

## **01. Identification of the substance / preparation and of the company**

<b>Product:</b>	<b>betasil® VARIO MEDIUM / LIGHT/ betasil® LIGHT fast set; betasil® VARIO IMPLANT base / catalyst</b>
<b>Registration number:</b>	not applicable
<b>Use / Method of operation:</b>	see product information / instructions for use
<b>Identified use:</b>	Medical device, dental impression material
<b>Company:</b>	Müller-Omicron GmbH & Co. KG Schlosserstraße 1 51789 Lindlar / GERMANY
<b>Phone :</b>	0049 (0) 2266-4742-0
<b>Fax :</b>	0049 (0) 2266-3417
<b>eMail :</b>	info@mueller-omicron.de
<b>Homepage :</b>	<a href="http://www.mueller-omicron.de">www.mueller-omicron.de</a>
<b>Emergency phone:</b>	0049 (0) 2266-4742-0 (8:00 – 17:00)
<b>Responsible:</b>	vschr@omicron-dental.de

## **02. Hazards identification**

<b>Physico-chemical hazards:</b>	No particular hazard known.
<b>Human health dangers:</b>	No particular hazard known.
<b>Environmental hazards:</b>	No particular hazard known.
<b>Other hazards:</b>	none
<b>Hazard symbols :</b>	none
<b>R-phrases :</b>	none

## **03. Composition / Information on ingredients**

<b>Description:</b>	Two-part polyvinylsiloxane-based dental impression material, comprising a base-component and matching catalyst-component.
<b>Hazardous Ingredients:</b>	not applicable

## **04. First aid measures**

<b>General information:</b>	none
<b>Inhalation:</b>	not applicable
<b>Skin contact:</b>	When in contact with the skin, clean with soap and water. Consult a doctor if skin irritation persists.
<b>Eye contact:</b>	In case of contact with eyes rinse thoroughly with plenty of water and seek medical advice.
<b>Ingestion:</b>	Supply with medical care. Rinse out mouth and give plenty of water to drink.
<b>Advice to doctor:</b>	Treat symptomatically.

## **05. Fire-fighting measures**

<b>Suitable extinguishing media:</b>	Dry powder. Foam. Water spray jet. Carbon dioxide.
<b>Extinguishing media that must not be used:</b>	Full water jet.

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Date printed: 11.05.2011, Revision: 08.10.2009



<b>Special exposure hazards arising from the substance or preparation itself or combustion products:</b>	Unknown risk of formation of toxic pyrolysis products.
<b>Special protective equipment for firefighters:</b>	Use self-contained breathing apparatus.
<b>Additional information:</b>	Fire residues and contaminated firefighting water must be disposed of in accordance with the local regulations.

## **06. Accidental release measures**

<b>Personal precautions:</b>	Forms slippery surfaces with water
<b>Environmental precautions:</b>	Do not discharge into the drains / surface waters / groundwater. Prevent spread over a wide area (e.g. by containment or oil barriers).
<b>Methods for cleaning up:</b>	Take up mechanically. Dispose of absorbed material in accordance within the regulations.

## **07. Handling and storage**

<b>Advice on safe handling:</b>	No special measures necessary if used correctly.
<b>Advice on protection against fire and explosion:</b>	No special measures necessary.
<b>Requirements for storage rooms and vessels:</b>	Keep only in original container.
<b>Advice on storage compatibility:</b>	No special measures necessary.
<b>Further information on storage conditions:</b>	Keep container tightly closed.

## **08. Exposure controls / personal protection**

<b>Additional advice on system design:</b>	not applicable
<b>Ingredients with occupational exposure limits to be monitored:</b>	not applicable
<b>Respiratory protection:</b>	not applicable
<b>Hand protection:</b>	butyl rubber, > 120 min (EN 374)
<b>Eye protection:</b>	not applicable
<b>Skin protection:</b>	none
<b>General protective measures:</b>	Avoid contact with eyes.
<b>Hygiene measures:</b>	Wash hands before breaks and after work. Use barrier skin cream.
<b>Delimitation and monitoring of the environment exposition:</b>	not determined

