

## Safety Data Sheet

according to Regulation (EC) No. 1907/2006

### Detaferm®

Revision date: 08.11.2022

Product code: 1748

Page 1 of 9

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

### 1.1. Product identifier

Detaferm®

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

#### Use of the substance/mixture

Provisional filling 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.com  |                           |
| Internet:               | www.detax.com   |                           |
| 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

#### Regulation (EC) No. 1907/2006

Eye Dam. 1; H318  
 Aquatic Acute 1; H400  
 Aquatic Chronic 1; H410

Full text of hazard statements: see SECTION 16.

### 2.2. Label elements

#### Regulation (EC) No. 1907/2006

#### Hazard components for labelling

Zinc sulfate monohydrate

Signal word: Danger

#### Pictograms:



#### Hazard statements

H318 Causes serious eye damage.  
 H410 Very toxic to aquatic life with long lasting effects.

#### Precautionary statements

P273 Avoid release to the environment.  
 P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.  
 P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
 P310 Immediately call a POISON CENTER/doctor.  
 P391 Collect spillage.  
 P501 Dispose of contents/container to according to local and applicable legislation of dispose of waste.

## Safety Data Sheet

according to Regulation (EC) No. 1907/2006

### Detaferm®

Revision date: 08.11.2022

Product code: 1748

Page 2 of 9

#### 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

##### Hazardous components

| CAS No    | Chemical name   |              |          | Quantity    |
|-----------|---|--------------|----------|-------------|
|           | EC No   | Index No     | REACH No |             |
|           | Classification (Regulation (EC) No. 1907/2006)                                    |              |          |             |
| 1314-13-2 | zinc oxide  |              |          | 20 - < 40 % |
|           | 215-222-5   | 030-013-00-7 |          |             |
|           | Aquatic Acute 1, Aquatic Chronic 1; H400 H410                                     |              |          |             |
| 7446-19-7 | Zinc sulfate monohydrate  |              |          | 5 - < 20 %  |
|           | 231-793-3   | 030-006-00-9 |          |             |
|           | Acute Tox. 4, Eye Dam. 1, Aquatic Acute 1, Aquatic Chronic 1; H302 H318 H400 H410 |              |          |             |
| 115-86-6  | triphenylphosphate  |              |          | 0.1 - < 5 % |
|           | 204-112-2   |              |          |             |
|           | Aquatic Acute 1, Aquatic Chronic 1; H400 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             |             |
| 1314-13-2 | 215-222-5 | zinc oxide   | 20 - < 40 % |
|           |           | oral: LD50 = > 5000 mg/kg                            |             |
| 7446-19-7 | 231-793-3 | Zinc sulfate monohydrate                             | 5 - < 20 %  |
|           |           | oral: LD50 = 2949 mg/kg                              |             |
| 115-86-6  | 204-112-2 | triphenylphosphate                                   | 0.1 - < 5 % |
|           |           | dermal: LD50 = 10000 mg/kg; oral: LD50 = 20000 mg/kg |             |

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

##### After inhalation

Provide fresh air.

##### After contact with skin

Wash with plenty of water. Take off contaminated clothing and wash it before reuse.

##### After contact with eyes

In case of contact with eyes flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart and consult an ophthalmologist.

##### After ingestion

Rinse mouth immediately and drink 1 glass of water.

#### 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.

## Safety Data Sheet

according to Regulation (EC) No. 1907/2006

**Detaferm®**

Revision date: 08.11.2022

Product code: 1748

Page 3 of 9

### 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**

Suppress gases/vapours/mists with water spray jet. 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**

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

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.

#### 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. Avoid dust formation. Do not breathe dust.

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

No special fire protection measures are necessary.

##### **Advice on general occupational hygiene**

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, drink, smoke, sniff.

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

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

Keep container tightly closed.

##### **Hints on joint storage**

No special measures are necessary.

#### 7.3. Specific end use(s)

Dental provisional filling cement.

For use by trained specialist staff.

## Safety Data Sheet

according to Regulation (EC) No. 1907/2006

### Detaferm®

Revision date: 08.11.2022

Product code: 1748

Page 4 of 9

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### Exposure limits (EH40)

| CAS No   | Substance           | ppm | mg/m <sup>3</sup> | fibres/ml | Category      | Origin |
|----------|---------------------|-----|-------------------|-----------|---------------|--------|
| 115-86-6 | Triphenyl phosphate | -   | 3                 |           | TWA (8 h)     | WEL    |
|          |                     | -   | 6                 |           | STEL (15 min) | WEL    |

### 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.

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

##### Eye/face protection

Suitable eye protection: goggles.

