

SAFETY DATA SHEETS

This SDS packet was issued with item:

077103484

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

077103476 077103500 077103591 077103609 077103633 077103641 077103658 077103666 077103674 077103682
077103690 077103708 077103716 077103724 077103732 077103773 077104011 077104029 077157050 077157068
077157076 077157100 077157118 077157126 077157134 077157142 077157159 077157167 077157209 077157217
077157225 273045205

Material Safety Data Sheet

Virtual



Date of issue / Reference

01.06.2011

liprt

Replaces version of

17.10.2007

lise / v5

Date of printing

01.06.2011

Sheet No. 1504

Version 6

Page 1 of 5

Company

Ivoclar Vivadent AG, Bendererstrasse 2, FL - 9494 Schaan
Fürstentum Liechtenstein

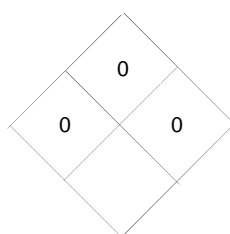
1 Commercial product name and supplier

1.1 Commercial product name /
Designation

Virtual

**Extra Light Body, Light Body, Medium Body,
Heavy Body, Monophase, Putty (fast und
regular set), CADbite Registration, Virtual 380**

NFPA



HMIS

HMIS	
H	0
F	0
R	0

1.2 Application / Use

Dental silicone impression materials

1.3 Producer

Ivoclar Vivadent AG, Bendererstrasse 2, 9494 Schaan
Principality of Liechtenstein (FL)

1.4 Supplier

Ivoclar Vivadent, Inc.
175 Pineview Drive, Amherst NY 14228, USA
2785 Skymark Ave., Unit 1 Mississauga, ON L4W4Y3, Canada
MSDS prepared by Anderjeet Gulati. Tel. No. 716 691-0010

1.5 24 Hour Emergency Assistance

Emergency-Call USA- Infotrac: 1-800-535-5053
Emergency-Call Canada - Canutec: 1-613-996-6666

General MSDS Assistance

US: 1-800-533-6825
Canada: 1-800-263-8182

2 Composition

2.1 Chemical characterization

Addition-reaction silicones of:
Vinylpolysiloxane, methylhydrogensiloxane, organic filler, pigment,
catalyst and food dyes

2.2 Hazardous components

2.3 Further information

None.

3 Hazards identification

None, if used in accordance to instructions. Prevent from accidental
ingestion.

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4 First aid measures

- | | | |
|-----|---------------------|---|
| 4.1 | Eye contact | Flush with plenty of water. |
| 4.2 | Skin contact | Wash with water. |
| 4.3 | Ingestion | No hazards anticipated from swallowing small amounts incidentally to normal handling. |
| 4.4 | Inhalation | No specific requirements. |
| 4.5 | Further information | None. |

5 Fire-fighting measures

- | | | |
|-----|------------------------------|---|
| 5.1 | Suitable extinguishing media | Water fog, carbon dioxide, foam, dry chemicals. |
| 5.2 | Extinguishing media to avoid | None known |
| 5.3 | Flash point | Test method: |
| 5.4 | Ignition temperature | |
| 5.5 | Explosion limits | Lower:
Upper:
not applicable |
| 5.6 | Further information | None. |

6 Accidental release measures

Clean up mechanically. Wash the area with soap and water. Do not allow to flow off into the drains or waters.
Dispose of according to local and national regulations.

7 Handling and storage

- | | | |
|-----|--------------------------------|--|
| 7.1 | Handling | Only adequately trained personnel should handle this product. |
| 7.2 | Industrial hygiene | Usual hygienic measures for dental practice. |
| 7.3 | Storage | Store at 5-28 °C / 41-82 °F. |
| 7.4 | Place of storage | Store in a well ventilated, cool, dry area.
Keep containers tightly closed. |
| 7.5 | Fire- and explosion-protection | No specific requirements. |

8 Exposure controls / Personal protection

- | | | |
|-----|-----------------------|---------------------------|
| 8.1 | Exposure controls | No specific requirements. |
| 8.2 | Exposure limit values | None established. |

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8.3 Occupational exposure controls

8.3.1 Respiratory protection

Not required.

8.3.2 Hand protection

Use vinyl gloves only or wash hands thoroughly. (The setting of vinylpolysiloxanes is inhibited by latex gloves.)

8.3.3 Eye protection

Safety goggles.

8.3.4 Other

None.

8.4 Environmental exposure controls

9 Physical and chemical properties

9.1 Appearance

Pastes / viscous liquids

9.2 Colour

various

9.3 Odour

low

9.4 Change of physical state

Test method:

not applicable

9.5 Density

1.0-1.6 g/cm³ (20°C)

9.6 Vapour pressure

not applicable

9.7 Viscosity

not known

9.8 Solubility

Solubility in water

nearly insoluble

9.9 pH

not known

9.10 Further information

Part. coeff. n-octanol/water

Evaporat. rate

None.

