

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 Hot Monomer
- \cdot 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

GIIDO7

- · Signal word Danger
- · Hazard-determining components of labelling:

methyl methacrylate

ethylene glycol 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.

(Contd. on page 2)

Printing date 21.05.2015 Version number 11 Revision: 12.03.2015

Trade name: ProBase Hot Monomer

(Contd. of page 1)

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 compone	ents:			
		Flam. Liq. 2, H225; Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3,	50-100%		
ŀ		H335 ethylene glycol dimethacrylate	3-<10%		
l	EINECS: 202-617-2	Skin Sens. 1, H317; STOT SE 3, H335			

[·] 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:

CO2, 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.

(Contd. on page 3)

Printing date 21.05.2015 Version number 11 Revision: 12.03.2015

Trade name: ProBase Hot Monomer

(Contd. of page 2)

· Additional information Cool endangered receptacles with water spray.

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.
- $\cdot \textit{Further information about storage conditions:} \\$

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/m³, 100 ppm Long-term value: 208 mg/m³, 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.

(Contd. on page 4)

Printing date 21.05.2015 Version number 11 Revision: 12.03.2015

Trade name: ProBase Hot Monomer

(Contd. of page 3)

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:
Colour:
Colouress
Odour:
Pungent
Not determined.

pH-value:
Not determined.

· Change in condition

· Self-igniting:

Melting point/Melting range: -48 °C
Boiling point/Boiling range: 101 °C

Flash point: 10 °C

Ignition temperature: 430 °C

Product is not selfigniting.

(Contd. on page 5)

Printing date 21.05.2015 Version number 11 Revision: 12.03.2015

Trade name: ProBase Hot Monomer

	(Contd. of p
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/cm³
Relative density	Not determined.
Vapour density	Not determined.
Evaporation rate	Not determined.
Solubility in / Miscibility with	
water at 20 °C:	1.6 g/l
Partition coefficient (n-octanol/wo	nter): Not determined.
Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
9.2 Other information	No further relevant information available.

SECTION 10: Stability and reactivity

- · 10.1 Reactivity No further relevant information available.
- $\cdot \ \textbf{10.2 Chemical stability} \ \textit{Stable under normal handling and storage conditions}.$
- 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:
- · LD/LC50 values relevant for classification:

80-62-6 methyl methacrylate

Oral LD50 7872 mg/kg (rat)

- · Primary irritant effect:
- · on the skin: Irritant to skin and mucous membranes.
- · on the eye: No irritating effect.
- · Sensitisation: Sensitisation possible through skin contact.
- $\cdot \textbf{\textit{Additional toxicological information:}} \ \textit{No further relevant information available.}$

CD

 Printing date 21.05.2015
 Version number 11
 Revision: 12.03.2015

Trade name: ProBase Hot Monomer

(Contd. of page 5)

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 undiluted product or large quantities of it 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.

- · Uncleaned packaging:
- · Recommendation: Disposal must be made according to official regulations.

· 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)	
$\cdot ADR$	
ADA	



Class
Label
3 (F1) Flammable liquids.
3

· IMDG, IATA



· Class 3 Flammable liquids.

(Contd. on page 7)

Printing date 21.05.2015 Version number 11 Revision: 12.03.2015

Trade name: ProBase Hot Monomer

	(Contd. of pa
Label	3
· 14.4 Packing group · ADR, IMDG, IATA	II
14.5 Environmental hazards: Marine pollutant:	No
· 14.6 Special precautions for user · Danger code (Kemler): · EMS Number:	Warning: Flammable liquids. 339 F-E,S-D
14.7 Transport in bulk according to Anne MARPOL73/78 and the IBC Code	e x II of Not applicable.
Transport/Additional information:	
· ADR · Limited quantities (LQ) · Excepted quantities (EQ) · Transport category · Tunnel restriction code	1L Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml 2 D/E
· IMDG · Limited quantities (LQ) · Excepted quantities (EQ)	1L 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:
- $\cdot \ Other \ regulations, \ limitations \ and \ prohibitive \ regulations$

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.

H317 May cause an allergic skin reaction.

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

(Contd. on page 8)

Printing date 21.05.2015 Version number 11 Revision: 12.03.2015

Trade name: ProBase Hot Monomer

(Contd. of page 7)

ELINCS: European List of Notified Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LC30: Lethal concentration, 30 percent LD50: Lethal dose, 50 percent Flam. Liq. 2: Flammable liquids, Hazard Category 2 Skin Irrit. 2: Skin corrosion/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.