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

Printing date 03.08.2022 Version number 4 (replaces version 3) Revision: 03.08.2022

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

- · 1.1 Product identifier
 - · Trade name: Meliodent Rapid Repair 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 Manufacture of dental prothesis
- · 1.3 Details of the supplier of the safety data sheet
 - Manufacturer/Supplier:

Kulzer GmbH

Leipziger Straße 2, 63450 Hanau (Germany)

Tel.: +49 (0)800 4372522

· Informing department: E-Mail: msds@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

H225 Highly flammable liquid and vapour. Flam. Lig. 2

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

1,4-butandioldimethacrylate

2- (2H-Benzotriazol-2-yl) -p-cresol

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.

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

P273 Avoid release to the environment.

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

protection.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

· 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 Mixtures
 - · Description:

Product based on methacrylates

· Dangerous components:		
CAS: 80-62-6 EINECS: 201-297-1	methyl methacrylate Flam. Liq. 2, H225 Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335	>90%
CAS: 2082-81-7 EINECS: 218-218-1	1,4-butandioldimethacrylate Skin Sens. 1B, H317	≥1-≤5%
CAS: 2440-22-4 EINECS: 219-470-5 Reg.nr.: 01-2119583811-34-xxxx	2- (2H-Benzotriazol-2-yl) -p-cresol Aquatic Chronic 1, H410 Skin Sens. 1B, H317	≥0.25-<1%
CAS: 99-97-8 EINECS: 202-805-4 Reg.nr.: 01-2119956633-31-xxxx	N,N-dimethyl-p-toluidine Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. (2, H330 STOT RE 2, H373 Aquatic Chronic 3, H412	<1%

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

SECTION 4: First aid measures

- · 4.1 Description of first aid measures
 - · After inhalation Supply fresh air; consult doctor in case of 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 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, 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.

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- 5.3 Advice for firefighters
 - **Protective equipment:** No special measures required.
 - Additional information -

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.

- 6.2 Environmental precautions: 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

6.4 Reference to other sections

No dangerous materials are released.

See Section 7 for information on safe handling

See Section 8 for information on personal protection equipment.

See Section 13 for information on disposal.

SECTION 7: Handling and storage

· 7.1 Precautions for safe handling

Keep containers tightly sealed.

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

Ensure good interior ventilation, especially at floor level. (Fumes are heavier than air).

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
 - - 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

· 8.1 Control parameters

Components with critical values that require monitoring at the workplace:

80-62-6 methyl methacrylate

OEL (Ireland) Short-term value: 100 ppm

Long-term value: 50 ppm IOELV, Sens

Short-term value: 100 ppm IOELV (European Union)

Long-term value: 50 ppm

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DAI				(Contd. of page
· DNI	ethyl methacrylate			
Oral		term systemic	8.2 mg/Kg (not defined)	
Dermal	general population, long term, systemic		13.67 mg/Kg/d (not defined)	
Dellilai	worker industrial, long term, systemic general population, long term, systemi		,	
labalati: .a		•	8.2 mg/Kg/d (not defined)	
innaiative	worker industrial, acute,		416 mg/m3 (not defined)	
	worker industrial, long te	•	348.4 mg/m3 (not defined)	
	worker industrial, long te		208 mg/m3 (not defined)	
	general population, acute		208 mg/m3 (not defined)	
0000 04 7	general population, long		74.3 mg/m3 (not defined)	
	1,4-butandioldimethaci	•	0.5	
Oral	general population, long	•	2.5 mg/Kg (not defined)	
Dermal	worker industrial, long te		4.2 mg/Kg/d (not defined)	
	general population, long		2.5 mg/Kg/d (not defined)	
Inhalative	worker professional, long			
	general population, long		4.3 mg/m3 (not defined)	
	2- (2H-Benzotriazol-2-y	· ·		
Oral	general population, long	-	1.2 mg/Kg (not defined)	
Dermal	worker industrial, long te		2.5 mg/Kg/d (not defined)	
	general population, long	•	1.2 mg/Kg/d (not defined)	
Inhalative	worker industrial, acute,	•	1 mg/m3 (not defined)	
	worker industrial, long te	rm, systemic	1 mg/m3 (not defined)	
	worker professional, long	term, local	1 mg/m3 (not defined)	
·PNE				
	ethyl methacrylate			
freshwater	•	0.94 mg/l (not defined)		
marine wa		0.094 mg/l (not defined)		
sewage tre	eatment plant	10 mg/l (not defined)		
sediment,	dry weight, freshwater	10.2 mg/Kg (not defined)		
sediment,	dry weight, marine water	0.102 mg/Kg (not defined)		
soil, dry w		1.48 mg/Kg (no	t defined)	
	1,4-butandioldimethacı	•		
freshwater	•	0.043 mg/l (not	defined)	
marine wa	ter	0.004 mg/l (not defined)		
sewage tre	eatment plant	2 mg/l (not defii	ned)	
sediment,	dry weight, freshwater	3.12 mg/Kg (no	t defined)	
sediment, dry weight, marine water		0.312 mg/Kg (n	ot defined)	
soil, dry w		0.573 mg/Kg (n	ot defined)	
	2- (2H-Benzotriazol-2-y	<u> </u>		
freshwater	•	0 mg/l (not defii	*	
marine water		0 mg/l (not defii		
-	eatment plant	1 mg/l (not defii		
sediment, dry weight, freshwater		0.136 mg/Kg (n		
	dry weight, marine water			



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soil, dry weight

100 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.

