

Safety Data Sheet

according to Regulation (EG) Nr. 1907/2006

tempofit® premium (Base + Catalyst), all colours

Revision date: 21.08.2023

Product code: 10659

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

1.1. Product identifier

tempofit® premium (Base + Catalyst), all colours

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	
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 (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 (EG) Nr. 1272/2008

Skin Irrit. 2; H315
Eye Irrit. 2; H319
Skin Sens. 1A; H317
Aquatic Chronic 3; H412

Full text of hazard statements: see SECTION 16.

2.2. Label elements

Regulation (EG) Nr. 1272/2008

Hazard components for labelling

2-hydroxyethyl methacrylate
isopropylidenediphenol peg dimethacrylate
Triethylene glycol dimethacrylate
aliphatic urethane acrylate

Signal word: Warning

Pictograms:



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/hearing protection.

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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.

Special labelling of certain mixtures

EUH210 Safety data sheet available on request.

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 (EG) Nr. 1272/2008)			
27138-31-4	Dipropylene glycol dibenzoate			40 - < 60 %
	248-258-5		01-2119529241-49	
	Aquatic Chronic 3; H412			
2143103-44-8	aliphatic urethane acrylate			20 - < 40 %
	944-336-4		01-2120266262-60	
	Skin Sens. 1B, Aquatic Chronic 3; H317 H412			
41637-38-1	isopropylidenediphenol peg-2 dimethacrylate			5 - < 20 %
	Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1, STOT SE 3; H315 H319 H317 H335			
109-16-0	Triethylene glycol dimethacrylate			5 - < 20 %
	203-652-6		01-2119969287-21	
	Skin Sens. 1B; H317			
72846-00-5	1-benzyl-5-phenyl-hexahydropyrimidine-2,4,-6-trione			5 - < 20 %
			01-2120226211-75	
	Acute Tox. 4; H302			
868-77-9	2-hydroxyethyl methacrylate			0.1 - < 5 %
	212-782-2	607-124-00-X	01-2119490169-29	
	Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1; H315 H319 H317			

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

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Specific Conc. Limits, M-factors and ATE

CAS No	EC No	Chemical name	Quantity
Specific Conc. Limits, M-factors and ATE			
27138-31-4	248-258-5	Dipropylene glycol dibenzoate	40 - < 60 %
inhalation: LC50 = >200 mg/l (vapours); dermal: LD50 = >2000 mg/kg; oral: LD50 = 3914 mg/kg			
2143103-44-8	944-336-4	aliphatic urethane acrylate	20 - < 40 %
oral: LD50 = >5000 mg/kg			
109-16-0	203-652-6	Triethylene glycol dimethacrylate	5 - < 20 %
oral: LD50 = 10800 mg/kg			
72846-00-5		1-benzyl-5-phenyl-hexahydropyrimidine-2,4,-6-trione	5 - < 20 %
oral: ATE = 500 mg/kg			
868-77-9	212-782-2	2-hydroxyethyl methacrylate	0.1 - < 5 %
dermal: LD50 = >5000 mg/kg; oral: LD50 = 5564 mg/kg			

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

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

General advice

Provide adequate ventilation. Do not breathe gas/fumes/vapour/spray. Avoid contact with skin, eyes and clothes. Use personal protection equipment.

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6.2. Environmental precautions

Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

Other information

Absorb with liquid-binding material (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.

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.

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

8.2. Exposure controls

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.

Suitable are gloves of the following material: Butyl caoutchouc (butyl rubber)

Skin protection

Wear suitable protective clothing.

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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
Melting point/freezing point:	not determined	
Boiling point or initial boiling point and boiling range:	not determined	
Flammability:	not applicable	
	not applicable	
Lower explosion limits:	not determined	
Upper explosion limits:	not determined	
Flash point:	>100 °C	DIN 51755
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	
Vapour pressure:	<1 hPa	
(at 20 °C)		
Density (at 20 °C):	1,5 g/cm³	DIN 51757
Relative vapour density:	not determined	

9.2. Other information

Information with regard to physical hazard classes

Explosive properties

The product is not: Explosive.

