



**Safety data sheet**  
**according to 1907/2006/EC, Article 31**

Printing date 13.06.2017

Version number 2

Revision: 13.06.2017

**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**  
-----
  - **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** *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.*

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- **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:**  
CO<sub>2</sub>, 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:** No special measures required.
- **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/m<sup>3</sup>

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**CAS: 1314-23-4 zirconium dioxide (5-10%)**

|                     |   |
|---------------------|---|
| WEL (Great Britain) | Short-term value: 10 mg/m <sup>3</sup><br>Long-term value: 5 mg/m <sup>3</sup><br>as Zr |
| MAK (Switzerland)   | Long-term value: 5e mg/m <sup>3</sup><br>als Zr berechnet                               |

**CAS: 1305-78-8 calcium oxide (<0.5%)**

|                     |  |
|---------------------|--|
| WEL (Great Britain) | Long-term value: 2 mg/m <sup>3</sup>   |
| IOELV (EU)          | Short-term value: 4 mg/m <sup>3</sup><br>Long-term value: 1 mg/m <sup>3</sup><br>Respirable fraction |
| MAK (Switzerland)   | Short-term value: 2 e mg/m <sup>3</sup><br>Long-term value: 2 e mg/m <sup>3</sup><br>SSc;            |

**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:**

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

**Gloves material :**

The selection of suitable gloves does not depend only on the material, but also on further marks of quality which may vary 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 before use.

**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.

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|  |  |
|--|--|
| · <b>Ignition temperature:</b>   | Not applicable.  |
| · <b>Decomposition temperature:</b>  | Not determined.  |
| · <b>Auto-ignition temperature:</b>  | Product is not self igniting.  |
| · <b>Explosive properties:</b>   | Product does not present an explosion hazard.                            |
| · <b>Explosion limits:</b><br><b>Lower:</b><br><b>Upper:</b>   | Not determined.<br>Not determined.                                       |
| · <b>Vapour pressure:</b>  | Not applicable.  |
| · <b>Density:</b><br>· <b>Relative density :</b><br>· <b>Vapour density :</b><br>· <b>Evaporation rate :</b> | Not determined.<br>Not determined.<br>Not applicable.<br>Not applicable. |
| · <b>Solubility in / Miscibility with water:</b>   | Fully soluble.   |
| · <b>Segregation coefficient (n-octanol/water):</b>  | Not determined.  |
| · <b>Viscosity:</b><br><b>Dynamic:</b><br><b>Kinematic:</b>  | Not applicable.<br>Not applicable.                                       |
| · <b>Solvent content:</b><br><b>VOC (EC)</b>   | 0,00 %   |
| · <b>9.2 Other information :</b>   | 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.

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- **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:** Generally not hazardous for water.
- **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**

- |  |   |
|--|---|
| · <b>14.1 UN-Number</b>  |   |
| · <b>ADR, ADN, IMDG, IATA</b>  | Not classified as hazardous for transport |
| · <b>14.2 UN proper shipping name</b>  |   |
| · <b>ADR, ADN, IMDG, IATA</b>  | Not classified as hazardous for transport |
| · <b>14.3 Transport hazard class(es)</b>   |   |
| · <b>ADR, ADN, IMDG, IATA</b>  |   |
| · <b>Class</b>   | Not classified as hazardous for transport |
| · <b>14.4 Packing group</b>  |   |
| · <b>ADR, IMDG, IATA</b>   | Not classified as hazardous for transport |
| · <b>14.5 Environmental hazards:</b>   |   |
| · <b>Marine pollutant:</b>   | No  |
| · <b>14.6 Special precautions for user</b>                                       | Not applicable.                           |
| · <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b> | Not applicable.                           |
| · <b>UN "Model Regulation":</b>  | Not classified as hazardous for transport |

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**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*

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