

Safety Data Sheet
acc. to OSHA HCS

Printing date 12/19/2022

Version number 6

Reviewed on 10/03/2022



1 Identification

- **Product identifier**
- **Trade name:** ***Adhese Universal***
- **Application of the substance / the mixture** Light-curing, single-component dental adhesive
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Ivoclar Vivadent Inc.
175 Pineview Drive, Amherst, N.Y. 14228
USA
Tel. +1 800 533 6825
Fax +1 716 691 2285

Ivoclar Vivadent Inc.
1-6600 Dixie Road
Mississauga, Ontario
L5T 2Y2
Canada
Phone: +1 905 670 8499
Fax: +1 905 670 3102
- **Information department:** Quality Assurance / Regulatory Affairs
- **Emergency telephone number:**
24 Hour Emergency Assistance:
Emergency-Call USA - Infotrac: 1-800-535-5053
Emergency-Call Canada - Canutec: 1-613-996-6666

General SDS Assistance:
US: 1-800-533-6825
Canada: 1-800-263-8182

2 Hazard(s) identification

- **Classification of the substance or mixture**
Flammable Liquids 3 H226 Flammable liquid and vapor.
Skin Irritation 2 H315 Causes skin irritation.
Eye Irritation 2A H319 Causes serious eye irritation.
Sensitization - Skin 1 H317 May cause an allergic skin reaction.
- **Label elements**
- **GHS label elements**
The product is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms**
 
GHS02 GHS07
- **Signal word** Warning
- **Hazard-determining components of labeling:**
2-hydroxyethyl methacrylate
Bis-GMA
1,10-decandiol dimethacrylate
methacrylated phosphoric acid ester

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2-dimethylaminoethyl methacrylate

Hazard statements

Flammable liquid and vapor.
Causes skin irritation.
Causes serious eye irritation.
May cause an allergic skin reaction.

Precautionary statements

Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
Avoid breathing dust/fume/gas/mist/vapors/spray
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.

Classification system:**NFPA ratings (scale 0 - 4)**

Health = 2
Fire = 3
Reactivity = 0

HMIS-ratings (scale 0 - 4)

Health = *2
Fire = 3
Reactivity = 0

Other hazards**Results of PBT and vPvB assessment**

PBT: Not applicable.
vPvB: Not applicable.

3 Composition/information on ingredients

Chemical characterization: Mixtures

Description: Mixture of the substances listed below with nonhazardous additions.

Dangerous components:

CAS: 868-77-9	2-hydroxyethyl methacrylate	10-25%
CAS: 36425-15-7	Bis-GMA	10-25%
CAS: 64-17-5	ethanol	10-25%
CAS: 6701-13-9	1,10-decandiol dimethacrylate	≥2.5-<10%
CAS: 85590-00-7	methacrylated phosphoric acid ester	≥2.5-<10%
CAS: 10373-78-1	camphorquinone	<2.5%
CAS: 2867-47-2	2-dimethylaminoethyl methacrylate	≥1-<2.5%

4 First-aid measures

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.

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- **After swallowing:**
Rinse out mouth and then drink plenty of water.
If symptoms persist consult doctor.
- **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

- **Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, extinguishing 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.
- **Advice for firefighters**
- **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).
- **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.
- **Protective Action Criteria for Chemicals**

· PAC-1:

CAS: 868-77-9	2-hydroxyethyl methacrylate	1.9 mg/m ³
CAS: 64-17-5	ethanol	1,800 ppm

· PAC-2:

CAS: 868-77-9	2-hydroxyethyl methacrylate	21 mg/m ³
CAS: 64-17-5	ethanol	3300* ppm

· PAC-3:

CAS: 868-77-9	2-hydroxyethyl methacrylate	1,000 mg/m ³
CAS: 64-17-5	ethanol	15000* ppm

7 Handling and storage

- **Handling:**
- **Precautions for safe handling**
Only adequately trained personnel should handle this product.
For use in dentistry only.
- **Information about protection against explosions and fires:**
Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.

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- **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.
Keep receptacle tightly sealed.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**

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

CAS: 64-17-5 ethanol

PEL Long-term value: 1900 mg/m³, 1000 ppm

REL Long-term value: 1900 mg/m³, 1000 ppm

TLV Short-term value: 1880 mg/m³, 1000 ppm

- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **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.
- **Breathing equipment:**
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.
- **Protection of hands:**



Protective gloves

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.

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Trade name: **Adhese Universal**

· Eye protection:

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Tightly sealed goggles

9 Physical and chemical properties

· Information on basic physical and chemical properties

· General Information

· Appearance:

Form:	Liquid
Color:	Yellow
Odor:	Characteristic
Odor threshold:	Not determined.

· pH-value: Not applicable.

· Change in condition

Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.

· Flash point: 36 °C (96.8 °F) (ASTM D7094)

· Auto igniting: Product is not selfigniting.

· Danger of explosion: Product does not present an explosion hazard.

· Explosion limits:

Lower:	Not determined.
Upper:	Not determined.

· Vapor pressure: Not determined.

Density:	Not determined.
Relative density	Not determined.
Vapor density	Not determined.
Evaporation rate	Not determined.

· Solubility in / Miscibility with

Water:	Fully miscible.
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· Partition coefficient (n-octanol/water): Not determined.

· Viscosity:

Dynamic:	Not determined.
Kinematic:	Not determined.

· Other information No further relevant information available.

10 Stability and reactivity

· Reactivity No further relevant information available.

· Chemical stability Stable under normal handling and storage conditions.

· Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

· Possibility of hazardous reactions No dangerous reactions known.

· Conditions to avoid

Protect from exposure to the light.

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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:**· **Specific symptoms in biological assay:**· **on the skin:** Irritant to skin and mucous membranes.· **on the eye:** Irritating effect.· **Sensitization:** Sensitization possible through skin contact.· **Additional toxicological information:**

The product shows the following dangers according to internally approved calculation methods for preparations:

Irritant

· **Carcinogenic categories**· **IARC (International Agency for Research on Cancer)**

CAS: 64-17-5 ethanol

I

· **NTP (National Toxicology Program)**

None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

12 Ecological information

· **Toxicity**· **Aquatic toxicity:** No further relevant information available.· **Persistence and degradability** No further relevant information available.· **Behavior 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 2 (Self-assessment): hazardous for water

Do not allow product to reach ground water, water course or sewage system.

· **Results of PBT and vPvB assessment**· **PBT:** Not applicable.· **vPvB:** Not applicable.· **Other adverse effects** No further relevant information available.

