

## Safety Data Sheet

according to UK REACH Regulation

### milkbite (base + catalyst)

Revision date: 28.03.2022

Product code: 10203

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

### 1.1. Product identifier

milkbite (base + catalyst)

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

#### Use of the substance/mixture

Bite registration material for use in dentistry.

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

|                         |   |                           |
|-------------------------|---|---------------------------|
| Company name:           | DETAX GmbH  |                           |
| Street:                 | Carl-Zeiss-Straße 4   |                           |
| Place:                  | D-76275 Ettlingen   |                           |
| Telephone:              | +49 7243/510-0  | Telefax: +49 7243/510-100 |
| e-mail:                 | post@detax.de   |                           |
| Internet:               | www.detax.de  |                           |
| Responsible Department: | This number is only obtainable during office hours<br>(Monday - Thursday 8.00 a.m. - 5.00 p.m., Friday 8.00 a.m. - 4.00 p.m.) |                           |

### 1.4. Emergency telephone number:

+1-800-424-9300 (CHEMTREC worldwide)

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

#### GB CLP Regulation

Hazard categories:

Hazardous to the aquatic environment: Aquatic Chronic 3

Hazard Statements:

Harmful to aquatic life with long lasting effects.

Due to physical form (paste) classification with H372 is not appropriate. An inhalation of the product is not possible.

### 2.2. Label elements

#### GB CLP Regulation

##### Precautionary statements

P273 Avoid release to the environment.

##### Additional advice on labelling

According to Regulation (EC) 1272/2008, art.1 No. 5 (d) this product as a medical product must not be labelled!

### 2.3. Other hazards

The mixture contains the following substances fulfilling the vPvB criteria according to UK REACH:

Dodecamethylcyclohexasiloxane.

## SECTION 3: Composition/information on ingredients

### 3.2. Mixtures

#### Chemical characterization

Contains polydimethylsiloxane with functional groups. + fillers and pigment  
catalyst: additionally platinum complex compound.

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#### Hazardous components

| CAS No     | Chemical name   |              |                  | Quantity    |
|------------|---|--------------|------------------|-------------|
|            | EC No   | Index No     | REACH No         |             |
|            | GHS Classification  |              |                  |             |
| 14464-46-1 | cristobalite flour  |              |                  | 55 - < 60 % |
|            | 238-455-4   |              |                  |             |
|            | STOT RE 1; H372   |              |                  |             |
| 541-02-6   | Decamethylcyclopentasiloxane                              |              |                  | < 0,15 %    |
|            | 208-764-9   |              | 01-2119511367-43 |             |
| 540-97-6   | Dodecamethylcyclohexasiloxane                             |              |                  | < 0,15 %    |
|            | 208-762-8   |              | 01-2119517435-42 |             |
| 556-67-2   | Octamethylcyclotetrasiloxane                              |              |                  | < 0,15 %    |
|            | 209-136-7   | 014-018-00-1 | 01-2119529238-36 |             |
|            | Flam. Liq. 3, Repr. 2, Aquatic Chronic 1; H226 H361f H410 |              |                  |             |

Full text of H and EUH statements: see section 16.

#### Specific Conc. Limits, M-factors and ATE

| CAS No   | EC No     | Chemical name   | Quantity |
|----------|-----------|---|----------|
|          |           | Specific Conc. Limits, M-factors and ATE  |          |
| 541-02-6 | 208-764-9 | Decamethylcyclopentasiloxane  | < 0,15 % |
|          |           | inhalation: LC50 = 8,67 mg/l (vapours); dermal: LD50 = >2000 mg/kg; oral: LD50 = >24100 mg/kg                     |          |
| 540-97-6 | 208-762-8 | Dodecamethylcyclohexasiloxane   | < 0,15 % |
|          |           | dermal: LD50 = 2000 mg/kg; oral: LD50 = 2000 mg/kg  |          |
| 556-67-2 | 209-136-7 | Octamethylcyclotetrasiloxane  | < 0,15 % |
|          |           | inhalation: LC50 = 36 mg/l (vapours); dermal: LD50 = >2400 mg/kg; oral: LD50 = 4800 mg/kg<br>M chron.; H410: M=10 |          |

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

##### After inhalation

Provide fresh air.

