

Safety Data Sheet

according to Regulation (EC) No 1907/2006

Revision date: 31.10.2019

tempofit® finish

Product code: 10175

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

1.1. Product identifier

tempofit® finish

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

Use of the substance/mixture

Ligth curing sealing lacquer for use in dentistry.

1.3. Details of the supplier of the safety data sheet

Manufacturer

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.)

Importer / Distributer

Company name: Ivoclar Vivadent Ltd
Place: PO Box 303011, North Harbour, Auckland, 0751
Telephone: +64 9 914 9999 Telefax: +64 9 914 9990

1.4. Emergency telephone number:

0800 764 766 Poison Hotline (24 hours / 7 days)
NZ: National Poison Centre (New Zealand)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No. 1272/2008

Hazard categories:

Flammable liquid: Flam. Liq. 2

Skin corrosion/irritation: Skin Irrit. 2

Serious eye damage/eye irritation: Eye Irrit. 2

Respiratory or skin sensitisation: Skin Sens. 1A

Specific target organ toxicity - single exposure: STOT SE 3

Hazardous to the aquatic environment: Aquatic Chronic 3

Hazard Statements:

Highly flammable liquid and vapour.

Causes skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

May cause respiratory irritation.

Harmful to aquatic life with long lasting effects.

2.2. Label elements

Regulation (EC) No. 1272/2008

Hazard components for labelling

"methyl 2-methylprop-2-enoate; methyl 2-methylpropenoate; methyl methacrylate, MMA"

acrylic acid derivatives

vinylester resin

phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide

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Signal word: Danger**Pictograms:****Hazard statements**

H225	Highly flammable liquid and vapour.
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.

Precautionary statements

P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P235	Keep cool.
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P280	Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
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 acrylic/ methacrylic resins with auxilliary matters.

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Hazardous components

CAS No	Chemical name	Quantity
	EC No	
	Index No	
	REACH No	
	GHS Classification	
80-62-6	"methyl 2-methylprop-2-enoate; methyl 2-methylpropenoate; methyl methacrylate, MMA"	10 - 50 %
	201-297-1	607-035-00-6
	Flam. Liq. 2, Skin Irrit. 2, Skin Sens. 1, STOT SE 3; H225 H315 H317 H335	
	acrylic acid derivates	20 - 50 %
	Eye Irrit. 2, Skin Sens. 1A, Aquatic Chronic 3; H319 H317 H412	
	aliphatic polyestertriurethane triacrylate	1 - 20 %
	Skin Irrit. 2, Eye Irrit. 2; H315 H319	
55818-57-0	vinylester resin	1 - < 5 %
		01-2119490020-53
	Skin Sens. 1; H317	
162881-26-7	phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide	0,1 - 5 %
	423-340-5	015-189-00-5
	Skin Sens. 1, Aquatic Chronic 4; H317 H413	01-2119489401-38

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. Medical treatment necessary.

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.

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

 Water spray jet, Carbon dioxide (CO₂), Foam, Extinguishing powder.

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5.2. Special hazards arising from the substance or mixture

Highly flammable. Vapours can form explosive mixtures with air.

5.3. Advice for firefighters

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

Additional information

Use water spray jet to protect personnel and to cool endangered containers. 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

Remove all sources of ignition. 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 uncontrolled discharge of product into the environment. Danger of explosion

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

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

Advice on protection against fire and explosion

Keep away from sources of ignition. - No smoking. Take precautionary measures against static discharges . Vapours can form explosive mixtures with air.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed. Keep in a cool, well-ventilated place. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Hints on joint storage

Do not store together with: Oxidising agent. Pyrophoric or self-heating substances.

Further information on storage conditions

Keep away from all kind of lighth. An inert gas blanket should not be applied, because the stability of the product depends on the presence of oxygen (air).

7.3. Specific end use(s)

Lacquer for sealing of dental restorations like crowns and bridges.

For use by trained specialist staff.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

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Exposure limits (EH40)

CAS No	Substance	ppm	mg/m ³	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
Appropriate engineering controls

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

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

Flame-retardant protective clothing. Wear anti-static footwear and 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:
 Colour: light yellow
 Odour: faintly like esters

Test method

pH-Value: not determined

Changes in the physical state

Melting point: not determined

Initial boiling point and boiling range: 92 °C DIN51356

Flash point: 12 °C DIN51755

Sustaining combustion: No data available

Flammability

Solid: not applicable

Gas: not applicable

Lower explosion limits: 2 vol. %

Upper explosion limits: 12 vol. %

Ignition temperature: >400 °C DIN 51794

Auto-ignition temperature

Solid: not applicable

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Gas:	not applicable
Decomposition temperature:	>100 °C
Oxidizing properties	
Not oxidizing.	
Vapour pressure: (at 20 °C)	40 hPa
Vapour pressure: (at 50 °C)	160 hPa
Density (at 20 °C):	1,07 g/cm ³ DIN 51757
Water solubility: (at 20 °C)	16 g/L
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

Highly flammable.

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

Keep away from sources of heat (e.g. hot surfaces), sparks and open flames. Vapours can form explosive mixtures with air. Ultra-violet light and daylight initiate polymerisation of the product. Therefore keep only in tightly closed containers away from any sources of light. Keep in a refrigerator at 2°C - 12°C / 36°F - 54 °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.

