

Safety data sheet
according to Regulation (EC) No 1907/2006, Article 31

Printing date 24.09.2024

Version number 7 (replaces version 6)

Revision: 03.09.2024


SECTION 1: Identification of the substance/mixture and of the company/undertaking

- **1.1 Product identifier**
- **Trade name: *Adhese Universal***
- **1.2 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, single-component dental adhesive
- **1.3 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
- **Further information obtainable from:**
Regulatory Affairs
sds@ivoclar.com
- **1.4 Emergency telephone number:** +423 / 235 33 13 (Ivoclar Vivadent AG, 9494 Schaan, Liechtenstein)

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
Flam. Liq. 3 H226 Flammable liquid and vapour.
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.
Repr. 1B H360 May damage fertility or the unborn child.

- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the GB CLP regulation.
- **Hazard pictograms**

GHS02 GHS07 GHS08
- **Signal word** *Danger*
- **Hazard-determining components of labelling:**
2-hydroxyethyl methacrylate
ethyl p-dimethylaminobenzoate
1,10-decandiol dimethacrylate
methacrylated phosphoric acid ester
2-dimethylaminoethyl methacrylate
- **Hazard statements**
H226 Flammable liquid and vapour.
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H317 May cause an allergic skin reaction.
H360 May damage fertility or the unborn child.

(Contd. on page 2)

Safety data sheet

according to Regulation (EC) No 1907/2006, Article 31

Printing date 24.09.2024

Version number 7 (replaces version 6)

Revision: 03.09.2024

Trade name: **Adhese Universal**

(Contd. of page 1)

· **Precautionary statements**

- P201 Obtain special instructions before use.
- P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
- P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
- P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
- P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
- P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P405 Store locked up.
- P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· **2.3 Other hazards**

· **Results of PBT and vPvB assessment**

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

SECTION 3: Composition/information on ingredients

· **3.2 Mixtures**

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

· **Dangerous components:**

CAS: 868-77-9 EINECS: 212-782-2 Reg.nr.: 01-2119490169-29-xxxx	2-hydroxyethyl methacrylate Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	10-25%
CAS: 64-17-5 EINECS: 200-578-6 Reg.nr.: 01-2119457610-43-xxxx	ethanol Flam. Liq. 2, H225; Eye Irrit. 2, H319	10-25%
CAS: 6701-13-9 EINECS: 229-745-1 Reg.nr.: 01-2120735533-57-0000	1,10-decandiol dimethacrylate Eye Irrit. 2, H319; Skin Sens. 1, H317	2.5-<10%
CAS: 85590-00-7	methacrylated phosphoric acid ester Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	2.5-<10%
CAS: 10373-78-1	camphorquinone Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	<2.5%
CAS: 2867-47-2 EINECS: 220-688-8	2-dimethylaminoethyl methacrylate Acute Tox. 4, H302; Acute Tox. 4, H312; Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	1-<2.5%
CAS: 10287-53-3 EINECS: 233-634-3 Reg.nr.: 01-2120766020-67-XXXX	ethyl p-dimethylaminobenzoate Repr. 1B, H360; Aquatic Chronic 2, H411	0.3-<2.5%
CAS: 128-37-0 EINECS: 204-881-4	Butylated hydroxytoluene Aquatic Chronic 1, H410	0.025-<0.25%

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

GB

(Contd. on page 3)

Safety data sheet

according to Regulation (EC) No 1907/2006, Article 31

Printing date 24.09.2024

Version number 7 (replaces version 6)

Revision: 03.09.2024

Trade name: **Adhese Universal**

(Contd. of page 2)

SECTION 4: First aid measures

- **4.1 Description of 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:**
Immediately 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.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **6.4 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.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**
Only adequately trained personnel should handle this product.
For use in dentistry only.
- **Information about fire - and explosion protection:**
Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **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.

(Contd. on page 4)

Safety data sheet

according to Regulation (EC) No 1907/2006, Article 31

Printing date 24.09.2024

Version number 7 (replaces version 6)

Revision: 03.09.2024

Trade name: **Adhese Universal**

(Contd. of page 3)

Keep container tightly sealed.

· **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

· 8.1 Control parameters

· **Ingredients with limit values that require monitoring at the workplace:**

CAS: 64-17-5 ethanol

WEL Long-term value: 1920 mg/m³, 1000 ppm

CAS: 128-37-0 Butylated hydroxytoluene

WEL Long-term value: 10 mg/m³

· **Regulatory information** WEL: EH40/2020

· **Additional information:** The lists valid during the making were used as basis.

· 8.2 Exposure controls

· **Appropriate engineering controls** No further data; see section 7.

· **Individual protection measures, such as 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.

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.

