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Tel.: +49 (0)800 4372522

Safety Data Sheet according to HPR, Schedule 1

Printing date 08/03/2020 Reviewed on 08/03/2020

1 Identification

- · Product identifier
 - · Trade name: Meliodent Rapid Repair Liquid
 - · Application of the substance / the mixture Manufacture of dental prothesis
- · Details of the supplier of the safety data sheet
 - Manufacturer/Supplier:

Kulzer GmbH

Leipziger Straße 2, 63450 Hanau (Germany)

· Information department:

Tel. +1 (800) 431-1785 Fax: +1 (800) 522-1545 e-mail: customer.servicehkna@kulzer-dental.com

· Emergency telephone number:

Emergency CONTACT (24-Hour-Number) ID 105860: (domestic) 1 800 535 5053 or international (001) 352 323 3500

2 Hazard identification

· Classification of the substance or mixture

Flammable Liquids - Category 2 H225 Highly flammable liquid and vapour.

H315 Causes skin irritation. Skin Irritation - Category 2

Skin Sensitizer - Category 1 H317 May cause an allergic skin reaction.

Carcinogenicity - Category 2 H351 Suspected of causing cancer.

Specific Target Organ Toxicity - Single Exposure - H335 May cause respiratory irritation. Category 3

· Label elements

GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

· Hazard pictograms







GHS02 GHS07

- · Signal word Danger
- · Hazard-determining components of labeling:

methyl methacrylate

tetramethylene dimethacrylate

2-(2H-Benzotriazol-2-yl)-4-methylphenol

Hazard statements

Highly flammable liquid and vapour.

Causes skin irritation.

May cause an allergic skin reaction.

Suspected of causing cancer.

May cause respiratory irritation.

Precautionary statements

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

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

Avoid release to the environment.

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

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

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· Classification system · NFPA ratings for USA (scale 0-4)



· HMIS-Ratings (Scale 0-4)



Health = 1 Fire = 3 Reactivity = 0

· Other hazards -

3 Composition/Information on ingredients

- · Chemical characterization: Mixtures
 - · Description:

Composition based on methacrylates

. Danger	· Dangerous components:			
80-62-6	methyl methacrylate	>90% w/w		
	Flammable Liquids - Category 2, H225 Skin Irritation - Category 2, H315; Skin Sensitizer - Category 1, H317; Specific Target Organ Toxicity - Single Exposure - Category 3, H335			
2082-81-7	tetramethylene dimethacrylate Skin Sensitizer - Category 1B, H317	<i>≥1-≤</i> 5% w/w *		
2440-22-4	2-(2H-Benzotriazol-2-yl)-4-methylphenol Skin Sensitizer - Category 1, H317	<i>≥</i> 0.1-<1% w/w *		
99-97-8	N,N-dimethyl-p-toluidine Acute Toxicity (Oral) - Category 3, H301; Acute Toxicity (Dermal) – Category 3, H311; Acute Toxicity (Inhalation) - Category 2, H330 Carcinogenicity – Category 2, H351; Specific Target Organ Toxicity - Repeated Exposure - Category 2, H373 Flammable Liquids - Category 4, H227	≥0.1-<1% w/w *		

^{*} Actual concentration ranges are withheld as a trade secret.

4 First-aid measures

- · 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.

If skin irritation continues, consult a doctor.

· 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.

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



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- · Information for doctor
 - · Most important symptoms and effects, both acute and delayed Allergic reactions
 - Indication of any immediate medical attention and special treatment needed No further relevant information available.

5 Fire-fighting measures

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

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

6 Accidental release measures

· Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.

Avoid contact with eyes and skin.

- · Environmental precautions: Prevent seepage into sewage system, workpits and cellars.
- 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

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.

7 Handling and storage

Handling

· Precautions for safe handling

Please observe the additional instructions in the product's instructions for use.

Keep receptacles 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.

- · 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: Not required.
 - Further information about storage conditions:

Keep cool, if possible (not above 25 °C).

Store in cool, dry conditions in well sealed receptacles.

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

8 Exposure controls/ Personal protection

- · Additional information about design of technical systems: No further data; see item 7.
- · Control parameters
 - · Components with limit values that require monitoring at the workplace:

80-62-6 methyl methacrylate

EL STEL: 100 ppm TWA: 50 ppm

S(D)

EV STÉL: 100 ppm TWA: 50 ppm

99-97-8 N,N-dimethyl-p-toluidine

EL IARC 2B

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

· 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.

· Breathing equipment:

Not necessary with efficient local exhaust. If exposition to vapours is possible, use breathing protective mask (filter A).

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

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 through 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 protection: Tightly sealed goggles.

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· Body protection: Light weight protective clothing

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9 Physical and chemical properties Information on basic physical and chemical properties

General Information	anical properties
Appearance: Form:	Fluid
· Color:	Colorless
· Odor:	Characteristic
Odor threshold:	Not determined.
· pH-value:	Not determined.
· Change in condition · Melting point/Melting range: · Boiling point/Boiling range:	undetermined 100°C (212°F)
· Flash point:	10 °C (50 °F)
· Flammability (solid, gaseous)	Not applicable.
· Ignition temperature:	430 °C (806 °F)
· Decomposition temperature:	Not determined.
· Auto igniting:	Product is not selfigniting.
· Danger of explosion:	Product is not explosive. However, formation of explosive air/vapor mixtures are possible.
· Explosion limits:	
· Lower: · Upper:	2.1 Vol % 12.5 Vol %
· Vapor pressure at 20 °C (68 °F):	47 hPa (35.3 mm Hg)
Density at 20 °C (68 °F): Relative density Vapor density Evaporation rate	0.94613 g/cm³ (7.89545 lbs/gal) Not determined. Not determined. Not determined.

