

Printing date 10/23/2019 Version number 4 Reviewed on 04/26/2019

1 Identification

- · Product identifier
- Trade name: Virtual XD: Light Fast Base, Light Regular Base
- · Application of the substance / the mixture Dental impression material
- · Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

Ivoclar Vivadent Inc.

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Ivoclar Vivadent Inc. 1-6600 Dixie Road Mississauga, Ontario L5T 2Y2 Canada

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· 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 identification

· Classification of the substance or mixture

Carcinogenicity - Category 1A

Reproductive Toxicity - Category 2

H350 May cause cancer.

H361 Suspected of damaging fertility or the unborn

Specific Target Organ Toxicity - Repeated Exposure - H372 Causes damage to the lung through Category 1

prolonged or repeated exposure. Route of exposure: Inhalation.

- · Label elements
- · GHS label elements

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

· Hazard pictograms



- · Signal word Danger
- · Hazard-determining components of labeling: cristobalite

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· Hazard statements

May cause cancer.

Suspected of damaging fertility or the unborn child.

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

Precautionary statements

Avoid release to the environment.

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 = 0Fire = 0Reactivity = 0

· HMIS-ratings (scale 0 - 4)



Health = *0Fire = 0

3 Composition/Information on ingredients

- · Chemical characterization: Mixtures
- · **Description:** Mixture of the substances listed below with nonhazardous additions.

· Dangerous components:		
CAS: 14464-46-1	cristobalite	10-30% w/w *
CAS: 27306-78-1	polysiloxane	1-5% w/w *
CAS: 556-67-2	octamethylcyclotetrasiloxane	0.1-1% w/w *

^{*} Actual concentration ranges are withheld as a trade secret.

4 First aid measures

- · Description of first aid measures
- · After inhalation: Supply fresh air; consult doctor in case of complaints.
- · After skin contact:

Immediately rinse with water.

If skin irritation continues, consult a doctor.

- · 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.

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5 Firefighting 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.

Protect from heat and direct sunlight.

· 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:

CAS: 14808-60-7 Quartz (SiO2)

EL Long-term value: 0.025 mg/m³

ACGIH A2; IARC 1

EV Long-term value: 0.10* mg/m³

*respirable fraction

CAS: 14464-46-1 cristobalite

EL Long-term value: 0.025 mg/m³ respirable, ACGIH A2; IARC 1

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EV Long-term value: 0.05* mg/m³

*respirable fraction

- · 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 and dental laboratories.

Keep away from foodstuffs, beverages and feed.

Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

- · Breathing equipment: Not required.
- Protection of hands:

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· 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

Goggles recommended during refilling.

9 Physical and chemical properties

· Information on basic physical and	chemical properties	
· General Information		
· Appearance:		
Form:	Viscous	
Color:	Orange	
· Odor:	like peppermint	
· Odor 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.	
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· Vapor pressure:	Not determined.	
Density at 20 °C:	$1,260 - 1,270 \text{ g/cm}^3$	
· Relative density	Not determined.	
· Vapor density	Not determined.	
· Evaporation rate	Not determined.	
· Solubility in / Miscibility with		
Water:	Nearly insoluble.	
· Partition coefficient (n-octanol/	water): Not determined.	
· Viscosity:		
Dynamic:	Not determined.	
Kinematic:	Not determined.	
· Solvent content:		
Solids content:	30.7 %	
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.
- · Hazardous decomposition products: None under normal conditions of storage and use.

11 Toxicological information

- · Information on toxicological effects
- · Acute toxicity:
- · on the skin: No irritant effect.
- · on the eye: No irritating effect.
- · Sensitization: No sensitizing effects known.
- · Additional toxicological information:
- · Carcinogenic categories

· IARC (International Agency for Research on Cancer)		
CAS: 14808-60-7		1
CAS: 14464-46-1	cristobalite	1
· NTP (National Toxicology Program)		
*		
CAS: 14808-60-7	Quartz (SiO2)	K

12 Ecological information

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.

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- · Behavior in environmental systems:
- · Bioaccumulative potential No further relevant information available.
- · Mobility in soil No further relevant information available.
- · Ecotoxical effects:
- · Remark: Harmful to fish
- · Additional ecological information:
- · General notes:

Water hazard class 1 (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.

Harmful to aquatic organisms

- · 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.

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

-CA

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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):

CAS: 14464-46-1 cristobalite

CAS: 27306-78-1 polysiloxane

· GHS label elements

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

· Hazard pictograms



- · Signal word Danger
- · Hazard-determining components of labeling:

cristobalite

· Hazard statements

May cause cancer.

Suspected of damaging fertility or the unborn child.

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

· Precautionary statements

Avoid release to the environment.

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

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 the latest revision of the safety data sheet 10/23/2019 / 3
- · Abbreviations and acronyms:

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

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)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative
* Data compared to the previous version altered.