

## Safety data sheet

according to 1907/2006/EC, Article 31

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Version number 2

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

- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
- **Product identifier**

- **Trade name:** **betasil® VARIO LIGHT / LIGHT fast set / MEDIUM / HEAVY / IMPLANT**
- **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**  
Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

- **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** Void

- **Signal word** Void

- **Hazard statements**

H412 Harmful to aquatic life with long lasting effects.

- **Precautionary statements**

P273 Avoid release to the environment.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

- **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**

This substance/mixture does not contain components classified as either persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

- **PBT:** Not applicable.

- **vPvB:** Not applicable.

- **Determination of endocrine-disrupting properties**

Endocrine disrupting properties - human health: The substance/mixture does not contain any components that exhibit endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated Regulation (EU) 2017/2100 or Commission Delegated Regulation (EU) 2018/605 in quantities of 0.1% or more.

Endocrine disrupting properties - Environment: The substance/mixture does not contain any components that exhibit endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated Regulation (EU) 2017/2100 or Commission Delegated Regulation (EU) 2018/605 in quantities of 0.1% or

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Trade name: betasil® VARIO LIGHT / LIGHT fast set / MEDIUM / HEAVY / IMPLANT

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more.

### SECTION 3: Composition/information on ingredients

#### - 3.2 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%
CAS: 556-67-2 EINECS: 209-136-7 Index number: 014-018-00-1	octamethylcyclotetrasiloxane ☠ Flam. Liq. 3, H226; ☠ Repr. 2, H361f; ☠ Aquatic Chronic 1, H410 (M=10) PBT; vPvB	≥0.025-<0.1%

- **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; 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.

#### - 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 product to reach sewage system or any water course.

Inform respective authorities in case of seepage into water course or sewage system.

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).

Dispose contaminated material as waste according to item 13.

#### - 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:** 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.

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## SECTION 8: Exposure controls/personal protection

### - 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

- **Appropriate engineering controls** No further data; see item 7.

- **Individual protection measures, such as personal protective equipment**

- **General protective and hygienic measures:** Wash hands before breaks and at the end of work.

- **Respiratory protection:** Not required.

#### - **Hand protection**

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.

#### - **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/face protection** Goggles recommended during refilling

## SECTION 9: Physical and chemical properties

### - 9.1 Information on basic physical and chemical properties

#### - **General Information**

- **Physical state**

Fluid

- **Colour:**

according to product description

- **Odour:**

Characteristic

- **Odour threshold:**

Not determined.

- **Melting point/freezing point:**

Undetermined.

- **Boiling point or initial boiling point and boiling range**

Undetermined.

- **Flammability**

Not applicable.

- **Lower and upper explosion limit**

- **Lower:**

Not determined.

- **Upper:**

Not determined.

- **Flash point:**

Not applicable.

- **Ignition temperature:**

>400 °C

- **Decomposition temperature:**

Not determined.

- **pH**

Not determined.

- **Viscosity:**

- **Kinematic viscosity**

Not determined.

- **Dynamic:**

Not determined.

- **Solubility**

- **water:**

Not miscible or difficult to mix.

- **Partition coefficient n-octanol/water (log value)** Not determined.

- **Vapour pressure at 20 °C:**

100 hPa

- **Density and/or relative density**

- **Density at 20 °C:**

1.4 g/cm<sup>3</sup>

- **Relative density**

Not determined.

- **Vapour density**

Not determined.

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- **9.2 Other information**
- **Appearance:**
- **Form:** Pasty
- **Important information on protection of health and environment, and on safety.**
- **Auto-ignition temperature:** Product is not selfigniting.
- **Explosive properties:** Product does not present an explosion hazard.
- **Solvent content:**
- **Organic solvents:** 0 %
- **VOC (EC)** 0-<0.01 %
- **Solids content:** 60.0 %
- **Change in condition**
- **Evaporation rate** Not determined.

- **Information with regard to physical hazard classes**
- **Explosives** Void
- **Flammable gases** Void
- **Aerosols** Void
- **Oxidising gases** Void
- **Gases under pressure** Void
- **Flammable liquids** Void
- **Flammable solids** Void
- **Self-reactive substances and mixtures** Void
- **Pyrophoric liquids** Void
- **Pyrophoric solids** Void
- **Self-heating substances and mixtures** Void
- **Substances and mixtures, which emit flammable gases in contact with water** Void
- **Oxidising liquids** Void
- **Oxidising solids** Void
- **Organic peroxides** Void
- **Corrosive to metals** Void
- **Desensitised explosives** Void

## 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.
- **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 hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **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.
- **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.

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**- 11.2 Information on other hazards**

**- Endocrine disrupting properties**

Endocrine disrupting properties - human health: The substance/mixture does not contain any components that exhibit endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated Regulation (EU) 2017/2100 or Commission Delegated Regulation (EU) 2018/605 in quantities of 0.1% or more.

None of the ingredients is listed.

**\* 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.

**- 12.5 Results of PBT and vPvB assessment**

This substance/mixture does not contain components classified as either persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

- **PBT:** Not applicable.

- **vPvB:** Not applicable.

**- 12.6 Endocrine disrupting properties**

Endocrine disrupting properties - Environment: The substance/mixture does not contain any components that exhibit endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated Regulation (EU) 2017/2100 or Commission Delegated Regulation (EU) 2018/605 in quantities of 0.1% or more.

**- 12.7 Other adverse effects**

- **Remark:** Harmful to fish

- **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.

Harmful to aquatic organisms

**\* 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.

- **Uncleaned packaging:**

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

**SECTION 14: Transport information**

- **14.1 UN number or ID 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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- |   |                 |
|---|-----------------|
| - <b>14.7 Maritime transport in bulk according to IMO instruments</b> | Not applicable. |
| - <b>UN "Model Regulation":</b>                                       | 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, 70
- **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**
- None of the ingredients is listed.
- **REGULATION (EU) 2019/1148**
- **Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**
- None of the ingredients is listed.
- **Annex II - REPORTABLE EXPLOSIVES PRECURSORS**
- None of the ingredients is listed.
- **Regulation (EC) No 273/2004 on drug precursors**
- None of the ingredients is listed.
- **Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**
- 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**
  - H226 Flammable liquid and vapour.
  - H361f Suspected of damaging fertility.
  - H372 Causes damage to organs through prolonged or repeated exposure.
  - H410 Very toxic to aquatic life with long lasting effects.
- **Contact:** sds@mueller-omicron.de
- **Date of previous version:** 12.05.2021
- **Abbreviations and acronyms:**
  - ADR: Accord relatif au transport international 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
  - Flam. Liq. 3: Flammable liquids – Category 3
  - Repr. 2: Reproductive toxicity – Category 2
  - STOT RE 1: Specific target organ toxicity (repeated exposure) – Category 1
  - Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1
  - Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3
- **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.**