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@dentsplysirona.com

Further information obtainable from:
- Department Research & Development for technical information
- Department 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.
Skin Sens. 1  H317  May cause an allergic skin reaction.
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
The product is classified and labelled according to the CLP regulation.

Hazard pictograms

GHS02  GHS07

Signal word: Danger

Hazard-determining components of labelling:
acetone
Di(ethylene glycol) dimethacrylate

Hazard statements

H225  Highly flammable liquid and vapour.
H315  Causes skin irritation.
H319  Causes serious eye irritation.
H317  May cause an allergic skin reaction.
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.

(Contd. on page 2)
Trade name: Prime & Bond NT

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.

Additional information:
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.

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:

<table>
<thead>
<tr>
<th>CAS</th>
<th>Description</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>67-64-1</td>
<td>acetone</td>
<td>50-100%</td>
</tr>
<tr>
<td>200-662-2</td>
<td><strong>Flam. Liq. 2, H225; Eye Irrit. 2, H319; STOT SE 3, H336</strong></td>
<td></td>
</tr>
<tr>
<td>105883-40-7</td>
<td>Urethane Dimethacrylate Resin</td>
<td>10-25%</td>
</tr>
<tr>
<td></td>
<td><strong>Skin Irrit. 2, H313; Eye Irrit. 2, H319</strong></td>
<td></td>
</tr>
<tr>
<td>87699-25-0</td>
<td>Dipentaerythritol pentaacrylate phosphate</td>
<td>2.5-&lt;10%</td>
</tr>
<tr>
<td></td>
<td><strong>Aquatic Chronic 2, H411; Skin Irrit. 2, H313; Eye Irrit. 2, H319; STOT SE 3, H335</strong></td>
<td></td>
</tr>
<tr>
<td>2358-84-1</td>
<td>Di(ethylene glycol) dimethacrylate</td>
<td>2.5-&lt;10%</td>
</tr>
<tr>
<td></td>
<td><strong>Skin Sens. 1, H317</strong></td>
<td></td>
</tr>
<tr>
<td>3290-92-4</td>
<td>propylidynetrimethyl trimethacrylate</td>
<td>0.25-&lt;2.5%</td>
</tr>
<tr>
<td></td>
<td><strong>Aquatic Chronic 2, H411</strong></td>
<td></td>
</tr>
<tr>
<td>128-37-0</td>
<td>2,6-di-tert-butyl-p-cresol</td>
<td>0.25-&lt;2.5%</td>
</tr>
<tr>
<td>EINECS: 204-881-4</td>
<td><strong>Aquatic Acute 1, H400; Aquatic Chronic 1, H410</strong></td>
<td></td>
</tr>
</tbody>
</table>

Additional information: For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures
General information: Immediately remove any clothing soiled by the product.
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
    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.

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
  - Observe normal care for working with chemicals.
  - Prevent formation of aerosols.
  - Ensure good ventilation/exhaustion at the workplace.
- 7.2 Conditions for safe storage, including any incompatibilities
  - 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.
- 7.3 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:

<table>
<thead>
<tr>
<th>CAS: 67-64-1 acetone</th>
</tr>
</thead>
<tbody>
<tr>
<td>WEL: Short-term value: 3620 mg/m³, 1500 ppm</td>
</tr>
<tr>
<td>Long-term value: 1210 mg/m³, 500 ppm</td>
</tr>
</tbody>
</table>

Regulatory information WEL: EH40/2011

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:
Not necessary if room is well-ventilated.
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.

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: ≥ 0.75 mm
Permeation: Level ≥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.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Appearance:
Form: Fluid
Trade name: Prime & Bond NT

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour</td>
<td>Yellow</td>
</tr>
<tr>
<td>Odour</td>
<td>Characteristic</td>
</tr>
<tr>
<td>Odour threshold</td>
<td>Not determined.</td>
</tr>
<tr>
<td>pH-value</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Melting point/freezing</td>
<td>undetermined</td>
</tr>
<tr>
<td>Initial boiling point</td>
<td>60 °C</td>
</tr>
<tr>
<td>Flash point</td>
<td>-19 °C (c.c. Abel)</td>
</tr>
<tr>
<td>Flammability (solid,</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>gaseous)</td>
<td></td>
</tr>
<tr>
<td>Ignition temperature</td>
<td>465 °C</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>Product is not selfigniting.</td>
</tr>
<tr>
<td>Explosion properties</td>
<td>Product is not explosive.</td>
</tr>
<tr>
<td></td>
<td>However, formation of</td>
</tr>
<tr>
<td></td>
<td>explosive air/vapour</td>
</tr>
<tr>
<td></td>
<td>mixtures are possible.</td>
</tr>
<tr>
<td>Vapour pressure at 20 °C</td>
<td>233 hPa</td>
</tr>
<tr>
<td>Density at 20 °C</td>
<td>0.9 g/cm³</td>
</tr>
<tr>
<td>Relative density</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Vapour density</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Solubility in / Miscibility with Water</td>
<td>Partly miscible</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Viscosity</td>
<td>dynamic: Not determined.</td>
</tr>
<tr>
<td></td>
<td>kinematic: Not determined.</td>
</tr>
<tr>
<td>Solvent content</td>
<td>Organic solvents: 67.0 %</td>
</tr>
<tr>
<td>Solids content</td>
<td>3.0 %</td>
</tr>
<tr>
<td>9.2 Other information</td>
<td>No further relevant information available.</td>
</tr>
</tbody>
</table>

