

according to UK REACH Regulation

# **Primeprint Tray**

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

#### 1.1. Product identifier

Primeprint Tray

UFI: PY21-S1SN-K00F-T4XW

#### 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** +1-800-424-9300 (CHEMTREC worldwide)

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 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.

H412 Harmful to aquatic life with long lasting effects.



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# **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			
	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-diox	an-5-yl)methyl ester		1 - < 5 %
	266-380-7			
	Skin Irrit. 2, Skin Sens. 1, Aquatic			
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide			1 - < 5 %
	278-355-8	015-203-00-X	01-2119972295-29	
	Repr. 2, Skin Sens. 1B, Aquatic Ch			
162881-26-7	phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide			< 1 %
	423-340-5	015-189-00-5	01-2119489401-38	
	Skin Sens. 1A, Aquatic Chronic 4; H317 H413			

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	Limits, 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		
162881-26-7	423-340-5	phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide	< 1 %
	dermal: LD50 = >2000 mg/kg; oral: LD50 = >2000 mg/kg		

# **SECTION 4: First aid measures**

# 4.1. Description of first aid measures





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#### 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 plenty of water and soap. 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

#### 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





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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.

#### 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, drink, smoke, sniff.

#### 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.

### 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 DNEL, long-term		inhalation	systemic	0,145 mg/m³	
Consumer DNEL, long-term		dermal	systemic	0,0833 mg/kg bw/day	
Consumer DNE	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

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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: blue

Odour: faintly like esters

**Test method** 

Changes in the physical state

Melting point/freezing point:

Boiling point or initial boiling point and

not determined

boiling range:

Flash point: >100 °C DIN 51755

**Flammability** 

Solid/liquid: not applicable
Gas: not applicable

**Explosive properties** 

The product is not: Explosive.

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: <1 hPa

(at 20 °C)

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

Oxidizing properties Not oxidizing.

Other safety characteristics



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Solid content: not determined Evaporation rate: not determined

**Further Information** 

# **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 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 dimethacrylate			
	oral	LD50 >2000 mg/kg	Rat		
	dermal	LD50 >2000 mg/kg	Rat		
66492-51-1	2-Propenoic acid, (5-ethy	l-1,3-dioxan-5-yl)methy	/l ester		
	oral	LD50 >2000 mg/kg	Rat		
	dermal	LD50 2000 mg/kg	Rat		
75980-60-8	0-8 diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide				
	oral	LD50 >5000 mg/kg	Rat		
	dermal	LD50 >2000 mg/kg	Rat		
162881-26-7	phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide				
	oral	LD50 >2000 mg/kg	Rat	OECD 401	
	dermal	LD50 >2000 mg/kg	Rat	OECD 402	

#### Irritation and corrosivity





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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; 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.

# 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].

# **SECTION 12: Ecological information**

# 12.1. Toxicity

Harmful to aquatic life with long lasting effects.



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CAS No	Chemical name						
	Aquatic toxicity	Dose		[h]   [d]	Species	Source	Method
41637-38-1	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-ethyl	-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-trimethylbenzoyl)phosphine oxide						
	Acute algae toxicity	ErC50 mg/l	>2,01	72 h	Pseudokirchneriella subcapitata		
	Acute crustacea toxicity	EC50 mg/l	3,53	48 h	Daphnia magna (Big water flea)		
	Acute bacteria toxicity	(EC50 mg/l)	>1000	3 h	Activated sludge		
162881-26-7	phenyl bis(2,4,6-trimethyll	penzoyl)-pho	osphine oxid	е			
	Acute fish toxicity	LC50 mg/l	>0,09	96 h	Danio rerio (zebrafish)	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	(EC50 mg/l)	>100	3 h	OECD 209		

# 12.2. Persistence and degradability

The product has not been tested.

- 1110 pi	T				
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)				
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
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
162881-26-7	phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide	5,8

#### **BCF**

CAS No	Chemical name	BCF	Species	Source
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphi ne oxide	47-55	Cyprinus carpio (Common Carp)	
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

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:	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.



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**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

Information according to 2012/18/EU

(SEVESO III):

Not subject to 2012/18/EU (SEVESO III)

#### **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%

LD50: Lethal dose, 50%

CLP: Classification, labelling and Packaging

REACH: Registration, Evaluation and Authorization of Chemicals

GHS: Globally Harmonised System of Classification, Labelling and Packaging of Chemicals

**UN: United Nations** 

DNEL: Derived No Effect Level
DMEL: Derived Minimal Effect Level
PNEC: Predicted No Effect Concentration

ATE: Acute toxicity estimate LL50: Lethal loading, 50% EL50: Effect loading, 50%

EC50: Effective Concentration 50%

ErC50: Effective Concentration 50%, growth rate

NOEC: No Observed Effect Concentration





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BCF: Bio-concentration factor

PBT: persistent, bioaccumulative, toxic vPvB: very persistent, very bioaccumulative

RID: Regulations concerning the international carriage of dangerous goods by rail

ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (Accord européen relatif au transport international des marchandises dangereuses par voies de navigation

intérieures)

EmS: Emergency Schedules MFAG: Medical First Aid Guide

ICAO: International Civil Aviation Organization

MARPOL: International Convention for the Prevention of Marine Pollution from Ships

IBC: Intermediate Bulk Container VOC: Volatile Organic Compounds SVHC: Substance of Very High Concern

For abbreviations and acronyms, see table at http://abbrev.esdscom.eu

#### Classification for mixtures and used evaluation method according to GB CLP Regulation

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.)