· **Hand protection**



Protective gloves (EN 374)

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

· **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/face protection**



Tightly sealed goggles (EN 166)

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· **General Information**

· **Colour:**

Yellow

· **Odour:**

Characteristic

(Contd. on page 5)

Safety data sheet

according to Regulation (EC) No 1907/2006, Article 31

Printing date 24.09.2024

Version number 7 (replaces version 6)

Revision: 03.09.2024

Trade name: **Adhese Universal**

(Contd. of page 4)

· Odour threshold:	Not determined.
· Melting point/freezing point:	Undetermined.
· Boiling point or initial boiling point and boiling range	Undetermined.
· Lower and upper explosion limit	
· Lower:	Not determined.
· Upper:	Not determined.
· Flash point:	36 °C (ASTM D7094)
· pH	Not applicable.
· Viscosity:	
· Kinematic viscosity	Not determined.
· Dynamic:	Not determined.
· Solubility	
· water:	Fully miscible.
· Partition coefficient n-octanol/water (log value)	Not determined.
· Vapour pressure:	Not determined.
· Density and/or relative density	
· Density:	Not determined.
· Relative density	Not determined.
· Vapour density	Not determined.
· 9.2 Other information	No further relevant information available.
· Appearance:	
· Form:	Liquid
· Important information on protection of health and environment, and on safety.	
· Ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product does not present an explosion hazard.
· Change in condition	
· Evaporation rate	Not determined.
· Information with regard to physical hazard classes	
· Explosives	Void
· Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Flammable liquid and vapour.
· Flammable solids	Void
· Self-reactive substances and mixtures	Void
· Pyrophoric liquids	Void
· Pyrophoric solids	Void
· Self-heating substances and mixtures	Void
· Substances and mixtures, which emit flammable gases in contact with water	Void
· Oxidising liquids	Void
· Oxidising solids	Void
· Organic peroxides	Void
· Corrosive to metals	Void
· Desensitised explosives	Void

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability** Stable under normal handling and storage conditions.

(Contd. on page 6)

Safety data sheet

according to Regulation (EC) No 1907/2006, Article 31

Printing date 24.09.2024

Version number 7 (replaces version 6)

Revision: 03.09.2024

Trade name: Adhese Universal

(Contd. of page 5)

- **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.

SECTION 11: Toxicological information

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Based on available data, the classification criteria are not met.

- **LD/LC50 values relevant for classification:**

CAS: 2867-47-2 2-dimethylaminoethyl methacrylate

Oral	LD50	1751 mg/kg (rat)
Inhalative	LC50/4 h	0.62 mg/l (rat)

- **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**
May damage fertility or the unborn child.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **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.
- **11.2 Information on other hazards**

- **Endocrine disrupting properties**

CAS: 128-37-0 Butylated hydroxytoluene

List II

SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and 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 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties** For information on endocrine disrupting properties see section 11.
- **12.7 Other adverse effects** No further relevant information available.
- **Additional ecological information:**
- **General notes:**
Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water
Do not allow product to reach ground water, water course or sewage system.

GB

(Contd. on page 7)

Safety data sheet

according to Regulation (EC) No 1907/2006, Article 31

Printing date 24.09.2024

Version number 7 (replaces version 6)

Revision: 03.09.2024



Trade name: **Adhese Universal**

(Contd. of page 6)

SECTION 13: Disposal considerations

- **13.1 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.

SECTION 14: Transport information

- | | |
|---|--|
| <ul style="list-style-type: none"> · 14.1 UN number or ID number · ADR/RID/ADN, IMDG, IATA | UN1170 |
| <ul style="list-style-type: none"> · 14.2 UN proper shipping name · ADR/RID/ADN · IMDG · IATA | 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
ETHANOL SOLUTION |
| <ul style="list-style-type: none"> · 14.3 Transport hazard class(es) · ADR/RID/ADN | <div style="text-align: center;">  </div> |
| <ul style="list-style-type: none"> · Class · Label | 3 (F1) Flammable liquids.
3 |
| <ul style="list-style-type: none"> · IMDG, IATA | <div style="text-align: center;">  </div> |
| <ul style="list-style-type: none"> · Class · Label | 3 Flammable liquids.
3 |
| <ul style="list-style-type: none"> · 14.4 Packing group · ADR/RID/ADN, IMDG, IATA | III |
| <ul style="list-style-type: none"> · 14.5 Environmental hazards: · Marine pollutant: | No |
| <ul style="list-style-type: none"> · 14.6 Special precautions for user · Hazard identification number (Kemler code): · EMS Number: · Stowage Category | Warning: Flammable liquids.
30
F-E,S-D
A |
| <ul style="list-style-type: none"> · 14.7 Maritime transport in bulk according to IMO instruments | Not applicable. |

(Contd. on page 8)

GB

Safety data sheet

according to Regulation (EC) No 1907/2006, Article 31

Printing date 24.09.2024

Version number 7 (replaces version 6)

Revision: 03.09.2024

Trade name: **Adhese Universal**

(Contd. of page 7)

· **Transport/Additional information:**

· **ADR/RID/ADN**

· **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**

D/E

· **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 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION), 3, III

SECTION 15: Regulatory information

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

· **Poisons Act**

· **Regulated explosives precursors**

None of the ingredients is listed.

· **Regulated poisons**

None of the ingredients is listed.

· **Reportable explosives precursors**

None of the ingredients is listed.

· **Reportable poisons**

None of the ingredients is listed.

