

safety data sheet

to product

ProBase Hot Monomer 1 Liter

1. Identification of the substance / preparation and company

Emergency number:

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Company name:

Company name:		
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A MEERRY SCHEIN* COMPANY	Condor Dental Research CO Sàrl	Ch. des Cibleries 2, CP 300, 1896 Vouvry Tel. 024 482 61 61, Fax 024 482 61 69
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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

GHS07

- · 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.

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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:			
	methyl methacrylate Flam. Liq. 2, H225; Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335	50-100%	
	ethylene glycol dimethacrylate 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:

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.

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· 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.
- · 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.

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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

Clash point: 10 °C

• Flash point: 10 °C • Ignition temperature: 430 °C

· Self-igniting: Product is not selfigniting.

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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.
- · 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:
- · 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.
- $\cdot \textbf{\textit{Additional toxicological information:}} \ \textit{No further relevant information available.}$

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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 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
• •	01(121)
· 14.2 UN proper shipping name	
$\cdot ADR$	1247 METHYL METHACRYLATE MONOMER,
	STABILIZED
· IMDG, IATA	METHYL METHACRYLATE MONOMER, STABILIZE
· 14.3 Transport hazard class(es)	
· ADR	



ClassLabel3 (F1) Flammable liquids.3

· IMDG, IATA



· Class 3 Flammable liquids.

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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:
- · 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

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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.