



Safety data sheet

according to 1907/2006/EC, Article 31 & 2020/878/EC

Printing date 25.09.2023

Version number 3 (replaces version 2)

Revision: 25.09.2023

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

· 1.1 Product identifier

· Trade name: **BIODENTINE POWDER**

· 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 : Medical device for dental use

· 1.3 Details of the supplier of the safety data sheet

· Manufacturer/Supplier:

SEPTODONT

58 rue du Pont de Créteil

94100 Saint Maur des Fosses

France

Téléphone: +33(0)149767000

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

Belgium - Brüssel: +32 070/245 245

UK : Call NHS 999 in a medical emergency. If you urgently need medical help or advice but it's not a life-threatening situation, call 111 (24/7). The NHS 111 number is currently only available in certain areas. If you're outside of these areas, you should call NHS Direct on 0845 4647

Swiss Toxicological Information Centre (Zürich) : +41 44 251 51 51 / www.toxi.ch.

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 GB CLP regulation.

· Additional information:

This Regulation shall not apply to substances and mixtures in the following finished forms intended for the end user

(a) medicinal products, as defined in Directive 2001/83/EC

(b) medical devices, as defined in Directives 90/385/EEC and 93/42/EEC, which are invasive or used in direct physical contact with the human body, and in Directive 98/79/EC;

· 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

The mixture shall not contain substances listed in accordance with Article 59(1) R.E.A.C.H as having endocrine disrupting properties, or be recognised as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation

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(EU) 2018/605 in a concentration equal to or greater than 0.1%.

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

· **3.2 Mixtures**

· **Description:** Preparation: composed of the substances listed below.

· **Dangerous components:** Not classified as hazardous

· **SVHC -**

· **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.

· **After 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.

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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

- **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
 - CAS: 1314-23-4 zirconium oxide (5-10%)**
WEL (Great Britain) Short-term value: 10 mg/m³
Long-term value: 5 mg/m³
as Zr
 - MAK (Switzerland) Short-term value: 10e mg/m³
Long-term value: 5e mg/m³
als Zr berechnet
- **Additional information**:
The most current valid lists have been used as a basis for the production of this document.
- **8.2 Exposure controls**
- **Appropriate engineering controls** No further data; see section 7.
- **Individual protection measures, such as personal protective equipment**
- **General protective and hygienic measures**:
The usual precautionary measures are to be adhered to when handling chemicals.
- **Respiratory protection**: Not required.
- **Hand protection** Not required.
- **Gloves material** : -
- **Eye/face protection** Not required.

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Physical state** Solid
- **Form**: Powder

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· Colour:	Light grey White
· Odour:	Characteristic
· Odour threshold:	Not determined.
· Melting point/freezing point:	Undetermined.
· Boiling point or initial boiling point and boiling range	Undetermined.
· Flammability	Not determined.
· Lower and upper explosion limit	
· Lower:	Not determined.
· Upper:	Not determined.
· Flash point:	Not applicable.
· Auto-ignition temperature:	Not applicable.
· Decomposition temperature:	Not determined.
· pH	Not applicable.
· Viscosity:	
· Kinematic viscosity	Not applicable.
· Kinematic:	Not applicable.
· Dynamic:	Not applicable.
· Solubility	
· water:	Fully soluble.
· Partition coefficient n-octanol/water (log value)	Not determined.
· Vapour pressure:	Not applicable.
· Density and/or relative density	
· Density:	Not determined.
· Relative density :	Not determined.
· Vapour density :	Not applicable.
· Particle characteristics	
See section 3.	
· 9.2 Other information :	
· Important information on protection of health and environment, and on safety.	
· Ignition temperature:	Product is not self igniting.
· Explosive properties:	Product does not present an explosion hazard.
· Solvent content:	
· VOC (EC)	0,00 %
· Change in condition	
· Evaporation rate :	Not applicable.
· Information with regard to physical hazard classes	
· Explosives	Not classified as hazardous
· Flammable gases	Not classified as hazardous
· Aerosols	Not classified as hazardous
· Oxidising gases	Not classified as hazardous
· Gases under pressure	Not classified as hazardous

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· Flammable liquids	Not classified as hazardous
· Flammable solids	Not classified as hazardous
· Self-reactive substances and mixtures	Not classified as hazardous
· Pyrophoric liquids	Not classified as hazardous
· Pyrophoric solids	Not classified as hazardous
· Self-heating substances and mixtures	Not classified as hazardous
· Substances and mixtures, which emit flammable gases in contact with water	Not classified as hazardous
· Oxidising liquids	Not classified as hazardous
· Oxidising solids	Not classified as hazardous
· Organic peroxides	Not classified as hazardous
· Corrosive to metals	Not classified as hazardous
· Desensitised explosives	Not classified as hazardous

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 hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **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.
- **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.
- **11.2 Information on other hazards**
- **Endocrine disrupting properties**

None of the ingredients is listed.

SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.

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- **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 Endocrine disrupting properties** For information on endocrine disrupting properties see section 11.
- **12.7 Other adverse effects** : 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.

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 or ID number**
- **DOT, ADR, ADN, IMDG, IATA** none
- **14.2 UN proper shipping name**
- **ADR, ADN, IMDG, IATA** none
- **14.3 Transport hazard class(es)**
- **ADR, ADN, IMDG, IATA**
- **Class** none
- **14.4 Packing group**
- **ADR, IMDG, IATA** none
- **14.5 Environmental hazards:**
- **Marine pollutant:** No
- **14.6 Special precautions for user** Not applicable.
- **14.7 Maritime transport in bulk according to IMO instruments** Not applicable.
- **UN "Model Regulation":** none

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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.
 - **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**
None of the ingredients is listed.
 - **REGULATION (EU) 2019/1148**
 - **Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**
None of the ingredients is listed.
 - **Annex II - REPORTABLE EXPLOSIVES PRECURSORS**
None of the ingredients is listed.
 - **Regulation (EC) No 273/2004 on drug precursors**
None of the ingredients is listed.
 - **Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**
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.

Classification in accordance with Delegated Regulation (EU) 2022/692 of 16 February 2022 adapting to technical and scientific progress GB CLP for the 18th time and amending table 3 of Annex VI part 3 of Regulation (EC) 1272/2008.

This Safety Data Sheet is in compliance with Regulation (EC) No 1907/2006, Article 31 as amended by Regulation (EU) 2020/878.

- **Date of previous version:** 24.09.2023
- **Version number of previous version:** 2
- **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 relatif au transport international 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
 - 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)

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PBT: Persistent, Bioaccumulative and Toxic

SVHC: Substances of Very High Concern

vPvB: very Persistent and very Bioaccumulative

— GB —