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

#### · 1.1 Product identifier

· Trade name: Prime & Bond NT

• 1.2 Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.

• Application of the substance / the preparation Adhesive

 $\cdot$  1.3 Details of the supplier of the safety data sheet

• Manufacturer/Supplier: DENTSPLY DeTrey GmbH De-Trey-Str. 1 D-78467 Konstanz GERMANY Tel.: +49-(0)7531-583-0 Fax: +49-(0)7531-583-104 email: KonstanzDEU.info-sdb@dentsply.com

#### · Further information obtainable from:

- Departement Analytical Research / Research & Development for technical information

- Departement Marketing & Sales for distribution of the safety data sheets
- 1.4 Emergency telephone number: +49-(0)7531-583-0 8:00 17:00 (GMT + 1:00)

## **2** Hazards identification

#### · 2.1 Classification of the substance or mixture

· Classification according to Directive 67/548/EEC or Directive 1999/45/EC

Xi; Irritant

R36/37/38: Irritating to eyes, respiratory system and skin.

F; Highly flammable

R11: Highly flammable.

R52/53-67: Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment. Vapours may cause drowsiness and dizziness.

• Information concerning particular hazards for human and environment:

The product has to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.

Has a narcotizing effect. • Classification system:

The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

· 2.2 Label elements

· Labelling according to EU guidelines:

The product has been classified and marked in accordance with EU Directives / Ordinance on Hazardous Materials

### · Code letter and hazard designation of product:



Xi Irritant F Highly flammable

#### · Risk phrases:

11 Highly flammable.

36/37/38 Irritating to eyes, respiratory system and skin.

52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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67 Vapours may cause drowsiness and dizziness.

#### · Safety phrases:

- 9 *Keep container in a well-ventilated place.*
- 16 Keep away from sources of ignition No smoking.
- 23 Do not breathe gas/fumes/vapour/spray (appropriate wording to be specified by the manufacturer).

24/25 Avoid contact with skin and eyes.

- 26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
- 61 Avoid release to the environment. Refer to special instructions/safety data sheets.
- · 2.3 Other hazards

· Results of PBT and vPvB assessment

- · PBT: Not applicable.
- · vPvB: Not applicable.

#### **3** Composition/information on ingredients

#### · 3.2 Chemical characterization: Mixtures

• Description: Mixture of substances listed below with nonhazardous additions.

CAS: 67-64-1	acetone	50-100%
EINECS: 200-662-2	🗙 Xi R36; 🔥 F R11	
Index number: 606-001-00-8	R66-67	
	🚸 Flam. Liq. 2, H225; 🚸 Eye Irrit. 2, H319; STOT SE 3, H336	
CAS: 105883-40-7	Urethan dimethacrylate resin	10-25%
	🗙 Xi R36/38	
	🚺 Skin Irrit. 2, H315; Eye Irrit. 2, H319	
Index number: 607-134-00-4	methacrylate with the exception of thosespecified elsewhere in this	2.5-10%
	Annex	
	🗙 Xi R36/37/38	
	🚸 Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	
Index number: 607-133-00-9	acrylates with the exception of those specified elsewhere in this Annex $\mathbf{X}$ Xi R36/37/38; $\mathbf{W}$ N R51/53	2.5-10%
	♦ Aquatic Chronic 2, H411; ♦ Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	
CAS: 3290-92-4	Trimethylolpropane Trimethacrylate (TMPTMA)	≤ 2.5%
	₩ N R51/53	
	🚯 Aquatic Chronic 2, H411	
CAS: 128-37-0	2,6-di-tert-butyl-p-cresol	≤ 2.5%
EINECS: 204-881-4	10 N R50/53	
	🚯 Aquatic Acute 1, H400; Aquatic Chronic 1, H410	

#### 4 First aid measures

• 4.1 Description of first aid measures

- After inhalation Supply fresh air; consult doctor in case of complaints.
- · After skin contact Immediately wash with water and soap and rinse thoroughly.
- · After eye contact
- Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- After swallowing If symptoms persist consult doctor.

• 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.

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• **4.3 Indication of any immediate medical attention and special treatment needed** *No further relevant information available.* 

#### **5** Firefighting measures

· 5.1 Extinguishing media

• Suitable extinguishing agents

- CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- · For safety reasons unsuitable extinguishing agents Water with full jet.
- 5.2 Special hazards arising from the substance or mixture No further relevant information available.
- · 5.3 Advice for firefighters
- · Protective equipment: Self-contained respiratory protective device.

