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

- **1.1 Product identifier**
  - Trade name: **Virtual 380 Heavy Fast / Regular Base**

- **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: Dental impression 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)

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**SECTION 2: Hazards identification**

- **2.1 Classification of the substance or mixture**
  - Classification according to Regulation (EC) No 1272/2008
    - STOT RE 1 H372 Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalative.

- **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**

  ![GHS08](image)

- **Signal word** Danger

- **Hazard-determining components of labelling:**
  - cristobalite

- **Hazard statements**
  - H372 Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalative.

- **Precautionary statements**
  - P314 Get medical advice/attention if you feel unwell.
  - P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

- **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.

(Contd. on page 2)
**SECTION 3: Composition/Information on ingredients**

### 3.2 Chemical characterisation: Mixtures

**Description:** Mixture of substances listed below with nonhazardous additions.

<table>
<thead>
<tr>
<th>CAS</th>
<th>EINECS:</th>
<th>Dangerous components</th>
</tr>
</thead>
<tbody>
<tr>
<td>14464-46-1</td>
<td>238-455-4</td>
<td>cristobalite STOT RE 1, H372 10-&lt;25%</td>
</tr>
<tr>
<td>9016-45-9</td>
<td>NLP: 500-024-6</td>
<td>4-Nonylphenyl-polyethylene glycol Eye Dam. 1, H318; Aquatic Acute 1, H400; Acute Tox. 4, H302; STOT SE 3, H335 0.1-&lt;0.3%</td>
</tr>
</tbody>
</table>

**SVHC**

- 9016-45-9 4-Nonylphenyl-polyethylene glycol

**Additional information:** For the wording of the listed risk phrases refer to section 16.

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**SECTION 4: First aid measures**

### 4.1 Description of first aid measures

**After inhalation:**

Supply fresh air and to be sure call for a doctor.

In case of unconsciousness place patient stably in side position for transportation.

**After skin contact:**

Rinse with water.

**After eye contact:**

Rinse opened eye for several minutes under running water. Then consult a doctor.

**After swallowing:**

Seek medical treatment.

**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.

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**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.

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**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:**

Pick up mechanically.

**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.

- **Information about fire - and explosion protection:** No special measures required.

- **7.2 Conditions for safe storage, including any incompatibilities**
  - **Storage:**
    - Requirements to be met by storerooms and receptacles: Store only in the original receptacle.
    - Information about storage in one common storage facility: Not required.
    - Further information about storage conditions:
      - Keep container tightly sealed.
      - Protect from heat and direct sunlight.
  - **7.3 Specific end use(s)**

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:
    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**
  - Personal protective equipment:
    - General protective and hygienic measures:
      - Usual hygienic measures for dental practice.
      - Keep away from foodstuffs, beverages and feed.
      - Wash hands before breaks and at the end of work.
    - Respiratory protection: Not required.
    - Protection of hands:
      - The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
      - After use of gloves apply skin-cleaning agents and skin cosmetics.
    - Material of gloves
      - The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
    - 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.
    - Eye protection: Safety glasses

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
  - **General Information**
    - **Appearance:**
      - Form: Viscous
      - Colour: Blue
      - Odour: like peppermint
Trade name: Virtual 380 Heavy Fast / Regular Base

- 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 applicable.
- Self-igniting: Product is not selfigniting.
- Danger of explosion: Product does not present an explosion hazard.
- Explosion limits: Not applicable.
  Lower: Not determined.
  Upper: Not determined.
- Vapour pressure: Not determined.
- Density: Not determined.
- Relative density: Not determined.
- Vapour density: Not determined.
- Evaporation rate: Not determined.
- Solubility in / Miscibility with water: Not miscible or difficult to mix.
- 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: No dangerous reactions known.
- 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:
  - Primary irritant effect:
    - on the skin: No irritant effect.
    - on the eye: No irritating effect.
  - Sensitisation: No sensitising effects known.
  - 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 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.
  - Uncleaned packaging:
    - Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport information

- 14.1 UN-Number
  - ADR, ADN, IMDG, IATA: Void
- 14.2 UN proper shipping name
  - ADR, ADN, IMDG, IATA: Void
- 14.3 Transport hazard class(es)
  - ADR, ADN, IMDG, IATA: 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 MARPOL73/78 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": -
Trade name: Virtual 380 Heavy Fast / Regular Base

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.

<table>
<thead>
<tr>
<th>Substances of very high concern (SVHC) according to REACH, Article 57</th>
</tr>
</thead>
<tbody>
<tr>
<td>9016-45-9 4-Nonylphenyl-polyethylene glycol</td>
</tr>
</tbody>
</table>

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
  H302 Harmful if swallowed.
  H318 Causes serious eye damage.
  H335 May cause respiratory irritation.
  H372 Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalative.
  H400 Very toxic to aquatic life.

- 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)
  Acute Tox. 4: Acute toxicity, Hazard Category 4
  Eye Dam. 1: Serious eye damage/eye irritation, Hazard Category 1
  STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3
  STOT RE 1: Specific target organ toxicity - Repeated exposure, Hazard Category 1
  Aquatic Acute 1: Hazardous to the aquatic environment - AcuteHazard, Category 1

* Data compared to the previous version altered.