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according to 1907/2006/EC, Article 31

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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@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.
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**
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:**
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
· **Hazard statements**
H225 Highly flammable liquid and vapour.
H315 Causes skin irritation.

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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.*
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/ 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: 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*	*3-<10%*
CAS: 109-16-0 *EINECS: 203-652-6*	*2,2'-Ethylendioxydiethyldimethacrylat* *Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335*	*3-<10%*
CAS: 105883-40-7	*Urethane Dimethacrylate Resin* *Skin Irrit. 2, H315; Eye Irrit. 2, H319*	*3-<10%*

· ***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***
· ***After inhalation*** *Supply fresh air; consult doctor in case of complaints.*
· ***After skin contact*** *Immediately wash with water and soap and rinse thoroughly.*

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· ***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, 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.

· ***Handling*** *Product is intended for dental use only.*
· ***Information about fire - and explosion protection:***



Keep ignition sources away - Do not smoke.

Protect from heat.
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.*

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· ***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.*

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:***	
75-65-0 tert-butyl alcohol	
WEL	*Short-term value: 462 mg/m³, 150 ppm* *Long-term value: 308 mg/m³, 100 ppm*
144144-04-7 Butanedioic acid, 1,4-bis[2-[(2-methyl-1-oxo-2-propen-1-yl)oxy]ethyl] ester 2,3 dicarboxylic acid	
WEL	*Short-term value: 0.2 mg/m³* *Long-term value: 0.1 mg/m³* *as Sn; Sk*

· ***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 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.

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· ***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.*
· ***pH-value:***	*Not determined.*
· ***Change in condition***	
Melting point/Melting range:	*undetermined*
Boiling point/Boiling range:	*111 °C*
· ***Flash point:***	*21 °C (c.c. Abel)*
· ***Flammability (solid, gaseous)***	*Not applicable.*
· ***Ignition temperature:***	*470 °C (tert-Butanol)*
· ***Decomposition temperature:***	*Not determined.*
· ***Self-igniting:***	*Product is not selfigniting.*
· ***Danger of explosion:***	*Product is not explosive. However, formation of explosive air/vapour mixtures are possible.*
· ***Explosion limits:***	
Lower:	*2.4 Vol % (tert-Butanol)*
Upper:	*8.0 Vol % (tert-Butanol)*
· ***Vapour pressure at 20 °C:***	*41 hPa*
· ***Density at 20 °C:***	*1.044 g/cm³*
· ***Relative density***	*Not determined.*
· ***Vapour density***	*Not determined.*
· ***Evaporation rate***	*Not determined.*
· ***Solubility in / Miscibility with***	
Water:	*Partly miscible*
· ***Partition coefficient (n-octanol/water):***	*Not determined.*
· ***Viscosity:***	
dynamic:	*Not determined.*
kinematic:	*Not determined.*
· ***Solvent content:***	
Organic solvents:	*0.0 %*
Solids content:	*8.0 %*
· ***9.2 Other information***	*No further relevant information available.*

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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*	*44.9 mg/l*

868-77-9 2-hydroxyethyl methacrylate		
Oral	*LD50*	*>5000 mg/kg (rat)*
Dermal	*LD50*	*>3000 mg/kg (rabbit)*
75-65-0 tert-butyl alcohol		
Oral	*LD50*	*2743 mg/kg (rat)*
Dermal	*LD50*	*> 2000 mg/kg (rabbit)*
Inhalative	*LC50/4 h*	*11 mg/l (ATE)*
109-16-0 2,2'-Ethylendioxydiethyldimethacrylat		
Oral	*LD50*	*>5000 mg/kg (rat)*
Dermal	*LD50*	*>2000 mg/kg (mouse)*

· ***Primary irritant effect:***
· ***on the skin:***
Irritant to skin and mucous membranes.
The unpolymerized product may be irritant to the skin for succeptible persons.
· ***on the eye:*** *Irritating effect.*
· ***Sensitisation:***
Sensitisation possible through skin contact.
Repeated or prolonged contact with the not polymerized product may cause sensitization for acrylates / methacrylates.
· ***Other information (about experimental toxicology):*** *Mutagenicity (AMES) : negative*
· ***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

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SECTION 12: Ecological information

· **12.1 Toxicity**

· **Aquatic toxicity:**	
868-77-9 2-hydroxyethyl methacrylate	
EC50/48h	380 mg/L (daphnia magna)
LC50/96h	>100 mg/l (Fish acute toxicity study)
75-65-0 tert-butyl alcohol	
EC50/48h	933 mg/L (daphnia magna)
LC50/96h	6.140 mg/l (Fish acute toxicity study)
109-16-0 2,2'-Ethylendioxydiethyldimethacrylat	
EC50/72h	>100 mg/l (Alg)
LC50/96h	16.4 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.
· **Ecotoxical 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.

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

· **Uncleaned packaging:**
· **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

· **14.1 UN-Number**
· **ADR, IMDG, IATA** UN1120

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· **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.
· **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-E
· **14.7 Transport in bulk according to Annex II of MARPOL73/78 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":**	UN1120, BUTANOLS mixture, 3, II

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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.
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 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)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
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.**