

Safety Data Sheet

according to Regulation (EC) No. 1907/2006

freeform® fixgel

Revision date: 21.12.2022

Product code: 10340

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

1.1. Product identifier

freeform® fixgel

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

Use of the substance/mixture

Light curing one-component material for repair and reinforcement of individual dental moulding parts.

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 (EC) No. 1907/2006

Skin Sens. 1; H317
 Repr. 1B; H360
 Aquatic Chronic 2; H411

Full text of hazard statements: see SECTION 16.

2.2. Label elements

Regulation (EC) No. 1907/2006

Hazard components for labelling

7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate
 tetrahydrofurfuryl methacrylate THFMA purified grade
 diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

Signal word: Danger

Pictograms:



Hazard statements

H317	May cause an allergic skin reaction.
H360	May damage fertility or the unborn child.
H411	Toxic to aquatic life with long lasting effects.

Precautionary statements

P201	Obtain special instructions before use.
P273	Avoid release to the environment.
P280	Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P308+P313	IF exposed or concerned: Get medical advice/attention.
P391	Collect spillage.

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Special labelling of certain mixtures

Restricted to professional users.

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.

Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (Regulation (EC) No. 1907/2006)			
72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate			60 - < 80 %
	276-957-5		01-2120751202-68	
	Skin Sens. 1B, Aquatic Chronic 2; H317 H411			
2455-24-5	tetrahydrofurfuryl methacrylate THFMA purified grade			5 - < 20 %
	219-529-5		01-2120748481-53	
	Repr. 1B, Skin Sens. 1, Aquatic Chronic 3; H360 H317 H412			
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide			0.1 - < 5 %
	278-355-8	015-203-00-X	01-2119972295-29	
	Repr. 2, Skin Sens. 1B, Aquatic Chronic 2; H361 H317 H411			
97-99-4	tetrahydrofurfuryl alcohol			0.1 - < 5 %
	202-625-6	603-061-00-7	01-2119968921-26	
	Repr. 1B, Eye Irrit. 2; H360 H319			

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

Specific Conc. Limits, M-factors and ATE

CAS No	EC No	Chemical name	Quantity
	Specific Conc. Limits, M-factors and ATE		
72869-86-4	276-957-5	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate	60 - < 80 %
	dermal: LD50 = >2000 mg/kg; oral: LD50 = >5000 mg/kg		
75980-60-8	278-355-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	0.1 - < 5 %
	dermal: LD50 = >2000 mg/kg; oral: LD50 = >5000 mg/kg		
97-99-4	202-625-6	tetrahydrofurfuryl alcohol	0.1 - < 5 %
	oral: LD50 = 1600 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 eye contact: Rinse immediately carefully and thoroughly with eye-bath or water. Consult an

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ophthalmologist.

After ingestion

If accidentally swallowed rinse the mouth with plenty of water (only if the person is conscious) and obtain immediate medical attention. 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

General advice

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

For cleaning up

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.

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

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

No special fire protection measures are necessary.

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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. 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.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed. Keep locked up. Store in a place accessible by authorized persons only. Provide adequate ventilation as well as local exhaust at critical locations.

Hints on joint storage

Keep away from spontaneous flammable or combustible substances.

Further information on storage conditions

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

Lighth curing material for processing of dental moulded parts.
For use by trained specialist staff.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

DNEL/DMEL values

CAS No	Substance	Exposure route	Effect	Value
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide			
Worker DNEL, long-term		inhalation	systemic	0,822 mg/m ³
Worker DNEL, long-term		dermal	systemic	0,233 mg/kg bw/day
Consumer DNEL, long-term		inhalation	systemic	0,145 mg/m ³
Consumer DNEL, long-term		dermal	systemic	0,0833 mg/kg bw/day
Consumer DNEL, long-term		oral	systemic	0,0833 mg/kg bw/day

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.

Individual protection measures, such as personal protective equipment

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)

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Skin protection

Use of 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	
Colour:	several shades, according to the product name	
Odour:	faintly like esters	
		Test method
Melting point/freezing point:	not determined	
Boiling point or initial boiling point and boiling range:	93 °C	
Flammability		
Solid/liquid:	not applicable	
Gas:	not applicable	
Lower explosion limits:	not determined	
Upper explosion limits:	not determined	
Flash point:	>100 °C	DIN 51755
Auto-ignition temperature:	250 °C	
Decomposition temperature:	>=190 °C	
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):	1,09 g/cm ³	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.

Oxidizing properties

The product is not: oxidising.

Other safety characteristics

Evaporation rate: not determined

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 : strong oxidising agents, strong alkaline or acidic materials.

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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 at 15°C - 28°C / 59°F - 82 °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 (EC) No. 1907/2006

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
72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate				
	oral	LD50 >5000 mg/kg	Rat	OECD 401	
	dermal	LD50 >2000 mg/kg	Rat	OECD 402	
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide				
	oral	LD50 >5000 mg/kg	Rat		
	dermal	LD50 >2000 mg/kg	Rat		
97-99-4	tetrahydrofurfuryl alcohol				
	oral	LD50 1600 mg/kg	Rat		

Irritation and corrosivity

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

Sensitising effects

May cause an allergic skin reaction. (7,7,9(or 7,9,9)

-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate; tetrahydrofurfuryl methacrylate THFMA purified grade; diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide)

Carcinogenic/mutagenic/toxic effects for reproduction

May damage fertility or the unborn child. (tetrahydrofurfuryl methacrylate THFMA purified grade; tetrahydrofurfuryl alcohol)

Germ cell mutagenicity: Based on available data, the classification criteria are not met.

