

Safety Data Sheet
in accordance with HSNO

Printing date 28.04.2023


Version number 3

Revision: 28.04.2023

1 Identification of the substance or mixture and of the supplier

- **Product identifier**
- **Trade name:** *Variolink Esthetic LC / Variolink Esthetic LC HV*
- **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** *Light-curing resin-based dental luting material*
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
*Ivoclar Vivadent AG
Bendererstrasse 2
9494 Schaan
PRINCIPALITY OF LIECHTENSTEIN
Tel: +423 235 35 35 / Fax: +423 235 33 60*
- **Importer:**
*Ivoclar Vivadent Ltd.
12 Omega St, Rosedale, Auckland
New Zealand
Tel: + 64 9 914 9999 / Fax: + 64 9 914 9990*
- **Further information obtainable from:**
*Regulatory Affairs
sds@ivoclarvivadent.com*
- **Emergency telephone number:** 0800 764 766 (*National Poison Centre - 24 hours / 7 days*)

2 Hazards identification

- **Classification of the substance or mixture**
*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.*
- **Label elements**
- **GHS label elements**
The product is classified and labelled according to the Globally Harmonised System (GHS).
- **Hazard pictograms**

GHS07
- **Signal word** *Warning*
- **Hazard-determining components of labelling:**
*urethane dimethacrylate
aromatic aliphatic urethane dimethacrylate
1,10-decandiol dimethacrylate*
- **Hazard statements**
*Causes skin irritation.
Causes serious eye irritation.
May cause an allergic skin reaction.
May cause respiratory irritation.*

(Contd. on page 2)

Safety Data Sheet in accordance with HSNO

Printing date 28.04.2023

Version number 3

Revision: 28.04.2023

Trade name: Variolink Esthetic LC / Variolink Esthetic LC HV

(Contd. of page 1)

· **Precautionary statements**

Wear protective gloves/protective clothing/eye protection/face protection.

If skin irritation or rash occurs: Get medical advice/attention.

If eye irritation persists: Get medical advice/attention.

Wash contaminated clothing before reuse.

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

· **Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

3 Composition/Information on ingredients

· **Chemical characterisation: Mixtures**

· **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**

CAS: 13760-80-0 EINECS: 237-354-2	ytterbium trifluoride Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	10-25%
CAS: 72869-86-4 EINECS: 276-957-5	urethane dimethacrylate Eye Irrit. 2, H319; Skin Sens. 1, H317; Aquatic Chronic 3, H412	2.5-10%
CAS: 1219495-43-8	aromatic aliphatic urethane dimethacrylate Skin Sens. 1, H317	2.5-10%
CAS: 6701-13-9 EINECS: 229-745-1	1,10-decandiol dimethacrylate Eye Irrit. 2, H319; Skin Sens. 1, H317	2.5-10%

· **Additional information:** For the wording of the listed hazard phrases refer to section 16.

4 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.

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:** Rinse out mouth and then drink plenty of water.

· **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

· **Suitable extinguishing agents:**

CO₂, 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.

· **Protective equipment:** No special measures required.

(Contd. on page 3)

Safety Data Sheet in accordance with HSNO

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Version number 3

Revision: 28.04.2023

Trade name: Variolink Esthetic LC / Variolink Esthetic LC HV

(Contd. of page 2)

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Wear protective clothing.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Ensure adequate ventilation.
- **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.
Prevent formation of aerosols.
- **Information about fire - and explosion protection:** No special measures required.
- **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:**
Protect from exposure to the light.
Keep container tightly sealed.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **Ingredients 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 valid during the making were used as basis.
- **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.
Do not inhale gases / fumes / aerosols.
Avoid contact with the eyes and skin.
- **Respiratory protection:**
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
- **Protection of hands:**



Protective gloves (EN 374)

After use of gloves apply skin-cleaning agents and skin cosmetics.

(Contd. on page 4)

Safety Data Sheet in accordance with HSNO

Printing date 28.04.2023

Version number 3

Revision: 28.04.2023

Trade name: Variolink Esthetic LC / Variolink Esthetic LC HV

(Contd. of page 3)

- **Material of gloves**

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

- **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.

