

according to Regulation (EC) No 1907/2006

freeprint ortho® UV

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

1.1. Product identifier

freeprint ortho® UV

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

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

e-mail: info@ivoclarvivadent.com

1.4. Emergency telephone number: 0800 764 766

Poisons 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:

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

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

2.2. Label elements

Regulation (EC) No. 1272/2008

Hazard components for labelling

isopropylidenediphenol peg-2 dimethacrylate

Urethane Dimethacrylate
Hydroxy propyl methacrylate

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

2-hydroxyethyl methacrylate

Signal word: Warning

Pictograms:





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Hazard statements

H315 Causes skin irritation.

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

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.

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

C No			
	Index No	REACH No	
lassification according to Regulation	on (EC) No. 1272/2008 [CLP]		
opropylidenediphenol peg-2 dimet	hacrylate		25 - 50 %
kin Irrit. 2, Eye Irrit. 2, Skin Sens. 1	A, STOT SE 3; H315 H319 H317 H3	335	
rethane Dimethacrylate			10 - 25 %
kin Irrit. 2, Eye Irrit. 2, Skin Sens. 1	, STOT SE 3; H315 H319 H317 H33	35	
,12-Dodecanediol Dimethacrylate			5 - 25 %
kin Irrit. 2, Eye Irrit. 2; H315 H319			
ydroxy propyl methacrylate			< 5 %
48-666-3		01-2119490226-37	
ye Irrit. 2, Skin Sens. 1; H319 H31	7		
trahydrofurfuryl methacrylate THF	MA purified grade		1 - 10 %
kin Irrit. 2, Eye Irrit. 2, Skin Sens. 1	, STOT SE 3; H315 H319 H317 H33	35	
iphenyl(2,4,6-trimethylbenzoyl)pho	sphine oxide		0,1 - < 5 %
78-355-8	015-203-00-X		
epr. 2, Skin Sens. 1B, Aquatic Chr	onic 2; H361f H317 H411		
-hydroxyethyl methacrylate			< 1 %
12-782-2	607-124-00-X		
kin Irrit. 2, Eye Irrit. 2, Skin Sens. 1	; H315 H319 H317		
	cin Irrit. 2, Eye Irrit. 2, Skin Sens. 1 Tethane Dimethacrylate Sin Irrit. 2, Eye Irrit. 2, Skin Sens. 1 Tethane Dimethacrylate Sin Irrit. 2, Eye Irrit. 2, Skin Sens. 1 Tethane Dimethacrylate Sin Irrit. 2, Eye Irrit. 2; H315 H319 Toroxy propyl methacrylate Tetrahydrofurfuryl methacrylate Tetrahydrofurfuryl methacrylate THF Tetrahydrofurfuryl methacrylate THF Tetrahydrofurfuryl methylbenzoyl)pho Tetrahydrofurfurfurfurfurfurfurfurfurfurfurfurfurf	cin Irrit. 2, Eye Irrit. 2, Skin Sens. 1, STOT SE 3; H315 H319 H317 H33 d12-Dodecanediol Dimethacrylate cin Irrit. 2, Eye Irrit. 2; H315 H319 droxy propyl methacrylate 8-666-3 dre Irrit. 2, Skin Sens. 1; H319 H317 drahydrofurfuryl methacrylate THFMA purified grade cin Irrit. 2, Eye Irrit. 2, Skin Sens. 1, STOT SE 3; H315 H319 H317 H33 dehenyl(2,4,6-trimethylbenzoyl)phosphine oxide 8-355-8 015-203-00-X depr. 2, Skin Sens. 1B, Aquatic Chronic 2; H361f H317 H411 dehydroxyethyl methacrylate	ppropylidenediphenol peg-2 dimethacrylate din Irrit. 2, Eye Irrit. 2, Skin Sens. 1A, STOT SE 3; H315 H319 H317 H335 ethane Dimethacrylate din Irrit. 2, Eye Irrit. 2, Skin Sens. 1, STOT SE 3; H315 H319 H317 H335 12-Dodecanediol Dimethacrylate din Irrit. 2, Eye Irrit. 2; H315 H319 vdroxy propyl methacrylate 8-666-3 01-2119490226-37 re Irrit. 2, Skin Sens. 1; H319 H317 trahydrofurfuryl methacrylate THFMA purified grade din Irrit. 2, Eye Irrit. 2, Skin Sens. 1, STOT SE 3; H315 H319 H317 H335 phenyl(2,4,6-trimethylbenzoyl)phosphine oxide 8-355-8 015-203-00-X ppr. 2, Skin Sens. 1B, Aquatic Chronic 2; H361f H317 H411 hydroxyethyl methacrylate 2-782-2 607-124-00-X

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

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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

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



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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.

