

according to Regulation (EC) No 1907/2006

freeform® fixgel

Revision date: 07.12.2018 Product code: 10340 Page 1 of 8

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 & 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 +49 7243/510-0

number: 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:

Skin corrosion/irritation: Skin Irrit. 2

Serious eye damage/eye irritation: Eye Irrit. 2 Respiratory or skin sensitisation: Skin Sens. 1

Reproductive toxicity: Repr. 2

Hazard Statements:
Causes skin irritation.
Causes serious eye irritation.
May cause an allergic skin reaction.

Suspected of damaging fertility or the unborn child.

2.2. Label elements

Regulation (EC) No. 1272/2008

Hazard components for labelling

tetrahydrofurfuryl methacrylate THFMA purified grade diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

Signal word: Warning

Pictograms:





Hazard statements

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.



according to Regulation (EC) No 1907/2006

freeform® fixgel

Revision date: 07.12.2018 Product code: 10340 Page 2 of 8

H361 Suspected of damaging fertility or the unborn child.

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.

P362+P364 Take off contaminated clothing and wash it before reuse.

P501 Dispose of contents/ container in accordance with local and national regulations.

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	Chemical name				
	EC No	Index No	REACH No			
	Classification according to Regul	ation (EC) No. 1272/2008 [CLP]	•			
2455-24-5	tetrahydrofurfuryl methacrylate THFMA purified grade					
	Repr. 2, Skin Irrit. 2, Eye Irrit. 2, S	kin Sens. 1, STOT SE 3; H361 H315 I	H319 H317 H335			
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)p	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide				
	278-355-8	015-203-00-X				
	Repr. 2, Skin Sens. 1B, Aquatic Chronic 2; H361f H317 H411					

Full text of H and FUH 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

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





according to Regulation (EC) No 1907/2006

freeform® fixqel

Revision date: 07.12.2018 Product code: 10340 Page 3 of 8

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

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.

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 exhaustion at critical locations.

Advice on storage compatibility

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 ligth. 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)

Ligth curing material for processing of dental moulded parts.

For use by trained specialist staff.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.2. Exposure controls



according to Regulation (EC) No 1907/2006

freeform® fixgel

Revision date: 07.12.2018 Product code: 10340 Page 4 of 8

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

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

Colour: several shades, according to the product name

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: not determined

Flash point: >100 °C 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: >=190 °C

Oxidizing properties

Not oxidizing.

Vapour pressure: <1 hPa

(at 20 °C)

Density (at 20 °C): 1,09 g/cm³ DIN 51757

Water solubility: insoluble



according to Regulation (EC) No 1907/2006

freeform® fixgel

Revision date: 07.12.2018 Product code: 10340 Page 5 of 8

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: strong oxidising agents, strong alcaline or acidic materials.

10.4. Conditions to avoid

Ultra-violet ligth and dayligth initiate polymerisation of the product. Therefore keep only in tigthly closed containers away from any sources of ligth 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 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				
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide								
	oral	LD50 >5000 mg/kg	Rat						
	dermal	LD50 >2000 mg/kg	Rat						

Irritation and corrosivity

Causes skin irritation.

Causes serious eye irritation.

Sensitising effects

May cause an allergic skin reaction. (tetrahydrofurfuryl methacrylate THFMA purified grade; diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide)

Carcinogenic/mutagenic/toxic effects for reproduction



according to Regulation (EC) No 1907/2006

freeform® fixgel

Revision date: 07.12.2018 Product code: 10340 Page 6 of 8

Suspected of damaging fertility or the unborn child. (tetrahydrofurfuryl methacrylate THFMA purified grade;

diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide)

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.

Additional information on tests

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

SECTION 12: Ecological information

12.1. Toxicity

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.

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CAS No	Chemical name							
	Aquatic toxicity	Dose		[h] [d]	Species	Source	Method	
2455-24-5	tetrahydrofurfuryl methacrylate THFMA purified grade							
	Acute fish toxicity	LC50 3 mg/l	34,7	96 h		GESTIS		
75980-60-8	diphenyl(2,4,6-trimethylbe	enzoyl)phosphin	ne oxide					
	Acute algae toxicity	ErC50 >	>2,01		Scenedesmus subspicatus			
	Acute crustacea toxicity	EC50 3 mg/l	3,53		Daphnia magna (Big water flea)			
Acute bacteria toxicity (>1000 mg/l) 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
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	3,1

BCF

CAS No	Chemical name	BCF	Species	Source
	diphenyl(2,4,6-trimethylbenzoyl)phosphi ne oxide		Cyprinus carpio (Common Carp)	

12.4. Mobility in soil

The product has not been tested.



according to Regulation (EC) No 1907/2006

freeform® fixgel

Revision date: 07.12.2018 Product code: 10340 Page 7 of 8

12.5. Results of PBT and vPvB assessment

Not identivied as PBT/ vPvB substances

12.6. Other adverse effects

No information available.

Further information

Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Advice on disposal

Do not allow to enter into surface water or drains. Dispose of waste according to applicable legislation.

Contaminated packaging

This material and its container must be disposed of as hazardous waste. Handle contaminated packages in the same way as the substance itself.

SECTION 14: Transport information

Land transport (ADR/RID)

14.1. UN 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:	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:	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:	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 information available.

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

National regulatory information



according to Regulation (EC) No 1907/2006

freeform® fixgel

Revision date: 07.12.2018 Product code: 10340 Page 8 of 8

Employment restrictions: Observe restrictions to employment for juvenils 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 contaminating class (D): 1 - slightly 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 Classification procedure					
Skin Irrit. 2; H315	Calculation method				
Eye Irrit. 2; H319	Calculation method				
Skin Sens. 1; H317	Calculation method				
Repr. 2; H361	Calculation method				

Relevant H and EUH statements (number and full text)

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.
 H319 Causes serious eye irritation.
 H335 May cause respiratory irritation.

H361 Suspected of damaging fertility or the unborn child.

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

PC: Product categories
ERC: Environmental release categories

SU: Sectors of use PROC: Process categories AC: Article categories

TF: Technical functions

LCS: Life cycle stages

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