

Revision: 29.04.2022

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

Printing date 29.04.2022

Version number 7 (replaces version 6)

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

- · 1.1 Product identifier
 - · Trade name: Technovit 8100 liquid
- · 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 histological examinations
- · 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

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

The product is classified and labelled according to the GB CLP regulation.

· Hazard pictograms



- · Signal word Warning
- Hazard-determining components of labelling:

2-hydroxyethyl methacrylate ethylenglycoldimethacrylate

· Hazard statements

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H317 May cause an allergic skin reaction.

Precautionary statements

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

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.

P337+P313 If eye irritation persists: Get medical advice/attention.

· 2.3 Other hazards -

· Results of PBT and vPvB assessment

PBT: Not applicable.

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· vPvB: Not applicable.

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SECTION 3: Composition/information on ingredients

· 3.2 Mixtures

· Dangerous components:		
CAS: 868-77-9 EINECS: 212-782-2 Reg.nr.: 01-2119490169-29-xxx	2-hydroxyethyl methacrylate Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, xH317	75-90%
CAS: 109-59-1 EINECS: 203-685-6	2-isopropoxyethanol Flam. Liq. 3, H226 Acute Tox. 4, H312; Acute Tox. 4, H332; Skin Irrit. 2, H315; Eye Irrit. 2, H319 ATE: LD50 dermal: 1,300 mg/kg LC50/4 h inhalative: 11 mg/l	≥5-<10%
CAS: 97-90-5 EINECS: 202-617-2	ethylenglycoldimethacrylate Skin Sens. 1, H317; STOT SE 3, H335 Specific concentration limit: STOT SE 3; H335: C ≥ 10%	≥0.1-<1%

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

SECTION 4: First aid measures

- · 4.1 Description of first aid measures
 - · General information

Instantly remove any clothing soiled by the product.

Personal protection for the First Aider.

· After inhalation

Supply fresh air; consult doctor in case of symptoms.

In case of unconsciousness bring patient into stable side position for transport.

· After skin contact

Instantly wash with water and soap and rinse thoroughly.

If skin irritation or rash occurs: Get medical advice/attention.

· After eve contact

Rinse opened eye for several minutes under running water. If symptoms persist, consult doctor. Remove contact lenses, if present and easy to do. Continue rinsing.

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 Allergic reactions
- 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, extinguishing powder or water jet. Fight larger fires with water jet or alcohol-resistant foam.

- For safety reasons unsuitable extinguishing agents Water with a full water jet.
- · 5.2 Special hazards arising from the substance or mixture

Formation of toxic gases is possible during heating or in case of fire.

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Can be released in case of fire Carbon dioxide (CO2) Carbon monoxide (CO)

- · 5.3 Advice for firefighters
 - Protective equipment:

Wear self-contained breathing apparatus. (EN 133)

· Additional information Cool endangered containers with water spray jet.

SECTION 6: Accidental release measures

· 6.1 Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.

Avoid contact with eyes and skin.

Do not breathe vapor / mist / gas.

Ensure adequate ventilation

Keep away from ignition sources

· 6.2 Environmental precautions:

Do not allow to enter drainage system, surface or ground water.

Do not allow to enter the ground/soil.

· 6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues).

Send for recovery or disposal in suitable containers.

6.4 Reference to other sections

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

Keep containers tightly sealed.

Avoid contact with eyes and skin.

Prevent formation of aerosols.

Do not breathe vapor / mist / gas.

Ensure good ventilation/exhaustion at the workplace.

Keep away from heat and direct sunlight.

Information about protection against explosions and fires:

Fumes can combine with air to form an explosive mixture.

Protect against electrostatic charges.

Do not spray on flames or red-hot objects.

Keep ignition sources away - Do not smoke.

· Handling

do not mix with

organic peroxides

amine

metals

reducing agent

Strong oxidizers

Strong acids

Radical initiator

7.2 Conditions for safe storage, including any incompatibilities

Storage

· Requirements to be met by storerooms and containers: Store in cool location.

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- · Information about storage in one common storage facility: Not required.
- · Further information about storage conditions:

Store cool (not above 25 °C).

Protect from humidity and keep away from water.

Do not seal container gastight.

• 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

· 8.1 Control parameters

Components with critical 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. Not required.