13 Disposal considerations

· **Waste treatment methods**· **Recommendation:**

Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

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- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

· UN-Number	
· DOT, ADR/RID/ADN, IMDG, IATA	UN1170
· UN proper shipping name	Ethanol solutions
· DOT	1170 Ethanol solutions (Ethyl alcohol solutions)
· ADR/RID/ADN	ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
· IMDG	ETHANOL SOLUTION
· IATA	
· Transport hazard class(es)	
· DOT	
	
· Class	3 Flammable liquids
· Label	3
· ADR/RID/ADN	
	
· Class	3 (F1) Flammable liquids
· Label	3
· IMDG, IATA	
	
· Class	3 Flammable liquids
· Label	3
· Packing group	
· DOT, ADR/RID/ADN, IMDG, IATA	III
· Environmental hazards:	
· Marine pollutant:	No
· Special precautions for user	Warning: Flammable liquids
· Hazard identification number (Kemler code):	30
· EMS Number:	F-E,S-D
· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.

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Trade name: **Adhese Universal**

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· **Transport/Additional information:**

· **ADR/RID/ADN**

· **Excepted quantities (EQ)**

Code: E1

Maximum net quantity per inner packaging: 30 ml

Maximum net quantity per outer packaging: 1000 ml

· **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":**

UN1170, Ethanol solutions (Ethyl alcohol solutions), 3, III

15 Regulatory information

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

· **Sara**

· **Section 355 (extremely hazardous substances):**

None of the ingredients is listed.

· **Section 313 (Specific toxic chemical listings):**

None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act):**

All components have the value ACTIVE.

· **Hazardous Air Pollutants**

None of the ingredients is listed.

· **Proposition 65**

· **Chemicals known to cause cancer:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**

CAS: 64-17-5 | ethanol

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **TLV (Threshold Limit Value)**

CAS: 64-17-5 | ethanol

A3

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

· **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

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Trade name: **Adhese Universal**

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· **Hazard pictograms**

GHS02 GHS07

· **Signal word** Warning· **Hazard-determining components of labeling:**

2-hydroxyethyl methacrylate

Bis-GMA

1,10-decandiol dimethacrylate

methacrylated phosphoric acid ester

2-dimethylaminoethyl methacrylate

· **Hazard statements**

Flammable liquid and vapor.

Causes skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

· **Precautionary statements**

Keep away from heat/sparks/open flames/hot surfaces. - No smoking.

Avoid breathing dust/fume/gas/mist/vapors/spray

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.

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

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

This product is classified as a medical device under US and Canadian regulations and has been reviewed by the US Food and Drug Administration and Health Canada.

· **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.

· **Contact:**· **Date of preparation / last revision** 12/19/2022· **Abbreviations and acronyms:**

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

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)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

Flammable Liquids 3: Flammable liquids – Category 3

Skin Irritation 2: Skin corrosion/irritation – Category 2

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Trade name: *Adhese Universal*

Eye Irritation 2A: Serious eye damage/eye irritation – Category 2A
Sensitization - Skin 1: Skin sensitisation – Category 1

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

US

1 Identification

- **Product identifier**
- **Trade name:** ***Liquid Strip***
- **Application of the substance / the mixture** *Water-soluble glycerine paste*
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Ivoclar Vivadent Inc.
175 Pineview Drive, Amherst, N.Y. 14228
USA
Tel. +1 800 533 6825
Fax +1 716 691 2285
-
- Ivoclar Vivadent Inc.
1-6600 Dixie Road
Mississauga, Ontario
L5T 2Y2
Canada
Phone: +1 905 670 8499
Fax: +1 905 670 3102
- **Information department:** *Quality Assurance / Regulatory Affairs*
- **Emergency telephone number:**
24 Hour Emergency Assistance:
Emergency-Call USA - Infotrac: 1-800-535-5053
Emergency-Call Canada - Canutec: 1-613-996-6666
-
- General SDS Assistance:
US: 1-800-533-6825
Canada: 1-800-263-8182

2 Hazard(s) identification

- **Classification of the substance or mixture**
The product is not classified, according to the Globally Harmonized System (GHS).

- **Label elements**
- **GHS label elements** *Void*
- **Hazard pictograms** *Void*
- **Signal word** *Void*
- **Hazard statements** *Void*
- **Classification system:**
- **NFPA ratings (scale 0 - 4)**



- **HMIS-ratings (scale 0 - 4)**



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

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Trade name: **Liquid Strip**· **vPvB:** Not applicable.

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3 Composition/information on ingredients

- **Chemical characterization:** Mixtures
- **Description:** Mixture of the substances listed below with nonhazardous additions.

· **Dangerous components:**

CAS: 56-81-5	glycerol	50-100%
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4 First-aid measures

- **Description of first aid measures**
- **General information:** No special measures required.
- **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.
- **After eye contact:**
Rinse opened eye for several minutes under running water. Then consult a doctor.
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- **After swallowing:**
Rinse out mouth and then drink plenty of water.
If symptoms persist consult doctor.
- **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

- **Extinguishing media**
- **Suitable extinguishing agents:** Use fire fighting measures that suit the environment.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Wear protective clothing.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Pick up mechanically.
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.

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Trade name: **Liquid Strip**

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7 Handling and storage

- **Handling:**
- **Precautions for safe handling**
Only adequately trained personnel should handle this product.
For use in dentistry only.
- **Information about protection against explosions and fires:** No special measures required.
- **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:**
This product is hygroscopic.
Keep receptacle tightly sealed.
Protect from heat and direct sunlight.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**

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

CAS: 56-81-5 glycerol

PEL Long-term value: 15* 5** mg/m³
mist; *total dust **respirable fraction

TLV TLV withdrawn-insufficient data human occup. exp.

- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Usual hygienic measures for dental practice and dental laboratories.
Wash hands before breaks and at the end of work.
Keep away from foodstuffs, beverages and feed.
Avoid contact with the eyes and skin.
- **Breathing equipment:**
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.
- **Recommended filter device for short term use:**
Combination filter A-P2
Combination filter A-P3
- **Protection of hands:**



Protective gloves

After use of gloves apply skin-cleaning agents and skin cosmetics.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

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

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- **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.

- **Eye protection:** Safety glasses

9 Physical and chemical properties

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

- **General Information**

- **Appearance:**

Form: Pasty

Color: White

- **Odor:** Characteristic

- **Odor threshold:** Not determined.

- **pH-value:** Not determined.

- **Change in condition**

Melting point/Melting range: Undetermined.

Boiling point/Boiling range: Undetermined.

- **Flash point:** Not applicable.

- **Auto igniting:** Product is not selfigniting.

- **Danger of explosion:** Product does not present an explosion hazard.

- **Explosion limits:**

Lower: Not determined.

Upper: Not determined.

- **Vapor pressure:** Not determined.

- **Density:** Not determined.

- **Relative density** Not determined.

- **Vapor density** Not determined.

- **Evaporation rate** Not determined.

