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

Printing date 08.04.2015 *Version number 3* *Revision: 08.04.2015*

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

· **1.1 Product identifier**

· **Trade name: Self Cure Activator**
· **1.2 Relevant identified uses of the substance or mixture and uses advised against**
· **Application of the substance / the mixture** Activator
· **Uses advised against** No further relevant information available.

· **1.3 Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
DENTSPLY DeTrey GmbH
De-Trey-Str. 1
D-78467 Konstanz
GERMANY
Tel.: +49-(0)7531-583-0
Fax: +49-(0)7531-583-104
email: KonstanzDEU.info-sdb@dentsply.com

· **Further information obtainable from:**
- Departement Analytical Research / Research & Development for technical information
- Departement Marketing & Sales for distribution of the safety data sheets
· **1.4 Emergency telephone number:** +49-(0)7531-583-0 8:00 - 17:00 (GMT + 1:00)

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SECTION 2: Hazards identification

· **2.1 Classification of the substance or mixture**
· **Classification according to Regulation (EC) No 1272/2008**

Flam. Liq. 2	H225	Highly flammable liquid and vapour.
Skin Irrit. 2	H315	Causes skin irritation.
Eye Irrit. 2	H319	Causes serious eye irritation.
Skin Sens. 1	H317	May cause an allergic skin reaction.
STOT SE 3	H336	May cause drowsiness or dizziness.

· **2.2 Label elements**
· **Labelling according to Regulation (EC) No 1272/2008**
As this product is a medical device in the meaning of Directive 93/42/EEC and intended for use by the end consumer and is applied in an invasive manner or body contact, it is exempt from the labelling requirements according to regulation 1272/2008.
The product is classified and labelled according to the CLP regulation.
· **Hazard pictograms**

GHS02 GHS07

· **Signal word** Danger

· **Hazard-determining components of labelling:**
acetone
2-hydroxyethyl methacrylate
· **Hazard statements**
H225 Highly flammable liquid and vapour.
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H317 May cause an allergic skin reaction.
H336 May cause drowsiness or dizziness.

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· **Precautionary statements**

P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P241	Use explosion-proof electrical/ventilating/lighting/equipment.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/ shower.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P405	Store locked up.
P501	Dispose of contents/container in accordance with local/regional/national/international regulations.

· **2.3 Other hazards**
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.

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SECTION 3: Composition/information on ingredients

· **3.2 Chemical characterisation: Mixtures**
· **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**		
CAS: 67-64-1 EINECS: 200-662-2	acetone Flam. Liq. 2, H225; Eye Irrit. 2, H319; STOT SE 3, H336	50-100%
CAS: 105883-40-7	Urethane Dimethacrylate Resin Skin Irrit. 2, H315; Eye Irrit. 2, H319	10-<25%
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	3-<10%
CAS: 75980-60-8 EINECS: 278-355-8	Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide Repr. 2, H361f; Aquatic Chronic 2, H411	1-≤2.5%

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

SECTION 4: First aid measures

· **4.1 Description of first aid measures**
· **After inhalation** Supply fresh air; consult doctor in case of complaints.
· **After skin contact** Immediately wash with water and soap and rinse thoroughly.
· **After eye contact**
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
· **After swallowing** If symptoms persist consult doctor.
· **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.
· **Information for doctor** No further relevant information available.
· **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

SECTION 5: Firefighting measures

· **5.1 Extinguishing media**
· **Suitable extinguishing agents** CO2, sand, extinguishing powder. Do not use water.
· **For safety reasons unsuitable extinguishing agents** Water.

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· **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:**
Prevent seepage into sewage system, workpits and cellars.
Do not allow to enter sewers/ surface or ground water.
· **6.3 Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Ensure adequate ventilation.
Do not flush with water or aqueous cleansing agents
· **6.4 Reference to other sections**
See Section 7 for information on safe handling
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

· **7.1 Precautions for safe handling**
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
Observe normal care for working with chemicals.

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

Keep ignition sources away - Do not smoke.

Protect 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.
Store in cool, dry conditions in well sealed receptacles.
· **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.

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· **8.1 Control parameters**

· **Ingredients with limit values that require monitoring at the workplace:**	
67-64-1 acetone	
WEL	Short-term value: 3620 mg/m³, 1500 ppm Long-term value: 1210 mg/m³, 500 ppm

· **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:**
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
Not necessary if room is well-ventilated.
· **Protection of hands:**

Protective gloves.

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
· **Material of gloves**
Butyl rubber, BR
Recommended thickness of the material: ≥ 0.7 mm
Permeation: Level ≥6
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
· **Penetration time of glove material**
The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed.
· **Eye protection:**

Tightly sealed goggles.

· **Body protection:** Protective work clothing.

SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**
· **General Information**
· **Appearance:**

Form:	Fluid
Colour:	Light yellow
· **Odour:**	Acetone-like

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· **Odour threshold:**	Not determined.
· **pH-value at 20 °C:**	7
· **Change in condition**	
Melting point/Melting range:	undetermined
Boiling point/Boiling range:	56 °C (Aceton)
· **Flash point:**	2 °C (Pensky-Marten Closed Cup)
· **Flammability (solid, gaseous)**	Not applicable.
· **Ignition temperature:**	465 °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:	2.6 Vol % (Aceton)
Upper:	12.8 Vol % (Aceton)
· **Vapour pressure at 20 °C:**	233 hPa
· **Density at 20 °C:**	0.9 g/cm³
· **Relative density**	Not determined.
· **Vapour density**	Not determined.
· **Evaporation rate**	Not determined.
· **Solubility in / Miscibility with**	
Water:	Partly miscible
· **Partition coefficient (n-octanol/water):**	Not determined.
· **Viscosity:**	
dynamic:	Not determined.
kinematic:	Not determined.
· **Solvent content:**	
Organic solvents:	61.0 %
Water:	16.0 %
Solids content:	4.0 %
· **9.2 Other information**	No further relevant information available.

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SECTION 10: Stability and reactivity

· **10.1 Reactivity** No further relevant information available.
· **10.2 Chemical stability**
· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
· **10.3 Possibility of hazardous reactions** No dangerous reactions known
· **10.4 Conditions to avoid** No further relevant information available.
· **10.5 Incompatible materials:** No further relevant information available.
· **10.6 Hazardous decomposition products:** No dangerous decomposition products known

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Trade name: Self Cure Activator

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SECTION 11: Toxicological information

· **11.1 Information on toxicological effects**
· **Acute toxicity:**

· **LD/LC50 values relevant for classification:**		
ATE (Acute Toxicity Estimates)		
Inhalative	LC50/4 h	125 mg/l

67-64-1 acetone		
Oral	LD50	5800 mg/kg (rat)
Dermal	LD50	20000 mg/kg (rabbit)
Inhalative	LC50/4 h	76 mg/l (rat)
868-77-9 2-hydroxyethyl methacrylate		
Oral	LD50	>5000 mg/kg (rat)
Dermal	LD50	>3000 mg/kg (rabbit)
75980-60-8 Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide		
Oral	LD50	5000 mg/kg (rat)

· **Primary irritant effect:**
· **on the skin:** Irritant to skin and mucous membranes.
· **on the eye:** Irritating effect.
· **Sensitisation:** Sensitisation possible through skin contact.
· **Additional toxicological information:**
The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.
Irritant

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SECTION 12: Ecological information

· **12.1 Toxicity**

· **Aquatic toxicity:**	
67-64-1 acetone	
EC50/48h	6100 mg/L (daphnia magna)
LC50/96h	5540 mg/l (Fish acute toxicity study)
868-77-9 2-hydroxyethyl methacrylate	
EC50/48h	380 mg/L (daphnia magna)
LC50/96h	>100 mg/l (Fish acute toxicity study)
75980-60-8 Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	
LC50/48h	6.53 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.
· **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.
· **12.5 Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.