##### After contact with skin

Take off contaminated clothing and wash it before reuse. Remove product mechanically with cloth or paper. Wash with plenty of water and soap. In case of visible changes on the skin or complaints, seek medical advice (if possible have label or safety data sheet with you).

##### After contact with eyes

Rinse immediately carefully and thoroughly with eye-bath or water.

##### After ingestion

Rinse mouth immediately and drink 1 glass of water. Let water be drunk in little sips (dilution effect). Do not induce vomiting. If you feel unwell, seek medical advice.

#### 4.2. Most important symptoms and effects, both acute and delayed

No information available.

#### 4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

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## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

#### Suitable extinguishing media

Co-ordinate fire-fighting measures to the fire surroundings.

### 5.2. Special hazards arising from the substance or mixture

Non-flammable.

### 5.3. Advice for firefighters

In case of fire: Wear self-contained breathing apparatus.

#### Additional information

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

#### General advice

Use personal protection equipment.

### 6.2. Environmental precautions

Do not allow to enter into surface water or drains.

### 6.3. Methods and material for containment and cleaning up

#### For cleaning up

Take up mechanically. Treat the recovered material as prescribed in the section on waste disposal.

#### Other information

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents). Treat the recovered material as prescribed in the section on waste disposal.

### 6.4. Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

#### Advice on safe handling

No special measures are necessary.

#### Advice on protection against fire and explosion

No special fire protection measures are necessary.

#### Advice on general occupational hygiene

Take off contaminated clothing. Wash hands before breaks and after work. When using do not eat, drink, smoke, sniff. Draw up and observe skin protection programme.

### 7.2. Conditions for safe storage, including any incompatibilities

#### Requirements for storage rooms and vessels

Keep container tightly closed.

#### Hints on joint storage

Do not store with acids, lyes, alcohols, metallic powders and metallic oxides (release of hydrogen is favoured).

#### Further information on storage conditions

Keep only in the original container in a cool, dry and well-ventilated place, away from foodstuffs.

### 7.3. Specific end use(s)

Bite registration material for use in dentistry.

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For use by trained specialist staff.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

### 8.2. Exposure controls

#### Individual protection measures, such as personal protective equipment

##### Eye/face protection

Wear eye/face protection.

##### Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

Suitable are gloves of the following material: NBR (Nitrile rubber)

##### Skin protection

Use of protective clothing.

##### Respiratory protection

In case of inadequate ventilation wear respiratory protection.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

|                 |                              |
|-----------------|------------------------------|
| Physical state: | Paste                        |
| Colour:         | base: white, catalyst: white |
| Odour:          | like ice-cream               |

#### Test method

#### Changes in the physical state

Melting point/freezing point: not determined

Boiling point or initial boiling point and boiling range: not determined

Flash point: >100 °C DIN 51755

#### Flammability

Solid/liquid: not determined

Gas: not applicable

#### Explosive properties

The product is not: Explosive.

Lower explosion limits: not determined

Upper explosion limits: not determined

Auto-ignition temperature: >400 °C DIN 51794

Decomposition temperature: >180 °C

pH-Value: not determined

Viscosity / dynamic:  
(at 23 °C) 95000 mPa·s BROOKFIELD

Water solubility: practically insoluble

#### Solubility in other solvents

not determined

Partition coefficient n-octanol/water: not determined

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|                                |                                  |
|--------------------------------|----------------------------------|
| Vapour pressure:<br>(at 20 °C) | <10 hPa                          |
| Density (at 20 °C):            | 1,48 g/cm <sup>3</sup> DIN 51757 |
| Relative vapour density:       | not determined                   |

#### 9.2. Other information

##### Information with regard to physical hazard classes

Oxidizing properties  
The product is not: oxidising.

