

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 19.03.2024

Version: 5 (replaces version 4)

Revision: 19.03.2024

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

- **1.1 Product identifier**
- **Trade name:** Zirkon Primer
- **Article number:** 440039
- **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** Dental bonding material
- **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**
Flam. Liq. 2 H225 Highly flammable liquid and vapour.
 - **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
- **Signal word** Danger
 - **Hazard statements**
H225 Highly flammable liquid and vapour.
 - **Precautionary statements**

P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P240	Ground and bond container and receiving equipment.
P241	Use explosion-proof [electrical/ventilating/lighting] equipment.
P280	Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P501	Dispose of contents/container in accordance with local/regional/national/international regulations.
 - **Labelling of packages where the contents do not exceed 125 ml**
 - **Hazard pictograms**
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GHS02

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- **Signal word** *Danger*
- **Hazard statements** *Void*
- **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:** *Mixture of substances listed below with nonhazardous additions.*

- **Dangerous components:**

CAS: 64-17-5	ethanol	 Flam. Liq. 2, H225	75-100%
EINECS: 200-578-6			

- **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.*
- **After eye contact**
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- **After swallowing**
Rinse out mouth and then drink plenty of water.
If symptoms persist 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**
Water spray
Carbon dioxide
Fire-extinguishing powder
Foam
- **For safety reasons unsuitable extinguishing agents** *Water with full jet.*
- **5.2 Special hazards arising from the substance or mixture** *No further relevant information available.*
- **5.3 Advice for firefighters**
- **Protective equipment:** *No special measures required.*

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Do not inhale vapours.
Wear protective equipment. Keep unprotected persons away.
Keep away from ignition sources
- **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.
Ensure adequate ventilation.

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- **6.4 Reference to other sections**
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** No special precautions are necessary if used correctly.
- **Information about fire - and explosion protection:**
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 receptacles:** Storage between 10 °C and 25 °C.
- **Information about storage in one common storage facility:** Store away from foodstuffs.
- **Further information about storage conditions:**
Keep receptacle tightly sealed.
Store in cool, dry conditions in well sealed receptacles.
- **Storage class 3A**
- **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:**

64-17-5 ethanol

OEL (Ireland)	Short-term value: 1000 ppm
WEL (Great Britain)	Long-term value: 1920 mg/m ³ , 1000 ppm
PEL (USA)	Long-term value: 1900 mg/m ³ , 1000 ppm
REL (USA)	Long-term value: 1900 mg/m ³ , 1000 ppm
TLV (USA)	Short-term value: 1000 ppm
	A3

- **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** Wash hands before breaks and at the end of work.
- **Respiratory protection:** Not necessary if room is well-ventilated.
- **Hand protection** Protective gloves.
- **Material of gloves**
Butyl rubber, BR
Nitrile rubber, NBR
- **Penetration time of glove material**
0,3 mm
Penetration time 60 min.
0,11 mm
Penetration time 10 min.
- **Eye/face protection** Safety glasses

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SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Physical state	Fluid
· Colour:	Colourless
· Odour:	Alcohol-like
· Odour threshold:	Not determined.
· Melting point/freezing point:	-114.5 °C
· Boiling point or initial boiling point and boiling range	78 °C
· Flammability	Not applicable.
· Lower and upper explosion limit	
· Lower:	3.5 Vol %
· Upper:	15 Vol %
· Flash point:	13 °C
· Auto-ignition temperature:	425 °C
· Decomposition temperature:	Not determined.
· pH	Mixture is non-polar/aprotic.
· Viscosity:	
· Kinematic viscosity	Not determined.
· dynamic:	Not determined.
· Solubility	
· Water at 20 °C:	1 g/l
· Partition coefficient n-octanol/water (log value)	Not determined.
· Vapour pressure at 20 °C:	59 hPa
· Density and/or relative density	
· Density at 20 °C:	0.79 g/cm ³
· Relative density	Not determined.
· Vapour density	Not determined.

· 9.2 Other information

· Appearance:	
· Form:	Fluid
· Important information on protection of health and environment, and on safety.	
· Ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product is not explosive. However, formation of explosive air/vapour mixtures are possible.
· Change in condition	
· 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.
· Flammable solids	Void
· Self-reactive substances and mixtures	Void
· Pyrophoric liquids	Void
· Pyrophoric solids	Void
· Self-heating substances and mixtures	Void
· Substances and mixtures, which emit flammable gases in contact with water	Void
· Oxidising liquids	Void
· Oxidising solids	Void
· Organic peroxides	Void

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- | | |
|----------------------------------|------|
| · Corrosive to metals | Void |
| · Desensitised explosives | Void |

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** 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:** 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:**

Ethanol	LD-50 oral	10470 mg/kg rat	OECD 401
	LC-50 inhalativ	117 mg/l rat	OECD 402
- **Skin corrosion/irritation**
Drying out of skin possible
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** Based on available data, the classification criteria are not met.
- **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 |
|--|

None of the ingredients is listed.

SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **Other information:** The product is biodegradable.
- **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.
- **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:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water.

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

SECTION 13: Disposal considerations

· **13.1 Waste treatment methods**

· **Recommendation**

After prior treatment product has to be disposed of in an incinerator for hazardous waste adhering to the regulations pertaining to the disposal of particularly hazardous waste.

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

· **European waste catalogue**

07 01 04*	other organic solvents, washing liquids and mother liquors
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· **Uncleaned packaging:**

· **Recommendation:**

Empty contaminated packagings thoroughly. They may be recycled after thorough and proper cleaning.

· **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

SECTION 14: Transport information

· **14.1 UN number or ID number**

· **ADR, IMDG, IATA**

UN1170

· **14.2 UN proper shipping name**

· **ADR**

1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)

· **IMDG**

ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)

· **IATA**

ETHANOL SOLUTION

· **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

· **14.6 Special precautions for user**

Warning: Flammable liquids.

· **Hazard identification number (Kemler code):**

33

· **EMS Number:**

F-E,S-D

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· Stowage Category	<i>A</i>
· 14.7 Maritime transport in bulk according to IMO instruments	<i>Not applicable.</i>
· Transport/Additional information:	
· ADR	
· Limited quantities (LQ)	<i>1L</i>
· Excepted quantities (EQ)	<i>Code: E2</i>
	<i>Maximum net quantity per inner packaging: 30 ml</i>
	<i>Maximum net quantity per outer packaging: 500 ml</i>
· Transport category	<i>2</i>
· Tunnel restriction code	<i>D/E</i>
· IMDG	
· Limited quantities (LQ)	<i>1L</i>
· Excepted quantities (EQ)	<i>Code: E2</i>
	<i>Maximum net quantity per inner packaging: 30 ml</i>
	<i>Maximum net quantity per outer packaging: 500 ml</i>
· UN "Model Regulation":	<i>UN 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION), 3, II</i>

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.

· **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**

· **Technical instructions (air):**

Class	Share in %
NK	75-100

· **Waterhazard class:** *Water hazard class 1 (Self-assessment): slightly hazardous for water.*

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

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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**

H225 Highly flammable liquid and vapour.

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

· **Contact:** Fr. R.Naveenakumar

· **Date of previous version:** 07.11.2022

· **Version number of previous version:** 4

· **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

Flam. Liq. 2: Flammable liquids – Category 2

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

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