

according to Regulation (EC) No 1907/2006

tempofill® 2

Revision date: 26.07.2018

Product code: 10069

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

1.1. Product identifier

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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 how	urs (Monday - Thursday 8.00 a.m.
	- 5.00 p.m., Friday 8.00 a.m 4.00 p.m.)	
1.4. Emergency telephone	+49 7243/510-0	
<u>number:</u>	This number is only obtainable during office how	urs (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. 1A
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

Signal word:

Pictograms:



Warning

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.
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.



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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				
	EC No	Index No	REACH No		
	Classification according to Regulation (EC) No. 1272/2008 [CLP]				
63225-53-6	2-[[(butylamino)carbonyl]oxy]ethyl a	acrylate		5 - < 10 %	
	264-036-0				
	Acute Tox. 3, Skin Sens. 1A, Aquatic Chronic 2; H331 H317 H411				
	urethane acrylate oligomer				
	Eye Irrit. 2; H319				

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. 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

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

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.



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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.

Advice on storage compatibility

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.

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 or drink.

Eye/face protection

Wear eye/face protection.

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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		
pH-Value:		not determined	Test method
Changes in the physical state			
Melting point:		not determined	
Initial boiling point and boiling range:		not determined	
Flash point:			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):		1,72 g/cm³	DIN 51757
Water solubility:		insoluble	
Solubility in other solvents not determined			
Partition coefficient:		not determined	
Vapour density:		not determined	
Evaporation rate:		not determined	
2. Other information			
Solid content:		not determined	

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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 ligth and dayligth 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.

CAS No	Chemical name					
	Exposure route	Dose		Species	Source	Method
63225-53-6	2-[[(butylamino)carbonyl]c	oxy]ethyl acry	/late			
	oral	LD50 5000 mg/kg	2000-	Ratte	OECD 423	
	inhalation vapour	ATE	3 mg/l			
	inhalation (4 h) aerosol	LC50	0,5 mg/l	Ratte	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)

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



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

CAS No	Chemical name						
	Aquatic toxicity	Dose		[h] [d]	Species	Source	Method
63225-53-6	2-[[(butylamino)carbonyl]o	xy]ethyl acry	late				
	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		Daphnia magna (Big water flea)	OECD 202	

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	

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

12.4. Mobility in soil

The product has not been tested.

12.5. Results of PBT and vPvB assessment

Not identivied 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	informat	ion
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Land transport (ADR/RID)

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

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14.4. Packing group:	No dangerous good in sense of this transport regulation.						
Inland waterways transport (ADN)							
<u>14.1. UN number:</u>	No dangerous good in sense of this transport regulation.						
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.						
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.						
14.4. Packing group:	No dangerous good in sense of this transport regulation.						
Marine transport (IMDG)							
<u>14.1. UN number:</u>	No dangerous good in sense of this transport regulation.						
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.						
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.						
14.4. Packing group:	No dangerous good in sense of this transport regulation.						
Air transport (ICAO-TI/IATA-DGR)							
<u>14.1. UN number:</u>	No dangerous good in sense of this transport regulation.						
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.						
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.						
14.4. Packing group:	No dangerous good in sense of this transport regulation.						
14.6. Special precautions for user No dangerous good in sense of this t	ransport regulation.						
14.7. Transport in bulk according to Annex No dangerous good in sense of this t							

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%

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

Classification procedure		
Calculation method		
Calculation method		



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Relevant H and EUH statements (number and full text)

H317	May cause an allergic skin reaction.
H331	Toxic if inhaled.
H411	Toxic to aquatic life with long lasting effects.

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 singulary 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 SU: Sectors of use									
PC: Product categories PROC: Process categories									
ERC: Environmental release categories AC: Arti					C: Article categories				
TF: Technical functions									

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