Self-ignition temperature

Solid:

not applicable

Gas:

not applicable

Oxidizing properties

Not oxidizing.

Other safety characteristics

Evaporation rate:

not determined

Solid content:

not determined

Viscosity / dynamic:

20000 mPa·s Rheostress

(at 23 °C)

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

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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 hazard classes as defined in Regulation (EG) Nr. 1272/2008

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.

ATEmix calculated

ATE (oral) > 2000 mg/kg; ATE (dermal) > 2000 mg/kg; ATE (inhalation vapour) > 20 mg/l; ATE (inhalation dust/mist) > 5 mg/l

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
27138-31-4	Dipropylene glycol dibenzoate				
	oral	LD50 mg/kg	3914	Rat	
	dermal	LD50 mg/kg	>2000	Rat	
	inhalation (4 h) vapour	LC50 mg/l	>200	Rat	
2143103-44-8	aliphatic urethane acrylate				
	oral	LD50 mg/kg	>5000	Ratte	Lieferanten-Sicherheit sdatenblatt
109-16-0	Triethylene glycol dimethacrylate				
	oral	LD50 mg/kg	10800	Rat	GESTIS
72846-00-5	1-benzyl-5-phenyl-hexahydropyrimidine-2,4,-6-trione				
	oral	ATE mg/kg	500		
868-77-9	2-hydroxyethyl methacrylate				
	oral	LD50 mg/kg	5564	Rat	
	dermal	LD50 mg/kg	>5000	Rabbit	

Irritation and corrosivity

Causes skin irritation.

Causes serious eye irritation.

Sensitising effects

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

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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

The 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.

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			
2143103-44-8	aliphatic urethane acrylate					
	Acute fish toxicity	LC50 18 mg/l	96 h	Oncorhynchus mykiss	Lieferanten-SDB	OECD 203
	Acute crustacea toxicity	EC50 15.9 mg/l	48 h	Daphnia magna	Lieferanten-SDB	OECD 202
	Acute bacteria toxicity	(EC50 25.4 mg/l)		Pseudokirchneriella subcapitata	Lieferanten-SDB	OECD 201
868-77-9	2-hydroxyethyl methacrylate					
	Acute fish toxicity	LC50 >100 mg/l	96 h	Oryzias latipes		OECD 203
	Acute algae toxicity	ErC50 836 mg/l	72 h	Selenastrum capricornutum		OECD 201
	Acute crustacea toxicity	EC50 380 mg/l	48 h	Daphnia magna		OECD 202

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			
		92-100%	14	
	Readily biodegradable (according to OECD criteria).			

12.3. Bioaccumulative potential

The product has not been tested.

Partition coefficient n-octanol/water

CAS No	Chemical name	Log Pow
72846-00-5	1-benzyl-5-phenyl-hexahydropyrimidine-2,4,-6-trione	2,3

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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.

Not identified as PBT/ vPvB substances

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)

14.1. UN number or ID number:

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.

Inland waterways transport (ADN)

14.1. UN number or ID number:

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)

14.1. UN number or ID number:

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)

14.1. UN number or ID number:

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 transport regulation.

14.7. Maritime transport in bulk according to IMO instruments

No dangerous good in sense of this transport regulation.

SECTION 15: Regulatory information

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

EU regulatory information

Restrictions on use (REACH, annex XVII):

Entry 3, Entry 75

Information according to 2012/18/EU
(SEVESO III):

Not subject to 2012/18/EU (SEVESO III)

Additional information

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

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

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
For abbreviations and acronyms, see table at <http://abbrev.esdscom.eu>
Acute Tox: Acute toxicity
Skin Irrit: Skin irritation
Eye Irrit: Eye irritation
Skin Sens: Skin sensitisation
STOT SE: Specific target organ toxicity - single exposure
Aquatic Chronic: Chronic aquatic hazard

Classification for mixtures and used evaluation method according to Regulation(EG) Nr. 1272/2008

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)

H302 Harmful if swallowed.
H315 Causes skin irritation.

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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.
EUH210	Safety data sheet available on request.

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.)