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

- **1.1 Product identifier**
  - Trade name: **Palavit 55 VS powder**

- **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
    Skin Sens. 1  H317  May cause an allergic skin reaction.

- **2.2 Label elements**
  - Labelling according to Regulation (EC) No 1272/2008
    The product is classified and labelled according to the CLP regulation.

  - **Hazard pictograms**
    GHS07

  - **Signal word** Warning

  - **Hazard-determining components of labelling:**
    dibenzoyl peroxide

  - **Hazard statements**
    H317  May cause an allergic skin reaction.

  - **Precautionary statements**
    P261  Avoid breathing dust/fume/gas/mist/vapours/spray.
    P280  Wear protective gloves/protective clothing/eye protection/face protection.
    P321  Specific treatment (see on this label).
    P363  Wash contaminated clothing before reuse.
    P333+P313  If skin irritation or rash occurs: Get medical advice/attention.
    P302+P352  IF ON SKIN: Wash with plenty of water.

- **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:** Product based on methacrylate copolymers

- **Dangerous components:**

<table>
<thead>
<tr>
<th>CAS</th>
<th>Substance</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>25086-15-1</td>
<td>Copolymersat</td>
<td>10-25%</td>
</tr>
<tr>
<td></td>
<td>Flam. Liq. 2, H225</td>
<td></td>
</tr>
<tr>
<td>94-36-0</td>
<td>5-Butylbarbitursäure mikronisiert</td>
<td>0-5%</td>
</tr>
<tr>
<td>EINECS: 202-327-6</td>
<td>Skin Irrit. 2; Eye Irrit. 2, H315; Eye Irrit. 2, H319</td>
<td></td>
</tr>
<tr>
<td>Reg.nr.: 01-2119511472-50</td>
<td>dibenzoyl peroxide</td>
<td>0-5%</td>
</tr>
<tr>
<td></td>
<td>Self-react. B, H241; Org. Perox. B, H241; Aquatic Acute 1, H400; Eye Irrit. 2, H319; Skin Sens. 1, H317</td>
<td></td>
</tr>
</tbody>
</table>

- **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 skin contact** The product is not skin irritating.

- **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.

#### 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** CO2, extinguishing powder or water jet. Fight larger fires with water jet or alcohol-resistant foam.

#### 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

Collect mechanically.

#### 6.4 Reference to other sections

No dangerous materials are released. See Section 8 for information on personal protection equipment.
SECTION 7: Handling and storage

7.1 Precautions for safe handling
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: Store cool (not above 25 °C).

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:
  The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

- DNELs

<table>
<thead>
<tr>
<th></th>
<th></th>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>94-36-0 dibenzoyl peroxide</td>
<td>1.65 mg/Kg (nd)</td>
<td>6.6 mg/Kg/d (nd)</td>
<td>11.75 mg/m3 (nd)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3.3 mg/Kg/d (nd)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>ge.pop., l.te, syst.</td>
<td>2.9 mg/m3 (nd)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- 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
    Wash hands during breaks and at the end of the work.
  - 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.
Trade name: Palavit 55 VS powder

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 neccessary
Body protection: Light weight protective clothing

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information
- Appearance: Powder
- Colour: According to product specification
- Smell: Odourless
- Odour threshold: Not determined.
- pH-value: Not applicable.

Change in condition
- Melting point/Melting range: Not determined
- Boiling point/Boiling range: Not determined

Flash point: Not applicable
Inflammability (solid, gaseous) Not determined.
Ignition temperature: 400.0 °C
Decomposition temperature: Not determined.

Self-inflammability: Product is not selfigniting.

Danger of explosion: Product is not explosive. However, formation of explosive powder/air mixtures is possible.

Critical values for explosion:
- Lower: Not determined.
- Upper: Not determined.

Steam pressure: Not applicable.

Density at 20 °C 0 g/cm³
- Relative density Not determined.
- Vapour density Not applicable.
- Evaporation rate Not applicable.

Solubility in / Miscibility with
- Water: Insoluble

Partition coefficient (n-octanol/water): Not determined.

Viscosity:
- dynamic: Not applicable.
- kinematic: Not applicable.
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.

SECTION 11: Toxicological information

- 11.1 Information on toxicological effects
  - Acute toxicity: Based on available data, the classification criteria are not met.
  - LD/LC50 values that are relevant for classification:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Oral LD50</th>
<th>Inhalative LC50/4 h</th>
</tr>
</thead>
<tbody>
<tr>
<td>94-36-0 dibenzoyl peroxide</td>
<td>5000 mg/kg (rat)</td>
<td>24300 mg/l (rat)</td>
</tr>
</tbody>
</table>

- 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: May cause an allergic skin reaction.
  - 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.
  - Aspiration hazard: Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

- 12.1 Toxicity
  - Aquatic toxicity:

<table>
<thead>
<tr>
<th>Substance</th>
<th>EC50/72h</th>
<th>EC50/48h</th>
<th>LC50/96h</th>
</tr>
</thead>
<tbody>
<tr>
<td>94-36-0 dibenzoyl peroxide</td>
<td>&gt;2 mg/l</td>
<td>&gt;2 mg/l</td>
<td>&gt;2 mg/l</td>
</tr>
</tbody>
</table>

- 12.2 Persistence and degradability: No further relevant information available.
**Trade name:** Palavit 55 VS powder

- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
  - **Additional ecological information:**
    - **General notes:**
      - Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system.
- **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**
    - Small quantities can be polymerized with the matching system component(s) and the cured solid material can be disposed of with the regular garbage. Larger quantities must be disposed of following the regulations of the local authorities.

  - **European waste catalogue**
    - 18 01 06 chemicals consisting of or containing dangerous substances
  - **Uncleaned packagings:**
    - **Recommendation:** Packaging can be reused or recycled after cleaning.

**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:**
  - **Marine pollutant:** No
- **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:** -

(Contd. on page 7)
### SECTION 15: Regulatory information

- **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.

- **Relevant phrases**
  - H225 Highly flammable liquid and vapour.
  - H241 Heating may cause a fire or explosion.
  - H315 Causes skin irritation.
  - H317 May cause an allergic skin reaction.
  - H319 Causes serious eye irritation.
  - H400 Very toxic to aquatic life.

- **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)
  - DNEL: Derived No-Effect Level (REACH)
  - LC50: Lethal concentration, 50 percent
  - LD50: Lethal dose, 50 percent
  - PBT: Persistent, Bioaccumulative and Toxic
  - vPvB: very Persistent and very Bioaccumulative
  - Flam. Liq. 2: Flammable liquids – Category 2
  - Self-react. B: Self-reactive substances and mixtures – Type B
  - Org. Perox. B: Organic peroxides – Type B
  - Skin Irrit. 2: Skin corrosion/irritation – Category 2
  - Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
  - Skin Sens. 1: Skin sensitisation – Category 1
  - Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1

*Data compared to the previous version altered.*