##### Other safety characteristics

|                   |                |
|-------------------|----------------|
| Solid content:    | not determined |
| Evaporation rate: | not determined |

##### Further Information

### SECTION 10: Stability and reactivity

#### 10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

#### 10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

#### 10.3. Possibility of hazardous reactions

Reacts with : Acids, alkalis, alcohols, powdered metals or metal oxides with release of hydrogen.

#### 10.4. Conditions to avoid

Temperatures > 150°C/ 302 °F.

#### 10.5. Incompatible materials

No information available.

#### 10.6. Hazardous decomposition products

In case of thermic decomposition hydrogen is released.  
At a temperature of approx. 150°C/ 302°F a small amount of formaldehyde can be released by oxidative degradation.

### SECTION 11: Toxicological information

#### 11.1. Information on hazard classes as defined in GB CLP Regulation

##### Acute toxicity

Based on available data, the classification criteria are not met.  
For the product itself no toxicological data are available. In products with a comparable composition, a LD50 (orally, species rat) of > 5000 mg/kg has been found.

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| CAS No   | Chemical name                 |                   |         |        |          |
|----------|-------------------------------|-------------------|---------|--------|----------|
|          | Exposure route                | Dose              | Species | Source | Method   |
| 541-02-6 | Decamethylcyclopentasiloxane  |                   |         |        |          |
|          | oral                          | LD50 >24100 mg/kg | Rat     | GESTIS |          |
|          | dermal                        | LD50 >2000 mg/kg  | Rabbit  |        | OECD 402 |
|          | inhalation (4 h) vapour       | LC50 8,67 mg/l    | Rat     |        | OECD 403 |
| 540-97-6 | Dodecamethylcyclohexasiloxane |                   |         |        |          |
|          | oral                          | LD50 2000 mg/kg   | Rat     |        |          |
|          | dermal                        | LD50 2000 mg/kg   | Rat     |        |          |
| 556-67-2 | Octamethylcyclotetrasiloxane  |                   |         |        |          |
|          | oral                          | LD50 4800 mg/kg   | Rat     |        | OECD 401 |
|          | dermal                        | LD50 >2400 mg/kg  | Rabbit  |        | OECD 402 |
|          | inhalation (4 h) vapour       | LC50 36 mg/l      | Rat     | GESTIS | OECD 403 |

#### Irritation and corrosivity

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

#### Sensitising effects

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

#### Carcinogenic/mutagenic/toxic effects for reproduction

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

#### STOT-single exposure

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

#### STOT-repeated exposure

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

Due to physical form (paste) classification with H372 is not appropriate. An inhalation of the product is not possible.

EC regulation 1272/2008 annex 1, section 1.1.1.5: "For the purpose of classification of health hazards (part 3), the route of exposure, information on mechanisms and metabolism studies are useful for determining the relevance of effects in humans. If this information raises doubts as to their relevance in humans, in spite of the indisputable data legitimacy and quality, a lower classification may be justified. When there is scientific evidence that the mechanism or mode of action is not relevant to humans, the substance or mixture should not be classified."

#### Aspiration hazard

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

#### Further information

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

## SECTION 12: Ecological information

### 12.1. Toxicity

The product is not: Ecotoxic.

### 12.2. Persistence and degradability

The product has not been tested.

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| CAS No   | Chemical name  |       |    |        |
|----------|--|-------|----|--------|
|          | Method   | Value | d  | Source |
|          | Evaluation   |       |    |        |
| 556-67-2 | Octamethylcyclotetrasiloxane                           |       |    |        |
|          |  | 3,7%  | 29 |        |
|          | Not readily biodegradable (according to OECD criteria) |       |    |        |

#### 12.3. Bioaccumulative potential

The product has not been tested.