- **Solubility in / Miscibility with**

Water: Nearly insoluble.

- **Partition coefficient (n-octanol/water):** Not determined.

- **Viscosity:**

Dynamic: Not determined.

Kinematic: Not determined.

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

10 Stability and reactivity

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

- **Chemical stability** Stable under normal handling and storage conditions.

- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.

- **Possibility of hazardous reactions** Reacts with strong oxidizing agents.

- **Conditions to avoid** Keep away from heat and direct sunlight.

- **Incompatible materials:** No further relevant information available.

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· **Hazardous decomposition products:** None under normal conditions of storage and use.

11 Toxicological information

· **Information on toxicological effects**· **Acute toxicity:**· **on the skin:** No irritant effect.· **on the eye:** No irritating effect.· **Sensitization:** No sensitizing effects known.· **Additional toxicological information:**

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

· **Carcinogenic categories**· **NTP (National Toxicology Program)**

None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

12 Ecological information

· **Toxicity**· **Aquatic toxicity:** No further relevant information available.· **Persistence and degradability** No further relevant information available.· **Behavior 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 (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

· **Results of PBT and vPvB assessment**· **PBT:** Not applicable.· **vPvB:** Not applicable.· **Other adverse effects** No further relevant information available.

13 Disposal considerations

· **Waste treatment methods**· **Recommendation:**

Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

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

14 Transport information

· **UN-Number**· **DOT, ADR/RID/ADN, ADN, IMDG, IATA** Void

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- | | |
|--|--|
| · UN proper shipping name | |
| · DOT, ADR/RID/ADN, ADN, IMDG, IATA | Void |
| · Transport hazard class(es) | |
| · DOT, ADR/RID/ADN, ADN, IMDG, IATA | |
| · Class | Void |
| · Packing group | |
| · DOT, ADR/RID/ADN, IMDG, IATA | Void |
| · Environmental hazards: | |
| · Marine pollutant: | No |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | Not applicable. |
| · Transport/Additional information: | Product is not classified as a dangerous good for transport (ADR, IMDG, IATA). |
| · UN "Model Regulation": | Void |

15 Regulatory information

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

- Sara

- **Section 355 (extremely hazardous substances):**

None of the ingredients is listed.

- **Section 313 (Specific toxic chemical listings):**

None of the ingredients is listed.

- **TSCA (Toxic Substances Control Act):**

CAS: 56-81-5 | glycerol

- **Proposition 65**

- **Chemicals known to cause cancer:**

None of the ingredients is listed.

- **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

- **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

- **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

- **Carcinogenic categories**

- **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

- **TLV (Threshold Limit Value established by ACGIH)**

None of the ingredients is listed.

- **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

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Safety Data Sheet

acc. to OSHA HCS

Printing date 01/31/2020

Version number 8

Reviewed on 01/30/2020

Trade name: *Liquid Strip*

(Contd. of page 6)

- *GHS label elements* Void
- *Hazard pictograms* Void
- *Signal word* Void
- *Hazard statements* Void
- **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.

- **Date of preparation / last revision** 01/31/2020 / 7

- **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

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)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

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

US

Safety Data Sheet

acc. to OSHA HCS

Printing date 02/05/2024

Version number 9

Reviewed on 02/05/2024



1 Identification

- **Product identifier**
- **Trade name:** ***Monobond Plus***
- **Application of the substance / the mixture** Universal primer
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Ivoclar Vivadent Inc.
175 Pineview Drive, Amherst, N.Y. 14228
USA
Tel. +1 800 533 6825
Fax +1 716 691 2285

Ivoclar Vivadent Inc.
1-6600 Dixie Road
Mississauga, Ontario
L5T 2Y2
Canada
Phone: +1 905 670 8499
Fax: +1 905 670 3102
- **Information department:** Quality Assurance / Regulatory Affairs
- **Emergency telephone number:**
24 Hour Emergency Assistance:
Emergency-Call USA - Infotrac: 1-800-535-5053
Emergency-Call Canada - Canutec: 1-613-996-6666

General SDS Assistance:
US: 1-800-533-6825
Canada: 1-800-263-8182

2 Hazard(s) identification

- **Classification of the substance or mixture**
Flammable Liquids 2 H225 Highly flammable liquid and vapor.
Eye Irritation 2A H319 Causes serious eye irritation.
Sensitization - Skin 1 H317 May cause an allergic skin reaction.
- **Label elements**
- **GHS label elements**
The product is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms**
 
GHS02 GHS07
- **Signal word** Danger
- **Hazard-determining components of labeling:**
sulphide methacrylate
methacrylated phosphoric acid ester
- **Hazard statements**
Highly flammable liquid and vapor.
Causes serious eye irritation.

(Contd. on page 2)

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acc. to OSHA HCS

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Reviewed on 02/05/2024

Trade name: **Monobond Plus**

(Contd. of page 1)

May cause an allergic skin reaction.

· **Precautionary statements**

Keep away from heat/sparks/open flames/hot surfaces. - No smoking.

Keep container tightly closed.

Avoid breathing dust/fume/gas/mist/vapors/spray

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

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

Store in a well-ventilated place. Keep cool.

· **Classification system:**

· **NFPA ratings (scale 0 - 4)**



Health = 2

Fire = 3

Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**



Health = *2

Fire = 3

Reactivity = 0

· **Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

3 Composition/information on ingredients

· **Chemical characterization: Mixtures**

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

· **Dangerous components:**

CAS: 64-17-5	ethanol	50-100%
CAS: 85590-00-7	methacrylated phosphoric acid ester	<2.5%
CAS: 1096164-11-2	sulphide methacrylate	<2.5%

4 First-aid measures

· **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.

· **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.

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(Contd. on page 3)

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acc. to OSHA HCS

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Version number 9

Reviewed on 02/05/2024

Trade name: **Monobond Plus**

(Contd. of page 2)

5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, extinguishing 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.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.
- **Additional information** Cool endangered receptacles with water spray.

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.
- **Protective Action Criteria for Chemicals**

· PAC-1:

CAS: 64-17-5	ethanol	1,800 ppm
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· PAC-2:

CAS: 64-17-5	ethanol	3300* ppm
--------------	---------	-----------

· PAC-3:

CAS: 64-17-5	ethanol	15000* ppm
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7 Handling and storage

- **Handling:**
- **Precautions for safe handling**
Only adequately trained personnel should handle this product.
For use in dentistry only.
- **Information about protection against explosions and fires:** No special measures required.
- **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 receptacle tightly sealed.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see section 7.

(Contd. on page 4)

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Trade name: **Monobond Plus**

(Contd. of page 3)

- **Control parameters**

- **Components with limit values that require monitoring at the workplace:**

The following constituent is the only constituent of the product which has a PEL, TLV or other recommended exposure limit.

