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
   No further relevant information available.

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: Void

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.
     In case of persistent symptoms consult doctor.
**Trade name:** Optosil P Plus

- **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**
      - OEL: Long-term value: \(10^* 4** \text{mg/m}^3\)
      - *total inhalable **respirable dust
**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 can not be calculated in advance and has therefore to be checked prior to the application.
  - **Penetration time of glove material**
    - The exact break trough 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.

**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.
### Trade name: Optosil P Plus

- **Critical values for explosion:**
  - Lower: Not determined.
  - Upper: Not determined.
- **Steam pressure:**
  - Not determined.
- **Density at 20 °C**
  - Not determined.
- **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 (carcinogenicity, 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.
Trade name: Optosil P Plus

- 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.
- 13.2 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
    - Class: 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: -
### 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

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**Trade name:** Optosil P Plus

**UN "Model Regulation":** Void