

## 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**  
No further relevant information available.
- **Application of the substance / the preparation** Denture base material
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Ivoclar Vivadent Inc.  
175 Pineview Drive, Amherst, N.Y. 14228  
USA  
Tel. +1 800 533 6825  
Fax +1 716 691 2285
  
- Ivoclar Vivadent Inc.  
1-6600 Dixie Road  
Mississauga, Ontario  
L5T 2Y2  
Canada  
Phone: +1 905 670 8499  
Fax: +1 905 670 3102
- **Information department:** Quality Assurance / Regulatory Affairs
- **Emergency telephone number:**  
24 Hour Emergency Assistance:  
Emergency-Call USA - Infotrac: 1-800-535-5053  
Emergency-Call Canada - Canutec: 1-613-996-6666
  
- General MSDS Assistance:  
US: 1-800-533-6825  
Canada: 1-800-263-8182

## 2 Hazards identification

- **Classification of the substance or mixture**  
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.

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- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**  
Irritant  
Irritating to respiratory system and skin. May cause sensitisation by skin contact.  
Highly flammable  
Highly flammable.
- **Classification system:**  
The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

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

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**Trade name: ProBase Cold Monomer**

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· **Hazard pictograms**



GHS02 GHS07

· **Signal word** *Danger*

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

*methyl methacrylate*

· **Hazard statements**

*Highly flammable liquid and vapour.*

*Causes skin irritation.*

*May cause an allergic skin reaction.*

*May cause respiratory irritation.*

· **Precautionary statements**

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

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

*Do not get in eyes, on skin, or on clothing.*

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

*IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.*

*Dispose of contents/container in accordance with local/regional/national/international regulations.*

· **Classification system:**

· **NFPA ratings (scale 0 - 4)**



Health = 2

Fire = 3

Reactivity = 2

· **HMIS-ratings (scale 0 - 4)**



Health = 2

Fire = 3

Reactivity = 2

· **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 the substances listed below with nonhazardous additions.*

· **Dangerous components:**

80-62-6	<i>methyl methacrylate</i>	25-100%
2082-81-7	<i>tetramethylene dimethacrylate</i>	1-<10%

### 4 First aid measures

· **Description of first aid measures**

· **General information:** *Immediately remove any clothing soiled by the product.*

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- **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; immediately call for medical help.
- **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>, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **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.

### 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.
- **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.  
For use in dentistry only.
- **Information about protection against explosions and fires:**  
Keep ignition sources away - Do not smoke.  
Protect against electrostatic charges.

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- **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 receptacle tightly sealed.  
Store receptacle in a well ventilated area.  
Protect from heat and direct sunlight.
- **Specific end use(s)** No further relevant information available.

### \* 8 Exposure controls/personal protection

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

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

#### 80-62-6 methyl methacrylate

PEL	410 mg/m <sup>3</sup> , 100 ppm
REL	410 mg/m <sup>3</sup> , 100 ppm
TLV	Short-term value: 410 mg/m <sup>3</sup> , 100 ppm Long-term value: 205 mg/m <sup>3</sup> , 50 ppm
SEN	

- **Additional information:** The lists that were valid during the creation 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 eyes and skin.  
Do not inhale gases / fumes / aerosols.
- **Breathing equipment:**  
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.
- **Recommended filter device for short term use:** Filter AX
- **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.

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- **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

### 9 Physical and chemical properties

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

· **General Information**

· **Appearance:**

· <b>Form:</b>	Fluid
· <b>Color:</b>	Colorless
· <b>Odor:</b>	Pungent
· <b>Odour threshold:</b>	Not determined.

· **pH-value:** Not determined.

· **Change in condition**

· <b>Melting point/Melting range:</b>	-48°C (-54 °F)
· <b>Boiling point/Boiling range:</b>	101°C (214 °F)

· **Flash point:** 10°C (50 °F)

· **Ignition temperature:** 430°C (806 °F)

· **Auto igniting:** Product is not selfigniting.

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

· **Explosion limits:**

· <b>Lower:</b>	2.1 Vol %
· <b>Upper:</b>	12.5 Vol %

· **Vapor pressure at 20°C (68 °F):** 47 hPa (35 mm Hg)

· **Density at 20°C (68 °F):** 0.943 g/cm<sup>3</sup> (7.869 lbs/gal)

· **Relative density** Not determined.