At this time, the other constituents have no known exposure limits.

CAS: 64-17-5 ethanol	
PEL	Long-term value: 1900 mg/m ³ , 1000 ppm
REL	Long-term value: 1900 mg/m ³ , 1000 ppm
TLV	Short-term value: 1000 ppm
A3	

- **Regulatory information**

PEL: Guide to Occupational Exposure Values (OSHA PELs)

REL: Guide to Occupational Exposure Values (NIOSH RELs)

TLV: Guide to Occupational Exposure Values (TLV)

- **Additional information:** The lists that were valid during the creation were used as basis.

- **Exposure controls**

- **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.

- **Breathing equipment:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

- **Protection of hands:**



Protective gloves

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 protection:**



Tightly sealed goggles

9 Physical and chemical properties

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

- **General Information**

- **Appearance:**

Form:

Fluid

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Trade name: **Monobond Plus**

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· Color:	Colorless
· Odor:	Alcohol-like
· Odor threshold:	Not determined.
· pH-value:	Not determined.
· Change in condition	
Melting point/Melting range:	-114.5 °C (-174.1 °F)
Boiling point/Boiling range:	78 °C (172.4 °F)
· Flash point:	13 °C (55.4 °F)
· Auto igniting:	425 °C (797 °F)
· Ignition temperature:	Product is not selfigniting.
· Danger of explosion:	Product is not explosive. However, formation of explosive air/vapor mixtures are possible.
· Explosion limits:	
Lower:	3.5 Vol %
Upper:	15 Vol %
· Vapor pressure at 20 °C (68 °F):	59 hPa (44.3 mm Hg)
· Vapor pressure at 50 °C (122 °F):	280 hPa (210 mm Hg)
· Density at 20 °C (68 °F):	0.794 g/cm ³ (6.626 lbs/gal)
· Relative density	Not determined.
· Vapor density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with Water:	Soluble.
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
· Solvent content:	
Organic solvents:	96.0 %
VOC content:	96.00 %
Solids content:	0.0 %
· 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.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** None under normal conditions of storage and use.

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Trade name: **Monobond Plus**

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11 Toxicological information

- **Information on toxicological effects**

- **Acute toxicity:**

- **LD/LC50 values that are 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)

- **Specific symptoms in biological assay:**

- **on the skin:** No irritant effect.

- **on the eye:** No irritating effect.

- **Sensitization:** Sensitization possible through skin contact.

- **Additional toxicological information:**

The substance ethanol is listed by IARC as carcinogen in alcoholic beverages (Group 1). This product contains ethanol but is not a consumable alcoholic beverage. Therefore it is not classified and labelled as carcinogenic.

- **Carcinogenic categories**

- **IARC (International Agency for Research on Cancer)**

CAS: 64-17-5	ethanol	1
--------------	---------	---

- **NTP (National Toxicology Program)**

None of the ingredients is listed.

- **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

12 Ecological information

- **Toxicity**

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

- **Persistence and degradability** No further relevant information available.

- **Behavior 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 (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

- **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.

- **vPvB:** Not applicable.

- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**

- **Recommendation:**

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

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Trade name: **Monobond Plus**

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- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agent:** Water, if necessary with cleansing agents.

14 Transport information

- **UN-Number**
- **DOT, ADR/RID/ADN, IMDG, IATA** UN1170

- **UN proper shipping name**
- **ADR/RID/ADN** 1170 ETHANOL (ETHYL ALCOHOL), solution
- **IMDG** ETHANOL (ETHYL ALCOHOL) solution
- **IATA** ETHANOL solution

- **Transport hazard class(es)**

- **DOT**



- **Class** 3 Flammable liquids
- **Label** 3

- **ADR/RID/ADN**



- **Class** 3 (F1) Flammable liquids
- **Label** 3

- **IMDG, IATA**



- **Class** 3 Flammable liquids
- **Label** 3

- **Packing group**

- **DOT, ADR/RID/ADN, IMDG, IATA** II

- **Environmental hazards:**

- **Marine pollutant:** No

- **Special precautions for user** Warning: Flammable liquids

- **Hazard identification number (Kemler code):** 33

- **EMS Number:** F-E,S-D

- **Stowage Category** A

- **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**

Not applicable.

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Trade name: **Monobond Plus**

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· Transport/Additional information:	
· ADR/RID/ADN	
· Excepted quantities (EQ)	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· 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

15 Regulatory information

· Safety, health and environmental regulations/legislation specific for the substance or mixture		
· Sara		
· Section 355 (extremely hazardous substances):		
None of the ingredients is listed.		
· Section 313 (Specific toxic chemical listings):		
None of the ingredients is listed.		
· TSCA (Toxic Substances Control Act):		
CAS: 64-17-5	ethanol	ACTIVE
· Hazardous Air Pollutants		
None of the ingredients is listed.		
· Proposition 65		
· Chemicals known to cause cancer:		
None of the ingredients is listed.		
· Chemicals known to cause reproductive toxicity for females:		
None of the ingredients is listed.		
· Chemicals known to cause reproductive toxicity for males:		
None of the ingredients is listed.		
· Chemicals known to cause developmental toxicity:		
CAS: 64-17-5	ethanol	
· Carcinogenic categories		
· EPA (Environmental Protection Agency)		
None of the ingredients is listed.		
· TLV (Threshold Limit Value)		
CAS: 64-17-5	ethanol	A3
· NIOSH-Ca (National Institute for Occupational Safety and Health)		
None of the ingredients is listed.		
· GHS label elements		
The product is classified and labeled according to the Globally Harmonized System (GHS).		

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Reviewed on 02/05/2024

Trade name: **Monobond Plus**

(Contd. of page 8)

· **Hazard pictograms**

GHS02 GHS07

· **Signal word** *Danger*· **Hazard-determining components of labeling:**

sulphide methacrylate
methacrylated phosphoric acid ester

· **Hazard statements**

Highly flammable liquid and vapor.
Causes serious eye irritation.
May cause an allergic skin reaction.

· **Precautionary statements**

Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
Keep container tightly closed.
Avoid breathing dust/fume/gas/mist/vapors/spray
Wear protective gloves/protective clothing/eye protection/face protection.
If skin irritation or rash occurs: Get medical advice/attention.
Store in a well-ventilated place. Keep cool.

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

The product is a medical device according to Regulation 2017/745 on Medical Devices (MDR).
This product is classified as a medical device under US and Canadian regulations and has been reviewed by the US Food and Drug Administration and Health Canada.

· **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.