· **Directive 2012/18/EU**

· **Qualifying quantity (tonnes) for the application of lower-tier requirements** 5000 t

· **Qualifying quantity (tonnes) for the application of upper-tier requirements** 50000 t

· **National regulations:**

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

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

· **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 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**

H225 Highly flammable liquid and vapour.

H302 Harmful if swallowed.

H312 Harmful in contact with skin.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

(Contd. on page 9)

Safety data sheet
according to Regulation (EC) No 1907/2006, Article 31

Printing date 24.09.2024

Version number 7 (replaces version 6)

Revision: 03.09.2024

Trade name: Adhese Universal

(Contd. of page 8)

H360 May damage fertility or the unborn child.

H410 Very toxic to aquatic life with long lasting effects.

H411 Toxic to aquatic life with long lasting effects.

Abbreviations and acronyms:

IMO: International Maritime Organization

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

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

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Flam. Liq. 2: Flammable liquids – Category 2

Flam. Liq. 3: Flammable liquids – Category 3

Acute Tox. 4: Acute toxicity – Category 4

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

Repr. 1B: Reproductive toxicity – Category 1B

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

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2

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

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 05.02.2024

Version number 9 (replaces version 8)

Revision: 05.02.2024



SECTION 1: Identification of the substance/mixture and of the company/undertaking

- **1.1 Product identifier**
- **Trade name: Monobond Plus**
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** Universal primer
- **1.3 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
- **Further information obtainable from:**
Regulatory Affairs
sds@ivoclar.com
- **1.4 Emergency telephone number:** +423 / 235 33 13 (Ivoclar Vivadent AG, 9494 Schaan, Liechtenstein)

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
Flam. Liq. 2 H225 Highly flammable liquid and vapour.
Eye Irrit. 2 H319 Causes serious eye irritation.
Skin Sens. 1 H317 May cause an allergic skin reaction.

- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the GB CLP regulation.
- **Hazard pictograms**
 
GHS02 GHS07
- **Signal word** Danger
- **Hazard-determining components of labelling:**
sulphide methacrylate
methacrylated phosphoric acid ester
- **Hazard statements**
H225 Highly flammable liquid and vapour.
H319 Causes serious eye irritation.
H317 May cause an allergic skin reaction.
- **Precautionary statements**
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P233 Keep container tightly closed.
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P403+P235 Store in a well-ventilated place. Keep cool.

(Contd. on page 2)

GB

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 05.02.2024

Version number 9 (replaces version 8)

Revision: 05.02.2024

Trade name: **Monobond Plus**

(Contd. of page 1)

- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

- **3.2 Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

- **Dangerous components:**

CAS: 64-17-5 EINECS: 200-578-6 Reg.nr.: 01-2119457610-43-xxxx	ethanol Flam. Liq. 2, H225; Eye Irrit. 2, H319	50-100%
CAS: 85590-00-7	methacrylated phosphoric acid ester Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	1-<2.5%
CAS: 1096164-11-2	sulphide methacrylate Acute Tox. 4, H302; Acute Tox. 4, H312; Acute Tox. 4, H332; Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335	1-<2.5%

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

SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **After inhalation:**
Supply fresh air; consult doctor in case of complaints.
In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact:** Immediately rinse with water.
- **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.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.
- **Additional information** Cool endangered receptacles with water spray.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.

(Contd. on page 3)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 05.02.2024

Version number 9 (replaces version 8)

Revision: 05.02.2024

Trade name: **Monobond Plus**

(Contd. of page 2)

- **6.3 Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Ensure adequate ventilation.
- **6.4 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.

SECTION 7: Handling and storage

- **7.1 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.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **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 heat and direct sunlight.
Keep container tightly sealed.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

· 8.1 Control parameters

· **Ingredients with limit values that require monitoring at the workplace:**

CAS: 64-17-5 ethanol

WEL Long-term value: 1920 mg/m ³ , 1000 ppm

- **Regulatory information WEL:** EH40/2020
- **Additional information:** The lists valid during the making were used as basis.
- **8.2 Exposure controls**
- **Appropriate engineering controls** No further data; see section 7.
- **Individual protection measures, such as 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.
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.
- **Hand protection**



Protective gloves (EN 374)

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

- **Material of gloves**
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

(Contd. on page 4)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 05.02.2024

Version number 9 (replaces version 8)

Revision: 05.02.2024

Trade name: **Monobond Plus**

(Contd. of page 3)

- **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/face protection**



Tightly sealed goggles (EN 166)

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**

- **General Information**

· Colour:	Colourless
· Odour:	Alcohol-like
· Odour threshold:	Not determined.
· Melting point/freezing point:	-114.5 °C
· Boiling point or initial boiling point and boiling range	78 °C
· Lower and upper explosion limit	
· Lower:	3.5 Vol %
· Upper:	15 Vol %
· Flash point:	13 °C
· Auto-ignition temperature:	425 °C
· pH	Not determined.
· Viscosity:	
· Kinematic viscosity	Not determined.
· Dynamic:	Not determined.
· Solubility	
· water:	Soluble.
· Partition coefficient n-octanol/water (log value)	Not determined.
· Vapour pressure at 20 °C:	59 hPa
· Vapour pressure at 50 °C:	280 hPa
· Density and/or relative density	
· Density at 20 °C:	0.794 g/cm ³
· Relative density	Not determined.
· Vapour density	Not determined.

