## SECTION 1. Product identification/preparation/company undertaking

**1.1. Product identifier:**

**Trade name:** **BISICO Lutesil V**
**(various packaging sizes)**

**Trade number:** **00360, 00370**

**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 silicone - for use in taking preliminary impressions in the field of complete denture prosthetics

**1.3. Details of the supplier of the safety data sheet:**
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

**1.4. Emergency telephone number:**

BISICO Bielefelder Dentalsilicone GmbH & Co. KG

Tel.: +49 521 8016800 (08:00-16:00 PM)
Fax: +49 521 8016801
S. Zimmermann

## SECTION 2. Hazards identification

**2.1 Classification of the substance or mixture:**

**Classification according to Directive 67/548/EEC or 1999/45/EC as amended:**
Xn; R48/20

**2.1.1. Regulation 1272/2008 (CLP) and following amendments and adjustments:**

Specific Target Organ Toxicity -
Repeated Exposure

Category 1

Causes damage to organs through prolonged or
repeated exposure.

Physical Hazards:

No specific recommendations.

**Health Hazards:**

Inhalation:

Quartz : When encapsulated in a polymer, is not expected to pose a health hazard when processed under normal conditions of use. Although classified according to EC criteria, this product is exempt from labelling according to article 23 and Annex 1 (section 1.3.4.1) of regulation (CE) n°1272/2008.

Eye contact: No specific symptoms noted.

Skin Contact: No specific symptoms noted.

Ingestion: No specific symptoms noted.

Other Health Effects: No other information noted.

Environmental hazards: Not regarded as dangerous for the environment.

**2.2 Label Elements:**
Safety data sheet available on request.

**2.3 Other hazards:**
No data available.

## SECTION 3. Composition/Information of Ingredients

**3.1. Substances:**

**3.2. Mixtures:**

**Description:** Mixture of Polyorganosiloxanes, fillers, additives.

| Chemical name | Concentration | CAS-No. | EC No. | REACH Registration No. | Notes |
|---|---|---|---|---|---|
| Quartz (SiO2) | <15% | 14808-60-7 | | | # |
| White mineral oil (petroleum) | <5% | 8042-47-5 | | | |

* All concentrations are percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.
#: This substance has workplace exposure limit(s).
PBT: persistent, bioaccumulative and toxic substance.
vPvB: very persistent and very bioaccumulative substance.

**Classification:**

| Chemical name | Classification | | Notes |
|---|---|---|---|
| Quartz (SiO2) | DSD: | Xn; R48/20 | |
| | CLP: | STOT RE 1;H372 | |
| White mineral oil (petroleum) | DSD: | Xn; R65 | |
| | CLP: | Asp. Tox. 1;H304 | |

DSD: Directive 67/548/EEC.
CLP: Regulation No. 1272/2008.:

The full text for all R- and H-phrases is displayed in section 16.

## SECTION 4. First-aid measures

**4.1. Description of first aid measures:**

**General information:**
Get medical attention if symptoms occur.
Contaminated clothing to be placed in closed container until disposal or decontamination.

**after skin contact:**
Remove contaminated clothing and shoes. Wash with soap and water.

**after eye contact:**
In the event of contact with the eyes, rinse thoroughly with clean water.
Continue to rinse for at least 15 minutes.

**after swallowing:**
Do not induce vomiting. Rinse mouth thoroughly.

**4.2. Most important symptoms and effects, both acute and delayed:**
Information not available

**4.3. Indication of any immediate medical attention and special treatment needed:**
**Hazards:** No specific recommendations.
**Treatment:** No specific recommendations.

## SECTION 5. Fire fighting measures

**5.1 Extinguishing media:**
Extinguish with foam, carbon dioxide or dry powder. Water spray.

**5.2 Special hazards arising from the substance or mixture:**
Combustible. For further information, refer to Section 10: "Stability and Reactivity".

**5.3. Advice for firefighters:**

**Special fire fighting procedures:**
Water spray should be used to cool containers.

**Protective equipment:**
Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

## SECTION 6. Accidental release measures

**6.1 Personal precautions:**
Use personal protective equipment. See Section 8 of the MSDS for Personal Protective Equipment.

