

according to Regulation (EC) No 1907/2006

Revision date: 11.09.2018

**tempofit® semi (Base + Catalyst)**

Product code: 915

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

#### 1.1. Product identifier

tempofit® semi (Base + Catalyst)

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

##### Use of the substance/mixture

Composite material for use in dentistry.

#### 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

Hazard categories:

Skin corrosion/irritation: Skin Irrit. 2

Serious eye damage/eye irritation: Eye Irrit. 2

Respiratory or skin sensitisation: Skin Sens. 1A

Hazardous to the aquatic environment: Aquatic Chronic 3

Hazard Statements:

Causes skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

Harmful to aquatic life with long lasting effects.

#### 2.2. Label elements

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

##### Hazard components for labelling

isopropylidenediphenol peg-2 dimethacrylate

Triethylene glycol dimethacrylate

aliphatic urethane acrylate

2-hydroxyethyl methacrylate

methyl 2-methylprop-2-enoate; methyl 2-methylpropenoate; methyl methacrylate

Signal word: Warning

Pictograms:



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#### Hazard statements

|      |                                                    |
|------|----------------------------------------------------|
| H315 | Causes skin irritation.                            |
| H317 | May cause an allergic skin reaction.               |
| H319 | Causes serious eye irritation.                     |
| H412 | Harmful to aquatic life with long lasting effects. |

#### Precautionary statements

|           |                                                                                   |
|-----------|-----------------------------------------------------------------------------------|
| P261      | Avoid breathing dust/fume/gas/mist/vapours/spray.                                 |
| P280      | Wear protective gloves/protective clothing/eye protection/face protection.        |
| P302+P352 | IF ON SKIN: Wash with plenty of water.                                            |
| P333+P313 | If skin irritation or rash occurs: Get medical advice/attention.                  |
| P362+P364 | Take off contaminated clothing and wash it before reuse.                          |
| P501      | Dispose of contents/ container in accordance with local and national regulations. |

#### 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 according to Regulation (EC) No. 1272/2008 [CLP]              |              |                  |             |
| 27138-31-4 | Dipropylene glycol dibenzoate                                                |              |                  | 45 - < 50 % |
|            | 248-258-5                                                                    |              | 01-2119529241-49 |             |
|            | Aquatic Chronic 3; H412                                                      |              |                  |             |
| 41637-38-1 | isopropylidenediphenol peg-2 dimethacrylate                                  |              |                  | 10 - < 15 % |
|            |                                                                              |              |                  |             |
|            | Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1A, STOT SE 3; H315 H319 H317 H335   |              |                  |             |
| 109-16-0   | Triethylene glycol dimethacrylate                                            |              |                  | 10 - < 15 % |
|            | 203-652-6                                                                    |              | 01-2119969287-21 |             |
|            | Skin Sens. 1B; H317                                                          |              |                  |             |
|            | aliphatic urethane acrylate                                                  |              |                  | 5 - < 10 %  |
|            | 906-949-5                                                                    |              | 01-2120266262-   |             |
|            | Skin Sens. 1B, Aquatic Chronic 2; H317 H411                                  |              |                  |             |
| 868-77-9   | 2-hydroxyethyl methacrylate                                                  |              |                  | < 1 %       |
|            | 212-782-2                                                                    | 607-124-00-X |                  |             |
|            | Eye Irrit. 2, Skin Irrit. 2, Skin Sens. 1; H319 H315 H317                    |              |                  |             |
| 80-62-6    | methyl 2-methylprop-2-enoate; methyl 2-methylpropenoate; methyl methacrylate |              |                  | < 1 %       |
|            | 201-297-1                                                                    | 607-035-00-6 | 01-2119452498-28 |             |
|            | Flam. Liq. 2, Skin Irrit. 2, Skin Sens. 1, STOT SE 3; H225 H315 H317 H335    |              |                  |             |

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

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

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#### After inhalation

Provide fresh air. When in doubt or if symptoms are observed, get medical advice.

