

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

1.1 Product identifier:

Trade name: BISICO Bulk-Fill (various packaging sizes)
Trade number: 75052, 75053, 75054, 75055

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 filling material

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:

BISICO Bielefelder Dentalsilicone GmbH & Co. KG

Johanneswerkstraße 3

D-33611 Bielefeld

Tel.: +49 521 8016800

Fax: +49 521 8016801

Email: info@Bisico.de

responsible for the Safety Data Sheet: Sebastian Zimmermann

Further information obtainable from:

BISICO Bielefelder Dentalsilicone GmbH & Co. KG

Tel.: +49 521 8016800 (08:00-17:00Uhr)

1.4. Emergency telephone number:

BISICO Bielefelder Dentalsilicone GmbH & Co. KG

Tel.: +49 521 8016800 (08:00-17:00 PM)

Fax: +49 521 8016801

M. Wassmann

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

Hazard statements

H317 May cause an allergic skin reaction.

Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P321 Specific treatment (see on this label).

P363 Wash contaminated clothing before reuse.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

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

Hazard statements

H317 May cause an allergic skin reaction.

Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P321 Specific treatment (see on this label).

P363 Wash contaminated clothing before reuse.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

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:

Urethandimethacrylate

1,4-Butandioldimethacrylate

Dangerous components:

CAS: 2082-81-7 EINECS: 218-218-1	tetramethylene dimethacrylate	 Skin Sens. 1B, H317	2,5-10%
-------------------------------------	-------------------------------	---	---------

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

General information No special measures required.

After inhalation Supply fresh air; consult doctor in case of complaints.

After skin contact

Immediately wash with water and soap and rinse thoroughly.

If skin irritation continues, consult a doctor.

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.

Call a doctor immediately.

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.

5.3 Advice for firefighters

Protective equipment: Adapt to environment.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Avoid eye and skin contact with the substance.

6.2 Environmental precautions: No special measures required.

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

No dangerous substances are released.

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 Keep away from heat and direct sunlight.

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: Store away from foodstuffs.

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

The usual precautionary measures are to be adhered to when handling chemicals.

Respiratory protection: Not necessary if room is well-ventilated.

Protection of hands: Protective gloves.

Material of gloves Butyl rubber, BR

Penetration time of glove material

0,1 - 0,2 mm

Penetration time: 5 min.

Eye protection: Goggles recommended during refilling.

Body protection: Protective work clothing.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Appearance:

Form: Pasty

Colour: Colourless

Odour: Characteristic

Odour threshold: Not determined.

pH-value: Not determined.

Change in condition

Melting point/Melting range: < - 20 °C

Boiling point/Boiling range: undetermined

Flash point: 113 °C

Flammability (solid, gaseous) Not applicable.

Ignition temperature: 400 °C

Decomposition temperature: Not determined.

Self-igniting: Product is not selfigniting.

Danger of explosion: Product does not present an explosion hazard.

Explosion limits:

Lower: Not determined.

Upper: Not determined.

Vapour pressure: 1,3 mbar (110 °C)

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:

Organic solvents: 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.

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: Not known to be hazardous to water.

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 be specially treated adhering to official regulations.

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

European waste catalogue: 08 04 10 waste adhesives and sealants other than those mentioned in 08 04 09

Uncleaned packaging:

Recommendation:

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

Packagings that may not be cleansed are to be disposed of in the same manner as the product.

Recommended cleansing agents: Ethyl acetate

SECTION 14: Transport information

14.1 UN-Number

ADR, ADN, IMDG, IATA Void

14.2 UN proper shipping name

ADR, ADN, IMDG, IATA Void

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

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.

National regulations

Technical instructions (air):

Class: III

Share in %: 2,5-10

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

H317 May cause an allergic skin reaction.

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 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

vPvB: very Persistent and very Bioaccumulative

Skin Sens. 1: Sensitisation - Skin, Hazard Category 1

Skin Sens. 1B: Sensitisation - Skin, Hazard Category 1B

Preparation by:

S. Zimmermann

Tel.: +49 521 8016800