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· **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

· **13.1 Waste treatment methods**
· **Recommendation**

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· **European waste catalogue**	
18 01 06*	chemicals consisting of or containing dangerous substances

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

SECTION 14: Transport information

· **14.1 UN-Number**	
· **ADR, IMDG, IATA**	UN1090
· **14.2 UN proper shipping name**	
· **ADR**	1090 ACETONE, mixture
· **IMDG, IATA**	ACETONE mixture
· **14.3 Transport hazard class(es)**	
· **ADR**	

· **Class**	3 (F1) Flammable liquids.
· **Label**	3
· **IMDG, IATA**	

· **Class**	3 Flammable liquids.
· **Label**	3
· **14.4 Packing group**	
· **ADR, IMDG, IATA**	II
· **14.5 Environmental hazards:**	
· **Marine pollutant:**	No
· **14.6 Special precautions for user**	Warning: Flammable liquids.
· **Danger code (Kemler):**	33

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Trade name: Self Cure Activator

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· **EMS Number:**	F-E,S-E
· **14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable.
· **Transport/Additional information:**	
· **ADR**	
· **Limited quantities (LQ)**	1L
· **Excepted quantities (EQ)**	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· **Transport category**	2
· **Tunnel restriction code**	D/E
· **IMDG**	
· **Limited quantities (LQ)**	1L
· **Excepted quantities (EQ)**	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· **UN "Model Regulation":**	UN1090, ACETONE mixture, 3, II

SECTION 15: Regulatory information

· **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
No further relevant information available.
· **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

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SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

The attached safety data sheet covers the dangers and measures to be taken when large quantities of material are released, for example due to accidents during transport or storage by the dealer.
For quantities of material typically used in clinical practice, information necessary for safe use and storage of the product is given in the DFU.

· **Relevant phrases**
H225 Highly flammable liquid and vapour.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
H336 May cause drowsiness or dizziness.
H361f Suspected of damaging fertility.
H411 Toxic to aquatic life with long lasting effects.

· **Department issuing MSDS:** Analytical Research
· **Contact:** HotLine for urgent technical support: +49-7531-583-350
· **Abbreviations and acronyms:**
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association

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GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
Flam. Liq. 2: Flammable liquids, Hazard Category 2
Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2
Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2
Skin Sens. 1: Sensitisation - Skin, Hazard Category 1
Repr. 2: Reproductive toxicity, Hazard Category 2
STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3
Aquatic Chronic 2: Hazardous to the aquatic environment - Chronic Hazard, Category 2

· **** Data compared to the previous version altered.***

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

Printing date 19.03.2015 *Version number 6* *Revision: 19.03.2015*

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

· **1.1 Product identifier**

· **Trade name: Calibra Try-In Paste**

· **Application:** Esthetic Resin Cement
· **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@dentsply.com

· **Further information obtainable from:**
- Departement Analytical Research / Research & Development for technical information
- Departement Marketing & Sales for distribution of the safety data sheets
· **1.4 Emergency telephone number:** +49-(0)7531-583-0 8:00 - 17:00 (GMT + 1:00)

*
SECTION 2: Hazards identification

· **2.1 Classification of the substance or mixture**
· **Classification according to Regulation (EC) No 1272/2008**
The product is not classified according to the CLP regulation.

· **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.
· **Hazard pictograms** Void
· **Signal word** Void
· **Hazard statements** Void
· **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: 56-81-5 EINECS: 200-289-5	glycerol	50-100%

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

SECTION 4: First aid measures

· **4.1 Description of first aid measures**
· **General information** No special measures required.
· **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.

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· ***After swallowing***
Rinse out mouth and then drink plenty of water.
If symptoms persist consult doctor.
· ***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.

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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*** *Not required.*
· ***6.2 Environmental precautions:***
Dilute with plenty of water.
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).
· ***6.4 Reference to other sections***
No dangerous substances are released.
See Section 7 for information on safe handling
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

· ***7.1 Precautions for safe handling*** *Observe normal care for working with chemicals.*

· ***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:*** *Store only in the original receptacle.*
· ***Information about storage in one common storage facility:*** *Not required.*
· ***Further information about storage conditions:*** *None.*
· ***Maximum storage temperature:*** *54 °C*
· ***Minimum storage temperature*** *18 °C*
· ***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:***	
56-81-5 glycerol	
WEL	*Long-term value: 10 mg/m³*

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· ***Additional information:*** *The lists valid during the making were used as basis.*

· ***8.2 Exposure controls***
· ***Personal protective equipment***
· ***General protective and hygienic measures***
The usual precautionary measures are to be adhered to when handling chemicals.
· ***Respiratory protection:*** *Not necessary if room is well-ventilated.*
· ***Protection of hands:***
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
· ***Material of gloves***
Nitrile rubber, NBR
Recommended thickness of the material: ≥ 0.11 mm
Permeation: Level ≥6
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
· ***Penetration time of glove material***
The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed.
· ***Eye protection:*** *Goggles recommended during refilling.*
· ***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:	*Different according to colouring*
· ***Odour:***	*Mild*
· ***Odour threshold:***	*Not determined.*
· ***pH-value:***	*Not determined.*
· ***Change in condition***	
Melting point/Melting range:	*undetermined*
Boiling point/Boiling range:	*Undetermined.*
· ***Flash point:***	*Not applicable*
· ***Flammability (solid, gaseous)***	*Not applicable.*
· ***Ignition temperature:***	*400 °C*
· ***Decomposition temperature:***	*Not determined.*
· ***Self-igniting:***	*Product is not selfigniting.*
· ***Danger of explosion:***	*Product does not present an explosion hazard.*
· ***Explosion limits:***	
Lower:	*2.6 Vol %*
Upper:	*11.3 Vol %*
· ***Vapour pressure:***	*Not determined.*
· ***Density at 20 °C:***	*1.4 g/cm³*
· ***Relative density***	*Not determined.*
· ***Vapour density***	*Not determined.*

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· **Evaporation rate**	Not determined.
· **Solubility in / Miscibility with Water:**	Partly soluble
· **Partition coefficient (n-octanol/water):**	Not determined.
· **Viscosity:**	
dynamic:	Not determined.
kinematic:	Not determined.
· **Solvent content:**	
Organic solvents:	85.0 %
Solids content:	15.0 %
· **9.2 Other information**	No further relevant information available.

