



according to Regulation (EC) No 1907/2006

primosplint

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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

Company name: primotec - Joachim Mosch e.K

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e-mail: primotec@primogroup.de
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Responsible Department: F&E

Telefax +49 (0)6172-997700-99

1.4. Emergency telephone Giftinformationszentrum Universitätsklinikum Mainz

<u>number:</u> Telefon +49 (0)6131-19240

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No. 1272/2008

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

Regulation (EC) No. 1272/2008

Hazard components for labelling

Urethane dimethacrylate (UDMA)

tricyclodecan dimethanol diacrylate (TCDDMDA)

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

Signal word: Warning

Pictograms:



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.



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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				
	EC No	Index No	REACH No		
	Classification according to Regulation (EC) No. 1272/2008 [CLP]				
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)				
	278-355-8	015-203-00-X			
	Repr. 2, Skin Sens. 1, Aquatic Chronic 2; H361 H317 H411				

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

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 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





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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

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

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

Provide good room ventilation.

Advice on protection against fire and explosion

Keep away from sources of ignition. - No smoking.

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.

Advice on storage compatibility

No special measures are necessary.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.2. Exposure controls

Protective and hygiene measures

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.

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



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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

Test method

pH-Value: not determined

Changes in the physical state

Melting point:

Initial boiling point and boiling range:

Flash point:

not determined

not determined

> 100 °C

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: not determined
Vapour pressure: not determined
Density: not determined
Water solubility: insoluble

Solubility in other solvents

The substance is not soluble in water.

Partition coefficient: not determined

Vapour density: not determined

Evaporation rate: not determined

9.2. Other information

Solid content: not determined

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.



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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 (Iye)

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.

CAS No	Chemical name						
	Exposure route	Dose		Dose		Species	Source
72869-86-4	Urethane dimethacrylate (UDMA)						
	oral	LD50	>2000 mg/kg	Rat	OECD 401		
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



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CAS No	Chemical name					
	Aquatic toxicity	Dose		[h] [d]	Species	Source
72869-86-4	Urethane dimethacrylate (UDMA)					
	Acute fish toxicity	LC50	10,1 mg/l	96 h	Brachydanio rerio (zebra-fish)	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	

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.

12.6. 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

Advice on disposal

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.

Waste disposal number of waste from 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

Classified as hazardous waste.

Waste disposal number of 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

Classified as hazardous waste.



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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)

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

not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

National regulatory information

Water contaminating class (D): 1 - slightly water contaminating

15.2. Chemical safety assessment

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

SECTION 16: Other information

Changes

Matter of revision: change of Classification

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.

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.





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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.)