· DNELs				
868-77-9	2-hydroxyethyl methacrylate			
Oral	general population, long term, systemic	0.83 mg/Kg (not defined)		
Dermal	worker industrial, long term, systemic	1.3 mg/Kg/d (not defined)		
	general population, long term, systemic	0.83 mg/Kg/d (not defined)		
Inhalative	worker industrial, long term, systemic	4.9 mg/m3 (not defined)		
	general population, long term, systemic	2.9 mg/m3 (not defined)		
109-59-1 2-isopropoxyethanol				
Oral	general population, acute, systemic	12 mg/Kg (not defined)		
	general population, long term, systemic	4.8 mg/Kg (not defined)		
Dermal	worker industrial, acute, systemic	26 mg/Kg/d (not defined)		
	worker industrial, long term, systemic	10.3 mg/Kg/d (not defined)		
	general population, acute, systemic	12 mg/Kg/d (not defined)		
	general population, long term, systemic	4.8 mg/Kg/d (not defined)		
Inhalative	worker industrial, acute, systemic	180 mg/m3 (not defined)		
	worker industrial, long term, systemic	72 mg/m3 (not defined)		
	general population, acute, systemic	108 mg/m3 (not defined)		
	general population, long term, systemic	43 mg/m3 (not defined)		
97-90-5 et	thylenglycoldimethacrylate			
Oral	general population, long term, systemic	0.83 mg/Kg (not defined)		
Dermal	worker industrial, long term, systemic	1.3 mg/Kg/d (not defined)		
	general population, long term, systemic	0.83 mg/Kg/d (not defined)		
Inhalative	worker professional, long term, systemic	2.45 mg/m3 (not defined)		
	general population, long term, systemic	1.45 mg/m3 (not defined)		
· PNI	FCs			

868-77-9 2-hydroxyethyl methacrylate freshwater

0.482 mg/l (not defined) 0.482 mg/l (not defined) marine water sewage treatment plant 10 mg/l (not defined) sediment, dry weight, freshwater 3.79 mg/Kg (not defined) sediment, dry weight, marine water 3.79 mg/Kg (not defined) soil, dry weight 0.476 mg/Kg (not defined)

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			Conta. or page +
97-90-5 ethylenglycoldimethacrylate		, ,	
	freshwater	0.139 mg/l (not defined)	
	marine water	0.014 mg/l (not defined)	
	sewage treatment plant	57 mg/l (not defined)	
	sediment, dry weight, freshwater	1.6 mg/Kg (not defined)	
	sediment, dry weight, marine water	0.16 mg/Kg (not defined)	
	soil, dry weight	0.239 mg/Kg (not defined)	

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

· 8.2 Exposure controls

- · Appropriate engineering controls No further data; see item 7.
- Individual protection measures, such as personal protective equipment
 - General protective and hygienic measures

Keep away from foodstuffs, beverages and food.

Do not eat or drink while working.

Do not inhale gases / fumes / aerosols.

The usual precautionary measures should be adhered to in handling the chemicals.

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:

Use breathing protection in case of insufficient ventilation.

Filter A/P2.

· Hand protection

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

Check protective gloves prior to each use for their proper condition.

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.

NBR: acrylonitrile-butadiene rubber (0,11 mm)

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.

>30 min

- · Eye/face protection eye protection (EN 166)
- Body protection: Light weight protective clothing
- Environmental exposure controls

Do not allow to enter drainage system, surface or ground water.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

· Physical state Fluid Colourless

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Smell: Odour threshold: Not determined. Not determined. Not determined. Not determined. Not determined. Not determined. Not applicable. Lower and upper explosion limit Lower: Upper: Not determined.		
Odour threshold: Melting point/freezing point: Boiling point or initial boiling point and boiling range Flammability Lower and upper explosion limit Lower: Upper: Flash point: Ignition temperature: Decomposition temperature: Not determined.		(Contd. of page 5
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Information with regard to physical hazard		rd
classes		Maid
Explosives Void		
Flammable gases Void	Flammable gases	
· Aerosols Void		
Oxidising gases Void		
Gases under pressure Void		
Flammable liquids Void		
Flammable solids Void		
Self-reactive substances and mixtures Void		
Pyrophoric liquids Void		
Pyrophoric solids Void		
Substances and mixtures Void		
Substances and mixtures, which emit flammable gases in contact with water Void		
Trammable gases in contact with water Volu (Contd. on page 7)	nammable gases in contact with water	

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· Oxidising liquids	Void
· Oxidising solids	Void
· Organic peroxides	Void
· Corrosive to metals	Void
· Desensitised explosives	Void

SECTION 10: Stability and reactivity

- · 10.1 Reactivity No further relevant information available.
- · 10.2 Chemical stability
 - · Conditions to be avoided: No decomposition if used and stored according to specifications.
- · 10.3 Possibility of hazardous reactions Exothermic polymerisation
- · 10.4 Conditions to avoid

Heat, flames and sparks.

moisture exposure

10.5 Incompatible materials:

organic peroxides

amine

metals

reducing agent

Strong oxidizers

Strong acids

Radical initiator

· 10.6 Hazardous decomposition products: None

SECTION 11: Toxicological information

• 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008
• Acute toxicity Based on available data, the classification criteria are not met.

· LD/LC50 values that are relevant for classification:		
868-77-9	868-77-9 2-hydroxyethyl methacrylate	
Oral	LD50	5,564 mg/kg (rat)
Dermal	LD50	>5,000 mg/kg (rabbit)
109-59-1	2-isopropo	oxyethanol
Oral	LD50	>2,000 mg/kg (rat) (OECD 401)
Dermal	LD50	1,300 mg/kg (ATE)
		1,300 mg/kg (rabbit)
Inhalative	LC50/4 h	11 mg/l (ATE)
	LC0/4h	≥3,500 ppm (rat)
97-90-5 ethylenglycoldimethacrylate		
Oral	LD50	8,300 mg/kg (rat)
Dermal	LD50	>2,000 mg/kg (rat) (OECD 402)

- Skin corrosion/irritation
- Causes skin irritation.
- Serious eye damage/irritation

Causes serious eye irritation.

