

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 25.08.2016

Version number 2

Revision: 25.08.2016

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

- **1.1 Product identifier**
- **Trade name: Calibra Ceram Catalyst**
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the mixture** Esthetic Resin Cement
- **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**
 - 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.
 - 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**



GHS07

- **Signal word** Warning
- **Hazard-determining components of labelling:**
Urethane modified Bis-GMA dimethacrylate resin
2,2'-Ethylendioxydiethylidimethacrylat
- **Hazard statements**
 - H315 Causes skin irritation.
 - H319 Causes serious eye irritation.
 - H317 May cause an allergic skin reaction.
 - H412 Harmful to aquatic life with long lasting effects.
- **Precautionary statements**
 - P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
 - P280 Wear protective gloves/protective clothing/eye protection/face protection.
 - P273 Avoid release to the environment.
 - P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 - P321 Specific treatment (see on this label).
 - P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

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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: 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%
CAS: 105883-40-7	Urethane Dimethacrylate Resin ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319	2.5-<10%
CAS: 41637-38-1	Urethane modified Bis-GMA dimethacrylate resin ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335	2.5-<10%
CAS: 3290-92-4	propylidynetrimehyl trimethacrylate ⚠ Aquatic Chronic 2, H411	2.5-<10%
CAS: 109-16-0 EINECS: 203-652-6	2,2'-Ethylendioxydiethylidimethacrylat ⚠ Skin Sens. 1, H317	2.5-<10%
CAS: 80-15-9 EINECS: 201-254-7	α,α -dimethylbenzyl hydroperoxide ⚠ Org. Perox. E, H242; ⚠ Acute Tox. 3, H331; ⚠ STOT RE 2, H373; ⚠ Skin Corr. 1B, H314; ⚠ Aquatic Chronic 2, H411; ⚠ Acute Tox. 4, H302; Acute Tox. 4, H312	0.1-<1%
CAS: 79-10-7 EINECS: 201-177-9	acrylic acid ⚠ Flam. Liq. 3, H226; ⚠ Skin Corr. 1A, H314; ⚠ Aquatic Acute 1, H400; ⚠ Acute Tox. 4, H302; Acute Tox. 4, H312; Acute Tox. 4, H332; 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

· **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.

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.

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- **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 clothing.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:** Ensure adequate ventilation.
- **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.
Observe normal care for working with chemicals.
- **Handling** Product is intended for dental use only.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **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:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **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.

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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**

Natural rubber, NR

Recommended thickness of the material: ≥ 0.12 mmPermeation: Level ≥ 1

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: paste

Colour: According to product specification

- **Odour:** Characteristic

- **Odour threshold:** Not determined.

- **pH-value:** Not applicable.

- **Change in condition**

Melting point/Melting range: undetermined

Boiling point/Boiling range: Undetermined.

- **Flash point:** Not applicable

- **Flammability (solid, gaseous)** Not determined.

- **Ignition temperature:** 360 °C

- **Decomposition temperature:** Not determined.

- **Self-igniting:** Product is not selfigniting.

- **Danger of explosion:** Product does not present an explosion hazard.

- **Explosion limits:**

Lower: Not determined.

Upper: Not determined.

- **Vapour pressure:** Not applicable.

- **Density:** Not determined

- **Relative density** Not determined.

- **Vapour density** Not applicable.

- **Evaporation rate** Not applicable.

- **Solubility in / Miscibility with**

Water: Insoluble

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- | | |
|---|-----------------|
| · Partition coefficient (n-octanol/water): Not determined. | |
| · Viscosity: | |
| dynamic: | Not applicable. |
| kinematic: | Not applicable. |
| · Solvent content: | |
| Organic solvents: | 0.0 % |
| · Solids content: 60.0 % | |
| · 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** Based on available data, the classification criteria are not met.

