

## Safety Data Sheet according to WHS Regulations

Printing date 07.03.2024

Version number 12



Revision: 07.03.2024

Hazardous according to criteria of Australian Safety and Compensation Council.

### 1 Identification

- **Product identifier**
- **Trade name:** ***ProBase Hot Monomer***
- **Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture** Heat-curing denture base material
- **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**  
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.
- **Label elements**
- **GHS label elements**  
The product is classified and labelled according to the Globally Harmonised System (GHS).
- **Hazard pictograms**  
   
GHS02 GHS07
- **Signal word** Danger
- **Hazard-determining components of labelling:**  
methyl methacrylate (50-100 %)  
ethylene glycol dimethacrylate (2.5-10 %)
- **Hazard statements**  
Highly flammable liquid and vapour.  
Causes skin irritation.

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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.

**· 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: 80-62-6	methyl methacrylate Flam. Liq. 2, H225; Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335	50-100%
CAS: 97-90-5	ethylene glycol dimethacrylate Skin Sens. 1, H317; STOT SE 3, H335	2.5-10%
CAS: 99-85-4	p-Mentha-1,4-diene Flam. Liq. 3, H226; Repr. 2, H361; Skin Irrit. 2, H315; Serious eye damage/irritation – Category 2A, H319; STOT SE 3, H335	<2.5%

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

### 4 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.

**· 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.

· **For safety reasons unsuitable extinguishing agents:** Water with full jet

· **Special hazards arising from the substance or mixture** No further relevant information available.

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- **Protective equipment:** No special measures required.
- **Additional information**  
Cool endangered receptacles with water spray.  
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).  
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 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 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.
- **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:**

**CAS: 80-62-6 methyl methacrylate**

WES	Short-term value: 416 mg/m <sup>3</sup> , 100 ppm
	Long-term value: 208 mg/m <sup>3</sup> , 50 ppm
	Sen

- **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.

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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 (EN 374)

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 (EN 166)

### 9 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/freezing point:**

-48 °C

· **Initial boiling point and boiling range:**

101 °C

· **Flash point:**

10 °C

· **Auto-ignition temperature:**

430 °C

· **Ignition temperature:**

Product is not selfigniting.

· **Explosive properties:**

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

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· <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</b>	
· <b>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>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 oxidising agents.  
Exothermic polymerisation.
- **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.

#### · **LD/LC50 values relevant for classification:**

**CAS: 80-62-6 methyl methacrylate**

Oral	LD50	7872 mg/kg (rat)
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- **Skin corrosion/irritation**  
Causes skin irritation.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **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**  
May cause respiratory irritation.
- **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.
- **Additional toxicological information:** No further relevant information available.

### 12 Ecological Information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.

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- **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 undiluted product or large quantities of it 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

- |   |   |
|---|---|
| <b>· UN-Number</b>  |   |
| <b>· ADG, IMDG, IATA</b>  | UN1247  |
| <b>· UN proper shipping name</b>  |   |
| <b>· ADG</b>  | 1247 METHYL METHACRYLATE MONOMER,<br>STABILIZED |
| <b>· IMDG, IATA</b>   | METHYL METHACRYLATE MONOMER, STABILIZED         |
| <b>· Transport hazard class(es)</b>   |   |
| <b>· ADG</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>· ADG, IMDG, IATA</b>  | II  |

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· <b>Environmental hazards:</b>	
· <b>Marine pollutant:</b>	No
· <b>Special precautions for user</b>	Warning: Flammable liquids.
· <b>Hazard identification number (Kemler code):</b>	339
· <b>Hazchem or Emergency Action Code:</b>	3YE
· <b>EMS Number:</b>	F-E,S-D
· <b>Stowage Category</b>	B
· <b>Stowage Code</b>	SW2 Clear of living quarters.
· <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>	1L
· <b>Excepted quantities (EQ)</b>	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· <b>Transport category</b>	2
· <b>Tunnel restriction code</b>	D/E
· <b>IMDG</b>	
· <b>Limited quantities (LQ)</b>	1L
· <b>Excepted quantities (EQ)</b>	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· <b>UN "Model Regulation":</b>	UN 1247 METHYL METHACRYLATE MONOMER, STABILIZED, 3, II

### 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**

CAS: 80-62-6 methyl methacrylate

S6 +APPENDIX C

· **GHS label elements**

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

· **Hazard pictograms**



GHS02 GHS07

· **Signal word** Danger

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

methyl methacrylate (50-100 %)

ethylene glycol dimethacrylate (2.5-10 %)

· **Hazard statements**

Highly flammable liquid and vapour.

Causes skin irritation.

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*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.*

**· 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 Regulation 2017/745 on Medical Devices (MDR).*

**· 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.*

*H226 Flammable liquid and vapour.*

*H315 Causes skin irritation.*

*H317 May cause an allergic skin reaction.*

*H319 Causes serious eye irritation.*

*H335 May cause respiratory irritation.*

*H361 Suspected of damaging fertility or the unborn child.*

**· 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*

*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*

*PBT: Persistent, Bioaccumulative and Toxic*

*vPvB: very Persistent and very Bioaccumulative*

*Flam. Liq. 2: Flammable liquids – Category 2*

*Flam. Liq. 3: Flammable liquids – Category 3*

*Skin Irrit. 2: Skin corrosion/irritation – Category 2*

*Serious eye damage/irritation – Category 2A: Serious eye damage/eye irritation – Category 2A*

*Skin Sens. 1: Skin sensitisation – Category 1*

*Repr. 2: Reproductive toxicity – Category 2*

*STOT SE 3: Specific target organ toxicity (single exposure) – Category 3*

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