1 Identification

- **Product identifier**
  - **Trade name:** Optosil P Plus

- **Application of the substance / the mixture** Dental impression material

- **Details of the supplier of the safety data sheet**
  - **Manufacturer/Supplier:** Kulzer GmbH
    Leipziger Straße 2, 63450 Hanau (Germany)  Tel.: +49 (0)800 4372522
  - **Information department:**
    Tel. +1 (800) 431-1785  Fax: +1 (800) 522-1545
e-mail: customer.servicehkna@kulzer-dental.com
  - **Emergency telephone number:**
    Emergency CONTACT (24-Hour-Number)
    GBK/Infotrac ID 105860: (domestic) 1 800 535 5053 or international (001) 352 323 3500

2 Hazard(s) identification

- **Classification of the substance or mixture**
  The product is not classified according to the Globally Harmonized System (GHS).

- **Label elements**
  - **GHS label elements** Void
  - **Hazard pictograms** Void
  - **Signal word** Void
  - **Hazard statements** Void

- **Classification system**
  - **NFPA ratings for USA (scale 0-4)**
    Health = 0
    Fire = 0
    Reactivity = 0
  - **HMIS-Ratings (Scale 0-4)**
    Health = 0
    Fire = 0
    Reactivity = 0

- **Results of PBT and vPvB assessment**
  - **PBT:** Not applicable.
  - **vPvB:** Not applicable.

3 Composition/information on ingredients

- **Chemical characterization:** Mixtures

- **Description:**

- **Dangerous components:**
  - 9005-25-8 Starch 10-25%
4 First-aid measures

- 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: Immediately 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.
  - Information for doctor:
    - Most important symptoms and effects, both acute and delayed: No further relevant information available.
    - Indication of any immediate medical attention and special treatment needed: No further relevant information available.

5 Fire-fighting measures

- Extinguishing media: void
- Suitable extinguishing agents: void
- Special hazards arising from the substance or mixture: No further relevant information available.
- Advice for firefighters:
  - Protective equipment: No special measures required.
  - Additional information: -

6 Accidental release measures

- Personal precautions, protective equipment and emergency procedures: Not required.
- Environmental precautions: No special measures required.
- Methods and material for containment and cleaning up:
  Absorb with liquid binding material (diatomite, universal binders, for small amounts tissues).
- 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.

7 Handling and storage

- Handling:
  - 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.

(Contd. on page 3)
43.0.7 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.
- Specific end use(s) No further relevant information available.

8 Exposure controls/personal protection

Control parameters

Components with limit values that require monitoring at the workplace:

<table>
<thead>
<tr>
<th>Substance</th>
<th>PEL Long-term value: 15* 5** mg/m³</th>
<th>REL Long-term value: 10* 5** mg/m³</th>
<th>TLV Long-term value: 10 mg/m³</th>
</tr>
</thead>
<tbody>
<tr>
<td>9005-25-8 Starch</td>
<td>*total dust **respirable fraction</td>
<td>*total dust **respirable fraction</td>
<td></td>
</tr>
</tbody>
</table>

Additional information: The lists that were valid during the creation were used as basis.

Exposure controls

General protective and hygienic measures

The usual precautionary measures for handling chemicals should be followed.

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 through 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
## 9 Physical and chemical properties

- **Information on basic physical and chemical properties**
  - **General Information**
    - **Appearance:**
      - **Form:** Pasty
      - **Color:** Yellow
      - **Odor:** Odorless
      - **Odor threshold:** Not determined.
    - **pH-value:** Not determined.
    - **Change in condition**
      - **Melting point/Melting range:** Undetermined
      - **Boiling point/Boiling range:** Undetermined
    - **Flash point:** Not applicable
    - **Flammability (solid, gaseous)** Not applicable.
    - **Ignition temperature:**
      - **Decomposition temperature:** Not determined.
    - **Auto igniting:** Product is not selfigniting.
    - **Danger of explosion:** Product does not present an explosion hazard.
    - **Explosion limits:**
      - **Lower:** Not determined.
      - **Upper:** Not determined.
    - **Vapor pressure:** Not determined.
    - **Density at 20 °C (68 °F):** 1.5 g/cm³ (12.518 lbs/gal)
      - **Relative density** Not determined.
      - **Vapor 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 %
    - **Other information** No further relevant information available.

## 10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Possibility of hazardous reactions** No dangerous reactions known
11 Toxicological information

· Information on toxicological effects
  · Acute toxicity:
    · Primary irritant effect:
      · on the skin: Based on available data, the classification criteria are not met.
      · on the eye: Based on available data, the classification criteria are not met.
    · Sensitization: Based on available data, the classification criteria are not met.
  · Additional toxicological information:
    The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version: When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

· Carcinogenic categories
  · IARC (International Agency for Research on Cancer)
    None of the ingredients is listed.
  · NTP (National Toxicology Program)
    None of the ingredients is listed.
  · OSHA-Ca (Occupational Safety & Health Administration)
    None of the ingredients is listed.

12 Ecological information

· Toxicity
  · Aquatic toxicity: No further relevant information available.
  · Persistence and degradability: No further relevant information available.
  · Behavior in environmental systems:
    · Bioaccumulative potential: No further relevant information available.
    · Mobility in soil: No further relevant information available.
  · Results of PBT and vPvB assessment
    · PBT: Not applicable.
    · vPvB: Not applicable.
  · Other adverse effects: No further relevant information available.

13 Disposal considerations

· Waste treatment methods
  · Recommendation: Smaller quantities can be disposed of with household waste.
Trade name: Optosil P Plus

- Uncleaned packagings:
  - Recommendation: Disposal must be made according to official regulations.

14 Transport information

- UN-Number
  - DOT, ADR, ADN, IMDG, IATA Void
- UN proper shipping name
  - DOT, ADR, ADN, IMDG, IATA Void
- Transport hazard class(es)
  - DOT, ADR, ADN, IMDG, IATA Void
  - Class Void
- Packing group
  - DOT, ADR, IMDG, IATA Void
- Environmental hazards: Not applicable.
- Special precautions for user Not applicable.
- Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code Not applicable.
- Transport/Additional information: -
- UN "Model Regulation": Void

15 Regulatory information

- Safety, health and environmental regulations/legislation specific for the substance or mixture
  - SARA Section 355 (extremely hazardous substances)
    - None of the ingredients is listed.
  - TSCA (Toxic Substances Control Act) None of the ingredients is listed.
  - Cancerogenity categories
  - TLV (Threshold Limit Value established by ACGIH)
    9005-25-8 Starch A4
    - GHS label elements Void
      - Hazard pictograms Void
      - Signal word Void
      - Hazard statements Void
  - Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

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.

(Contd. on page 7)
Trade name: Optosil P Plus

· Relevant phrases
  H304 May be fatal if swallowed and enters airways.

· Date of preparation / last revision 06/03/2017 / 2

· 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
  DOT: US Department of Transportation
  IATA: International Air Transport Association
  ACGIH: American Conference of Governmental Industrial Hygienists
  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)
  NFPA: National Fire Protection Association (USA)
  HMIS: Hazardous Materials Identification System (USA)
  PBT: Persistent, Bioaccumulative and Toxic
  vPvB: very Persistent and very Bioaccumulative
  OSHA: Occupational Safety & Health
  TLV: Threshold Limit Value
  PEL: Permissible Exposure Limit
  REL: Recommended Exposure Limit
  Asp. Tox. 1: Aspiration hazard – Category 1

USA