- **9.2 Other information**

No further relevant information available.

- **Appearance:**

- **Form:**

Fluid

- **Important information on protection of health and environment, and on safety.**

- **Ignition temperature:**

Product is not selfigniting.

- **Explosive properties:**

Product is not explosive. However, formation of explosive air/vapour mixtures are possible.

- **Solvent content:**

- **Organic solvents:**

96.0 %

- **Solids content:**

0.0 %

- **Change in condition**

- **Evaporation rate**

Not determined.

(Contd. on page 5)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 05.02.2024

Version number 9 (replaces version 8)

Revision: 05.02.2024

Trade name: **Monobond Plus**

(Contd. of page 4)

- **Information with regard to physical hazard classes**
- **Explosives** Void
- **Flammable gases** Void
- **Aerosols** Void
- **Oxidising gases** Void
- **Gases under pressure** Void
- **Flammable liquids** Highly flammable liquid and vapour.
- **Flammable solids** Void
- **Self-reactive substances and mixtures** Void
- **Pyrophoric liquids** Void
- **Pyrophoric solids** Void
- **Self-heating substances and mixtures** Void
- **Substances and mixtures, which emit flammable gases in contact with water** Void
- **Oxidising liquids** Void
- **Oxidising solids** Void
- **Organic peroxides** Void
- **Corrosive to metals** Void
- **Desensitised explosives** Void

SECTION 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** 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.

SECTION 11: Toxicological information

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Based on available data, the classification criteria are not met.

· **LD/LC50 values relevant for classification:**

Oral	LD50	> 5000 mg/kg (rat)
------	------	--------------------

CAS: 64-17-5 ethanol

Oral	LD50	7060 mg/kg (rat)
Inhalative	LC50/4 h	20000 mg/l (rat)

- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **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** Based on available data, the classification criteria are not met.
- **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.

(Contd. on page 6)

GB

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 05.02.2024

Version number 9 (replaces version 8)

Revision: 05.02.2024

Trade name: **Monobond Plus**

(Contd. of page 5)

· 11.2 Information on other hazards

· Endocrine disrupting properties

None of the ingredients is listed.

SECTION 12: Ecological information

· 12.1 Toxicity

· **Aquatic toxicity:** No further relevant information available.

· **12.2 Persistence and 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 Results of PBT and vPvB assessment

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

· 12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

· **12.7 Other adverse effects** 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.

SECTION 13: Disposal considerations

· 13.1 Waste treatment methods

· Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· Uncleaned packaging:

· **Recommendation:** Disposal must be made according to official regulations.

· **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

SECTION 14: Transport information

· 14.1 UN number or ID number

· ADR/RID/ADN, IMDG, IATA

UN1170

· 14.2 UN proper shipping name

· ADR/RID/ADN

1170 ETHANOL (ETHYL ALCOHOL), solution

· IMDG

ETHANOL (ETHYL ALCOHOL) solution

· IATA

ETHANOL solution

· 14.3 Transport hazard class(es)

· ADR/RID/ADN



· Class

3 (F1) Flammable liquids.

(Contd. on page 7)

Safety data sheet
according to 1907/2006/EC, Article 31


Printing date 05.02.2024

Version number 9 (replaces version 8)

Revision: 05.02.2024

Trade name: **Monobond Plus**

(Contd. of page 6)

· Label	3
· IMDG, IATA	
	
· Class	3 Flammable liquids.
· Label	3
· 14.4 Packing group	
· ADR/RID/ADN, IMDG, IATA	II
· 14.5 Environmental hazards:	
· Marine pollutant:	No
· 14.6 Special precautions for user	Warning: Flammable liquids.
· Hazard identification number (Kemler code):	33
· EMS Number:	F-E,S-D
· Stowage Category	A
· 14.7 Maritime transport in bulk according to IMO instruments	Not applicable.
· Transport/Additional information:	
· ADR/RID/ADN	
· Limited quantities (LQ)	1L
· Excepted quantities (EQ)	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· Transport category	2
· Tunnel restriction code	D/E
· IMDG	
· Limited quantities (LQ)	1L
· Excepted quantities (EQ)	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· UN "Model Regulation":	UN1170, ETHANOL (ETHYL ALCOHOL) solution, 3, II

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Qualifying quantity (tonnes) for the application of lower-tier requirements** 5000 t
- **Qualifying quantity (tonnes) for the application of upper-tier requirements** 50000 t
- **National regulations:**
- **Other regulations, limitations and prohibitive regulations**
The product is a medical device according to Regulation 2017/745 on Medical Devices (MDR).
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

GB

(Contd. on page 8)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 05.02.2024

Version number 9 (replaces version 8)

Revision: 05.02.2024

Trade name: **Monobond Plus**

(Contd. of page 7)

SECTION 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**

H225 Highly flammable liquid and vapour.

H302 Harmful if swallowed.

H312 Harmful in contact with skin.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H332 Harmful if inhaled.