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).

Hand protection

The glove material has to be impermeable and resistant to the product/ the substance/ the

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

If skin contact cannot be avoided, protective gloves are recommended to avoid possible sensitization.

Solvent resistant gloves

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

recommended

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

Nitrile rubber, NBR

- Eye/face protection Tightly sealed safety glasses.
- · Body protection: Light weight protective clothing

SECTION 9: Physical and chemical properties

- · 9.1 Information on basic physical and chemical properties
 - General Information

Physical state

Colour:

Colourless

Smell:

Characteristic

Odour threshold:

Not determined.

· Melting point/freezing point:

Not determined

· Boiling point or initial boiling point and

100 °C (80-62-6 methyl methacrylate)

boiling range

· Flammability

Not applicable.

· Lower and upper explosion limit

· Lower:

2.1 Vol %

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· Upper:	12.5 Vol %
· Flash point:	10 °C (80-62-6 methyl methacrylate)
Ignition temperature:	430 °C
· Ďecomposition temperature:	Not determined.
· SAPT	
Meliodent Rapid Repair Liquid > 60 °C	
SADT	
· pH	Mixture is non-soluble (in water).
Viscosity:	
Kinematic viscosity	Not determined.
dynamic at 20 °C:	1 mPas
Solubility	
· Water:	Not miscible or difficult to mix
Partition coefficient n-octanol/water (log	
value)	Not determined.
· Steam pressure at 20 °C:	47 hPa
Density and/or relative density	
Density at 20 °C	0.94613 g/cm³
Relative density	Not determined.
· Vapour density	Not determined.
• 9.2 Other information Not	further relevant information available.
· Appearance:	
Form:	Fluid
Important information on protection of	
health and environment, and on safety.	
· Self-inflammability:	Product is not selfigniting.
Explosive properties:	Product is not explosive. However, formation
Explosive proportion	explosive air/vapour mixtures is possible.
· Change in condition	expressive and rapear inixtaries to possible.
· Evaporation rate	Not determined.
Information with regard to physical hazard	
classes	
· Explosives	Void
· Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Highly flammable liquid and vapour.
	Void
· Flammable solids · Self-reactive substances and mixtures	
Con rouding capotaness and inixtares	Void Void
· Pyrophoric liquids	
Pyrophoric solids	Void Void
Self-heating substances and mixtures	Void
Substances and mixtures, which emit	1/2:4
flammable gases in contact with water	Void
Oxidising liquids	Void
Oxidising solids	Void
Organic peroxides	Void
· Corrosive to metals	Void
· Desensitised explosives	Void



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

· LD/	· LD/LC50 values that are relevant for classification:		
80-62-6 m	80-62-6 methyl methacrylate		
Oral	LD50	~7,900 mg/kg (rat)	
Dermal	LD50	>5,000 mg/kg (guinea pig) (OECD 402)	
Inhalative	LC50/4 h	29.8 mg/l (rat)	
2082-81-7	2082-81-7 1,4-butandioldimethacrylate		
Oral		10,066 mg/kg (rat) (OECD 401)	
2440-22-4	2440-22-4 2- (2H-Benzotriazol-2-yl) -p-cresol		
Oral	LD50	10,000 mg/kg (rat) (OECD 423)	
99-97-8 N	99-97-8 N,N-dimethyl-p-toluidine		
Oral	LD50	139 mg/kg (rat)	

· 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.

- 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.
- · 11.2 Information on other hazards
 - Endocrine disrupting properties

None of the ingredients is listed.

