Safety Information Sheet for Medical Devices
following 1907/2006/EG, Article 31

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This product is a medical device as defined in Directive 93/42/EEC on medical devices (MDD) respectively Regulation (EU) 2017/745 (MDR), which is invasive or used in direct physical contact with the human body. For this product a safety data sheet is not legally required. The provision of this document is on a voluntary basis.

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

1.1 Product identifier
Trade name:
MetalBond 4M Plus

1.2 Relevant identified uses of the substance or mixture and uses advised against
Identified uses:
Dental product.

Restrictions on use:
This product should only be supplied or handled to dentists or dental technicians or upon their instructions.

1.3 Details of the supplier of the safety information sheet
Manufacturer/supplier:
S&C Polymer Silicon- und Composite Spezialitäten GmbH
Robert-Bosch-Strasse 2
25335 Elmshorn, Germany
info@sc-polymer.com

Australian Distributor:
Ultimate Dental Supply
660A South Rd, Moorabbin Vic 3189
03 9532 1799
info@ultimatedental.com.au

1.4 Emergency telephone number
+49 4121 483-0

Australian Emergency No.
13 11 26 - Poisons Hotline 24/7

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
Medical devices as defined in Directive 93/42/EEC on medical devices (MDD) respectively Regulation (EU) 2017/245, which are invasive or used in direct physical contact with the human body are exempt from labeling requirements of Regulation (EC) No. 1272/2008 (CLP/GHS). Although not required, classification and labeling are indicated as follows:

Classification:
Flammable liquid, Category 2, H225 Highly flammable liquid and vapour
Skin irritation, Category 2; H315 Causes skin irritation.
Skin Sensitization, Category 1; H317 May cause allergic skin reaction.
Specific target organ toxicity – single exposure (STOT SE), Category 3; H335 May cause respiratory irritation.

2.2 Label elements
CLP Regulation (EC) No. 1272/2008

Signal word:
Danger.

Hazard pictograms:


GHS02


GHS07

Hazard statements:

H225	Highly flammable liquid and vapour
H315	Causes skin irritation.
H317	May cause allergic skin reaction.
H335	May cause respiratory irritation.

Precautionary statements:

P280	Wear protective gloves/protective clothing/eye protection/face protection.
P302 + P352	IF ON SKIN: Wash with plenty of soap and water.

2.3 Other hazards
Results of PBT and vPvB assessment:

PBT:	not applicable.
vPvB:	not applicable.

SECTION 3: Composition/information on ingredients

3.1 Substances
Not applicable.

3.2 Mixtures
Chemical characterization (description):
Methacrylates, 4-Meta and initiators.

Hazardous components:

CAS-No. 80-62-6	Methyl methacrylate	GHS02, GHS07, H225, H315, H317, H335

SECTION 4: First aid measures

4.1 Description of first aid measures
General information:
Seek medical advice, if symptoms occur, which can be caused by the product.

after skin contact:
Wash with plenty of water and soap.

after inhalation:
Fresh air.

after eye contact:
Rinse with plenty of water and consult a doctor.

after swallowing:
If symptoms persist consult a doctor.

SECTION 5: Firefighting measures

5.1 Extinguishing media
Extinguishing media:
CO_2, extinguishing powder, water spray. Use extinguishing method and media suitable to surrounding fire.

5.2 Special hazards arising from the substance or mixture
No further relevant information available.

Protective equipment:
Wear self-contained respiratory protective equipment.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures
Personal precautions:
Do not inhale vapours/aerosols. Avoid substance contact. Ensure supply of fresh air in enclosed rooms.

6.2 Environmental precautions
Do not allow to enter drains/surface water/ ground-water.

6.3 Methods and material for containment and cleaning up
Absorb with liquid binding material. Clean up affected area. Ensure fresh air.

6.4 Reference to other sections
See Section 7: Handling and storage
See Section 8: Exposure controls/personal protection
See Section 13: Disposal considerations

SECTION 7: Handling and storage

7.1 Precautions for safe handling
Handling:
This product should only be supplied or handled to dentists or dental technicians or upon their instructions.

Information for safe handling:
Observe normal care for working with chemicals.

