

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 31.10.2018

Version: 7

Revision: 31.10.2018

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

- **1.1 Product identifier**
- **Trade name:** *Ena Bond Seal (Rev.1)*
- **Article number:** *COSZ10, COSZ10-2*
- **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 sealing material*
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Micerium spa., Via G. Marconi, 83 - 16036 Avegno (GE), Italy, Tel.: +39-0185-7887870, Fax: +39-0185-7887970
- **Further information obtainable from:** *Dr. Eugenio Miceli*
- **1.4 Emergency telephone number:**
Poison Control Center San Martino Hospital (Genoa, Italy) Tel.: +39-010-352808 (available 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.

- **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

- **Signal word** *Warning*
- **Hazard-determining components of labelling:**
tetramethylene dimethacrylate
diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide
- **Hazard statements**
H317 May cause an allergic skin reaction.
- **Precautionary statements**
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P280 Wear protective gloves.
P362+P364 Take off contaminated clothing and wash it before reuse.
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.
- **Labelling of packages where the contents do not exceed 125 ml**
- **Hazard pictograms**



GHS07

- **Signal word** *Warning*
- **Hazard-determining components of labelling:**
tetramethylene dimethacrylate
diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide

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- **Hazard statements**
H317 May cause an allergic skin reaction.
- **Precautionary statements**
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P280 Wear protective gloves.
P362+P364 Take off contaminated clothing and wash it before reuse.
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 Chemical characterisation: Mixtures**
- **Description:** Liquid based on methacryl acid ester, containing an activator.

· **Dangerous components:**

CAS: 2082-81-7 EINECS: 218-218-1	tetramethylene dimethacrylate ⚠ Skin Sens. 1B, H317	25-50%
CAS: 75980-60-8 EINECS: 278-355-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide ⚠ Repr. 2, H361f; ⚠ Aquatic Chronic 2, H411; ⚠ Skin Sens. 1B, H317	<2.5%
CAS: 25973-55-1	2-(2H-benzotriazol-2-yl)-4,6-di-tert-pentylphenol ⚠ Acute Tox. 4, H302; ⚠ Aquatic Chronic 4, H413	<2.5%

· **SVHC**

25973-55-1	2-(2H-benzotriazol-2-yl)-4,6-di-tert-pentylphenol
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- **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 and to be sure call for a doctor.
In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact**
If skin irritation continues, consult a doctor.
Immediately wash with water and soap and rinse thoroughly.
- **After eye contact** Rinse opened eye for several minutes under running water.
- **After swallowing**
Rinse out mouth and then drink plenty of water.
Seek medical treatment.
- **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.
- **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.

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- **5.3 Advice for firefighters**
- **Protective equipment:** *Wear self-contained respiratory protective device.*

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** *Not required.*
- **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).
- **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:** *No special measures required.*
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage**
- **Requirements to be met by storerooms and receptacles:**
Close container immediately after use and protect product from light incidence.
Storage between 10 °C and 25 °C.
- **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

- **Additional information about design of technical facilities:** *No further data; see item 7.*
- **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**
- **Personal protective equipment**
- **General protective and hygienic measures**
Do not inhale gases / fumes / aerosols.
Avoid contact with the skin.
Immediately remove all soiled and contaminated clothing
- **Respiratory protection:** *Not necessary if room is well-ventilated.*
- **Protection of hands:** *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 protection:** *Safety glasses*

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- **Body protection:**
Protective work clothing.
(Only when handling large quantities)

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Appearance:

· Form:	Fluid
· Colour:	Light yellow
· Odour:	Ester-like
· Odour threshold:	Not determined.

· **pH-value:** Not determined.

· Change in condition

· Melting point/freezing point:	undetermined
· Initial boiling point and boiling range:	251 °C

· **Flash point:** 113 °C

· **Flammability (solid, gaseous)** Not applicable.

· **Decomposition temperature:** Not determined.

· **Auto-ignition temperature:** Product is not selfigniting.

· **Explosive properties:** Product does not present an explosion hazard.

· Explosion limits:

· Lower:	Not determined.
· Upper:	Not determined.

· **Vapour pressure:** Not determined.

· **Density:** Not determined

· **Relative density** Not determined.

· **Vapour density** Not determined.

· **Evaporation rate** Not determined.

· Solubility in / Miscibility with

· **Water:** Not miscible or difficult to mix

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

· Viscosity:

· **dynamic:** Not determined.

· **kinematic:** Not determined.

· Solvent content:

· **Solids content:** 0.0 %

· **9.2 Other information** No further relevant information available.

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.

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- **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 toxicological effects**
- **Acute toxicity** *Based on available data, the classification criteria are not met.*
- **LD/LC50 values relevant for classification:**
tetramethylene dimethacrylate LD-50 oral > 5000 mg/kg (rat)
- **Primary irritant effect:**
- **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.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **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.*

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

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.
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.*
 - **European waste catalogue**
- | | |
|-----------|---|
| 07 01 04* | <i>other organic solvents, washing liquids and mother liquors</i> |
|-----------|---|

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

SECTION 14: Transport information

- **14.1 UN-Number**
· **ADR, ADN, IMDG, IATA** Void
- **14.2 UN proper shipping name**
· **ADR, ADN, 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:**
· **Marine pollutant:** No
- **14.6 Special precautions for user** Not applicable.
- **14.7 Transport in bulk according to Annex II of Marpol and the IBC Code** Not applicable.
- **UN "Model Regulation":** Void

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
- **National regulations**
- **Technical instructions (air):**

Class	Share in %
III	25-50

- **Waterhazard class:** Water hazard class 2 (Self-assessment): hazardous for water.
- **Other regulations, limitations and prohibitive regulations**

- **Substances of very high concern (SVHC) according to REACH, Article 57**

25973-55-1	2-(2H-benzotriazol-2-yl)-4,6-di-tert-pentylphenol
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- **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**
- H302 Harmful if swallowed.
- H317 May cause an allergic skin reaction.
- H361f Suspected of damaging fertility.
- H411 Toxic to aquatic life with long lasting effects.

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H413 May cause long lasting harmful effects to aquatic life.

· **Department issuing SDS:** Micerium S.p.a.

· **Contact:** Dr. Eugenio Miceli

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport 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

SVHC: Substances of Very High Concern

vPvB: very Persistent and very Bioaccumulative

Acute Tox. 4: Acute toxicity – Category 4

Skin Sens. 1: Skin sensitisation – Category 1

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

Repr. 2: Reproductive toxicity – Category 2

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

Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4

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

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