

according to UK REACH Regulation

# **Primeprint Splint**

Revision date: 17.12.2020

Product code: 1113

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

## 1.1. Product identifier

Primeprint Splint

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UFI:
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WEX0-Y16M-C007-R22G

## 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 of	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	+1-800-424-9300 (CHEMTREC	worldwide)
un un a la anu		

number:

## **SECTION 2: Hazards identification**

## 2.1. Classification of the substance or mixture

## **GB CLP Regulation**

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

Full text of hazard statements: see SECTION 16.

## 2.2. Label elements

## **GB CLP Regulation**

## Hazard components for labelling

isopropylidenediphenol peg dimethacrylate 2-Propenoic acid, (5-ethyl-1,3-dioxan-5-yl)methyl ester diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide **nal word:** Warning

Signal word:

Pictograms:



#### Hazard statements

H315 H317 H319 H335	Causes skin irritation. May cause an allergic skin reaction. Causes serious eye irritation. May cause respiratory irritation
H335	May cause respiratory irritation.
H412	Harmful to aquatic life with long lasting effects.

#### **Precautionary statements**

Avoid breathing dust/fume/gas/mist/vapours/spray.

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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			
	EC No	Index No	REACH No	
	Classification (GB CLP Regulation)			
41637-38-1	isopropylidenediphenol peg dimeth	acrylate		90 - < 95 %
	609-946-4		01-2119980659-17	
	Aquatic Chronic 4; H413	•		
66492-51-1	2-Propenoic acid, (5-ethyl-1,3-dioxa	an-5-yl)methyl ester		1 - < 5 %
	266-380-7			
	Skin Irrit. 2, Skin Sens. 1, Aquatic (	Chronic 2; H315 H317 H411		
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)pho	osphine oxide		1 - < 5 %
	278-355-8	015-203-00-X	01-2119972295-29	
	Repr. 2, Skin Sens. 1B, Aquatic Ch	ronic 2; H361 H317 H411		

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. I	imits, M-factors and ATE	
41637-38-1	609-946-4	isopropylidenediphenol peg dimethacrylate	90 - < 95 %
	dermal: LD50 =	= >2000 mg/kg; oral: LD50 = >2000 mg/kg	
66492-51-1	266-380-7	2-Propenoic acid, (5-ethyl-1,3-dioxan-5-yl)methyl ester	1 - < 5 %
	dermal: LD50 =	= 2000 mg/kg; oral: LD50 = >2000 mg/kg	
75980-60-8	278-355-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	1 - < 5 %
	dermal: LD50 =	= >2000 mg/kg; oral: LD50 = >5000 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.



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## 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.

rieat 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

#### 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.



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## 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 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

#### **DNEL/DMEL** values

CAS No	Substance		_	-
DNEL type		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 DN	EL, long-term	inhalation	systemic	0,145 mg/m³
Consumer DN	EL, long-term	dermal	systemic	0,0833 mg/kg bw/day
Consumer DN	EL, 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.

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# **SECTION 9: Physical and chemical properties**

9.1. Information on basic physical and cher	nical properties	
Physical state:	liquid:	
Colour:	blue	
Odour:	faintly like esters	
		Test method
Changes in the physical state		
Melting point/freezing point:	not determined	
Boiling point or initial boiling point and boiling range:	not determined	
Flash point:	>100 °C	DIN 51755
Flammability Solid/liquid:	not applicable	
Gas:	not applicable	
Lower explosion limits:	not determined	
Upper explosion limits:	not determined	
Self-ignition temperature Solid:	not applicable	
Gas:	not applicable	
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: (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 haza	ard classes	
Oxidizing properties Not oxidizing.		
Other safety characteristics		
Solid content:	not determined	
Evaporation rate:	not determined	
Further Information		
SECTION 10: Stability and reactivity		

## **SECTION 10: Stability and reactivity**

# 10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

## 10.2. Chemical stability



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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 hazard classes as defined in GB CLP Regulation

#### Acute toxicity

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

CAS No	Chemical name					
	Exposure route	Dose		Species	Source	Method
41637-38-1	isopropylidenediphenol p	eg dimethacry	late			
	oral	LD50 mg/kg	>2000	Rat		
	dermal	LD50 mg/kg	>2000	Rat		
66492-51-1	2-Propenoic acid, (5-ethy	l-1,3-dioxan-5	i-yl)methyl e	ester		
	oral	LD50 mg/kg	>2000	Rat		
	dermal	LD50 mg/kg	2000	Rat		
75980-60-8	diphenyl(2,4,6-trimethylbe	enzoyl)phosph	nine oxide			
	oral	LD50 mg/kg	>5000	Rat		
	dermal	LD50 mg/kg	>2000	Rat		

## Irritation and corrosivity

Causes skin irritation.

Causes serious eye irritation.

#### Sensitising effects

May cause an allergic skin reaction. (2-Propenoic acid, (5-ethyl-1,3-dioxan-5-yl)methyl ester; diphenyl(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.

#### 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

Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

CAS No	Chemical name						
	Aquatic toxicity	Dose		[h]   [d]	Species	Source	Method
41637-38-1	isopropylidenediphenol peg dimethacrylate						
	Acute fish toxicity	LC50 mg/l	>100	96 h			
	Acute crustacea toxicity	EC50 mg/l	>100	48 h			
66492-51-1	2-Propenoic acid, (5-ethy	I-1,3-dioxan	-5-yl)methyl e	ester	-		
	Acute fish toxicity	LC50	4 mg/l	96 h	Oncorhynchus mykiss (Rainbow trout)		
	Acute algae toxicity	ErC50	34 mg/l	72 h	Desmodesmus subspicatus		
	Acute crustacea toxicity	EC50	20 mg/l	48 h	Daphnia magna (Big water flea)		
	Acute bacteria toxicity	(EC50 mg/l)	>1,000	3 h	Activated sludge		
75980-60-8	diphenyl(2,4,6-trimethylbe	enzoyl)phos	phine oxide	-	-		
	Acute algae toxicity	ErC50 mg/l	>2,01	72 h	Pseudokirchneriella subcapitata		
	Acute crustacea toxicity	EC50 mg/l	3,53		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				
66492-51-1	2-Propenoic acid, (5-ethyl-1,3-dioxan-5-yl)methyl ester				
	Evidence for inherent biodegradability.	28%	28		
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
66492-51-1	2-Propenoic acid, (5-ethyl-1,3-dioxan-5-yl)methyl ester	1,9
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)phosphi ne oxide		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

The substances in the mixture do not meet the PBT/vPvB criteria according to UK REACH. Not identivied 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**

#### Land transport (ADR/RID)

14.1. UN number or ID number:14.2. UN proper shipping name:14.3. Transport hazard class(es):14.4. Packing group:Inland waterways transport (ADN)14.1. UN number or ID number:14.2. UN proper shipping name:

14.3. Transport hazard class(es): 14.4. Packing group:

## Marine transport (IMDG)

14.1. UN number or ID number: 14.2. UN proper shipping name: 14.3. Transport hazard class(es): 14.4. Packing group:

## Air transport (ICAO-TI/IATA-DGR) <u>14.1. UN number or ID number:</u> <u>14.2. UN proper shipping name:</u> 14.3. Transport hazard class(es):

14.4. Packing group:

No dangerous good in sense of this transport regulation. No dangerous good in sense of this transport regulation. No dangerous good in sense of this transport regulation. No dangerous good in sense of this transport regulation.

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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**

### according to UK REACH Regulation

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## 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:

Water hazard class (D): Skin resorption/Sensitization: Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC). 3 - highly hazardous to water 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	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
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.
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.
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.)