- **Eye protection:**



Tightly sealed goggles (EN 166)

9 Physical and chemical properties

- **General Information**

- **Appearance:**

- **Form:**

Pasty

- **Colour:**

According to product specification

- **Odour:**

Characteristic

- **Odour threshold:**

Not determined.

- **pH-value:**

Not applicable.

- **Change in condition**

- **Melting point/freezing point:**

Undetermined.

- **Initial boiling point and boiling range:**

Undetermined.

- **Flash point:**

Not applicable.

- **Flammability (solid, gas):**

Not applicable.

- **Decomposition temperature:**

Not determined.

- **Auto-ignition temperature:**

Product is not selfigniting.

- **Explosive properties:**

Product does not present an explosion hazard.

- **Explosion limits:**

- **Lower:**

Not determined.

- **Upper:**

Not determined.

- **Vapour pressure:**

Not determined.

- **Density:**

Not determined.

- **Relative density**

Not determined.

- **Vapour 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.

- **Other information**

No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.

- **Chemical stability**

Photoreactive (Danger of polymerization).

(Contd. on page 5)

Safety Data Sheet in accordance with HSNO

Printing date 28.04.2023

Version number 3

Revision: 28.04.2023

Trade name: Variolink Esthetic LC / Variolink Esthetic LC HV

(Contd. of page 4)

- 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**
Protect from exposure to the light.
Keep away from heat and direct sunlight.
- **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** Based on available data, the classification criteria are not met.
- **Skin corrosion/irritation** Causes skin irritation.
- **Serious eye damage/irritation** Causes serious eye irritation.
- **Respiratory or skin sensitisation** May cause an allergic skin reaction.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** May cause respiratory irritation.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.
- **Additional toxicological information:** No further relevant information available.

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (German Regulation) (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.
- **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 packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

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(Contd. on page 6)

Safety Data Sheet in accordance with HSNO

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Version number 3

Revision: 28.04.2023

Trade name: Variolink Esthetic LC / Variolink Esthetic LC HV

(Contd. of page 5)

14 Transport information

· UN-Number · NZS/RID/ADN, ADN, IMDG, IATA	Void
· UN proper shipping name · NZS/RID/ADN, ADN, IMDG, IATA	Void
· Transport hazard class(es) · NZS/RID/ADN, ADN, IMDG, IATA · Class	Void
· Packing group · NZS/RID/ADN, IMDG, IATA	Void
· Environmental hazards: · Marine pollutant:	No
· Special precautions for user	Not applicable.
· Transport in bulk according to Annex II of Marpol 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":	Void

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**

· **New Zealand Inventory of Chemicals**

CAS: 13760-80-0 ytterbium trifluoride

CAS: 72869-86-4 urethane dimethacrylate

CAS: 6701-13-9 1,10-decandiol dimethacrylate

· **HSNO Approval numbers**

None of the ingredients is listed.

· **GHS label elements**

The product is classified and labelled according to the Globally Harmonised System (GHS).

· **Hazard pictograms**



GHS07

· **Signal word** Warning

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

urethane dimethacrylate

aromatic aliphatic urethane dimethacrylate

1,10-decandiol dimethacrylate

· **Hazard statements**

Causes skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

May cause respiratory irritation.

(Contd. on page 7)

Safety Data Sheet in accordance with HSNO

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Version number 3

Revision: 28.04.2023

Trade name: Variolink Esthetic LC / Variolink Esthetic LC HV

(Contd. of page 6)

· **Precautionary statements**

Wear protective gloves/protective clothing/eye protection/face protection.

If skin irritation or rash occurs: Get medical advice/attention.

If eye irritation persists: Get medical advice/attention.

Wash contaminated clothing before reuse.

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

· **Directive 2012/18/EU**

· **Named dangerous substances - ANNEX I** None of the ingredients is listed.

· **National regulations:**

· **Other regulations, limitations and prohibitive regulations**

The product is a medical device according to Regulation 2017/745 on Medical Devices (MDR).

· **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.

· **Relevant phrases**

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H412 Harmful to aquatic life with long lasting effects.

· **Contact:**

· **Abbreviations and acronyms:**

ADR: Accord relatif au transport international 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

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)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Skin Sens. 1: Skin sensitisation – Category 1

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

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