#### After contact with skin

After contact with skin, wash immediately with polyethylene glycol, followed by plenty of water. Take off immediately all contaminated clothing and wash it before reuse. Medical treatment necessary.

#### After contact with eyes

After contact with the eyes, rinse with water with the eyelids open for a sufficient length of time, then consult an ophthalmologist immediately.

#### After ingestion

Rinse mouth immediately and drink plenty 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.

### 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**

Wear a self-contained breathing apparatus and chemical protective clothing. Full protection suit.

#### **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**

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**

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

No special measures are necessary.

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

No special fire protection measures are necessary.

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

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#### Requirements for storage rooms and vessels

Keep container tightly closed.

#### 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)

Composite material for the fabrication of dental restorations like provisional crowns and bridges.  
For use by trained specialist staff.

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

##### Exposure limits (EH40)

| CAS No  | Substance           | ppm | mg/m³ | fibres/ml | Category      | Origin |
|---------|---------------------|-----|-------|-----------|---------------|--------|
| 80-62-6 | Methyl methacrylate | 50  | 208   |           | TWA (8 h)     | WEL    |
|         |                     | 100 | 416   |           | STEL (15 min) | WEL    |

#### 8.2. Exposure controls

##### 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

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.

Suitable are gloves of the following material: Butyl caoutchouc (butyl 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, low-viscosity  
Colour: base: tooth-like, catalyst: white  
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

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Flash point: >100 °C DIN 51755

#### Flammability

Solid: not applicable

Gas: not applicable

Lower explosion limits: not determined

Upper explosion limits: not determined

#### Auto-ignition temperature

Solid: not applicable

Gas: not applicable

Decomposition temperature: not determined

#### Oxidizing properties

Not oxidizing.

Vapour pressure:  
(at 20 °C) <1 hPa

Density (at 20 °C): 1,5 g/cm³ DIN 51757

Water solubility: insoluble

#### Solubility in other solvents

not determined

Partition coefficient: not determined

Viscosity / dynamic:  
(at 23 °C) 20000 mPa·s Rheostress

Vapour density: not determined

Evaporation rate: not determined

#### 9.2. Other information

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

Reacts with : oxidising agents, radicals forming substances or heavy metal ions.

#### 10.4. Conditions to avoid

The product may polymerise under the influence of higher temperatures, therefore keep in tightly closed containers at temperature not exceeding 25°C/ 77°F.

#### 10.5. Incompatible materials

No information available.

#### 10.6. Hazardous decomposition products

In case of fire, acrid acrylic fumes may occur.

### SECTION 11: Toxicological information

#### 11.1. Information on toxicological effects

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#### 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 |
| 27138-31-4 | Dipropylene glycol dibenzoate                                                |                  |         |        |        |
|            | oral                                                                         | LD50 3914 mg/kg  | Rat     |        |        |
|            | dermal                                                                       | LD50 >2000 mg/kg | Rat     |        |        |
|            | inhalation (4 h) vapour                                                      | LC50 >200 mg/l   | Rat     |        |        |
| 109-16-0   | Triethylene glycol dimethacrylate                                            |                  |         |        |        |
|            | oral                                                                         | LD50 10800 mg/kg | Rat     | GESTIS |        |
| 868-77-9   | 2-hydroxyethyl methacrylate                                                  |                  |         |        |        |
|            | oral                                                                         | LD50 5050 mg/kg  | Rat     |        |        |
|            | dermal                                                                       | LD50 >3000 mg/kg | Rabbit  |        |        |
| 80-62-6    | methyl 2-methylprop-2-enoate; methyl 2-methylpropenoate; methyl methacrylate |                  |         |        |        |
|            | oral                                                                         | LD50 7870 mg/kg  | Rat     |        |        |
|            | dermal                                                                       | LD50 >5000 mg/kg | Rabbit  |        |        |
|            | inhalation (4 h) vapour                                                      | LC50 78 mg/l     | Rat     |        |        |

#### Irritation and corrosivity

Causes skin irritation.

Causes serious eye irritation.