H335 May cause respiratory irritation.

· **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

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

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Flam. Liq. 2: Flammable liquids – Category 2

Acute Tox. 4: Acute toxicity – Category 4

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

· *** Data compared to the previous version altered.**

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 23.02.2024

Version number 1



Revision: 21.02.2024

SECTION 1: Identification of the substance/mixture and of the company/undertaking

- **1.1 Product identifier**
- **Trade name:** Variolink Esthetic DC (light, light+, neutral, warm, warm+)
(Base)
- **1.2 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)
- **1.3 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
- **Further information obtainable from:**
Regulatory Affairs
sds@ivoclar.com
- **1.4 Emergency telephone number:** +423 / 235 33 13 (Ivoclar Vivadent AG, 9494 Schaan, Liechtenstein)

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
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.
Aquatic Acute 1 H400 Very toxic to aquatic life.
Aquatic Chronic 2 H411 Toxic to aquatic life with long lasting effects.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the GB CLP regulation.
- **Hazard pictograms**
 
GHS07 GHS09
- **Signal word** Warning
- **Hazard-determining components of labelling:**
urethane dimethacrylate
ytterbium trifluoride
aromatic aliphatic urethane dimethacrylate
1,10-decandiol dimethacrylate
- **Hazard statements**
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H317 May cause an allergic skin reaction.

(Contd. on page 2)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 23.02.2024

Version number 1

Revision: 21.02.2024

Trade name: Variolink Esthetic DC (light, light+, neutral, warm, warm+) (Base)

(Contd. of page 1)

H335 May cause respiratory irritation.

H400 Very toxic to aquatic life.

H411 Toxic to aquatic life with long lasting effects.

· **Precautionary statements**

P273 Avoid release to the environment.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P337+P313 If eye irritation persists: Get medical advice/attention.

P363 Wash contaminated clothing before reuse.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Additional information:**

Medical devices as defined in Regulation (EU) 2017/745 (MDR) 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 (GB CLP/GHS) if they are in the finished state and intended for the final user.

· **2.3 Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

· **3.2 Mixtures**

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

· **Dangerous components:**

CAS: 13760-80-0 EINECS: 237-354-2 Reg.nr.: 17-2119404130-64-XXXX	ytterbium trifluoride ----- Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	20-25%
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 EC number: 943-136-4 Reg.nr.: 01-2120115133-75-XXXX	aromatic aliphatic urethane dimethacrylate ----- Skin Sens. 1, H317	2.5-10%
CAS: 6701-13-9 EINECS: 229-745-1 Reg.nr.: 01-2120735533-57-XXXX	1,10-decandiol dimethacrylate ----- Aquatic Acute 1, H400 (M=10); Aquatic Chronic 1, H410 (M=1); Skin Sens. 1, H317	2.5-10%
CAS: 591-08-2 EINECS: 209-699-9	acetyl-2-thiourea ----- Acute Tox. 2, H300	<2.5%
CAS: 128-37-0 EINECS: 204-881-4	Butylated hydroxytoluene ----- Aquatic Chronic 1, H410	0.025-<0.25%

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

SECTION 4: First aid measures

· **4.1 Description of 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.

(Contd. on page 3)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 23.02.2024

Version number 1

Revision: 21.02.2024

Trade name: Variolink Esthetic DC (light, light+, neutral, warm, warm+) (Base)

(Contd. of page 2)

- **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.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Ensure adequate ventilation.
- **6.4 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.

SECTION 7: Handling and storage

- **7.1 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.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **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.
- **7.3 Specific end use(s)** No further relevant information available.

GB

(Contd. on page 4)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 23.02.2024

Version number 1

Revision: 21.02.2024

Trade name: **Variolink Esthetic DC (light, light+, neutral, warm, warm+) (Base)**

(Contd. of page 3)

SECTION 8: Exposure controls/personal protection

· 8.1 Control parameters

· **Ingredients with limit values that require monitoring at the workplace:**

CAS: 128-37-0 Butylated hydroxytoluene

WEL	Long-term value: 10 mg/m ³
-----	---------------------------------------

· **Regulatory information** WEL: EH40/2020

· **Additional information:** The lists valid during the making were used as basis.

· 8.2 Exposure controls

· **Appropriate engineering controls** No further data; see section 7.

· **Individual protection measures, such as 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.

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.

· **Hand protection**



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/face protection**



Tightly sealed goggles (EN 166)

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· **General Information**

· **Colour:**

According to product specification

· **Odour:**

Characteristic

· **Odour threshold:**

Not determined.

· **Melting point/freezing point:**

Undetermined.

· **Boiling point or initial boiling point and boiling range**

Undetermined.

· **Flammability**

Not determined.