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SECTION 10: Stability and reactivity

· **10.1 Reactivity** No further relevant information available.
· **10.2 Chemical stability**
· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
· **10.3 Possibility of hazardous reactions** No dangerous reactions known
· **10.4 Conditions to avoid** No further relevant information available.
· **10.5 Incompatible materials:**
strong oxidants
strong bases
· **10.6 Hazardous decomposition products:** No dangerous decomposition products known

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SECTION 11: Toxicological information

· **11.1 Information on toxicological effects**
· **Acute toxicity:**

· **LD/LC50 values relevant for classification:**		
56-81-5 glycerol		
Oral	LD50	12600 mg/kg (rat)
Dermal	LD50	> 18700 mg/kg (rabbit)

· **Primary irritant effect:**
· **on the skin:** No irritant effect.
· **on the eye:** Irritating effect.
· **Sensitisation:** No sensitising effects known.
· **Additional toxicological information:**
The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.
When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

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SECTION 12: Ecological information

· **12.1 Toxicity**

· **Aquatic toxicity:**	
56-81-5 glycerol	
EC50/24h	> 10000 mg/L (daphnia magna)
LC50/24h	> 5000 mg/l (Fish acute toxicity study)

· **12.2 Persistence and degradability** No further relevant information available.

(Contd. on page 5)

(Contd. of page 4)

· ***12.3 Bioaccumulative potential*** *No further relevant information available.*
· ***12.4 Mobility in soil*** *No further relevant information available.*
· ***Additional ecological information:***
· ***General notes:***
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
· ***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***
Can be disposed of with household garbage after consulting with the waste disposal facility operator and the pertinent authorities and adhering to the necessary technical regulations.
Smaller quantities can be disposed of with household waste.

· ***European waste catalogue***	
18 01 07	*chemicals other than those mentioned in 18 01 06*

· ***Uncleaned packaging:***
· ***Recommendation:*** *Disposal must be made according to official regulations.*
· ***Recommended cleansing agents:*** *Water, if necessary together with cleansing agents.*

SECTION 14: Transport information

· ***14.1 UN-Number***	
· ***ADR, ADN, IMDG, IATA***	*Void*
· ***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:***	
· ***Marine pollutant:***	*No*
· ***14.6 Special precautions for user***	*Not applicable.*
· ***14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code***	*Not applicable.*
· ***UN "Model Regulation":***	-

SECTION 15: Regulatory information

· ***15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture***
No further relevant information available.
· ***15.2 Chemical safety assessment:*** *A Chemical Safety Assessment has not been carried out.*

(Contd. on page 6)

(Contd. of page 5)

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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.

· ***Department issuing MSDS:*** *Analytical Research*
· ***Contact:*** *HotLine for urgent technical support: +49-7531-583-350*
· ***Abbreviations and acronyms:***
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
· **** Data compared to the previous version altered.***

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

· **1.1 Product identifier**

· **Trade name: Calibra Silane Coupling Agent**
· **1.2 Relevant identified uses of the substance or mixture and uses advised against**
· **Application of the substance / the mixture** Silane Coupling Agent
· **Uses advised against** No further relevant information available.

· **1.3 Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
DENTSPLY DeTrey GmbH
De-Trey-Str. 1
D-78467 Konstanz
GERMANY
Tel.: +49-(0)7531-583-0
Fax: +49-(0)7531-583-104
email: KonstanzDEU.info-sdb@dentsply.com

· **Further information obtainable from:**
- Departement Analytical Research / Research & Development for technical information
- Departement Marketing & Sales for distribution of the safety data sheets
· **1.4 Emergency telephone number:** +49-(0)7531-583-0 8:00 - 17:00 (GMT + 1:00)

*
SECTION 2: Hazards identification

· **2.1 Classification of the substance or mixture**
· **Classification according to Regulation (EC) No 1272/2008**
Flam. Liq. 2 H225 Highly flammable liquid and vapour.

· **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

· **Signal word** Danger
· **Hazard statements**
H225 Highly flammable liquid and vapour.
· **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.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
P403+P235	Store in a well-ventilated place. Keep cool.
P501	Dispose of contents/container in accordance with local/regional/national/international regulations.

· **2.3 Other hazards**
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.

(Contd. on page 2)

(Contd. of page 1)

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SECTION 3: Composition/information on ingredients

· **3.2 Chemical characterisation: Mixtures**
· **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**		
CAS: 64-17-5 EINECS: 200-578-6	ethanol Flam. Liq. 2, H225	50-100%
CAS: 67-64-1 EINECS: 200-662-2	acetone Flam. Liq. 2, H225; Eye Irrit. 2, H319; STOT SE 3, H336	2.5-10%

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

SECTION 4: First aid measures

· **4.1 Description of first aid measures**
· **After inhalation** Supply fresh air; consult doctor in case of complaints.
· **After skin contact** Immediately wash with water and soap and rinse thoroughly.
· **After eye contact** Rinse opened eye for several minutes under running water. Then consult a doctor.
· **After swallowing** Rinse out mouth and then drink plenty of water.
· **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**
CO_2, 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**
Ensure adequate ventilation
Wear protective equipment. Keep unprotected persons away.
· **6.2 Environmental precautions:**
Dilute with plenty of water.
Do not allow to enter sewers/ surface or ground water.
· **6.3 Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Ensure adequate ventilation.
· **6.4 Reference to other sections**
See Section 7 for information on safe handling
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

· **7.1 Precautions for safe handling** Observe normal care for working with chemicals.

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

(Contd. on page 3)

(Contd. of page 2)

· ***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:*** *Store in cool, dry conditions in well sealed receptacles.*
· ***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:***	
64-17-5 ethanol	
WEL	*Long-term value: 1920 mg/m³, 1000 ppm*
67-64-1 acetone	
WEL	*Short-term value: 3620 mg/m³, 1500 ppm* *Long-term value: 1210 mg/m³, 500 ppm*

· ***Additional information:*** *The lists valid during the making were used as basis.*

· ***8.2 Exposure controls***
· ***Personal protective equipment***
· ***General protective and hygienic measures*** *Wash hands before breaks and at the end of work.*
· ***Respiratory protection:*** *Not necessary if room is well-ventilated.*
· ***Protection of hands:***
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***
Butyl rubber, BR
Recommended thickness of the material: ≥ 0.7 mm
Permeation: Level ≥6
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
· ***Penetration time of glove material***
The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed.
· ***Eye protection:***

Tightly sealed goggles.

(Contd. on page 4)

(Contd. of page 3)

· **Body protection:** Protective work clothing.

SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**	
· **General Information**	
· **Appearance:**	
Form:	Liquid
Colour:	Clear
· **Odour:**	Alcohol-like
· **Odour threshold:**	Not determined.
· **pH-value:**	Not determined.
· **Change in condition**	
Melting point/Melting range:	undetermined
Boiling point/Boiling range:	78 °C
· **Flash point:**	6 °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:	3.5 Vol %
Upper:	15.0 Vol %
· **Vapour pressure at 20 °C:**	59 hPa
· **Density at 20 °C:**	0.8 g/cm³
· **Relative density**	Not determined.
· **Vapour density**	Not determined.
· **Evaporation rate**	Not determined.
· **Solubility in / Miscibility with**	
Water:	Partly miscible
· **Partition coefficient (n-octanol/water):**	Not determined.
· **Viscosity:**	
dynamic:	Not determined.
kinematic:	Not determined.
· **Solvent content:**	
Organic solvents:	98.0 %
· **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.

(Contd. on page 5)

(Contd. of page 4)

· ***10.6 Hazardous decomposition products:*** *No dangerous decomposition products known*

*

SECTION 11: Toxicological information

· ***11.1 Information on toxicological effects***
· ***Acute toxicity:***

· ***LD/LC50 values relevant for classification:***		
ATE (Acute Toxicity Estimates)		
Inhalative	*LC50/4 h*	*95.7 mg/l*

64-17-5 ethanol		
Oral	*LD50*	*6200 mg/kg (rat)*
Inhalative	*LC50/4 h*	*95.6 mg/l (rat)*
67-64-1 acetone		
Oral	*LD50*	*5800 mg/kg (rat)*
Dermal	*LD50*	*20000 mg/kg (rabbit)*
Inhalative	*LC50/4 h*	*76 mg/l (rat)*

· ***Primary irritant effect:***
· ***on the skin:*** *No irritant effect.*
· ***on the eye:*** *No irritating effect.*
· ***Sensitisation:*** *No sensitising effects known.*

*

SECTION 12: Ecological information

· ***12.1 Toxicity***

· ***Aquatic toxicity:***	
64-17-5 ethanol	
EC50/48h	*9268 mg/L (daphnia magna)*
LC50/48h	*8140 mg/l (Fish acute toxicity study)*
67-64-1 acetone	
EC50/48h	*6100 mg/L (daphnia magna)*
LC50/96h	*5540 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.*
· ***Additional ecological information:***
· ***General notes:***
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
· ***12.5 Results of PBT and vPvB assessment***
· ***PBT:*** *Not applicable.*
· ***vPvB:*** *Not applicable.*
· ***12.6 Other adverse effects*** *No further relevant information available.*

(Contd. on page 6)

(Contd. of page 5)

SECTION 13: Disposal considerations

· **13.1 Waste treatment methods**
· **Recommendation**

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· **European waste catalogue**	
18 01 06*	chemicals consisting of or containing dangerous substances

· **Uncleaned packaging:**
· **Recommendation:** Disposal must be made according to official regulations.
· **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

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SECTION 14: Transport information

· **14.1 UN-Number**	
· **ADR, IMDG, IATA**	UN1993
· **14.2 UN proper shipping name**	
· **ADR**	1993 FLAMMABLE LIQUID, N.O.S. (ETHANOL (ETHYL ALCOHOL), ACETONE)
· **IMDG**	FLAMMABLE LIQUID, N.O.S. (ETHANOL (ETHYL ALCOHOL), ACETONE)
· **IATA**	FLAMMABLE LIQUID, N.O.S. (ETHANOL, ACETONE)
· **14.3 Transport hazard class(es)**	
· **ADR**	

· **Class**	3 (F1) Flammable liquids.
· **Label**	3
· **IMDG, IATA**	

· **Class**	3 Flammable liquids.
· **Label**	3
· **14.4 Packing group**	
· **ADR, IMDG, IATA**	II
· **14.5 Environmental hazards:**	
· **Marine pollutant:**	No
· **14.6 Special precautions for user**	Warning: Flammable liquids.
· **Danger code (Kemler):**	33
· **EMS Number:**	F-E,S-E
· **14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable.

(Contd. on page 7)

(Contd. of page 6)

· **Transport/Additional information:**

· **ADR**	
· **Limited quantities (LQ)**	1L
· **Excepted quantities (EQ)**	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· **Transport category**	2
· **Tunnel restriction code**	D/E
· **IMDG**	
· **Limited quantities (LQ)**	1L
· **Excepted quantities (EQ)**	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· **UN "Model Regulation":**	UN1993, FLAMMABLE LIQUID, N.O.S. (ETHANOL (ETHYL ALCOHOL), ACETONE), 3, II

SECTION 15: Regulatory information

· **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

· **National regulations**

· **Information about limitation of use:** Employment restrictions concerning juveniles must be observed.
· **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

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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.
H319 Causes serious eye irritation.
H336 May cause drowsiness or dizziness.

· **Department issuing MSDS:** Analytical Research
· **Contact:** HotLine for urgent technical support: +49-7531-583-350
· **Abbreviations and acronyms:**
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
Flam. Liq. 2: Flammable liquids, Hazard Category 2
Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2
STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3
· *** Data compared to the previous version altered.**

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

· **1.1 Product identifier**

· **Trade name: Calibra Catalyst Paste**

· **Application:** Esthetic Resin Cement
· **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@dentsply.com

· **Further information obtainable from:**
- Departement Analytical Research / Research & Development for technical information
- Departement Marketing & Sales for distribution of the safety data sheets
· **1.4 Emergency telephone number:** +49-(0)7531-583-0 8:00 - 17:00 (GMT + 1:00)

*
SECTION 2: Hazards identification

· **2.1 Classification of the substance or mixture**
· **Classification according to Regulation (EC) No 1272/2008**
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.

· **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**

GHS07

· **Signal word** Warning

· **Hazard-determining components of labelling:**
Bis-GMA
Ethoxylated Bisphenol A Dimethacrylate
2,2'-Ethylendioxydiethyldimethacrylat
dibenzoyl peroxide
· **Hazard statements**
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H317 May cause an allergic skin reaction.
· **Precautionary statements**
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

(Contd. on page 2)

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P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P337+P313	If eye irritation persists: Get medical advice/attention.
P501	Dispose of contents/container in accordance with local/regional/national/international regulations.

· **2.3 Other hazards**
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.

*

SECTION 3: Composition/information on ingredients

· **3.2 Chemical characterisation: Mixtures**
· **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**		
CAS: 1565-94-2 EINECS: 216-367-7	Bis-GMA Skin Sens. 1, H317	10-<25%
CAS: 24448-20-2	Ethoxylated Bisphenol A Dimethacrylate Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335	10-<25%
CAS: 109-16-0 EINECS: 203-652-6	2,2'-Ethylendioxydiethyldimethacrylat Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335	3-<10%
CAS: 94-36-0 EINECS: 202-327-6	dibenzoyl peroxide Org. Perox. B, H241; Eye Irrit. 2, H319; Skin Sens. 1, H317	0.3-<1%

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

SECTION 4: First aid measures

· **4.1 Description of first aid measures**
· **After inhalation** Supply fresh air; consult doctor in case of complaints.
· **After skin contact** Immediately wash with water and soap and rinse thoroughly.
· **After eye contact**
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
· **After swallowing**
Rinse out mouth and then drink plenty of water.
If symptoms persist consult doctor.
· **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**
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.