#### 12.4. Mobility in soil

The product has not been tested.

#### 12.5. Results of PBT and vPvB assessment

The mixture contains the following substances fulfilling the vPvB criteria according to UK REACH:

Dodecamethylcyclohexasiloxane.

Not identified as PBT/ vPvB substances

Dodecamethylcyclohexasiloxane (D6) fulfills the current criteria set forth under Annex XIII of the EU REACH Regulation for very persistent and very bioaccumulative substances (vPvB) and was included in the candidate list of substances of very high concern (SVHC). According to our knowledge of the state of the art, however, D6 cannot be compared with known persistent, bioaccumulative and toxic (PBT) and/or vPvB substances. The interpretation of the available data by the silicone industry reveals that scientific evidence obtained from field tests essentially points out that D6 does not lead to biomagnification in aquatic and terrestrial food chains. In air, D6 is decomposed by naturally occurring processes in the atmosphere. D-residues which do not decompose in this way in the air are not expected to accumulate from the air in water, the soil or living organisms.

Decamethylcyclopentasiloxane (D5) fulfills the current criteria set forth under Annex XIII of the EU REACH Regulation for vPvB substances and was included in the candidate list of SVHCs. According to our knowledge of the state of the art, however, D5 cannot be compared with known PBT and/or vPvB substances. The interpretation of the available data by the silicone industry reveals that scientific evidence obtained from field tests essentially points out that D5 does not lead to biomagnification in aquatic and terrestrial food chains. In air, D5 is decomposed by naturally occurring processes in the atmosphere. D-residues which do not decompose in this way in the air are not expected to accumulate from the air in water, the soil or living organisms.

Octamethylcyclotetrasiloxane (D4) fulfills the current criteria set forth under Annex XIII of the EU REACH Regulation for PBT and vPvB substances and was included in the candidate list of SVHCs. According to our knowledge of the state of the art, however, D4 cannot be compared with known PBT and/or vPvB substances. The interpretation of the available data by the silicone industry reveals that scientific evidence obtained from field tests essentially points out that D4 does not lead to biomagnification in aquatic and terrestrial food chains. In air, D4 is decomposed by naturally occurring processes in the atmosphere. D-residues which do not decompose in this way in the air are not expected to accumulate from the air in water, the soil or living organisms.

#### 12.7. Other adverse effects

No information available.

#### **Further information**

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

##### **Disposal recommendations**

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil. Dispose of waste according to applicable legislation.

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#### Contaminated packaging

Non-contaminated packages may be recycled. Handle contaminated packages in the same way as the substance itself.

### SECTION 14: Transport information

#### Land transport (ADR/RID)

- |   |  |
|---|--|
| <b><u>14.1. UN number or ID number:</u></b>     | No dangerous good in sense of this transport regulation. |
| <b><u>14.2. UN proper shipping name:</u></b>    | No dangerous good in sense of this transport regulation. |
| <b><u>14.3. Transport hazard class(es):</u></b> | No dangerous good in sense of this transport regulation. |
| <b><u>14.4. Packing group:</u></b>              | No dangerous good in sense of this transport regulation. |

#### Inland waterways transport (ADN)

- |   |  |
|---|--|
| <b><u>14.1. UN number or ID number:</u></b>     | No dangerous good in sense of this transport regulation. |
| <b><u>14.2. UN proper shipping name:</u></b>    | No dangerous good in sense of this transport regulation. |
| <b><u>14.3. Transport hazard class(es):</u></b> | No dangerous good in sense of this transport regulation. |
| <b><u>14.4. Packing group:</u></b>              | No dangerous good in sense of this transport regulation. |

