

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

1.1 Product identifier

Product name: BISICO Double Green (various packaging sizes)

Trade number: 04010, 04030

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:

Dental-impression-silicone

1.3. Details of the supplier of the safety data sheet:

BISICO Bielefelder Dentalsilicone GmbH & Co. KG

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Fax: +49 521 8016801 Email: <u>info@Bisico.de</u>

responsible for the Safety Data Sheet: Sebastian Zimmermann

1.4. Emergency telephone number:

BISICO Bielefelder Dentalsilicone GmbH & Co. KG

Tel.: +49 521 8016800 (08:00-16:00 PM)

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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 - Category 1 H372: Causes damage to organs through

prolonged or repeated exposure.

2.2 Label Elements:

EUH210: Safety data sheet available on request.

2.3 Other hazards:

Physical Hazards:

No specific recommendations.



Health Hazards:

Inhalation:

Quartz/cristobalite: 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 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).

SECTION 3: Composition/information on ingredients

3.2 Mixtures:

General information: Mixture of Polyorganosiloxanes, fillers, additives.

Hazardous Component(s):

| Chemical name | Concentration* | Туре | CAS-No. | | REACH Registration No. | Notes |
|--------------------------------|----------------|------------|------------|-----------|------------------------------|---------|
| Quartz (SiO2) | 10 - <20% | Component | 14808-60-7 | 238-878-4 | Exempt | # |
| Dodecamethylcyclohexas iloxane | 0,1 - <1% | Impurities | 540-97-6 | 208-762-8 | Not relevant. | ## vPvB |



| octamethylcyclotetrasilox | 0,01 - <0,079% | Impurities | 556-67-2 | 209-136-7 | Not relevant. | ## |
|---------------------------|----------------|------------|----------|-----------|---------------|-----------|
| ane; [D4] | | | | | | 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

Classification:

| Chemical name | | Specific concentration limits / ATE / M-Factor: | Notes |
|-------------------------------|--------------------------------|---|-------|
| Quartz (SiO2) | STOT RE 1 H372; | | |
| Dodecamethylcyclohexasiloxan | None known. | | |
| е | | | |
| octamethylcyclotetrasiloxane; | Flam. Liq. 3 H226; Repr. 2 | Aquatic Toxicity (Acute): 1 | |
| [D4] | H361f; Aquatic Chronic 1 H410; | Aquatic Toxicity (Chronic): 10 | |

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

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 immediately.

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:

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



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. Vapors 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 vapors.

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 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:

Wear appropriate personal protective equipment. See Section 8 of the SDS for Personal Protective Equipment. Keep away from Alkalis and caustic products. Eliminate all sources of ignition.

6.2 Environmental Precautions:

Collect spillage. Prevent entry into waterways, sewer, basements or confined areas.

6.3 Methods and material for containment and cleaning up:

Containers with collected spillage must be properly labelled with correct contents and hazard symbol. Absorb with sand or other inert absorbent. Do NOT use products which are basic. To clean the floor and all objects contaminated by this material, use an appropriate solvent (see § 9). Flush area with plenty of water.

6.4 Reference to other sections:

Caution: Contaminated surfaces may be slippery. For waste disposal, see Section 13 of the SDS.

SECTION 7: Handling and storage:

7.1 Precautions for safe handling:

Precautions:

Avoid inhalation of vapors/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 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. 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.

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:

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

octamethylcyclotetrasiloxane; [D4]

| Туре | Exposure | Limit Values | Source | Date | Remarks |
|------|----------|--------------|--------|------|---------|
| TWA | 10 ppm | 120 mg/m3 | 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 vapors/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

Additional Information: Gloves commonly used in Elkem's facilities.

Short contact:

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

Additional Information: Gloves commonly used in Elkem's labs.

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 airpurifying 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

Color: A: White, B: Green

Odorless Odorless

Odor Threshold:No data available.pH:No data available.Melting Point:No data available.Boiling Point:No data available.

Flash Point: > 200 °C (Closed cup according to method ASTM D-56.)

Evaporation Rate:No data available. **Flammability (solid, gas):**No data available.

Flammability Limit - Upper (%)-: Flammability Limit - Lower (%)-:

Vapor pressure:< 0,1 hPa (20 °C)</th>Vapor density (air=1):No data available.

Relative density: Approx. 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.

Autoignition Temperature: $> 400 \, ^{\circ}\text{C}$ Decomposition Temperature: $> 200 \, ^{\circ}\text{C}$

Kinematic viscosity:Approximate 3 800 mm2/s (20 °C) **Dynamic viscosity:**Approximate 4 000 mPa.s

Explosive properties: No data available.