(Contd. on page 5)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 23.02.2024

Version number 1

Revision: 21.02.2024

Trade name: Variolink Esthetic DC (light, light+, neutral, warm, warm+) (Base)

(Contd. of page 4)

· Lower and upper explosion limit	
· Lower:	Not determined.
· Upper:	Not determined.
· Flash point:	Not applicable.
· pH	Not applicable.
· Viscosity:	
· Kinematic viscosity	Not applicable.
· Dynamic:	Not applicable.
· Solubility	
· water:	Nearly insoluble.
· Partition coefficient n-octanol/water (log value)	Not determined.
· Vapour pressure:	Not applicable.
· Density and/or relative density	
· Density at 20 °C:	1.8567 g/cm ³
· Relative density	Not determined.
· Vapour density	Not applicable.
· 9.2 Other information	No further relevant information available.
· Appearance:	
· Form:	Pasty
· Important information on protection of health and environment, and on safety.	
· Ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product does not present an explosion hazard.
· Change in condition	
· Evaporation rate	Not applicable.
· Information with regard to physical hazard classes	
· Explosives	Void
· Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Void
· Flammable solids	Void
· Self-reactive substances and mixtures	Void
· Pyrophoric liquids	Void
· Pyrophoric solids	Void
· Self-heating substances and mixtures	Void
· Substances and mixtures, which emit flammable gases in contact with water	Void
· Oxidising liquids	Void
· Oxidising solids	Void
· Organic peroxides	Void
· Corrosive to metals	Void
· Desensitised explosives	Void

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 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.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.

(Contd. on page 6)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 23.02.2024

Version number 1

Revision: 21.02.2024

Trade name: Variolink Esthetic DC (light, light+, neutral, warm, warm+) (Base)

(Contd. of page 5)

- **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.

SECTION 11: Toxicological information

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **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.
- **STOT-single exposure** May cause respiratory irritation.
- **Additional toxicological information:** No further relevant information available.
- **11.2 Information on other hazards**

- **Endocrine disrupting properties**

None of the ingredients is listed.

SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and 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 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties** For information on endocrine disrupting properties see section 11.
- **12.7 Other adverse effects** 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.

SECTION 13: Disposal considerations

- **13.1 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.

SECTION 14: Transport information

- **14.1 UN number or ID number**
- **ADR/RID/ADN, IMDG, IATA** UN3082

(Contd. on page 7)

Safety data sheet

according to 1907/2006/EC, Article 31





Printing date 23.02.2024

Version number 1

Revision: 21.02.2024

Trade name: Variolink Esthetic DC (light, light+, neutral, warm, warm+) (Base)

(Contd. of page 6)

<ul style="list-style-type: none"> · 14.2 UN proper shipping name · ADR/RID/ADN · IMDG · IATA 	<p>3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (1,10-decandiol dimethacrylate)</p> <p>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Butylated hydroxytoluene, 2-(2-Hydroxy-5-methylphenyl)-benzotriazol; 2-(2H-Benzotriazol-2-yl)-p-kresol), MARINE POLLUTANT</p> <p>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Butylated hydroxytoluene, 2-(2-Hydroxy-5-methylphenyl)-benzotriazol; 2-(2H-Benzotriazol-2-yl)-p-kresol)</p>
<ul style="list-style-type: none"> · 14.3 Transport hazard class(es) · ADR/RID/ADN 	<div style="display: flex; align-items: center; gap: 10px;">   </div> <p>· Class 9 (M6) Miscellaneous dangerous substances and articles.</p> <p>· Label 9</p>
<ul style="list-style-type: none"> · IMDG, IATA 	<div style="display: flex; align-items: center; gap: 10px;">   </div> <p>· Class 9 Miscellaneous dangerous substances and articles.</p> <p>· Label 9</p>
<ul style="list-style-type: none"> · 14.4 Packing group · ADR/RID/ADN, IMDG, IATA 	<p>III</p>
<ul style="list-style-type: none"> · 14.5 Environmental hazards: · Marine pollutant: · Special marking (ADR/RID/ADN): · Special marking (IATA): 	<p>No</p> <p>Symbol (fish and tree)</p> <p>Symbol (fish and tree)</p> <p>Symbol (fish and tree)</p>
<ul style="list-style-type: none"> · 14.6 Special precautions for user · Hazard identification number (Kemler code): · EMS Number: · Stowage Category 	<p>Warning: Miscellaneous dangerous substances and articles.</p> <p>90</p> <p>F-A,S-F</p> <p>A</p>
<ul style="list-style-type: none"> · 14.7 Maritime transport in bulk according to IMO instruments 	<p>Not applicable.</p>
<ul style="list-style-type: none"> · Transport/Additional information: · ADR/RID/ADN · Limited quantities (LQ) · Excepted quantities (EQ) · Transport category 	<p>5L</p> <p>Code: E1</p> <p>Maximum net quantity per inner packaging: 30 ml</p> <p>Maximum net quantity per outer packaging: 1000 ml</p> <p>3</p>

(Contd. on page 8)

GB

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 23.02.2024

Version number 1

Revision: 21.02.2024

Trade name: Variolink Esthetic DC (light, light+, neutral, warm, warm+) (Base)

(Contd. of page 7)

