

## Safety Data Sheet

according to UK REACH Regulation

### primosplint

Revision date: 22.11.2021

Product code: PS100

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

### 1.1. Product identifier

primosplint

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

#### Use of the substance/mixture

dental use

### 1.3. Details of the supplier of the safety data sheet

#### Manufacturer

Company name: DeltaMed GmbH  
Street: Raiffeisenstr. 8a  
Place: 61169 Friedberg (GER)  
Telephone: +49 6031 7283-0      Telefax: +49 6031 7283-29  
e-mail: info@deltamed.de  
Internet: www.deltamed.de

#### Supplier

Company name: primotec - Joachim Mosch e.K  
Street: Tannenwaldallee 4  
Place: 61348 Bad Homburg (GER)  
Telephone: +49 (0)6172-997700-0      Telefax: +49 (0)6172-997700-99  
e-mail: primotec@primogroup.de  
Internet: www.primogroup.de  
Responsible Department: F&E  
Telefax +49 (0)6172-997700-99

### 1.4. Emergency telephone number:

Giftinformationszentrum Universitätsklinikum Mainz  
Telefon +49 (0)6131-19240

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

#### GB CLP Regulation

Hazard categories:

Respiratory or skin sensitisation: Skin Sens. 1

Hazardous to the aquatic environment: Aquatic Chronic 3

Hazard Statements:

May cause an allergic skin reaction.

Harmful to aquatic life with long lasting effects.

### 2.2. Label elements

#### GB CLP Regulation

#### Hazard components for labelling

urethane dimethacrylate (UDMA)

tricyclodecan dimethanol diacrylate (TCDDMDA)

Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (TPO)

Signal word: Warning

Pictograms:



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#### Hazard statements

H317 May cause an allergic skin reaction.  
 H412 Harmful to aquatic life with long lasting effects.

#### Precautionary statements

P273 Avoid release to the environment.  
 P280 Wear protective gloves/protective clothing/eye protection.  
 P302+P350 IF ON SKIN: Gently wash with plenty of soap and water.  
 P333+P313 If skin irritation or rash occurs: Get medical advice/attention.  
 P501 Dispose of contents/container in accordance with local regulation.

#### Special labelling of certain mixtures

Restricted to professional users.

#### 2.3. Other hazards

Polymerization with heat evolution may occur in the presence of radical forming substances (e.g. peroxides), reducing substances, and/or heavy metal ions.

### SECTION 3: Composition/information on ingredients

#### 3.2. Mixtures

##### Chemical characterization

Mixture of acrylic resins, fillers and initiators.

##### Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	GHS Classification			
72869-86-4	urethane dimethacrylate (UDMA)			20 - 50 %
	Skin Sens. 1, Aquatic Chronic 3; H317 H412			
42594-17-2	tricyclodecan dimethanol diacrylate (TCDDMDA)			< 20 %
	Skin Sens. 1B, Aquatic Chronic 2; H317 H411			
75980-60-8	Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (TPO)			< 1 %
	278-355-8	015-203-00-X		
	Repr. 2, Skin Sens. 1, Aquatic Chronic 2; H361f 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. Limits, M-factors and ATE	
72869-86-4		urethane dimethacrylate (UDMA)	20 - 50 %
		inhalation: LC50 = >5 mg/l (dusts or mists); oral: LD50 = >2000 mg/kg	
42594-17-2		tricyclodecan dimethanol diacrylate (TCDDMDA)	< 20 %
		dermal: LD50 = > 2000 mg/kg; oral: LD50 = > 2000 mg/kg	
75980-60-8	278-355-8	Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (TPO)	< 1 %
		oral: LD50 = > 5000 mg/kg	

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

##### General information

Medical treatment is necessary if symptoms occur which are obviously caused by skin or eye contact with the

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product or by inhalation of its vapours. Take off all contaminated clothing immediately.

#### After inhalation

Provide fresh air. Medical treatment necessary.

#### After contact with skin

After contact with skin, wash immediately with plenty of water and soap. Immediately remove any contaminated clothing, shoes or stockings. Medical treatment necessary.

#### After contact with eyes

After eye contact: Rinse immediately carefully and thoroughly with eye-bath or water. Consult an ophthalmologist.

#### After ingestion

Do NOT induce vomiting. Medical treatment necessary.

#### **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**

Foam. Extinguishing powder Carbon dioxide

##### **Unsuitable extinguishing media**

Full water jet

#### **5.2. Special hazards arising from the substance or mixture**

In case of fire may be liberated: Carbon monoxide Carbon dioxide Hazardous decomposition products

#### **5.3. Advice for firefighters**

In case of fire: Wear self-contained breathing apparatus.

#### **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**

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**

Provide good room ventilation.

**Advice on protection against fire and explosion**

Keep away from sources of ignition - No smoking.

**Advice on general occupational hygiene**

Avoid contact with skin, eyes and clothes. 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**

Protect from the action of light. Keep only in the original container at a temperature between 4 -25 °C. Can polymerize with intense heat release.

**Hints on joint storage**

No special measures are necessary.

**SECTION 8: Exposure controls/personal protection****8.1. Control parameters****8.2. Exposure controls****Individual protection measures, such as personal protective equipment****Eye/face protection**

tightly fitting goggles

**Hand protection**

Gloves should be replaced regularly, especially after extended contact with the product. For each work-place a suitable glove type has to be selected.

**Skin protection**

Wear suitable protective clothing.