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CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
80-62-6	"methyl 2-methylprop-2-enoate; methyl 2-methylpropenoate; methyl methacrylate, MMA"				
	oral	LD50 mg/kg	7870	Rat	
	dermal	LD50 mg/kg	>5000	Rabbit	
	inhalation (4 h) vapour	LC50	78 mg/l	Rat	
	acrylic acid derivatives				
	oral	LD50 mg/kg	2000	Rat	OECD 423
	dermal	LD50 mg/kg	2000	Rabbit	OECD 402
162881-26-7	phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide				
	oral	LD50 mg/kg	>2000	Rat	OECD 401
	dermal	LD50 mg/kg	>2000	Rat	OECD 402

Irritation and corrosivity

Causes skin irritation.

Causes serious eye irritation.

Sensitising effects

May cause an allergic skin reaction. ("methyl 2-methylprop-2-enoate; methyl 2-methylpropenoate; methyl methacrylate, MMA"; acrylic acid derivatives; vinyl ester resin; phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide)

Carcinogenic/mutagenic/toxic effects for reproduction

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

STOT-single exposure

May cause respiratory irritation. ("methyl 2-methylprop-2-enoate; methyl 2-methylpropenoate; methyl methacrylate, MMA")

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
80-62-6	"methyl 2-methylprop-2-enoate; methyl 2-methylpropenoate; methyl methacrylate, MMA"					
	Acute fish toxicity	LC50 mg/l	>100	96 h		
	acrylic acid derivatives					
	Algae toxicity	NOEC	10 mg/l	72 d	Pseudokirchneriella subcapitata	OECD 201
162881-26-7	phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide					
	Acute fish toxicity	LC50 mg/l	>0,09	96 h	Brachydanio rerio (zebra-fish)	OECD 203
	Acute algae toxicity	ErC50 mg/l	>0,26	72 h	Desmodesmus subspicatus.	OECD 201
	Acute crustacea toxicity	EC50 mg/l	>1,175	48 h	Daphnia magna (Big water flea)	OECD 202
	Crustacea toxicity	NOEC mg/l	>0,008	21 d	Daphnia magna (Big water flea)	OECD 211
	Acute bacteria toxicity	(>100 mg/l)		3 h	OECD 209	

12.2. Persistence and degradability

The product has not been tested.

CAS No	Chemical name			
	Method	Value	d	Source
	Evaluation			
162881-26-7	phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide			
	CO2 formation (% of the theoretical value).	1%	29	
	Not 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
162881-26-7	phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide	5,8

BCF

CAS No	Chemical name	BCF	Species	Source
162881-26-7	phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide	<5	Cyprinus carpio (Common Carp)	OECD 305

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

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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:	UN 1866
14.2. UN proper shipping name:	Resin solution
14.3. Transport hazard class(es):	3
14.4. Packing group:	II
Hazard label:	3
Classification code:	F1
Limited quantity:	5 L/ 30 kg
Hazard No:	33
Tunnel restriction code:	D/E

Other applicable information (land transport)

Flammable liquid

Marine transport (IMDG)

14.1. UN number:	UN 1866
14.2. UN proper shipping name:	Resin solution
14.3. Transport hazard class(es):	3
14.4. Packing group:	II
Hazard label:	3
Marine pollutant:	-
Special Provisions:	-
Limited quantity:	5 L/ 30 kg
EmS:	F-E, S-E

Other applicable information (marine transport)

Flash point: 12°C c.c.

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number:	UN 1866
14.2. UN proper shipping name:	Resin solution
14.3. Transport hazard class(es):	3
14.4. Packing group:	II
Hazard label:	3
Limited quantity Passenger:	1 L/ 30 kg
Passenger LQ:	Y341
IATA-packing instructions - Passenger:	353
IATA-max. quantity - Passenger:	5 L
IATA-packing instructions - Cargo:	364
IATA-max. quantity - Cargo:	60 L

Other applicable information (air transport)

Flash point: 12°C c.c.

14.6. Special precautions for user

Warning: Combustible liquid.

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14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

not applicable

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

Classified as Hazardous according to the criteria of the National Occupational Health and Safety Commission (NOHSC) approved criteria for the classifying hazardous substances [NOHSC: 1008] 3rd edition.

Standard for the Uniform Scheduling of Medicines and Poisons.

Carcinogen classification under WHS Regulation 2011, Schedule 10.

Notification status in accordance with section 3 and current national legislation.

HSNO Approval: HSR001195

EPA NZ Classes of hazardous properties:

Classification 3.1B Flammable liquid - high hazard

Classification 6.1D (All) Substances that are acutely toxic - Fatal

Classification 6.1D (I)

Classification 6.1E (O)

Classification 6.3B Substances that are mildly irritating to the skin

Classification 6.4A Substances that are irritating to the eye

Classification 6.5B Substances that are contact sensitisers

Classification 6.9B (All) Substances that are harmful to human target organs or systems

Classification 6.9B (I)

Classification 9.1D (All) Substances that are slightly harmful to the aquatic environment or are otherwise designed for biocidal action

Classification 9.1D (F)

Classification 9.1D (C)

Classification 9.1D (A)

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%

Relevant H and EUH statements (number and full text)

H225 Highly flammable liquid and vapour.

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.
H413	May cause long lasting harmful effects to aquatic life.

Further Information

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

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: 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.)