance.
vPvB	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 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.
H372	Causes damage to organs through prolonged or repeated exposure.
H373	May cause damage to organs through prolonged or repeated exposure.
H410	Very toxic to aquatic life with long lasting effects.

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.