

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

Printing date 23.09.2014

Version number 2

Revision: 23.09.2014

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

- **1.1 Product identifier**
- **Trade name:** *Biodentine liquid*
- **Article number / formula:** 245S
- **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 impression material*
- **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 (ORFILA 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

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008 :**



Eye Irrit. 2 H319 Causes serious eye irritation.

- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC :** *Not applicable.*
- **Information concerning particular hazards for human and environment:**
The product has to be labelled in the latest valid version according to the calculation procedure of the "General Classification guideline for preparations of the EU".
- **Classification system:**
The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

- **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**



- **Signal word** *Warning*
- **Hazard statements**
H319 Causes serious eye irritation.

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Trade name: Biodentine liquid



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- **Precautionary statements**
 - P280 Wear protective gloves/protective clothing/eye protection/face protection.
 - P264 Wash hands thoroughly after handling.
 - P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- **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:**

10035-04-8	Chlorure de calcium dihydraté	 Xi R36	10-25%
		 Eye Irrit. 2, H319	

- **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**
- **After excessive inhalation:** Supply fresh air; consult a doctor in case of complaints.
- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:**
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- **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:** Dilute with plenty of water.
- **6.3 Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **6.4 Reference to other sections :**
See Section 7 for information on safe handling.
See Section 8 for information on personal protective equipment.

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See Section 13 for disposal information.

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SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** : No special precautions are necessary if used correctly.
- **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**: Keep container tightly sealed.
- **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**:
The product does not contain any significant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information**:
As a basis for the production of this document, the most current valid lists were used.
- **8.2 Exposure controls**
- **Personal protective equipment**:
- **General protective and hygienic measures**:
Keep away from food, beverages and petfood.
Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of work.
Avoid all contact with the eyes.
Avoid contact with the eyes and skin.
- **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 only depend 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**:



Tightly sealed goggles

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SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

· Form:	Liquid
· Colour:	Colourless
· Odour:	Characteristic
· Odour threshold:	Not determined.

· **pH-value at 20 °C:** 3.5-5

· **Change in condition**

· Melting point/Melting range:	Undetermined.
· Boiling point/Boiling range:	Undetermined.

· **Flash point:** Not applicable.

· **Flammability (solid, gaseous):** Not applicable.

· **Ignition temperature:** Not applicable.

· **Decomposition temperature:** Not determined.

· **Self-igniting:** Product is not self igniting.

· **Danger of explosion:** Product does not present an explosion hazard.

· **Explosion limits:**

· Lower:	Not determined.
· Upper:	Not determined.

· **Vapour pressure at 20 °C:** 23 hPa

· **Density at 20 °C:** 1.18-1.22 g/cm³

· **Relative density :** Not determined.

· **Vapour density :** Not determined.

· **Evaporation rate :** Not determined.

· **Solubility in / Miscibility with water:** Fully miscible.

· **Segregation coefficient (n-octanol/water):** Not determined.

· **Viscosity:**

· Dynamic:	Not determined.
· Kinematic:	Not determined.

· **9.2 Other information :** No further relevant information available.

SECTION 10: Stability and reactivity

· **10.1 Reactivity**

· **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.

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· **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

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SECTION 11: Toxicological information

· **11.1 Information on toxicological effects**

- **Acute toxicity:**
- **Primary irritant effect:**
- **On the skin:** No irritant effect.
- **On the eyes:** No irritant effect.
- **Sensitisation:** No sensitising effects known.
- **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.

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 :**



Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

- **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

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- | | |
|---|--|
| · 14.3 Transport hazard class(es)
· ADR, ADN, IMDG, IATA
· Class | <i>Not classified as hazardous for transport</i> |
| · 14.4 Packing group
· ADR, IMDG, IATA | <i>Not classified as hazardous for transport</i> |
| · 14.5 Environmental hazards:
· Marine pollutant: | <i>No</i> |
| · 14.6 Special precautions for user | <i>Not applicable.</i> |
| · 14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | <i>Not applicable.</i> |
| · UN "Model Regulation": | <i>-</i> |

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
No further relevant information available.
- **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.

- **Relevant phrases**
H319 Causes serious eye irritation.
R36 Irritating to eyes.
- **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)
Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2

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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 (ORFILA 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

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.
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC :** Not applicable.
- **Information concerning particular hazards for human and environment:**
The product does not have to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.
- **Classification system:**
The classification is according to the latest editions of the EU-lists, and extended by company and literature data.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** Not classified as hazardous for transport
- **Hazard pictograms** Not classified as hazardous for transport
- **Signal word** Not classified as hazardous for transport
- **Hazard statements** Not classified as hazardous for transport
- **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 for transport

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· **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 excessive inhalation:** Supply fresh air; consult a doctor in case of 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:** 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.

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· 8.1 Control parameters

· Ingredients with limit values that require monitoring at the workplace:

471-34-1 calcium carbonate (50-100%)

MAK (Switzerland) Long-term value: 3 a mg/m³

1314-23-4 zirconium dioxide (2.5-10%)

WEL (Great Britain) Short-term value: 10 mg/m³
Long-term value: 5 mg/m³
as Zr

MAK (Switzerland) Long-term value: 5e mg/m³
als Zr berechnet

· Additional information:

As a basis for the production of this document, the most current valid lists were used.

· 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 only depend 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/Melting range: Undetermined.

Boiling point/Boiling range: Undetermined.

· Flash point: Not applicable.

· Flammability (solid, gaseous): Not determined.

· Ignition temperature: Not applicable.

· Decomposition temperature: Not determined.

· Self-igniting: Product is not self igniting.

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· Danger of explosion:	<i>Product does not present an explosion hazard.</i>
· Explosion limits:	
Lower:	<i>Not determined.</i>
Upper:	<i>Not determined.</i>
· Vapour pressure:	<i>Not applicable.</i>
· Density:	<i>Not determined.</i>
· Relative density :	<i>Not determined.</i>
· Vapour density :	<i>Not applicable.</i>
· Evaporation rate :	<i>Not applicable.</i>
· Solubility in / Miscibility with water:	<i>Soluble.</i>
· Segregation coefficient (n-octanol/water):	<i>Not determined.</i>
· Viscosity:	
Dynamic:	<i>Not applicable.</i>
Kinematic:	<i>Not applicable.</i>
· Solvent content:	
VOC (EC)	<i>0,00 %</i>
· 9.2 Other information :	<i>No further relevant information available.</i>

SECTION 10: Stability and reactivity

- **10.1 Reactivity**
- **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:**
- **Primary irritant effect:**
- **On the skin:** *No irritant effect.*
- **On the eyes:** *No irritant effect.*
- **Sensitisation:** *No sensitising effects known.*
- **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 to our experience and the information provided to us.

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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

- | | |
|---|---|
| · 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 | |
| · Class | 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 MARPOL73/78 and the IBC Code | Not applicable. |
| · UN "Model Regulation": | - |

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
No further relevant information available.

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· 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)

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