

## 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:** *alphasil® PERFECT PUTTY SOFT*
- **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*

- **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 more.*

### SECTION 3: Composition/information on ingredients

- **3.2 Mixtures**
- **Description:** *Mixture of substances listed below with nonhazardous additions.*
- **Dangerous components:** *Void*

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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.
- **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**

##### **- 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:**

The usual precautionary measures are to be adhered to when handling chemicals.

- **Respiratory protection:** Not required.

- **Hand protection**

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

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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 specification

**- 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:**

Not determined.

**- 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:**

Not determined.

**- Density and/or relative density**

**- Density:**

Not determined.

**- Relative density**

Not determined.

**- Vapour density**

Not determined.

**- 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:**

**- VOC (EC)**

0.00 %

**- Solids content:**

70.0 %

**- Change in condition**

**- Evaporation rate**

Not determined.

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<b>- Information with regard to physical hazard classes</b>	
- 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.

- **LD/LC50 values relevant for classification:**

### Zeolite

Oral	LD50	>10,000 mg/kg (rat)
Dermal	LD50	>2,000 mg/kg (rabbit)
Inhalative	LC50/4 h	>18.3 mg/l (rat)

- **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.
- **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.

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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**
- **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.

## **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**

- |   |                 |
|---|-----------------|
| - <b>14.1 UN number or ID number</b><br>- ADR, IMDG, IATA                     | Void            |
| - <b>14.2 UN proper shipping name</b><br>- ADR, IMDG, IATA                    | Void            |
| - <b>14.3 Transport hazard class(es)</b><br>- ADR, ADN, IMDG, IATA<br>- Class | Void            |
| - <b>14.4 Packing group</b><br>- ADR, IMDG, IATA                              | Void            |
| - <b>14.5 Environmental hazards:</b>  | Not applicable. |
| - <b>14.6 Special precautions for user</b>                                    | Not applicable. |
| - <b>14.7 Maritime transport in bulk according to IMO instruments</b>         | Not applicable. |
| - <b>UN "Model Regulation":</b>   | Void            |

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## 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.
- **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.

- **Contact:** [sds@mueller-omicron.de](mailto: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)
  - LC50: Lethal concentration, 50 percent
  - LD50: Lethal dose, 50 percent
  - PBT: Persistent, Bioaccumulative and Toxic
  - vPvB: very Persistent and very Bioaccumulative
- **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.**