## 6 Accidental release measures

- 6.1 Personal precautions, protective equipment and emergency procedures Wear protective equipment. Keep unprotected persons away.
- · 6.2 Environmental precautions:

Inform respective authorities in case of seepage into water course or sewage system. Dilute with plenty of water.

Do not allow to enter sewers/ surface or ground water.

- **6.3 Methods and material for containment and cleaning up:** Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Ensure adequate ventilation.
- 6.4 Reference to other sections
  See Section 7 for information on safe handling
  See Section 8 for information on personal protection equipment.
  See Section 13 for disposal information.

## 7 Handling and storage

- 7.1 Precautions for safe handling Ensure good ventilation/exhaustion at the workplace. Prevent formation of aerosols. Observe normal care for working with chemicals.
- Handling Product is intended for dental use only.
- Information about fire and explosion protection:



Keep ignition sources away - Do not smoke.

Protect against electrostatic charges.

- · 7.2 Conditions for safe storage, including any incompatibilities
- · Storage
- *Requirements to be met by storerooms and receptacles:* Store only in the original receptacle.

Store in a cool location.

• Information about storage in one common storage facility: Store away from oxidizing agents.

• Further information about storage conditions: Store in cool, dry conditions in well sealed receptacles.

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• 7.3 Specific end use(s) No further relevant information available.

### 8 Exposure controls/personal protection

• Additional information about design of technical facilities: No further data; see item 7.

· 8.1 Control parameters

· Ingredients with limit values that require monitoring at the workplace:

#### 67-64-1 acetone

WEL Short-term value: 3620 mg/m<sup>3</sup>, 1500 ppm

Long-term value: 1210 mg/m<sup>3</sup>, 500 ppm

 $\cdot DNELs$ 

128-37-0 2,6-di-tert-butyl-p-cresol

Inhalative DNEL Werte 3.5 mg/m<sup>3</sup> bw/day (rat)

• Additional information: The lists valid during the making were used as basis.

- · 8.2 Exposure controls
- · Personal protective equipment

• General protective and hygienic measures Keep away from foodstuffs, beverages and feed. Immediately remove all soiled and contaminated clothing Wash hands before breaks and at the end of work. Avoid contact with the eyes and skin.

• Respiratory protection: Use suitable respiratory protective device in case of insufficient ventilation.

• Protection of hands:



Protective gloves.

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation  $\cdot$  *Material of gloves* 

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application. Natural rubber, NR

Recommended thickness of the material:  $\geq 0.75$  mm Permeation: Level  $\geq 2$ 

• Penetration time of glove material

The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed.

• Eye protection:



Tightly sealed goggles.

• **Body protection:** Protective work clothing.

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9.1 Information on basic physical a	und chemical properties
General Information	
Appearance:	
Form: Colour:	Fluid Yellow
Odour:	Characteristic
Odour threshold:	Not determined.
pH-value:	Not determined.
-	Not actermined.
Change in condition	
Melting point/Melting range:	undetermined
Boiling point/Boiling range:	60 °C
Flash point:	-19 °C (c.c. Abel)
Flammability (solid, gaseous)	Not applicable.
Ignition temperature:	465 °C
Decomposition temperature:	Not determined.
Self-igniting:	Product is not selfigniting.
Danger of explosion:	Product is not explosive. However, formation of explosive air/vapou mixtures are possible.
Explosion limits:	
Lower:	2.6 Vol %
Upper:	12.8 Vol %
Vapour pressure at 20 °C:	233 hPa
Density at 20 °C:	$0.9 \ g/cm^3$
Relative density	Not determined.
Vapour density	Not determined.
Evaporation rate	Not determined.
Solubility in / Miscibility with	
Water:	Partly miscible
Partition coefficient (n-octanol/wat	er): Not determined.
Viscosity:	
dynamic:	Not determined.
kinematic:	Not determined.
Solvent content:	
Organic solvents:	66.0 %
Solids content:	3 %
9.2 Other information	No further relevant information available.

## 10 Stability and reactivity

- · 10.1 Reactivity
- · 10.2 Chemical stability
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · 10.3 Possibility of hazardous reactions No dangerous reactions known

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• 10.4 Conditions to avoid No further relevant information available.

• 10.5 Incompatible materials: No further relevant information available.

