

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

Printing date 09.04.2018

Version number 3

Revision: 09.04.2018

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****Supplier:**

IVOCLAR VIVADENT LTD.

12 Omega Street, Rosedale, Auckland 0632, New Zealand

PO Box 303011, North Harbour, Auckland 0751, New Zealand

Telephone: +649 914 9999

Fax: +649 914 9990

orders.nz@ivoclarvivadent.com

<http://www.ivoclarvivadent.co.nz>**· 1.4 Emergency telephone number:**

0800 764 766 (National Poisons Centre)

SECTION 2: Hazards identification**· 2.1 Classification of the substance or mixture****· Classification according to Regulation (EC) No 1272/2008 :**

GHS06

Acute Tox. 3 H301 Toxic if swallowed.

· 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

GHS06

· Signal word Danger**· Hazard-determining components of labelling:**

chlorhydrate d'articaïne

epinephrine hydrogen tartrate

· Hazard statements

H301 Toxic if swallowed.

· Precautionary statements

P264 Wash hands thoroughly after handling.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/ doctor.

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- P330 Rinse mouth.
 P405 Store locked up.
 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:**

CAS: 23964-57-0 EINECS: 245-957-7	chlorhydrate d'articaïne ⚠ Acute Tox. 4, H302; Acute Tox. 4, H332	<5%
CAS: 51-42-3 EINECS: 200-097-1 RTECS: DO 3500000	epinephrine hydrogen tartrate ⚠ Acute Tox. 2, H300; ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	≤2.5%

- **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 excessive 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.

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· **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).
- 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

- **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:**

- 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.

· **Respiratory protection:**



In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

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· **Protection of hands:**



Protective gloves

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

· **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.

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity**
Toxic if swallowed.

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

CAS: 23964-57-0 chlorhydrate d'articaine

Oral	LD50	500 mg/kg (ATE)
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Inhalative	LC50/4 h	11 mg/l (ATE)
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CAS: 51-42-3 epinephrine hydrogen tartrate

Oral	LD50	5 mg/kg (ATE)
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- **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.
- **Additional ecological information:**
- **General notes:**
Water hazard class 3 (German Regulation) (Self-assessment): extremely hazardous for water
Do not allow product to reach ground water, water course or sewage system, even in small quantities.
Danger to drinking water if even extremely small quantities leak into the ground.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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· **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.

· **European waste catalogue**

HP 6 Acute Toxicity

· **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 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.

· **Seveso category H2 ACUTE TOXIC**

· **Qualifying quantity (tonnes) for the application of lower-tier requirements** 50 t

· **Qualifying quantity (tonnes) for the application of upper-tier requirements** 200 t

· **REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction:** 3

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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.

· **Relevant phrases**

- H300 Fatal if swallowed.
- H302 Harmful if swallowed.
- H315 Causes skin irritation.
- H319 Causes serious eye irritation.
- H332 Harmful if inhaled.
- H335 May cause respiratory irritation.

· **Classification according to Regulation (EC) No 1272/2008**

Acute toxicity - oral

The classification of the mixture is generally based on the calculation method using substance data according to Regulation (EC) No 1272/2008.

· **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)
- 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
- Acute Tox. 2: Acute toxicity – Category 2
- Acute Tox. 3: Acute toxicity – Category 3
- Acute Tox. 4: Acute toxicity – Category 4
- Skin Irrit. 2: Skin corrosion/irritation – Category 2
- Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
- STOT SE 3: Specific target organ toxicity (single exposure) – Category 3