- IE



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12.1 Toxicity	,		
Aquatic to	oxicity:		
30-62-6 meth	nyl methacrylate		
EC50/21d	49 mg/L (daphnia) (OECD 211)		
EC50/48h	69 mg/l (daphnia) (EPA OTS 797.1300)		
NOEC / 21d	37 mg/l (daphnia) (OECD 211)		
ErC50 / 72 h	>110 mg/l (algae) (OECD 201)		
VOEC / 72h	110 mg/l (algae) (OECD 201)		
VOEC / 48h	48 mg/l (daphnia) (EPA OTS 797.1300)		
EbC50 / 72h	>110 mg/l (algae) (OECD 201)		
NOEC/ 35d	9.4 mg/L (fish) (OECD 210)		
_C50/ 35d	33.7 mg/L (fish) (OECD 210)		
2082-81-7 1,4	4-butandioldimethacrylate		
EC50/21d	14.1 mg/L (daphnia) (OECD 211)		
EC50/48h	32.5 mg/l (fish)		
VOEC / 21d	5.09 mg/l (daphnia) (OECD 211)		
	9.79 mg/l (algae) (OECD 201)		
VOEC / 72h	2.11 mg/l (algae) (OECD 201)		
VOEC / 48h	25 mg/l (fish)		
ErC10/72h	4.35 mg/L (algae) (OECD 201)		
?44 <mark>0-22-4</mark> 2-	(2H-Benzotriazol-2-yl) -p-cresol		
EC50/72h	>100 mg/l (algae)		
EC50/21d	0.015 mg/L (daphnia) (OECD 211)		
_C50/96h	>0.17 mg/l (fish) (OECD 203)		
	0.013 mg/l (daphnia) (OECD 211)		
	>0.0822 mg/l (algae) (OECD 201)		
	0.17 mg/l (fish) (OECD 203)		
EC50 / 24h	>1,000 mg/l (daphnia) (OECD 202)		
ErC10/72h	0.0588 mg/L (algae) (OECD 201)		
	dimethyl-p-toluidine		
LC50/96h 100 mg/l (fish)			
	ence and degradability		
	nyl methacrylate		
•	on 94 % /14d (not defined) (OECD 301C)		
•	4-butandioldimethacrylate		
	on 84 % /28d (not defined) (OECD 310)		
	(2H-Benzotriazol-2-yl) -p-cresol		
3iodegradatio	on 0-2 % /28d (not defined) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)		

- 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.
 vPvB: Not applicable.

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· 12.6 Endocrine disrupting properties

For information on endocrine disrupting properties see section 11.

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

Do not allow product to reach ground water, water bodies or sewage system.

Danger to drinking water if even small quantities leak into soil.

SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
 - Recommendation

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

Disposal must be made according to official regulations.

- European waste catalogue
- 18 01 06* chemicals consisting of or containing hazardous substances
 - Uncleaned packagings:
 - Recommendation:

Disposal must be made according to official regulations. Non contaminated packagings can be used for recycling.

SECTION 14: Transport information

· 14.1 UN number or ID number	
· ADR, IMDG, IATA	UN1247

· 14.2 UN proper shipping name

· ADR 1247 METHYL METHACRYLATE MONOMER, STABILIZED solution

METHYL METHACRYLATE MONOMER, · IMDG, IATA STABILIZED solution

- · 14.3 Transport hazard class(es)



3 (F1) Flammable liquids. · Class · Label

· IMDG, IATA



· Class 3 Flammable liquids.

· Label

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14.4 Packing group ADR, IMDG, IATA	II .
· 14.5 Environmental hazards: · Marine pollutant:	No
· 14.6 Special precautions for user · Kemler Number: · EMS Number: · Stowage Category	Warning: Flammable liquids. 339 F-E,S-D B
Stowage Code	SW2 Clear of living quarters.
· 14.7 Maritime transport in bulk according i IMO instruments	to Not applicable.
· Transport/Additional information:	-
· ADR · Limited quantities (LQ) · Excepted quantities (EQ)	1L Code: E2 Maximum net quantity per inner packaging 30 ml Maximum net quantity per outer packaging 500 ml
· Transport category · Tunnel restriction code	2 D/E
· IMDG · Limited quantities (LQ) · Excepted quantities (EQ)	1L Code: E2 Maximum net quantity per inner packaging 30 ml Maximum net quantity per outer packaging 500 ml
· UN "Model Regulation":	UN 1247 METHYL METHACRYLAT MONOMER, STABILIZED SOLUTION, 3, II

SECTION 15: Regulatory information

- · 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
 - Directive 2012/18/EU
 - · Named dangerous substances ANNEX I None of the ingredients is listed.
 - · Seveso category P5c FLAMMABLE LIQUIDS
 - Qualifying quantity (tonnes) for the application of lower-tier requirements 5.000 t
 - Qualifying quantity (tonnes) for the application of upper-tier requirements 50.000 t REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3

 - DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment - Annex II

None of the ingredients is listed.

15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.



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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.

H301 Toxic if swallowed.

H311 Toxic in contact with skin.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H330 Fatal if inhaled.

H335 May cause respiratory irritation.

H373 May cause damage to organs through prolonged or repeated exposure.

H410 Very toxic to aquatic life with long lasting effects.

H412 Harmful to aquatic life with long lasting effects.

Date of previous version: 03.08.2022

· Version number of previous version: 3

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 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)

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. 3: Acute toxicity – Category 3 Acute Tox. 2: Acute toxicity – Category 2

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

Skin Sens. 1: Skin sensitisation - Category 1

Skin Sens. 1B: Skin sensitisation - Category 1B

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3 STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard — Category 1 Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard — Category 3 * Data compared to the previous version altered.