

**Safety data sheet**  
according to 1907/2006/EC, Article 31

Printing date 21.05.2015

Version number 11

Revision: 12.03.2015

**SECTION 1: Identification of the substance/mixture and of the company/undertaking**

- **1.1 Product identifier**
- **Trade name: ProBase Cold Monomer**
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture** Denture base material
- **1.3 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  
sds@ivoclarvivadent.com
- **1.4 Emergency telephone number:** +423 / 235 33 13 (Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein)

**SECTION 2: Hazards identification**

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
Flam. Liq. 2 H225 Highly flammable liquid and vapour.  
Skin Irrit. 2 H315 Causes skin irritation.  
Skin Sens. 1 H317 May cause an allergic skin reaction.  
STOT SE 3 H335 May cause respiratory irritation.
- 
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**  
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms**



GHS02 GHS07

- **Signal word** Danger
- **Hazard-determining components of labelling:**  
methyl methacrylate  
1,4-butanediol dimethacrylate
- **Hazard statements**  
H225 Highly flammable liquid and vapour.  
H315 Causes skin irritation.  
H317 May cause an allergic skin reaction.  
H335 May cause respiratory irritation.
- **Precautionary statements**  
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.  
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.  
P262 Do not get in eyes, on skin, or on clothing.

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- P280 Wear protective gloves/protective clothing/eye protection/face protection.  
P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.  
P501 Dispose of contents/container in accordance with local/regional/national/international 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 of substances listed below with nonhazardous additions.

· **Dangerous components:**

CAS: 80-62-6 EINECS: 201-297-1	methyl methacrylate Flam. Liq. 2, H225; Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335	50-100%
CAS: 2082-81-7 EINECS: 218-218-1	1,4-butanediol dimethacrylate Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335	3-<10%

- **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:** 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.  
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.  
Do not induce vomiting; call for medical help 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**  
No further relevant information available.

### SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**  
CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **For safety reasons unsuitable extinguishing agents:** Water with full jet
- **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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· **Additional information** Cool endangered receptacles with water spray.

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### SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**  
Wear protective equipment. Keep unprotected persons away.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface 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).  
Ensure adequate ventilation.
- **6.4 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.

### SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**  
Only adequately trained personnel should handle this product.  
Ensure good ventilation/exhaustion at the workplace.  
For use in dentistry only.
- **Information about fire - and explosion protection:**  
Keep ignition sources away - Do not smoke.  
Protect against electrostatic charges.
- **7.2 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 oxidising agents.
- **Further information about storage conditions:**  
Keep container tightly sealed.  
Store receptacle in a well ventilated area.  
Protect from heat and direct sunlight.
- **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 item 7.

#### · 8.1 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

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

#### · 8.2 Exposure controls

· **Personal protective equipment:**

· **General protective and hygienic measures:**

Usual hygienic measures for dental practice.

Keep away from foodstuffs, beverages and feed.

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Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

Do not inhale gases / fumes / aerosols.

· **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.

· **Recommended filter device for short term use:**

Filter A1

Filter A2

Filter A3

· **Protection of hands:**



Protective gloves

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

· **Material of gloves**

Butyl rubber, BR

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

## SECTION 9: Physical and chemical properties

· **9.1 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.

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· <b>Danger of explosion:</b>	Product is not explosive. However, formation of explosive air/vapour mixtures are possible.
· <b>Explosion limits:</b>	
<b>Lower:</b>	2.1 Vol %
<b>Upper:</b>	12.5 Vol %
· <b>Vapour pressure at 20 °C:</b>	47 hPa
· <b>Density at 20 °C:</b>	0.943 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 water at 20 °C:</b>	1.6 g/l
· <b>Partition coefficient (n-octanol/water):</b>	Not determined.
· <b>Viscosity:</b>	
<b>Dynamic:</b>	Not determined.
<b>Kinematic:</b>	Not determined.
· <b>9.2 Other information</b>	No further relevant information available.

### SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability** Stable under normal handling and storage conditions.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions**  
Forms explosive gas mixture with air.  
Reacts with strong oxidising agents.  
Exothermic polymerisation.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** None under normal conditions of storage and use.

### SECTION 11: Toxicological information

- **11.1 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.
- **Sensitisation:** Sensitisation possible through skin contact.
- **Additional toxicological information:** No further relevant information available.

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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 product 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.


### SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**  
Must not be disposed together with household garbage. Do not allow product to reach sewage system.  
Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.
- **European waste catalogue**

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.

### SECTION 14: Transport information

- **14.1 UN-Number**
  - **ADR, IMDG, IATA** UN1247
  - **14.2 UN proper shipping name**
  - **ADR** 1247 METHYL METHACRYLATE MONOMER,  
STABILIZED
  - **IMDG, IATA** METHYL METHACRYLATE MONOMER, STABILIZED
  - **14.3 Transport hazard class(es)**
  - **ADR**
- 
  - **Class** 3 (F1) Flammable liquids.
  - **Label** 3

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· **IMDG, IATA**

· **Class** 3 Flammable liquids.  
· **Label** 3

· **14.4 Packing group**  
· **ADR, IMDG, IATA** II

· **14.5 Environmental hazards:**  
· **Marine pollutant:** No

· **14.6 Special precautions for user** Warning: Flammable liquids.  
· **Danger code (Kemler):** 339  
· **EMS Number:** F-E,S-D

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

· **Transport/Additional information:**

· **ADR**  
· **Limited quantities (LQ)** 1L  
· **Excepted quantities (EQ)** Code: E2  
Maximum net quantity per inner packaging: 30 ml  
Maximum net quantity per outer packaging: 500 ml

· **Transport category** 2  
· **Tunnel restriction code** D/E

· **IMDG**  
· **Limited quantities (LQ)** 1L  
· **Excepted quantities (EQ)** Code: E2  
Maximum net quantity per inner packaging: 30 ml  
Maximum net quantity per outer packaging: 500 ml

· **UN "Model Regulation":** UN1247, METHYL METHACRYLATE MONOMER, STABILIZED, 3, II

### SECTION 15: Regulatory information

- **15.1 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 Directive 93/42/EEC.
- **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**  
H225 Highly flammable liquid and vapour.  
H315 Causes skin irritation.

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*H317 May cause an allergic skin reaction.*

*H319 Causes serious eye irritation.*

*H335 May cause respiratory irritation.*

**· Abbreviations and acronyms:**

*ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)*

*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*

*Flam. Liq. 2: Flammable liquids, Hazard Category 2*

*Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2*

*Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2*

*Skin Sens. 1: Sensitisation - Skin, Hazard Category 1*

*STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3*

**· \* Data compared to the previous version altered.**

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