

1 Identification


- **Product identifier**
- **Trade name:** *Virtual CADbite Registration Catalyst*
- **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
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Ivoclar Vivadent Inc.
175 Pineview Drive, Amherst, N.Y. 14228
USA
Tel. +1 800 533 6825
Fax +1 716 691 2285

- Ivoclar Vivadent Inc.
1-6600 Dixie Road
Mississauga, Ontario
L5T 2Y2
Canada
Phone: +1 905 670 8499
Fax: +1 905 670 3102
- **Information department:** Quality Assurance / Regulatory Affairs
- **Emergency telephone number:**
24 Hour Emergency Assistance:
Emergency-Call USA - Infotrac: 1-800-535-5053
Emergency-Call Canada - Canutec: 1-613-996-6666

- General SDS Assistance:
US: 1-800-533-6825
Canada: 1-800-263-8182

2 Hazard(s) identification

- **Classification of the substance or mixture**
Carc. 1A H350 May cause cancer.
STOT RE 1 H372 Causes damage to the lung through prolonged or repeated exposure. Route of exposure:
Inhalative.

 - **Label elements**
 - **GHS label elements**
The product is classified and labeled according to the Globally Harmonized System (GHS).
 - **Hazard pictograms**
- 

GHS08
- **Signal word** *Danger*
 - **Hazard-determining components of labeling:**
crystalite
 - **Hazard statements**
May cause cancer.
Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalative.

Material Safety Data Sheet acc. to ISO 11014

Printing date 05/04/2015

Version number 7

Reviewed on 04/28/2015

Trade name: Virtual CADbite Registration Catalyst

(Contd. of page 1)

- **Precautionary statements**

Get medical advice/attention if you feel unwell.

Dispose of contents/container in accordance with local/regional/national/international regulations.

- **Additional information:**

Medical devices are exempt from the labeling provisions of GHS according to the Hazard Communication Standard (HCS).

- **Hazard description:**

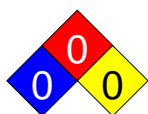
- **WHMIS-symbols:**

D2A - Very toxic material causing other toxic effects

D1B - Toxic material causing immediate and serious toxic effects

- **Classification system:**

- **NFPA ratings (scale 0 - 4)**



Health = 0

Fire = 0

Reactivity = 0

- **HMIS-ratings (scale 0 - 4)**



Health = *0

Fire = 0

Reactivity = 0

- **Other hazards**

- **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

* 3 Composition/information on ingredients

- **Chemical characterization: Mixtures**

· **Description:** Mixture of the substances listed below with nonhazardous additions.

- **Dangerous components:**

14464-46-1 cristobalite	3-5%
-------------------------	------

4 First-aid measures

- **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.

- **After swallowing:** Seek medical treatment.

- **Information for 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.

CA

(Contd. on page 3)

Material Safety Data Sheet acc. to ISO 11014

Printing date 05/04/2015

Version number 7

Reviewed on 04/28/2015

Trade name: Virtual CADbite Registration Catalyst

(Contd. of page 2)

5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, extinguishing 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.

6 Accidental release measures

- **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.

7 Handling and storage

- **Handling:**
- **Precautions for safe handling**
Only adequately trained personnel should handle this product.
For use in dentistry only.
- **Information about protection against explosions and fires:** No special measures required.
- **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 receptacle tightly sealed.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**
- **Components 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 that were valid during the creation were used as basis.
- **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.
- **Breathing equipment:** 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.

(Contd. on page 4)

Material Safety Data Sheet acc. to ISO 11014

Printing date 05/04/2015

Version number 7

Reviewed on 04/28/2015

Trade name: Virtual CADbite Registration Catalyst

(Contd. of page 3)

· **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

9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

· Form:	Pasty
· Color:	White
· Odor:	Odorless
· 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.

· **Flammability (solid, gaseous):** Not applicable.

· **Auto igniting:** Product is not selfigniting.

· **Danger of explosion:** Product does not present an explosion hazard.

· **Explosion limits:**

· Lower:	Not determined.
· Upper:	Not determined.

· **Vapor 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.

10 Stability and reactivity

· **Reactivity** No further relevant information available.

· **Chemical stability** Stable under normal handling and storage conditions.

(Contd. on page 5)

Material Safety Data Sheet

acc. to ISO 11014

Printing date 05/04/2015

Version number 7

Reviewed on 04/28/2015

Trade name: Virtual CADbite Registration Catalyst

(Contd. of page 4)

- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** None under normal conditions of storage and use.

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:** No further relevant information available.

- **Carcinogenic categories**

- **IARC (International Agency for Research on Cancer)**

14464-46-1	cristobalite	I
------------	--------------	---

- **NTP (National Toxicology Program)**

14464-46-1	cristobalite	K
------------	--------------	---

- **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.		
------------------------------------	--	--

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:** Generally not hazardous for water
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:**
Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

CA

(Contd. on page 6)

Material Safety Data Sheet

acc. to ISO 11014

Printing date 05/04/2015

Version number 7

Reviewed on 04/28/2015

Trade name: Virtual CADbite Registration Catalyst

(Contd. of page 5)

14 Transport information

· UN-Number · DOT, TDG, ADN, IMDG, IATA	Void
· UN proper shipping name · DOT, TDG, ADN, IMDG, IATA	Void
· Transport hazard class(es) · DOT, TDG, ADN, IMDG, IATA · Class	Void
· Packing group · DOT, TDG, IMDG, IATA	Void
· Environmental hazards: · Marine pollutant:	No
· Special precautions for user	Not applicable.
· 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":	-

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**

· **Sara**

· **Section 355 (extremely hazardous substances):**

None of the ingredients is listed.

· **Section 313 (Specific toxic chemical listings):**

None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act):**

All ingredients are listed.

· **Proposition 65**

· **Chemicals known to cause cancer:**

All ingredients are listed.

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

(Contd. on page 7)

Material Safety Data Sheet

acc. to ISO 11014

Printing date 05/04/2015

Version number 7

Reviewed on 04/28/2015

Trade name: Virtual CADbite Registration Catalyst

(Contd. of page 6)

· **TLV (Threshold Limit Value established by ACGIH)**

14464-46-1 cristobalite

A2

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

All ingredients are listed.

· **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

· **Hazard pictograms**



GHS08

· **Signal word Danger**

· **Hazard-determining components of labeling:**

cristobalite

· **Hazard statements**

May cause cancer.

Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalative.

· **Precautionary statements**

Get medical advice/attention if you feel unwell.

Dispose of contents/container in accordance with local/regional/national/international regulations.

· **National regulations:**

· **Other regulations, limitations and prohibitive regulations**

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

This product is classified as a medical device under US and Canadian regulations and has been reviewed by the US Food and Drug Administration and Health Canada.

· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

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.

· **Date of preparation / last revision** 05/04/2015 / 6

· **Abbreviations and acronyms:**

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

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)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

WHMIS: Workplace Hazardous Materials Information System (Canada)

Carc. 1A: Carcinogenicity, Hazard Category 1A

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

· *** Data compared to the previous version altered.**

CA