· **Contact:**· **Date of preparation / last revision** 02/05/2024· **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
DOT: US Department of Transportation
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)
NFPA: National Fire Protection Association (USA)
HMIS: Hazardous Materials Identification System (USA)
VOC: Volatile Organic Compounds (USA, EU)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
NIOSH: National Institute for Occupational Safety
OSHA: Occupational Safety & Health
TLV: Threshold Limit Value
PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit

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Safety Data Sheet
acc. to OSHA HCS

Printing date 02/05/2024

Version number 9

Reviewed on 02/05/2024

Trade name: Monobond Plus

(Contd. of page 9)

*Flammable Liquids 2: Flammable liquids – Category 2**Eye Irritation 2A: Serious eye damage/eye irritation – Category 2A**Sensitization - Skin 1: Skin sensitisation – Category 1**· * Data compared to the previous version altered.*

US

Safety Data Sheet

acc. to OSHA HCS

Printing date 02/21/2024

Version number 3

Reviewed on 02/21/2024

1 Identification

- **Product identifier**
- **Trade name:** *Variolink Esthetic DC (Catalyst)*
- **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 Inc.
175 Pineview Drive, Amherst, N.Y. 14228
USA
Tel. +1 800 533 6825
Fax +1 716 691 2285

Ivoclar Vivadent Inc.
1-6600 Dixie Road
Mississauga, Ontario
L5T 2Y2
Canada
Phone: +1 905 670 8499
Fax: +1 905 670 3102
- **Information department:** Quality Assurance / Regulatory Affairs
- **Emergency telephone number:**
24 Hour Emergency Assistance:
Emergency-Call USA - Infotrac: 1-800-535-5053
Emergency-Call Canada - Canutec: 1-613-996-6666

General SDS Assistance:
US: 1-800-533-6825
Canada: 1-800-263-8182

2 Hazard(s) identification

- **Classification of the substance or mixture**
Skin Irritation 2 H315 Causes skin irritation.
Eye Irritation 2A H319 Causes serious eye irritation.
Sensitization - Skin 1 H317 May cause an allergic skin reaction.
Specific Target Organ Toxicity - Single Exposure 3 H335 May cause respiratory irritation.
Specific Target Organ Toxicity - Repeated Exposure 2 H373 May cause damage to organs through prolonged or repeated exposure.

- **Label elements**
- **GHS label elements**
The product is classified and labeled according to the Globally Harmonized System (GHS).

- **Hazard pictograms**



GHS07 GHS08

- **Signal word** Warning
- **Hazard-determining components of labeling:**
urethane dimethacrylate
ytterbium trifluoride

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acc. to OSHA HCS

Printing date 02/21/2024

Version number 3

Reviewed on 02/21/2024

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

(Contd. of page 1)

α,α -dimethylbenzyl hydroperoxide
aromatic aliphatic urethane dimethacrylate
1,10-decandiol dimethacrylate

· **Hazard statements**

Causes skin irritation.
Causes serious eye irritation.
May cause an allergic skin reaction.
May cause respiratory irritation.
May cause damage to organs through prolonged or repeated exposure.

· **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.

· **Classification system:**

· **NFPA ratings (scale 0 - 4)**



Health = 2
 Fire = 0
 Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**



Health = 2
 Fire = 0
 Reactivity = 0

· **Other hazards**

· **Results of PBT and vPvB assessment**

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

3 Composition/information on ingredients

· **Chemical characterization: Mixtures**

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

· **Dangerous components:**

CAS: 13760-80-0	ytterbium trifluoride	10-25%
CAS: 72869-86-4	urethane dimethacrylate	2.5-10%
CAS: 1219495-43-8	aromatic aliphatic urethane dimethacrylate	2.5-10%
CAS: 6701-13-9	1,10-decandiol dimethacrylate	2.5-10%
CAS: 80-15-9	α,α -dimethylbenzyl hydroperoxide	<2.5%

4 First-aid measures

· **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.

(Contd. on page 3)

Safety Data Sheet

acc. to OSHA HCS

Printing date 02/21/2024

Version number 3

Reviewed on 02/21/2024

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

(Contd. of page 2)

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.

· **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

· **Extinguishing media**

· **Suitable extinguishing agents:**

CO₂, extinguishing 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.

· **Advice for firefighters**

· **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:** Pick up mechanically.

· **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.

· **Protective Action Criteria for Chemicals**

· **PAC-1:**

CAS: 13760-80-0	ytterbium trifluoride	30 mg/m ³
CAS: 72869-86-4	urethane dimethacrylate	120 mg/m ³
CAS: 80-15-9	α,α -dimethylbenzyl hydroperoxide	0.15 ppm

· **PAC-2:**

CAS: 13760-80-0	ytterbium trifluoride	330 mg/m ³
CAS: 72869-86-4	urethane dimethacrylate	1,300 mg/m ³
CAS: 80-15-9	α,α -dimethylbenzyl hydroperoxide	1.6 ppm

· **PAC-3:**

CAS: 13760-80-0	ytterbium trifluoride	2,000 mg/m ³
CAS: 72869-86-4	urethane dimethacrylate	7,900 mg/m ³
CAS: 80-15-9	α,α -dimethylbenzyl hydroperoxide	9.7 ppm

7 Handling and storage

· **Handling:**

· **Precautions for safe handling**

Only adequately trained personnel should handle this product.

For use in dentistry only.

(Contd. on page 4)

Safety Data Sheet

acc. to OSHA HCS

Printing date 02/21/2024

Version number 3

Reviewed on 02/21/2024

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

(Contd. of page 3)

- **Information about protection against explosions and fires:** No special measures required.
- **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 receptacle tightly sealed.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see section 7.
- **Control parameters**

- **Components with limit values that require monitoring at the workplace:**

CAS: 80-15-9 α,α -dimethylbenzyl hydroperoxide

WEEL	Long-term value: 6 mg/m ³ , 1 ppm
	Skin

- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **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.
- **Breathing equipment:**
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.
- **Protection of hands:**



Protective gloves

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.

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

· Eye protection:

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Tightly sealed goggles

9 Physical and chemical properties

· Information on basic physical and chemical properties

· General Information

· Appearance:

Form:	Pasty
Color:	According to product specification
Odor:	Characteristic
Odor threshold:	Not determined.

· pH-value: Not applicable.

· Change in condition

Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.

· Flash point: Not applicable.

· Flammability (solid, gaseous): Not determined.

· Ignition temperature: Product is not selfigniting.

· Danger of explosion: Product does not present an explosion hazard.

· Explosion limits:

Lower:	Not determined.
Upper:	Not determined.

· Vapor pressure: Not applicable.

· Density at 20 °C (68 °F): 1.8705 g/cm³ (15.609 lbs/gal)

· Relative density: Not determined.

· Vapor density: Not applicable.

· Evaporation rate: Not applicable.

· Solubility in / Miscibility with

Water: Nearly insoluble.

· Partition coefficient (n-octanol/water): Not determined.

· 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.

· Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

· Possibility of hazardous reactions: No dangerous reactions known.

