

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 11.01.2019

Version number 2

Revision: 11.01.2019

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

- **1.1 Product identifier**
 - **Trade name: Prime&Bond active**
- **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. 3	H226 Flammable liquid and vapour.
Acute Tox. 4	H302 Harmful if swallowed.
Skin Corr. 1B	H314 Causes severe skin burns and eye damage.
Eye Dam. 1	H318 Causes serious eye damage.
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 GHS05 GHS07

- **Signal word** Danger
- **Hazard-determining components of labelling:**

Bisacrylamide 1
 10-Methacryloyl-oxydecyl-dihydrogenphosphate
 Bisacrylamide 2
- **Hazard statements**

H226 Flammable liquid and vapour.
 H302 Harmful if swallowed.
 H314 Causes severe skin burns and eye damage.
 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.
 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.

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P310 Immediately call a POISON CENTER/doctor.
 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 (EC) 1272/2008.

Contains 4-(dimethylamino)benzonitrile. May produce an allergic reaction.

• **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:**

	Bisacrylamide 1 Acute Tox. 4, H302; Eye Irrit. 2, H319	25 – 50%
CAS: 67-63-0 EINECS: 200-661-7	propan-2-ol Flam. Liq. 2, H225; Eye Irrit. 2, H319; STOT SE 3, H336	≥ 10 – < 20%
CAS: 85590-00-7	10-Methacryloyl-oxydecyl-dihydrogenphosphate Skin Corr. 1B, H314	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	≥ 2.5 – < 10%
	Bisacrylamide 2 Acute Tox. 4, H302; Eye Irrit. 2, H319	≥ 2.5 – < 10%
CAS: 10373-78-1 EINECS: 233-814-1	dl-bornane-2,3-dione Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	≤ 2.5%
CAS: 1197-19-9 EINECS: 214-819-8	4-(dimethylamino)benzonitrile Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335	≥ 0.1 – < 1%

• **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. Then consult a doctor.

• **After swallowing**

Call for a doctor immediately.

Drink plenty of water and provide fresh air. Call for a doctor immediately.

• **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.

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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 with full jet.
Water.
- **5.2 Special hazards arising from the substance or mixture**
Formation of toxic gases is possible during heating or in case of fire.
- **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 product to reach sewage system or any water course.
- **6.3 Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Use neutralising agent.
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.
- **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.
Keep respiratory protective device available.

- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage**
- **Requirements to be met by storerooms and receptacles:**
Store in a cool location.
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.
- **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: 67-63-0 propan-2-ol

WEL	Short-term value: 1250 mg/m ³ , 500 ppm
	Long-term value: 999 mg/m ³ , 400 ppm

· **Regulatory information** WEL: EH40/2018

· **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.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

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.

· 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:

Yellow

· Odour:

Product specific

· Odour threshold:

Not determined.

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· pH-value at 20 °C:	2.5
· Change in condition	
Melting point/freezing point:	undetermined
Initial boiling point and boiling range:	Undetermined.
· Flash point:	30 °C
· Flammability (solid, gaseous)	Not applicable.
· Ignition temperature:	425 °C
· Decomposition temperature:	Not determined.
· Auto-ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product is not explosive. However, formation of explosive air/vapour mixtures are possible.
· Explosion limits:	
Lower:	2 Vol %
Upper:	13.4 Vol %
· Vapour pressure at 20 °C:	43 hPa
· Density at 20 °C:	1.013 g/cm ³
· Relative density	Not determined.
· Vapour density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with Water:	Not miscible or difficult to mix
· Partition coefficient: n-octanol/water:	Not determined.
· Viscosity:	
dynamic at 20 °C:	20 mPas
kinematic:	Not determined.
· Solvent content:	
Organic solvents:	15.5 %
Water:	19.5 %
· 9.2 Other information	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**
Harmful if swallowed.

· LD/LC50 values relevant for classification:		
ATE (Acute Toxicity Estimate)		
Oral	LD50	1,104 mg/kg (rat)

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Bisacrylamide 1		
Oral	LD50	500 mg/kg (rat)
CAS: 67-63-0 propan-2-ol		
Oral	LD50	5,045 mg/kg (rat)
Dermal	LD50	12,800 mg/kg (rab)
CAS: 85590-00-7 10-Methacryloyl-oxydecyl-dihydrogenphosphate		
Oral	LD50	> 2,000 mg/kg (rat)
Bisacrylamide 2		
Oral	LD50	500 mg/kg (rat)
CAS: 1197-19-9 4-(dimethylamino)benzonitrile		
Oral	LD50	500 mg/kg (ATE)

- **Primary irritant effect:**
- **Skin corrosion/irritation**
Causes severe skin burns and eye damage.
- **Serious eye damage/irritation**
Causes serious eye damage.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **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** Based on available data, the classification criteria are not met.
- **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:**

CAS: 67-63-0 propan-2-ol	
LC50/96h	1,400 mg/l (Fish acute toxicity study)
EC50/48h	13,299 mg/L (daphnia magna)
CAS: 85590-00-7 10-Methacryloyl-oxydecyl-dihydrogenphosphate	
EC50/48h	> 100 mg/L (daphnia magna)

- **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
- **Additional ecological information:**
- **General notes:**
Do not allow product to reach ground water, water course or sewage system.
Must not reach sewage water or drainage ditch undiluted or unneutralised.
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.

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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 6	Acute Toxicity
HP 8	Corrosive
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

UN2920

- 14.2 UN proper shipping name
- ADR

2920 CORROSIVE LIQUID, FLAMMABLE, N.O.S. (10-Methacryloyl-oxydecyl-dihydrogenphosphate, ISOPROPANOL (ISOPROPYL ALCOHOL))

- IMDG, IATA

CORROSIVE LIQUID, FLAMMABLE, N.O.S. (10-Methacryloyl-oxydecyl-dihydrogenphosphate, ISOPROPANOL (ISOPROPYL ALCOHOL))

- 14.3 Transport hazard class(es)

- ADR



- Class
- Label

8 (CF1) Corrosive substances.
8+3

- IMDG



- Class
- Label

8 Corrosive substances.
8/3

- IATA



- Class

8 Corrosive substances.

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· Label	8 (3)
· 14.4 Packing group · ADR, IMDG, IATA	II
· 14.5 Environmental hazards:	Not applicable.
· 14.6 Special precautions for user · Danger code (Kemler): · EMS Number: · Stowage Category · Stowage Code	Warning: Corrosive substances. 83 F-E,S-C E SW1 Protected from sources of heat. SW2 Clear of living quarters.
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	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
· UN "Model Regulation":	UN 2920 CORROSIVE LIQUID, FLAMMABLE, N.O.S. (1 0 - M E T H A C R Y L O Y L - O X Y D E C Y L - D I H Y D R O G E N P H O S P H A T E , I S O P R O P A N O L (ISOPROPYL ALCOHOL)), 8 (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.
- H302 Harmful if swallowed.
- H314 Causes severe skin burns and eye damage.
- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H319 Causes serious eye irritation.

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*H335 May cause respiratory irritation.**H336 May cause drowsiness or dizziness.**H411 Toxic to aquatic life with long lasting effects.*

- **Classification according to Regulation (EC) No 1272/2008** Calculation method

- **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

Flam. Liq. 3: Flammable liquids – Category 3

Acute Tox. 4: Acute toxicity – Category 4

Skin Corr. 1B: Skin corrosion/irritation – Category 1B

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Dam. 1: Serious eye damage/eye irritation – Category 1

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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