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

1.1 Product identifier

Trade name: Virtual 380 Monophase Fast 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
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, 9494 Schaan, Liechtenstein)

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: Inhalation.

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

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: Inhalation.

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.
SECTION 3: Composition/information on ingredients

3.2 Chemical characterisation: Mixtures
- Description: Mixture of substances listed below with nonhazardous additions.
- Dangerous components:
  - CAS: 14464-46-1
cristobalite
  - EINECS: 238-455-4
  - STOT RE 1, H372 10-25%
- Additional information: For the wording of the listed hazard phrases refer to section 16.

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.
- Most important symptoms and effects, both acute and delayed: No further relevant information available.
- 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.
- Special hazards arising from the substance or mixture: No further relevant information available.
- 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.
- Environmental precautions: Do not allow to enter sewers/surface or ground water.
- Methods and material for containment and cleaning up: Pick up mechanically.
- 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) 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:
    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 and dental laboratories.
      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:** Viscous
    - **Colour:** Blue
    - **Odour:** like peppermint
    - **Odour threshold:** Not determined.
    - **pH-value:** Not applicable.
  - **Change in condition**
    - Melting point/freezing point: Undetermined.
    - Initial boiling point and boiling range: Undetermined.
Flash point: Not applicable.

Flammability (solid, gas): Not applicable.

Auto-ignition temperature: Product is not selfigniting.

Explosive properties: Product does not present an explosion hazard.

Explosion limits:
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.

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.

10.3 Possibility of hazardous reactions: No decomposition if used according to specifications.

10.4 Conditions to avoid: No further relevant information available.

10.5 Incompatible materials: None under normal conditions of storage and use.

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: Based on available data, the classification criteria are not met.

Skin corrosion/irritation: Based on available data, the classification criteria are not met.

Serious eye damage/irritation: Based on available data, the classification criteria are not met.

Respiratory or skin sensitisation: Based on available data, the classification criteria are not met.

Additional toxicological information: No further relevant information available.

Germ cell mutagenicity: Based on available data, the classification criteria are not met.

Carcinogenicity: Based on available data, the classification criteria are not met.

Reproductive toxicity: Based on available data, the classification criteria are not met.

STOT-single exposure: Based on available data, the classification criteria are not met.

STOT-repeated exposure: Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.

Aspiration hazard: Based on available data, the classification criteria are not met.
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/RID/ADN, ADN, IMDG, IATA: Void
- 14.2 UN proper shipping name
  - ADR/RID/ADN, ADN, IMDG, IATA: Void
- 14.3 Transport hazard class(es)
  - ADR/RID/ADN, ADN, IMDG, IATA: Void
- 14.4 Packing group
  - ADR/RID/ADN, 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 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": Void
### SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
  
  REGULATION (EC) No 1907/2006 ANNEX XVII
  
  Conditions of restriction: 3

- **National regulations:**

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

  The product is a medical device according to the Directive 93/42/EEC.

- **Substances of very high concern (SVHC) according to REACH, Article 57**

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

- **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)
  - PBT: Persistent, Bioaccumulative and Toxic
  - SVHC: Substances of Very High Concern
  - vPvB: very Persistent and very Bioaccumulative
  - STOT RE 1: Specific target organ toxicity (repeated exposure) – Category 1

* Data compared to the previous version altered.