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

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- **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:**
- **Specific symptoms in biological assay:**
 - **on the skin:** Irritant to skin and mucous membranes.
 - **on the eye:** Irritating effect.
- **Sensitization:** Sensitization possible through skin contact.
- **Additional toxicological information:** No further relevant information available.
- **Carcinogenic categories**

- **IARC (International Agency for Research on Cancer)**

CAS: 13760-80-0 ytterbium trifluoride

3

- **NTP (National Toxicology Program)**

None of the ingredients is listed.

- **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior 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 (Self-assessment): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:**
Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

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

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- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

· UN-Number	
· DOT	Void
· ADR/RID/ADN, IMDG, IATA	UN3082
· UN proper shipping name	
· DOT	Void
· 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)
· Transport hazard class(es)	
· DOT	
· Class	Void
· ADR/RID/ADN	
	
	
· Class	9 (M6) Miscellaneous dangerous substances and articles
· Label	9
· IMDG, IATA	
	
	
· Class	9 Miscellaneous dangerous substances and articles
· Label	9
· Packing group	
· DOT	Void
· ADR/RID/ADN, IMDG, IATA	III
· Environmental hazards:	
· Marine pollutant:	No
· Special marking (ADR/RID/ADN):	Symbol (fish and tree)
· Special marking (IATA):	Symbol (fish and tree)
· 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

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

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· Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable.
· Transport/Additional information:	
· ADR/RID/ADN	
· Excepted quantities (EQ)	Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· 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**· **Sara**· **Section 355 (extremely hazardous substances):**

None of the ingredients is listed.

· **Section 313 (Specific toxic chemical listings):**CAS: 80-15-9 α,α -dimethylbenzyl hydroperoxide· **TSCA (Toxic Substances Control Act):**

CAS: 13760-80-0	ytterbium trifluoride	ACTIVE
CAS: 72869-86-4	urethane dimethacrylate	ACTIVE
CAS: 6701-13-9	1,10-decandiol dimethacrylate	ACTIVE
CAS: 80-15-9	α,α -dimethylbenzyl hydroperoxide	ACTIVE

· **Hazardous Air Pollutants**

None of the ingredients is listed.

· **Proposition 65**· **Chemicals known to cause cancer:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

· **Carcinogenic categories**· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

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

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· **TLV (Threshold Limit Value)**

CAS: 13760-80-0 Ytterbium trifluoride

A4

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

· **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

· **Hazard pictograms**

GHS07 GHS08

· **Signal word** Warning· **Hazard-determining components of labeling:**

urethane dimethacrylate

ytterbium trifluoride

 α,α -dimethylbenzyl hydroperoxide

aromatic aliphatic urethane dimethacrylate

1,10-decandiol dimethacrylate

· **Hazard statements**

Causes skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

May cause respiratory irritation.

May cause damage to organs through prolonged or repeated exposure.

· **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.

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

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

This product is classified as a medical device under US and Canadian regulations and has been reviewed by the US Food and Drug Administration and Health Canada.

· **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.

· **Contact:**· **Date of preparation / last revision** 02/21/2024· **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

DOT: US Department of Transportation

IATA: International Air Transport Association

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*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)**NFPA: National Fire Protection Association (USA)**HMIS: Hazardous Materials Identification System (USA)**PBT: Persistent, Bioaccumulative and Toxic**vPvB: very Persistent and very Bioaccumulative**NIOSH: National Institute for Occupational Safety**OSHA: Occupational Safety & Health**TLV: Threshold Limit Value**PEL: Permissible Exposure Limit**REL: Recommended Exposure Limit**Skin Irritation 2: Skin corrosion/irritation – Category 2**Eye Irritation 2A: Serious eye damage/eye irritation – Category 2A**Sensitization - Skin 1: Skin sensitisation – Category 1**Specific Target Organ Toxicity - Single Exposure 3: Specific target organ toxicity (single exposure) – Category 3**Specific Target Organ Toxicity - Repeated Exposure 2: Specific target organ toxicity (repeated exposure) – Category 2*** Data compared to the previous version altered.*

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1 Identification

- **Product identifier**
- **Trade name:** ***Variolink Esthetic DC (light, light+, neutral, warm, warm+)***
(Base)
- **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 Inc.
175 Pineview Drive, Amherst, N.Y. 14228
USA
Tel. +1 800 533 6825
Fax +1 716 691 2285

Ivoclar Vivadent Inc.
1-6600 Dixie Road
Mississauga, Ontario
L5T 2Y2
Canada
Phone: +1 905 670 8499
Fax: +1 905 670 3102
- **Information department:** Quality Assurance / Regulatory Affairs
- **Emergency telephone number:**
24 Hour Emergency Assistance:
Emergency-Call USA - Infotrac: 1-800-535-5053
Emergency-Call Canada - Canutec: 1-613-996-6666

General SDS Assistance:
US: 1-800-533-6825
Canada: 1-800-263-8182

2 Hazard(s) identification

- **Classification of the substance or mixture**

Skin Irritation 2	H315 Causes skin irritation.
Eye Irritation 2A	H319 Causes serious eye irritation.
Sensitization - Skin 1	H317 May cause an allergic skin reaction.
Specific Target Organ Toxicity - Single Exposure 3	H335 May cause respiratory irritation.

- **Label elements**
- **GHS label elements**
The product is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms**



GHS07

- **Signal word** Warning
- **Hazard-determining components of labeling:**
urethane dimethacrylate
ytterbium trifluoride
aromatic aliphatic urethane dimethacrylate

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

(Contd. of page 1)

1,10-decandiol dimethacrylate

· **Hazard statements**

Causes skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

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.

Take off contaminated clothing and wash it before reuse.

Wash contaminated clothing before reuse.

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

· **Classification system:**

· **NFPA ratings (scale 0 - 4)**



Health = 2

Fire = 0

Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**



Health = 2

Fire = 0

Reactivity = 0

· **Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

3 Composition/information on ingredients

· **Chemical characterization: Mixtures**

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

· **Dangerous components:**

CAS: 13760-80-0	ytterbium trifluoride	10-25%
CAS: 72869-86-4	urethane dimethacrylate	2.5-10%
CAS: 1219495-43-8	aromatic aliphatic urethane dimethacrylate	2.5-10%
CAS: 6701-13-9	1,10-decandiol dimethacrylate	2.5-10%
CAS: 591-08-2	acetyl-2-thiourea	<2.5%

4 First-aid measures

· **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.