## **09. Physical and chemical properties**

<b>Appearance:</b>	pasty	<b>Density at 23°C [g/ml]:</b>	1,35 – 1,55
<b>Color:</b>	different	<b>Evaporation speed:</b>	not determined
<b>Odor:</b>	characteristic	<b>Vapour pressure [kPa]:</b>	not determined
<b>pH-value:</b>	not applicable	<b>Viscosity [mPas]:</b>	not determined
<b>Boiling point [°C]:</b>	not determined	<b>Solubility in water:</b>	immiscible
<b>Flash point [°C]:</b>	not determined	<b>Oxidizing properties:</b>	no
<b>Flammability:</b>	not determined	<b>Melting point [°C]:</b>	not determined

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<b>Upper explosion limit:</b>	not applicable	<b>Autoignition temperature:</b>	not determined
<b>Lower explosion limit:</b>	not applicable	<b>Decomposition temperature:</b>	not determined

## **10. Stability and reactivity**

<b>Hazardous reactions:</b>	No hazardous reactions known.
<b>Hazardous decomposition products:</b>	No hazardous decomposition products known.

## **11. Toxicological information**

<b>Acute toxicity oral / dermal / inhalational:</b>	not determined
<b>Irritant effect on eye:</b>	not determined
<b>Irritant effect on skin :</b>	not determined
<b>Sensitization:</b>	not determined
<b>Subacute / Chronic toxicity:</b>	not determined
<b>CMR-activity</b>	not determined
<b>Experiences made in practice:</b>	none.
<b>General remarks:</b>	Toxicological data are not available. No classification on the basis of the calculation procedure of the preparation directive.

## **12. Ecological information**

<b>Fish / Daphnia / Bacteria toxicity:</b>	not determined
<b>Behaviour in environment compartments:</b>	not determined
<b>Behaviour in sewage plant:</b>	not determined
<b>Biological degradability:</b>	not determined
<b>Chemical (COD) / Biochemical (BOD 5) oxygen demand:</b>	not determined
<b>AOX-advice:</b>	No dangerous components.
<b>2006/11/EC:</b>	not determined
<b>General information:</b>	Ecological data are not available. No classification on the basis of the calculation procedure of the preparation directive.

## **13. Disposal considerations**

<b>Product:</b>	For recycling, consult manufacturer. Coordinate disposal with the authorities if necessary.
<b>Contaminated packaging:</b>	Uncontaminated packaging may be taken for recycling. Packaging that cannot be cleaned should be disposed of as for product.
<b>Waste no. (recommended):</b>	070799

## **14. Transport information**

### **Classification according to ADR:**

<b>Classification according to ADR:</b>	no dangerous goods
<b>- Classification Code:</b>	-
<b>- Label:</b>	-
<b>- ADR LQ</b>	-

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- ADR 1.1.3.6 (8.6):	Transport category (tunnel restriction code): -
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**Classification according to IMDG:**

<b>Classification according to IMDG:</b>	not classified as « Dangerous Goods »
- EMS:	-
- Label:	-
IMDG LQ:	-

**Classification according to IATA:**

<b>Classification according to IATA:</b>	not classified as « Dangerous Goods »
- Label:	-

**15. Regulatory information**

<b>Exposure scenario:</b>	not determined
<b>Chemical safety report:</b>	not determined
<b>Labelling:</b>	The product does not require a hazard warning label in accordance with EC-directives.
<b>Hazard symbols:</b>	none
<b>R-phrases:</b>	none
<b>S-phrases:</b>	none
<b>Special labelling:</b>	Safety data sheet available for professional user on request.
<b>Authorisation, TITEL VII:</b>	not applicable
<b>Restrictions, TITEL VIII:</b>	not applicable
<b>EEC-REGULATIONS:</b>	1967/548 (2008/58, 30. ATP/ 31. ATP); 1991/689 (2001/118); 1999/13; 2004/42; 648/2004; 1907/2006.
<b>TRANSPORT- REGULATIONS:</b>	DOT-Classification, ADR (2009); IMDG-Code (34. Amdt.); IATA-DGR (2009).
<b>NATIONAL REGULATIONS:</b>	EH40/2005 Workplace exposure limits with amendments October 2007

**16. Other informations**

<b>R-phrases (Chapter 03):</b>	not applicable
<b>Observe employment restrictions for people:</b>	not applicable
<b>VOC (1999/13/CE):</b>	not determined
<b>Customs tariff:</b>	not determined

Disclaimer: 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.