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according to 1907/2006/EC, Article 31

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

· **1.1 Product identifier**

· **Trade name:** **Technovit 2000 LC varnish**

· **1.2 Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.

· **Application of the substance / the mixture** Resin for metallographic testing

· **1.3 Details of the supplier of the safety data sheet**

· **Manufacturer/Supplier:**
Kulzer GmbH
Leipziger Straße 2, 63450 Hanau (Germany)
Tel.: +49 (0)6181 9689-2570 (Wehrheim)

· **Informing department:** email: technik.wehrheim@kulzer-dental.com

· **1.4 Emergency telephone number:** Emergency CONTACT (24-Hour-Number): +49 (0)6132-84463

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.
Skin Sens. 1	H317	May cause an allergic skin reaction.
STOT SE 3	H335	May cause respiratory irritation.
Aquatic Chronic 3	H412	Harmful to aquatic life with long lasting effects.

· **2.2 Label elements**

· **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the CLP regulation.

· **Hazard pictograms**

GHS02 GHS07

· **Signal word** Danger

· **Hazard-determining components of labelling:**
methyl methacrylate
diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide

· **Hazard statements**
H225 Highly flammable liquid and vapour.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H335 May cause respiratory irritation.
H412 Harmful to aquatic life with long lasting effects.

· **Precautionary statements**

P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P243	Take precautionary measures against static discharge.
P262	Do not get in eyes, on skin, or on clothing.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P370+P378	In case of fire: Use for extinction: CO2, sand, extinguishing powder.
P403	Store in a well-ventilated place.

· **2.3 Other hazards** -

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

*
SECTION 3: Composition/information on ingredients

· **3.2 Chemical characterisation: Mixtures**
· **Description:** Product based on methacrylates

· **Dangerous components:**

CAS: 80-62-6 EINECS: 201-297-1 Reg.nr.: 01-2119452498-28-XXXX	methyl methacrylate Flam. Liq. 2, H225; Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335	50-75%
CAS: 3290-92-4 EINECS: 221-950-4 Reg.nr.: 01-2119542176-41-XXXX	propylidynetrimethyl trimethacrylate Aquatic Chronic 2, H411	5-10%
CAS: 3077-12-1 EINECS: 221-359-1	N,N-bis(2-hydroxyethyl)-p-toluidine Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	0-5%
CAS: 75980-60-8 EINECS: 278-355-8 Reg.nr.: 01-2119972295-29	diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide Repr. 2, H361f; Aquatic Chronic 2, H411; Skin Sens. 1B, H317	<3%

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

SECTION 4: First aid measures

· **4.1 Description of first aid measures**
· **After inhalation** Supply fresh air; consult doctor in case of symptoms.
· **After skin contact**
Instantly wash with water and soap and rinse thoroughly.
If skin irritation continues, consult a doctor.
· **After eye contact**
Rinse opened eye for several minutes under running water. Then consult doctor.
· **After swallowing**
Rinse out mouth and then drink plenty of water.
In case of persistent symptoms 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, sand, extinguishing powder. Do not use water.
· **For safety reasons unsuitable extinguishing agents** Water.
· **5.2 Special hazards arising from the substance or mixture**
Can form explosive gas-air mixtures.
Formation of toxic gases is possible during heating or in case of fire.
· **5.3 Advice for firefighters**
· **Protective equipment:** No special measures required.

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· **Additional information** -

SECTION 6: Accidental release measures

· **6.1 Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
Ensure adequate ventilation
· **6.2 Environmental precautions:**
Inform respective authorities in case product reaches water or sewage system.
Prevent material from reaching sewage system, holes and cellars.
· **6.3 Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues).
Do not flush with water or aqueous cleansing agents
Send for recovery or disposal in suitable containers.
· **6.4 Reference to other sections**
See Section 13 for information on disposal.
See Section 8 for information on personal protection equipment.
See Section 7 for information on safe handling

SECTION 7: Handling and storage

· **7.1 Precautions for safe handling**
Wear protective equipment. Keep unprotected persons away.
Keep containers tightly sealed.
Ensure good ventilation/exhaustion at the workplace.
· **Information about protection against explosions and fires:**
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 containers:** Store in cool location.
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:**
Store cool (not above 25 °C).
Store in cool, dry conditions in well sealed containers.
· **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

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

· **8.1 Control parameters**

· **Components with critical values that require monitoring at the workplace:**	
80-62-6 methyl methacrylate	
WEL	Short-term value: 416 mg/m³, 100 ppm Long-term value: 208 mg/m³, 50 ppm

· **DNELs**		
80-62-6 methyl methacrylate		
Dermal	worker industr., l.te., syst.	74.3 mg/Kg/d (human)
Inhalative	worker industr., l.te., syst.	210 mg/m3 (human)

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· **PNECs**	
80-62-6 methyl methacrylate	
freshwater	0.94 mg/l (aqua)
3290-92-4 propylidynetrimethyl trimethacrylate	
freshwater	0.002 mg/l (nd)
marine water	0.0002 mg/l (nd)
STP	10 mg/l (nd)
sedim., dw, fre.wat.	0.3588 mg/Kg (nd)
sedim., dw, mar.wat.	0.0359 mg/Kg (nd)
soil,dw	0.7056 mg/Kg (nd)

