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

1.1 Product identifier

Trade name: Biodentine Pulver

Article number / formula: 246S

1.2 Relevant identified uses of the substance or mixture and uses advised against

No further relevant information available.

Application of the substance / the preparation: dental product

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier: SEPTODONT.
58 rue du Pont de Creteil
94100 Saint Maur des Fosses
France
Téléphone: +33(0)149767000
Fax: +33(0)148855401
msds@septodont.com
http://www.septodont.com

1.4 Emergency telephone number:

France (INRS 24h/24) - Tel : +33 (0)1 45 42 59 59
Ireland - Tel : 00 353 1 8092568 - 00 353 1 8379964 (24h/24) EU Tel: 112
Belgique - Tel : 32 070/245 245
UK : +44 (0)-870-190-6777 (CARECHEM24)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

The product is not classified according to the CLP regulation.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 Not classified as hazardous

Hazard pictograms Not classified as hazardous

Signal word Not classified as hazardous

Hazard statements Not classified as hazardous

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: Mixture: consisting of the following components.

Dangerous components: Not classified as hazardous

SVHC No

Additional information: For the wording of the listed risk phrases, refer to section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General information: No special measures required.

(Contd. on page 2)
**Trade name:** Biodentine Pulver

- **After excessive inhalation:** Provide fresh air; consult a doctor in case of medical 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 a 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 Suitable extinguishing agents:**
  - CO₂, powder or water spray. Fight larger fires with water spray 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.

**SECTION 6: Accidental release measures**

- **6.1 Personal precautions, protective equipment and emergency procedures:** Not required.
- **6.2 Environmental precautions:** Do not allow the product to enter sewers/surface water or ground water.
- **6.3 Methods and material for containment and cleaning up:** Pick up mechanically.
- **6.4 Reference to other sections:**
  - No dangerous substances are released.
  - See Section 7 for information on safe handling.
  - See Section 8 for information on personal protective 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**

- **Additional information about design of technical facilities:** No further data; see section 7.
- **8.1 Control parameters**
  - **Ingredients with limit values that require monitoring at the workplace:**
    - **CAS:** 471-34-1 calcium carbonate (50-100%)
    - **MAK (Switzerland):** Long-term value: 3 a mg/m³
**Safety data sheet**

According to 1907/2006/EC, Article 31

Printing date 02.12.2017  
Revision: 02.12.2017  
Version number 2

---

### Trade name: Biodentine Pulver

---

<table>
<thead>
<tr>
<th>CAS: 1314-23-4 zirconium dioxide (5-10%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>WEL (Great Britain)</strong></td>
</tr>
<tr>
<td>Short-term value: 10 mg/m³</td>
</tr>
<tr>
<td>Long-term value: 5 mg/m³</td>
</tr>
<tr>
<td>as Zr</td>
</tr>
<tr>
<td><strong>MAK (Switzerland)</strong></td>
</tr>
<tr>
<td>Long-term value: 5 mg/m³</td>
</tr>
<tr>
<td>als Zr berechnet</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAS: 1305-78-8 calcium oxide (&lt;0.5%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>WEL (Great Britain)</strong></td>
</tr>
<tr>
<td>Long-term value: 2 mg/m³</td>
</tr>
<tr>
<td><strong>JOELV (EU)</strong></td>
</tr>
<tr>
<td>Short-term value: 4 mg/m³</td>
</tr>
<tr>
<td>Long-term value: 1 mg/m³</td>
</tr>
<tr>
<td>Respirable fraction</td>
</tr>
<tr>
<td><strong>MAK (Switzerland)</strong></td>
</tr>
<tr>
<td>Short-term value: 2 mg/m³</td>
</tr>
<tr>
<td>Long-term value: 2 mg/m³</td>
</tr>
<tr>
<td>als Zr berechnet</td>
</tr>
</tbody>
</table>

---

- **Additional information:**
  The most current valid lists have been used as a basis for the production of this document.

- **8.2 Exposure controls**
  - **Personal protective equipment:**
    - **General protective and hygienic measures:**
      The usual precautionary measures are to be adhered to when handling chemicals.
    - **Respiratory protection:** Not required.
    - **Protection of hands:** Not required.
    - **Gloves material:**
    - **Eye protection:** Not required.

---

**SECTION 9: Physical and chemical properties**

- **9.1 Information on basic physical and chemical properties**
  - **General Information**
    - **Appearance:**
      - **Form:** Powder
      - **Colour:** Light grey, White
    - **Odour:** Characteristic
    - **Odour threshold:** Not determined.
  - **pH-value:** Not applicable.
  - **Change in condition**
    - Melting point/freezing point: Undetermined.
    - Initial boiling point and boiling range: Undetermined.
  - **Flash point:** Not applicable.
  - **Flammability (solid, gas):** Not determined.
  - **Ignition temperature:** Not applicable.
  - **Decomposition temperature:** Not determined.
  - **Auto-ignition temperature:** Product is not self igniting.
  - **Explosive properties:** Product does not present an explosion hazard.

---
Trade name: Biodentine Pulver

- Explosion limits:
  - Lower: Not determined.
  - Upper: Not determined.

- Vapour pressure: Not applicable.
- Density: Not determined.
  - Relative density: Not determined.
  - Vapour density: Not applicable.
  - Evaporation rate: Not applicable.

- Solubility in / Miscibility with water: Fully soluble.
- Segregation coefficient (n-octanol/water): Not determined.
- Viscosity:
  - Dynamic: Not applicable.
  - Kinematic: Not applicable.
- Solvent content:
  - VOC (EC) 0,00 %
- 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
  - 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 toxicological effects
  - Acute toxicity: Based on available data, the classification criteria are not met.
  - Primary irritant effect:
    - On the skin: Based on available data, the classification criteria are not met.
    - On the eyes: Based on available data, the classification criteria are not met.
  - Respiratory or skin sensitization: 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.
  - 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.
- 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.
- 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 of with household waste.
- Uncleaned packaging:
  - Recommendation: Disposal must be made according to official regulations.
- Recommended cleansing agents: Water, if necessary together with cleansing agents.

SECTION 14: Transport information

- 14.1 UN-Number
  - ADR, ADN, IMDG, IATA Not classified as hazardous for transport
- 14.2 UN proper shipping name
  - ADR, ADN, IMDG, IATA Not classified as hazardous for transport
- 14.3 Transport hazard class(es)
  - ADR, ADN, IMDG, IATA Not classified as hazardous for transport
- 14.4 Packing group
  - ADR, IMDG, IATA Not classified as hazardous for transport
- 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.
- UN "Model Regulation": Not classified as hazardous for transport
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

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.

- Abbreviations and acronyms:
  - RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
  - ICAO: International Civil Aviation Organisation
  - 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)
  - VOC: Volatile Organic Compounds (USA, EU)
  - PBT: Persistent, Bioaccumulative and Toxic
  - SVHC: Substances of Very High Concern
  - vPvB: very Persistent and very Bioaccumulative