Carcinogenicity: 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.

Further information

The mixture is classified as hazardous according to regulation (EC) No 1272/2008 [CLP]. Special hazards arising from the substance or mixture!

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SECTION 12: Ecological information

12.1. Toxicity

Toxic to aquatic life with long lasting effects. For the product itself no toxicological data are available. In products with a comparable composition, a LD50 (orally, species rat) of more than 5.000 mg/kg has been found.

CAS No	Chemical name					
	Aquatic toxicity	Dose	[h] [d]	Species	Source	Method
72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate					
	Acute fish toxicity	LC50 mg/l	10,1	96 h		OECD 203
	Acute algae toxicity	ErC50 mg/l	0,21	72 h		OECD 201
	Acute crustacea toxicity	EC50 mg/l	>1,2	48 h	Daphnia magna (Big water flea)	OECD 202
2455-24-5	tetrahydrofurfuryl methacrylate THFMA purified grade					
	Acute fish toxicity	LC50 mg/l	34,7	96 h		GESTIS
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide					
	Acute algae toxicity	ErC50 mg/l	>2,01	72 h	Pseudokirchneriella subcapitata	
	Acute crustacea toxicity	EC50 mg/l	3,53	48 h	Daphnia magna (Big water flea)	
	Acute bacteria toxicity	(EC50 mg/l)	>1000	3 h	Activated sludge	

12.2. Persistence and degradability

The product has not been tested.

CAS No	Chemical name				
	Method	Value	d	Source	
	Evaluation				
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide				
		0-10%	28		
	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
72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate	3,39
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	3,1

BCF

CAS No	Chemical name	BCF	Species	Source
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	47-55	Cyprinus carpio (Common Carp)	

12.4. Mobility in soil

The product has not been tested.

12.5. Results of PBT and vPvB assessment

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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

Hazardous waste according to Directive 2008/98/EC (waste framework directive). Handle contaminated packages in the same way as the substance itself.

SECTION 14: Transport information

Land transport (ADR/RID)

<u>14.1. UN number or ID number:</u>	UN 3082
<u>14.2. UN proper shipping name:</u>	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
<u>14.3. Transport hazard class(es):</u>	9
<u>14.4. Packing group:</u>	III
Hazard label:	9
Classification code:	M6
Special Provisions:	274 335 375 601
Limited quantity:	5 L
Excepted quantity:	E1
Transport category:	3
Hazard No:	90
Tunnel restriction code:	-

Other applicable information (land transport)

Contains: 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahehexadecane-1,16-diylbismethacrylate

Marine transport (IMDG)

<u>14.1. UN number or ID number:</u>	UN 3082
<u>14.2. UN proper shipping name:</u>	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. Contains: 7,7,9(or 7,9,9) -trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahehexadecane-1,16-diylbismetha crylate
<u>14.3. Transport hazard class(es):</u>	9
<u>14.4. Packing group:</u>	III
Hazard label:	9
Marine pollutant:	YES
Special Provisions:	274, 335, 969
Limited quantity:	5 L/ 30 kg
Excepted quantity:	E1
EmS:	F-A, S-F

Other applicable information (marine transport)

Contains: 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahehexadecane-1,16-diylbismethacrylate
Flash point: > 100°C

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Air transport (ICAO-TI/IATA-DGR)

14.1. UN number or ID number:	UN 3082
14.2. UN proper shipping name:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. Contains: 7,7,9(or 7,9,9) -trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahehexadecane-1,16-diylbismethacrylate
14.3. Transport hazard class(es):	9
14.4. Packing group:	III
Hazard label:	9
Special Provisions:	A97 A158 A197
Limited quantity Passenger:	30 kg G
Passenger LQ:	Y964
Excepted quantity:	E1
IATA-packing instructions - Passenger:	964
IATA-max. quantity - Passenger:	450 L
IATA-packing instructions - Cargo:	964
IATA-max. quantity - Cargo:	450 L

Other applicable information (air transport)

Contains: 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahehexadecane-1,16-diylbismethacrylate

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: Yes

14.6. Special precautions for user

No information available.

14.7. Maritime transport in bulk according to IMO instruments

not applicable

SECTION 15: Regulatory information

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 30, Entry 75

Information according to 2012/18/EU (SEVESO III): E2 Hazardous to the Aquatic Environment

National regulatory information

Employment restrictions: Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC). Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers.

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

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

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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
 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
 SVHC: Substance of Very High Concern
 For abbreviations and acronyms, see: ECHA Guidance on information requirements and chemical safety assessment, chapter R.20 (Table of terms and abbreviations).

Classification for mixtures and used evaluation method according to Regulation (EC) No. 1907/2006

Classification	Classification procedure
Skin Sens. 1; H317	Calculation method
Repr. 1B; H360	Calculation method
Aquatic Chronic 2; H411	Calculation method

Relevant H and EUH statements (number and full text)

H317 May cause an allergic skin reaction.
 H319 Causes serious eye irritation.
 H360 May damage fertility or the unborn child.
 H361 Suspected of damaging fertility or the unborn child.
 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 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.

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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.)