**SECTION 9: Physical and chemical properties****9.1. Information on basic physical and chemical properties**

Physical state:	pasty
Colour:	transparent
Odour:	hardly noticeable

**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

**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:	not determined
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**

The substance is not soluble in water.

Partition coefficient n-octanol/water: not determined

Vapour pressure: not determined

Density: not determined

Relative vapour density: not determined

**9.2. Other information****Other safety characteristics**

Solid content: not determined

Evaporation rate: not determined

**Further Information**

Product has not been tested. The statement is derived from the properties of the components.

**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**

Polymerization with heat evolution may occur in the presence of radical forming substances (e.g. peroxides), reducing substances, and/or heavy metal ions.

**10.4. Conditions to avoid**

Protect from the action of light. Keep only in the original container at a temperature between 4 -25 °C. Can polymerize with intense heat release.

**10.5. Incompatible materials**

Oxidising agent, Reducing agent, Heavy metals, acids, Alkali (lye)

**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.

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CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
72869-86-4	urethane dimethacrylate (UDMA)				
	oral	LD50 >2000 mg/kg	Rat	OECD 401	
	inhalation (4 h) aerosol	LC50 >5 mg/l			
42594-17-2	tricyclodecan dimethanol diacrylate (TCDDMDA)				
	oral	LD50 > 2000 mg/kg	Rat		
	dermal	LD50 > 2000 mg/kg	Rat		
75980-60-8	Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (TPO)				
	oral	LD50 > 5000 mg/kg	Rat	RTECS	

#### Irritation and corrosivity

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

#### Sensitising effects

May cause an allergic skin reaction. (urethane dimethacrylate (UDMA); tricyclodecan dimethanol diacrylate (TCDDMDA); Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (TPO))  
 Possible sensitization in case of persons suffering from hypersensitivity.

#### Carcinogenic/mutagenic/toxic effects for reproduction

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

#### STOT-single exposure

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

#### 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.

#### Further information

Product has not been tested. The statement is derived from the properties of the components.

## SECTION 12: Ecological information

### 12.1. Toxicity

CAS No	Chemical name					
	Aquatic toxicity	Dose	[h]   [d]	Species	Source	Method
72869-86-4	urethane dimethacrylate (UDMA)					
	Acute fish toxicity	LC50 10,1 mg/l	96 h	Danio rerio (zebrafish)	OECD 203	
42594-17-2	tricyclodecan dimethanol diacrylate (TCDDMDA)					
	Acute fish toxicity	LC50 4,95 mg/l	96 h			
	Acute algae toxicity	ErC50 1,6 mg/l	72 h	Pseudokirchneriella subcapitata	OECD 201	
	Acute crustacea toxicity	EC50 2,36 mg/l	48 h	Daphnia magna (Big water flea)	OECD 202	
75980-60-8	Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (TPO)					
	Acute crustacea toxicity	EC50 3,53 mg/l	48 h	Daphnia		

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#### 12.2. Persistence and degradability

The product has not been tested.

CAS No	Chemical name			
	Method	Value	d	Source
	Evaluation			
72869-86-4	urethane dimethacrylate (UDMA)			
	Biodegradation	22 %	28	OECD 301 F

#### 12.3. Bioaccumulative potential

The product has not been tested.

#### 12.4. Mobility in soil

The product has not been tested.

#### 12.5. Results of PBT and vPvB assessment

The product has not been tested.

#### 12.7. Other adverse effects

No information available.

#### Further information

Do not allow uncontrolled discharge of product into the environment. Do not allow to enter into surface water or drains.

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

##### Disposal recommendations

Small quantities can be polymerized by light and the cured solid material can be disposed of with the regular garbage. Larger quantities must be disposed of following the regulations of the local authorities. Do not allow to enter into surface water or drains. Dispose of waste according to applicable legislation.

##### List of Wastes Code - residues/unused products

070208 WASTES FROM ORGANIC CHEMICAL PROCESSES; wastes from the MFSU of plastics, synthetic rubber and man-made fibres; other still bottoms and reaction residues; hazardous waste

##### List of Wastes Code - contaminated packaging

070208 WASTES FROM ORGANIC CHEMICAL PROCESSES; wastes from the MFSU of plastics, synthetic rubber and man-made fibres; other still bottoms and reaction residues; hazardous waste

##### Contaminated packaging

This material and its container must be disposed of as hazardous waste. Handle contaminated packages in the same way as the substance itself.

### SECTION 14: Transport information

#### Land transport (ADR/RID)

##### Other applicable information (land transport)

No dangerous good in sense of these transport regulations.

#### Inland waterways transport (ADN)

##### Other applicable information (inland waterways transport)

No dangerous good in sense of these transport regulations.

#### Marine transport (IMDG)

##### Other applicable information (marine transport)

No dangerous good in sense of these transport regulations.

#### Air transport (ICAO-TI/IATA-DGR)

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**Other applicable information (air transport)**

No dangerous good in sense of these transport regulations.

**14.6. Special precautions for user**

No information available.

**14.7. Maritime transport in bulk according to IMO instruments**

not applicable

**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

**National regulatory information**

Water hazard class (D): 1 - slightly hazardous to water

**15.2. Chemical safety assessment**

Chemical safety assessments for substances in this mixture were not carried out.

**SECTION 16: Other information****Changes**

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

**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%

**Relevant H and EUH statements (number and full text)**

H317	May cause an allergic skin reaction.
H361f	Suspected of damaging fertility.
H411	Toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.

**Further Information**

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

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