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

CAS: 3290-92-4 propylidynetrimethyl trimethacrylate

Oral	LD50	>2000 mg/kg (rat)
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CAS: 109-16-0 2,2'-Ethylendioxydiethylmethacrylat

Oral	LD50	>5000 mg/kg (rat)
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Dermal	LD50	>2000 mg/kg (mouse)
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CAS: 80-15-9 α,α -dimethylbenzyl hydroperoxide

Oral	LD50	382 mg/kg (rat)
------	------	-----------------

Dermal	LD50	500 mg/kg (rat)
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Inhalative	LC50/4 h	220 mg/l (rat)
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CAS: 79-10-7 acrylic acid

Oral	LD50	1500 mg/kg (rat)
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Dermal	LD50	>2000 mg/kg (rabbit)
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Inhalative	LC50/4 h	1.5 mg/l (ATE)
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- **Primary irritant effect:**
- **Skin corrosion/irritation**
Causes skin irritation.
- **Serious eye damage/irritation**
Causes serious eye irritation.
- **Respiratory or skin sensitisation**
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** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.

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· **Aspiration hazard** Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

· **12.1 Toxicity**· **Aquatic toxicity:**

CAS: 3290-92-4 propylidynetrimehyl trimethacrylate

LC50/96h 2 mg/l (Fish acute toxicity study)

EC50/48h >9.22 mg/L (daphnia magna)

CAS: 109-16-0 2,2'-Ethylendioxydiethylidimethacrylat

LC50/96h 16.4 mg/l (Fish acute toxicity study)

CAS: 79-10-7 acrylic acid

LC50/96h 27 mg/l (Fish acute toxicity study)

EC50/48h 95 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.

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 4 Irritant - skin irritation and eye damage

HP 14 Ecotoxic

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

SECTION 14: Transport information

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

Void

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· 14.2 UN proper shipping name · ADR, ADN, IMDG, IATA	Void
· 14.3 Transport hazard class(es) · ADR, ADN, IMDG, IATA · Class	Void
· 14.4 Packing group · ADR, IMDG, IATA	Void
· 14.5 Environmental hazards:	Not applicable.
· 14.6 Special precautions for user	Not applicable.
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· UN "Model Regulation":	Void

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.
- **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**

- H226 Flammable liquid and vapour.
- H242 Heating may cause a fire.
- H302 Harmful if swallowed.
- H312 Harmful in contact with skin.
- H314 Causes severe skin burns and eye damage.
- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H319 Causes serious eye irritation.
- H331 Toxic if inhaled.
- H332 Harmful if inhaled.
- H335 May cause respiratory irritation.
- H373 May cause damage to organs through prolonged or repeated exposure.
- H400 Very toxic to aquatic life.
- 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

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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. 3: Flammable liquids – Category 3
Org. Perox. E: Organic peroxides – Type E/F
Acute Tox. 4: Acute toxicity – Category 4
Acute Tox. 3: Acute toxicity – Category 3
Skin Corr. 1A: Skin corrosion/irritation – Category 1A
Skin Corr. 1B: Skin corrosion/irritation – Category 1B
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
STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2
Aquatic Acute 1: Hazardous to the aquatic environment - acute 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.**

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

- **1.1 Product identifier**
- **Trade name: Calibra Ceram Base**
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the mixture** Esthetic Resin Cement
- **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**
 - 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.
 - 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**



GHS07

- **Signal word** Warning
- **Hazard-determining components of labelling:**
 - 2-hydroxyethyl methacrylate
 - Urethane modified Bis-GMA dimethacrylate resin
 - 3-(Acryloyloxy)-2-hydroxypropyl methacrylate
 - 2,2'-Ethylendioxydiethylmethacrylat
- **Hazard statements**
 - H315 Causes skin irritation.
 - H319 Causes serious eye irritation.
 - H317 May cause an allergic skin reaction.
 - H412 Harmful to aquatic life with long lasting effects.
- **Precautionary statements**
 - P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
 - P280 Wear protective gloves/protective clothing/eye protection/face protection.
 - P273 Avoid release to the environment.
 - P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 - P321 Specific treatment (see on this label).