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 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 fabrication of dental splints and guides.

For use by trained specialist staff.

SECTION 8: Exposure controls/personal protection

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: clear

Odour: faintly like esters

Test method

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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

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

No known hazardous decomposition products.

SECTION 11: Toxicological information

11.1. Information on toxicological effects



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Acute toxicity

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

CAS No	Chemical name					
	Exposure route	Dose		Species	Source	Method
27813-02-1	Hydroxy propyl methacryl	ate				
	oral	LD50 > mg/kg	2000	Rat	OECD 401	
	dermal	LD50 > mg/kg	- 5000	Rabbit		
75980-60-8	diphenyl(2,4,6-trimethylbe	enzoyl)phosphi	ine oxide			
	oral	LD50 > mg/kg	- 5000	Rat		
	dermal	LD50 > mg/kg	2000	Rat		
868-77-9	2-hydroxyethyl methacryla					
	oral	LD50 5 mg/kg	5050	Rat		

Irritation and corrosivity

Causes skin irritation.

Causes serious eye irritation.

Sensitising effects

May cause an allergic skin reaction. (isopropylidenediphenol peg-2 dimethacrylate; Urethane 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. (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
27813-02-1	Hydroxy propyl methacryl	ate					
	Acute fish toxicity	LC50	493 mg/l	96 h	Leuciscus idus (golden orfe)		
	Acute algae toxicity	ErC50 mg/l	>97,2		Pseudokirchneriella subcapitata	OECD 201	
	Acute crustacea toxicity	EC50	380 mg/l		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			
75980-60-8	diphenyl(2,4,6-trimethylbe	nzoyl)phos	phine oxide				
	Acute algae toxicity	ErC50 mg/l	>2,01	72 h	Scenedesmus subspicatus		
	Acute crustacea toxicity	EC50 mg/l	3,53	48 h	Daphnia magna (Big water flea)		
	Acute bacteria toxicity	(>1000	mg/l)	3 h	Activated sludge		
868-77-9	2-hydroxyethyl methacryla	ate					
	Acute fish toxicity	LC50	227 mg/l	96 h	Pimephales promelas		

12.2. Persistence and degradability

The product has not been tested.

CAS No	Chemical name			
	Method	Value	d	Source
	Evaluation	-	-	
72829-09-5	1,12-Dodecanediol Dimethacrylate			
	OECD 301C/ ISO 9408/ EEC 92/69/V, C.4-F	90 %	28	
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	a)	-	
868-77-9	2-hydroxyethyl methacrylate			
	84	%	28	
-	Leicht biologisch abbaubar		-	

12.3. Bioaccumulative potential

The product has not been tested.

Partition coefficient n-octanol/water

CAS No	Chemical name	Log Pow
27813-02-1	Hydroxy propyl methacrylate	0,97
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	3,1
868-77-9	2-hydroxyethyl methacrylate	0,47

BCF

CAS No	Chemical name	BCF	Species	Source
72829-09-5	1,12-Dodecanediol Dimethacrylate	1230		
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphi ne oxide	47-55	Cyprinus carpio (Common Carp)	

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12.4. Mobility in soil

The product has not been tested.

12.5. Results of PBT and vPvB assessment

Not identivied 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

Advice on disposal

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)

<u>14.1. UN number:</u>	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 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.



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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:

HSR007296, HSR003915, HSR003005.

GHS Classifications:

Skin irritation Category 2

Eye irritation Category 2,

Skin sensitisation Category 1,

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. 1A; H317	Calculation method
STOT SE 3; H335	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.





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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.

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