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

1.1 Product identifier
   - Trade name: Optosil P Plus

1.2 Relevant identified uses of the substance or mixture and uses advised against
   - Application of the substance / the mixture: Dental impression material

1.3 Details of the supplier of the safety data sheet
   - Manufacturer/Supplier: Kulzer GmbH
     Leipziger Straße 2, 63450 Hanau (Germany) Tel.: +49 (0)800 4372522
   - Informing department: E-Mail: msds@kulzer-dental.com

1.4 Emergency telephone number:
   - Emergency CONTACT (24-Hour-Number): +49 (0)6132-84463

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:
     Safety data sheet available on request.

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: -

   Dangerous components:
   - CAS: 14808-60-7
   - EINECS: 238-878-4
   - Quartz (SiO2) 25-50%

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 symptoms.
   - After skin contact: Instantly wash with water and soap and rinse thoroughly.
   - After eye contact: Rinse opened eye for several minutes under running water.
   - After swallowing: Rinse out mouth and then drink plenty of water.

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according to 1907/2006/EC, Article 31

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In case of persistent symptoms 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 void

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.
Additional information -

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures Not required.

6.2 Environmental precautions: No special measures required.

6.3 Methods and material for containment and cleaning up:
Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues).

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 information on disposal.

SECTION 7: Handling and storage

7.1 Precautions for safe handling
Please observe the additional instructions in the product's instructions for use.

Information about protection against explosions and fires: No special measures required.

7.2 Conditions for safe storage, including any incompatibilities
Storage

Requirements to be met by storerooms and containers: 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

Components with critical values that require monitoring at the workplace:

9005-25-8 Starch

WEL Long-term value: 10* 4** mg/m²
*total inhalable **respirable

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· **Additional information**: The lists that were valid during the compilation were used as basis.

· **8.2 Exposure controls**
  · **Personal protective equipment**
  · **General protective and hygienic measures**
    The usual precautionary measures should be adhered to in handling the chemicals.
  · **Breathing equipment**: Not required.
  · **Protection of hands**: Check protective gloves prior to each use for their proper condition.
    recommended
  · **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 cannot be calculated in advance and has therefore to be checked prior to the application.
  · **Penetration time of glove material**
    The exact breakthrough time has to be found out by the manufacturer of the protective gloves and has to be observed.
  · **For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable:**
    Butyl rubber, BR
    Nitrile rubber, NBR
  · **Eye protection**: not absolutely necessary
  · **Body protection**: Light weight protective clothing

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**SECTION 9: Physical and chemical properties**

· **9.1 Information on basic physical and chemical properties**
  · **General Information**
    · **Appearance**:
    · **Form**: Pasty
    · **Colour**: Yellow
    · **Smell**: Odourless
    · **Odour threshold**: Not determined.
  · **pH-value**: Not determined.
  · **Change in condition**
    · **Melting point/Melting range**: Not determined
    · **Boiling point/Boiling range**: Not determined
  · **Flash point**: Not applicable
  · **Inflammability (solid, gaseous)**: Not applicable.
  · **Ignition temperature**:
    · **Decomposition temperature**: Not determined.
  · **Self-inflammability**: Product is not selfigniting.
  · **Danger of explosion**: Product is not explosive.
Critical values for explosion:
- Lower: Not determined.
- Upper: Not determined.

Steam pressure: Not determined.

Density at 20 °C: 1.5 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:
- Solids content: 69.0 %

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
- Conditions to be avoided: No decomposition if used and stored 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: None
- Additional information: -

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 (carcinogeneity, 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.
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- **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.
- **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 with household garbage.
  - **European waste catalogue**
    - **18 01 07 chemicals other than those mentioned in 18 01 06**
      - **Uncleaned packagings:**
        - **Recommendation:** Disposal must be made according to official regulations.

**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: Void
- **14.4 Packing group**
  - ADR, IMDG, IATA: Void
- **14.5 Environmental hazards:** Not applicable.
- **14.6 Special precautions for user** Not applicable.
- **14.7 Transport in bulk according to Annex II of Marpol and the IBC Code** Not applicable.
  - **Transport/Additional information:** -

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- **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**

These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **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)
  
  - PBT: Persistent, Bioaccumulative and Toxic
  
  - vPvB: very Persistent and very Bioaccumulative

- * Data compared to the previous version altered.*