

Safety data sheet according to Regulation (EC) No 1907/2006, Article 31

Printing date 10.07.2024

Version number 5





Revision: 10.07.2024

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

- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
- **Product identifier**
- **Trade name: M+W Sioplast C Pastenhärter DBTL-frei**
- **Application of the substance / the mixture** Hardener for impression material, medical device.
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**

Manufacturer: Müller-Omicron GmbH & Co. KG Schlosserstr. 1 D-51789 Lindlar www.mueller-omicron.com	Exclusive distribution: M&W Dental Müller & Weygandt GmbH Reichardsweide 40 D - 63654 Büdingen Phone: +49 (0) 6042/8800-88 Fax: +49 (0) 800/88008001 www.mwdental.de
---	---
- **Further information obtainable from:**
Product safety department
sds@mueller-omicron.de
- **1.4 Emergency telephone number:**
Emergency CONTACT (24-Hour-Number): GBK GmbH +49 (0)6132-84463

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
 -  **GHS08 health hazard**
STOT RE 2 H373 May cause damage to the blood through prolonged or repeated exposure.
Route of exposure: Oral.
 -  **GHS07**
Skin Irrit. 2 H315 Causes skin irritation.
Skin Sens. 1 H317 May cause an allergic skin reaction.
 - 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**
 -  
GHS07 GHS08
- **Signal word** Warning
- **Hazard-determining components of labelling:**
Diocetylzinnbisacetylacetonate (CAS 54068-28-9)
Tetrakis(2-butoxyethoxy)silane (CAS 18765-38-3)

(Contd. on page 2)

EU

Safety data sheet

according to Regulation (EC) No 1907/2006, Article 31

Printing date 10.07.2024

Version number 5

Revision: 10.07.2024

Trade name: M+W Sioplast C Pastenhärter DBTL-frei

(Contd. of page 1)

Aroma mixture

- Hazard statements

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H373 May cause damage to the blood through prolonged or repeated exposure. Route of exposure: Oral.

H412 Harmful to aquatic life with long lasting effects.

- Precautionary statements

P101 If medical advice is needed, have product container or label at hand.

P102 Keep out of reach of children.

P103 Read carefully and follow all instructions.

P260 Do not breathe 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.

- Additional information: Restricted to professional users**- 2.3 Other hazards****- Results of PBT and vPvB assessment**

This substance/mixture does not contain components classified as either persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

- PBT: Not applicable.**- vPvB:** Not applicable.**- Determination of endocrine-disrupting properties**

Endocrine disrupting properties - human health: The substance/mixture does not contain any components that exhibit endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated Regulation (EU) 2017/2100 or Commission Delegated Regulation (EU) 2018/605 in quantities of 0.1% or more.

Endocrine disrupting properties - Environment: The substance/mixture does not contain any components that exhibit endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated Regulation (EU) 2017/2100 or Commission Delegated Regulation (EU) 2018/605 in quantities of 0.1% or more.

SECTION 3: Composition/information on ingredients

- 3.2 Mixtures**- Description:** Mixture of substances listed below with nonhazardous additions.**- Dangerous components:**

	Tetrakis(2-butoxyethoxy)silane (CAS 18765-38-3)	10-25%
	☠ STOT RE 2, H373; ⚠ Skin Irrit. 2, H315	
	Diocetylzindineodecanoat (CAS: 68299-15-0)	≥2.5-<10%
	☠ STOT SE 2, H371	
	Diocetylzinnbisacetylacetonate (CAS 54068-28-9)	≥2.5-<10%
	☠ STOT SE 2, H371; ⚠ Skin Sens. 1, H317	
CAS: 111-76-2 EINECS: 203-905-0 Index number: 603-014-00-0	2-butoxyethanol	0.1-1%
	☠ Acute Tox. 3, H311; Acute Tox. 3, H331; ⚠ Acute Tox. 4, H302; ⚠ Skin Irrit. 2, H315; ⚠ Eye Irrit. 2, H319 ATE: LD50 oral: 1,200 mg/kg LC50/4 h inhalative: 3 mg/l	
	Aroma mixture	≥0.25-<1%
	☠ Flam. Liq. 3, H226; ☠ Asp. Tox. 1, H304; ⚠ Aquatic Acute 1, H400; ⚠ Aquatic Chronic 1, H410; ⚠ Skin Irrit. 2, H315; ⚠ Eye Irrit. 2, H319; ⚠ Skin Sens. 1, H317	

