

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 12.02.2024

Version: 7

Revision: 12.02.2024

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

- **1.1 Product identifier**
- **Trade name:** Zirkonium Cem
- **Article number:** 438222, 438224, 170013
- **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** polymerbased Luting composite
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
MANI MEDICAL GERMANY GmbH
Hertha-Sponer-Straße 2
D-61191 Rosbach v.d.H.
Germany
Tel: +49 6003/8286-0
www.mani-germany.com
- **Further information obtainable from:** R&D, MANI MEDICAL GERMANY GmbH, Tel: +049 6003/8286-0
- **1.4 Emergency telephone number:**
+49 (0) 6003 82 86-0, MANI MEDICAL GERMANY GmbH (8:00 - 17:00) or
+49 (0) 6131 19240 Poison Information Center, University Mainz (24 h)

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
Skin Sens. 1 H317 May cause an allergic skin reaction.
Aquatic Chronic 2 H411 Toxic 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**



GHS07 GHS09

- **Signal word** Warning
- **Hazard-determining components of labelling:**
di-urethane dimethacrylate
2-[[(butylamino)carbonyl]oxy]ethyl acrylate
dibenzoyl peroxide
- **Hazard statements**
H317 May cause an allergic skin reaction.
H411 Toxic to aquatic life with long lasting effects.
- **Precautionary statements**
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P273 Avoid release to the environment.
P280 Wear protective gloves.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P321 Specific treatment (see on this label).
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

(Contd. on page 2)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 12.02.2024

Version: 7

Revision: 12.02.2024

Trade name: Zirkonium Cem

(Contd. of page 1)

- **Labelling of packages where the contents do not exceed 125 ml**
- **Hazard pictograms**



GHS07 GHS09

- **Signal word** *Warning*
- **Hazard-determining components of labelling:**
di-urethane dimethacrylate
2-[[[(butylamino)carbonyl]oxy]ethyl acrylate
dibenzoyl peroxide
- **Hazard statements**
H317 May cause an allergic skin reaction.
- **Precautionary statements**
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P280 Wear protective gloves.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P321 Specific treatment (see on this label).
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 Mixtures**
- **Description:** *Adhesive material for dental use.*

· **Dangerous components:**

CAS: 41137-60-4	di-urethane dimethacrylate ⚠ Aquatic Chronic 2, H411; ⚠ Skin Sens. 1B, H317	25-50%
CAS: 63225-53-6	2-[[[(butylamino)carbonyl]oxy]ethyl acrylate ⚠ Acute Tox. 4, H332; Skin Sens. 1A, H317	2.5-10%
CAS: 94-36-0 EINECS: 202-327-6	dibenzoyl peroxide ⚠ Org. Perox. B, H241; ⚠ Aquatic Chronic 1, H410; ⚠ Eye Irrit. 2, H319; Skin Sens. 1, H317	<2.5%

- **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 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.
Call a doctor immediately.
- **4.2 Most important symptoms and effects, both acute and delayed** *No further relevant information available.*

(Contd. on page 3)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 12.02.2024

Version: 7

Revision: 12.02.2024

Trade name: Zirkonium Cem

(Contd. of page 2)

- **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** Use fire extinguishing methods suitable to surrounding conditions.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** Adapt to environment.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Avoid eye and skin contact with the substance.
- **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).
Dispose contaminated material as waste according to section 13.
- **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** Store in cool, dry place in tightly closed receptacles.
- **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 in refrigerator.
- **Information about storage in one common storage facility:** Store away from foodstuffs.
- **Further information about storage conditions:** None.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **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**
- **Appropriate engineering controls** No further data; see section 7.
- **Individual protection measures, such as 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.
- **Hand protection** Solvent resistant gloves
- **Material of gloves**
Butyl rubber, BR
Nitrile rubber, NBR

(Contd. on page 4)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 12.02.2024