· **Vapour density** Not determined.

· **Evaporation rate** Not determined.

· **Solubility in / Miscibility with**

· **Water at 20°C (68 °F):** 1.6 g/l

· **Partition coefficient (n-octanol/water):** Not determined.

· **Viscosity:**

· **Dynamic:** Not determined.

· **Kinematic:** Not determined.

· **Other information** No further relevant information available.

### 10 Stability and reactivity

· **Reactivity** No further relevant information available.

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- **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:**

· **LD/LC50 values that are relevant for classification:**

**80-62-6 methyl methacrylate**

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 internally approved calculation methods for preparations:

Irritant

- **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**

80-62-6	methyl methacrylate	3
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- **NTP (National Toxicology Program)**

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.
- **Behavior 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 (Self-assessment): slightly 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.

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### 13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:**  
Must not be disposed of 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.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

### 14 Transport information

- |                                       |   |
|---------------------------------------|---|
| · <b>UN-Number</b>                    |   |
| · <b>DOT</b>                          | UN1247  |
| · <b>ADR, IMDG, IATA</b>              | 1247  |
| · <b>UN proper shipping name</b>      |   |
| · <b>DOT, IMDG, IATA</b>              | METHYL METHACRYLATE MONOMER, STABILIZED   |
| · <b>ADR</b>                          | 1247 METHYL METHACRYLATE MONOMER, STABILIZED  |
| · <b>Transport hazard class(es)</b>   |   |
| · <b>DOT</b>                          |   |
|                                       |  |
| · <b>Class</b>                        | 3 Flammable liquids.  |
| · <b>Label</b>                        | 3   |
| · <b>ADR</b>                          |   |
|                                       |  |
| · <b>Class</b>                        | 3 (F1) Flammable liquids  |
| · <b>Label</b>                        | 3   |
| · <b>IMDG, IATA</b>                   |   |
|                                       |  |
| · <b>Class</b>                        | 3 Flammable liquids.  |
| · <b>Label</b>                        | 3   |
| · <b>Packing group</b>                |   |
| · <b>DOT, ADR, IMDG, IATA</b>         | II  |
| · <b>Environmental hazards:</b>       |   |
| · <b>Marine pollutant:</b>            | No  |
| · <b>Special precautions for user</b> | Warning: Flammable liquids  |
| · <b>Danger code (Kemler):</b>        | 339   |

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- |  |  |
|--|--|
| <b>· EMS Number:</b>   | F-E,S-D  |
| <b>· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b> | Not applicable.  |
| <b>· UN "Model Regulation":</b>  | UN1247, METHYL METHACRYLATE MONOMER, STABILIZED, 3, II |

### 15 Regulatory information

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

· Sara

· **Section 355 (extremely hazardous substances):**

None of the ingredients is listed.

· **Section 313 (Specific toxic chemical listings):**

80-62-6 methyl methacrylate

· **TSCA (Toxic Substances Control Act):**

All ingredients are 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.

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

80-62-6 methyl methacrylate

NL

· **TLV (Threshold Limit Value established by ACGIH)**

80-62-6 methyl methacrylate

A4

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

· **GHS label elements**

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

· **Hazard pictograms**



GHS02 GHS07

· **Signal word Danger**

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

*methyl methacrylate*

- **Hazard statements**

*Highly flammable liquid and vapour.*

*Causes skin irritation.*

*May cause an allergic skin reaction.*

*May cause respiratory irritation.*

- **Precautionary statements**

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

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

*Do not get in eyes, on skin, or on clothing.*

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

*IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.*

*Dispose of contents/container in accordance with local/regional/national/international regulations.*

- **National regulations:**

- **Other regulations, limitations and prohibitive regulations**

*The product is a medical device according to the EC-directive 93/42/EEC.*

*This product is classified as a medical device under US and Canadian regulations and has been reviewed by the US Food and Drug Administration and Health Canada.*

- **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.*

- **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*

*DOT: US Department of Transportation*

*IATA: International Air Transport Association*

*ACGIH: American Conference of Governmental Industrial Hygienists*

*NFPA: National Fire Protection Association (USA)*

*HMIS: Hazardous Materials Identification System (USA)*

*LC50: Lethal concentration, 50 percent*

*LD50: Lethal dose, 50 percent*

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