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

1.1 Product identifier

- **Trade name:** Vivaglass Liner (Liquid)

1.2 Relevant identified uses of the substance or mixture and uses advised against

- No further relevant information available.

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**
  - Skin Irrit. 2  H315 Causes skin irritation.
  - Eye Irrit. 2  H319 Causes serious eye irritation.
  - Skin Sens. 1  H317 May cause an allergic skin reaction.

2.2 Label elements

- **The product is classified and labelled according to the CLP regulation.**
- **Hazard pictograms**

![GHS07](image)

- **Signal word** Warning

- **Hazard-determining components of labelling:**
  - 2-hydroxyethyl methacrylate
  - urethane dimethacrylate
  - triethylene glycol dimethacrylate

- **Hazard statements**
  - H315 Causes skin irritation.
  - H319 Causes serious eye irritation.
  - H317 May cause an allergic skin reaction.

- **Precautionary statements**
  - P261 Avoid breathing vapours.
  - P280 Wear protective gloves/protective clothing/eye protection/face protection.
  - P363 Wash contaminated clothing before reuse.
  - P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

(Contd. on page 2)
Trade name: Vivaglass Liner (Liquid)

- **Additional information:**
  Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Regulation (EC) No 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

- **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</th>
<th>Name</th>
<th>concentrations</th>
</tr>
</thead>
<tbody>
<tr>
<td>868-77-9</td>
<td>2-hydroxyethyl methacrylate</td>
<td>25-50%</td>
</tr>
<tr>
<td>212-782-2</td>
<td>Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317</td>
<td></td>
</tr>
<tr>
<td>9003-01-4</td>
<td>carboxamer</td>
<td>25-50%</td>
</tr>
<tr>
<td></td>
<td>Eye Irrit. 2, H319</td>
<td></td>
</tr>
<tr>
<td>72869-86-4</td>
<td>urethane dimethacrylate</td>
<td>3-&lt;10%</td>
</tr>
<tr>
<td>276-957-5</td>
<td>Eye Irrit. 2, H319; Skin Sens. 1, H317; Aquatic Chronic 3, H412</td>
<td></td>
</tr>
<tr>
<td>109-16-0</td>
<td>triethylene glycol dimethacrylate</td>
<td>3-&lt;10%</td>
</tr>
<tr>
<td></td>
<td>Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335</td>
<td></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**
  - **After inhalation:** Supply fresh air; consult doctor in case of complaints.
  - **After skin contact:**
    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.
    If symptoms persist consult doctor.

- **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.

- **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 Not required.
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).
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.
For use in dentistry only.

7.2 Conditions for safe storage, including any incompatibilities

Storage:
7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters
Ingredients with limit values that require monitoring at the workplace:
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

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.
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.
Keep away from foodstuffs, beverages and feed.

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.

Protection of hands:

Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
### SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
  - **General Information**
    - **Appearance:**
      - **Form:** Fluid
      - **Colour:** Colourless
      - **Odour:** Characteristic
      - **Odour threshold:** Not determined.
    - **pH-value:** Not applicable.
  - **Change in condition**
    - **Melting point/Melting range:** Undetermined.
    - **Boiling point/Boiling range:** Undetermined.
  - **Flash point:** Not applicable.
  - **Flammability (solid, gaseous):** Not determined.
  - **Self-igniting:** Product is not selfigniting.
  - **Danger of explosion:** Product does not present an explosion hazard.
  - **Explosion limits:**
    - **Lower:** Not determined.
    - **Upper:** Not determined.
  - **Vapour pressure:** Not applicable.
  - **Density:**
    - Not determined.
  - **Relative density**
    - Not determined.
  - **Vapour density**
    - Not applicable.
  - **Evaporation rate**
    - Not applicable.
  - **Solubility in / Miscibility with water:** Fully miscible.
  - **Partition coefficient (n-octanol/water):** Not determined.
  - **Viscosity:**
    - **Dynamic:** Not applicable.
    - **Kinematic:** Not applicable.
  - **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: No dangerous reactions known.
- 10.4 Conditions to avoid:
  - Protect from exposure to the light.
  - Keep away from heat and direct sunlight.
- 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:
    - Primary irritant effect:
      - on the skin: Irritant to skin and mucous membranes.
      - on the eye: Irritating effect.
    - Sensitisation: Sensitisation possible through skin contact.
  - Additional toxicological information:
    The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:
    Irritant

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
    Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.
SECTION 14: Transport information

- 14.1 UN-Number
  - ADR, ADN, IMDG, IATA Void

- 14.2 UN proper shipping name
  - ADR Void
  - ADN, IMDG, IATA Void

- 14.3 Transport hazard class(es)
  - ADR, ADN, IMDG, IATA Void
  - Class Void

- 14.4 Packing group
  - ADR, IMDG, IATA Void

- 14.5 Environmental hazards:
  - Marine pollutant: No

- 14.6 Special precautions for user
  - Not applicable.

- 14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
  - Not applicable.

- Transport/Additional information:
  - Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).

- UN "Model Regulation": -

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
  - H315 Causes skin irritation.
  - H317 May cause an allergic skin reaction.
  - H319 Causes serious eye irritation.
  - H335 May cause respiratory irritation.
  - H412 Harmful to aquatic life with long lasting effects.

- 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
Trade name: Vivaglass Liner (Liquid)

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)
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
Aquatic Chronic 3: Hazardous to the aquatic environment - Chronic Hazard, Category 3