#### Marine transport (IMDG)

- |   |  |
|---|--|
| <b><u>14.1. UN number or ID number:</u></b>     | No dangerous good in sense of this transport regulation. |
| <b><u>14.2. UN proper shipping name:</u></b>    | No dangerous good in sense of this transport regulation. |
| <b><u>14.3. Transport hazard class(es):</u></b> | No dangerous good in sense of this transport regulation. |
| <b><u>14.4. Packing group:</u></b>              | No dangerous good in sense of this transport regulation. |

#### Air transport (ICAO-TI/IATA-DGR)

- |   |  |
|---|--|
| <b><u>14.1. UN number or ID number:</u></b>     | No dangerous good in sense of this transport regulation. |
| <b><u>14.2. UN proper shipping name:</u></b>    | No dangerous good in sense of this transport regulation. |
| <b><u>14.3. Transport hazard class(es):</u></b> | No dangerous good in sense of this transport regulation. |
| <b><u>14.4. Packing group:</u></b>              | No dangerous good in sense of this transport regulation. |

#### **14.5. Environmental hazards**

ENVIRONMENTALLY HAZARDOUS: No

#### **14.6. Special precautions for user**

No dangerous good in sense of this transport regulation.

#### **14.7. Maritime transport in bulk according to IMO instruments**

No dangerous good in sense of this transport regulation.

### SECTION 15: Regulatory information

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

##### EU regulatory information

Authorisations (REACH, annex XIV):

Substances of very high concern, SVHC (REACH, article 59):

Decamethylcyclopentasiloxane; Dodecamethylcyclohexasiloxane; Octamethylcyclotetrasiloxane

Restrictions on use (REACH, annex XVII):

Entry 70

Information according to 2012/18/EU (SEVESO III): Not subject to 2012/18/EU (SEVESO III)

##### National regulatory information

Water hazard class (D): 2 - obviously hazardous to water



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#### 15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

### SECTION 16: Other information

#### Abbreviations and acronyms

ADR: Accord européen sur le transport 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 Harmonized 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  
LC50: Lethal concentration, 50%  
LD50: Lethal dose, 50%  
CLP: Classification, labelling and Packaging  
REACH: Registration, Evaluation and Authorization of Chemicals  
GHS: Globally Harmonised System of Classification, Labelling and Packaging of Chemicals  
UN: United Nations  
DNEL: Derived No Effect Level  
DMEL: Derived Minimal Effect Level  
PNEC: Predicted No Effect Concentration  
ATE: Acute toxicity estimate  
LL50: Lethal loading, 50%  
EL50: Effect loading, 50%  
EC50: Effective Concentration 50%  
ErC50: Effective Concentration 50%, growth rate  
NOEC: No Observed Effect Concentration  
BCF: Bio-concentration factor  
PBT: persistent, bioaccumulative, toxic  
vPvB: very persistent, very bioaccumulative  
RID: Regulations concerning the international carriage of dangerous goods by rail  
ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways  
(Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures)  
EmS: Emergency Schedules  
MFAG: Medical First Aid Guide  
ICAO: International Civil Aviation Organization  
MARPOL: International Convention for the Prevention of Marine Pollution from Ships  
IBC: Intermediate Bulk Container  
SVHC: Substance of Very High Concern  
For abbreviations and acronyms, see table at <http://abbrev.esdscom.eu>

#### Classification for mixtures and used evaluation method according to GB CLP Regulation

| Classification          | Classification procedure |
|-------------------------|--------------------------|
| Aquatic Chronic 3; H412 | Calculation method       |

#### Relevant H and EUH statements (number and full text)

|       |   |
|-------|---|
| H226  | Flammable liquid and vapour.  |
| H361f | Suspected of damaging fertility.  |
| H372  | Causes damage to organs (lung) through prolonged or repeated exposure if inhaled. |
| H410  | Very toxic to aquatic life with long lasting effects.                             |
| H412  | Harmful to aquatic life with long lasting effects.                                |

#### Further Information

The information is based on the present level of our knowledge. It does not, however, give assurance of

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product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations.

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*(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)*