**6.2 Environmental precautions:**
Collect spillage. Do not discharge into drains, water courses or onto the ground.

**6.3 Methods for cleaning up:**
Containers with collected spillage must be properly labelled with correct contents and hazard symbol. Container must be kept tightly closed. Absorb with sand or other inert absorbent. To clean the floor and all objects contaminated by this material, use an appropriate solvent.(cf. : § 9) Flush area with plenty of water. Incinerate in suitable combustion chamber.

**Notification Procedures:**
Caution: Contaminated surfaces may be slippery. For waste disposal, see section 13 of the MSDS.

**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:**

**Precautions for safe handling:**

No specific precautions.

**7.2. Conditions for safe storage, including any incompatibilities:**

No special storage precautions noted. Material is stable under normal conditions. Avoid contact with oxidizing agents. Suitable containers: polyethylene. Plastic lined steel drum.

**7.3. Specific end use(s):**

No specific recommendations.

## SECTION 8. Exposure controls/personal protection

**8.1. Control parameters:**

Quartz : When encapsulated in a polymer, is not expected to pose a health hazard when processed under normal conditions of use.

None of the components have assigned exposure limits.

**Appropriate engineering controls:** No special precautions.

**8.2 Exposure controls:**

**Personal protective equipment:** -

**General measures of protection and hygiene:** Provide eyewash station and safety shower.

**Respiratory protection:** not required

**Protection of hands:** Use protective gloves made of: Nitrile.
**Eye protection:** Safety Glasses

**Other:**
No skin protection is ordinarily required under normal conditions of use. In accordance with good industrial hygiene practices, precautions should be taken to avoid skin contact.

## SECTION 9. Physical and chemical properties

**Appearance:**

| | | |
|---|---|---|
| **Form:** | Paste | |
| **Color:** | Grey | |
| **Odor:** | odorless | |
| | Value Unit Method | |
| **Information on change in the physical state** | | |
| **Melting point/melting range:** | n.a. | °C |
| **Boiling point/boiling range:** | n.a. | °C |
| **Flash point:** | 110 | °C |
| **Autoignition temperature:** | >400 | °C |
| **Danger of explosion:** | n.a. | |
| **Density:** | ~1,90 (20°C) | g/cm$^3$ |
| **Vapor pressure:** | < 0,1 | hPa (20 °C) |
| **Viscosity:** | Viscous paste | |
| **pH:** | Not applicable | |

| | |
|---|---|
| **Solubility in/miscibility with:** | Acetone.: Very slightly soluble.<br>Ethanol.: Very slightly soluble.<br>Diethylether.: Miscible (in all proportions).<br>Aliphatic hydrocarbons.: Miscible (in all proportions).<br>Aromatic hydrocarbons.: Miscible (in all proportions).<br>Chlorinated solvents.: Miscible (in all proportions). |
| **Water:** | Practically Insoluble |
| **Content of solvents:** | n.a. |
| **Organic solvents:** | n.a. |
| **Water:** | n.a. |
| **Content of solids:** | n.a. |
| **Oxidizing properties:** | According to the data on the components Not considered as oxidizing. (evaluation by structure-activity relationship) |

**9.2. Other information:** no information available

## SECTION 10. Stability and reactivity

**10.1 Reactivity:** Not relevant.

**10.2 Chemical Stability:** Stable

**10.3 Possibility of Hazardous Reactions:** No data available.

**10. 4 Conditions to Avoid:** No other information noted.

**10.5 Incompatible Materials:** Strong oxidizing agents.

**10.6 Hazardous decomposition products:**

Thermal decomposition or combustion may liberate carbon oxides and other toxic gases or vapors. Amorphous silica.

## SECTION 11. Toxicological information

**Information on likely routes of exposure**

**Inhalation:** No data available.

**Ingestion:** No data available.

**Skin Contact:** No data available.

**Eye contact:** No data available.

**11.1. Information on toxicological effects:**

**Acute Toxicity:**

**Oral:**
**Product:** No effects expected (assessment based on ingredients).
Not classified for acute toxicity based on available data.

**Dermal:**
**Product:** No effects expected (assessment based on ingredients).
Not classified for acute toxicity based on available data.