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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	2.5- <10%
CAS: 41637-38-1	Urethane modified Bis-GMA dimethacrylate resin ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335	2.5- <10%
CAS: 105883-40-7	Urethane Dimethacrylate Resin ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319	2.5- <10%
CAS: 3290-92-4	propylidyntrimethyl trimethacrylate ⚠ Aquatic Chronic 2, H411	2.5- <10%
CAS: 109-16-0 EINECS: 203-652-6	2,2'-Ethylendioxydiethyl dimethacrylat ⚠ Skin Sens. 1, H317	2.5- <10%
CAS: 1709-71-3	3-(Acryloyloxy)-2-hydroxypropyl methacrylate ⚠ Eye Dam. 1, H318; ⚠ Acute Tox. 4, H302; ⚠ Skin Irrit. 2, H315; Skin Sens. 1, H317	1- ≤2.5%

· **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. 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, 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.

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- **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 clothing.
- **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).
Pick up mechanically.
Ensure adequate ventilation.
- **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.
Observe normal care for working with chemicals.
- **Handling** Product is intended for dental use only.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **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:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **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.

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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.

Natural rubber, NR

Recommended thickness of the material: ≥ 0.12 mm

Permeation: Level ≥ 1

· **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:	<i>paste</i>
· Colour:	<i>According to product specification</i>
· Odour:	<i>Characteristic</i>
· Odour threshold:	<i>Not determined.</i>

· **pH-value:** *Not determined.*

· **Change in condition**

· Melting point/Melting range:	<i>undetermined</i>
· Boiling point/Boiling range:	<i>Undetermined.</i>

· **Flash point:** *Not applicable*

· **Flammability (solid, gaseous)** *Not applicable.*

· **Ignition temperature:** *Not applicable*

· **Decomposition temperature:** *Not determined.*

· **Self-igniting:** *Product is not selfigniting.*

· **Danger of explosion:** *Product does not present an explosion hazard.*

· **Explosion limits:**

· Lower:	<i>Not determined.</i>
· Upper:	<i>Not determined.</i>

· **Vapour pressure:** *Not determined.*

· Density:	<i>Not determined</i>
· Relative density	<i>Not determined.</i>
· Vapour density	<i>Not determined.</i>
· Evaporation rate	<i>Not determined.</i>

· **Solubility in / Miscibility with**

· **Water:** *Not miscible or difficult to mix*

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- **Partition coefficient (n-octanol/water):** Not determined.
- **Viscosity:**
 - dynamic:** Not determined.
 - kinematic:** Not determined.
- **Solvent content:**
 - Organic solvents:** 0,0 %
- **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** Based on available data, the classification criteria are not met.

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

CAS: 868-77-9 2-hydroxyethyl methacrylate

Oral	LD50	>5000 mg/kg (rat)
Dermal	LD50	>3000 mg/kg (rabbit)

CAS: 3290-92-4 propylidynetrimethyl trimethacrylate

Oral	LD50	>2000 mg/kg (rat)
------	------	-------------------

CAS: 109-16-0 2,2'-Ethylendioxydiethyldimethacrylat

Oral	LD50	>5000 mg/kg (rat)
Dermal	LD50	>2000 mg/kg (mouse)

CAS: 1709-71-3 3-(Acryloyloxy)-2-hydroxypropyl methacrylate

Oral	LD50	500 mg/kg (ATE)
------	------	-----------------

- **Primary irritant effect:**
- **Skin corrosion/irritation**
Causes skin irritation.
- **Serious eye damage/irritation**
Causes serious eye irritation.
- **Respiratory or skin sensitisation**
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** 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.

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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: 3290-92-4 propylidynetrimehyl trimethacrylate

LC50/96h 2 mg/l (Fish acute toxicity study)

EC50/48h >9.22 mg/L (daphnia magna)

CAS: 109-16-0 2,2'-Ethylendioxydiethyl dimethacrylat

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.