 $\cdot$  10.6 Hazardous decomposition products: No dangerous decomposition products known

## **11 Toxicological information**

· 11.1 Information on toxicological effects

• Acute toxicity:

· LD/LC50 values	relevant for	classification:
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67-64-1 ac		
Oral	LD50	5800 mg/kg (rat)
Dermal	LD50	20000 mg/kg (rabbit)
Inhalative	LC50/4 h	5800 mg/kg (rat) 20000 mg/kg (rabbit) 76 mg/l (rat)

## 3290-92-4 Trimethylolpropane Trimethacrylate (TMPTMA)

Oral LD50 >2000 mg/kg (rat)

128-37-0 2,6-di-tert-butyl-p-cresol

Oral LD50 2930 mg/kg (rat)

|LD50| > 2000 mg/kg (rabbit)

## · Primary irritant effect:

on the skin:

Dermal

Irritant to skin and mucous membranes.

The unpolymerized product may be irritant to the skin for succeptible persons.

• on the eye: Irritating effect.

• Sensitization:

Repeated or prolonged contact with the not polymerized product may cause sensitization for acrylates / methacrylates.

 $\cdot$  Additional toxicological information:

The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version. Irritant

## **12 Ecological information**

Aquatic to	xicity:
67-64-1 ac	cetone contract of the second s
EC50/48h	6100 mg/L (daphnia)
LC50/96h	5540 mg/l (fish)
3290-92-4	Trimethylolpropane Trimethacrylate (TMPTMA)
EC50/48h	>9.22 mg/L (daphnia)
LC50/96h	2 mg/l (fish)
128-37-0 2	2,6-di-tert-butyl-p-cresol
EC50/72h	>0.42 mg/l (algae)
LC50/48h	>0.57 mg/l (daphnia)
LC50/96h	>0.42 mg/l (fish)

• 12.3 Bioaccumulative potential No further relevant information available.

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• <b>12.4 Mobility in soil</b> No further relevant information available.	
· Ecotoxical effects:	
• <b>Remark:</b> Harmful to fish	
· Additional ecological information:	
· General notes:	
Harmful to aquatic organisms	
Do not allow product to reach ground water, water course or sewage system.	
Danger to drinking water if even small quantities leak into the ground.	
· 12.5 Results of PBT and vPvB assessment	
• <b>PBT:</b> Not applicable.	
• <b>vPvB:</b> Not applicable.	
· 12.6 Other adverse effects No further relevant information available.	

## 13 Disposal considerations

#### · 13.1 Waste treatment methods

· Recommendation



Must not be disposed together with household garbage. Do not allow product to reach sewage system.

#### · European waste catalogue

18 01 06\* chemicals consisting of or containing dangerous substances

· Uncleaned packaging:

- Recommendation: Disposal must be made according to official regulations.
- Recommended cleansing agents: Water, if necessary together with cleansing agents.

## 14 Transport information

14.1 UN-Number ADR, IMDG, IATA	UN1090	
14.2 UN proper shipping name ADR IMDG, IATA	1090 ACETONE, mixture ACETONE, mixture	
14.3 Transport hazard class(es)		
ADR		
Class	3 (F1) Flammable liquids.	
Label	3	
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· IMDG, IATA		
- Class	3 Flammable liquids.	
Label	3	
14.4 Packing group		
ADR, IMDG, IATA	II	
14.5 Environmental hazards:		
Marine pollutant:	No	
14.6 Special precautions for user	Warning: Flammable liquids.	
Danger code (Kemler):	33	
EMS Number:	F- $E$ , $S$ - $D$	
14.7 Transport in bulk according to Anne	ex II of	
MARPOL73/78 and the IBC Code	Not applicable.	
Transport/Additional information:		
ADR		
Limited quantities (LQ)	1L	
Transport category	2	
Tunnel restriction code	D/E	

## **15 Regulatory information**

· 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

### **16 Other information**

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

The attached safety data sheet covers the dangers and measures to be taken when large quantities of material are released, for example due to accidents during transport or storage by the dealer. For quantities of material typically used in clinical practice, information necessary for safe use and storage of the product is given in the DFU.

#### · Relevant phrases

H225	Highly flammable liquid and vapour.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H336	May cause drowsiness or dizziness.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H411	Toxic to aquatic life with long lasting effects.
R11	Highly flammable.
R36	Irritating to eyes.
R36/37/.	38 Irritating to eyes, respiratory system and skin.
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R36/38 Irritating to eyes and skin.

*R50/53* Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

*R66 Repeated exposure may cause skin dryness or cracking.* 

*R67 Vapours may cause drowsiness and dizziness.* 

· Department issuing MSDS: Analytical Research

• Contact: HotLine for urgent technical support: +49-7531-583-333

 $\cdot$  \* Data compared to the previous version altered.

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