

## Safety data sheet according to 1907/2006/EC, Article 31

Printing date 04.05.2015

Version number 7

Revision: 27.04.2015

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

- **1.1 Product identifier**
- **Trade name:** **Virtual 380 Mono 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  
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**  
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

- **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**  
P264 Wash thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.  
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.

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 · **vPvB:** Not applicable.

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### 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<br>EINECS: 238-455-4 | cristobalite<br>STOT RE 1, H372                                                                                   | ≤10%    |
| CAS: 9016-45-9<br>NLP: 500-024-6     | 4-Nonylphenyl-polyethylene glycol<br>Eye Dam. 1, H318; Aquatic Acute 1, H400; Acute Tox. 4, H302; STOT SE 3, H335 | 0.3-<1% |

#### · **SVHC**

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

 · **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 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.

### SECTION 5: Firefighting measures

#### · 5.1 Extinguishing media

##### · **Suitable extinguishing agents:**

 CO<sub>2</sub>, 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:** 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.

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### 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.  
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

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|                                                                     |                                               |
|---------------------------------------------------------------------|-----------------------------------------------|
| · <b>Odour threshold:</b>                                           | Not determined.                               |
| · <b>pH-value:</b>                                                  | Not applicable.                               |
| · <b>Change in condition</b><br><b>Melting point/Melting range:</b> | Undetermined.                                 |
| <b>Boiling point/Boiling range:</b>                                 | Undetermined.                                 |
| · <b>Flash point:</b>                                               | Not applicable.                               |
| · <b>Flammability (solid, gaseous):</b>                             | Not applicable.                               |
| · <b>Self-igniting:</b>                                             | Product is not selfigniting.                  |
| · <b>Danger of explosion:</b>                                       | Product does not present an explosion hazard. |
| · <b>Explosion limits:</b><br><b>Lower:</b>                         | Not determined.                               |
| <b>Upper:</b>                                                       | Not determined.                               |
| · <b>Vapour pressure:</b>                                           | Not determined.                               |
| · <b>Density:</b>                                                   | Not determined.                               |
| · <b>Relative density</b>                                           | Not determined.                               |
| · <b>Vapour density</b>                                             | Not determined.                               |
| · <b>Evaporation rate</b>                                           | Not determined.                               |
| · <b>Solubility in / Miscibility with water:</b>                    | Not miscible or difficult to mix.             |
| · <b>Partition coefficient (n-octanol/water):</b>                   | Not determined.                               |
| · <b>Viscosity:</b><br><b>Dynamic:</b>                              | Not determined.                               |
| <b>Kinematic:</b>                                                   | Not determined.                               |
| · <b>9.2 Other information</b>                                      | 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.

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#### 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

- |                                                                                       |                                                                                |
|---------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|
| · <b>14.1 UN-Number</b>                                                               |                                                                                |
| · <b>ADR, ADN, IMDG, IATA</b>                                                         | Void                                                                           |
| · <b>14.2 UN proper shipping name</b>                                                 |                                                                                |
| · <b>ADR, ADN, IMDG, IATA</b>                                                         | Void                                                                           |
| · <b>14.3 Transport hazard class(es)</b>                                              |                                                                                |
| · <b>ADR, ADN, IMDG, IATA</b>                                                         |                                                                                |
| · <b>Class</b>                                                                        | Void                                                                           |
| · <b>14.4 Packing group</b>                                                           |                                                                                |
| · <b>ADR, IMDG, IATA</b>                                                              | Void                                                                           |
| · <b>14.5 Environmental hazards:</b>                                                  |                                                                                |
| · <b>Marine pollutant:</b>                                                            | No                                                                             |
| · <b>14.6 Special precautions for user</b>                                            | Not applicable.                                                                |
| · <b>14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b> | Not applicable.                                                                |
| · <b>Transport/Additional information:</b>                                            | Product is not classified as a dangerous good for transport (ADR, IMDG, IATA). |
| · <b>UN "Model Regulation":</b>                                                       | -                                                                              |

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### 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.

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

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

· **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.**

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