

Material Safety Data Sheet Cover-Sheet – This page provides additional New Zealand specific information for this product and must be read in conjunction with the Safety Data Sheet (SDS) attached

Product Name: SEPTANEST

Manufacturer: Septodont

SDS Expiry: 15 November 2024

Supplier Details: Henry Schein New Zealand
243-249 Bush Road, Rosedale, Auckland, 0632
PO Box 101 140, North Shore, Auckland 0745
Ph. 0800 808 855
www.henryschein.co.nz

Emergency Contacts: Poisons/Hazardous Chemical Info Centre –
0800POISON/0800764766 (24 Hours)
Phone 111 for Fire, Ambulance or Police

HSNO Class/Category: 6

HSNO Group Standard: Dental Products Subsidiary Hazard Group Standard 2020
HSR002558

Statements/Pictograms: As per attached Safety Data Sheet (SDS)

Date Prepared: This coversheet was prepared – May 2023

This SDS coversheet has been produced by Henry Schein NZ and has been prepared in accordance with NZ EPA advice on making overseas SDS compliant to HSNO Act. The above information is based on the present state of our knowledge of the product at the time of publication. It is given in good faith, no warranty is implied with respect to the quality or the specifications of the product. Users must satisfy that the product is entirely suitable for their purpose. The SDS and this coversheet may be revised from time to time, please ensure you have a current copy.

Safety data sheet

According to GHS 3rd Edition

Printing date 15.11.2019

Version number 4

Revision: 15.11.2019

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**

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 GHS:**



Acute Tox. 4 H302 Harmful if swallowed.

· **2.2 Label elements**

· **Labelling according to GHS**

The product is classified and labelled according to GHS, 3rd Edition.



GHS07

· **Signal word** *Warning*

· **Hazard-determining components of labelling:**

articaine hydrochloride

epinephrine hydrogen tartrate

· **Hazard statements**

H302 Harmful if swallowed.

· **Precautionary statements**

P264 Wash hands thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P301+P312 IF SWALLOWED: Call a POISON CENTER or doctor /physician if you feel unwell

(Contd. on page 2)

Safety data sheet According to GHS, 3rd Edition

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Version number 4

Revision: 15.11.2019

Trade name: SEPTANEST WITH ADRENALINE 1:200 000

- P330 Rinse mouth (Contd. of page 1)
P501 Dispose of contents/container in accordance with local, state & federal 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 and their GHS classifications.

· **Dangerous components:**

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

- **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:**
Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.
- **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:** Call a poison center or for a doctor 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 :**

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).

(Contd. on page 3)

Safety data sheet

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Dispose contaminated material as waste according to item 13.
Ensure adequate ventilation.

(Contd. of page 2)

· 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.

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.

· Protection of hands:

Protective gloves

· Gloves material : Butyl rubber, BR**· Eye protection:** Goggles recommended during refilling

Safety data sheet
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Version number 4

Revision: 15.11.2019

Trade name: SEPTANEST WITH ADRENALINE 1:200 000

(Contd. of page 3)

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.

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

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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***Harmful if swallowed.***· LD/LC50 values relevant for classification:****CAS: 23964-57-0 chlorhydrate d'articaïne**

Oral LD50 500 mg/kg (ATE)

Inhalative LC50/4 h 11 mg/l (ATE)

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.**· 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.

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.

GB

(Contd. on page 6)

Safety data sheet
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Revision: 15.11.2019

Trade name: SEPTANEST WITH ADRENALINE 1:200 000

(Contd. of page 5)

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 | |
| · ADG, ADN, IMDG, IATA | Not classified as hazardous for transport |
| · 14.2 UN proper shipping name | |
| · ADG, ADN, IMDG, IATA | Not classified as hazardous for transport |
| · 14.3 Transport hazard class(es) | |
| · ADG, ADN, IMDG, IATA | |
| · Class | Not classified as hazardous for transport |
| · 14.4 Packing group | |
| · ADG, 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
- Model WHS Regulations, Classification according to GHS 3rd Revised Edition
- Classified under the Therapeutic Goods Act 1989 and Poisons Schedule as prescription Only medicine

GB

(Contd. on page 7)



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(Contd. of page 6)

New Zealand:**HSNO HSR003812****HSNO Classifications:** 6.1A (All), 6.1A (O), 6.1A (D), 6.1A (I), 6.3A, 6.4A, 6.9A (All), 6.9A (I), 9.3A**Substance Grouping: Active Ingredient****GHS Classifications:** Acute oral toxicity Category 1, Acute dermal toxicity Category 1, Acute inhalation toxicity Category 1, Skin irritation Category 2, Eye irritation Category 2, Specific target organ toxicity (repeated exposure) Category 1, Specific target organ toxicity (single exposure) Category 3 respiratory irritation, Hazardous to terrestrial vertebrates.**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 GHS, 3rd Edition

Acute toxicity - oral

The classification of the mixture is generally based on the calculation methods using substance data according to Part 3, Health Hazards of the GHS.

· Abbreviations and acronyms:

ADG: Australian Code for the Transport of Dangerous Goods by Road & Rail

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. 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

AUS