· **Ecotoxicological effects:**

· **Remark:** Harmful to fish

· **Additional ecological information:**

· **General notes:**

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

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 4 Irritant - skin irritation and eye damage

HP 14 Ecotoxic

· **Uncleaned packaging:**

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

SECTION 14: Transport information

· **14.1 UN-Number**

· **ADR, ADN, IMDG, IATA** Void

· **14.2 UN proper shipping name**

· **ADR, ADN, IMDG, IATA** Void

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· 14.3 Transport hazard class(es)	
· ADR, ADN, IMDG, IATA	
· Class	Void
· 14.4 Packing group	
· ADR, IMDG, IATA	Void
· 14.5 Environmental hazards:	Not applicable.
· 14.6 Special precautions for user	Not applicable.
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· UN "Model Regulation":	Void

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.
- **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**

H302 Harmful if swallowed.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
H319 Causes serious eye irritation.
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
Acute Tox. 4: Acute toxicity – Category 4
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

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*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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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@dentsply.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**
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	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.

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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.

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:**

Contains 4-(dimethylamino)benzotriazole. 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-<25%
CAS: 85590-00-7	10-Methacryloyl-oxydecyl-dihydrogenphosphate ⚠ Skin Corr. 1B, H314	10-<25%
	Bisacrylamide 2 ⚠ Acute Tox. 4, H302; Eye Irrit. 2, H319	2.5-<10%
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%
CAS: 1197-19-9 EINECS: 214-819-8	4-(dimethylamino)benzotriazole ⚠ 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.
- **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).
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.

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

SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.

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· 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: EH40/2011**· 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.

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.**· pH-value at 20 °C:** 2.5**· Change in condition****Melting point/Melting range:** undetermined

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Boiling point/Boiling range:	Undetermined.
· Flash point:	30 °C (c.c. Abel)
· Flammability (solid, gaseous)	Not applicable.
· Ignition temperature:	425 °C
· 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:	2.0 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 %
Water:	20 %
· 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 Estimates)

Oral	LD50	1114 mg/kg (rat)
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Bisacrylamide I

Oral	LD50	500 mg/kg (rat)
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CAS: 67-63-0 propan-2-ol

Oral LD50 5045 mg/kg (rat)

Dermal LD50 12800 mg/kg (rab)

CAS: 85590-00-7 10-Methacryloyl-oxydecyl-dihydrogenphosphate

Oral LD50 >2000 mg/kg (rat)

Bisacrylamide 2

Oral LD50 500 mg/kg (rat)

CAS: 1197-19-9 4-(dimethylamino)benzotrile

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**
Repeated or prolonged contact with the not polymerized product may cause sensitization for acrylates / methacrylates.
- **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 1400 mg/l (Fish acute toxicity study)

EC50/48h 13299 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.
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.

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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

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

- IATA

Corrosive liquid, flammable, n.o.s. (10-Methacryloyl-oxydecyl-dihydrogenphosphate, Isopropanol)

- 14.3 Transport hazard class(es)

- ADR



- Class

8 (CF1) Corrosive substances.

- Label

8+3

- IMDG



- Class

8 Corrosive substances.

- Label

8/3

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· IATA



· Class 8 Corrosive substances.
· Label 8 (3)

· 14.4 Packing group II
· ADR, IMDG, IATA

· 14.5 Environmental hazards: Not applicable.

· 14.6 Special precautions for user Warning: Corrosive substances.
· Danger code (Kemler): 83
· EMS Number: F-E,S-C
· Stowage Category E
· Stowage Code 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) 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

· UN "Model Regulation": UN 2920 CORROSIVE LIQUID, FLAMMABLE, N.O.S. (10 - METHACRYLOYL - OXYDECYL - DIHYDROGENPHOSPHATE, ISOPROPANOL (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
- 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.

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· **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.*
- H335 May cause respiratory irritation.*
- H336 May cause drowsiness or dizziness.*
- 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, Hazard Category 2*
- Flam. Liq. 3: Flammable liquids, Hazard Category 3*
- Acute Tox. 4: Acute toxicity, Hazard Category 4*
- Skin Corr. 1B: Skin corrosion/irritation, Hazard Category 1B*
- Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2*
- Eye Dam. 1: Serious eye damage/eye irritation, Hazard Category 1*
- 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*

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