

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 13.12.2022

Version number 7 (replaces version 6)

Revision: 13.12.2022

Start

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:** Research and Development
- **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.
Repr. 1B	H360 May damage fertility or the unborn child.
STOT SE 3	H335 May cause respiratory irritation.
Aquatic Chronic 3	H412 Harmful to aquatic life with long lasting effects.
- **Additional information:**
The reproductive toxicity effect only occurs when several bottles of Prime & Bond XP are used daily on a 50 kg patient.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the GB CLP regulation.
- **Hazard pictograms**





GHS02
GHS07
GHS08
- **Signal word** Danger
- **Hazard-determining components of labelling:**
 - 2-hydroxyethyl methacrylate
 - Ethyl-4-dimethylaminobenzoat
 - tert-butyl alcohol
 - Butan-1,2,3,4-tetracarbonsäure di-2-hydroxyethylmethacrylat
 - 2,2'-ethylenedioxydiethyl dimethacrylate
 - 2-tert-butylhydroquinone
- **Hazard statements**
 - H225 Highly flammable liquid and vapour.
 - H315 Causes skin irritation.
 - H319 Causes serious eye irritation.
 - H317 May cause an allergic skin reaction.
 - H360 May damage fertility or the unborn child.

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*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 [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 regulation (EC) 2017/745 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 (EC) 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 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	≥ 20 – ≤ 25%
CAS: 87699-25-0	Dipentaerythritol pentaacrylate phosphate Aquatic Chronic 2, H411; Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335 Specific concentration limit: STOT SE 3; C ≥ 10 %	≥ 10 – < 25%
CAS: 144144-04-7	Butan-1,2,3,4-tetracarbonsäure di-2-hydroxyethylmethacrylat 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'-ethylenedioxydiethyl dimethacrylate 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%
CAS: 10287-53-3	Ethyl-4-dimethylaminobenzoat Repr. 1B, H360; Aquatic Chronic 2, H411	≥ 0.3 – < 2.5%
CAS: 1948-33-0 EINECS: 217-752-2	2-tert-butylhydroquinone Aquatic Acute 1, H400; Aquatic Chronic 1, H410; Acute Tox. 4, H302; Acute Tox. 4, H312; Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	≥ 0.1 – < 0.25%

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

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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.
- **Information for doctor** No further relevant information available.
- **4.2 Most important symptoms and effects, both acute and delayed** 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:** 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).
Dispose contaminated material as waste according to item 13.
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.
- **Information about fire - and explosion protection:**



Keep ignition sources away - Do not smoke.

Protect against electrostatic charges.
Keep respiratory protective device available.

- **Handling** Product is intended for dental use only.

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- **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.

SECTION 8: Exposure controls/personal protection

· 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 ³ , 150 ppm
	Long-term value: 308 mg/m ³ , 100 ppm

- **Regulatory information** WEL: EH40/2020
- **Additional information:** The lists valid during the making were used as basis.

· 8.2 Exposure controls

- **Appropriate engineering controls** No further data; see item 7.
- **Individual protection measures, such as 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.
- **Hand protection**



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: ≥ 0.4 mmPermeation: Level ≥ 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/face 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

· Physical state	Fluid
· Colour:	Light yellow
· Odour:	Characteristic
· Odour threshold:	Not determined.
· Melting point/freezing point:	undetermined
· Boiling point or initial boiling point and boiling range	111 °C
· Flammability	Not applicable.
· Lower and upper explosion limit	
· Lower:	2.4 Vol %
· Upper:	8 Vol %
· Flash point:	21 °C (c.c. Abel)
· Ignition temperature:	470 °C (tert.-Butanol)
· Decomposition temperature:	Not determined.
· pH	Not determined.
· Viscosity:	
· Kinematic viscosity	Not determined.
· dynamic:	Not determined.
· Solubility	
· Water:	Partly miscible
· Partition coefficient n-octanol/water (log value)	Not determined.
· Vapour pressure at 20 °C:	41 hPa
· Density and/or relative density	
· Density at 20 °C:	1.044 g/cm ³
· Relative density	Not determined.
· Vapour density	Not determined.

· 9.2 Other information

· Appearance:	
· Form:	Fluid
· Important information on protection of health and environment, and on safety.	
· Auto-ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product is not explosive. However, formation of explosive air/vapour mixtures are possible.
· Solvent content:	
· Solids content:	8.0 %
· Change in condition	
· Evaporation rate	Not determined.

