

## Safety Data Sheet

according to Regulation (EC) No 1907/2006

Revision date: 28.08.2018

**exasoft wash**

Product code: 911

Page 1 of 8

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

#### 1.1. Product identifier

exasoft wash

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

##### Use of the substance/mixture

Impression material for use in dental technology.

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

|                         |                     |                           |
|-------------------------|---------------------|---------------------------|
| Company name:           | DETAX GmbH & Co. KG |                           |
| Street:                 | Carl-Zeiss-Strasse  |                           |
| 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: | Emergency number:   |                           |

+49 7243/510-0

This number is only obtainable during office hours (Monday - Thursday 8.00 a.m. - 5.00 p.m., Friday 8.00 a.m. - 4.00 p.m.)

#### 1.4. Emergency telephone number:

+49 7243/510-0

This number is only obtainable during office hours (Monday - Thursday 8.00 a.m. - 5.00 p.m., Friday 8.00 - 4.00 p.m.)

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### Regulation (EC) No. 1272/2008

This mixture is not classified as hazardous in accordance with Regulation (EC) No. 1272/2008.

#### 2.2. Label elements

##### Regulation (EC) No. 1272/2008

##### Special labelling of certain mixtures

EUH210 Safety data sheet available on request.

##### 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

No information available.

### SECTION 3: Composition/information on ingredients

#### 3.2. Mixtures

##### Chemical characterization

Contains polydimethylsiloxane with functional groups. + fillers and pigment

according to Regulation (EC) No 1907/2006

**exasoft wash**

Revision date: 28.08.2018

Product code: 911

Page 2 of 8

**Hazardous components**

| CAS No     | Chemical name   |              |                  | Quantity    |
|------------|---|--------------|------------------|-------------|
|            | EC No   | Index No     | REACH No         |             |
|            | Classification according to Regulation (EC) No. 1272/2008 [CLP] |              |                  |             |
| 14808-60-7 | quartz  |              |                  | 10 - < 15 % |
|            | 238-878-4   |              |                  |             |
|            | STOT RE 1; H372   |              |                  |             |
| 14464-46-1 | cristobalite flour  |              |                  | 5 - < 10 %  |
|            | 238-455-4   |              |                  |             |
|            | STOT RE 1; H372   |              |                  |             |
| 556-67-2   | octamethylcyclotetrasiloxane                                    |              |                  | < 0,5 %     |
|            | 209-136-7   | 014-018-00-1 | 01-2119529238-36 |             |
|            | Flam. Liq. 3, Repr. 2, Aquatic Chronic 4; H226 H361f H413       |              |                  |             |

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

**SECTION 4: First aid measures**
**4.1. Description of first aid measures**
**After inhalation**

Provide fresh air. Medical treatment necessary.

**After contact with skin**

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**

After eye contact: Rinse immediately carefully and thoroughly with eye-bath or water. Consult an ophthalmologist.

**After ingestion**

Rinse mouth thoroughly with water. Let water be drunken 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.

**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. Vapours can form explosive mixtures with air.

**5.3. Advice for firefighters**

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

**Additional information**

Use water spray jet to protect personnel and to cool endangered containers. Suppress gases/vapours/mists with water spray jet.

**SECTION 6: Accidental release measures**

according to Regulation (EC) No 1907/2006

Revision date: 28.08.2018

**exasoft wash**

Product code: 911

Page 3 of 8

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

Provide adequate ventilation. Do not breathe gas/fumes/vapour/spray. Avoid contact with skin, eyes and clothes. Use personal protection equipment.

### **6.2. Environmental precautions**

No special environmental measures are necessary. Clean contaminated objects and areas thoroughly observing environmental regulations.

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

Absorb with liquid-binding material (e.g. 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**

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

#### **Advice on protection against fire and explosion**

No special fire protection measures are necessary.

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

#### **Requirements for storage rooms and vessels**

Keep container tightly closed. Keep locked up. Store in a place accessible by authorized persons only. Provide adequate ventilation as well as local exhaustion at critical locations.

#### **Advice on storage compatibility**

No special measures are necessary.

#### **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)**

Component B of a silicone based dental impression material.

For use by trained specialist staff.

## **SECTION 8: Exposure controls/personal protection**

### **8.1. Control parameters**

### **8.2. Exposure controls**

#### **Appropriate engineering controls**

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

#### **Protective and hygiene measures**

Remove contaminated, saturated clothing immediately. Draw up and observe skin protection programme.

Wash hands and face before breaks and after work and take a shower if necessary. When using do not eat or drink.