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

· **8.2 Exposure controls**
· **Personal protective equipment**
· **General protective and hygienic measures**
Keep away from foodstuffs, beverages and food.
Instantly remove any soiled and impregnated garments.
Wash hands during breaks and at the end of the work.
Avoid contact with the eyes and skin.
· **Breathing equipment:**
Not neccessary with efficient local exhaust. If exposition to vapours is possible, use breathing protective mask (filter A).
· **Protection of hands:**
If skin contact cannot be avoided, protective gloves are recommended to avoid possible sensitization.
Solvent resistant 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.
· **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.
· **For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable:**
Butyl rubber, BR
Fluorocarbon rubber (Viton)
Nitrile rubber, NBR
Chloroprene rubber, CR
· **Eye protection:** Safety glasses
· **Body protection:** Light weight protective 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:**	Colourless
· **Smell:**	Characteristic
· **Odour threshold:**	Not determined.
· **pH-value:**	Not determined.
· **Change in condition**	
· **Melting point/freezing point:**	Not determined
· **Initial boiling point and boiling range:**	100 °C
· **Flash point:**	10 °C
· **Inflammability (solid, gaseous)**	Not applicable.
· **Ignition temperature:**	430.0 °C
· **Decomposition temperature:**	Not determined.
· **Self-inflammability:**	Product is not selfigniting.
· **Explosive properties:**	Product is not explosive. However, formation of explosive air/vapour mixtures is possible.
· **Critical values for explosion:**	
· **Lower:**	2.1 Vol %
· **Upper:**	12.5 Vol %
· **Steam pressure at 20 °C:**	47 hPa
· **Density**	Not determined
· **Relative density**	Not determined.
· **Vapour density**	Not determined.
· **Evaporation rate**	Not determined.
· **Solubility in / Miscibility with**	
· **Water:**	Not miscible or difficult to mix
· **Partition coefficient: n-octanol/water:**	Not determined.
· **Viscosity:**	
· **dynamic:**	Not determined.
· **kinematic:**	Not determined.
· **Solvent content:**	
· **VOC EU**	689.9 g/l
· **Solids content:**	23.8 %
· **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**
· **Conditions to be avoided:** No decomposition if used and stored according to specifications.
· **10.3 Possibility of hazardous reactions** No dangerous reactions known
· **10.4 Conditions to avoid** No further relevant information available.

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· **10.5 Incompatible materials:** No further relevant information available.
· **10.6 Hazardous decomposition products:** None
· **Additional information:**
If stored longer than recommended and/or above recommended temperature, product may polymerize generating heat.

SECTION 11: Toxicological information

· **11.1 Information on toxicological effects**
· **Acute toxicity** Based on available data, the classification criteria are not met.

· **LD/LC50 values that are relevant for classification:**		
80-62-6 methyl methacrylate		
Oral	LD50	>5000 mg/kg (rat)
Dermal	LD50	>5000 mg/kg (rab)
Inhalative	LC50/4 h	29.8 mg/l (rat)
3290-92-4 propylidynetrimethyl trimethacrylate		
Oral	LD50	> 2000 mg/kg (rat)
3077-12-1 N,N-bis(2-hydroxyethyl)-p-toluidine		
Oral	LD50	300 mg/kg (rat)
75980-60-8 diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide		
Oral	LD50	> 5000 mg/kg (rat)

· **Primary irritant effect:**
· **Skin corrosion/irritation**
Causes skin irritation.
· **Serious eye damage/irritation**
Based on available data, the classification criteria are not met.
· **Respiratory or skin sensitisation**
May cause an allergic skin reaction.
· **CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)**
· **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
· **Carcinogenicity** Based on available data, the classification criteria are not met.
· **Reproductive toxicity** Based on available data, the classification criteria are not met.
· **STOT-single exposure**
May cause respiratory irritation.
· **STOT-repeated exposure** Based on available data, the classification criteria are not met.
· **Aspiration hazard** Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

· **12.1 Toxicity**

· **Aquatic toxicity:**	
3290-92-4 propylidynetrimethyl trimethacrylate	
EC50/48h	>9.22 mg/l (daphnia)
LC50/96h	2 mg/l (fish)
75980-60-8 diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide	
EC50/48h	10 100 mg/l (algae)
	10 - 100 mg/l (daphnia)

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

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· **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 bodies 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**
Small quantities can be polymerized with the matching system component(s) and the cured solid material can be disposed of with the regular garbage. Larger quantities must be disposed of following the regulations of the local authorities.

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

SECTION 14: Transport information

· **14.1 UN-Number**	
· **ADR, IMDG, IATA**	1263
· **14.2 UN proper shipping name**	
· **ADR**	1263 PAINT, special provision 640D
· **IMDG, IATA**	PAINT
· **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

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· **14.6 Special precautions for user**	Warning: Flammable liquids.
· **Kemler Number:**	33
· **EMS Number:**	F-E,S-E
· **14.7 Transport in bulk according to Annex II of Marpol and the IBC Code**	Not applicable.
· **Transport/Additional information:**	-
· **UN "Model Regulation":**	UN1263, PAINT, special provision 640D, 3, II

SECTION 15: Regulatory information

· **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
· **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3
· **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Relevant phrases**
H225 Highly flammable liquid and vapour.
H302 Harmful if swallowed.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
H361f Suspected of damaging fertility.
H411 Toxic to aquatic life with long lasting effects.

· **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)
VOCV: Lenkungsabgabe auf flüchtigen organischen Verbindungen, Schweiz (Swiss Ordinance on volatile organic compounds)
DNEL: Derived No-Effect Level (REACH)
PNEC: Predicted No-Effect Concentration (REACH)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Flam. Liq. 2: Flammable liquids – Category 2
Acute Tox. 4: Acute toxicity – Category 4
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
Skin Sens. 1: Skin sensitisation – Category 1
Skin Sens. 1B: Skin sensitisation – Category 1B
Repr. 2: Reproductive toxicity – Category 2
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2
Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

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