Version: 7

Revision: 12.02.2024

Trade name: Zirkonium Cem

(Contd. of page 3)

- **Penetration time of glove material**
0,3 mm
Penetration time 60 min.
0,11 mm
Penetration time 10 min.
- **Eye/face 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

- | | |
|---|---|
| · Physical state | Fluid |
| · Colour: | White |
| · Odour: | Weak, characteristic |
| · Odour threshold: | Not determined. |
| · Melting point/freezing point: | undetermined |
| · Boiling point or initial boiling point and boiling range | undetermined |
| · Flammability | Not applicable. |
| · Lower and upper explosion limit | |
| · Lower: | Not determined. |
| · Upper: | Not determined. |
| · Flash point: | Not applicable |
| · Auto-ignition temperature: | 400 °C |
| · Decomposition temperature: | Not determined. |
| · pH | Mixture is non-soluble (in water).
Not determined. |
| · Viscosity: | |
| · Kinematic viscosity | Not determined. |
| · dynamic: | Not determined. |
| · Solubility | |
| · Water: | Not miscible or difficult to mix |
| · Partition coefficient n-octanol/water (log value) | Not determined. |
| · Vapour pressure: | 1,3 mbar (110 °C)
Not determined. |
| · Density and/or relative density | |
| · Density: | Not determined |
| · Relative density | Not determined. |
| · Vapour density | Not determined. |

· 9.2 Other information

- | | |
|--|---|
| · Appearance: | |
| · Form: | Viscous |
| · Important information on protection of health and environment, and on safety. | |
| · Ignition temperature: | Product is not selfigniting. |
| · Explosive properties: | Product does not present an explosion hazard. |
| · Solvent content: | |
| · Solids content: | 0.0 % |
| · Change in condition | |
| · Evaporation rate | Not determined. |

· Information with regard to physical hazard classes

- | | |
|--------------------------|------|
| · Explosives | Void |
| · Flammable gases | Void |
| · Aerosols | Void |
| · Oxidising gases | Void |

(Contd. on page 5)

Trade name: Zirkonium Cem

(Contd. of page 4)

· <i>Gases under pressure</i>	<i>Void</i>
· <i>Flammable liquids</i>	<i>Void</i>
· <i>Flammable solids</i>	<i>Void</i>
· <i>Self-reactive substances and mixtures</i>	<i>Void</i>
· <i>Pyrophoric liquids</i>	<i>Void</i>
· <i>Pyrophoric solids</i>	<i>Void</i>
· <i>Self-heating substances and mixtures</i>	<i>Void</i>
· <i>Substances and mixtures, which emit flammable gases in contact with water</i>	<i>Void</i>
· <i>Oxidising liquids</i>	<i>Void</i>
· <i>Oxidising solids</i>	<i>Void</i>
· <i>Organic peroxides</i>	<i>Void</i>
· <i>Corrosive to metals</i>	<i>Void</i>
· <i>Desensitised explosives</i>	<i>Void</i>

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** Exothermic polymerization
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:**
In presence of radical formers (e. g. peroxides), deoxidizing substances, and/or heavy metal ions, polymerization with heat release is possible.
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known

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 relevant for classification:**
 dibenzoyl peroxide: 78 % in water oral > 5000 mg/kg rat
 inhalation > 24,3 mg/l/4h rat
- N,N-Bis(2-hydroxyethyl)-p-toluidine LD-50 oral 300 mg/kg rat
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **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** 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***

131-57-7	oxybenzone
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List II

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.

(Contd. on page 6)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 12.02.2024

Version: 7

Revision: 12.02.2024

Trade name: Zirkonium Cem

(Contd. of page 5)

- **12.4 Mobility in soil** No further relevant information available.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties** For information on endocrine disrupting properties see section 11.
- **12.7 Other adverse effects**
- **Remark:** Toxic for fish
- **Additional ecological information:**
- **General notes:**
 Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water.
 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.
 Also poisonous for fish and plankton in water bodies.
 Toxic for aquatic organisms

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation** Must be specially treated adhering to official regulations.