#### **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

according to Regulation (EC) No 1907/2006

### exasoft wash

Revision date: 28.08.2018

Product code: 911

Page 4 of 8

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

Wear suitable 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:         | pink      |
| Odour:          | odourless |

#### Test method

|           |                |
|-----------|----------------|
| pH-Value: | not determined |
|-----------|----------------|

#### Changes in the physical state

|                |                |
|----------------|----------------|
| Melting point: | not determined |
|----------------|----------------|

|  |                |
|--|----------------|
| Initial boiling point and boiling range: | not determined |
|--|----------------|

|              |         |           |
|--------------|---------|-----------|
| Flash point: | >100 °C | DIN 51755 |
|--------------|---------|-----------|

#### Flammability

|        |                |
|--------|----------------|
| Solid: | not applicable |
|--------|----------------|

|      |                |
|------|----------------|
| Gas: | not applicable |
|------|----------------|

|                         |                |
|-------------------------|----------------|
| Lower explosion limits: | not determined |
|-------------------------|----------------|

|                         |                |
|-------------------------|----------------|
| Upper explosion limits: | not determined |
|-------------------------|----------------|

|                       |         |           |
|-----------------------|---------|-----------|
| Ignition temperature: | >200 °C | DIN 51794 |
|-----------------------|---------|-----------|

#### Auto-ignition temperature

|        |                |
|--------|----------------|
| Solid: | not applicable |
|--------|----------------|

|      |                |
|------|----------------|
| Gas: | not applicable |
|------|----------------|

|                            |         |
|----------------------------|---------|
| Decomposition temperature: | >250 °C |
|----------------------------|---------|

#### Oxidizing properties

Not oxidizing.

|                                |        |
|--------------------------------|--------|
| Vapour pressure:<br>(at 20 °C) | <1 hPa |
|--------------------------------|--------|

|                     |                        |           |
|---------------------|------------------------|-----------|
| Density (at 20 °C): | 1,19 g/cm <sup>3</sup> | DIN 51757 |
|---------------------|------------------------|-----------|

|                   |                       |
|-------------------|-----------------------|
| Water solubility: | practically insoluble |
|-------------------|-----------------------|

#### Solubility in other solvents

not determined

|                        |                |
|------------------------|----------------|
| Partition coefficient: | not determined |
|------------------------|----------------|

|                                    |             |            |
|------------------------------------|-------------|------------|
| Viscosity / dynamic:<br>(at 23 °C) | 18000 mPa·s | BROOKFIELD |
|------------------------------------|-------------|------------|

|                 |                |
|-----------------|----------------|
| Vapour density: | not determined |
|-----------------|----------------|

|                   |                |
|-------------------|----------------|
| Evaporation rate: | not determined |
|-------------------|----------------|

### 9.2. Other information

|                |                |
|----------------|----------------|
| Solid content: | not determined |
|----------------|----------------|

according to Regulation (EC) No 1907/2006

### exasoft wash

Revision date: 28.08.2018

Product code: 911

Page 5 of 8

## 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

No known hazardous reactions.

### 10.4. Conditions to avoid

Temperatures > 150°C/ 302 °F.

### 10.5. Incompatible materials

No information available.

### 10.6. Hazardous decomposition products

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 toxicological effects

#### 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.

| CAS No   | Chemical name                |               |         |        |                    |
|----------|------------------------------|---------------|---------|--------|--------------------|
|          | Exposure route               | Dose          | Species | Source | Method             |
| 556-67-2 | octamethylcyclotetrasiloxane |               |         |        |                    |
|          | oral                         | LD50<br>mg/kg | 4800    | Rat    | OECD 401           |
|          | dermal                       | LD50<br>mg/kg | >2400   | Rabbit | OECD 402           |
|          | inhalation (4 h) vapour      | LC50          | 36 mg/l | Rat    | GESTIS<br>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

## Safety Data Sheet

according to Regulation (EC) No 1907/2006

### exasoft wash

Revision date: 28.08.2018

Product code: 911

Page 6 of 8

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. Due to physical form (paste) classification with H373 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.

## SECTION 12: Ecological information

### 12.1. Toxicity

The product is not: Ecotoxic.

### 12.2. Persistence and degradability

The product has not been tested.

| 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

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.

### 12.6. Other adverse effects

No information available.

#### Further information

Avoid release to the environment.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

#### Advice on disposal

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

#### Contaminated packaging

This material and its container must be disposed of as hazardous waste. Handle contaminated packages in the same way as the substance itself.

## Safety Data Sheet

according to Regulation (EC) No 1907/2006

Revision date: 28.08.2018

**exasoft wash**

Product code: 911

Page 7 of 8

### SECTION 14: Transport information

#### Land transport (ADR/RID)

- |   |  |
|---|--|
| <b><u>14.1. UN 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:</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:</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:</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. |

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

No dangerous good in sense of this transport regulation.

#### **14.7. Transport in bulk according to Annex II of Marpol and the IBC Code**

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

##### Additional information

The mixture contains substances of very high concern (SVHC candidates):  
Octamethylcyclotetrasiloxane (D4), CAS no. 556-67-2

##### National regulatory information

|                          |  |
|--------------------------|--|
| Employment restrictions: | Observe restrictions to employment for juvenils according to the 'juvenile work protection guideline' (94/33/EC). Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers. |
|--------------------------|--|

|                                |                            |
|--------------------------------|----------------------------|
| Water contaminating class (D): | -- not water contaminating |
|--------------------------------|----------------------------|

#### **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)

## Safety Data Sheet

according to Regulation (EC) No 1907/2006

**exasoft wash**

Revision date: 28.08.2018

Product code: 911

Page 8 of 8

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%

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

H226 Flammable liquid and vapour.  
H361f Suspected of damaging fertility.  
H413 May cause long lasting harmful effects to aquatic life.  
EUH210 Safety data sheet available on request.

**Further Information**

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

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