

## Safety Data Sheet according to WHS Regulations

Printing date 04.11.2024

Version number 1



Revision: 17.03.2021

Hazardous according to criteria of Australian Safety and Compensation Council.

### 1 Identification

- **Product identifier**
- **Trade name:** ***Cention Primer***
- **Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture** Self-curing primer for Cention
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Ivoclar Vivadent AG  
Bendererstrasse 2  
9494 Schaan  
PRINCIPALITY OF LIECHTENSTEIN  
Tel: +423 235 35 35 / Fax: +423 235 33 60
- **Importer:**  
Ivoclar Vivadent Pty. Ltd.  
1- 5 Overseas Drive  
Noble Park North VIC 3174  
Tel: + 61 3 9795 9599 / Fax: + 61 3 9795 9645
- **Further information obtainable from:**  
Regulatory Affairs  
sds@ivoclar.com
- **Emergency telephone number:** 131 126 (Poisons Information Centre - 24 hours / 7 days)

### 2 Hazard(s) Identification

- **Classification of the substance or mixture**  
Flammable liquids – Category 3      H226 Flammable liquid and vapour.  
Skin corrosion/irritation – Category 2      H315 Causes skin irritation.  
Eye damage/irritation – Category 2A      H319 Causes serious eye irritation.  
Skin sensitisation – Category 1      H317 May cause an allergic skin reaction.
- **Label elements**
- **GHS label elements**  
The product is classified and labelled according to the Globally Harmonised System (GHS).
- **Hazard pictograms**  
   
GHS02      GHS07
- **Signal word** Warning
- **Hazard-determining components of labelling:**  
2-hydroxyethyl methacrylate (10-<25 %)  
Bis-GMA (19.23 %)  
methacrylated phosphoric acid ester (10-<25 %)  
1,10-decandiol dimethacrylate (2.5-<10 %)  
methacrylate modified polyacrylic acid (2.5-<10 %)

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2-dimethylaminoethyl methacrylate (<2.5 %)

· **Hazard statements**

Flammable liquid and vapour.

Causes skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

· **Precautionary statements**

Keep away from heat/sparks/open flames/hot surfaces. No smoking.

Avoid breathing dust/fume/gas/mist/vapours/spray.

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

If skin irritation or rash occurs: Get medical advice/attention.

If eye irritation persists: Get medical advice/attention.

· **Additional information:**

Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Regulation (EC) No 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

· **Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

### 3 Composition and Information on Ingredients

· **Chemical characterisation: Mixtures**

· **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**

CAS: 868-77-9	2-hydroxyethyl methacrylate Skin corrosion/irritation – Category 2, H315; Eye damage/irritation – Category 2A, H319; Skin sensitisation – Category 1, H317	10-<25%
CAS: 64-17-5	ethanol Flammable liquids – Category 2, H225; Eye damage/irritation – Category 2A, H319	10-<25%
CAS: 85590-00-7	methacrylated phosphoric acid ester Skin corrosion/irritation – Category 2, H315; Eye damage/irritation – Category 2A, H319; Skin sensitisation – Category 1, H317	10-<25%
CAS: 6701-13-9	1,10-decandiol dimethacrylate Eye damage/irritation – Category 2A, H319; Skin sensitisation – Category 1, H317	2.5-<10%
CAS: 54351-53-0	methacrylate modified polyacrylic acid Skin corrosion/irritation – Category 2, H315; Eye damage/irritation – Category 2A, H319; Skin sensitisation – Category 1, H317	2.5-<10%
CAS: 10373-78-1	camphorquinone Skin corrosion/irritation – Category 2, H315; Eye damage/irritation – Category 2A, H319; Specific target organ toxicity (single exposure) – Category 3, H335	<2.5%
CAS: 2867-47-2	2-dimethylaminoethyl methacrylate Skin corrosion/irritation – Category 1B, H314; Eye damage/irritation – Category 1, H318; Acute toxicity - oral – Category 4, H302; Acute toxicity - dermal – Category 4, H312; Skin sensitisation – Category 1, H317	<2.5%
CAS: 10287-53-3	ethyl p-dimethylaminobenzoate Reproductive toxicity – Category 1B, H360; Aquatic Chronic 2, H411	<2.5%

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CAS: 128-37-0	Butylated hydroxytoluene
	Aquatic Chronic 1, H410

&lt;2.5%

· **Additional information:** For the wording of the listed hazard phrases refer to section 16.

### 4 First Aid Measures

· **After inhalation:**

Supply fresh air and to be sure call for a doctor.

In case of unconsciousness place patient stably in side position for transportation.

· **After skin contact:**

Immediately rinse with water.

If skin irritation continues, consult a doctor.

· **After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.

· **After swallowing:**

Rinse out mouth and then drink plenty of water.

If symptoms persist consult doctor.

· **Information for doctor:**

· **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.

### 5 Fire Fighting Measures

· **Suitable extinguishing agents:**

CO<sub>2</sub>, 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.

