

**SAFETY DATA SHEET (GHS)**

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**1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE/PRODUCT AND MANUFACTURER/IMPORTER****1.1 Product identifier:-**

**Product name:** Virtual Heavy Regular / Fast Base  
**Product number:** Void

**1.2 Other means of identification:-**

Not applicable.

**1.3 Recommended use of the chemical and restrictions on use:-**

Not applicable.

**Identified uses:** Dental impression material

**1.4 Details of the manufacturer and importer:-**

**Manufacturer:** Ivoclar Vivadent AG  
 Bendererstrasse 2  
 FL-9494 Schaan  
 PRINCIPALITY OF LIECHTENSTEIN

**Importer:** Ivoclar Vivadent Pty Ltd  
 1- 5 Overseas Drive Noble Park North VIC 3174  
 Tel: + 61 3 9795 9599 Fax: + 61 3 9795 9645  
 Email: [info@ivoclarvivadent.com](mailto:info@ivoclarvivadent.com)  
 13 11 26  
 Poisons Hotline (24 hours / 7 days)

**1.5 Emergency phone number:****2. HAZARD(S) IDENTIFICATION****2.1 GHS Classification:-**

STOT RE 1 H372 Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalative.

**2.2 GHS Label elements, including precautionary statements:-****Hazard Pictogram:**

GHS08

**Signal word:**

Danger  
 cristobalite

**Hazard-determining components of labelling:****Hazard statements:**

H372 Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalative  
 P314 Get medical advice/attention if you feel unwell.  
 P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

**Precautionary statements:****2.3 Additional information:**

Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Regulation (EC) No 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

**Other hazards:-**

Void

**Results of PBT and vPvB assessment;**

**PBT:** Not applicable.  
**vPvB:** Not applicable.

### 3 COMPOSITION/INFORMATION ON INGREDIENTS

Mixture of substances listed below with nonhazardous additions.

Ingredient name	CAS No.	Classification	Concentration
cristobalite	14464-46-1	STOT RE 1, H372	10-<25%
4- Nonylphenyl- polyethylene glycol	9016-45-9	Eye Dam. 1, H318; Aquatic Acute 1, H400; Acute Tox. 4, H302; STOT SE 3, H335	0.1-<0.3%

- SVHC

9016-45-9 4- Nonylphenyl- polyethylene glycol

### 4. FIRST AID MEASURES

#### 4.1 Description of necessary first aid measures:-

**If inhaled:**

Supply fresh air and to be sure call for a doctor.  
In case of unconsciousness place patient stably in side position for transportation.

**In case of skin contact:**

Rinse with water.

**In case of eye contact:**

Rinse opened eye for several minutes under running water. Then consult a doctor.

**If swallowed:**

Seek medical treatment

#### 4.2 Symptoms caused by exposure:-

No further relevant information available

#### 4.3 Medical attention and special treatment:-

No further relevant information available.

### 5. FIRE FIGHTING MEASURES

#### 5.1 Suitable extinguishing equipment:-

**Suitable extinguishing media:**

CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam

**Unsuitable extinguishing media:**

No further relevant information available

#### 5.2 Specific hazards arising from the substance/mixture/product:-

No further relevant information available

#### 5.3 Special protective equipment and precautions for fire fighters:-

**Special personal protective equipment:**

No further relevant information available.

**Precautions:**

No further relevant information available.

### 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 materials for containment and cleaning up:-

Pick up mechanically.

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

#### 7.1 Precautions for safe handling:-

Only adequately trained personnel should handle this product.

For use in dentistry only.

#### 7.2 Conditions for safe storage, including any incompatibilities:-

Store only in the original receptacle.

Keep container tightly sealed.

Protect from heat and direct sunlight.

**8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

**8.1 Exposure control measures:-  
Occupational exposure limits:**

Component	CAS No.	Value	Parameters	Basis
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**Ingredients with biological limit values:**

**8.2 Biological monitoring:-**

The lists valid during the making were used as basis.

**Exposure controls / Personal protective equipment / General protective and hygienic measures:**

Usual hygienic measures for dental practice.

Keep away from foodstuffs, beverages and feed.

Wash hands before breaks and at the end of work.

**8.3 Control banding:-**

Void

**8.4 Engineering controls:-**

Void

**8.5 Individual protection measures include PPE:-**

**Eye/face protection:**



**Safety glasses**

Required Use tightly fitting safety glasses as per Australian Standard AS 1336 and AS/NZS 1337.