- Respiratory or skin sensitisation
- May cause an allergic skin reaction.
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.

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- Carcinogenicity Based on available data, the classification criteria are not met.
- Reproductive toxicity Based on available data, the classification criteria are not met.
- STOT-single exposure Based on available data, the classification criteria are not met. STOT-repeated exposure Based on available data, the classification criteria are not met.
- Aspiration hazard Based on available data, the classification criteria are not met.
- · 11.2 Information on other hazards
 - · Endocrine disrupting properties

None of the ingredients is listed.

SECTION 12: Ecological information

· 12.1 Toxicity

· 40	uatic	tos	/IC	IIV'

868-77-9 2	?-hydroxyethyl	l methacrylate
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	345 mg/l (algae) (OECD 201)
EC50/21d	90.1 mg/L (daphnia) (OECD 211)
EC50/48h (static)	380 mg/l (daphnia) (OECD 202)
LC50/96h	>100 mg/l (fish) (OECD 203)
NOEC / 21d	24.1 mg/l (daphnia) (OECD 211)
ErC50 / 72 h	836 mg/l (algae) (OECD 201)
NOEC / 72h	400 mg/l (algae) (OECD 201)
NOEC / 48h	171 mg/l (daphnia) (OECD 202)

109-59-1 2-isopropoxyethanol

EC50/21d	>98 mg/L (not defined) (OECD 211)
LC50/96h	>100 mg/l (fish) (OECD 203)
NOEC / 21d	98 mg/l (daphnia) (OECD 211)
LC50/48h	>970 mg/L (daphnia) (OECD 202)

97-90-5 ethylenglycoldimethacrylate

	
EC50/48h	44.9 mg/l (daphnia) (OECD 202)
LC50/96h	44.9 mg/l (daphnia) (OECD 202) 15.95 mg/l (fish) (OECD 203)
NOEC / 21d	5.05 mg/l (daphnia) (OECD 211)
ErC50 / 72 h	19 mg/l (algae) (OECD 201)
NOEC / 72h	0.804 mg/l (algae) (OECD 201)
NOEC / 48h	13.2 mg/l (daphnia) (OECD 202)
EbC50 / 72h	5.05 mg/l (daphnia) (OECD 211) 19 mg/l (algae) (OECD 201) 0.804 mg/l (algae) (OECD 201) 13.2 mg/l (daphnia) (OECD 202) 10.1 mg/l (algae) (OECD 201)

12.2 Persistence and degradability

868-77-9 2-hydroxyethyl methacrylate

Biodegradation 92-100 % /14d (not defined) (OECD 301C)

109-59-1 2-isopropoxyethanol

Biodegradation 20-26 % /28d (not defined) (OECD 301F; ISO 9408/ EEC 92/69/V, C.4-D)

97-90-5 ethylenglycoldimethacrylate

Biodegradation 71.2 % /28d (not defined) (OECD 301D)

- 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
- · 12.5 Results of PBT and vPvB assessment

· PBT: Not applicable.

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- · vPvB: Not applicable.
- · 12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

- · 12.7 Other adverse effects
 - Additional ecological information:
 - · General notes:

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

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 or ID number ADR, IMDG, IATA	Void	
14.2 UN proper shipping name ADR, 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 Maritime transport in bulk accordin IMO instruments	g to Not applicable.	
· Transport/Additional information:	-	
· UN "Model Regulation":	Void	

SECTION 15: Regulatory information

- · 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
 - Directive 2012/18/EU
 - · Named dangerous substances ANNEX I None of the ingredients is listed.
 - Information about limitation of use:
 Employment restrictions concerning young persons must be observed.

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Employment restrictions concerning pregnant and lactating women must be observed. 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

H226 Flammable liquid and vapour.

H312 Harmful in contact with skin.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H332 Harmful if inhaled.

H335 May cause respiratory irritation.

Abbreviations and acronyms:

SADT: Self Accelerating Decomposition Temperature SAPT: Self Accelerating Polymerisation Temperature

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement

Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances ELINCS: European List of Notified Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society) DNEL: Derived No-Effect Level (GB REACH)

PNEC: Predicted No-Effect Concentration (GB REACH)

LOSO: Lethal concentration 50 percent

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Flam. Liq. 3: Flammable liquids – Category 3
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

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

Sources

(EC) 1272/2008: classification, labelling and packaging of substances and mixtures

(EC) 1907/2006: GB REACH

`ADŔ/RID/ADN - IDMG - IATA: transport of dangerous goods by road, rail, inland waterway, with maritime vessels and for the air transport

* Data compared to the previous version altered.