Information about fire and explosion protection:
Keep away from sources of ignition.

7.2 Conditions for safe storage, including any incompatibilities
Storage:
Store at a dry place. Store tightly closed. Storage temperature < 25°C.

Requirements at storerooms and containers:
Store only in the original containers.

Information about storage in one common storage facility:
Store away from food stuffs.

Further information on storage conditions:
None.

Storage class:
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7.3 Specific end use(s)
No further relevant information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters
Additional information on the design of technical systems:
-

Components with limits of values to be supervised at the workplace:

CAS-No.	name	art		value	unit
80-62-6	Methyl methacrylate	TRGS 900		210	mg/m3
			or	50	ml/m3

Additional information:
The lists valid during the making were used as basis.

8.2 Exposure controls
Personal protective equipment:
General protective and hygienic measures:
Normal hygienic measures. The usual precautionary measures are to be adhered to when handling chemicals. Keep away from foodstuffs and beverages. Avoid contact with eyes or skin.

Respiratory protection:
Required, when aerosols are generated.

Hand protection:
Protective gloves. Due to missing tests no recommendation to the glove material can be given for the product.

Eye protection:
Safety glasses.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties
Appearance:

Form:	liquid
Color:	colorless
Odor:	characteristic

Change in condition:

Melting point/melting range:	not applicable

Boiling point/boiling range:	100 °C	
Flash point:	10 °C	
Ignition temperature:	no information available	
Danger of explosion:	lower limit of explosion:	1.7 Vol %
	upper limit of explosion:	12.5 Vol %
Density:	~ 0.95 (20°C) g/cm^3	
Vapor pressure:	not determined	
Solubility in/miscibility with:		
Water:	slightly soluble	
Content of solvents:		
Organic solvents:	none	

SECTION 10: Stability and reactivity

10.1 Reactivity
Expected to be non-reactive under normal conditions of use.

10.2 Chemical stability
The product is stable by proper use and storage.

10.4 Conditions to avoid
Heat, sunlight, peroxides, radical initiators.

10.6 Hazardous decomposition products
No information available.

SECTION 11: Toxicological information

11.1 Information on toxicological effects
Acute toxicity:
LD50 (oral,rat) 7870 mg/kg.
LD50 (dermal, rabbit) > 5000 mg/kg.

Primary irritation:
Skin: irritant.

Eye: irritant.

Sensitization: sensitization by skin contact possible.

Additional toxicological information:
Allergic reactions to the product after long-term exposure are possible. When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

SECTION 12: Ecological information

General information:
Avoid transfer into environment.

Classification hazardous to water:
Water hazard class 1 (self-classification): slightly hazardous to water.

SECTION 13: Disposal considerations

13.1 Waste treatment methods
Recommendation:
Use proper landfill disposal or incineration in accordance with local, state and federal regulations.

Uncleaned packaging:
Recommendation:
Disposal must be made according to official regulations.

SECTION 14: Transport information

Land transport ADR/RID and GGVSE (Germany):
UN 1247 METHYLMETHACRYLAT, MONOMER, STABILISIERT, GEMISCH, 3,II.

Sea transport IMDG Code:
UN 1247 METHYL METHACRYLATE, MONOMER, STABILIZED, MIXTURE, 3, II
EmS: F-E S-D.

Air transport ICAO-TI and IATA-DGR:
UN 1247 METHYL METHACRYLATE, MONOMER, STABILIZED, MIXTURE, 3, II..

The transport regulations are cited according to international regulations and in the form applicable in Germany. Possible national deviations in other countries are not considered.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
National regulations:
Water hazard class 1 (self-classification): slightly hazardous to water.

15.2 Chemical safety assessment
A chemical safety assessment has not been carried out.

SECTION 16: Other information

For invasive medical devices or medical devices in direct contact with the human body, the Medical Device Regulation does not require a safety data sheet. The safe use of the product is indicated in the instructions for use and/or the labeling.

The above information is based on our present day knowledge and relates solely to the safety requirements of the product. The data do not signify any warranty with regards to products properties.
Users of the product should satisfy themselves that the information given is sufficient and correct for their specific circumstances of use.