- **European waste catalogue**

08 04 10	waste adhesives and sealants other than those mentioned in 08 04 09
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- **Uncleaned packaging:**
- **Recommendation:**
 Empty contaminated packagings thoroughly. They may be recycled after thorough and proper cleaning.
 Packagings that may not be cleansed are to be disposed of in the same manner as the product.
- **Recommended cleansing agents:** Ethyl acetate

SECTION 14: Transport information

- **14.1 UN number or ID number**
- **ADR, IMDG, IATA**

UN3082

- **14.2 UN proper shipping name**
- **ADR**

3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (di-urethane dimethacrylate, 2-[[[(butylamino)carbonyl]oxy]ethyl acrylate)

- **IMDG**

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (di-urethane dimethacrylate, 2-[[[(butylamino)carbonyl]oxy]ethyl acrylate), MARINE POLLUTANT

- **IATA**

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (di-urethane dimethacrylate, 2-[[[(butylamino)carbonyl]oxy]ethyl acrylate)

- **14.3 Transport hazard class(es)**

- **ADR**



- **Class**

9 (M6) Miscellaneous dangerous substances and articles.

(Contd. on page 7)

Safety data sheet
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Version: 7

Revision: 12.02.2024

Trade name: Zirkonium Cem

(Contd. of page 6)

· Label	9
· IMDG, IATA	
	
· Class	9 Miscellaneous dangerous substances and articles.
· Label	9
· 14.4 Packing group	
· ADR, IMDG, IATA	III
· 14.5 Environmental hazards:	
· Marine pollutant:	No
	Symbol (fish and tree)
· Special marking (ADR):	Symbol (fish and tree)
· Special marking (IATA):	Symbol (fish and tree)
· 14.6 Special precautions for user	Warning: Miscellaneous dangerous substances and articles.
· Hazard identification number (Kemler code):	90
· EMS Number:	F-A,S-F
· Stowage Category	A
· 14.7 Maritime transport in bulk according to IMO instruments	Not applicable.
· 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	(-)
· 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":	UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (DI-URETHANE DIMETHACRYLATE, 2-[[(BUTYLAMINO) CARBONYL] OXY]ETHYL ACRYLATE), 9, III

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 E2** Hazardous to the Aquatic Environment
- **Qualifying quantity (tonnes) for the application of lower-tier requirements** 200 t
- **Qualifying quantity (tonnes) for the application of upper-tier requirements** 500 t
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3

(Contd. on page 8)

IE

Safety data sheet

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(Contd. of page 7)

· **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.

· **REGULATION (EU) 2019/1148**

· **Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**

None of the ingredients is listed.

· **Annex II - REPORTABLE EXPLOSIVES PRECURSORS**

None of the ingredients is listed.

· **Regulation (EC) No 273/2004 on drug precursors**

None of the ingredients is listed.

· **Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**

None of the ingredients is listed.

· **National regulations**

· **Waterhazard class:** Water hazard class 2 (Self-assessment): hazardous for water.

· **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.

· **Relevant phrases**

H241 Heating may cause a fire or explosion.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H332 Harmful if inhaled.

H410 Very toxic to aquatic life with long lasting effects.

H411 Toxic to aquatic life with long lasting effects.

· **Department issuing SDS:** R&D, MANI MEDICAL GERMANY GmbH

· **Contact:** Fr. R.Naveenakumar

· **Date of previous version:** 07.11.2022

· **Abbreviations and acronyms:**

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

ICAO: International Civil Aviation Organisation

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)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Org. Perox. B: Organic peroxides – Type B

Acute Tox. 4: Acute toxicity – Category 4

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Skin Sens. 1: Skin sensitisation – Category 1

Skin Sens. 1A: Skin sensitisation – Category 1A

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

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2

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