SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
   Trade name: SR Ivolen Monomer

1.2 Relevant identified uses of the substance or mixture and uses advised against
   No further relevant information available.

1.3 Application of the substance / the mixture
   Custom tray material

1.4 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

1.5 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.

2.3 Hazard pictograms
   GHS02
   GHS07
   Signal word Danger

2.4 Hazard-determining components of labelling:
   methyl methacrylate

2.5 Hazard statements
   H225 Highly flammable liquid and vapour.
   H315 Causes skin irritation.
   H317 May cause an allergic skin reaction.
   H335 May cause respiratory irritation.

2.6 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)
Trade name: SR Ivolen Monomer

41.1.9

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:

<table>
<thead>
<tr>
<th>CAS: 80-62-6</th>
<th>methyl methacrylate</th>
<th>Flamm. Liq. 2, H225; Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335</th>
</tr>
</thead>
<tbody>
<tr>
<td>EINECS: 201-297-1</td>
<td></td>
<td>50-100%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAS: 8002-74-2</th>
<th>Paraffin waxes and Hydrocarbon waxes</th>
</tr>
</thead>
<tbody>
<tr>
<td>EINECS: 232-315-6</td>
<td>substance with a Community workplace exposure limit</td>
</tr>
<tr>
<td></td>
<td>≤10%</td>
</tr>
</tbody>
</table>

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.
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 only in the original receptacle.
Store in a cool location.

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:

<table>
<thead>
<tr>
<th>CAS: 80-62-6 methyl methacrylate</th>
</tr>
</thead>
<tbody>
<tr>
<td>WEL Short-term value: 416 mg/m³, 100 ppm</td>
</tr>
<tr>
<td>Long-term value: 208 mg/m³, 50 ppm</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAS: 8002-74-2 Paraffin waxes and Hydrocarbon waxes</th>
</tr>
</thead>
<tbody>
<tr>
<td>WEL Short-term value: 6 mg/m³</td>
</tr>
<tr>
<td>Long-term value: 2 mg/m³</td>
</tr>
</tbody>
</table>

Additional information: The lists valid during the making were used as basis.
8.2 Exposure controls

- **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.

- **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]

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**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

(Contd. on page 5)
Trade name: SR Ivolen Monomer

- **Flash point:** 10 °C
- **Ignition temperature:** 430 °C
- **Self-igniting:** Product is not self-igniting.
- **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/water):** 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:**
      - **CAS:** 80-62-6 methyl methacrylate
      - **Oral LD50:** 7872 mg/kg (rat)
  - **Primary irritant effect:**
  - **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.
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.

- 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,RID,ADN, IMDG, IATA 1247
- 14.2 UN proper shipping name
  - ADR/RID/ADN 1247 METHYL METHACRYLATE MONOMER, STABILIZED
  - IMDG, IATA METHYL METHACRYLATE MONOMER, STABILIZED
**Safety data sheet**

according to 1907/2006/EC, Article 31

Printing date 05.08.2015  
Revision: 03.08.2015  
Version number 10

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**Trade name:** SR Ivolen Monomer

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### 14.3 Transport hazard class(es)

- **ADR/RID/ADN**
  - Class 3 (F1) Flammable liquids.
  - Label 3

- **IMDG, IATA**
  - Class 3 Flammable liquids.
  - Label 3

### 14.4 Packing group

- **ADR, RID, ADN, IMDG, IATA**  
  - Packing Group II

### 14.5 Environmental hazards:

- **Marine pollutant:** No

### 14.6 Special precautions for user

- **Warning:** Flammable liquids.
- **Danger code (Kemler):** 33
- **EMS Number:** F-E,S-E

### 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

- **Not applicable.**

### Transport/Additional information:

- **ADR/RID/ADN**
  - Limited quantities (LQ) LQ4
  - Transport category 2
  - Tunnel restriction code D/E

- **UN "Model Regulation":** UN1247, METHYL METHACRYLATE MONOMER, STABILIZED, 3, II

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**SECTION 15: Regulatory information**

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

  - **National regulations:** The product is a medical device according to the Directive 93/42/EEC.

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

  - **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

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**SECTION 16: Other information**

- **Relevant phrases**

  - H225 Highly flammable liquid and vapour.

  *(Contd. on page 8)*

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**Trade name: SR Ivolen Monomer**

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
- 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, 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.