






## 1 Identification of the substance/mixture and of the company/undertaking

- **Product identifier**
- **Trade name: ProBase Cold Monomer**
- **Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the preparation** Denture base material
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Ivoclar Vivadent AG  
Bendererstrasse 2  
FL-9494 Schaan  
PRINCIPALITY OF LIECHTENSTEIN
- **Tel:** +423 235 35 35  
**Fax:** +423 235 33 60
- **Further information obtainable from:**  
Regulatory Affairs  
msds@ivoclarvivadent.com
- **Emergency telephone number:** +423 / 235 33 13

## 2 Hazards identification

- **Classification of the substance or mixture**
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
-  **Xi; Irritant**  
R37/38: Irritating to respiratory system and skin.
-  **Xi; Sensitising**  
R43: May cause sensitisation by skin contact.
-  **F; Highly flammable**  
R11: Highly flammable.
- **Information concerning particular hazards for human and environment:**  
The product has to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.
- **Classification system:**  
The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

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- **Label elements**
- **Labelling according to EU guidelines:**  
The product has been classified and marked in accordance with EU Directives / Ordinance on Hazardous Materials.
- **Code letter and hazard designation of product:**
-   **Xi Irritant**  
**F Highly flammable**
- **Hazard-determining components of labelling:**  
methyl methacrylate
- **Risk phrases:**  
11 Highly flammable.  
37/38 Irritating to respiratory system and skin.  
43 May cause sensitisation by skin contact.

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· **Safety phrases:**

- 9 Keep container in a well-ventilated place.
- 16 Keep away from sources of ignition - No smoking.
- 23 Do not breathe fumes/aerosol.
- 24 Avoid contact with skin.
- 37 Wear suitable gloves.
- 60 This material and its container must be disposed of as hazardous waste.

· **Other hazards**· **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.
- **vPvB:** Not applicable.

### 3 Composition/information on ingredients

· **Chemical characterization: Mixtures**· **Description:** Mixture of substances listed below with nonhazardous additions.· **Dangerous components:**

CAS: 80-62-6 EINECS: 201-297-1	methyl methacrylate ☒ Xi R37/38; ☒ Xi R43; ☒ F R11	50-100%
CAS: 2082-81-7 EINECS: 218-218-1	tetramethylene dimethacrylate ☒ Xi R36/37/38	2.5-10%

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

### 4 First aid measures

· **Description of first aid measures**· **General information:** Immediately remove any clothing soiled by the product.· **After inhalation:**

Supply fresh air; consult doctor in case of complaints.

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

· **After skin contact:** Immediately rinse with water.· **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.

Do not induce vomiting; call for medical help immediately.

· **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 Firefighting measures

· **Extinguishing media**· **Suitable extinguishing agents:** CO<sub>2</sub>, sand, extinguishing powder. Do not use water.· **For safety reasons unsuitable extinguishing agents:** Water with full jet· **Special hazards arising from the substance or mixture** No further relevant information available.· **Advice for firefighters**· **Protective equipment:** No special measures required.· **Additional information** Cool endangered receptacles with water spray.

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**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).  
Ensure adequate ventilation.  
Do not flush with water or aqueous cleansing agents
- **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.  
Ensure good ventilation/exhaustion at the workplace.
- **Information about fire - and explosion protection:**  
Keep ignition sources away - Do not smoke.  
Protect against electrostatic charges.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:**  
Store in a cool location.  
Store only in the original receptacle.
- **Information about storage in one common storage facility:** Store away from oxidizing agents.
- **Further information about storage conditions:**  
Keep container tightly sealed.  
Store receptacle in a well ventilated area.
- **Specific end use(s)** No further relevant information available.

