



## Safety Data Sheet

acc. to OSHA HCS

Printing date 04/24/2023

Reviewed on 04/24/2023

### 1 Identification

- **Product identifier**
- **Trade name: BIODENTINE XP (Liquid Biodentine)**
- **Article number / formula: 338S**
- **Application of the substance / the mixture** Medical device for dental use
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
SEPTODONT  
58 rue du Pont de Créteil  
94100 Saint Maur des Fosses  
France  
Téléphone: +33(0)149767000  
msds@septodont.com  
<http://www.septodont.com>
- **Emergency telephone number:**  
For Hazardous Materials [or Dangerous Goods] Incident  
Spill, Leak, Fire, Exposure, or Accident  
Call CHEMTREC  
Toll Free: 1-800-424-9300/ +1 703-527-3887 CCN 1005298

### 2 Hazard(s) identification

- **Classification of the substance or mixture**



GHS07

Eye Irritation 2A H319 Causes serious eye irritation.

- **Additional information:**  
This Regulation shall not apply to substances and mixtures in the following forms, in their finished state, intended for the end user  
  
(a) medicinal products, as defined in Directive 2001/83/EC  
(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;

- **Label elements**
- **GHS label elements**  
The product is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms**



GHS07

- **Signal word** Warning

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**· 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.

**· Classification system:****· NFPA ratings (scale 0 - 4)**

Health = 2

Fire = 0

Reactivity = 0

**· HMIS-ratings (scale 0 - 4)**

Health = 2

Fire = 0

Reactivity = 0

**· Other hazards**

The mixture does not contain substances listed in accordance with Article 59(1) of REACH as having endocrine disrupting properties, or is not known to have endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0.1% .

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

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### 3 Composition/information on ingredients

**· Chemical characterization: Mixtures****· Description:** Preparation: composed of the substances indicated below.**· Dangerous components:**

CAS: 10035-04-8 calcium chloride, dihydrate

25-&lt;50%

EINECS: 233-140-8 Eye Irritation 2A, H319

**· SVHC -**

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### 4 First-aid measures

**· Description of first aid measures****· After inhalation:** Supply fresh air; consult doctor in case of complaints.**· After skin contact:** Generally the product does not irritate the skin.**· After eye contact:**

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

**· After swallowing:** If symptoms persist consult doctor.

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- **Most important symptoms and effects, both acute and delayed**  
No further relevant information available.
  - **Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.
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### 5 Fire-fighting measures

- **Suitable extinguishing agents:**  
CO<sub>2</sub>, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
  - **Special hazards arising from the substance or mixture** No further relevant information available.
  - **Advice for firefighters**
  - **Protective equipment:** No special measures required.
- 

### 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
  - **Environmental precautions:**  
Dilute with plenty of water.  
Do not allow to enter sewers/ surface or ground water.
  - **Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
  - **Protective Action Criteria for Chemicals**
  - **PAC-1:**  
CAS: 10035-04-8 calcium chloride, dihydrate: 16 mg/m<sup>3</sup>
  - **PAC-2:**  
CAS: 10035-04-8 calcium chloride, dihydrate: 170 mg/m<sup>3</sup>
  - **PAC-3:**  
CAS: 10035-04-8 calcium chloride, dihydrate: 1,100 mg/m<sup>3</sup>
  - **Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.
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### 7 Handling and storage

- **Precautions for safe handling** No special precautions are necessary if used correctly.
  - **Information about protection against explosions and fires:** No special measures required.
  - **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 receptacle tightly sealed.
  - **Specific end use(s)** No further relevant information available.
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### 8 Exposure controls/personal protection

- **Control parameters**
- **Components with limit values that require monitoring at the workplace:**  
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **Additional information about design of technical systems:** No further data; see section 7.
- **Personal protective equipment:**
- **General protective and hygienic measures:** Avoid contact with the eyes.
- **Breathing equipment:** Not required.
- **Protection of hands:**



Protective gloves

- **Material of gloves** Nitrile rubber, NBR
- **Eye protection:**



Tightly sealed goggles

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### 9 Physical and chemical properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Form:** Liquid
- **Color:** Colorless
- **Odor:** Characteristic
- **Odor threshold:** Not determined.
- **Melting point/Melting range:** Undetermined.
- **Boiling point/Boiling range:** Undetermined.
- **Flammability (solid, gaseous):** Not applicable.
- **Explosion limits:**
- **Lower:** Not determined.
- **Upper:** Not determined.
- **Flash point:** Not applicable.
- **Auto igniting:** Not applicable.
- **Decomposition temperature:** Not determined.
- **pH-value:** Not determined.
- **Viscosity:**
- **Kinematic:** Not determined.
- **Dynamic:** Not determined.

