

SAFETY DATA SHEET (GHS)

Issue Date: 30.11.2018
Version: 1.0.0
Revision Date: 29.11.2023
Print Date: 30.11.2018

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE/PRODUCT AND MANUFACTURER/IMPORTER

1.1 Product identifier:-

Product name: Virtual Monophase Regular / Fast Catalyst , Virtual Medium Regular / Fast Catalyst
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 Ltd
12 Omega St, Rosedale, Auckland, New Zealand
Phone +64 9 914 9999 Fax +64 9 914 9990
www.ivoclarvivadent.co.nz

Emergency phone number: 0800 764 766 (National Poison Centre)
Poisons Hotline (24 hours / 7 days)

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:

Warning
cristobalite

Hazard-determining components of labelling:

Hazard statements:

H373 May cause damage to organs through prolonged or repeated exposure.

Precautionary statements:

P314 Get medical advice/attention if you feel unwell.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

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	3-<10%
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
-----------	---------	-------	------------	-------

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

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

Skin corrosion/irritation:	No irritant effect
Serious eye damage/eye irritation:	No irritating effect.
Respiratory or skin sensitization:	No sensitising effects known
Germ cell mutagenicity:	No further relevant information available.
Carcinogenicity:	No further relevant information available.
Reproductive toxicity:	No further relevant information available.

Specific target organ toxicity - single exposure:	No further relevant information available.
Specific target organ toxicity - repeated exposure:	No further relevant information available.
Aspiration hazard:	No further relevant information available.
Additional information:	

11.2 Information on possible routes of exposure:-

Short Term (Acute) Exposure:	No further relevant information available.
Swallowed:	No further relevant information available.
Eyes:	No further relevant information available.
Skin:	No further relevant information available.
Inhaled:	No further relevant information available.
Long Term (Chronic) Exposure:	No further relevant information available.
Swallowed:	No further relevant information available.
Eyes:	No further relevant information available.
Skin:	No further relevant information available.
Inhaled:	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
Environmental hazards:	Void
Special precautions for user:	Void
Danger code:	Void
EMS Number:	Void
Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code:	Void
Transport/Additional information:	Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).
UN "Model Regulation":	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**

Disclaimer:-

Ivoclar Vivadent Ltd believes the information in this document to be accurate as at the date of preparation, but, to the maximum extent permitted by law, Ivoclar Vivadent Ltd accepts no responsibility for any loss or damage caused by any person acting or refraining from action because of this information. The provision of this information should not be construed by anyone as a recommendation to use this product. In particular, no one should use any product in violation of any patent or other intellectual proprietary rights or in breach of any statute or regulation.

Users should rely on their own knowledge and inquiries and make their own determination as to the applicability of this information in relation to their particular purposes and specific circumstances. Each user should read this SDS and consider the information in the context of how the product will be handled and used in the workplace and in conjunction with other substances or products.

These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.