

SAFETY DATA SHEET (GHS)

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

Product name: Variolink Esthetic DC (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: Dual-curing resin-based dental luting 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
 13 11 26

Emergency phone number: Poisons Hotline (24 hours / 7 days)

2. HAZARD(S) IDENTIFICATION**2.1 GHS Classification:-**

Skin Irrit. 2 H315 Causes skin irritation.
 Eye Irrit. 2 H319 Causes serious eye irritation.
 Skin Sens. 1 H317 May cause an allergic skin reaction.
 STOT SE 3 H335 May cause respiratory irritation.

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

GHS07

Signal word:**Hazard-determining components of labelling:****Hazard statements:****Precautionary statements:**

Warning
 urethane dimethacrylate
 ytterbium trifluoride
 1,10-decandiol dimethacrylate
 H315 Causes skin irritation.
 H319 Causes serious eye irritation.
 H317 May cause an allergic skin reaction.
 H335 May cause respiratory irritation.
 P280 Wear protective gloves/protective clothing/eye protection/face protection.
 P363 Wash contaminated clothing before reuse.
 P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
 P337+P313 If eye irritation persists: Get medical

advice/attention.
 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:-

Results of PBT and vPvB assessment;

Void

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
ytterbium trifluoride	13760-80-0	Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	10-<25%
urethane dimethacrylate	72869-86-4	Eye Irrit. 2, H319; Skin Sens. 1, H317; Aquatic Chronic 3, H412	3-<10%
1,10-decandiol dimethacrylate	6701-13-9	Eye Irrit. 2, H319; Skin Sens. 1, H317	3-<10%
α,α -dimethylbenzyl hydroperoxide	80-15-9	Org. Perox. EF, H242; Acute Tox. 3, H331; STOT RE 2, H373; Skin Corr. 1B, H314; Aquatic Chronic 2, H411; Acute Tox. 4, H302; Acute Tox. 4, H312	1-<2.5%

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:

If skin irritation continues, consult a doctor.
 Rinse opened eye for several minutes under running water. Then consult a doctor.

If swallowed:

Rinse out mouth and then drink plenty of water.
 If symptoms persist consult doctor

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.

Protect from exposure to the light.

Protect from heat and direct sunlight.

Keep container tightly sealed.

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.

Avoid contact with the eyes and skin.

8.3 Control banding:-

Void

8.4 Engineering controls:-

Void

8.5 Individual protection measures include PPE:-

Eye/face protection:



Skin protection:

Safety glasses

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

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 cannot 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.

• **Not suitable are gloves made of the following materials:**

Commercial medical gloves do not provide protection against the sensitizing effect of methacrylates.

Respiratory protection:

Not required



9. PHYSICAL/CHEMICAL PROPERTIES

9.1 Information on physical/chemical properties:-

a) Appearance/Form:	Pasty
b) Colour:	According to product specification
c) Odour:	Characteristic
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:	1.8705 g/cm ³
o) Relative density:	Not determined.
p) Vapour density:	Not determined.
q) Evaporation rate:	Not determined.
r) Solubility in / Miscibility with water:	Nearly insoluble.
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 dangerous reactions known

10.4 Conditions to avoid:-

Protect from exposure to the light.

Keep away from heat and direct sunlight.

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:

LD/LC50 values relevant for classification:

80-15-9 α,α -dimethylbenzyl hydroperoxide

Oral LD50 382 mg/kg (rat)

Dermal LD50 500 mg/kg (rat)

Inhalative LC50/4 h 220 mg/l (rat)

Skin corrosion/irritation:

Serious eye damage/eye irritation:

Respiratory or skin sensitization:

Germ cell mutagenicity:

Carcinogenicity:

Reproductive toxicity:

Specific target organ toxicity - single exposure:

Specific target organ toxicity - repeated exposure:

Aspiration hazard:

Additional information:

Irritant to skin and mucous membranes.

Irritating effect.

Sensitisation possible through skin contact

No further relevant information available.

No further relevant information available.

No further relevant information available.

No further relevant information available.

No further relevant information available.

No further relevant information available.

11.2 Information on possible routes of exposure:-

Short Term (Acute) Exposure:

Swallowed:

Eyes:

Skin:

Inhaled:

Long Term (Chronic) Exposure:

Swallowed:

Eyes:

Skin:

Inhaled:

11.3 Early onset symptoms related to exposure:-

11.4 Delayed health effects from exposure:-

11.5 Exposure levels and health effects:-

11.6 Interactive effects:-

11.7 Other:-

No further relevant information available.

No further relevant information available.

No further relevant information available.

No further relevant information available.

No further relevant information available.

No further relevant information available.

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No further relevant information available.

No further relevant information available.

No further relevant information available.

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

Void

MARPOL73/78 and the IBC Code:

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.

15.2 Chemical safety assessment:

A Chemical Safety Assessment has not been carried out.

16. OTHER INFORMATION

Key to abbreviations/acronyms used in SDS:-

H242 Heating may cause a fire.

H302 Harmful if swallowed.

H312 Harmful in contact with skin.

H314 Causes severe skin burns and eye damage.

H315 Causes skin irritation

H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H331 Toxic if inhaled.
H335 May cause respiratory irritation.
H373 May cause damage to organs through prolonged or repeated exposure.
H411 Toxic to aquatic life with long lasting effects.
H412 Harmful to aquatic life with long lasting effects

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:-

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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.

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Variolink Esthetic DC (Catalyst)