· **Protective equipment:** Wear self-contained respiratory protective device.

· **Additional information** See Section 14 for Hazchem Code.

### 6 Accidental Release Measures

· **Personal precautions, protective equipment and emergency procedures**

Wear protective equipment. Keep unprotected persons away.

· **Environmental precautions:** 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).

· **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.

### 7 Handling and Storage

· **Handling:**

· **Precautions for safe handling**

Only adequately trained personnel should handle this product.

For use in dentistry only.

· **Information about fire - and explosion protection:**

Keep ignition sources away - Do not smoke.

Protect against electrostatic charges.

· **Storage:**

· **Requirements to be met by storerooms and receptacles:** Store only in the original receptacle.

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- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Keep container tightly sealed.
- **Specific end use(s)** No further relevant information available.

### 8 Exposure controls and personal protection

- **Additional information about design of technical facilities:** No further data; see section 7.

- **Ingredients with limit values that require monitoring at the workplace:**

<b>CAS: 64-17-5 ethanol</b>
WES Long-term value: 1880 mg/m <sup>3</sup> , 1000 ppm
<b>CAS: 128-37-0 Butylated hydroxytoluene</b>
WES Long-term value: 10 mg/m <sup>3</sup>

- **Regulatory information WES:** Workplace exposure standards for airborne contaminants

- **Additional information:** The lists valid during the making were used as basis.

- **Personal protective equipment:**

- **General protective and hygienic measures:**

Usual hygienic measures for dental practice and dental laboratories.

Keep away from foodstuffs, beverages and feed.

Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

- **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 (EN 374)

After use of gloves apply skin-cleaning agents and skin cosmetics.

- **Material of gloves**

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

- **Not suitable are gloves made of the following materials:**

Commercial medical gloves do not provide protection against the sensitizing effect of methacrylates.

- **Eye protection:**



Tightly sealed goggles (EN 166)

### 9 Physical and Chemical Properties

- **General Information**

- **Appearance:**

- **Form:**

Liquid

- **Colour:**

Yellow

- **Odour:**

Characteristic

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· <b>Odour threshold:</b>	Not determined.
· <b>pH-value:</b>	Not applicable.
· <b>Change in condition</b>	
· <b>Melting point/freezing point:</b>	Undetermined.
· <b>Initial boiling point and boiling range:</b>	Undetermined.
· <b>Flash point:</b>	33.5 °C (ISO 13736)
· <b>Ignition temperature:</b>	Product is not selfigniting.
· <b>Explosive properties:</b>	Product does not present an explosion hazard.
· <b>Explosion limits:</b>	
· <b>Lower:</b>	Not determined.
· <b>Upper:</b>	Not determined.
· <b>Vapour pressure:</b>	Not determined.
· <b>Density at 20 °C:</b>	1.06 g/cm <sup>3</sup>
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not determined.
· <b>Evaporation rate</b>	Not determined.
· <b>Solubility in / Miscibility with</b>	
· <b>water:</b>	Fully miscible.
· <b>Partition coefficient: n-octanol/water:</b>	Not determined.
· <b>Viscosity:</b>	
· <b>Dynamic:</b>	Not determined.
· <b>Kinematic:</b>	Not determined.
· <b>Other information</b>	No further relevant information available.

### 10 Stability and Reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability** Stable under normal handling and storage conditions.
- **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:** None under normal conditions of storage and use.

### 11 Toxicological Information

- **Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **Skin corrosion/irritation**  
Causes skin irritation.
- **Serious eye damage/irritation**  
Causes serious eye irritation.
- **Respiratory or skin sensitisation**  
May cause an allergic skin reaction.
- **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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### 12 Ecological Information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**  
Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water  
Do not allow product to reach ground water, water course or sewage system.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

### 13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**  
Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

### 14 Transport information

- |  |   |
|--|---|
| <ul style="list-style-type: none"> <li>· <b>UN-Number</b></li> <li>· <b>ADG, IMDG, IATA</b></li> </ul>   | <p style="text-align: right;">UN1170</p>  |
| <ul style="list-style-type: none"> <li>· <b>UN proper shipping name</b></li> <li>· <b>ADG</b></li> <li>· <b>IMDG</b></li> <li>· <b>IATA</b></li> </ul> | <p style="text-align: right;">1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)</p> <p style="text-align: right;">ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)</p> <p style="text-align: right;">ETHANOL SOLUTION</p> |
| <ul style="list-style-type: none"> <li>· <b>Transport hazard class(es)</b></li> <li>· <b>ADG</b></li> </ul>  | <div style="text-align: center;">  </div>  |
| <ul style="list-style-type: none"> <li>· <b>Class</b></li> <li>· <b>Label</b></li> </ul>   | <p style="text-align: right;">3 (F1) Flammable liquids.</p> <p style="text-align: right;">3</p>   |
| <ul style="list-style-type: none"> <li>· <b>IMDG, IATA</b></li> </ul>  | <div style="text-align: center;">  </div>  |
| <ul style="list-style-type: none"> <li>· <b>Class</b></li> </ul>   | <p style="text-align: right;">3 Flammable liquids.</p>  |