(Contd. on page 3)

(Contd. of page 2)

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** 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:** Store only in the original receptacle.
· **Information about storage in one common storage facility:** Store away from oxidising agents.
· **Further information about storage conditions:**
Protect from exposure to the light.
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.

· **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.

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**
Natural rubber, NR
Permeation: Level ≥1

(Contd. on page 4)

(Contd. of page 3)

Recommended thickness of the material: ≥ 0.12 mm
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· **Penetration time of glove material**
The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **Eye protection:**

Tightly sealed goggles.

· **Body protection:** *Protective work clothing.*

SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**	
· **General Information**	
· **Appearance:**	
Form:	*Pasty*
Colour:	*Various colours*
· **Odour:**	*Product specific*
· **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:**	*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:	*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*
· **Partition coefficient (n-octanol/water):**	*Not determined.*
· **Viscosity:**	
dynamic:	*Not applicable.*
kinematic:	*Not applicable.*

(Contd. on page 5)

(Contd. of page 4)

· **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:**

· **LD/LC50 values relevant for classification:**		
ATE (Acute Toxicity Estimates)		
Dermal	LD50	26316 mg/kg

1565-94-2 Bis-GMA		
Oral	LD50	>5000 mg/kg (rat)
109-16-0 2,2'-Ethylendioxydiethyldimethacrylat		
Oral	LD50	>5000 mg/kg (rat)
Dermal	LD50	>2000 mg/kg (mouse)
94-36-0 dibenzoyl peroxide		
Oral	LD50	7710 mg/kg (rat)

· **Primary irritant effect:**
· **on the skin:**
Irritant to skin and mucous membranes.
The unpolymerized product may be irritant to the skin for succeptible persons.
· **on the eye:** Irritating effect.
· **Sensitisation:**
Sensitisation possible through skin contact.
Repeated or prolonged contact with the not polymerized product may cause sensitization for acrylates / methacrylates.
· **Additional toxicological information:**
The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.
Irritant

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SECTION 12: Ecological information

· **12.1 Toxicity**

· **Aquatic toxicity:**	
109-16-0 2,2'-Ethylendioxydiethyldimethacrylat	
LC50/96h	16.4 mg/l (Fish acute toxicity study)

· **12.2 Persistence and degradability** No further relevant information available.

(Contd. on page 6)

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· **12.3 Bioaccumulative potential** No further relevant information available.
· **12.4 Mobility in soil** No further relevant information available.
· **Additional ecological information:**
· **General notes:**
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
· **12.5 Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

· **13.1 Waste treatment methods**
· **Recommendation**

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· **European waste catalogue**	
18 01 06*	chemicals consisting of or containing dangerous substances

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

SECTION 14: Transport information

· **14.1 UN-Number** · **ADR, ADN, IMDG, IATA**	Void
· **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:** · **Marine pollutant:**	No
· **14.6 Special precautions for user**	Not applicable.
· **14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable.
· **UN "Model Regulation":**	-

SECTION 15: Regulatory information

· **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
No further relevant information available.
· **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

(Contd. on page 7)

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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**
H241 Heating may cause a fire or explosion.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.

· **Department issuing MSDS:** *Analytical Research*
· **Contact:** *HotLine for urgent technical support: +49-7531-583-350*
· **Abbreviations and acronyms:**
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
Org. Perox. B: Organic Peroxides, Type B
Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2
Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2
Skin Sens. 1: Sensitisation - Skin, Hazard Category 1
STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3
· *** Data compared to the previous version altered.**

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

· **1.1 Product identifier**

· **Trade name: Calibra Base Paste**

· **Application:** Esthetic Resin Cement
· **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@dentsply.com

· **Further information obtainable from:**
- Departement Analytical Research / Research & Development for technical information
- Departement Marketing & Sales for distribution of the safety data sheets
· **1.4 Emergency telephone number:** +49-(0)7531-583-0 8:00 - 17:00 (GMT + 1:00)

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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.

· **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**

GHS07

· **Signal word** Warning

· **Hazard-determining components of labelling:**
Bis-GMA
Ethoxylated Bisphenol A Dimethacrylate
2,2'-Ethylendioxydiethyldimethacrylat
· **Hazard statements**
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H317 May cause an allergic skin reaction.
· **Precautionary statements**

P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.

(Contd. on page 2)

(Contd. of page 1)

P337+P313 If eye irritation persists: Get medical advice/attention.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· **2.3 Other hazards**
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.

*

SECTION 3: Composition/information on ingredients

· **3.2 Chemical characterisation: Mixtures**
· **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**		
CAS: 1565-94-2 EINECS: 216-367-7	Bis-GMA Skin Sens. 1, H317	10-<25%
CAS: 24448-20-2	Ethoxylated Bisphenol A Dimethacrylate Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335	10-<25%
CAS: 109-16-0 EINECS: 203-652-6	2,2'-Ethylendioxydiethyldimethacrylat Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335	3-<10%

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

SECTION 4: First aid measures

· **4.1 Description of first aid measures**
· **General information** No special measures required.
· **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**
Rinse out mouth and then drink plenty of water.
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.

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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**
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 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.

(Contd. on page 3)

(Contd. of page 2)

· **6.4 Reference to other sections**
See Section 7 for information on safe handling
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

· **7.1 Precautions for safe handling** Observe normal care for working with chemicals.

· **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:** Store only in the original receptacle.
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:**
Protect from exposure to the light.
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:**
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**
Immediately remove all soiled and contaminated clothing
Keep away from foodstuffs, beverages and feed.
Avoid contact with the eyes and skin.
Wash hands before breaks and at the end of work.
· **Respiratory protection:** Not necessary if room is well-ventilated.
· **Protection of hands:**

Protective gloves.

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
· **Material of gloves**
Natural rubber, NR
Recommended thickness of the material: ≥ 0.12 mm
Permeation: 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 trough time has to be found out by the manufacturer of the protective gloves and has to be observed.

(Contd. on page 4)

(Contd. of page 3)

· **Eye protection:** Safety glasses
· **Body protection:** Protective work clothing.

SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**	
· **General Information**	
· **Appearance:**	
Form:	Pasty
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:**	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:	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
· **Partition coefficient (n-octanol/water):**	Not determined.
· **Viscosity:**	
dynamic:	Not applicable.
kinematic:	Not applicable.
· **Solvent content:**	
Organic solvents:	0.0 %
Solids content:	67.0 %
· **9.2 Other information**	No further relevant information available.

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SECTION 10: Stability and reactivity

· **10.1 Reactivity** No further relevant information available.
· **10.2 Chemical stability**
· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
· **10.3 Possibility of hazardous reactions** No dangerous reactions known
· **10.4 Conditions to avoid** No further relevant information available.

