

Safety data sheet according to UK REACH



Printing date 06.08.2025

Version number 4 (replaces version 3)

Revision: 06.08.2025

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

- **1.1 Product identifier**
- **Trade name:** DUOSIL EXTRA HART
- **Article number:** 321070
- **1.2 Relevant identified uses of the substance or mixture and uses advised against:**
No further relevant information available.
- **Application of the substance / the mixture:**
Addition-curing two-component duplicating silicone for dental technology
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
SHERA Werkstoff-Technologie GmbH
Espohlstraße 53
D-49448 Lemförde
GERMANY
sdb@shera.de
+ 49 (0) 54 43 - 9933 - 0
- **Further information obtainable from:** Department of product security.
- **1.4 Emergency telephone number:**
Giftinformationszentrum-Nord +49 (0) 551-19240
(Information in german or english)

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008:**
STOT RE 1 H372 Causes damage to the lung through prolonged or repeated exposure.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008:** Void.
- **Hazard pictograms:** Void.
- **Signal word:** Void.
- **Hazard statements:** Void.
- **Precautionary statements:** Void.
- **Additional information:**
Quartz / cristobalite: Fibres that are embedded in polymer are not likely to pose a health risk as long as they are processed under normal application conditions. Even though the product is graded in accordance with EU criteria, labelling is not required according to Article 23 and Annex 1 (section 1.3.4.1) of Directive n°1272/2008.
- **2.3 Other hazards** Component B (coloured): Chemical bonds that contain silicon-hydrogen bonds (Si-H).
- **Results of PBT and vPvB assessment:**

· **PBT:**

540-97-6	Dodecamethylcyclhexasiloxane
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· **vPvB:**

540-97-6	Dodecamethylcyclhexasiloxane
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SECTION 3: Composition/information on ingredients

- **3.2 Mixtures**
- **Description:**
Polyorganosiloxane mixture, fillers, additive.
Component A, white: Catalyst Component B, coloured: Base, contains polymethyl hydrogen siloxane
- **Dangerous components:**
Component B, colored:

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CAS: 14808-60-7 EINECS: 238-878-4	Quartz (SiO ₂) STOT RE 1, H372	10-<20%
CAS: 68909-20-6 EINECS: 272-697-1 Index number: 014-052-00-7	Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products withsilica STOT RE 2, H373, EUH066 Nanoform: set including amorphous nanoforms, Particle size: 1 - 100 nm	10-<20%
CAS: 540-97-6 EINECS: 208-762-8	Dodecamethylcyclohexasiloxane Non-classified vPvB substance. Non-classified PBT substance. Substance identified as having endocrine disrupting properties (II).	0.1-1%
CAS: 556-67-2 EINECS: 209-136-7 Index number: 014-018-00-1 Reg.nr.: 01-2119529238-36	octamethylcyclotetrasiloxane Flam. Liq. 3, H226; Repr. 2, H361f; Aquatic Chronic 1, H410 (M=10) PBT; vPvB	0.01-<0.1%

Ingredients 2. component product:

Component A, white

CAS: 14808-60-7 EINECS: 238-878-4	Quartz (SiO ₂) STOT RE 1, H372
CAS: 68909-20-6 EINECS: 272-697-1 Index number: 014-052-00-7	Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products withsilica STOT RE 2, H373, EUH066
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SVHC

540-97-6 | Dodecamethylcyclohexasiloxane

Additional information: For the wording of the listed hazard phrases refer to section 16.**SECTION 4: First aid measures****4.1 Description of first aid measures****General information:** No special measures required.**After inhalation:** The product can't be breathed in under normal circumstances.**After skin contact:**

Wash with water and soap.

Remove dirty clothing and wash before using again.

After eye contact:

Rinse opened eye for several minutes under running water.

In case of troubles or persistent symptoms, consult an ophthalmologist.

After swallowing:

Rinse out mouth and then drink plenty of water.

Do not induce vomiting. Risk of aspiration!

In case of troubles, consult a medical.

4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

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SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**
Foam.
Use fire extinguishing methods suitable to surrounding conditions.
- **For safety reasons unsuitable extinguishing agents:** Alkaline powder extinguishing agent.
- **5.2 Special hazards arising from the substance or mixture**
Component B: This product can produce hydrogen. Vapours can form mixtures with air which pose a risk of explosion.
- **5.3 Advice for firefighters** In case of fire, cool endangered receptacles with water spray.
- **Protective equipment:**
Wear self-contained respiratory protective device.
Wear fully protective suit.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Particular danger of slipping on leaked / spilled product.
Keep away from ignition sources.
- **6.2 Environmental precautions** No special measures required.
- **6.3 Methods and material for containment and cleaning up**
Component B: Do not use a basic product.
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Dispose contaminated material as waste according to section 13.
- **6.4 Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**
The usual precautionary measures are to be adhered to when handling chemicals.
Keep receptacles tightly sealed.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage**
- **Requirements to be met by storerooms and receptacles:** Keep container in a well-ventilated and dry place.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.
- **Storage class:** No information available.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **8.1 Control parameters**

- **Ingredients with limit values that require monitoring at the workplace:**

14808-60-7 Quartz (SiO₂)

MAK (Germany)	Alveolar fraction
BOELV (EU)	Long-term value: 0.1* mg/m ³ *respirable fraction

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- **Additional information:**

Quartz: Fibres that are embedded in polymer are not likely to pose a health risk as long as they are processed under normal application conditions.

