

according to Regulation (EC) No 1907/2006

### tempofill® 2

Revision date: 22.10.2020

Product code: 10069

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

### 1.1. Product identifier

tempofill® 2

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

#### Use of the substance/mixture

Ligth curing 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:

Respiratory or skin sensitisation: Skin Sens. 1

Hazardous to the aquatic environment: Aquatic Chronic 3

Hazard Statements:

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

2-[[[(butylamino)carbonyl]oxy]ethyl acrylate

2-hydroxyethyl acrylate

Signal word: Warning

Pictograms:



#### Hazard statements

H317 May cause an allergic skin reaction.

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/hearing protection.

P302+P352 IF ON SKIN: Wash with plenty of water.

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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

##### Chemical characterization

Mixture of methacrylic resins with auxiliary matters.

Contains: Calcium fluoride

##### Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	GHS Classification			
63225-53-6	2-[[butylamino]carbonyl]oxyethyl acrylate			5 - < 10 %
	264-036-0			
	Acute Tox. 3, Skin Sens. 1A, Aquatic Chronic 2; H331 H317 H411			
	urethane acrylate oligomer			1 - < 5 %
	Eye Irrit. 2; H319			
21245-02-3	2-Ethylhexyl 4-(dimethylamino)benzoate			< 1 %
	244-289-3		01-2120766649-35	
	Repr. 1B; H360			
818-61-1	2-hydroxyethyl acrylate			< 0.1 %
	212-454-9			
	Acute Tox. 3, Acute Tox. 4, Skin Corr. 1B, Skin Sens. 1, Aquatic Acute 1; H311 H302 H314 H317 H400			

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

##### Specific concentration limits and M-factors

CAS No	EC No	Chemical name	Quantity
	Specific concentration limits and M-factors		
818-61-1	212-454-9	2-hydroxyethyl acrylate	< 0,1 %
	Skin Sens. 1; H317: >= 0,2 - 100		

### 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 plenty of water and soap. Take off immediately all contaminated clothing and wash it before reuse. Medical treatment necessary.

##### After contact with eyes

Rinse immediately carefully and thoroughly with eye-bath or water. In case of eye irritation consult an ophthalmologist.

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**After ingestion**

Rinse mouth immediately and drink plenty of water.

Seek immediately medical advice. Do not induce vomiting. In case of spontaneous vomiting take care of an unhindered flow out of the vomit (danger of suffocation).

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

Keep container tightly closed.

**Hints on joint storage**

Do not store with strong oxidising materials. Keep away from strong acidic or alkaline substances.

**Further information on storage conditions**

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

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

Dental composite material for provisional filling and sealing.  
For use by trained specialist staff.

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

#### 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, drink, smoke, sniff.

##### 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: 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:	liquid: , viscous
Colour:	opaque
Odour:	aromatic

#### Test method

pH-Value:	not determined
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##### Changes in the physical state

Melting point:	not determined
Initial boiling point and boiling range:	not determined

Flash point:	>100 °C	DIN 51755
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##### Flammability

Solid:	not applicable
Gas:	not applicable

##### Explosive properties

The product is not: Explosive.

Lower explosion limits:	not determined
Upper explosion limits:	not determined

##### Auto-ignition temperature

Solid:	not applicable
Gas:	not applicable

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Decomposition temperature: not determined

#### **Oxidizing properties**

Not oxidizing.

Vapour pressure: <1 hPa  
(at 20 °C)

Density (at 20 °C): 1,72 g/cm<sup>3</sup> DIN 51757

Water solubility: insoluble

#### **Solubility in other solvents**

not determined

Partition coefficient: not determined

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**

Ultra-violet light and daylight initiate polymerisation of the product. Therefore keep only in tightly closed containers away from any sources of light. Keep 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**

##### **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
63225-53-6	2-[[[(butylamino)carbonyl]oxy]ethyl acrylate				
	oral	LD50 2000-5000 mg/kg	Ratte	OECD 423	
	inhalation vapour	ATE 3 mg/l			
	inhalation (4 h) aerosol	LC50 0,5 mg/l	Ratte	OECD 436	
21245-02-3	2-Ethylhexyl 4-(dimethylamino)benzoate				
	oral	LD50 14,900 mg/kg	Rat		
818-61-1	2-hydroxyethyl acrylate				
	oral	LD50 500 mg/kg	Rat		OECD 423
	dermal	LD50 150 mg/kg	Rabbit		OECD 436

#### Irritation and corrosivity

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

#### Sensitising effects

May cause an allergic skin reaction. (2-[[[(butylamino)carbonyl]oxy]ethyl acrylate; 2-hydroxyethyl acrylate)

#### 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 life with long lasting effects.

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CAS No	Chemical name					
	Aquatic toxicity	Dose	[h]   [d]	Species	Source	Method
63225-53-6	2-[[[(butylamino)carbonyl]oxy]ethyl acrylate					
	Acute fish toxicity	LC50 mg/l	2,52	96 h		OECD 203
	Acute algae toxicity	ErC50 mg/l	5,98	72 h		OECD 201
	Acute crustacea toxicity	EC50 mg/l	18,6	48 h	Daphnia magna (Big water flea)	OECD 202
21245-02-3	2-Ethylhexyl 4-(dimethylamino)benzoate					
	Acute fish toxicity	LC50 mg/l	0,235	96 h	QSAR	
	Acute algae toxicity	ErC50 mg/l	<0,015	72 h	Pseudokirchneriella subcapitata	
	Acute crustacea toxicity	EC50 mg/l	>0,031	48 h	Daphnia magna (Big water flea)	
	Acute bacteria toxicity	(1000 mg/l)		3 h	Activated sludge	
818-61-1	2-hydroxyethyl acrylate					
	Acute fish toxicity	LC50 mg/l	2,52	96 h		GESTIS OECD 203

#### 12.2. Persistence and degradability

The product has not been tested.

CAS No	Chemical name			
	Method	Value	d	Source
	Evaluation			
63225-53-6	2-[[[(butylamino)carbonyl]oxy]ethyl acrylate			
	OECD 301F	15%	28	
	Nicht leicht biologisch abbaubar			

#### 12.3. Bioaccumulative potential

The product has not been tested.

#### Partition coefficient n-octanol/water

CAS No	Chemical name	Log Pow
63225-53-6	2-[[[(butylamino)carbonyl]oxy]ethyl acrylate	1,82
818-61-1	2-hydroxyethyl acrylate	1,82

#### 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

##### Disposal recommendations

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

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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)

<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

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

##### 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 - strongly hazardous to water  
 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



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#### 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  
 VOC: Volatile Organic Compounds  
 SVHC: Substance of Very High Concern  
 @1602.B016012

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

Classification	Classification procedure
Skin Sens. 1; H317	Calculation method
Aquatic Chronic 3; H412	Calculation method

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

H302	Harmful if swallowed.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H331	Toxic if inhaled.
H360	May damage fertility or the unborn child.
H400	Very toxic to aquatic life.
H411	Toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.

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**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.

**Identified uses**

No	Short title	LCS	SU	PC	PROC	ERC	AC	TF	Specification
1	Gewerblich	-	-	-	-	-	-	-	2

LCS: Life cycle stages

PC: Product categories

ERC: Environmental release categories

TF: Technical functions

SU: Sectors of use

PROC: Process categories

AC: Article categories

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