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

1.1 Product identifier

Trade name: Virtual CADbite Registration 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
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 2 H373 May cause damage to organs through prolonged or repeated exposure.

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.

vPvB: 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
- EINECS: 238-455-4
- STOT RE 1, H372
- 3-<10%
- 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.
  Generally the product does not irritate the skin.
- 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.
- 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.

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.
    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: White
  - Odour: Odourless
  - 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.
### 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:**
  - **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** 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.
40.1.5 Additional ecological information:

General notes: Generally 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, 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
Class 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": -

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.

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: Inhalative.

- 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)
  STOT RE 1: Specific target organ toxicity - Repeated exposure, Hazard Category 1
  STOT RE 2: Specific target organ toxicity - Repeated exposure, Hazard Category 2

- * Data compared to the previous version altered.*