

Safety data sheet

according to 1907/2006/EC, Article 31

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Version number 1

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

- **Product identifier**
- **Trade name:** **betasil® VARIO LIGHT / LIGHT fast set / MEDIUM / HEAVY / IMPLANT**
- **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
D-51789 Lindlar
GERMANY
www.mueller-omicron.com
- **Further information obtainable from:**
Product safety department
sds@mueller-omicron.de
- **1.4 Emergency telephone number:**
Mon-Thu: +49 (0)2266 / 4742-0 (8 am - 5 pm CET)
Fri: +49 (0)2266 / 4742-0 (8 am - 1 pm CET)


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
- **Additional information:**
This Product contains a substance which is classified as STOT RE 1. Due to its physical form, exposure through inhalation is not expected (Regulation (EC) No 1272/2008 (CLP) - Annex I, 1.1.1.5).
- **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:**

EINECS: 238-455-4	Cristobalite (CAS 14464-46-1)	 STOT RE 1, H372	25-50%
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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**
- **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.

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- **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:** Use fire extinguishing methods suitable to surrounding conditions.
- **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**
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: according to product description

- Odour: Characteristic

- Odour threshold: Not determined.

- pH-value: Not determined.

- Change in condition

Melting point/freezing point: Undetermined.

Initial boiling point and boiling range: Undetermined.

- Flash point: Not applicable.

- Flammability (solid, gas): Not applicable.

- Ignition temperature: >400 °C

- 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 at 20 °C: 100 hPa

- Density at 20 °C: 1.4 g/cm³

- 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 %

VOC (EC) 0.00 %

Solids content: 60.0 %

- 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 No dangerous reactions known.

- 10.4 Conditions to avoid No further relevant information available.

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- **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 (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 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

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|-------------------------------------------------------------------------------|-----------------|
| - 14.1 UN-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. |

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| - 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.
- **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.**