· Information with regard to physical hazard classes

· Explosives	Void
· Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Highly flammable liquid and vapour.
· Flammable solids	Void
· Self-reactive substances and mixtures	Void
· Pyrophoric liquids	Void
· Pyrophoric solids	Void

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- | | |
|---|------|
| · Self-heating substances and mixtures | Void |
| · Substances and mixtures, which emit flammable gases in contact with water | Void |
| · Oxidising liquids | Void |
| · Oxidising solids | Void |
| · Organic peroxides | Void |
| · Corrosive to metals | Void |
| · Desensitised explosives | Void |

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 hazard classes as defined in Regulation (EC) No 1272/2008**

- **Acute toxicity**

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

ATE (Acute Toxicity Estimate)

Inhalative	LC50/4 h	44.9 mg/l
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CAS: 868-77-9 2-hydroxyethyl methacrylate

Oral	LD50	> 5,000 mg/kg (rat)
Dermal	LD50	> 3,000 mg/kg (rabbit)

CAS: 75-65-0 tert-butyl alcohol

Oral	LD50	2,743 mg/kg (rat)
Dermal	LD50	> 2,000 mg/kg (rabbit)
Inhalative	LC50/4 h	11 mg/l (ATE)

CAS: 109-16-0 2,2'-ethylenedioxydiethyl dimethacrylate

Oral	LD50	> 5,000 mg/kg (rat)
Dermal	LD50	> 2,000 mg/kg (mouse)

CAS: 10287-53-3 Ethyl-4-dimethylaminobenzoate

Oral	LD50	> 2,000 mg/kg (rat) (OECD 401)
Dermal	LD50	> 2,000 mg/kg (rat)

CAS: 1948-33-0 2-tert-butylhydroquinone

Oral	LD50	700 mg/kg (rat)
Dermal	LD50	1,100 mg/kg (ATE)

- **Skin corrosion/irritation** Causes skin irritation.
- **Serious eye damage/irritation** Causes serious eye irritation.
- **Respiratory or skin sensitisation**
May cause an allergic skin reaction.
Repeated or prolonged contact with the not polymerized product may cause sensitization for acrylates / methacrylates.
- **Reproductive toxicity** May damage fertility or the unborn child.
- **STOT-single exposure** May cause respiratory irritation.

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· 11.2 Information on other hazards

· Endocrine disrupting properties

None of the ingredients is listed.

· Other information

The reproductive toxicity effect only occurs when several bottles of Prime & Bond XP are used daily on a 50 kg patient.

SECTION 12: Ecological information

· 12.1 Toxicity

· Aquatic toxicity:

CAS: 868-77-9 2-hydroxyethyl methacrylate

LC50/96h > 100 mg/l (Fish acute toxicity study)

EC50/48h 380 mg/L (daphnia magna)

CAS: 75-65-0 tert-butyl alcohol

LC50/96h 6,140 mg/l (Fish acute toxicity study)

EC50/48h 933 mg/L (daphnia magna)

CAS: 109-16-0 2,2'-ethylenedioxydiethyl dimethacrylate

LC50/96h 16.4 mg/l (Brachydanio rerio)

EC50/72h > 100 mg/l (Pseudokirchnerella subcapitata)

CAS: 1948-33-0 2-tert-butylhydroquinone

LC50/48h 0.37 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.

· 12.5 Results of PBT and vPvB assessment

· PBT: Not applicable.

· vPvB: Not applicable.

· 12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

· 12.7 Other adverse 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

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.

· Uncleaned packaging:

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

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SECTION 14: Transport information

· 14.1 UN number or ID number · ADR, IMDG, IATA	UN1120
· 14.2 UN proper shipping name · ADR · IMDG, IATA	1120 BUTANOLS mixture BUTANOLS mixture
· 14.3 Transport hazard class(es) · ADR	
	
· Class · Label	3 (F1) Flammable liquids. 3
· IMDG, IATA	
	
· Class · Label	3 Flammable liquids. 3
· 14.4 Packing group · ADR, IMDG, IATA	II
· 14.5 Environmental hazards:	Not applicable.
· 14.6 Special precautions for user · Hazard identification number (Kemler code): · EMS Number: · Stowage Category	Warning: Flammable liquids. 33 F-E,S-D B
· 14.7 Maritime transport in bulk according to IMO instruments	Not applicable.
· Transport/Additional information:	
· ADR · Limited quantities (LQ) · Excepted quantities (EQ)	1L Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· Transport category · Tunnel restriction code	2 D/E
· IMDG · Limited quantities (LQ) · Excepted quantities (EQ)	1L Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· UN "Model Regulation":	UN 1120 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**
- **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
- **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.
- H302 Harmful if swallowed.
- H312 Harmful in contact with skin.
- 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.
- H360 May damage fertility or the unborn child.
- 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 SDS:** Research & Development

- **Contact:** HotLine for urgent technical support: +49-7531-583-350

- **Abbreviations and acronyms:**

- ADR: Accord relatif au transport international 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
- Repr. 1B: Reproductive toxicity – Category 1B
- 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.**