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· <b>Label</b>	3
· <b>Packing group</b> · <b>ADG, IMDG, IATA</b>	III
· <b>Environmental hazards:</b> · <b>Marine pollutant:</b>	No
· <b>Special precautions for user</b> · <b>Hazard identification number (Kemler code):</b> · <b>Hazchem or Emergency Action Code:</b> · <b>EMS Number:</b> · <b>Stowage Category</b>	Warning: Flammable liquids. 30 •2Y F-E,S-D A
· <b>Transport in bulk according to Annex II of Marpol and the IBC Code</b>	Not applicable.
· <b>Transport/Additional information:</b>	
· <b>ADG</b> · <b>Limited quantities (LQ)</b> · <b>Excepted quantities (EQ)</b>	5L Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· <b>Transport category</b> · <b>Tunnel restriction code</b>	3 D/E
· <b>IMDG</b> · <b>Limited quantities (LQ)</b> · <b>Excepted quantities (EQ)</b>	5L Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· <b>UN "Model Regulation":</b>	UN 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION), 3, III

### 15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**

· **Australian Inventory of Industrial Chemicals**

All ingredients are listed.

· **Standard for the Uniform Scheduling of Medicines and Poisons**

None of the ingredients is listed.

· **Australia: Priority Existing Chemicals**

None of the ingredients is listed.

· **GHS label elements**

The product is classified and labelled according to the Globally Harmonised System (GHS).

· **Hazard pictograms**



GHS02 GHS07

· **Signal word** Warning

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

- 2-hydroxyethyl methacrylate (10-<25 %)
- Bis-GMA (19.23 %)
- methacrylated phosphoric acid ester (10-<25 %)
- 1,10-decandiol dimethacrylate (2.5-<10 %)
- methacrylate modified polyacrylic acid (2.5-<10 %)
- 2-dimethylaminoethyl methacrylate (<2.5 %)

· **Hazard statements**

- Flammable liquid and vapour.
- Causes skin irritation.
- Causes serious eye irritation.
- May cause an allergic skin reaction.

· **Precautionary statements**

- Keep away from heat/sparks/open flames/hot surfaces. No smoking.
- Avoid breathing dust/fume/gas/mist/vapours/spray.
- Wear protective gloves/protective clothing/eye protection/face protection.
- If skin irritation or rash occurs: Get medical advice/attention.
- If eye irritation persists: Get medical advice/attention.

· **Directive 2012/18/EU**

· **Named dangerous substances - ANNEX I** None of the ingredients is listed.

· **Seveso category** P5c FLAMMABLE LIQUIDS

· **Qualifying quantity (tonnes) for the application of lower-tier requirements** 5000 t

· **Qualifying quantity (tonnes) for the application of upper-tier requirements** 50000 t

· **National regulations:**

· **Other regulations, limitations and prohibitive regulations**

The product is a medical device according to the Directive 93/42/EEC.

· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

## 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**

- H225 Highly flammable liquid and vapour.
- H302 Harmful if swallowed.
- H312 Harmful in contact with skin.
- H314 Causes severe skin burns and eye damage.
- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H318 Causes serious eye damage.
- H319 Causes serious eye irritation.
- H335 May cause respiratory irritation.
- H360 May damage fertility or the unborn child.
- H410 Very toxic to aquatic life with long lasting effects.
- H411 Toxic to aquatic life with long lasting effects.

· **Contact:**

· **Abbreviations and acronyms:**

- IMO: International Maritime Organization
- ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)
- RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
- IMDG: International Maritime Code for Dangerous Goods
- IATA: International Air Transport Association
- EINECS: European Inventory of Existing Commercial Chemical Substances

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*ELINCS: European List of Notified Chemical Substances**CAS: Chemical Abstracts Service (division of the American Chemical Society)**PBT: Persistent, Bioaccumulative and Toxic**vPvB: very Persistent and very Bioaccumulative**Flammable liquids – Category 2: Flammable liquids – Category 2**Flammable liquids – Category 3: Flammable liquids – Category 3**Acute toxicity - oral – Category 4: Acute toxicity – Category 4**Skin corrosion/irritation – Category 1B: Skin corrosion/irritation – Category 1B**Skin corrosion/irritation – Category 2: Skin corrosion/irritation – Category 2**Eye damage/irritation – Category 1: Serious eye damage/eye irritation – Category 1**Eye damage/irritation – Category 2A: Serious eye damage/eye irritation – Category 2A**Skin sensitisation – Category 1: Skin sensitisation – Category 1**Reproductive toxicity – Category 1B: Reproductive toxicity – Category 1B**Specific target organ toxicity (single exposure) – Category 3: Specific target organ toxicity (single exposure) – Category 3**Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1**Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2*

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