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

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- **After swallowing:**
Rinse out mouth and then drink plenty of water.
If symptoms persist consult doctor.
- **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

- **Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, extinguishing 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.
- **Advice for firefighters**
- **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.
- **Protective Action Criteria for Chemicals**

· **PAC-1:**

CAS: 13760-80-0	ytterbium trifluoride	30 mg/m ³
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· **PAC-2:**

CAS: 13760-80-0	ytterbium trifluoride	330 mg/m ³
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· **PAC-3:**

CAS: 13760-80-0	ytterbium trifluoride	2,000 mg/m ³
-----------------	-----------------------	-------------------------

7 Handling and storage

- **Handling:**
- **Precautions for safe handling**
Only adequately trained personnel should handle this product.
For use in dentistry only.
- **Information about protection against explosions and fires:** No special measures required.
- **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.

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Keep receptacle tightly sealed.

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

8 Exposure controls/personal protection

· **Additional information about design of technical systems:** No further data; see section 7.

· **Control parameters**

· **Components 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 that were valid during the creation were used as basis.

· **Exposure controls**

· **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.

· **Breathing equipment:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

· **Protection of hands:**



Protective gloves

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

9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

Form:

Pasty

Color:

According to product specification

· **Odor:**

Characteristic

· **Odor threshold:**

Not determined.

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· pH-value:	Not applicable.
· Change in condition	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.
· Flash point:	Not applicable.
· Flammability (solid, gaseous):	Not determined.
· Ignition temperature:	Product is not selfigniting.
· Danger of explosion:	Product does not present an explosion hazard.
· Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
· Vapor pressure:	Not applicable.
· Density at 20 °C (68 °F):	1.8567 g/cm ³ (15.494 lbs/gal)
· Relative density	Not determined.
· Vapor density	Not applicable.
· Evaporation rate	Not applicable.
· Solubility in / Miscibility with Water:	Nearly insoluble.
· Partition coefficient (n-octanol/water):	Not determined.
· 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:**
- **Specific symptoms in biological assay:**
- **on the skin:** Irritant to skin and mucous membranes.
- **on the eye:** Irritating effect.
- **Sensitization:** Sensitization possible through skin contact.

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

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· **Additional toxicological information:** No further relevant information available.

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**

CAS: 13760-80-0 ytterbium trifluoride

3

· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

12 Ecological information

· **Toxicity**

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

· **Persistence and degradability** No further relevant information available.

· **Behavior 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 (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

· **Other adverse effects** No further relevant information available.

13 Disposal considerations

· **Waste treatment methods**

· **Recommendation:**

Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

· **Uncleaned packagings:**

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

14 Transport information

· **UN-Number**

· **DOT**

· **ADR/RID/ADN, IMDG, IATA**

Void

UN3082

· **UN proper shipping name**

· **DOT**

· **ADR/RID/ADN**

Void

3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Butylated hydroxytoluene, 2-(2-Hydroxy-5-methylphenyl)-benzotriazol; 2-(2H-Benzotriazol-2-yl)-p-kresol)

· **IMDG**

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Butylated hydroxytoluene, 2-(2-Hydroxy-5-methylphenyl)-benzotriazol; 2-(2H-Benzotriazol-2-yl)-p-kresol), MARINE POLLUTANT

· **IATA**

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Butylated hydroxytoluene, 2-(2-Hydroxy-5-

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

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methylphenyl)-benzotriazol; 2-(2H-Benzotriazol-2-yl)-p-kresol)	
· Transport hazard class(es)	
· DOT	
· Class	Void
· ADR/RID/ADN	
	
· Class	9 (M6) Miscellaneous dangerous substances and articles
· Label	9
· IMDG, IATA	
	
· Class	9 Miscellaneous dangerous substances and articles
· Label	9
· Packing group	
· DOT	Void
· ADR/RID/ADN, IMDG, IATA	III
· 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)
· 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
· Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable.
· Transport/Additional information:	
· ADR/RID/ADN	
· Excepted quantities (EQ)	Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· 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

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· **UN "Model Regulation":**

UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (BUTYLATED HYDROXYTOLUENE, 2-(2-HYDROXY-5-METHYLPHENYL)-BENZOTRIAZOL; 2-(2H-BENZOTRIAZOL-2-YL)-P-KRESOL), 9, III

15 Regulatory information

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

· **Sara**

· **Section 355 (extremely hazardous substances):**

None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act):**

CAS: 13760-80-0	ytterbium trifluoride	ACTIVE
CAS: 6701-13-9	1,10-decandiol dimethacrylate	ACTIVE
CAS: 591-08-2	acetyl-2-thiourea	ACTIVE

· **Proposition 65**

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **TLV (Threshold Limit Value)**

CAS: 13760-80-0	ytterbium trifluoride	A4
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· **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

· **Hazard pictograms**



GHS07

· **Signal word** Warning

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

urethane dimethacrylate
ytterbium trifluoride
aromatic aliphatic urethane dimethacrylate
1,10-decandiol dimethacrylate

· **Hazard statements**

Causes skin irritation.
Causes serious eye irritation.
May cause an allergic skin reaction.
May cause respiratory irritation.

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Safety Data Sheet

acc. to OSHA HCS

Printing date 02/21/2024

Version number 1

Reviewed on 02/21/2024

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

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· **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.

Take off contaminated clothing and wash it before reuse.

Wash contaminated clothing before reuse.

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

· **National regulations:**

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

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

This product is classified as a medical device under US and Canadian regulations and has been reviewed by the US Food and Drug Administration and Health Canada.

· **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.

· **Contact:**

· **Date of preparation / last revision 02/21/2024**

· **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

DOT: US Department of Transportation

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)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

Skin Irritation 2: Skin corrosion/irritation – Category 2

Eye Irritation 2A: Serious eye damage/eye irritation – Category 2A

Sensitization - Skin 1: Skin sensitisation – Category 1

Specific Target Organ Toxicity - Single Exposure 3: Specific target organ toxicity (single exposure) – Category 3

US

Safety Data Sheet
acc. to OSHA HCS

Printing date 02/21/2024

Version number 4

Reviewed on 02/21/2024



1 Identification

- **Product identifier**
- **Trade name:** ***Variolink Esthetic Try-In***
- **Application of the substance / the mixture** Water-soluble glycerine try-in paste
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Ivoclar Vivadent Inc.
175 Pineview Drive, Amherst, N.Y. 14228
USA
Tel. +1 800 533 6825
Fax +1 716 691 2285

Ivoclar Vivadent Inc.
1-6600 Dixie Road
Mississauga, Ontario
L5T 2Y2
Canada
Phone: +1 905 670 8499
Fax: +1 905 670 3102
- **Information department:** Quality Assurance / Regulatory Affairs
- **Emergency telephone number:**
24 Hour Emergency Assistance:
Emergency-Call USA - Infotrac: 1-800-535-5053
Emergency-Call Canada - Canutec: 1-613-996-6666

General SDS Assistance:
US: 1-800-533-6825
Canada: 1-800-263-8182

2 Hazard(s) identification

- **Classification of the substance or mixture**
Sensitization - Skin 1 H317 May cause an allergic skin reaction.
Carcinogenicity 2 H351 Suspected of causing cancer. Route of exposure: Inhalation.
- **Label elements**
- **GHS label elements**
The product is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms**
 
GHS07 GHS08
- **Signal word** Warning
- **Hazard-determining components of labeling:**
titanium dioxide
urethane dimethacrylate
1,10-decandiol dimethacrylate
- **Hazard statements**
May cause an allergic skin reaction.
Suspected of causing cancer. Route of exposure: Inhalation.