· 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

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Qualifying quantity (tonnes) for the application of lower-tier requirements** 100 t
- **Qualifying quantity (tonnes) for the application of upper-tier requirements** 200 t
- **National regulations:**
- **Other regulations, limitations and prohibitive regulations**
The product is a medical device according to Regulation 2017/745 on Medical Devices (MDR).
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 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.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.
H412 Harmful to aquatic life with long lasting effects.
- **Classification according to Regulation (EC) No 1272/2008**
The classification of the mixture is generally based on the calculation method using substance data according to Regulation (EC) No 1272/2008.
- **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
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)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Acute Tox. 2: Acute toxicity – Category 2
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

(Contd. on page 9)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 23.02.2024

Version number 1

Revision: 21.02.2024

Trade name: Variolink Esthetic DC (light, light+, neutral, warm, warm+) (Base)

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1
Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1
Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2
Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

(Contd. of page 8)

GB

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 23.02.2024

Version number 3 (replaces version 2)

Revision: 21.02.2024

SECTION 1: Identification of the substance/mixture and of the company/undertaking



- **1.1 Product identifier**
- **Trade name: *Variolink Esthetic DC (Catalyst)***
- **1.2 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)
- **1.3 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
- **Further information obtainable from:**
Regulatory Affairs
sds@ivoclar.com
- **1.4 Emergency telephone number:** +423 / 235 33 13 (Ivoclar Vivadent AG, 9494 Schaan, Liechtenstein)

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**

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.
Aquatic Acute 1	H400 Very toxic to aquatic life.
Aquatic Chronic 2	H411 Toxic to aquatic life with long lasting effects.

- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the GB CLP regulation.
- **Hazard pictograms**

	
GHS07	GHS09

- **Signal word** Warning
- **Hazard-determining components of labelling:**
urethane dimethacrylate
ytterbium trifluoride
aromatic aliphatic urethane dimethacrylate
1,10-decandiol dimethacrylate
- **Hazard statements**
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H317 May cause an allergic skin reaction.
H335 May cause respiratory irritation.
H400 Very toxic to aquatic life.

(Contd. on page 2)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 23.02.2024

Version number 3 (replaces version 2)

Revision: 21.02.2024

Trade name: Variolink Esthetic DC (Catalyst)

(Contd. of page 1)

H411 Toxic to aquatic life with long lasting effects.

· **Precautionary statements**

P273 Avoid release to the environment.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P337+P313 If eye irritation persists: Get medical advice/attention.

P363 Wash contaminated clothing before reuse.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Additional information:**

Medical devices as defined in Regulation (EU) 2017/745 (MDR) 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 (GB CLP/GHS) if they are in the finished state and intended for the final user.

· **2.3 Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

· **3.2 Mixtures**

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

· **Dangerous components:**

CAS: 13760-80-0 EINECS: 237-354-2 Reg.nr.: 17-2119404130-64-XXXX	ytterbium trifluoride Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	20-25%
CAS: 72869-86-4 EINECS: 276-957-5 Reg.nr.: 01-2120751202-68-XXXX	urethane dimethacrylate Aquatic Chronic 2, H411; Skin Sens. 1, H317	2.5-<10%
CAS: 1219495-43-8 EC number: 943-136-4 Reg.nr.: 01-2120115133-75-XXXX	aromatic aliphatic urethane dimethacrylate Skin Sens. 1, H317	2.5-10%
CAS: 6701-13-9 EINECS: 229-745-1 Reg.nr.: 01-2120735533-57-XXXX	1,10-decandiol dimethacrylate Aquatic Acute 1, H400 (M=10); Aquatic Chronic 1, H410 (M=1); Skin Sens. 1, H317	2.5-10%
CAS: 80-15-9 EINECS: 201-254-7	α,α -dimethylbenzyl hydroperoxide Org. Perox. E, 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 Specific concentration limits: Skin Corr. 1B; H314: C \geq 10 % Skin Irrit. 2; H315: 3 % \leq C < 10 % Eye Dam. 1; H318: C \geq 3 % Eye Irrit. 2; H319: 1 % \leq C < 3 % STOT SE 3; H335: C < 10 %	1-<2.5%
CAS: 128-37-0 EINECS: 204-881-4	Butylated hydroxytoluene Aquatic Chronic 1, H410	0.025-<0.25%

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

GB

(Contd. on page 3)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 23.02.2024

Version number 3 (replaces version 2)

Revision: 21.02.2024

Trade name: Variolink Esthetic DC (Catalyst)

(Contd. of page 2)

SECTION 4: First aid measures

- **4.1 Description of 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.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:** Pick up mechanically.
- **6.4 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.

SECTION 7: Handling and storage

- **7.1 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.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **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.

(Contd. on page 4)

Safety data sheet according to 1907/2006/EC, Article 31

Printing date 23.02.2024

Version number 3 (replaces version 2)

Revision: 21.02.2024

Trade name: Variolink Esthetic DC (Catalyst)

(Contd. of page 3)

- 7.3 **Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **8.1 Control parameters**
- **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.
- **8.2 Exposure controls**
- **Appropriate engineering controls** No further data; see section 7.
- **Individual protection measures, such as 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.
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.
- **Hand protection**



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/face protection**



Tightly sealed goggles (EN 166)

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Colour:** According to product specification
- **Odour:** Characteristic
- **Odour threshold:** Not determined.
- **Melting point/freezing point:** Undetermined.
- **Boiling point or initial boiling point and boiling range** Undetermined.
- **Flammability** Not determined.