**Inhalation:**
**Product:** No effects expected (assessment based on ingredients).

**Repeated Dose Toxicity:**
**Product:** No effects expected (assessment based on ingredients).

**Skin Corrosion/Irritation:**
**Product:** No effects expected (assessment based on ingredients).

**Serious Eye Damage/Eye Irritation:**
**Product:** No effects expected (assessment based on ingredients).

**Respiratory or Skin Sensitization:**
**Product:** No effects expected (assessment based on ingredients).

**Germ Cell Mutagenicity:**
**In vitro:**
**Product:** No effects expected (assessment based on ingredients).

**In vivo:**
**Product:** No effects expected (assessment based on ingredients).

**Carcinogenicity:** No effects expected (assessment based on ingredients).
**Product:** No data available.

**Reproductive Toxicity:**
**Product:** No effects expected (assessment based on ingredients).

**Reproductive Toxicity (Fertility):**
**Product:** No data available.

**Developmental Toxicity (Teratogenicity):**
**Product:** No data available.

**Specific Target Organ Toxicity - Single Exposure:**
**Product:** No effects expected (assessment based on ingredients).

**Specific Target Organ Toxicity - Repeated Exposure:**
**Product:** No effects expected (assessment based on ingredients).

**Aspiration Hazard:**
**Product:** No effects expected (assessment based on ingredients).
**Other Adverse Effects:** None known.

## SECTION 12. Ecological information

**General information:**

Avoid transfer into environment

**12.1 Toxicity:**

**Acute toxicity:**

**Fish:**
**Product:** No effects expected (assessment based on ingredients).

**Aquatic Invertebrates:**
**Product:** No effects expected (assessment based on ingredients).

**Chronic Toxicity:**
**Fish:**
**Product:** No effects expected (assessment based on ingredients).

**Aquatic Invertebrates:**
**Product:** No effects expected (assessment based on ingredients).

**Toxicity to Aquatic Plants:**
**Product:** No effects expected (assessment based on ingredients).

**12.2 Persistence and Degradability:**

**Biodegradation:**
**Product:** Not applicable

**BOD/COD Ratio:**
**Product:** No data available.

**Specified substance(s):**
Quartz (SiO2) No data available.
White mineral oil
(petroleum)
No data available.

**12.3 Bioaccumulative Potential:**
**Product:** No data available.

**Specified substance(s):**
Quartz (SiO2) No data available.
White mineral oil (petroleum) Bioaccumulation is unlikely to be significant because of the low water solubility of this product.

**12.4 Mobility in Soil:** No data available.

**Known or predicted distribution to environmental compartments:**
Quartz (SiO2) No data available.
White mineral oil (petroleum) No data available.

**12.5 Results of PBT and vPvB assessment:** None Reported

**12.6 Other Adverse Effects:** None known.

## SECTION 13. Disposal consideration

**13.1 Waste treatment methods:**

**General:**
The user's attention is drawn to the possible existence of local regulations regarding disposal.

**Product:**

Recommendation: Dispose of waste at an appropriate treatment and disposal facility in accordance with applicable laws and regulations, and product characteristics at time of disposal. Incinerate in suitable combustion
chamber.

**Uncleaned packaging:**

Recommendation: Contaminated packages should be as empty as possible. Dispose of waste at an appropriate treatment and disposal facility in accordance with applicable laws and regulations, and product characteristics at time of disposal. Recycle following cleaning or dispose of at an authorised site.

## 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:**
Packaging with a breathing/venting bung are FORBIDDEN for transport by air.

**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**

**MARPOL73/78 and the IBC Code:** Not applicable.

## SECTION 15. Regulatory information

**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture:**

**National Regulations:**

Wassergefährdungsklasse
(WGK):
WGK 1: schwach wassergefährdend.

Water Hazard Class
(WGK):
WGK 1: slightly water-endangering.

**15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

## SECTION 16. Other information:

**Changes compared with the previous version:** 1.1 Product identifier

The above information is based on our present day knowledge and relates solely to the safety requirements of the product. The data do not signify any warranty with regards to products properties. However users of the product should satisfy themselves that the information given is sufficient and correct for their specific circumstances of use.

**Wording of the R-phrases and H-statements in section 2 and 3:**
H304 May be fatal if swallowed and enters airways.
H372 Causes damage to organs through prolonged or repeated exposure.
R48/20 Harmful: danger of serious damage to health by prolonged exposure through inhalation.
R65 Harmful: may cause lung damage if swallowed.

**Preparation by:**
S. Zimmermann
Tel.: +49 521 8016800