

## **SAFETY DATA SHEETS**

**This SDS packet was issued with item:**

071803626

**The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).**

070446948 070447177 071803352 071803360 071805324 071805332

**The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).**

070446955 070447433 071704550 071837202

# Safety data sheet

## according to 1907/2006/EC, Article 31

Printing date 17.06.2015

Version number 5

Revision: 17.06.2015



### SECTION 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**
- **Application of the substance / the mixture** Adhesive
- **Uses advised against** No further relevant information available.
- **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)

### SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**

Flam. Liq. 2	H225 Highly flammable liquid and vapour.
Skin Irrit. 2	H315 Causes skin irritation.
Eye Irrit. 2	H319 Causes serious eye irritation.
STOT SE 3	H336 May cause drowsiness or dizziness.
Aquatic Chronic 3	H412 Harmful to aquatic life with long lasting effects.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**  
As this product is a medical device in the meaning of Directive 93/42/EEC and intended for use by the end consumer and is applied in an invasive manner or body contact, it is exempt from the labelling requirements according to regulation 1272/2008.  
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms**  

GHS02
GHS07
- **Signal word** Danger
- **Hazard-determining components of labelling:**  
acetone
- **Hazard statements**
  - H225 Highly flammable liquid and vapour.
  - H315 Causes skin irritation.
  - H319 Causes serious eye irritation.
  - H336 May cause drowsiness or dizziness.
  - H412 Harmful to aquatic life with long lasting effects.
- **Precautionary statements**
  - P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
  - P241 Use explosion-proof electrical/ventilating/lighting/equipment.

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**P303+P361+P353 IF ON SKIN (or hair):** Take off immediately all contaminated clothing. Rinse skin with water/shower.

**P305+P351+P338 IF IN EYES:** Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

**P405** Store locked up.

**P501** Dispose of contents/container in accordance with local/regional/national/international regulations.

- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

### SECTION 3: Composition/information on ingredients

- **3.2 Chemical characterisation: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

#### · **Dangerous components:**

CAS: 67-64-1 EINECS: 200-662-2	acetone ⚠ Flam. Liq. 2, H225; ⚠ Eye Irrit. 2, H319; STOT SE 3, H336	50-100%
CAS: 105883-40-7	Urethane Dimethacrylate Resin ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319	10-<25%
CAS: 87699-25-0	Dipentaerythritol pentaacrylate phosphate ⚠ Aquatic Chronic 2, H411; ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	3-<10%
CAS: 2358-84-1	Di(ethylene glycol) dimethacrylate ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	3-<10%
CAS: 3290-92-4	Trimethylolpropane Trimethacrylate (TMPTMA) ⚠ Aquatic Chronic 2, H411	1-≤2.5%
CAS: 128-37-0 EINECS: 204-881-4	2,6-di-tert-butyl-p-cresol ⚠ Aquatic Acute 1, H400; Aquatic Chronic 1, H410	0.3-<1%

- **Additional information** For the wording of the listed risk phrases refer to section 16.

### SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information** No special measures required.
- **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.
- **Information for doctor** No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

### SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents**  
CO<sub>2</sub>, 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.

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- **5.3 Advice for firefighters**
- **Protective equipment:** Self-contained respiratory protective device.

### SECTION 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.

### SECTION 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 in a cool location.  
Store only in the original receptacle.
- **Information about storage in one common storage facility:** Store away from oxidising agents.
- **Further information about storage conditions:** Store in cool, dry conditions in well sealed receptacles.
- **7.3 Specific end use(s)** No further relevant information available.

### SECTION 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

#### · DNELs

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

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

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

Not necessary if room is well-ventilated.

· **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

· **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 through 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.

**SECTION 9: Physical and chemical properties**

· **9.1 Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

Form: Fluid

Colour: Yellow

· **Odour:** Characteristic

· **Odour threshold:** Not determined.

· **pH-value:** Not determined.

· **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.

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· <b>Ignition temperature:</b>	465 °C
· <b>Decomposition temperature:</b>	Not determined.
· <b>Self-igniting:</b>	Product is not selfigniting.
· <b>Danger of explosion:</b>	Product is not explosive. However, formation of explosive air/vapour mixtures are possible.
· <b>Explosion limits:</b>	
<b>Lower:</b>	2.6 Vol %
<b>Upper:</b>	12.8 Vol %
· <b>Vapour pressure at 20 °C:</b>	233 hPa
· <b>Density at 20 °C:</b>	0.9 g/cm <sup>3</sup>
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not determined.
· <b>Evaporation rate</b>	Not determined.
· <b>Solubility in / Miscibility with Water:</b>	Partly miscible
· <b>Partition coefficient (n-octanol/water):</b>	Not determined.
· <b>Viscosity:</b>	
<b>dynamic:</b>	Not determined.
<b>kinematic:</b>	Not determined.
· <b>Solvent content:</b>	
<b>Organic solvents:</b>	67.0 %
<b>Solids content:</b>	3.0 %
· <b>9.2 Other information</b>	No further relevant information available.

### SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **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
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known

### SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity:**

· **LD/LC50 values relevant for classification:**

**ATE (Acute Toxicity Estimates)**

Inhalative	LC50/4 h	113 mg/l
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**67-64-1 acetone**

Oral	LD50	5800 mg/kg (rat)
Dermal	LD50	20000 mg/kg (rabbit)
Inhalative	LC50/4 h	76 mg/l (rat)

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

Oral	LD50	>2000 mg/kg (rat)
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**128-37-0 2,6-di-tert-butyl-p-cresol**

Oral	LD50	2930 mg/kg (rat)
Dermal	LD50	> 2000 mg/kg (rabbit)

· **Primary irritant effect:**· **on the skin:**

Irritant to skin and mucous membranes.

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

· **on the eye:** Irritating effect.· **Sensitisation:**

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

· **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

**SECTION 12: Ecological information**· **12.1 Toxicity**· **Aquatic toxicity:****67-64-1 acetone**

EC50/48h 6100 mg/L (daphnia magna)

LC50/96h 5540 mg/l (Fish acute toxicity study)

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

EC50/48h &gt;9.22 mg/L (daphnia magna)

LC50/96h 2 mg/l (Fish acute toxicity study)

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

EC50/72h &gt;0.42 mg/l (Algae, growth inhibition test)

LC50/48h &gt;0.57 mg/l (daphnia magna)

LC50/96h &gt;0.42 mg/l (Fish acute toxicity study)

· **12.2 Persistence and degradability** No further relevant information available.· **12.3 Bioaccumulative potential** No further relevant information available.· **12.4 Mobility in soil** No further relevant information available.· **Ecotoxicological effects:**· **Remark:** Harmful to fish· **Additional ecological information:**· **General notes:**

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.

Harmful to aquatic organisms

· **12.5 Results of PBT and vPvB assessment**· **PBT:** Not applicable.· **vPvB:** Not applicable.· **12.6 Other adverse effects** No further relevant information available.

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

### SECTION 14: Transport information

- 14.1 UN-Number

· ADR, IMDG, IATA	UN1090
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- 14.2 UN proper shipping name

· ADR	1090 ACETONE mixture
· IMDG, IATA	ACETONE mixture

- 14.3 Transport hazard class(es)

- ADR



· Class	3 (F1) Flammable liquids.
· Label	3

- IMDG, IATA



· Class	3 Flammable liquids.
· Label	3

- 14.4 Packing group

· ADR, IMDG, IATA	II
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- 14.5 Environmental hazards:

· Marine pollutant:	No
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- 14.6 Special precautions for user

· Danger code (Kemler):	Warning: Flammable liquids.
· EMS Number:	33

- 14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable.
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**· Transport/Additional information:****· ADR****· Limited quantities (LQ)**

1L

**· Excepted quantities (EQ)**

Code: E2

Maximum net quantity per inner packaging: 30 ml

Maximum net quantity per outer packaging: 500 ml

**· Transport category**

2

**· Tunnel restriction code**

D/E

**· IMDG****· Limited quantities (LQ)**

1L

**· Excepted quantities (EQ)**

Code: E2

Maximum net quantity per inner packaging: 30 ml

Maximum net quantity per outer packaging: 500 ml

**· UN "Model Regulation":**

UN1090, ACETONE mixture, 3, II

**SECTION 15: Regulatory information****· 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

No further relevant information available.

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

**· Department issuing MSDS:** Analytical Research**· Contact:** HotLine for urgent technical support: +49-7531-583-350**· 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 Harmonised 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 (division of the American Chemical Society)

DNEL: Derived No-Effect Level (REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

Flam. Liq. 2: Flammable liquids, Hazard Category 2

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2

Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2

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*STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3*  
*Aquatic Acute 1: Hazardous to the aquatic environment - Acute Hazard, Category 1*  
*Aquatic Chronic 1: Hazardous to the aquatic environment - Chronic Hazard, Category 1*  
*Aquatic Chronic 2: Hazardous to the aquatic environment - Chronic Hazard, Category 2*  
*Aquatic Chronic 3: Hazardous to the aquatic environment - Chronic Hazard, Category 3*  
· **\* Data compared to the previous version altered.**

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