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

1.1 Product identifier
- Trade name: Virtual Putty Regular / Fast Catalyst, Virtual Putty Regular / 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 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.

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.

Dangerous components:

| CAS: 14464-46-1 | cristobalite | STOT RE 1, H372 | ≤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.

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:
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.
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.
Wash hands before breaks and at the end of work.
Keep away from foodstuffs, beverages and feed.
・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: Pasty
  Colour: According to product specification
  Odour: Characteristic
  Odour threshold: Not determined.
・pH-value: Not applicable.

(Contd. on page 4)
Trade name: Virtual Putty Regular / Fast Catalyst, Virtual Putty Regular / Fast Base

- 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.
- 10.3 Thermal decomposition / conditions to be avoided
  - No decomposition if used according to specifications.
- 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.
  - 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
    - May cause damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.
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: Not hazardous for water.
- 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
    - Class 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
Trade name: Virtual Putty Regular / Fast Catalyst, Virtual Putty Regular / Fast Base

*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.
- **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
  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.*