

Printing date 02.12.2017 Version number 3 Revision: 02.12.2017

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 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
- Additional information:

EUH210 Safety data sheet available on request.

- 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
- · Other components:

CAS: 10035-04-8 calcium chloride, dihydrate

Description (1984) Eye Irrit. 2, H319

· SVHC No

(Contd. on page 2)



Printing date 02.12.2017 Version number 3 Revision: 02.12.2017

Trade name: Biodentine liquid

(Contd. of page 1)

• 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: 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. 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.

Do not allow the product to enter sewers/ surface water or ground 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.

See Section 13 for disposal information.

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.

GB





Printing date 02.12.2017 Version number 3 Revision: 02.12.2017

Trade name: Biodentine liquid

(Contd. of page 2)

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 signifiant quantities of materials with critical values that have to be monitored at the workplace.

· 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:

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: Not required.
- · Gloves material : -
- Eye protection: Not required.

SECTION 9: Physical and chemical properties

SECTION 7. Thysical and chemic	X X
9.1 Information on basic physical and ch General Information	emical properties
· General Injormation · Appearance:	
Form:	Liquid
Colour:	Colourless
· Odour:	Characteristic
· Odour threshold:	Not determined.
pH-value at 20 °C:	3.5-5
· Change in condition	
Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	Undetermined.
· Flash point:	Not applicable.
Flammability (solid, gas):	Not applicable.
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.
Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
· Vapour pressure at 20 °C:	23 hPa
	(C44





Printing date 02.12.2017 Version number 3 Revision: 02.12.2017

Trade name: Biodentine liquid

(Contd. of page 3)

Density at 20 °C:
 Relative density:
 Vapour density:
 Evaporation rate:

1.18-1.22 g/cm³
Not determined.
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 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.

(Contd. on page 5)





Printing date 02.12.2017 Version number 3 Revision: 02.12.2017

Trade name: Biodentine liquid

(Contd. of page 4)

- · 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.
- European waste catalogue

HP 4 Irritant - skin irritation and eye damage

- · Uncleaned packaging:
- · Recommendation: Disposal must be made according to official regulations.
- · Recommended cleansing agents: Water, if necessary together with cleansing agents.

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, IMDĞ, 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 Ann	ex 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.

(Contd. on page 6)





Printing date 02.12.2017 Version number 3 Revision: 02.12.2017

Trade name: Biodentine liquid

(Contd. of page 5)

· 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.

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)

PBT: Persistent, Bioaccumulative and Toxic SVHC: Substances of Very High Concern

vPvB: very Persistent and very Bioaccumulative





Printing date 02.12.2017 Version number 2 Revision: 02.12.2017

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.

(Contd. on page 2)





Printing date 02.12.2017 Version number 2 Revision: 02.12.2017

Trade name: Biodentine Pulver

(Contd. of page 1)

- 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

(Contd. on page 3)





Printing date 02.12.2017 Version number 2 Revision: 02.12.2017

Trade name: Biodentine Pulver

CAS: 1314-23-4 zirc	(Contd. of page 2) onium dioxide (5-10%)
	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
CAS: 1305-78-8 calc	ium oxide (<0.5%)
WEL (Great Britain)	Long-term value: 2 mg/m³
IOELV (EU)	Short-term value: 4 mg/m³ Long-term value: 1 mg/m³ Respirable fraction
MAK (Switzerland)	Short-term value: 2 e mg/m³ Long-term value: 2 e mg/m³ 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: Not required.
- · Gloves material : -
- Eye protection: Not required.

OP	CTI	$\mathbf{O} \mathbf{A} T$	0. DI	maigal	CHARLE	ahamiaal	nronerties

9.1 Information on basic physical and ch	emical properties
· General Information	
· Appearance:	D. I
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.

(Contd. on page 4)



Printing date 02.12.2017 Version number 2 Revision: 02.12.2017

Trade name: Biodentine Pulver

		(Contd. of page
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/v	vater): 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.

GB -





Printing date 02.12.2017 Version number 2 Revision: 02.12.2017

Trade name: Biodentine Pulver

(Contd. of page 4)

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

- · 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.

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 Ann	ex II of
Marpol and the IBC Code	Not applicable.
UN "Model Regulation":	Not classified as hazardous for transport

GB -





Printing date 02.12.2017 Version number 2 Revision: 02.12.2017

Trade name: Biodentine Pulver

(Contd. of page 5)

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

GB