



according to Regulation (EC) No 1907/2006

### tempofit® regular (Base + Catalyst)

Revision date: 01.04.2019

Product code: 10302

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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]	
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	
3077-12-1	2,2-(4-methylphenylimino)-diethanol	0,1 - 5 %
	221-359-1	
	Skin Irrit. 2, Eye Irrit. 2; H315 H319	
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	
94-36-0	dibenzoyl peroxide; benzoyl peroxide	< 1 %
	202-327-6	617-008-00-0
	01-2119511472-50	
	Org. Perox. B, Eye Irrit. 2, Skin Sens. 1, Aquatic Acute 1, Aquatic Chronic 1; H241 H319 H317 H400 H410	
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.

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

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#### 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.

##### 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/m <sup>3</sup>	fibres/ml	Category	Origin
94-36-0	Dibenzoyl peroxide	-	5		TWA (8 h)	WEL
		-	-		STEL (15 min)	WEL
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

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pH-Value:	not determined
<b>Changes in the physical state</b>	
Melting point:	not determined
Initial boiling point and boiling range:	not determined
Flash point:	>100 °C DIN 51755
<b>Flammability</b>	
Solid:	not applicable
Gas:	not applicable
Lower explosion limits:	not determined
Upper explosion limits:	not determined
<b>Auto-ignition temperature</b>	
Solid:	not applicable
Gas:	not applicable
Decomposition temperature:	not determined
<b>Oxidizing properties</b>	
Not oxidizing.	
Vapour pressure: (at 20 °C)	<1 hPa
Density (at 20 °C):	1,5 g/cm <sup>3</sup> DIN 51757
Water solubility:	insoluble
<b>Solubility in other solvents</b>	
not determined	
Partition coefficient:	not determined
Viscosity / dynamic: (at 23 °C)	20000 mPa·s Rheostress
Vapour density:	not determined
Evaporation rate:	not determined
<b>9.2. Other information</b>	
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.

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## 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
109-16-0	Triethylene glycol dimethacrylate				
	oral	LD50 mg/kg 10800	Rat	GESTIS	
868-77-9	2-hydroxyethyl methacrylate				
	oral	LD50 mg/kg 5050	Rat		
	dermal	LD50 mg/kg >3000	Rabbit		
94-36-0	dibenzoyl peroxide; benzoyl peroxide				
	oral	LD50 mg/kg >5000	Rat		
	inhalation (4 h) aerosol	LC50 24,3 mg/l	Rat	OECD 403	
80-62-6	methyl 2-methylprop-2-enoate; methyl 2-methylpropenoate; methyl methacrylate				
	oral	LD50 mg/kg 7870	Rat		
	dermal	LD50 mg/kg >5000	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; dibenzoyl peroxide; benzoyl peroxide; 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
868-77-9	2-hydroxyethyl methacrylate					
	Acute fish toxicity	LC50 227 mg/l	96 h	Pimephales promelas		
94-36-0	dibenzoyl peroxide; benzoyl peroxide					
	Acute fish toxicity	LC50 0,06 mg/l	96 h	Oncorhynchus mykiss (Rainbow trout)	OECD 203	
	Acute algae toxicity	ErC50 0,07 mg/l	72 h	Pseudokirchneriella subcapitata	OECD 201	
	Acute crustacea toxicity	EC50 0,11 mg/l	48 h	Daphnia magna (Big water flea)	OECD 202	
	Acute bacteria toxicity	(35 mg/l)	0,5 h		OECD 209	
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				
868-77-9	2-hydroxyethyl methacrylate				
	84	%	28		
	Leicht biologisch abbaubar				
94-36-0	dibenzoyl peroxide; benzoyl peroxide				
	OECD 301D/ EEC 92/69/V, C.4-E	71%	28		
	Biodegradable.				

#### 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

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substance itself.

#### SECTION 14: Transport information

##### Land transport (ADR/RID)

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

##### Inland waterways transport (ADN)

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

##### Marine transport (IMDG)

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

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

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

To follow: 850/2004/EC, 79/117/EEC, 689/2008/EC

###### 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)

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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%

#### 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.  
 H335 May cause respiratory 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.)*