**8 Exposure controls/personal protection**

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

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

**80-62-6 methyl methacrylate**

WEL ()	Short-term value: 416 mg/m <sup>3</sup> , 100 ppm Long-term value: 208 mg/m <sup>3</sup> , 50 ppm
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- **Additional information:** The lists valid during the making were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
Usual hygienic measures for dental practice.  
Keep away from foodstuffs, beverages and feed.  
Immediately remove all soiled and contaminated clothing  
Wash hands before breaks and at the end of work.  
Avoid contact with the skin.  
Avoid contact with the eyes and skin.  
Do not inhale gases / fumes / aerosols.

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· **Respiratory protection:**

Use suitable respiratory protective device in case of insufficient ventilation.

Filter AX

· **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· **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.

· **For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable:**

Butyl rubber, BR

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

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

· **Eye protection:** Safety glasses

## 9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

**Form:** Fluid

**Colour:** Colourless

· **Odour:** Pungent

· **Odour threshold:** Not determined.

· **pH-value:** Not determined.

· **Change in condition**

**Melting point/Melting range:** -48°C

**Boiling point/Boiling range:** 101°C

· **Flash point:** 10°C

· **Ignition temperature:** 430°C

· **Self-igniting:** Product is not selfigniting.

· **Danger of explosion:** Product is not explosive. However, formation of explosive air/vapour mixtures are possible.

· **Explosion limits:**

**Lower:** 2.1 Vol %

**Upper:** 12.5 Vol %

· **Vapour pressure at 20°C:** 47 hPa

· **Density at 20°C:** 0.943 g/cm<sup>3</sup>

· **Relative density** Not determined.

· **Vapour density** Not determined.

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· <b>Evaporation rate</b>	Not determined.
· <b>Solubility in / Miscibility with water at 20°C:</b>	1.6 g/l
· <b>Segregation 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**  
Forms explosive gas mixture with air.  
Reacts with strong oxidizing agents.  
Exothermic polymerization.
- **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:**

· <b>LD/LC50 values relevant for classification:</b>
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<b>80-62-6 methyl methacrylate</b>
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Oral	LD50	7872 mg/kg (rat)
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- **Primary irritant effect:**
- **on the skin:** Irritant to skin and mucous membranes.
- **on the eye:** No irritating effect.
- **Sensitization:** Sensitization possible through skin contact.
- **Additional toxicological information:**  
The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:  
Irritant
- **Sensitisation** May cause sensitisation by skin contact.

### 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 1 (German Regulation) (Self-assessment): slightly hazardous for water  
Do not allow product to reach ground water, water course or sewage system.

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- **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**  
Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· <b>European waste catalogue</b>
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18 01 06*	chemicals consisting of or containing dangerous substances
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- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

**14 Transport information**

- **Land transport ADR/RID (cross-border)**



- **ADR/RID class:** 3 (F1) Flammable liquids.
- **Danger code (Kemler):** 339
- **UN-Number:** 1247
- **Packaging group:** II
- **Hazard label:** 3
- **UN proper shipping name:** 1247 METHYL METHACRYLATE MONOMER, STABILIZED
- **Tunnel restriction code** D/E

- **Maritime transport IMDG:**



- **IMDG Class:** 3
- **UN Number:** 1247
- **Label** 3
- **Packaging group:** II
- **EMS Number:** F-E,S-D
- **Marine pollutant:** No
- **Proper shipping name:** METHYL METHACRYLATE MONOMER, STABILIZED

- **Air transport ICAO-TI and IATA-DGR:**



- **ICAO/IATA Class:** 3
- **UN/ID Number:** 1247
- **Label** 3
- **Packaging group:** II
- **Proper shipping name:** METHYL METHACRYLATE MONOMER, STABILIZED

- **Special precautions for user** Warning: Flammable liquids.

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· *Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code Not applicable.*

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### 15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **National regulations:**
- **Other regulations, limitations and prohibitive regulations**  
*The product is a medical device according to the EC-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**  
R11      *Highly flammable.*  
R36/37/38 *Irritating to eyes, respiratory system and skin.*  
R37/38   *Irritating to respiratory system and skin.*  
R43      *May cause sensitisation by skin contact.*

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