

Safety Data Sheet

according to Regulation (EC) No. 1907/2006

freeprint® ortho 385

Revision date: 17.12.2020

Product code: 839

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

1.1. Product identifier

freeprint® ortho 385

UFI: 6QA0-M1R2-K00A-JN1E

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 the fabrication of dental splints and guides.

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 Irrit. 2; H315
Eye Irrit. 2; H319
Skin Sens. 1; H317
STOT SE 3; H335
Aquatic Chronic 3; H412

Full text of hazard statements: see SECTION 16.

2.2. Label elements

Regulation (EC) No. 1907/2006

Hazard components for labelling

isopropylidenediphenol peg dimethacrylate
7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate
@0000030484.1
Hydroxy propyl methacrylate
tetrahydrofurfuryl methacrylate THFMA purified grade
diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide
@0000030484.2

Signal word: Warning

Pictograms:



Hazard statements

H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.

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H335 May cause respiratory 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.
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.

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-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate			40 - < 60 %
	276-957-5		01-2120751202-68	
	Skin Sens. 1B, Aquatic Chronic 2; H317 H411			
41637-38-1	isopropylidenediphenol peg dimethacrylate			20 - < 40 %
	609-946-4		01-2119980659-17	
	Aquatic Chronic 4; H413			
72829-09-5	1,12-Dodecanediol Dimethacrylate			5 - < 20 %
	276-900-4		01-2120756306-53	
	Skin Sens. 1B, Aquatic Acute 1, Aquatic Chronic 1; H317 H400 H410			
27813-02-1	Hydroxy propyl methacrylate			0.1 - < 5 %
	248-666-3		01-2119490226-37	
	Eye Irrit. 2, Skin Sens. 1; H319 H317			
2455-24-5	tetrahydrofurfuryl methacrylate THFMA purified grade			0.1 - < 5 %
	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			
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	
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	40 - < 60 %
		dermal: LD50 = >2000 mg/kg; oral: LD50 = >5000 mg/kg	
41637-38-1	609-946-4	isopropylidenediphenol peg dimethacrylate	20 - < 40 %
		dermal: LD50 = >2000 mg/kg; oral: LD50 = >2000 mg/kg	
72829-09-5	276-900-4	1,12-Dodecanediol Dimethacrylate	5 - < 20 %
		oral: LD50 = >2000 mg/kg	
27813-02-1	248-666-3	Hydroxy propyl methacrylate	0.1 - < 5 %
		dermal: LD50 = >5000 mg/kg; oral: LD50 = >2000 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	
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 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

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

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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

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.

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 or drink.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed.

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 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 fabrication of dental splints and guides.

For use by trained specialist staff.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

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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/m³
Worker DNEL, long-term		dermal	systemic	0,233 mg/kg bw/day
Consumer DNEL, long-term		inhalation	systemic	0,145 mg/m³
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

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: clear
 Odour: faintly like esters

Test method

Melting point/freezing point: not determined
 Boiling point or initial boiling point and boiling range: not determined
 Flammability
 Solid/liquid: not applicable
 Gas: not applicable
 Lower explosion limits: not determined
 Upper explosion limits: not determined
 Flash point: >100 °C DIN 51755
 Decomposition temperature: >=190 °C
 pH-Value: not determined

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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: (at 20 °C)	<1 hPa
Density (at 20 °C):	1,09 g/cm³ DIN 51757
Relative vapour density:	not determined

9.2. Other information

Information with regard to physical hazard classes

Self-ignition temperature

Solid:

not applicable

Gas:

not applicable

Oxidizing properties

Not oxidizing.

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.

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

No known hazardous decomposition products.

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.

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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	
41637-38-1	isopropylidenediphenol peg dimethacrylate				
	oral	LD50 >2000 mg/kg	Rat		
	dermal	LD50 >2000 mg/kg	Rat		
72829-09-5	1,12-Dodecanediol Dimethacrylate				
	oral	LD50 >2000 mg/kg	Rat		
27813-02-1	Hydroxy propyl methacrylate				
	oral	LD50 >2000 mg/kg	Rat	OECD 401	
	dermal	LD50 >5000 mg/kg	Rabbit		
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide				
	oral	LD50 >5000 mg/kg	Rat		
	dermal	LD50 >2000 mg/kg	Rat		
868-77-9	2-hydroxyethyl methacrylate				
	oral	LD50 5564 mg/kg	Rat		
	dermal	LD50 >5000 mg/kg	Rabbit		

Irritation and corrosivity

Causes skin irritation.

Causes serious eye irritation.

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; 1,12-Dodecanediol Dimethacrylate; Hydroxy propyl methacrylate; tetrahydrofurfuryl methacrylate THFMA purified grade; diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide; 2-hydroxyethyl methacrylate)

Carcinogenic/mutagenic/toxic effects for reproduction

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

STOT-single exposure

May cause respiratory irritation.

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].

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SECTION 12: Ecological information

12.1. Toxicity

The product is not: Ecotoxic.

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-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate					
	Acute fish toxicity	LC50 10,1 mg/l	96 h			OECD 203
	Acute algae toxicity	ErC50 0,21 mg/l	72 h			OECD 201
	Acute crustacea toxicity	EC50 >1,2 mg/l	48 h	Daphnia magna (Big water flea)	OECD 202	
41637-38-1	isopropylidenediphenol peg dimethacrylate					
	Acute fish toxicity	LC50 >100 mg/l	96 h			
	Acute crustacea toxicity	EC50 >100 mg/l	48 h			
72829-09-5	1,12-Dodecanediol Dimethacrylate					
	Acute crustacea toxicity	EC50 >100 mg/l	48 h	Daphnia		
27813-02-1	Hydroxy propyl methacrylate					
	Acute fish toxicity	LC50 493 mg/l	96 h	Leuciscus idus (golden orfe)		
	Acute algae toxicity	ErC50 >97,2 mg/l	72 h	Pseudokirchneriella subcapitata	OECD 201	
	Acute crustacea toxicity	EC50 380 mg/l	48 h	Daphnia magna (Big water flea)	OECD 202	
2455-24-5	tetrahydrofurfuryl methacrylate THFMA purified grade					
	Acute fish toxicity	LC50 34,7 mg/l	96 h		GESTIS	
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide					
	Acute algae toxicity	ErC50 >2,01 mg/l	72 h	Pseudokirchneriella subcapitata		
	Acute crustacea toxicity	EC50 3,53 mg/l	48 h	Daphnia magna (Big water flea)		
	Acute bacteria toxicity	(EC50 >1000 mg/l)	3 h	Activated sludge		
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.

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CAS No	Chemical name			
	Method	Value	d	Source
	Evaluation			
27813-02-1	Hydroxy propyl methacrylate			
	OECD	94%	28	
	Readily biodegradable (according to OECD criteria).			
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide			
		0-10%	28	
	Not 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
72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate	3,39
27813-02-1	Hydroxy propyl methacrylate	0,97
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

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

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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

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

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

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%

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LD50: Lethal dose, 50%

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

Classification	Classification procedure
Skin Irrit. 2; H315	Calculation method
Eye Irrit. 2; H319	Calculation method
Skin Sens. 1; H317	Calculation method
STOT SE 3; H335	Calculation method
Aquatic Chronic 3; H412	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.
H360	May damage fertility or the unborn child.
H361	Suspected of damaging fertility or the unborn child.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H411	Toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.
H413	May cause long lasting harmful effects to aquatic life.

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.)