· Solubility in / Miscibility with

• Water: Not miscible or difficult to mix

· Partition coefficient (n-octanol/water): Not determined.

· Viscosity:

· dynamic at 20 °C (68 °F): 1 mPas

· kinematic: Not determined.

· Other information No further relevant information available.

10 Stability and reactivity

- · Reactivity No further relevant information available.
- · Possibility of hazardous reactions No dangerous reactions known
- · Conditions to avoid No further relevant information available.
- · Incompatible materials: No further relevant information available.
- · Hazardous decomposition products: none

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· Additional information:

Product might polymerize after considerable exceeding of recommended storage time or temperature.

11 Toxicological information

- · Information on toxicological effects
 - · Acute toxicity:

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· 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) weight of evidence					
Dermal	LD50	>5,000 mg/kg (rab) (OECD 402)					
Inhalative	LC50/4 h	29.8 mg/l (rat)					
2082-81-7	2082-81-7 tetramethylene dimethacrylate						
Oral	LD50	10,066 mg/kg (rat) (OECD 401)					
2440-22-4	2440-22-4 2-(2H-Benzotriazol-2-yl)-4-methylphenol						
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)					

- · Primary irritant effect:
- on the skin: Irritant to skin and mucous membranes.
 on the eye: No irritating effect.
 Sensitization: Sensitization possible through skin contact.
- · Additional toxicological information: Irritant
 - · Carcinogenic categories

-		
	· IARC (International Agency for Research on Cancer)	
80-62-6	methyl methacrylate	3
99-97-8	N,N-dimethyl-p-toluidine	2B
	· NTP (National Toxicology Program)	
None of	the ingredients is listed.	

12 Ecological information

· Toxicity

· Aquatio	· Aquatic toxicity:				
80-62-6 methyl methacrylate					
EC50/48h	69 mg/l (daphnia)				
LC50/96h	191 mg/l (fish)				
2440-22-4 2-(2H-Benzotriazol-2-yl)-4-methylphenol					
EC50/72h	>100 mg/l (algae)				
LC50/96h	>0.17 mg/l (fish)				
99-97-8 N,N-dimethyl-p-toluidine					
LC50/96h	100 mg/l (fish)				

· Persistence and degradability No further relevant information available.

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- · Behavior in environmental systems:
 - · Bioaccumulative potential No further relevant information available.
 - · 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.

- Results of PBT and vPvB assessment
 - · PBT: Not applicable.
 - vPvB: Not applicable.
- · Other adverse effects No further relevant information available.

13 Disposal considerations

- · 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.

- · Uncleaned packagings:
 - Recommendation:

Disposal must be made according to official regulations.

Non contaminated packagings can be used for recycling.

14 Transport information

	UN	-Nu	ımber
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· **DOT/TDG, ADR, IMDG, IATA** UN1247

· UN proper shipping name

DOT/TDG

Methyl methacrylate monomer, stabilized solution

1247 METHYL METHACRYLATE MONOMER,

STABILIZED solution

· IMDG, IATA METHYL METHACRYLATE MONOMER,

STABILIZED solution

- · Transport hazard class(es)
 - · DOT/TDG (Transport dangerous goods):



· Class 3 Flammable liquids · Label 3

· ADR



· Class 3 (F1) Flammable liquids

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· Label

· IMDG, IATA

· Class 3 Flammable liquids

· Label

· Packing group

· DOŤ/ŤDG, ADR, IMDG, IATA

· Environmental hazards:

· Marine pollutant: No

· Special precautions for user Warning: Flammable liquids

· Hazard identification number (Kemler

 code):
 339

 EMS Number:
 F-E,S-D

Stowage Category
Stowage Code
B
SW2 Clear of living quarters.

· Transport in bulk according to Annex II of

MARPOL73/78 and the IBC Code Not applicable.

· Transport/Additional information: -

· ADR

Excepted quantities (EQ) Code: E2

Maximum net quantity per inner packaging: 30

ml

Maximum net quantity per outer packaging: 500

ml

·IMDG

· Limited quantities (LQ) 1L

· Excepted quantities (ÉQ) Code: E2

Maximum net quantity per inner packaging: 30

ml

Maximum net quantity per outer packaging: 500

ml

· UN "Model Regulation": UN 1247 METHYL METHACRYLATE MONOMER,

STABILIZED SOLUTION, 3, II

15 Regulatory information

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

· SARA Section 355 (extremely hazardous substances)

None of the ingredients is listed.

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

CDN-



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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.

H227 Combustible liquid.

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.

H351 Suspected of causing cancer.

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

Date of the latest revision of the safety data sheet 08/03/2020 / 3

Abbreviations and acronyms:

IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation

IATA: International Air Transport Association

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)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative

* Data compared to the previous version altered.