

# Safety data sheet

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

Printing date 14.09.2017

Version number 5

Revision: 14.09.2017

### 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
- **Further information obtainable from:**
  - Departement 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.
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-[(2-methyl-1-oxo-2-propen-1-yl)oxy]ethyl] ester 2,3 dicarboxylic acid
  - Dipentaerythritol pentaacrylate phosphate
  - 2,2'-Ethylendioxydiethyldimethacrylat
- **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.

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

CAS: 868-77-9 EINECS: 212-782-2	2-hydroxyethyl methacrylate ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335	25-50%
CAS: 75-65-0 EINECS: 200-889-7	tert-butyl alcohol ⚠ Flam. Liq. 2, H225; ⚠ Acute Tox. 4, H332; Eye Irrit. 2, H319; STOT SE 3, H335	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	10-<25%
CAS: 144144-04-7	Butanedioic acid, 1,4-bis[2-[(2-methyl-1-oxo-2-propen-1-yl)oxy]ethyl] ester 2,3 dicarboxylic acid ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335	2.5-<10%
CAS: 109-16-0 EINECS: 203-652-6	2,2'-Ethylendioxydiethyldimethacrylat ⚠ Skin Sens. 1, H317	2.5-<10%
CAS: 105883-40-7	Urethane Dimethacrylate Resin ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319	2.5-<10%

• **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.

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- **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, 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**  
Observe normal care for working with chemicals.  
Prevent formation of aerosols.  
Ensure good ventilation/exhaustion at the workplace.

- **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.  
Protect from heat.

- **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.
- **Further information about storage conditions:**  
Keep receptacle tightly sealed.  
Protect from heat and direct sunlight.
- **7.3 Specific end use(s)** No further relevant information available.

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### 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:**

CAS: 75-65-0 tert-butyl alcohol

WEL	Short-term value: 462 mg/m <sup>3</sup> , 150 ppm
	Long-term value: 308 mg/m <sup>3</sup> , 100 ppm

· **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

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.

Nitrile rubber, NBR

Recommended thickness of the material:  $\geq 0.4$  mm

Permeation: Level  $\geq 6$

##### · 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:

Light yellow

##### · Odour:

Characteristic

##### · Odour threshold:

Not determined.

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· <b>pH-value:</b>	Not determined.
· <b>Change in condition</b> Melting point/freezing point:	undetermined
Initial boiling point and boiling range:	111 °C
· <b>Flash point:</b>	21 °C (c.c. Abel)
· <b>Flammability (solid, gaseous)</b>	Not applicable.
· <b>Ignition temperature:</b>	470 °C (tert-Butanol)
· <b>Decomposition temperature:</b>	Not determined.
· <b>Auto-ignition temperature:</b>	Product is not selfigniting.
· <b>Explosive properties:</b>	Product is not explosive. However, formation of explosive air/vapour mixtures are possible.
· <b>Explosion limits:</b> Lower:	2.4 Vol % (tert-Butanol)
Upper:	8.0 Vol % (tert-Butanol)
· <b>Vapour pressure at 20 °C:</b>	41 hPa
· <b>Density at 20 °C:</b>	1.044 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> dynamic:	Not determined.
kinematic:	Not determined.
· <b>Solvent content:</b> Organic solvents:	0.0 %
Solids content:	8.0 %
· <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** Based on available data, the classification criteria are not met.

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<b>· LD/LC50 values relevant for classification:</b>		
<b>ATE (Acute Toxicity Estimate)</b>		
Dermal	LD50	>7,257 mg/kg
Inhalative	LC50/4 h	44.9 mg/l
<b>CAS: 868-77-9 2-hydroxyethyl methacrylate</b>		
Oral	LD50	>5,000 mg/kg (rat)
Dermal	LD50	>3,000 mg/kg (rabbit)
<b>CAS: 75-65-0 tert-butyl alcohol</b>		
Oral	LD50	2,743 mg/kg (rat)
Dermal	LD50	>2,000 mg/kg (rabbit)
Inhalative	LC50/4 h	11 mg/l (ATE)
<b>CAS: 109-16-0 2,2'-Ethylendioxydiethyldimethacrylat</b>		
Oral	LD50	>5,000 mg/kg (rat)
Dermal	LD50	>2,000 mg/kg (mouse)

- **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 (carcinogenicity, 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

<b>· Aquatic toxicity:</b>	
<b>CAS: 868-77-9 2-hydroxyethyl methacrylate</b>	
LC50/96h	>100 mg/l (Fish acute toxicity study)
EC50/48h	380 mg/L (daphnia magna)
<b>CAS: 75-65-0 tert-butyl alcohol</b>	
LC50/96h	6,140 mg/l (Fish acute toxicity study)
EC50/48h	933 mg/L (daphnia magna)
<b>CAS: 109-16-0 2,2'-Ethylendioxydiethyldimethacrylat</b>	
LC50/96h	16.4 mg/l (Fish acute toxicity study)
EC50/72h	>100 mg/l (Pseudokirchnerella subcapitata)

- **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

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- **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.

### 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** 1120 BUTANOLS mixture
- **IMDG, IATA** BUTANOLS mixture

- **14.3 Transport hazard class(es)**

- **ADR**



- **Class** 3 (F1) Flammable liquids.
- **Label** 3

- **IMDG, IATA**



- **Class** 3 Flammable liquids.

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· <b>Label</b>	3
· <b>14.4 Packing group</b>	
· <b>ADR, IMDG, IATA</b>	II
· <b>14.5 Environmental hazards:</b>	Not applicable.
· <b>14.6 Special precautions for user</b>	Warning: Flammable liquids.
· <b>Danger code (Kemler):</b>	33
· <b>EMS Number:</b>	F-E,S-D
· <b>Stowage Category</b>	B
· <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b>	Not applicable.
· <b>Transport/Additional information:</b>	
· <b>ADR</b>	
· <b>Limited quantities (LQ)</b>	1L
· <b>Excepted quantities (EQ)</b>	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· <b>Transport category</b>	2
· <b>Tunnel restriction code</b>	D/E
· <b>IMDG</b>	
· <b>Limited quantities (LQ)</b>	1L
· <b>Excepted quantities (EQ)</b>	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· <b>UN "Model Regulation":</b>	UN 1120 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**
- **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.
- H332 Harmful if inhaled.

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*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

· **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 – Category 2

Acute Tox. 4: Acute toxicity – Category 4

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 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.**

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