



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 1:200 000**

· 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.

(Contd. on page 2)



Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 15.09.2021

Version number 2

Revision: 15.09.2021

Trade name: SEPTANEST WITH ADRENALINE 1:200 000

(Contd. of page 1)

- **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**
- **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.
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.

(Contd. on page 3)



Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 15.09.2021

Version number 2

Revision: 15.09.2021

Trade name: SEPTANEST WITH ADRENALINE 1:200 000

(Contd. of page 2)

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:** 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:** Wash hands before breaks and at the end of work.
 - **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:** Liquid
- **Colour:** According to product specification
- **Odour:** Characteristic
- **Odour threshold:** Not determined.

- **pH-value at 20 °C:** 5.3

- **Change in condition**
- **Melting point/freezing point:** Undetermined.

(Contd. on page 4)



Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 15.09.2021

Version number 2

Revision: 15.09.2021

Trade name: SEPTANEST WITH ADRENALINE 1:200 000

(Contd. of page 3)

- 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.
 - **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.

(Contd. on page 5)



Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 15.09.2021

Version number 2

Revision: 15.09.2021

Trade name: SEPTANEST WITH ADRENALINE 1:200 000

(Contd. of page 4)

- **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.
 - **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.
-

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 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 :**



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.

(Contd. on page 6)



Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 15.09.2021

Version number 2

Revision: 15.09.2021

Trade name: SEPTANEST WITH ADRENALINE 1:200 000

(Contd. of page 5)

- **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 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.
 - **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**
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)
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
-