

SECTION 1. Product identification/preparation/company undertaking

1.1 Product identifier:

Trade name: BISICO Bisi-tray (various packaging sizes)

Trade number: 03290, 03250

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

Application of the substance / the mixture:

Light curing tray material

Intendes purpose:

Making of individual impression- and functional trays

Occlusal registration

Precized impression for part- or totalprosthetics

Disadvised uses:

Impressions

Prosthesis Plastic

Filling Material

1.3. Details of the supplier of the safety data sheet:

BISICO Bielefelder Dentsilicone GmbH & Co. KG

Johanneswerkstraße 3

D-33611 Bielefeld

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Fax: +49 521 8016801

Email: info@Bisico.de

responsible for the Safety Data Sheet: Sebastian Zimmermann

1.4. Emergency telephone number:

BISICO Bielefelder Dentsilicone GmbH & Co. KG

Tel.: +49 521 8016800 (08:00-16:00 PM)

Fax: +49 521 8016801

S. Zimmermann

SECTION 2. Hazards identification

2.1 Classification of the substance or mixture:

2.1.1 Classification according to Regulation (EC) No 1272/2008:

Skin sens. 1 (may cause allergical reactions)

Safety Data Sheet according to 1907/2006/EC, Article 31



2.2 Label elements:

Labelling according to Regulation (EC) No 1272/2008:

Hazard pictograms:



Signal word:

Warning

H317 may cause skin irritations P272 Contaminated work clothing should not wear outside the workplace

P280 Wear protective gloves/protective clothing/

eye protection/

face protection

P302 In contact with skin:

P352 Flush with plenty of water and soap

P333 When skin irritation or rash occurs:

P313 Seek medical advice resp. medical attendance

P362 Take off contaminated clothing and wash before wearing again

P364 wash before wearing again

P501 Ingredients/container have to be disposed in accordance with local/regional/national/international regulations

2.3 Other hazards:

Can become warm during light curing process

Do not use if known allergy against Acrylates and Methacrylates

SECTION 3. Composition/Information of Ingredients

3.1 Substances:

3.2 Mixtures:

Chemical characterization:

Hazardous ingredients:

| Ingredients | CAS-No./ EINECS-No./ EG-No. | Percentage (%) | Identification |
|---------------------------------|---|----------------|--|
| Triethylenglykoldi-methacrylate | CAS-No. 109-16-0 EINECS-No.203-652-6 | 2-5 | Skin Sens. 1B H317 Skin sensitisation |
| Phosphine oxide | CAS-No. 75980-60-8 EG-No. 278-355-8 | 0,05 – 0,1 | Repr 2 H361f suspected human carcinogen; probably harmful to fertility, probably damaging effect on the unborn child Aqu. Chron. 3, H412 hazardous to the aquatic environment, chronic |
| Vinylester Resin | CAS Nr. 55818-57-0 | 5-8 | Skin Sens. 1B H317 Skin sensitisation |

Additional information:

For the wording of the listed risk phrases refer to section 16.

SECTION 4. First-aid measures

4.1 Description of first aid measures:

If inhaled:

Take person to fresh air.

No further first aid measures are required.

In case of skin contact:

Wash off skin with soap and water and flush with plenty of Water.

Contact a physician if the skin is irritated.

In case of eye contact:

Rinse open eyes an efficient time with plenty of Water.

Contact ophthalmologist if irritation is persisting.

If swallowed:

Seek medical advice immediately.

4.2 Most important symptoms and effects, both acute and delayed:

Sensitization of skin is possible

4.3 Indication of any immediate medical attention and special treatment needed:

Contact physician if sensitization of skin is persisting

SECTION 5. Fire fighting measures

5.1 Extinguishing media:

Suitable extinguishing media:

Foam, Dry powder, carbon dioxide, waterspray-stream.

Adjust fire-fighting-measures to ambiance.

For safety reasons unsuitable extinguishing media: none

5.2 Special hazards arising from the substance or mixture:

Particular danger through the product itself, its combustion products or gases are not known

5.3 Advice for firefighters:

Use conventional measures to combat chemical fires, that means use self-contained breathing apparatus (isolating-unit).

SECTION 6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures:

Arrange for fresh air.

6.2 Environmental precautions:

Do not drain into canalization.

6.3 Methods for cleaning up:

Pick up material mechanically. Dispose only complete light cured material. Dispose material under adherence to the local official rules for hazardous wastes.

6.4 Reference to other sections:

None

SECTION 7. Handling and storage

7.1 Precautions for safe handling:

Recommendation:

The conventional precautions for works with chemicals are to be adhered.
Wear overall while working.

Information about fire - and explosion protection:

No special measures necessary.

7.2 Conditions for safe storage, including any incompatibilities:

Store at a cool, dry and light protected place.
Storage time: 3 years if storage conditions will be kept

7.3 Specific end use(s):

Wear gloves while working. Good ventilation during grinding the cured material is recommended

SECTION 8. Exposure controls/personal protection

8.1. Control parameters:

None known
PNCE and DNCL-Values as to be possibly worked out in a preparation safety report do not exist.

