



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

Printing date 10.09.2019

Version number 1

Revision: 10.09.2019

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

- **1.1 Product identifier**
- **Trade name: Bioroot 2.0**
- **Article number / formula: PA1704**
- **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 : 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

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008 :**
Aquatic Chronic 4 H413 May cause long lasting harmful effects to aquatic life.
- **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** Not classified as hazardous
- **Signal word** Not classified as hazardous
- **Hazard statements**
H413 May cause long lasting harmful effects to aquatic life.
- **Precautionary statements**
P273 Avoid release to the environment.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
- **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

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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 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:** Do not induce vomiting; call for medical help immediately.
- **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:** Use fire extinguishing methods suitable to surrounding conditions.
- **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 product to reach sewage system or any water course.
Inform respective authorities in case of seepage into water course or sewage system.
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 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.

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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: 1314-23-4 zirconium oxide (25-50%)

WEL (Great Britain)	Short-term value: 10 mg/m ³ Long-term value: 5 mg/m ³ as Zr
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MAK (Switzerland)	Long-term value: 5e mg/m ³ als Zr berechnet
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CAS: 57-55-6 Propylene glycol (25-50%)

WEL (Great Britain)	Long-term value: 474* 10** mg/m ³ , 150* ppm *total vapour and particulates **particulates
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CAS: 471-34-1 calcium carbonate (<5%)

MAK (Switzerland)	Long-term value: 3 a mg/m ³
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· **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:** Goggles recommended during refilling

SECTION 9: Physical and chemical properties

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

· **General Information**

· **Appearance:**

Form:	Pasty
Colour:	According to product specification
Odour:	Characteristic
Odour threshold:	Not determined.

pH-value:	Not determined.
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· **Change in condition**

Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	Undetermined.

Flash point:	>100 °C
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Flammability (solid, gas):	Not applicable.
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Ignition temperature:	371 °C
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Decomposition temperature:	Not determined.
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- **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:** *Not determined.*
- **Density:** *Not determined.*
- **Relative density :** *Not determined.*
- **Vapour density :** *Not determined.*
- **Evaporation rate :** *Not determined.*
- **Solubility in / Miscibility with water:** *Not miscible or difficult to mix.*
- **Segregation coefficient (n-octanol/water):** *Not determined.*
- **Viscosity:**
 - Dynamic: Not determined.*
 - Kinematic: Not determined.*
- **Solvent content:**
 - COV (CH) : 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.*

· **LD/LC50 values relevant for classification:**

CAS: 57-55-6 Propylene glycol

Oral	LD50	2,000 mg/kg (rat)
Dermal	LD50	20,800 mg/kg (rabbit)

CAS: 471-34-1 calcium carbonate

Oral	LD50	6,450 mg/kg (rat)
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CAS: 60908-77-2 isohexadecane

Inhalative	LC50/4 h	11 mg/l (ATE)
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- **Primary irritant effect:**
- **On the skin:** *Based on available data, the classification criteria are not met.*

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- **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:**

CAS: 57-55-6 Propylene glycol

LC50 48h	>900 mg/l (fish)
LC50 96h	40,613 mg/l (Oncorhynchus mykiss)
NOEC	>20,000 mg/l (Algae)
EC50 96h	19,000 mg/l (Algae)

- **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.

· **European waste catalogue**

HPI4 | Ecotoxic

- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

- **14.1 UN-Number**
- **ADR, ADN, IMDG, IATA** Not classified as hazardous for transport

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· 14.2 UN proper shipping name · ADR, ADN, IMDG, IATA	<i>Not classified as hazardous for transport</i>
· 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:	<i>Not applicable.</i>
· 14.6 Special precautions for user	<i>Not applicable.</i>
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	<i>Not applicable.</i>
· UN "Model Regulation":	<i>Not classified as hazardous for transport</i>

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.
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3
- **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 according to Regulation (EC) No 1272/2008**

<i>Hazardous to the aquatic environment - long-term (chronic) aquatic hazard</i>	<i>The classification of the mixture is generally based on the calculation method using substance data according to Regulation (EC) No 1272/2008.</i>
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· **Abbreviations and acronyms:**

- 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)*
- VOCV: Lenkungsabgabe auf flüchtigen organischen Verbindungen, Schweiz (Swiss Ordinance on volatile organic compounds)*
- LC50: Lethal concentration, 50 percent*
- LD50: Lethal dose, 50 percent*
- PBT: Persistent, Bioaccumulative and Toxic*
- SVHC: Substances of Very High Concern*
- vPvB: very Persistent and very Bioaccumulative*
- Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4*