(Contd. on page 5)

(Contd. of page 4)

· **10.5 Incompatible materials:** No further relevant information available.
· **10.6 Hazardous decomposition products:** No dangerous decomposition products known

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SECTION 11: Toxicological information

· **11.1 Information on toxicological effects**
· **Acute toxicity:**

· **LD/LC50 values relevant for classification:**		
ATE (Acute Toxicity Estimates)		
Oral	LD50	563636 mg/kg
Dermal	LD50	29412 mg/kg

1565-94-2 Bis-GMA		
Oral	LD50	>5000 mg/kg (rat)
109-16-0 2,2'-Ethylendioxydiethyldimethacrylat		
Oral	LD50	>5000 mg/kg (rat)
Dermal	LD50	>2000 mg/kg (mouse)

· **Primary irritant effect:**
· **on the skin:**
The unpolymerized product may be irritant to the skin for succeptible persons.
Irritant to skin and mucous membranes.
· **on the eye:** Irritating effect.
· **Sensitisation:**
Sensitisation possible through skin contact.
Repeated or prolonged contact with the not polymerized product may cause sensitization for acrylates / methacrylates.
· **Additional toxicological information:**
The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.
Irritant

*
SECTION 12: Ecological information

· **12.1 Toxicity**

· **Aquatic toxicity:**	
109-16-0 2,2'-Ethylendioxydiethyldimethacrylat	
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.
· **Additional ecological information:**
· **General notes:**
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
· **12.5 Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **12.6 Other adverse effects** No further relevant information available.

(Contd. on page 6)

(Contd. of page 5)

SECTION 13: Disposal considerations

· **13.1 Waste treatment methods**
· **Recommendation**

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· **European waste catalogue**	
18 01 06*	chemicals consisting of or containing dangerous substances

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

SECTION 14: Transport information

· **14.1 UN-Number** · **ADR, ADN, IMDG, IATA**	Void
· **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:** · **Marine pollutant:**	No
· **14.6 Special precautions for user**	Not applicable.
· **14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable.
· **UN "Model Regulation":**	-

SECTION 15: Regulatory information

· **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
No further relevant information available.
· **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

*

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

The attached safety data sheet covers the dangers and measures to be taken when large quantities of material are released, for example due to accidents during transport or storage by the dealer.
For quantities of material typically used in clinical practice, information necessary for safe use and storage of the product is given in the DFU.

· **Relevant phrases**
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.

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H319 Causes serious eye irritation.
H335 May cause respiratory irritation.

· ***Department issuing MSDS:*** *Analytical Research*
· ***Contact:*** *HotLine for urgent technical support: +49-7531-583-350*
· ***Abbreviations and acronyms:***
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2
Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2
Skin Sens. 1: Sensitisation - Skin, Hazard Category 1
STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3
· **** 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: De Trey Conditioner 36 / De Trey Etch**
· **1.2 Relevant identified uses of the substance or mixture and uses advised against**
· **Application of the substance / the mixture** Discharging agent
· **Uses advised against** No further relevant information available.

· **1.3 Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
DENTSPLY DeTrey GmbH
De-Trey-Str. 1
D-78467 Konstanz
GERMANY
Tel.: +49-(0)7531-583-0
Fax: +49-(0)7531-583-104
email: KonstanzDEU.info-sdb@dentsply.com

· **Further information obtainable from:**
- Departement Analytical Research / Research & Development for technical information
- Departement Marketing & Sales for distribution of the safety data sheets
· **1.4 Emergency telephone number:** +49-(0)7531-583-0 8:00 - 17:00 (GMT + 1:00)

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SECTION 2: Hazards identification

· **2.1 Classification of the substance or mixture**
· **Classification according to Regulation (EC) No 1272/2008**
Skin Corr. 1A H314 Causes severe skin burns and eye damage.
Eye Dam. 1 H318 Causes serious eye damage.

· **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**

GHS05

· **Signal word** Danger

· **Hazard-determining components of labelling:**
phosphoric acid
· **Hazard statements**
H314 Causes severe skin burns and eye damage.
· **Precautionary statements**

P260	Do not breathe dust/fume/gas/mist/vapours/spray.
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.

· **2.3 Other hazards**
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.

(Contd. on page 2)

(Contd. of page 1)

· ***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: 7664-38-2 *EINECS: 231-633-2*	*phosphoric acid*	*Met. Corr.1, H290; Skin Corr. 1B, H314*	*25-50%*

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

SECTION 4: First aid measures

· ***4.1 Description of first aid measures***
· ***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***
Drink plenty of water and provide fresh air. Call for a doctor immediately.
Do not induce vomiting; call for medical help 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.

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:*** *No special measures required.*

SECTION 6: Accidental release measures

· ***6.1 Personal precautions, protective equipment and emergency procedures***
Wear protective clothing.
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.
· ***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.

(Contd. on page 3)

(Contd. of page 2)

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.
Open and handle receptacle with care.

· **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:** Store only in the original receptacle.
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:**
Store receptacle in a well ventilated area.
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.

· **8.1 Control parameters**

· **Ingredients with limit values that require monitoring at the workplace:**	
7664-38-2 phosphoric acid	
WEL	Short-term value: 2 mg/m³ Long-term value: 1 mg/m³

· **Additional information:** The lists valid during the making were used as basis.

· **8.2 Exposure controls**
· **Personal protective equipment**
· **General protective and hygienic measures**
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.
· **Respiratory protection:** Not necessary if room is well-ventilated.
· **Protection of hands:**

Protective gloves.

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
· **Material of gloves**
Natural rubber, NR
Recommended thickness of the material: ≥ 0.6 mm
Permeation: Level ≥6
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
· **Penetration time of glove material**
The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed.

(Contd. on page 4)

(Contd. of page 3)

· **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:	Viscous
Colour:	Blue
· **Odour:**	Odourless
· **Odour threshold:**	Not determined.
· **pH-value at 20 °C:**	< 2
· **Change in condition**	
Melting point/Melting range:	undetermined
Boiling point/Boiling range:	Undetermined.
· **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:	Not determined.
Upper:	Not determined.
· **Vapour pressure at 20 °C:**	23 hPa
· **Density at 20 °C:**	1.2 g/cm³
· **Relative density**	Not determined.
· **Vapour density**	Not determined.
· **Evaporation rate**	Not determined.
· **Solubility in / Miscibility with**	
Water:	Partly miscible
· **Partition coefficient (n-octanol/water):**	Not determined.
· **Viscosity:**	
dynamic:	Not determined.
kinematic:	Not determined.
· **Solvent content:**	
Organic solvents:	0.0 %
Water:	51.0 %
Solids content:	6.0 %
· **9.2 Other information**	No further relevant information available.