(Contd. on page 3)

Safety data sheet

according to Regulation (EC) No 1907/2006, Article 31

Printing date 10.07.2024

Version number 5

Revision: 10.07.2024

Trade name: M+W Sioplast C Pastenhärter DBTL-frei

(Contd. of page 2)

- **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

- General information:

Immediately remove any clothing soiled by the product.

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

- After inhalation:

Supply fresh air and to be sure call for a doctor.

In case of unconsciousness place patient stably in side position for transportation.

- After skin contact: Immediately wash with water and soap and rinse thoroughly.

- After eye contact: Rinse opened eye for several minutes under running water.

- After swallowing: 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:

CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

- 5.2 Special hazards arising from the substance or mixture

During heating or in case of fire poisonous gases are produced.

- 5.3 Advice for firefighters

- Protective equipment: Mouth respiratory protective device.

SECTION 6: Accidental release measures

- 6.1 Personal precautions, protective equipment and emergency procedures

Mount respiratory protective device.

- 6.2 Environmental precautions:

Do not allow product to reach sewage system or any water course.

Inform respective authorities in case of seepage into water course or sewage system.

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.

- 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

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

- Information about fire - and explosion protection: Keep respiratory protective device available.

(Contd. on page 4)

Safety data sheet

according to Regulation (EC) No 1907/2006, Article 31

Printing date 10.07.2024

Version number 5

Revision: 10.07.2024

Trade name: M+W Sioplast C Pastenhärter DBTL-frei

(Contd. of page 3)

- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **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:**

111-76-2 2-butoxyethanol

IOELV	Short-term value: 246 mg/m ³ , 50 ppm
	Long-term value: 98 mg/m ³ , 20 ppm
	Skin

- **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:**

Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of work.
Store protective clothing separately.
Avoid contact with the skin.
Avoid contact with the eyes and skin.

- **Respiratory protection:**

In case of intensive or longer exposure use self-contained respiratory protective device.

- **Hand protection**



Protective gloves

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

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

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

- **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.

- **Eye/face protection**



Tightly sealed goggles

EU

(Contd. on page 5)

Safety data sheet

according to Regulation (EC) No 1907/2006, Article 31

Printing date 10.07.2024

Version number 5

Revision: 10.07.2024

Trade name: M+W Sioplast C Pastenhärter DBTL-frei

(Contd. of page 4)

SECTION 9: Physical and chemical properties

- 9.1 Information on basic physical and chemical properties

- General Information

- Physical state	Fluid
- Colour:	According to product specification
- Odour:	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:	>70 °C
- Auto-ignition temperature:	Not determined.
- Decomposition temperature:	Not determined.
- pH	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 at 20 °C:	0.1 hPa
- Density and/or relative density	
- Density:	Not determined.
- Relative density	Not determined.
- Vapour density	Not determined.

- 9.2 Other information

- Appearance:	
- Form:	Pasty
- 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:	
- Organic solvents:	<0.7 %
- VOC (EC)	<0.75 %
- Solids content:	91.6 %
- 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	Void
- Flammable solids	Void
- Self-reactive substances and mixtures	Void
- Pyrophoric liquids	Void
- Pyrophoric solids	Void

(Contd. on page 6)

Safety data sheet

according to Regulation (EC) No 1907/2006, Article 31

Printing date 10.07.2024

Version number 5

Revision: 10.07.2024

Trade name: M+W Sioplast C Pastenhärter DBTL-frei

(Contd. of page 5)

- 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
- 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:

Vaseline

Oral	LD50	>5,000 mg/kg (rat)
Dermal	LD50	>2,000 mg/kg (rabbit)

- **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** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure**
May cause damage to the blood through prolonged or repeated exposure. Route of exposure: Oral.
- **Aspiration hazard** Based on available data, the classification criteria are not met.
- **11.2 Information on other hazards**
- **Endocrine disrupting properties**
Endocrine disrupting properties - human health: The substance/mixture does not contain any components that exhibit endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated Regulation (EU) 2017/2100 or Commission Delegated Regulation (EU) 2018/605 in quantities of 0.1% or more.

