

**Safety Data Sheet**

according to Regulation (EC) No 1907/2006

**PRIMOBYTE centric registration base plate**

Revision date: 25.04.2017

Product code: PB101

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**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1. Product identifier**

PRIMOBYTE centric registration base plate

Product group: tray material

**1.2. Relevant identified uses of the substance or mixture and uses advised against****Use of the substance/mixture**

For the preparation of dental biteplates and bite templates.

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

Company name:	primodent	
	Bad Homburg, Germany	
Street:	Tannenwaldallee 4	
Place:	D-61348 Bad Homburg	
Telephone:	+49-(0)6172-99770-50	Telefax: +49-(0)6172-99770-99
e-mail:	primodent@primogroup.de	
Internet:	www.primogroup.de	

**1.4. Emergency telephone number:** +49-(0)6172-99770-50 (during usual office time: GMT+1)**SECTION 2: Hazards identification****2.1. Classification of the substance or mixture****Regulation (EC) No. 1272/2008**

Hazard categories:  
Acute toxicity: Acute Tox. 4  
Respiratory or skin sensitisation: Skin Sens. 1  
Hazard Statements:  
Harmful in contact with skin.  
May cause an allergic skin reaction.

**2.2. Label elements****Regulation (EC) No. 1272/2008****Hazard components for labelling**

Diurethane Dimethacrylate  
4-methoxyphenol, hydroquinone monomethyl ether, mequinol

**Signal word:** Warning**Pictograms:****Hazard statements**

Harmful in contact with skin.  
May cause an allergic skin reaction.

**Precautionary statements**

Avoid breathing dust/fume/gas/mist/vapours/spray.  
Contaminated work clothing should not be allowed out of the workplace.  
Wear protective gloves/protective clothing/eye protection/face protection.  
IF ON SKIN: Wash with plenty of water.  
Call a POISON CENTER/doctor if you feel unwell.  
If skin irritation or rash occurs: Get medical advice/attention.  
Take off contaminated clothing and wash it before reuse.

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**2.3. Other hazards**

No information available.

**SECTION 3: Composition/information on ingredients****3.2. Mixtures****Chemical characterization**

Matrix of polyfunctional methacrylates, glass, photochemical initiators and petroleum jelly.

**Hazardous components**

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification according to Regulation (EC) No. 1272/2008 [CLP]			
72869-86-4	Diurethane Dimethacrylate			10 - < 15 %
	276-957-5			
	Skin Sens. 1; H317			

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

**SECTION 4: First aid measures****4.1. Description of first aid measures****General information**

Polymerized material is non-hazardous.

**After inhalation**

Not applicable as all components have got a boiling point above 250°C.

**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 skin: wash with water and soap.

**After contact with eyes**

Rinse immediately carefully and thoroughly with eye-bath or water. In case of eye irritation consult an ophthalmologist.

**After ingestion**

Rinse mouth immediately and drink plenty of water.

**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.

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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**

Take up mechanically. 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. Avoid generation of dust. Do not breathe dust. Only adequately trained personnel should handle this product. For use in dentistry only.

**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. Protect from exposure to the light. Store not above 25°C.

**Advice on storage compatibility**

No special measures are necessary.

**7.3. Specific end use(s)**

For the preparation of individual impression trays on an isolated plaster model for the production of dentures. While grinding of the hardened plate please vacuum the sanding dust. Adhere to professional industrial hygiene.

**SECTION 8: Exposure controls/personal protection****8.1. Control parameters****8.2. Exposure controls****Appropriate engineering controls**

Use a suitable dust extraction when grinding the polymerized plate.

**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**

Wear eye/face protection.

**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

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supplier of these gloves.

**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:	Paste
Colour:	pink
Odour:	characteristic

**Test method**

pH-Value:	not applicable
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**Changes in the physical state**

Melting point:	-20 °C
Initial boiling point and boiling range:	200 °C
Flash point:	> 150 °C

**Flammability**

Solid:	not determined
Gas:	not applicable

Lower explosion limits:	not determined
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Upper explosion limits:	not determined
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Ignition temperature:	445 °C
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**Auto-ignition temperature**

Solid:	not determined
Gas:	not applicable

Decomposition temperature:	not determined
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**Oxidizing properties**

Not oxidizing.

Vapour pressure: (at 20 °C)	1 hPa
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Density:	1,89 g/cm <sup>3</sup>
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Water solubility:	insoluble
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**Solubility in other solvents**

not determined

Partition coefficient:	not determined
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Flow time:	Data not available
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Vapour density:	not determined
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Evaporation rate:	not determined
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**9.2. Other information**

Solid content:	76,15 %
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**SECTION 10: Stability and reactivity**

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**10.1. Reactivity**

Material will polymerize when exposed to daylight.

**10.2. Chemical stability**

The product is stable under storage at normal ambient temperatures.

**10.3. Possibility of hazardous reactions**

No known hazardous reactions.

**10.4. Conditions to avoid**

Direct light.

**10.5. Incompatible materials**

No information available.

**10.6. Hazardous decomposition products**

With incomplete combustion toxic gases such as carbon monoxide may be generated.

**SECTION 11: Toxicological information**

**11.1. Information on toxicological effects**

**Acute toxicity**

Harmful in contact with skin.

**ATEmix tested**

	Dose	Species	Source
LD50, oral	5000 mg/kg	Rat	
LD50, dermal	2000 mg/kg	Rat	

**Irritation and corrosivity**

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

**Sensitising effects**

May cause an allergic skin reaction. (Diurethane Dimethacrylate)

**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.

**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.

**12.2. Persistence and degradability**

The product has not been tested.

**12.3. Bioaccumulative potential**

The product has not been tested.

**Partition coefficient n-octanol/water**

CAS No	Chemical name	Log Pow
72869-86-4	Diurethane Dimethacrylate	3

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#### **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 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.

##### **Waste disposal number of waste from residues/unused products**

200139 MUNICIPAL WASTES (HOUSEHOLD WASTE AND SIMILAR COMMERCIAL, INDUSTRIAL AND INSTITUTIONAL WASTES) INCLUDING SEPARATELY COLLECTED FRACTIONS; separately collected fractions (except 15 01); Plastics

##### **Waste disposal number of used product**

200139 MUNICIPAL WASTES (HOUSEHOLD WASTE AND SIMILAR COMMERCIAL, INDUSTRIAL AND INSTITUTIONAL WASTES) INCLUDING SEPARATELY COLLECTED FRACTIONS; separately collected fractions (except 15 01); Plastics

##### **Contaminated packaging**

Non-contaminated packages may be recycled. Handle contaminated packages in the same way as the substance itself.

### SECTION 14: Transport information

#### **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**

##### **EU regulatory information**

2010/75/EU (VOC): 11,38 % (215,082 g/l)

2004/42/EC (VOC): 12,104 % (228,766 g/l)

##### **National regulatory information**

Employment restrictions: Observe restrictions to employment for juvenils according to the 'juvenile work protection guideline' (94/33/EC). Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers.

Water contaminating class (D): 2 - water contaminating

Skin resorption/Sensitization: Permeates easily through outer skin and causes poisoning. Causes allergic hypersensitivity reactions.

#### **15.2. Chemical safety assessment**

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

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

This data sheet contains changes from the previous version in section(s): 2,3,6,9,12,15.

**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)**

Harmful in contact with skin.

May cause an allergic skin reaction.

**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.

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