(Contd. on page 5)

(Contd. of page 4)

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SECTION 10: Stability and reactivity

· **10.1 Reactivity** No further relevant information available.
· **10.2 Chemical stability**
· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
· **10.3 Possibility of hazardous reactions** No dangerous reactions known
· **10.4 Conditions to avoid** No further relevant information available.
· **10.5 Incompatible materials:** No further relevant information available.
· **10.6 Hazardous decomposition products:** No dangerous decomposition products known

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SECTION 11: Toxicological information

· **11.1 Information on toxicological effects**
· **Acute toxicity:**

· **LD/LC50 values relevant for classification:**		
ATE (Acute Toxicity Estimates)		
Oral	LD50	3612 mg/kg (rat)
Dermal	LD50	6468 mg/kg

7664-38-2 phosphoric acid		
Oral	LD50	1530 mg/kg (rat)
Dermal	LD50	2740 mg/kg (rabbit)

· **Primary irritant effect:**
· **on the skin:** Caustic effect on skin and mucous membranes.
· **on the eye:** Strong caustic effect.
· **Sensitisation:** No sensitising effects known.
· **Additional toxicological information:**
The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.
Corrosive
Swallowing will lead to a burning respectively to a caustic effect on mouth and throat and to the danger of perforation of esophagus and stomach.

SECTION 12: Ecological information

· **12.1 Toxicity**
· **Aquatic toxicity:** No further relevant information available.
· **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.
· **Additional ecological information:**
· **General notes:**
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
Must not reach sewage water or drainage ditch undiluted or unneutralised.
· **12.5 Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **12.6 Other adverse effects** No further relevant information available.

(Contd. on page 6)

(Contd. of page 5)

SECTION 13: Disposal considerations

· **13.1 Waste treatment methods**
· **Recommendation**

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· **European waste catalogue**	
18 01 06*	chemicals consisting of or containing dangerous substances

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

*

SECTION 14: Transport information

· **14.1 UN-Number**	
· **ADR, IMDG, IATA**	UN1805
· **14.2 UN proper shipping name**	
· **ADR**	1805 PHOSPHORIC ACID, SOLUTION
· **IMDG, IATA**	PHOSPHORIC ACID, SOLUTION
· **14.3 Transport hazard class(es)**	
· **ADR**	

· **Class**	8 (C1) Corrosive substances.
· **Label**	8
· **IMDG, IATA**	

· **Class**	8 Corrosive substances.
· **Label**	8
· **14.4 Packing group**	
· **ADR, IMDG, IATA**	III
· **14.5 Environmental hazards:**	
· **Marine pollutant:**	No
· **14.6 Special precautions for user**	Warning: Corrosive substances.
· **Danger code (Kemler):**	80
· **EMS Number:**	F-A,S-B
· **Segregation groups**	Acids
· **14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable.

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· **Transport/Additional information:**

· **ADR**	
· **Limited quantities (LQ)**	5L
· **Excepted quantities (EQ)**	Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· **Transport category**	3
· **Tunnel restriction code**	E
· **IMDG**	
· **Limited quantities (LQ)**	5L
· **Excepted quantities (EQ)**	Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· **UN "Model Regulation":**	UN1805, PHOSPHORIC ACID, SOLUTION, 8, III

SECTION 15: Regulatory information

· **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
No further relevant information available.
· **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

* SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

The attached safety data sheet covers the dangers and measures to be taken when large quantities of material are released, for example due to accidents during transport or storage by the dealer.
For quantities of material typically used in clinical practice, information necessary for safe use and storage of the product is given in the DFU.

· **Relevant phrases**
H290 May be corrosive to metals.
H314 Causes severe skin burns and eye damage.

· **Department issuing MSDS:** Analytical Research
· **Contact:** HotLine for urgent technical support: +49-7531-583-350
· **Abbreviations and acronyms:**
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
Met. Corr.1: Corrosive to metals, Hazard Category 1
Skin Corr. 1A: Skin corrosion/irritation, Hazard Category 1A
Skin Corr. 1B: Skin corrosion/irritation, Hazard Category 1B
Eye Dam. 1: Serious eye damage/eye irritation, Hazard Category 1
· ***** **Data compared to the previous version altered.**

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

· **1.1 Product identifier**

· **Trade name: Prime & Bond NT**
· **1.2 Relevant identified uses of the substance or mixture and uses advised against**
· **Application of the substance / the mixture** Adhesive
· **Uses advised against** No further relevant information available.

· **1.3 Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
DENTSPLY DeTrey GmbH
De-Trey-Str. 1
D-78467 Konstanz
GERMANY
Tel.: +49-(0)7531-583-0
Fax: +49-(0)7531-583-104
email: KonstanzDEU.info-sdb@dentsply.com

· **Further information obtainable from:**
- Departement Analytical Research / Research & Development for technical information
- Departement Marketing & Sales for distribution of the safety data sheets
· **1.4 Emergency telephone number:** +49-(0)7531-583-0 8:00 - 17:00 (GMT + 1:00)

SECTION 2: Hazards identification

· **2.1 Classification of the substance or mixture**
· **Classification according to Regulation (EC) No 1272/2008**

Flam. Liq. 2	H225	Highly flammable liquid and vapour.
Skin Irrit. 2	H315	Causes skin irritation.
Eye Irrit. 2	H319	Causes serious eye irritation.
STOT SE 3	H336	May cause drowsiness or dizziness.
Aquatic Chronic 3	H412	Harmful to aquatic life with long lasting effects.

· **2.2 Label elements**
· **Labelling according to Regulation (EC) No 1272/2008**
As this product is a medical device in the meaning of Directive 93/42/EEC and intended for use by the end consumer and is applied in an invasive manner or body contact, it is exempt from the labelling requirements according to regulation 1272/2008.
The product is classified and labelled according to the CLP regulation.
· **Hazard pictograms**

GHS02 GHS07

· **Signal word** Danger

· **Hazard-determining components of labelling:**
acetone
· **Hazard statements**
H225 Highly flammable liquid and vapour.
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H336 May cause drowsiness or dizziness.
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.

(Contd. on page 2)

(Contd. of page 1)

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P405 Store locked up.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· **2.3 Other hazards**
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

· **3.2 Chemical characterisation: Mixtures**
· **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**		
CAS: 67-64-1 EINECS: 200-662-2	acetone Flam. Liq. 2, H225; Eye Irrit. 2, H319; STOT SE 3, H336	50-100%
CAS: 105883-40-7	Urethane Dimethacrylate Resin Skin Irrit. 2, H315; Eye Irrit. 2, H319	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	3-<10%
CAS: 2358-84-1	Di(ethylene glycol) dimethacrylate Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	3-<10%
CAS: 3290-92-4	Trimethylolpropane Trimethacrylate (TMPTMA) Aquatic Chronic 2, H411	1-≤2.5%
CAS: 128-37-0 EINECS: 204-881-4	2,6-di-tert-butyl-p-cresol Aquatic Acute 1, H400; Aquatic Chronic 1, H410	0.3-<1%

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

SECTION 4: First aid measures

· **4.1 Description of first aid measures**
· **General information** No special measures required.
· **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**
CO_2, 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.

(Contd. on page 3)

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(Contd. of page 2)

· **5.3 Advice for firefighters**
· **Protective equipment:** Self-contained respiratory protective device.