The lists valid during the making were used as basis.

- **8.2 Exposure controls**

- **Appropriate engineering controls** No further data; see section 7.

- **Individual protection measures, such as personal protective equipment**

- **General protective and hygienic measures:**

The usual precautionary measures are to be adhered to when handling chemicals.

Keep away from foodstuffs, beverages and feed.

Wash hands before breaks and at the end of work.

- **Respiratory protection:** Not necessary if room is well-ventilated.

- **Hand protection**

The glove material has to be impermeable and resistant to the product. Due to missing tests no recommendation to the glove material can be given for the product. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.

- **Material of gloves:**

Nitrile rubber, NBR

Neoprene gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

- **Penetration time of glove material:**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

- **Eye/face protection** Goggles recommended during refilling

- **Body protection:** Protective work clothing.

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**

- **General Information**

- **Physical state**

Liquid

- **Colour:**

Component A: white, Component B: lime green.

- **Odour:**

Odourless

- **Melting point/freezing point:**

Undetermined.

- **Boiling point or initial boiling point and boiling range**

Undetermined.

- **Flammability**

Not applicable.

- **Lower and upper explosion limit**

- **Lower:**

4 Vol % (hydrogen / Comp. B)

- **Upper:**

74 Vol % (hydrogen / Comp. B))

- **Flash point:**

>200 °C

- **Auto-ignition temperature:**

>400 °C

- **Decomposition temperature:**

>200 °C

- **Viscosity:**

- **Kinematic viscosity at 20 °C**

5,000 mm²/s

- **Dynamic:**

Not determined.

- **Solubility**

- **water:**

Not miscible or difficult to mix.

- **Partition coefficient n-octanol/water (log value)**

Not determined.

- **Vapour pressure at 20 °C:**

<0.1 hPa

- **Density and/or relative density**

- **Density at 20 °C:**

1.05 g/cm³

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· Relative density	Not determined.
· Vapour density	Not determined.
· 9.2 Other information	Solubility: Diethyl ether: Miscible in any proportion. Chlorinated solvents: Miscible in any proportion. Aromatic hydrocarbons: Miscible in any proportion. Aliphatic hydrocarbons: Miscible in any proportion. Acetone: Barely soluble. Ethanol: Barely soluble.
· Appearance:	
· Form:	Viscous
· Important information on protection of health and environment, and on safety.	
· Ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product does not present an explosion hazard.
· Change in condition:	
· Evaporation rate	Not determined.
· Information with regard to physical hazard classes	
· Explosives	Void.
· Flammable gases	Void.
· Aerosols	Void.
· Oxidising gases	Void.
· Gases under pressure	Void.
· Flammable liquids	Void.
· Flammable solids	Void.
· Self-reactive substances and mixtures	Void.
· Pyrophoric liquids	Void.
· Pyrophoric solids	Void.
· Self-heating substances and mixtures	Void.
· Substances and mixtures, which emit flammable gases in contact with water	Void.
· Oxidising liquids	Void.
· Oxidising solids	Void.
· Organic peroxides	Void.
· Corrosive to metals	Void.
· Desensitised explosives	Void.

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No data available.
- **10.2 Chemical stability** No decomposition if used according to specifications.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions**
 Component B: The product can produce hydrogen.
 Component A: Unknown.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials**
 Oxidizing agents, strong.
 Alkalis (alkalis).
 Metal salts and metal complexes.
- **10.6 Hazardous decomposition products**
 Component B: Reaction with alkalis, amines, strong acids, metal salts. The reaction occurs with formation of hydrogen. Explosion hazard.
 Can be released in case of fire:
 Poisonous gases / vapours.

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Carbon monoxide (CO).
Carbon dioxide (CO₂).
Hydrogen (H).
Amorphous silica.

SECTION 11: Toxicological information

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

• **Acute toxicity:** No data available.