8.2 Exposure controls:

Personal protective equipment:
Pay attention of protection- and hygienic measures. Protection clothes must be stored separately. The usual precaution measures must be attended.

| | |
|----------------------------|---|
| Breathing protection: | not necessary |
| Eye protection: | Wear protection goggles when working at material |
| Hand protection: | Sensibilisation: Wearing of applicable protection gloves is recommended. (by experience of the past/literature) for example Ethiparat®-gloves for 5- 10 minutes, application of No-touch-Technik, minimal-contact-techniques is recommended |
| Body protection: | Wear business usual protection clothes. |
| Other protection measures: | none |

Advices for hygienic at work station:
Comply business usual protection- and hygienic measures.
Preventive skin protection. Wash hands and skin after finishing work.

SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties:

All Information are for the Acrylate Resin, except point the appearance

Appearance:

Form: upper jaw and lower jaw pattern, kneadable mass

Color: pink, blue

| | |
|--|--|
| Odour: | acrylates / methacrylates |
| | <u>Value</u> <u>Unit</u> <u>Method</u> |
| pH-value: | no data available |
| Change in condition | |
| Melting point/Melting range: | no data available |
| Boiling point/Boiling range: | no data available |
| Flash point: | not available (approx. > 100°C) appreciated by the flash point of the ingredients |
| Flammability (solid, gaseous): | no data available |
| Ignition temperature: | no data available |
| Decomposition temperature: | no data available |
| Self-igniting: | no data available |
| Danger of explosion: | no data available |
| Explosion limits: | no data available |
| Vapour pressure at 20 °C: | no data available |
| Density at 20 °C: | no data available |
| Relative density: | no data available |
| Vapour density: | no data available |
| Evaporation rate: | no data available |
| Solubility in / Miscibility with Water: | insoluble in water |

9.2 Other information
no data available

SECTION 10. Stability and reactivity

10.1. Reactivity:
Product polymerizes slowly by contact with Sunlight or other Light

10.2. Chemical stability:
If protected against heat, solar radiation and light the material is chemical stable.

10.3 Possibility of hazardous reactions:
No hazardous heat emission during slow polymerizing

10.4 Conditions to avoid:
Protect against Sunlight, heat and other light to avoid slowly polymerization.

10.5 Incompatible materials:

Protect against radical formers to avoid slowly polymerization

10.6 Hazardous decomposition products:

None, if used according to directions.

After considerably exceedance of storage time and / or exceedance of storage temperature it is possible that the product starts polymerizing under low heat impact.

SECTION 11. Toxicological information

11.1. Information on toxicological effects:

Acute toxicity:

According to the single ingredients the mixture is not acute toxic

Skin corrosion/irritation:

No irritation to skin

Serious eye damage/eye irritation:

No irritation to eyes

Respiratory or skin irritation:

No irritation to Respiratory or skin

Skin sensitization:

Skin sensitization possible according to the ingredients

Toxicity – repeated exposure:

No toxicity known after repeated exposure

Germ cell mutagenicity

Carcinogenicity:

No carcinogenicity according to the ingredients

Mutagenicity:

No mutagenicity according to the ingredients

Reproductive toxicity:

No reproductive toxicity according to the concentration of the single components.

Kinetic of the toxic reaction:

According the new Material Safety Data Sheet according to REACH, specifications about kinetic of the toxic reaction, metabolism of the substance and allocation of the substance in the human body must be mentioned at this place. Data for this is not available .

Further Information:

By appropriate exposure and conventionally use and to our experiences and informations the product causes no hazardous effects.

The product has to handled with the usual care when handling chemicals.

Methacrylates may cause allergical reactions.

SECTION 12. Ecological information

12.1 Toxicity:

Fish toxicity: no data available for this mixture
Water organism: no data available
Bacteria toxicity: no data available

12.2 Persistence and degradability:

The ingredients of the mixture are not degradable

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 1 (German Regulation) (Self-assessment):
slightly hazardous for water.

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

12.5 Results of PBT and vPvB assessment:

If the material causes hormonal effects or prevents them is unknown to us.

12.6 Other adverse effects:

No further relevant information available.

SECTION 13. Disposal consideration

13.1. Waste treatment methods:

To dispose of accordingly with notice of the local regulations of authority.
Do not empty into drains.

Disposal key according to AVV regulation:

16 03 05 (organic disposal, that contains hazardous substances)

Package:

Packages that are not contaminated can be recycled.

SECTION 14. Transport information

14.1 UN-Number

ADR, IMDG, IATA: none

14.2 UN proper shipping name

None

14.3 Transport hazard class(es)

None

14.4 Packing group

ADR, IMDG, IATA:

None

14.5 Environmental hazards:

Marine pollutant:

none

14.6 Special precautions for user:

None

14.7 Transport in bulk according to Annex II of

Marpol and the IBC Code:

No

SECTION 15. Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture:

GHS-Labeling according to guideline 1272/2008 (GHS/CL):



Signal word: Warning

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15.2 Chemical safety assessment:

Safety Assessments for substances in this preparation were not executed

SECTION 16. Other information:

Changes compared with the previous version: 1.1 Product identifier

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. However users of the product should satisfy themselves that the information given is sufficient and correct for their specific circumstances of use.

Manufacturer's suggested application restriction:

Only for commercial use – no public product

H-phrases on which is referred in chapter 2 and 3:

H317 May cause an allergic skin reaction

Preparation by:

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