##### 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.

##### 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:   | white  |                |
| Odour:  | odourless  |                |
| Melting point/freezing point:                             |  | not determined |
| Boiling point or initial boiling point and boiling range: |  | 239 °C         |
| Flammability  |  |                |
| Solid/liquid:   |  | not determined |
| Gas:  |  | not applicable |
| Lower explosion limits:                                   |  | not determined |
| Upper explosion limits:                                   |  | not determined |
| Flash point:  |  | 224 °C         |
| Auto-ignition temperature:                                |  | not determined |
| Decomposition temperature:                                |  | not determined |
| pH-Value:   |  | not determined |
| Water solubility:   | The study does not need to be conducted because the substance is known to be insoluble in water. |                |
| Solubility in other solvents                              | not determined   |                |
| Partition coefficient n-octanol/water:                    | not determined   |                |

## Safety Data Sheet

according to Regulation (EC) No. 1907/2006

### Detaferm®

Revision date: 08.11.2022

Product code: 1748

Page 5 of 9

|                                |                        |
|--------------------------------|------------------------|
| Vapour pressure:<br>(at 20 °C) | 0,27 hPa               |
| Vapour pressure:<br>(at 50 °C) | 2,13 hPa               |
| Density:                       | 2,52 g/cm <sup>3</sup> |
| Relative vapour density:       | not determined         |

#### 9.2. Other information

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

Explosive properties

The product is not: Explosive.

Oxidizing properties

The product is not: oxidising.

##### Other safety characteristics

Evaporation rate:

not determined

Solid content:

not determined

### 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

none

#### 10.5. Incompatible materials

No information available.

#### 10.6. Hazardous decomposition products

No known hazardous decomposition products.

### SECTION 11: Toxicological information

#### 11.1. Information on hazard classes as defined in Regulation (EC) No. 1907/2006

##### Acute toxicity

| CAS No    | Chemical name            |                      |         |        |        |
|-----------|--------------------------|----------------------|---------|--------|--------|
|           | Exposure route           | Dose                 | Species | Source | Method |
| 1314-13-2 | zinc oxide               |                      |         |        |        |
|           | oral                     | LD50<br>mg/kg > 5000 | Rat     | IUCLID |        |
| 7446-19-7 | Zinc sulfate monohydrate |                      |         |        |        |
|           | oral                     | LD50<br>mg/kg 2949   | Rat     |        |        |
| 115-86-6  | triphenylphosphate       |                      |         |        |        |
|           | oral                     | LD50<br>mg/kg 20000  | Rat     | ECHA   |        |
|           | dermal                   | LD50<br>mg/kg 10000  | Rabbit  | ECHA   |        |

## Safety Data Sheet

according to Regulation (EC) No. 1907/2006

### Detaferm®

Revision date: 08.11.2022

Product code: 1748

Page 6 of 9

#### Further information

The mixture is classified as hazardous according to regulation (EC) No 1272/2008 [CLP].

### SECTION 12: Ecological information

#### 12.1. Toxicity

Very toxic to aquatic life with long lasting effects.

| CAS No    | Chemical name            |               |           |         |                              |        |
|-----------|--------------------------|---------------|-----------|---------|------------------------------|--------|
|           | Aquatic toxicity         | Dose          | [h]   [d] | Species | Source                       | Method |
| 1314-13-2 | zinc oxide               |               |           |         |                              |        |
|           | Acute fish toxicity      | LC50<br>mg/l  | 1120      | 96 h    |                              | GESTIS |
|           | Acute algae toxicity     | ErC50<br>mg/l | 0,21      | 72 h    | Selenastrum<br>capricornutum | CSR    |
|           | Acute crustacea toxicity | EC50<br>mg/l  | 0,67      | 48 h    | Ceriodaphnia spec            | CSR    |
| 115-86-6  | triphenylphosphate       |               |           |         |                              |        |
|           | Acute fish toxicity      | LC50          | 0,4 mg/l  | 96 h    |                              | ECHA   |
|           | Acute algae toxicity     | ErC50         | 2 mg/l    | 96 h    |                              | GESTIS |
|           | Acute crustacea toxicity | EC50          | 1 mg/l    | 48 h    |                              | GESTIS |

#### 12.2. Persistence and degradability

The product has not been tested.

#### 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 substances in the mixture do not meet the PBT/vPvB criteria according to UK REACH.

The product has not been tested.