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.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.

(Contd. on page 7)

Safety data sheet

according to Regulation (EC) No 1907/2006, Article 31

Printing date 10.07.2024

Version number 5

Revision: 10.07.2024

Trade name: M+W Sioplast C Pastenhärter DBTL-frei

(Contd. of page 6)

- 12.5 Results of PBT and vPvB assessment

This substance/mixture does not contain components classified as either persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

- **PBT:** Not applicable.

- **vPvB:** Not applicable.

- 12.6 Endocrine disrupting properties

Endocrine disrupting properties - Environment: The substance/mixture does not contain any components that exhibit endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated Regulation (EU) 2017/2100 or Commission Delegated Regulation (EU) 2018/605 in quantities of 0.1% or more.

- 12.7 Other adverse effects

- **Remark:** Harmful to fish

- **Additional ecological information:**

- **General notes:**

Harmful to aquatic organisms

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.

SECTION 13: Disposal considerations

- 13.1 Waste treatment methods

- **Recommendation**

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

- **Uncleaned packaging:**

- **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

- **14.1 UN number or ID number**

- **ADR, IMDG, IATA**

Void

- **14.2 UN proper shipping name**

- **ADR, IMDG, IATA**

Void

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

- **ADR, ADN, IMDG, IATA**

- **Class**

Void

- **14.4 Packing group**

- **ADR, IMDG, IATA**

Void

- **14.5 Environmental hazards:**

Not applicable.

- **14.6 Special precautions for user**

Not applicable.

- **14.7 Maritime transport in bulk according to IMO instruments**

Not applicable.

- **UN "Model Regulation":**

Void

EU

(Contd. on page 8)

Safety data sheet

according to Regulation (EC) No 1907/2006, Article 31

Printing date 10.07.2024

Version number 5

Revision: 10.07.2024

Trade name: M+W Sioplast C Pastenhärter DBTL-frei

(Contd. of page 7)

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.

- **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.

- **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**

H226 Flammable liquid and vapour.

H302 Harmful if swallowed.

H304 May be fatal if swallowed and enters airways.

H311 Toxic in contact with skin.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H331 Toxic if inhaled.

H371 May cause damage to organs.

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

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

- **Contact:** sds@mueller-omicron.de

- **Date of previous version:** 12.05.2021

- **Abbreviations and acronyms:**

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)

VOC: Volatile Organic Compounds (USA, EU)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

ATE: Acute toxicity estimate values

(Contd. on page 9)

Safety data sheet

according to Regulation (EC) No 1907/2006, Article 31

Printing date 10.07.2024

Version number 5

Revision: 10.07.2024

Trade name: M+W Sioplast C Pastenhärter DBTL-frei

(Contd. of page 8)

*Flam. Liq. 3: Flammable liquids – Category 3**Acute Tox. 4: Acute toxicity – Category 4**Acute Tox. 3: Acute toxicity – Category 3**Skin Irrit. 2: Skin corrosion/irritation – Category 2**Eye Irrit. 2: Serious eye damage/eye irritation – Category 2**Skin Sens. 1: Skin sensitisation – Category 1**STOT SE 2: Specific target organ toxicity (single exposure) – Category 2**STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2**Asp. Tox. 1: Aspiration hazard – Category 1**Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1**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***- Sources**

The data for the hazardous ingredients were taken respectively from the last version of Safety Data Sheets of suppliers.

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

EU