(Contd. on page 5)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 23.02.2024

Version number 3 (replaces version 2)

Revision: 21.02.2024

Trade name: **Variolink Esthetic DC (Catalyst)**

(Contd. of page 4)

· Lower and upper explosion limit	
· Lower:	Not determined.
· Upper:	Not determined.
· Flash point:	Not applicable.
· pH	Not applicable.
· Viscosity:	
· Kinematic viscosity	Not applicable.
· Dynamic:	Not applicable.
· Solubility	
· water:	Nearly insoluble.
· Partition coefficient n-octanol/water (log value)	Not determined.
· Vapour pressure:	Not applicable.
· Density and/or relative density	
· Density at 20 °C:	1.8705 g/cm ³
· Relative density	Not determined.
· Vapour density	Not applicable.
· 9.2 Other information	No further relevant information available.
· Appearance:	
· Form:	Pasty
· Important information on protection of health and environment, and on safety.	
· Ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product does not present an explosion hazard.
· Change in condition	
· Evaporation rate	Not applicable.
· Information with regard to physical hazard classes	
· Explosives	Void
· Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Void
· Flammable solids	Void
· Self-reactive substances and mixtures	Void
· Pyrophoric liquids	Void
· Pyrophoric solids	Void
· Self-heating substances and mixtures	Void
· Substances and mixtures, which emit flammable gases in contact with water	Void
· Oxidising liquids	Void
· Oxidising solids	Void
· Organic peroxides	Void
· Corrosive to metals	Void
· Desensitised explosives	Void

SECTION 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.

(Contd. on page 6)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 23.02.2024

Version number 3 (replaces version 2)

Revision: 21.02.2024

Trade name: Variolink Esthetic DC (Catalyst)

(Contd. of page 5)

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.

SECTION 11: Toxicological information

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **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.
- **STOT-single exposure** May cause respiratory irritation.
- **Additional toxicological information:** No further relevant information available.
- **11.2 Information on other hazards**

· **Endocrine disrupting properties**

None of the ingredients is listed.

SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and 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 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties**
The product does not contain substances with endocrine disrupting properties.
- **12.7 Other adverse effects** 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.

SECTION 13: Disposal considerations

- **13.1 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.

SECTION 14: Transport information

- **14.1 UN number or ID number**
- **ADR/RID/ADN, IMDG, IATA** UN3082

(Contd. on page 7)

GB

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 23.02.2024

Version number 3 (replaces version 2)

Revision: 21.02.2024

Trade name: Variolink Esthetic DC (Catalyst)



(Contd. of page 6)

· **14.2 UN proper shipping name**
 · **ADR/RID/ADN** 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)

· **14.3 Transport hazard class(es)**
 · **ADR/RID/ADN**

· **Class** 9 (M6) Miscellaneous dangerous substances and articles.
 · **Label** 9

· **IMDG, IATA**

· **Class** 9 Miscellaneous dangerous substances and articles.
 · **Label** 9

· **14.4 Packing group**
 · **ADR/RID/ADN, IMDG, IATA** III

· **14.5 Environmental hazards:**
 · **Marine pollutant:** No
 Symbol (fish and tree)

· **Special marking (ADR/RID/ADN):** Symbol (fish and tree)
 · **Special marking (IATA):** Symbol (fish and tree)

· **14.6 Special precautions for user** Warning: Miscellaneous dangerous substances and articles.
 · **Hazard identification number (Kemler code):** 90
 · **EMS Number:** F-A,S-F
 · **Stowage Category** A

· **14.7 Maritime transport in bulk according to IMO instruments** Not applicable.

· **Transport/Additional information:**

· **ADR/RID/ADN**
 · **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** (-)

(Contd. on page 8)

GB

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 23.02.2024

Version number 3 (replaces version 2)

Revision: 21.02.2024

Trade name: Variolink Esthetic DC (Catalyst)

(Contd. of page 7)

· 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

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Qualifying quantity (tonnes) for the application of lower-tier requirements** 100 t
- **Qualifying quantity (tonnes) for the application of upper-tier requirements** 200 t
- **National regulations:**
- **Other regulations, limitations and prohibitive regulations**
The product is a medical device according to Regulation 2017/745 on Medical Devices (MDR).
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 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**
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.
H318 Causes serious eye damage.
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.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.
H411 Toxic to aquatic life with long lasting effects.
- **Classification according to Regulation (EC) No 1272/2008**
The classification of the mixture is generally based on the calculation method using substance data according to Regulation (EC) No 1272/2008.
- **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
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)

(Contd. on page 9)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 23.02.2024

Version number 3 (replaces version 2)

Revision: 21.02.2024

Trade name: Variolink Esthetic DC (Catalyst)

(Contd. of page 8)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Org. Perox. E: Organic peroxides – Type E/F

Acute Tox. 4: Acute toxicity – Category 4

Acute Tox. 3: Acute toxicity – Category 3

Skin Corr. 1B: Skin corrosion/irritation – Category 1B

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

STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2

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

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