

Safety Data Sheet

according to Regulation (EC) No 1907/2006

freeprint® denture 385

Revision date: 24.09.2020

Product code: 1115

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

1.1. Product identifier

freeprint® denture 385

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

Use of the substance/mixture

Light-curing resin for generative manufacturing of removable prosthetic base plates.

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
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.)
Telefax: +49 7243/510-100

Importer / Distributer

Company name: Ivoclar Vivadent Pty Ltd
Place: 1-5 Overseas Drive Noble Park North VIC 3174
Telephone: +61 3 9795 9599
e-mail: info@ivoclarvivadent.com
Telefax: Fax: +61 3 9795 9645

1.4. Emergency telephone number:

13 11 26
Poisons Hotline (24 hours / 7 days)

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
Specific target organ toxicity - single exposure: STOT SE 3
Hazardous to the aquatic environment: Aquatic Chronic 2
Hazard Statements:
Causes skin irritation.
Causes serious eye irritation.
May cause an allergic skin reaction.
May cause respiratory irritation.
Toxic to aquatic life with long lasting effects.

2.2. Label elements

Regulation (EC) No. 1272/2008

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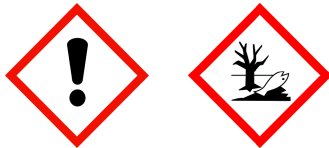
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Hazard components for labelling

isopropylidenediphenol peg-2 dimethacrylate
 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate
 2-hydroxyethyl methacrylate
 diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide
 Hydroxy propyl methacrylate
 phenyl bis(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.
 H335 May cause respiratory irritation.
 H411 Toxic to aquatic life with long lasting effects.

Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
 P273 Avoid release to the environment.
 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.
 P391 Collect spillage.
 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.

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Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	GHS Classification			
41637-38-1	isopropylidenediphenol peg-2 dimethacrylate			35 - < 60 %
	Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1A, STOT SE 3; H315 H319 H317 H335			
72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahehexadecane-1,16-diyl bismethacrylate			30 - < 35 %
	276-957-5		01-2120751202-68	
	Skin Sens. 1B, Aquatic Chronic 2; H317 H411			
6606-59-3	1,6-hexanediol dimethacrylate			1 - < 5 %
	229-551-7			
	Skin Irrit. 2, Eye Irrit. 2, STOT SE 3; H315 H319 H335			
868-77-9	2-hydroxyethyl methacrylate			1 - < 5 %
	212-782-2	607-124-00-X		
	Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1; H315 H319 H317			
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide			1 - < 5 %
	278-355-8	015-203-00-X	01-2119972295-	
	Repr. 2, Skin Sens. 1, Aquatic Chronic 2; H361f H317 H411			
27813-02-1	Hydroxy propyl methacrylate			1 - < 5 %
	248-666-3		01-2119490226-37	
	Eye Irrit. 2, Skin Sens. 1; H319 H317			
162881-26-7	phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide			< 1 %
	423-340-5	015-189-00-5	01-2119489401-38	
	Skin Sens. 1, Aquatic Chronic 4; H317 H413			

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. 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.

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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**

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.

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)

Light-curing resin for generative manufacturing of removable prosthetic base plates.
For use by trained specialist staff.

SECTION 8: Exposure controls/personal protection

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8.1. Control parameters

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

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:	gingiva coloured
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)

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

Water solubility: insoluble

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 alkaline or acidic materials.

10.4. Conditions to avoid

Ultra-violet lighth and daylighth initiate polymerisation of the product. Therefore keep only in tightly closed containers away from any sources of lighth 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 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
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 mg/kg	>5000	Rat	OECD 401
	dermal	LD50 mg/kg	>2000	Rat	OECD 402
868-77-9	2-hydroxyethyl methacrylate				
	oral	LD50 mg/kg	5050	Rat	
	dermal	LD50 mg/kg	>3000	Rabbit	
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide				
	oral	LD50 mg/kg	>5000	Rat	
	dermal	LD50 mg/kg	>2000	Rat	
27813-02-1	Hydroxy propyl methacrylate				
	oral	LD50 mg/kg	>2000	Rat	OECD 401
	dermal	LD50 mg/kg	>5000	Rabbit	
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. (isopropylidenediphenol peg-2 dimethacrylate; 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate; 2-hydroxyethyl methacrylate; diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide; Hydroxy propyl methacrylate; 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. (isopropylidenediphenol peg-2 dimethacrylate)

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

The product is not: Ecotoxic.

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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 crustacea toxicity	EC50 mg/l	>1,2	48 h	Daphnia magna (Big water flea)	OECD 202
868-77-9	2-hydroxyethyl methacrylate					
	Acute fish toxicity	LC50	227 mg/l	96 h	Pimephales promelas	
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide					
	Acute algae toxicity	ErC50 mg/l	>2,01	72 h		
	Acute crustacea toxicity	EC50 mg/l	3,53	48 h	Daphnia magna (Big water flea)	
	Acute bacteria toxicity	(>1000 mg/l)			Activated sludge	
27813-02-1	Hydroxy propyl methacrylate					
	Acute fish toxicity	LC50	493 mg/l	96 h	Leuciscus idus (golden orfe)	
	Acute algae toxicity	ErC50 mg/l	>97,2	72 h	Pseudokirchneriella subcapitata	OECD 201
	Acute crustacea toxicity	EC50	380 mg/l	48 h	Daphnia magna (Big water flea)	OECD 202
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			
868-77-9	2-hydroxyethyl methacrylate			
	84	%	28	
	Leicht biologisch abbaubar			
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide			
	OECD 301F/ ISO 9408/ EEC 92/69/V, C.4-D	<20%	28	
	Poorly biodegradable.			
27813-02-1	Hydroxy propyl methacrylate			
	OECD	94%	28	
	Readily biodegradable (according to OECD criteria).			
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.

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Partition coefficient n-octanol/water

CAS No	Chemical name	Log Pow
868-77-9	2-hydroxyethyl methacrylate	0,47
27813-02-1	Hydroxy propyl methacrylate	0,97
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

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 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-dioxo-5,12-diazahexadecane-1,16-diylbis methacrylate
14.3. Transport hazard class(es):	9
14.4. Packing group:	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-dioxo-5,12-diazahexadecane-1,16-diylbismethacrylate

Marine transport (IMDG)

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14.1. UN 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-diylbis methacrylate
14.3. Transport hazard class(es):	9
14.4. Packing group:	III
Hazard label:	9
Marine pollutant:	YES
Special Provisions:	274, 335, 969
Limited quantity:	5 L
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

Air transport (ICAO-TI/IATA-DGR)

14.1. UN 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-diylbis methacrylate
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 dangerous good in sense of this transport regulation.

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

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

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 - strongly hazardous to water
Skin resorption/Sensitization:	Causes allergic hypersensitivity reactions.

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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
STOT SE 3; H335	Calculation method
Aquatic Chronic 2; H411	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.
H361f Suspected of damaging fertility.
H411 Toxic 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.)