SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
- Trade name: Prime & Bond XP

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

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  H335 May cause respiratory irritation.
  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:
  2-hydroxyethyl methacrylate
tert-butyl alcohol
Butanedioic acid, 1,4-bis[(2-methyl-1-oxo-2-propen-1-yl)oxy]ethyl ester 2,3 dicarboxylic acid
Dipentaerythritol pentaacrylate phosphate

- Hazard statements
  H225 Highly flammable liquid and vapour.
  H315 Causes skin irritation.
  H319 Causes serious eye irritation.
  H317 May cause an allergic skin reaction.
  H335 May cause respiratory irritation.
  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.
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>EINECS:</th>
<th>Description</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>868-77-9</td>
<td>212-782-2</td>
<td>2-hydroxyethyl methacrylate</td>
<td>25-50%</td>
</tr>
<tr>
<td>75-65-0</td>
<td>200-889-7</td>
<td>tert-butyl alcohol</td>
<td>10-&lt;25%</td>
</tr>
<tr>
<td>87699-25-0</td>
<td></td>
<td>Dipentaerythritol pentaacrylate phosphate</td>
<td>10-&lt;25%</td>
</tr>
<tr>
<td>144144-04-7</td>
<td></td>
<td>Butanedioic acid, 1,4-bis[2-[(2-methyl-1-oxo-2-propen-1-yl)oxy]ethyl] ester 2,3 dicarboxylic acid</td>
<td>2.5-&lt;10%</td>
</tr>
<tr>
<td>109-16-0</td>
<td>203-652-6</td>
<td>2,2'-Ethylendioxydiethylidimethacrylat</td>
<td>2.5-&lt;10%</td>
</tr>
<tr>
<td>105883-40-7</td>
<td></td>
<td>Urethane Dimethacrylate Resin</td>
<td>2.5-&lt;10%</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
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.

(Contd. on page 3)
SECTION 5: Firefighting measures

5.1 Extinguishing media
- Suitable extinguishing agents: CO₂, sand, extinguishing powder. Do not use water.
- For safety reasons unsuitable extinguishing agents: Water.

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.
- 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.
- Do not flush with water or aqueous cleansing agents.

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.

7.2 Conditions for safe storage, including any incompatibilities
- Storage
  - Requirements to be met by storerooms and receptacles: Store only in the original receptacle.
  - Information about storage in one common storage facility: Store away from oxidising agents.

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: 75-65-0 tert-butyl alcohol</th>
</tr>
</thead>
<tbody>
<tr>
<td>WEL:</td>
</tr>
<tr>
<td>Short-term value: 462 mg/m³, 150 ppm</td>
</tr>
<tr>
<td>Long-term value: 308 mg/m³, 100 ppm</td>
</tr>
</tbody>
</table>

- Regulatory information WEL: EH40/2011
- 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: 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
    
    Nitrile rubber, NBR
    Recommended thickness of the material: ≥ 0.4 mm
    Permeation: Level ≥6
    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.

  - Penetration time of glove material
    
    The exact breakthrough 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: Light yellow
  Odour: Characteristic
  Odour threshold: Not determined.
**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.
- **LD/LC50 values relevant for classification:**
  - **ATE (Acute Toxicity Estimates)**
  - Inhalative [LC50/4 h] 44.9 mg/l
### 2.0.15

<table>
<thead>
<tr>
<th>CAS: 868-77-9 2-hydroxyethyl methacrylate</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral LD50</td>
<td>&gt;5000 mg/kg (rat)</td>
</tr>
<tr>
<td>Dermal LD50</td>
<td>&gt;3000 mg/kg (rabbit)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAS: 75-65-0 tert-butyl alcohol</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral LD50</td>
<td>2743 mg/kg (rat)</td>
</tr>
<tr>
<td>Dermal LD50</td>
<td>&gt; 2000 mg/kg (rabbit)</td>
</tr>
<tr>
<td>Inhalative LC50/4 h 11 mg/l (ATE)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAS: 109-16-0 2,2'-Ethylendioxydiethylmethacrylat</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral LD50</td>
<td>&gt;5000 mg/kg (rat)</td>
</tr>
<tr>
<td>Dermal LD50</td>
<td>&gt;2000 mg/kg (mouse)</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.
- **Other information (about experimental toxicology):**
  Mutagenicity (AMES) : negative
  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 respiratory irritation.
  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

**Aquatic toxicity:**

<table>
<thead>
<tr>
<th>CAS: 868-77-9 2-hydroxyethyl methacrylate</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>LC50/96 h</td>
<td>&gt;100 mg/l (Fish acute toxicity study)</td>
</tr>
<tr>
<td>EC50/48 h</td>
<td>380 mg/L (daphnia magna)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAS: 75-65-0 tert-butyl alcohol</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>LC50/96 h</td>
<td>6,140 mg/l (Fish acute toxicity study)</td>
</tr>
<tr>
<td>EC50/48 h</td>
<td>933 mg/L (daphnia magna)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAS: 109-16-0 2,2'-Ethylendioxydiethylmethacrylat</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>LC50/96 h</td>
<td>16.4 mg/l (Fish acute toxicity study)</td>
</tr>
<tr>
<td>EC50/72 h</td>
<td>&gt;100 mg/l (Alg)</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.

**Ecotoxic 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
2.0.15 12.5 Results of PBT and vPvB assessment
- PBT: Not applicable.
- vPvB: Not applicable.

12.6 Other adverse effects: No further relevant information available.

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.

SECTION 14: Transport information

14.1 UN-Number
- ADR, IMDG, IATA UN1120

14.2 UN proper shipping name
- ADR
- IMDG BUTANOLS mixture
- IATA Butanols 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
Trade name: Prime & Bond XP

- **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-E
  - Stowage Category: B

- **14.7 Transport in bulk according to Annex II of Marpol and the IBC Code**
  - Not applicable.

- **14.8 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":** UN1120, BUTANOLS 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
  - 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

- **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.
  - H332 Harmful if inhaled.
  - H335 May cause respiratory irritation.
  - H411 Toxic to aquatic life with long lasting effects.

- **Department issuing SDS:** Research & Development
- **Contact:** HotLine for urgent technical support: +49-7531-583-350

(Contd. on page 9)
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)
- 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, Hazard Category 2
- Acute Tox. 4: Acute toxicity, Hazard Category 4
- Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2
- Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2
- Skin Sens. 1: Sensitisation - Skin, Hazard Category 1
- STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3
- 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.