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.
Trade name: ProBase Cold Monomer

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.

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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.

- 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.
Trade name: ProBase Cold Monomer

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.
**Section 10: Stability and Reactivity**

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical Stability** Stable under normal handling and storage conditions.
- **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.
- **Additional Toxicological Information:** No further relevant information available.
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
  - 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
**Trade name: ProBase Cold Monomer**

- IMDG, IATA

  - Class
  - Label 3 Flammable liquids.

- 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 MARPOL 73/78 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.
Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 21.05.2015
Version number 11
Revision: 12.03.2015

Trade name: ProBase Cold Monomer

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.