

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

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

- Product identifier

- Trade name: betasil® VARIO PUTTY / PUTTY SOFT
- **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 impression material, medical device
- 1.3 Details of the supplier of the safety data sheet
- Manufacturer/Supplier: Müller-Omicron GmbH & Co. KG Schlosserstr. 1 51789 Lindlar / Köln GERMANY www.mueller-omicron.de
- Further information obtainable from: Product safety department sds@mueller-omicron.de
- **1.4 Emergency telephone number:** During normal opening times (08:00 a.m. - 05:00 p.m.): +49 (0) 2771 / 3304 - 23

SECTION 2: Hazards identification

- 2.1 Classification of the substance or mixture
- Classification according to Regulation (EC) No 1272/2008 The product is not classified according to the CLP regulation.
- 2.2 Label elements
- Labelling according to Regulation (EC) No 1272/2008 Void
- Hazard pictograms Void
- Signal word Void
- Hazard statements Void
- 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: Mixture of substances listed below with nonhazardous additions.
- Dangerous components:

Cristobalite (CAS 14464-46-1)

🚸 STOT RE 1, H372 🛛 50 - < 75%

- 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: No special measures required.
- After inhalation: Supply fresh air; consult doctor in case of complaints.
- After skin contact: Generally the product does not irritate the skin.
- 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.

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- **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 No further relevant information available.
- 5.3 Advice for firefighters
- Protective equipment: No special measures required.

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
- 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 No special measures required.
- 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: 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

- 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 required.
- Protection of hands:

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.

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- 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 protection: Goggles recommended during refilling

SECTION 9: Physical and chemical properties		
- 9.1 Information on basic physical and chemical properties		
- General Information - Appearance:		
Form:	Pasty	
Colour:	Base: different	
	Catalyst: white	
- Odour:	Characteristic	
	Base: mint Catalyst: characteristic	
- Odour threshold:	Not determined.	
- pH-value:	Not determined.	
- Change in condition		
Melting point/Melting range:	Undetermined.	
Boiling point/Boiling range:	Undetermined.	
- Flash point:	Not applicable.	
- Flammability (solid, gaseous):	Not applicable.	
- Ignition temperature:	430 °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 at 20 °C:	1 hPa	
- Density at 20 °C:	1.6 g/cm ³	
- Relative density	Not determined.	
- Vapour density - Evaporation rate	Not determined. Not determined.	
•	Not dotominou.	
 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 %	
VOC (EC)	0.00 %	
Solids content:	70.0 %	
- 9.2 Other information	No further relevant information available.	
SECTION 10: Stability and reactivity		

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- 10.1 Reactivity No further relevant information available.

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- 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 toxicological effects
- Acute toxicity Based on available data, the classification criteria are not met.
- 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 Based on available data, the classification criteria are not met.
- CMR effects (carcinogenity, 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 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
- 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 Smaller quantities can be disposed of with household waste.
- 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

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- 14.4 Packing group - ADR, IMDG, IATA	Void
- 14.5 Environmental hazards: - Marine pollutant:	Νο
- 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 No further relevant information available.

- 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

H372 Causes damage to organs through prolonged or repeated exposure.

- Department issuing SDS: Product safety department
- Contact: sds@mueller-omicron.de
- 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)

VOC: Volatile Organic Compounds (USA, EU) PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

STOT RE 1: Specific target organ toxicity (repeated exposure) - Category 1

- 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.