Oxidizing properties: According to the data on the components Not

considered as oxidizing. (evaluation by structure-activity

relationship)

9.2 Other information:No data available.

SECTION 10: Stability and reactivity

10.1 Reactivity:

Not relevant.

10.2 Chemical Stability:

Stable

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 this product 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 vapors. Amorphous silica.

Quantity of hydrogen potentially released (I/kg of product): <4

SECTION 11: Toxicological information

Information on likely routes of exposure:

Inhalation: No data available.

Ingestion: No data available.

Skin contact: No data available.

Eye contact: No data available.

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):

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.

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

NOAEL: 1,82 mg/l; (Rat; Female, Male; Inhalation - vapour); Method: Similar to OECD 453; Chronic exposure.

NOAEL: 960 mg/kg; (Rabbit; Female, Male; Dermal); Method: Similar to OECD 410; Subacute exposure.

Skin Corrosion/Irritation:

Based on our knowledge of the composition information:

DODECAMETHYLCYCLOHEXASILOXANE (540-97-6):

Not irritating (Rabbit); Method: OECD 404

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

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

Not irritating (Rabbit); Method: OECD 405

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

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

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

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: >= 8,492 mg/l (Rat; Female, Male; Inhalation - vapor); 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.

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

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

NOAEL (terato): >= 8,492 mg/l; NOAEL (mater): 3,64 mg/l (Rat; Inhalation - vapor); 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 - vapor); 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.

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: Causes damage to organs through prolonged or repeated exposure.

QUARTZ (SIO2) (14808-60-7):

Causes damage to organs through prolonged or repeated exposure if inhaled.

DODECAMETHYLCYCLOHEXASILOXANE (540-97-6):

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.

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.

Other information:

None known.

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

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:

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

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:

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

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:

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

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

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

NOEC (Water flea (Daphnia magna); 21 d): 0,0079 mg/l; Method: EPA OTS 797.1330 (Daphnid Chronic Toxicity Test); CLH report / RAC Opinion

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.

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:

DODECAMETHYLCYCLOHEXASILOXANE (540-97-6):

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

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

Bioconcentration Factor (BCF): 14 900 (Fathead Minnow) ; Method: OECD 305 ; Not bioaccumulable based on the depuration rate constant $\frac{1}{2}$



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

DODECAMETHYLCYCLOHEXASILOXANE (540-97-6):

Log Kow: 8,87 (23 °C)

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

Log Kow: 5,10

Log Kow: 6,49 (25 °C); Method: OECD 123

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)

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:

None known.

SECTION 13: Disposal considerations

13.1 Waste treatment methods:

General information:

The user's attention is drawn to the possible existence of local regulations regarding disposal.

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. Waste of this material should not be mixed with other waste.

Contaminated packages should be as empty as possible. Dispose of waste at an appropriate treatment and disposal facility in accordance with applicable laws and regulations, and product characteristics at time of disposal. Recycle following cleaning or dispose of at an authorised site.

SECTION 14: Transport information

This material is not subject to transport regulations.

Other information: No special precautions.

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code: Not applicable.



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.

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: |
|------------------------------------|----------|----------------|--|
| Dodecamethylcyclohexasiloxane | 540-97-6 | 0,1 - 1,0% | very Persistent and very Bioaccumulative (vPvB) |
| octamethylcyclotetrasiloxane; [D4] | 556-67-2 | 0,01 - <0,079% | Persistent, Bioaccumulative and Toxic (PBT), very Persistent and very Bioaccumulative (vPvB) |

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: 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:

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

15.2 Chemical safety assessment:

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: 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. 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. EINECS, ELINCS or NLP: On or in compliance with the inventory. **US TSCA Inventory:** Not in compliance with the inventory. Japan (ENCS) List: On or in compliance with the inventory.

SECTION 16: Other information

Changes compared with the previous version: Regeneration

The above information is based on our present day knowledge and relates solely to the safety requirements of the product. The data do not signify any warranty with regards to products properties. However users of the product should satisfy themselves that the information given is sufficient and correct for their specific circumstances of use.

Revision Information:

SECTION 3: Modification: Composition/information on ingredients

SECTION 8: Modification: Exposure controls
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:

EUH210 Safety data sheet available on request.

H226 Flammable liquid and vapor.
H361f Suspected of damaging fertility.

H372 Causes damage to organs through prolonged or repeated exposure.

H410 Very toxic to aquatic life with long lasting effects.

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