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10 Stability and reactivity

- | | | |
|------|----------------------------------|--|
| 10.1 | Thermal decomposition | > 250 °C |
| 10.2 | Hazardous decomposition products | None, if used in accordance to instructions. |
| 10.3 | Conditions / materials to avoid | None, if used in accordance to instructions. |
| 10.4 | Further information | None. |

11 Toxicological information

- | | | |
|------|-----------------------------|---|
| 11.1 | Acute toxicity | --- |
| 11.2 | Subacute / Chronic toxicity | No adverse effects anticipated by this route of exposure incidental to proper industrial handling.
Virtual possesses no cytotoxic potential. |
| 11.3 | Further information | Avoid eye contact. |

12 Ecological information

- | | | |
|------|-------------------------------|---|
| 12.1 | Ecotoxicity | No data available. |
| 12.2 | Mobility | No data available. |
| 12.3 | Persistence and degradability | No data available. |
| 12.4 | Bioaccumulative potential | No data available. |
| 12.5 | Further information | No ecological problems to be anticipated if properly handled and used.
nearly insoluble
Material is not degradable in the environment.
Do not discharge to sewers or natural waters. |

13 Disposal considerations

Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

14 Transport information

- | | | | | | |
|------|-------------------|----------------------|-----|---------------|-----|
| 14.1 | Transport at land | ADR | --- | RID | --- |
| | | UN Number | --- | Kemler Number | |
| | | Packing Group | --- | | |
| | | Proper shipping name | --- | | |

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14.2	Transport at sea	ADNR	---	IMDG	---
		UN Number	---		
		EMS	---	MFAG	---
		Packing Group			
		Proper shipping name	---		
		Marine pollutant			
14.3	Air transport	ICAO / IATA-DGR	---		
		UN Number	---		
		Proper shipping name	---		
		Subsidiary Risk	---		
		Labels	---		
		Packing Group	---		
	Passenger airplane	Packing Instructions	---		
		max.	---		
	Cargo Airplane	Packing Instructions	---		
		max.	---		
14.4	Further information	Product is not classified as a dangerous good for transport.			

15 Regulatory information

The product is a medical device according to the EC-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.

- 15.1 National regulations
- 15.2 NFPA Storage
- 15.3 Further information

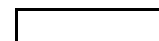
None.

16 Other information

No other information.

The above mentioned data correspond to our present state of knowledge and experience. The safety data sheet serves as description of the products in regard to necessary safety measures. The indications do not have the meaning of guarantees on properties.

This safety data sheet has been generated with the safety database 'ChemManager',
© ASSiST Applied Software Solutions in Science and Technology AG,
Weiherweg 3, CH-4104 Oberwil, Switzerland




1 Identification

- **Product identifier**
- **Trade name:** ***Virtual CADbite Registration Base***
- **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:**
cristobalite
- **Hazard statements**
May cause cancer.
Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalative.

Safety Data Sheet

acc. to OSHA HCS

Printing date 05/04/2015

Version number 7

Reviewed on 04/28/2015

Trade name: **Virtual CADbite Registration Base**

(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).

- **Classification system:**

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



Health = 2

Fire = 0

Reactivity = 0

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



Health = *2

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

10-<25%

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.

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.

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Reviewed on 04/28/2015

Trade name: *Virtual CADbite Registration Base*

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- **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.
- **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.

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acc. to OSHA HCS

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Trade name: **Virtual CADbite Registration Base**

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· **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:	Light blue
Odor:	like peppermint
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.

· **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.

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Safety Data Sheet

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Trade name: **Virtual CADbite Registration Base**

(Contd. of page 4)

· **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.

14 Transport information

- **UN-Number**
- **DOT, ADR, ADN, IMDG, IATA** Void

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US

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Reviewed on 04/28/2015

Trade name: *Virtual CADbite Registration Base*

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

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.

· *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.

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Trade name: **Virtual CADbite Registration Base**

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· **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:**

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

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)

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.**

US


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:**
cristobalite
- **Hazard statements**
May cause cancer.
Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalative.

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Trade name: **Virtual CADbite Registration Catalyst**

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- **Precautionary statements**

Get medical advice/attention if you feel unwell.

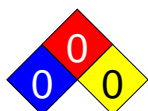
Dispose of contents/container in accordance with local/regional/national/international regulations.

- **Additional information:**

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

- **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

2.5-<10%

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.

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.

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US

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acc. to OSHA HCS

Printing date 05/04/2015

Version number 7

Reviewed on 04/28/2015

Trade name: **Virtual CADbite Registration Catalyst**

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- **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.
- **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.

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· **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.

· **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.

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· **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)**

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I

· **NTP (National Toxicology Program)**

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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.

14 Transport information

· **UN-Number**

· **DOT, ADR, ADN, IMDG, IATA**

Void

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· UN proper shipping name	
· DOT, ADR, ADN, IMDG, IATA	Void
· Transport hazard class(es)	
· DOT, ADR, ADN, IMDG, IATA	
· Class	Void
· Packing group	
· DOT, ADR, 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.

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

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A2

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

All ingredients are listed.

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· **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:**

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

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)

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.**

US