• LD/LC50 values relevant for classification:

540-97-6 Dodecamethylcyclotetrasiloxane

Oral NOAEL $\geq 1,000$ mg/kg (Rat) (OECD 422)

Inhalative NOAEL ≥ 0.0182 mg/l (Rat) (OECD 413)

556-67-2 octamethylcyclotetrasiloxane

Oral NOAEL 960 mg/kg (Rabbit) (OECD 411)

Inhalative NOAEL 1.82 mg/l (Rat) (OECD 453)

• Primary irritant effect:

• **Serious eye damage/irritation** Based on available data, the classification criteria are not met.

• **STOT-repeated exposure** Causes damage to the lung through prolonged or repeated exposure.

• 11.2 Information on other hazards

• Endocrine disrupting properties

540-97-6 Dodecamethylcyclotetrasiloxane

List II

SECTION 12: Ecological information

12.1 Toxicity

• Aquatic toxicity:

540-97-6 Dodecamethylcyclotetrasiloxane

NOEC, 72h ≥ 0.0022 mg/l (Algae)

NOEC, 21d ≥ 0.0046 mg/l (Daphnia (Daphnia magna))

EC50/72 h > 0.002 mg/l (Algae)

556-67-2 octamethylcyclotetrasiloxane

EC50/48 h > 0.0029 mg/l (Daphnia (Daphnia magna)) (OECD 202)

LC50/96 h > 0.016 mg/l (Fish) (OECD 204)

• **12.2 Persistence and degradability** No further relevant information available.

• **12.3 Bioaccumulative potential** No further relevant information available.

• **12.4 Mobility in soil** No further relevant information available.

• 12.5 Results of PBT and vPvB assessment

• PBT:

540-97-6 Dodecamethylcyclotetrasiloxane

• vPvB:

540-97-6 Dodecamethylcyclotetrasiloxane

• **12.6 Endocrine disrupting properties** For information on endocrine disrupting properties see section 11.

• 12.7 Other adverse effects

• Additional ecological information:

• **General notes:** Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water.

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SECTION 13: Disposal considerations

· 13.1 Waste treatment methods

· **Recommendation:** Waste disposal according to official state regulations.

· Waste disposal key:

The waste disposal code as prescribed in the European Waste Catalogue (EWC) depends on the waste producer and can thus vary for a product. The waste disposal code should thus be obtained separately from the waste producer in each case.

· Uncleaned packaging:

· **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

· 14.1 UN number or ID number

· ADR, ADN, IMDG, IATA Void.

· 14.2 UN proper shipping name

· ADR, ADN, IMDG, IATA Void.

· 14.3 Transport hazard class(es)

· ADR, ADN, IMDG, IATA

· Class Void.

· 14.4 Packing group

· ADR, IMDG, IATA Void.

· 14.5 Environmental hazards:

· Marine pollutant: No.

· 14.6 Special precautions for user

Not applicable.

· 14.7 Maritime transport in bulk according to IMO instruments

Not applicable.

· UN "Model Regulation":

Void.

SECTION 15: Regulatory information

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

· Poisons Act

· Regulated explosives precursors

None of the ingredients is listed.

· Regulated poisons

None of the ingredients is listed.

· Reportable explosives precursors

None of the ingredients is listed.

· Reportable poisons

None of the ingredients is listed.

· Directive 2012/18/EU

· **Named dangerous substances - ANNEX I** None of the ingredients is listed.

· National regulations:

· Information about limitation of use:

Employment restrictions concerning juveniles must be observed.

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Employment restrictions concerning pregnant and lactating women must be observed.

· **Substances of very high concern (SVHC) according to UK REACH**

540-97-6	Dodecamethylcyclohexasiloxane
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· **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on the state of knowledge and experience pertaining on the date of issue. The information is not to be taken as a guarantee of product properties and do not constitute the basis for a contractual legal relationship. The details must not be changed or transferred to other products. Duplication in an unchanged state is permissible.

· **Relevant phrases**

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.
 EUH066 Repeated exposure may cause skin dryness or cracking.

· **Department issuing SDS:** Department of product security.

· **Abbreviations and acronyms:**

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)
 IMDG: International Maritime Code for Dangerous Goods
 IATA: International Air Transport Association
 GHS: Globally Harmonised System of Classification and Labelling of Chemicals
 EINECS: European Inventory of Existing Commercial Chemical Substances
 ELINCS: European List of Notified Chemical Substances
 CAS: Chemical Abstracts Service (division of the American Chemical Society)
 LC50: Lethal concentration, 50 percent
 LD50: Lethal dose, 50 percent
 PBT: Persistent, Bioaccumulative and Toxic
 vPvB: very Persistent and very Bioaccumulative
 Flam. Liq. 3: Flammable liquids – Category 3
 Repr. 2: Reproductive toxicity – Category 2
 STOT RE 1: Specific target organ toxicity (repeated exposure) – Category 1
 STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2
 Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

· *** Data compared to the previous version altered.**

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