



Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 15.09.2021

Version number 2

Revision: 15.09.2021

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

· 1.1 Product identifier

· Trade name: **SEPTANEST WITH ADRENALINE 1:100 000**

· 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

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

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.

· Additional information:

Substances and mixtures are exempted from the requirements of the CLP Regulation as a whole (CLP Article 1):

- medicinal products, as defined in Directive 2001/83/EC

- medical devices as defined in Directive 90/385/EEC (active implantable medical devices) and 93/42/EEC (medical devices in general), which are invasive or used in direct physical contact with the human body, and in vitro diagnostic medical devices (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

· Additional information:

EUH210 Safety data sheet available on request.

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- **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:**
- | | | |
|-------------------|-------------------------|-----|
| CAS: 23964-57-0 | Articaine hydrochloride | <5% |
| EINECS: 245-957-7 | Aquatic Chronic 3, H412 | |
- **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:**
Immediately remove any clothing soiled by the product.
In case of irregular breathing or respiratory arrest provide artificial respiration.
- **After inhalation:**
In case of unconsciousness place patient in a stable laying down side position for transportation.
- **After skin contact:** Immediately wash with water and soap and rinse thoroughly.
- **After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.
- **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:**
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 product to reach sewage system or any water course.
Inform respective authorities in case of seepage into water course or sewage system.
Dilute with plenty of water.

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- 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).
Dispose contaminated material as waste according to item 13.
Ensure adequate ventilation.
- **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 :**
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
- **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:** Protect from frost.
- **7.3 Specific end use(s) :** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **8.1 Control parameters**
- **Additional information about design of technical facilities:** No further data; see section 7.
- **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:**
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.
- **Protection of hands:**



Protective gloves

- **Gloves material :** Butyl rubber, BR

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- **Eye protection:** Goggles recommended during refilling
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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:** 5.3

· Change in condition

· Melting point/freezing point:	Undetermined.
· Initial boiling point and boiling range:	100 °C

· **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

· **Density:** Not determined.

· **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.

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- **Solvent content:**
 - **COV (CH) :** 0.00 %
 - **9.2 Other information :** No further relevant information available.
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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.
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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: 51-42-3 epinephrine hydrogen tartrate
Oral LD50 5 mg/kg (ATE)
 - **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.
 - **Additional toxicological information:**
 - **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.
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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.

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- **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.
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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.
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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 Marpol and the IBC Code** Not applicable.
- **UN "Model Regulation":** 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.
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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**
H412 Harmful to aquatic life with long lasting effects.
 - **Abbreviations and acronyms:**
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
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 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3
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