#### Sensitising effects

May cause an allergic skin reaction. (isopropylidenediphenol peg-2 dimethacrylate; Triethylene glycol dimethacrylate; aliphatic urethane acrylate; 2-hydroxyethyl methacrylate; methyl 2-methylprop-2-enoate; methyl 2-methylpropenoate; methyl methacrylate)

#### 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.

#### Aspiration hazard

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

#### Additional information on tests

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

## SECTION 12: Ecological information

### 12.1. Toxicity

Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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| CAS No     | Chemical name                                                                |      |           |         |                     |        |
|------------|------------------------------------------------------------------------------|------|-----------|---------|---------------------|--------|
|            | Aquatic toxicity                                                             | Dose | [h]   [d] | Species | Source              | Method |
| 27138-31-4 | Dipropylene glycol dibenzoate                                                |      |           |         |                     |        |
|            | Acute fish toxicity                                                          | LC50 | 3,7 mg/l  | 96 h    |                     |        |
| 868-77-9   | 2-hydroxyethyl methacrylate                                                  |      |           |         |                     |        |
|            | Acute fish toxicity                                                          | LC50 | 227 mg/l  | 96 h    | Pimephales promelas |        |
| 80-62-6    | methyl 2-methylprop-2-enoate; methyl 2-methylpropenoate; methyl methacrylate |      |           |         |                     |        |
|            | Acute fish toxicity                                                          | LC50 | >130 mg/l | 96 h    |                     |        |

#### 12.2. Persistence and degradability

The product has not been tested.

| CAS No     | Chemical name                                       |       |    |        |
|------------|-----------------------------------------------------|-------|----|--------|
|            | Method                                              | Value | d  | Source |
|            | Evaluation                                          |       |    |        |
| 27138-31-4 | Dipropylene glycol dibenzoate                       |       |    |        |
|            | CO2 Evolution Test                                  | 87%   | 28 |        |
|            | Readily biodegradable (according to OECD criteria). |       |    |        |
| 868-77-9   | 2-hydroxyethyl methacrylate                         |       |    |        |
|            | 84                                                  | %     | 28 |        |
|            | Leicht biologisch abbaubar                          |       |    |        |

#### 12.3. Bioaccumulative potential

The product has not been tested.

#### Partition coefficient n-octanol/water

| CAS No   | Chemical name               | Log Pow |
|----------|-----------------------------|---------|
| 868-77-9 | 2-hydroxyethyl methacrylate | 0,47    |

#### 12.4. Mobility in soil

The product has not been tested.

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

Not identified as PBT/ vPvB substances

#### 12.6. 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

##### Advice on disposal

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)

##### 14.1. UN number:

No dangerous good in sense of this transport regulation.

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|                                                 |                                                          |
|-------------------------------------------------|----------------------------------------------------------|
| <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**

##### National regulatory information

|                                |                                                                                                                   |
|--------------------------------|-------------------------------------------------------------------------------------------------------------------|
| Employment restrictions:       | Observe restrictions to employment for juvenils according to the 'juvenile work protection guideline' (94/33/EC). |
| Water contaminating class (D): | 3 - highly water contaminating                                                                                    |
| Skin resorption/Sensitization: | Causes allergic hypersensitivity reactions.                                                                       |

#### **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%

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#### Classification for mixtures and used evaluation method according to Regulation (EC) No. 1272/2008 [CLP]

| Classification          | Classification procedure |
|-------------------------|--------------------------|
| Skin Irrit. 2; H315     | Calculation method       |
| Eye Irrit. 2; H319      | Calculation method       |
| Skin Sens. 1A; H317     | Calculation method       |
| Aquatic Chronic 3; H412 | Calculation method       |

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

|      |                                                    |
|------|----------------------------------------------------|
| H315 | Causes skin irritation.                            |
| H317 | May cause an allergic skin reaction.               |
| H319 | Causes serious eye irritation.                     |
| H412 | Harmful to aquatic life with long lasting effects. |

#### Further Information

The information is based on present level of our knowledge. It does not, however, give assurances 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.)*