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- **Solubility in / Miscibility with**
- **Water:** Fully miscible.
- **Partition coefficient (n-octanol/water):** Not determined.
- **Vapor pressure at 20 °C (68 °F):** 23 hPa (17.3 mm Hg)
- **Vapor pressure:**
- **Density:** Not determined.
- **Relative density** Not determined.
- **Vapor density** Not determined.
  
- **Other information**
- **Important information on protection of health and environment, and on safety.**
- **Ignition temperature:** Product is not selfigniting.
- **Danger of explosion:** Product does not present an explosion hazard.
- **Change in condition**
- **Evaporation rate** Not determined.

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### 10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

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### 11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:** Based on available data, the classification criteria are not met.
- **on the eye:** Causes serious eye irritation.
- **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.
- **Specific target organ toxicity - single exposure** Based on available data, the classification criteria are not met.
- **Specific target organ toxicity - repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.
- **Additional toxicological information:**
  
- **Carcinogenic categories**
- **IARC (International Agency for Research on Cancer)**

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None of the ingredients is listed.

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- **NTP (National Toxicology Program)**  
None of the ingredients is listed.
- **OSHA-Ca (Occupational Safety & Health Administration)**  
None of the ingredients is listed.

## 12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.
- **Additional ecological information:**
- **General notes:**  
Water hazard class 1 (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.

## 13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:** Smaller quantities can be disposed of with household waste.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agent:** Water, if necessary with cleansing agents.

## 14 Transport information

- **UN-Number**
- **DOT, ADR, ADN, IMDG, IATA** Not classified as hazardous for transport
- **UN proper shipping name**
- **DOT, ADR, ADN, IMDG, IATA** Not classified as hazardous for transport
- **Transport hazard class(es)**
- **ADR, ADN, IMDG, IATA**
- **Class** Not classified as hazardous for transport
- **Packing group**
- **DOT, ADR, IMDG, IATA** Not classified as hazardous for transport
- **Environmental hazards:**
- **Marine pollutant:** No
- **Special precautions for user** Not applicable.

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- **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.
  - **UN "Model Regulation":** Not classified as hazardous for transport
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### 15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**  
No further relevant information available.
  - **Sara**
  - **Section 355 (extremely hazardous substances):**  
None of the ingredient is listed.
  - **Section 313 (Specific toxic chemical listings):**  
None of the ingredients is listed.
  - **TSCA (Toxic Substances Control Act):**  
CAS: 7732-18-5 water, distilled, conductivity or of similar purity: ACTIVE
  - **Hazardous Air Pollutants**  
None of the ingredients is listed.
  - **Proposition 65**
  - **Chemicals known to cause cancer:**  
None of the ingredients is listed.
  - **Chemicals known to cause reproductive toxicity for females:**  
None of the ingredients is listed.
  - **Chemicals known to cause reproductive toxicity for males:**  
None of the ingredients is listed.
  - **Chemicals known to cause developmental toxicity:**  
None of the ingredients is listed.
  - **Carcinogenity categories**
  - **EPA (Environmental Protection Agency)**  
None of the ingredients is listed.
  - **TLV (Threshold Limit Value)**  
None of the ingredients is listed.
  - **NIOSH-Ca (National Institute for Occupational Safety and Health)**  
None of the ingredients is listed.
  - **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.
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### 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.  
Classification in accordance with Delegated Regulation (EU) 2022/692 of 16 February 2022 adapting to technical and scientific progress CLP for the 18th time and amending table 3 of Annex VI part 3 of Regulation (EC) 1272/2008.

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**· Relevant phrases**

H319 Causes serious eye irritation.

**· Date of previous version 01/18/2022****· Version number of previous version: 1****· Date of preparation / last revision 04/24/2023****· 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

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)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

PBT: Persistent, Bioaccumulative and Toxic

SVHC: Substances of Very High Concern

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety &amp; Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

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

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— US —