#### 12.6. Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

#### 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.

##### 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)

## Safety Data Sheet

according to Regulation (EC) No. 1907/2006

### Detaferm®

Revision date: 08.11.2022

Product code: 1748

Page 7 of 9

|  |  |
|--|--|
| <b>14.1. UN number or ID number:</b>     | UN 3077  |
| <b>14.2. UN proper shipping name:</b>    | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. |
| <b>14.3. Transport hazard class(es):</b> | 9  |
| <b>14.4. Packing group:</b>              | III  |
| Hazard label:                            | 9  |
| Classification code:                     | M7   |
| Special Provisions:                      | 274 335 375 601                                    |
| Limited quantity:                        | 5 kg   |
| Excepted quantity:                       | E1   |
| Transport category:                      | 3  |
| Hazard No:                               | 90   |
| Tunnel restriction code:                 | -  |

#### Inland waterways transport (ADN)

|  |  |
|--|--|
| <b>14.1. UN number or ID number:</b>     | UN 3077  |
| <b>14.2. UN proper shipping name:</b>    | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. |
| <b>14.3. Transport hazard class(es):</b> | 9  |
| <b>14.4. Packing group:</b>              | III  |
| Hazard label:                            | 9  |
| Classification code:                     | M7   |
| Special Provisions:                      | 274 335 375 601                                    |
| Limited quantity:                        | 5 kg   |
| Excepted quantity:                       | E1   |

#### Marine transport (IMDG)

|  |  |
|--|--|
| <b>14.1. UN number or ID number:</b>     | UN 3077  |
| <b>14.2. UN proper shipping name:</b>    | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. |
| <b>14.3. Transport hazard class(es):</b> | 9  |
| <b>14.4. Packing group:</b>              | III  |
| Hazard label:                            | 9  |
| Special Provisions:                      | 274, 335, 966, 967, 969                            |
| Limited quantity:                        | 5 kg   |
| Excepted quantity:                       | E1   |
| EmS:                                     | F-A, S-F   |

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

|  |  |
|--|--|
| <b>14.1. UN number or ID number:</b>     | UN 3077  |
| <b>14.2. UN proper shipping name:</b>    | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. |
| <b>14.3. Transport hazard class(es):</b> | 9  |
| <b>14.4. Packing group:</b>              | III  |
| Hazard label:                            | 9  |
| Special Provisions:                      | A97 A158 A179 A197 A215                            |
| Limited quantity Passenger:              | 30 kg G  |
| Passenger LQ:                            | Y956   |
| Excepted quantity:                       | E1   |
| IATA-packing instructions - Passenger:   | 956  |
| IATA-max. quantity - Passenger:          | 400 kg   |
| IATA-packing instructions - Cargo:       | 956  |
| IATA-max. quantity - Cargo:              | 400 kg   |

#### 14.6. Special precautions for user

No information available.

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

not applicable

### SECTION 15: Regulatory information

## Safety Data Sheet

according to Regulation (EC) No. 1907/2006

### Detaferm®

Revision date: 08.11.2022

Product code: 1748

Page 8 of 9

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

##### EU regulatory information

Restrictions on use (REACH, annex XVII):

Entry 75

Information according to 2012/18/EU (SEVESO III): E1 Hazardous to the Aquatic Environment

##### National regulatory information

Employment restrictions: Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC).

Water hazard class (D): 3 - highly hazardous to water

#### 15.2. Chemical safety assessment

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

### SECTION 16: Other information

#### Abbreviations and acronyms

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

CAS: Chemical Abstracts Service

DNEL: Derived No Effect Level

DMEL: Derived Minimal Effect Level

PNEC: Predicted No Effect Concentration

ATE: Acute toxicity estimate

LC50: Lethal concentration, 50%

LD50: Lethal dose, 50%

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

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

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)

IMDG: International Maritime Code for Dangerous Goods

EmS: Emergency Schedules

MFAG: Medical First Aid Guide

IATA: International Air Transport Association

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: ECHA Guidance on information requirements and chemical safety assessment, chapter R.20 (Table of terms and abbreviations).



## Safety Data Sheet

according to Regulation (EC) No. 1907/2006

**Detaferm®**

Revision date: 08.11.2022

Product code: 1748

Page 9 of 9

**Classification for mixtures and used evaluation method according to Regulation (EC) No. 1907/2006**

| Classification          | Classification procedure |
|-------------------------|--------------------------|
| Eye Dam. 1; H318        | Calculation method       |
| Aquatic Acute 1; H400   | Calculation method       |
| Aquatic Chronic 1; H410 | Calculation method       |

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

|      |   |
|------|---|
| H302 | Harmful if swallowed.                                 |
| H318 | Causes serious eye damage.                            |
| H400 | Very toxic to aquatic life.                           |
| H410 | Very toxic 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 product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations.

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