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

1.1 Product identifier

Trade name: Virtual Monophase Regular / Fast Catalyst, Virtual Medium Regular / Fast Catalyst

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 2 H373 May cause 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 Warning

Hazard-determining components of labelling:
cristobalite

Hazard statements
H373 May cause 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 ≥2.5-%<10%

- 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.

- 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:
  - 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.
**Trade name:** Virtual Monophase Regular / Fast Catalyst, Virtual Medium Regular / Fast Catalyst

- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
  - **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.

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**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

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**SECTION 9: Physical and chemical properties**

- **9.1 Information on basic physical and chemical properties**
  - **General Information**
    - **Appearance:**
      - Form: Viscous
      - Colour: White
      - Odour: Odourless
    - **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.
· 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 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.

(Contd. on page 5)
SECTION 12: Ecological information

12.1 Toxicity
- Aquatic toxicity: No further relevant information available.
- Persistence and degradability: No further relevant information available.
- Bioaccumulative potential: No further relevant information available.
- 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.
  - Results of PBT and vPvB assessment
    - PBT: Not applicable.
    - vPvB: Not applicable.
  - 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

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
vPvB: very Persistent and very Bioaccumulative
STOT RE 1: Specific target organ toxicity (repeated exposure) – Category 1
STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2

* Data compared to the previous version altered.