



## Safety Data Sheet

in accordance with The New Zealand's hazard classification system (Based on GHS Rev.7)

Date of issue: 20.05.2025

Version number 2

Revision: 20.05.2025

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### SECTION 1: Identification of the substance or mixture and of the supplier

- **1.1 Product identifier**
- Trade name: **BIODENTINE XP (Liquid Biodentine)**
- Article number / formula: 338S
- **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** : Medical device for dental use
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Supplier name: Ivoclar Vivadent Ltd  
Address: 12 Omega St, Rosedale, Auckland, New Zealand.  
Téléphone: + 64 9 914 9999  
Fax: + 64 9 914 9990  
Email: SDSPacific@ivoclar.com  
Website: [https://www.ivoclar.com/en\\_nz](https://www.ivoclar.com/en_nz)

Manufacturer :  
SEPTODONT  
58 rue du Pont de Créteil  
94100 Saint Maur des Fosses  
France  
Téléphone: +33(0)149767000  
[msds@septodont.com](mailto:msds@septodont.com)  
<http://www.septodont.com>

- **1.4 Emergency telephone number:**  
National Poison Information Centre: 0800 764 766 (24 hours / 7 days).  
Fire & Emergency Dial 111  
Emergency Contact: 0800 CHEMCALL (0800 243 622)

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### SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according the New Zealand's hazard classification system**



GHS07

Eye irritation Category 2 H319 Causes serious eye irritation.

- **Additional information:**  
This Regulation shall not apply to substances and mixtures in the following finished forms intended for the end user

(a) medicinal products, as defined in Directive 2001/83/EC

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(b) medical devices, as defined in Directives 90/385/EEC and 93/42/EEC, which are invasive or used in direct physical contact with the human body, and in Directive 98/79/EC;

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- **2.2 Label elements**
- **Hazard pictograms**



GHS07

- **Signal word** Warning
- **Hazard statements**  
H319 Causes serious eye irritation.
- **Precautionary statements**  
P280 Wear eye protection / face protection.  
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P337+P313 If eye irritation persists: Get medical advice/attention.


- **2.3 Other hazards**

The mixture shall not contain substances listed in accordance with Article 59(1) R.E.A.C.H as having endocrine disrupting properties, or be recognised as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 in a concentration equal to or greater than 0.1%.

- **Results of PBT and vPvB assessment**
  - **PBT:** Not applicable.
  - **vPvB:** Not applicable.
- 

### SECTION 3: Composition/Information on ingredients

- **3.2 Chemical characterisation: Mixtures**
- **Description:** Preparation: composed of the substances listed below.
- **Dangerous components:**

CAS: 10035-04-8	calcium chloride, dihydrate	25-<50%
EINECS: 233-140-8	 Eye irritation Category 2, H319	

- **SVHC** Not applicable
  - **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.

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- **After eye contact:**  
Rinse opened eye for several minutes under running water. If symptoms persist, 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 is available.
  - **4.3 Indication of any immediate medical attention and special treatment needed :**  
No further relevant information is available.
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### SECTION 5: Fire fighting measures

- **5.1 Suitable extinguishing agents:**  
CO<sub>2</sub>, 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.
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### 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).
  - **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.
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### 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:** Keep container tightly sealed.

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- **7.3 Specific end use(s)** : No further relevant information available.

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**SECTION 8: Exposure controls/personal protection**

- **8.1 Control parameters**
- **Appropriate engineering controls** 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:** Avoid all contact with the eyes.
- **Respiratory protection:** No special measures required.
- **Protection of hands:**



Protective gloves

- **Gloves material** : Nitrile rubber, NBR
- **Eye protection:**



Tightly sealed goggles

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**SECTION 9: Physical and chemical properties**

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Form:** Liquid
- **Colour:** Colourless
- **Odour:** Characteristic
- **Odour threshold:** Not determined.
- **pH-value:** Not determined.
- **Change in condition**
- **Melting point/freezing point:** Not determined.
- **Initial boiling point and boiling range:** Not determined.
- **Flash point:** Not applicable.
- **Flammability** Not applicable.
- **Auto-ignition temperature:** Not applicable.
- **Decomposition temperature:** Not determined.
- **Ignition temperature:** Product is not self igniting.

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- **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 :**
- **Particle characteristics** Not applicable.
- **Physical state** Liquid

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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.
- **Primary irritant effect:**
- **On the skin:** Based on available data, the classification criteria are not met.
- **On the eyes:** Causes serious eye irritation.
- **Respiratory or skin sensitization** Based on available data, the classification criteria are not met.
- **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.
- **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 :** Smaller quantities can be disposed of with household waste.
- **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**
- **DOT, NZS, ADN, IMDG, IATA** none
- **14.2 UN proper shipping name**
- **NZS, ADN, IMDG, IATA** none
- **14.3 Transport hazard class(es)**
- **NZS, ADN, IMDG, IATA**
- **Class** none
- **14.4 Packing group**
- **NZS, IMDG, IATA** none
- **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":** none

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**SECTION 15: Regulatory information**

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **New Zealand Inventory of Chemicals**

All ingredients are listed.

- **HSNO Approval numbers**

None of the ingredients is listed.

HSR003217 – Additives, Process Chemicals and Raw Materials (Subsidiary Hazard) Group Standard 2020

- **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**

H319 Causes serious eye irritation.

- **Abbreviations and acronyms:**

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

ICAO: International Civil Aviation Organisation

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

DOT: US Department of Transportation

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)

PBT: Persistent, Bioaccumulative and Toxic

SVHC: Substances of Very High Concern

vPvB: very Persistent and very Bioaccumulative

Eye irritation Category 2: Serious eye damage/eye irritation – Category 2