**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: Based on available data, the classification criteria are not met.
Trade name: Prime & Bond NT

[LD/LC50 values relevant for classification:

<table>
<thead>
<tr>
<th>CAS: 67-64-1 acetone</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Oral</strong></td>
</tr>
<tr>
<td><strong>Dermal</strong></td>
</tr>
<tr>
<td><strong>Inhalative</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAS: 3290-92-4 propyldydatrimethyl trimethacrylate</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Oral</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAS: 128-37-0 2,6-di-tert-butyl-p-cresol</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Oral</strong></td>
</tr>
<tr>
<td><strong>Dermal</strong></td>
</tr>
</tbody>
</table>

· Primary irritant effect:
· Skin corrosion/irritation
  Causes skin irritation.
· Serious eye damage/irritation
  Causes serious eye irritation.
· Respiratory or skin sensitisation
  Repeated or prolonged contact with the not polymerized product may cause sensitization for acrylates / methacrylates.
  May cause an allergic skin reaction.
· CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
  · Germ cell mutagenicity
    Based on available data, the classification criteria are not met.
  · Carcinogenicity
    Based on available data, the classification criteria are not met.
  · Reproductive toxicity
    Based on available data, the classification criteria are not met.
  · STOT-single exposure
    May cause drowsiness or dizziness.
· 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.

SECTION 12: Ecological information

· 12.1 Toxicity

<table>
<thead>
<tr>
<th>CAS: 67-64-1 acetone</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>LC50/96h</strong></td>
</tr>
<tr>
<td><strong>EC50/48h</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAS: 3290-92-4 propyldydatrimethyl trimethacrylate</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>LC50/96h</strong></td>
</tr>
<tr>
<td><strong>EC50/48h</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAS: 128-37-0 2,6-di-tert-butyl-p-cresol</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>LC50/96h</strong></td>
</tr>
<tr>
<td><strong>LC50/96h</strong></td>
</tr>
<tr>
<td><strong>EC50/72h</strong></td>
</tr>
</tbody>
</table>

· 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.
· Ecological 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
Trade name: Prime & Bond NT

**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 hazardous substances
  - HP 3 Flammable
  - HP 4 Irritant - skin irritation and eye damage
  - HP 5 Specific Target Organ Toxicity (STOT)/Aspiration Toxicity
  - HP 13 Sensitising
  - HP 14 Ecotoxic

- **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

- **14.2 UN proper shipping name**
  - ADR
  - IMDG, IATA 1090 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
4.1.9  

· 14.5 Environmental hazards: Not applicable. 
· 14.6 Special precautions for user Warning: Flammable liquids. 
  · Danger code (Kemler): 33 
  · EMS Number: F-E,S-D 
  · Stowage Category E 
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code Not applicable. 

· 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": UN 1090 ACETONE MIXTURE, 3, II 

*SECTION 15: Regulatory information* 

· 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture 
  · Directive 2012/18/EU 
  · Named dangerous substances - ANNEX I None of the ingredients is listed. 
  · Seveso category P5c FLAMMABLE LIQUIDS 
  · Qualifying quantity (tonnes) for the application of lower-tier requirements 5,000 t 
  · Qualifying quantity (tonnes) for the application of upper-tier requirements 50,000 t 
  · REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3 
· 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. 
  H317 May cause an allergic skin reaction. 
  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. 

(Contd. on page 9)
H411 Toxic to aquatic life with long lasting effects.

- **Department issuing SDS:** Research & Development
- **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
  - PBT: Persistent, Bioaccumulative and Toxic
  - vPvB: very Persistent and very Bioaccumulative
  - Flam. Liq. 2: Flammable liquids – Category 2
  - Skin Irrit. 2: Skin corrosion/irritation – Category 2
  - Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
  - Skin Sens. 1: Skin sensitisation – Category 1
  - STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
  - Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1
  - Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1
  - Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2
  - Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3
- *Data compared to the previous version altered.*