ivoclar

Safety Data Sheet
according to WHS Regulations

Printing date 23.02.2024 Version number 1 Revision: 21.02.2024

Hazardous according to criteria of Australian Safety and Compensation Council.

1 Identification

· **Product identifier**

· **Trade name:** **Variolink Esthetic DC (white opaque) (Base)**

· **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.

· **Application of the substance / the mixture** Polymer-based dental luting material (intraoral dual-curing)

· **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 Pty. Ltd.
1- 5 Overseas Drive
Noble Park North VIC 3174
Tel: + 61 3 9795 9599 / Fax: + 61 3 9795 9645

· **Further information obtainable from:**
Regulatory Affairs
sds@ivoclar.com

· **Emergency telephone number:** 131 126 (Poisons Information Centre - 24 hours / 7 days)

2 Hazard(s) Identification

· **Classification of the substance or mixture**

Skin Irrit. 2	H315 Causes skin irritation.
Serious eye damage/irritation – Category 2A	H319 Causes serious eye irritation.
Skin Sens. 1	H317 May cause an allergic skin reaction.
Carc. 2	H351 Suspected of causing cancer. Route of exposure: Inhalation.
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 GHS08

· **Signal word** Warning

· **Hazard-determining components of labelling:**
urethane dimethacrylate (10-25 %)
ytterbium trifluoride (10-25 %)
titanium dioxide (<2.5 %)

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aromatic aliphatic urethane dimethacrylate (2.5-10 %)
1,10-decandiol dimethacrylate (2.5-10 %)
· **Hazard statements**
Causes skin irritation.
Causes serious eye irritation.
May cause an allergic skin reaction.
Suspected of causing cancer. Route of exposure: Inhalation.
May cause respiratory irritation.
· **Precautionary statements**
Avoid release to the environment.
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 and Information on Ingredients

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

· **Dangerous components:**

CAS: 13760-80-0	ytterbium trifluoride Skin Irrit. 2, H315; Serious eye damage/irritation – Category 2A, H319; STOT SE 3, H335	10-25%
CAS: 72869-86-4	urethane dimethacrylate Serious eye damage/irritation – Category 2A, H319; Skin Sens. 1, H317	10-25%
CAS: 1219495-43-8	aromatic aliphatic urethane dimethacrylate Skin Sens. 1, H317	2.5-10%
CAS: 6701-13-9	1,10-decandiol dimethacrylate Skin Sens. 1, H317	2.5-10%
CAS: 13463-67-7	titanium dioxide Carc. 2, H351	<2.5%
CAS: 591-08-2	acetyl-2-thiourea Acute Tox. 2, H300; Acute Tox. 3, H311; Acute Tox. 3, H331	<2.5%

· **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.
If symptoms persist consult doctor.

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· **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.

6 Accidental Release Measures

· **Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
· **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.
· **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.
Protect from heat and direct sunlight.
Keep container tightly sealed.
· **Specific end use(s)** No further relevant information available.

8 Exposure controls and personal protection

· **Additional information about design of technical facilities:** No further data; see section 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.

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Wash hands before breaks and at the end of work.
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.

· **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.

· **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 determined.
· **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 applicable.
· **Density at 20 °C:**	1.8567 g/cm³
· **Relative density**	Not determined.
· **Vapour density**	Not applicable.
· **Evaporation rate**	Not applicable.
· **Solubility in / Miscibility with**	
· **water:**	Nearly insoluble.
· **Partition coefficient: n-octanol/water:**	Not determined.

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· **Viscosity:**	
· **Dynamic:**	Not applicable.
· **Kinematic:**	Not applicable.
· **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.
Photoreactive (Danger of polymerization).
· **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** Suspected of causing cancer. Route of exposure: Inhalation.
· **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.

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· **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.

14 Transport information

· **UN-Number**	
· **ADG, IMDG, IATA**	UN3082
· **UN proper shipping name**	
· **ADG**	3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (1,10-decandiol dimethacrylate)
· **IMDG**	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (1,10-decandiol dimethacrylate), MARINE POLLUTANT
· **IATA**	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (1,10-decandiol dimethacrylate)
· **Transport hazard class(es)**	
· **ADG**	
· **Class**	9 (M6) Miscellaneous dangerous substances and articles.
· **Label**	9
· **IMDG, IATA**	
· **Class**	9 Miscellaneous dangerous substances and articles.
· **Label**	9
· **Packing group**	
· **ADG, IMDG, IATA**	III
· **Environmental hazards:**	
· **Marine pollutant:**	No Symbol (fish and tree)
· **Special marking (ADG):**	Symbol (fish and tree)
· **Special marking (IATA):**	Symbol (fish and tree)
· **Special precautions for user**	Warning: Miscellaneous dangerous substances and articles.

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· **Hazard identification number (Kemler code):**	90
· **Hazchem or Emergency Action Code:**	•3Z
· **EMS Number:**	F-A,S-F
· **Stowage Category**	A
· **Transport in bulk according to Annex II of Marpol and the IBC Code**	Not applicable.
· **Transport/Additional information:**	
· **ADG**	
· **Limited quantities (LQ)**	5L
· **Excepted quantities (EQ)**	Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· **Transport category**	3
· **Tunnel restriction code**	(-)
· **IMDG**	
· **Limited quantities (LQ)**	5L
· **Excepted quantities (EQ)**	Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· **UN "Model Regulation":**	UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (1,10-DECANDIOL DIMETHACRYLATE), 9, III

15 Regulatory information

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

· **Australian Inventory of Industrial Chemicals**

CAS: 13463-67-7	titanium dioxide

· **Standard for the Uniform Scheduling of Medicines and Poisons**

None of the ingredients is listed.

· **Australia: Priority Existing Chemicals**

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 GHS08

· **Signal word** Warning

· **Hazard-determining components of labelling:**
urethane dimethacrylate (10-25 %)
ytterbium trifluoride (10-25 %)
titanium dioxide (<2.5 %)
aromatic aliphatic urethane dimethacrylate (2.5-10 %)
1,10-decandiol dimethacrylate (2.5-10 %)

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· **Hazard statements**
Causes skin irritation.
Causes serious eye irritation.
May cause an allergic skin reaction.
Suspected of causing cancer. Route of exposure: Inhalation.
May cause respiratory irritation.
· **Precautionary statements**
Avoid release to the environment.
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**
H300 Fatal if swallowed.
H311 Toxic in contact with skin.
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.
H351 Suspected of causing cancer.
· **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)
RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
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
Acute Tox. 2: Acute toxicity – Category 2
Acute Tox. 3: Acute toxicity – Category 3
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Serious eye damage/irritation – Category 2A: Serious eye damage/eye irritation – Category 2A
Skin Sens. 1: Skin sensitisation – Category 1
Carc. 2: Carcinogenicity – Category 2
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3