**Skin protection:**



**- 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.

**Respiratory protection:**



Not Required

## 9. PHYSICAL/CHEMICAL PROPERTIES

### 9.1 Information on physical/chemical properties:-

a) <b>Appearance/Form:</b>	Viscous
b) <b>Colour:</b>	Blue
c) <b>Odour:</b>	like peppermint
d) <b>Odour threshold:</b>	Not determined.
e) <b>pH-value (10 g/l) at 20 °C:</b>	Not determined.
f) <b>Melting point/melting range:</b>	Not determined.
g) <b>Boiling point/boiling range:</b>	Not determined.
h) <b>Flash point:</b>	Not determined.
i) <b>Ignition temperature:</b>	Not determined.
j) <b>Self-igniting:</b>	Product is not self-igniting.
k) <b>Danger of explosion:</b>	Product does not present an explosion hazard.
l) <b>Upper/lower flammability or explosive limits:</b>	Lower   Not determined. Upper   Not determined.
m) <b>Vapour pressure 20°C:</b>	Not determined.
n) <b>Density at 20°C:</b>	Not determined.
o) <b>Relative density:</b>	Not determined.
p) <b>Vapour density:</b>	Not determined.
q) <b>Evaporation rate:</b>	Not determined.
r) <b>Solubility in / Miscibility with water:</b>	Not miscible or difficult to mix.
s) <b>Partition coefficient: n- octanol/water:</b>	Not determined.
t) <b>Viscosity:</b>	Dynamic   Not applicable. Kinematic   Not applicable.
u) <b>Solids content:</b>	Not determined.

## 10. STABILITY AND REACTIVITY

### 10.1 Reactivity:-

No further relevant information available.

### 10.2 Chemical stability:-

Stable under normal handling and storage conditions.

#### Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications

### 10.3 Possibility of hazardous reactions:-

No further relevant information available.

### 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.

## 11. TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects:-

#### Acute toxicity / Values relevant for classification:

<b>Skin corrosion/irritation:</b>	No irritant effect
<b>Serious eye damage/eye irritation:</b>	No irritating effect.
<b>Respiratory or skin sensitization:</b>	No sensitising effects known
<b>Germ cell mutagenicity:</b>	No further relevant information available.
<b>Carcinogenicity:</b>	No further relevant information available.
<b>Reproductive toxicity:</b>	No further relevant information available.
<b>Specific target organ toxicity - single</b>	No further relevant information available.

<b>exposure:</b>	
<b>Specific target organ toxicity - repeated exposure:</b>	No further relevant information available.
<b>Aspiration hazard:</b>	
<b>Additional information:</b>	No further relevant information available.

**11.2 Information on possible routes of exposure:-**

<b>Short Term (Acute) Exposure:</b>	No further relevant information available.
<b>Swallowed:</b>	No further relevant information available.
<b>Eyes:</b>	No further relevant information available.
<b>Skin:</b>	No further relevant information available.
<b>Inhaled:</b>	No further relevant information available.
<b>Long Term (Chronic) Exposure:</b>	No further relevant information available.
<b>Swallowed:</b>	No further relevant information available.
<b>Eyes:</b>	No further relevant information available.
<b>Skin:</b>	No further relevant information available.
<b>Inhaled:</b>	No further relevant information available.

**11.3 Early onset symptoms related to exposure:-**

No further relevant information available.

**11.4 Delayed health effects from exposure:-**

No further relevant information available.

**11.5 Exposure levels and health effects:-**

No further relevant information available.

**11.6 Interactive effects:-**

No further relevant information available.

**11.7 Other:-**

No further relevant information available.

**12. ECOLOGICAL INFORMATION****12.1 Ecotoxicity:-**

No further relevant information available

**12.2 Persistence/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.

**12.5 Other adverse effects:-**

No further relevant information available.

**Additional ecological information / General notes:-**

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

**12.6 Other adverse effects:-**

No further relevant information available.

**13. DISPOSAL CONSIDERATIONS****13.1 Disposal methods:-**

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.**14. TRANSPORT INFORMATION****UN number ADR / IMDG / IATA:-** | Void**UN proper shipping name or technical name:-****ADR:** | Void**IMDG, IATA:** | Void**Transport hazard class(es):** | Void**Label:** | Void**Packaging group:** | Void

<b>Environmental hazards:</b>	Void
<b>Special precautions for user:</b>	Void
<b>Danger code:</b>	Void
<b>EMS Number:</b>	Void
<b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code:</b>	Void
<b>Transport/Additional information:</b>	Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).
<b>UN "Model Regulation":</b>	Void

## 15. REGULATORY INFORMATION

### 15.1 Safety, health and environmental regulations/legislation specific for the substance/mixture/product:-

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

#### - Substances of very high concern (SVHC) according to REACH, Article 57

9016-45-9 4- Nonylphenyl- polyethylene glycol

### 15.2 Chemical safety assessment:

A Chemical Safety Assessment has not been carried out.

## 16. OTHER INFORMATION

### Key to abbreviations/acronyms used in SDS:-

H302 Harmful if swallowed.  
H318 Causes serious eye damage.  
H335 May cause respiratory irritation.  
H372 Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalative.  
H400 Very toxic to aquatic life.

### Key literature references/data sources used to compile SDS:-

Void

### Copyright statement:-

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.

### 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).

LC50: Lethal concentration, 50 percent.

LD50: Lethal dose, 50 percent.

Flam. Liq. 2: Flammable liquids, Hazard Category 2.

Flam. Liq. 3: Flammable liquids, Hazard Category 3.

Acute Tox. 4: Acute toxicity, Hazard Category 4.

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2.

Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2.

Repr. 2: Reproductive toxicity, Hazard Category 2.

STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3.

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

Asp. Tox. 1: Aspiration hazard, Hazard Category 1.

**\* Data compared to the previous version altered**

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