SECTION 6: Accidental release measures

· **6.1 Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
· **6.2 Environmental precautions:**
Inform respective authorities in case of seepage into water course or sewage system.
Dilute with plenty of water.
Do not allow to enter sewers/ surface or ground water.
· **6.3 Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Ensure adequate ventilation.
· **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.
Store only in the original receptacle.
· **Information about storage in one common storage facility:** Store away from oxidising agents.
· **Further information about storage conditions:** Store in cool, dry conditions in well sealed receptacles.
· **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:**	
67-64-1 acetone	
WEL	Short-term value: 3620 mg/m³, 1500 ppm Long-term value: 1210 mg/m³, 500 ppm

· **DNELs**		
128-37-0 2,6-di-tert-butyl-p-cresol		
Inhalative	DNEL Werte	3.5 mg/m³ bw/day (rat)

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· **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:**
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
Not necessary if room is well-ventilated.
· **Protection of hands:**

Protective gloves.

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
· **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
Natural rubber, NR
Recommended thickness of the material: ≥ 0.75 mm
Permeation: Level ≥2
· **Penetration time of glove material**
The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed.
· **Eye protection:**

Tightly sealed goggles.

· **Body protection:** Protective work clothing.

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SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**	
· **General Information**	
· **Appearance:**	
Form:	Fluid
Colour:	Yellow
· **Odour:**	Characteristic
· **Odour threshold:**	Not determined.
· **pH-value:**	Not determined.
· **Change in condition**	
Melting point/Melting range:	undetermined
Boiling point/Boiling range:	60 °C
· **Flash point:**	-19 °C (c.c. Abel)
· **Flammability (solid, gaseous)**	Not applicable.

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· **Ignition temperature:**	465 °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:	2.6 Vol %
Upper:	12.8 Vol %
· **Vapour pressure at 20 °C:**	233 hPa
· **Density at 20 °C:**	0.9 g/cm³
· **Relative density**	Not determined.
· **Vapour density**	Not determined.
· **Evaporation rate**	Not determined.
· **Solubility in / Miscibility with**	
Water:	Partly miscible
· **Partition coefficient (n-octanol/water):**	Not determined.
· **Viscosity:**	
dynamic:	Not determined.
kinematic:	Not determined.
· **Solvent content:**	
Organic solvents:	67.0 %
Solids content:	3.0 %
· **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

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SECTION 11: Toxicological information

· **11.1 Information on toxicological effects**
· **Acute toxicity:**

· **LD/LC50 values relevant for classification:**		
ATE (Acute Toxicity Estimates)		
Inhalative	LC50/4 h	113 mg/l

67-64-1 acetone		
Oral	LD50	5800 mg/kg (rat)
Dermal	LD50	20000 mg/kg (rabbit)
Inhalative	LC50/4 h	76 mg/l (rat)
3290-92-4 Trimethylolpropane Trimethacrylate (TMPTMA)		
Oral	LD50	>2000 mg/kg (rat)

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128-37-0 2,6-di-tert-butyl-p-cresol		
Oral	LD50	2930 mg/kg (rat)
Dermal	LD50	> 2000 mg/kg (rabbit)

· **Primary irritant effect:**
· **on the skin:**
Irritant to skin and mucous membranes.
The unpolymerized product may be irritant to the skin for succeptible persons.
· **on the eye:** Irritating effect.
· **Sensitisation:**
Repeated or prolonged contact with the not polymerized product may cause sensitization for acrylates / methacrylates.
· **Additional toxicological information:**
The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.
Irritant

SECTION 12: Ecological information

· **12.1 Toxicity**

· **Aquatic toxicity:**	
67-64-1 acetone	
EC50/48h	6100 mg/L (daphnia magna)
LC50/96h	5540 mg/l (Fish acute toxicity study)
3290-92-4 Trimethylolpropane Trimethacrylate (TMPTMA)	
EC50/48h	>9.22 mg/L (daphnia magna)
LC50/96h	2 mg/l (Fish acute toxicity study)
128-37-0 2,6-di-tert-butyl-p-cresol	
EC50/72h	>0.42 mg/l (Algea, gowth inhibition test)
LC50/48h	>0.57 mg/l (daphnia magna)
LC50/96h	>0.42 mg/l (Fish acute toxicity study)

· **12.2 Persistence and degradability** No further relevant information available.
· **12.3 Bioaccumulative potential** No further relevant information available.
· **12.4 Mobility in soil** No further relevant information available.
· **Ecotoxical effects:**
· **Remark:** Harmful to fish
· **Additional ecological information:**
· **General notes:**
Do not allow product to reach ground water, water course or sewage system.
Danger to drinking water if even small quantities leak into the ground.
Harmful to aquatic organisms
· **12.5 Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **12.6 Other adverse effects** No further relevant information available.

(Contd. on page 7)

(Contd. of page 6)

SECTION 13: Disposal considerations

· **13.1 Waste treatment methods**
· **Recommendation**

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· **European waste catalogue**	
18 01 06*	chemicals consisting of or containing dangerous substances

· **Uncleaned packaging:**
· **Recommendation:** Disposal must be made according to official regulations.
· **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

SECTION 14: Transport information

· **14.1 UN-Number**
· **ADR, IMDG, IATA** UN1090

· **14.2 UN proper shipping name**
· **ADR** 1090 ACETONE mixture
· **IMDG, IATA** ACETONE mixture

· **14.3 Transport hazard class(es)**

· **ADR**

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

· **IMDG, IATA**

· **Class** 3 Flammable liquids.
· **Label** 3

· **14.4 Packing group**
· **ADR, IMDG, IATA** II

· **14.5 Environmental hazards:**
· **Marine pollutant:** No

· **14.6 Special precautions for user** Warning: Flammable liquids.
· **Danger code (Kemler):** 33
· **EMS Number:** F-E,S-D

· **14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.

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· **Transport/Additional information:**

· **ADR**	
· **Limited quantities (LQ)**	1L
· **Excepted quantities (EQ)**	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· **Transport category**	2
· **Tunnel restriction code**	D/E
· **IMDG**	
· **Limited quantities (LQ)**	1L
· **Excepted quantities (EQ)**	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· **UN "Model Regulation":**	UN1090, ACETONE mixture, 3, II

SECTION 15: Regulatory information

· **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
No further relevant information available.
· **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

The attached safety data sheet covers the dangers and measures to be taken when large quantities of material are released, for example due to accidents during transport or storage by the dealer.
For quantities of material typically used in clinical practice, information necessary for safe use and storage of the product is given in the DFU.

· **Relevant phrases**
H225 Highly flammable liquid and vapour.
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
H336 May cause drowsiness or dizziness.
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 MSDS:** Analytical Research
· **Contact:** HotLine for urgent technical support: +49-7531-583-350
· **Abbreviations and acronyms:**
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
DNEL: Derived No-Effect Level (REACH)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
Flam. Liq. 2: Flammable liquids, Hazard Category 2
Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2
Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2

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STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3
Aquatic Acute 1: Hazardous to the aquatic environment - AcuteHazard, Category 1
Aquatic Chronic 1: Hazardous to the aquatic environment - Chronic Hazard, Category 1
Aquatic Chronic 2: Hazardous to the aquatic environment - Chronic Hazard, Category 2
Aquatic Chronic 3: Hazardous to the aquatic environment - Chronic Hazard, Category 3
· **** Data compared to the previous version altered.***