(Contd. on page 2)

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Safety Data Sheet

acc. to OSHA HCS

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Version number 4

Reviewed on 02/21/2024

Trade name: **Variolink Esthetic Try-In**

(Contd. of page 1)

Precautionary statements

Obtain special instructions before use.
 Do not handle until all safety precautions have been read and understood.
 Avoid breathing dust/fume/gas/mist/vapors/spray
 Contaminated work clothing must not be allowed out of the workplace.
 Wear protective gloves/protective clothing/eye protection/face protection.
 If on skin: Wash with plenty of water.
 IF exposed or concerned: Get medical advice/attention.
 Specific treatment (see on this label).
 If skin irritation or rash occurs: Get medical advice/attention.
 Wash contaminated clothing before reuse.
 Store locked up.
 Dispose of contents/container in accordance with local/regional/national/international regulations.

Classification system:

NFPA ratings (scale 0 - 4)



HMIS-ratings (scale 0 - 4)



Other hazards

Results of PBT and vPvB assessment

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

3 Composition/information on ingredients

Chemical characterization: Mixtures

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

Dangerous components:

CAS: 56-81-5	glycerol	50-100%
CAS: 72869-86-4	urethane dimethacrylate	<2.5%
CAS: 13463-67-7	titanium dioxide	<2.5%
CAS: 6701-13-9	1,10-decandiol dimethacrylate	<2.5%

4 First-aid measures

Description of first aid measures

· **General information:** No special measures required.

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.

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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Trade name: **Variolink Esthetic Try-In**

(Contd. of page 2)

- **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

- **Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, extinguishing 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.
- **Advice for firefighters**
- **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:**
Pick up mechanically.
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 protection against explosions and fires:** No special measures required.
- **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:** Store away from oxidizing agents.
- **Further information about storage conditions:**
This product is hygroscopic.
Keep receptacle tightly sealed.
Protect from heat and direct sunlight.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see section 7.
- **Control parameters**
- **Components with limit values that require monitoring at the workplace:**
The following constituent is the only constituent of the product which has a PEL, TLV or other recommended exposure limit.

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Trade name: **Variolink Esthetic Try-In**

(Contd. of page 3)

At this time, the other constituents have no known exposure limits.

CAS: 56-81-5 glycerol

PEL Long-term value: 15* 5** mg/m³
mist; *total dust **respirable fraction

TLV TLV withdrawn-insufficient data human occup. exp.

· **Regulatory information**

PEL: Guide to Occupational Exposure Values (OSHA PELs)

TLV: Guide to Occupational Exposure Values (TLV)

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

· **Exposure controls**· **Personal protective equipment:**· **General protective and hygienic measures:**

Usual hygienic measures for dental practice and dental laboratories.

Wash hands before breaks and at the end of work.

Keep away from foodstuffs, beverages and feed.

Avoid contact with the eyes and skin.

· **Breathing equipment:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

· **Recommended filter device for short term use:**

Combination filter A-P2

Combination filter A-P3

· **Protection of hands:**

Protective gloves

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.

· **Eye protection:**

Tightly sealed goggles

9 Physical and chemical properties

· **Information on basic physical and chemical properties**· **General Information**· **Appearance:**

Form:

Pasty

Color:

According to product specification

· **Odor:**

Characteristic

· **Odor threshold:**

Not determined.

· **pH-value:**

Not determined.

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Trade name: **Variolink Esthetic Try-In**

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· Change in condition	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.
· Flash point:	Not applicable.
· Flammability (solid, gaseous):	Not applicable.
· Ignition temperature:	Product is not selfigniting.
· Danger of explosion:	Product does not present an explosion hazard.
· Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
· Vapor pressure:	Not determined.
· Density:	Not determined.
· Relative density	Not determined.
· Vapor density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with Water:	Partly soluble.
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
· Other information	No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability** Stable under normal handling and storage conditions.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** Reacts with strong oxidizing agents.
- **Conditions to avoid** 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:**
- **Specific symptoms in biological assay:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:** No further relevant information available.

· **Carcinogenic categories**

· **NTP (National Toxicology Program)**

None of the ingredients is listed.

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Trade name: **Variolink Esthetic Try-In**

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· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior 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 (Self-assessment): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:**
Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- **UN-Number**
- **DOT, ADR/RID/ADN, ADN, IMDG, IATA** Void
- **UN proper shipping name**
- **DOT, ADR/RID/ADN, ADN, IMDG, IATA** Void
- **Transport hazard class(es)**
- **DOT, ADR/RID/ADN, ADN, IMDG, IATA**
- **Class** Void
- **Packing group**
- **DOT, ADR/RID/ADN, IMDG, IATA** Void
- **Environmental hazards:**
- **Marine pollutant:** No
- **Special precautions for user** Not applicable.
- **Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** Not applicable.

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Safety Data Sheet

acc. to OSHA HCS

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Version number 4

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Trade name: **Variolink Esthetic Try-In**

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- | | |
|--|--|
| · Transport/Additional information: | Product is not classified as a dangerous good for transport (ADR, IMDG, IATA). |
| · UN "Model Regulation": | Void |

15 Regulatory information

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

- **Sara**

- **Section 355 (extremely hazardous substances):**

None of the ingredients is listed.

- **Section 313 (Specific toxic chemical listings):**

None of the ingredients is listed.

- **TSCA (Toxic Substances Control Act):**

CAS: 56-81-5 | glycerol

- **Proposition 65**

- **Chemicals known to cause cancer:**

None of the ingredients is listed.

- **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

- **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

- **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

- **Carcinogenic categories**

- **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

- **TLV (Threshold Limit Value)**

None of the ingredients is listed.

- **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

- **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

- **Hazard pictograms**



GHS07 GHS08

- **Signal word** Warning

- **Hazard-determining components of labeling:**

titanium dioxide

urethane dimethacrylate

1,10-decandiol dimethacrylate

(Contd. on page 8)

Safety Data Sheet

acc. to OSHA HCS

Printing date 02/21/2024

Version number 4

Reviewed on 02/21/2024

Trade name: **Variolink Esthetic Try-In**

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- **Hazard statements**

May cause an allergic skin reaction.
Suspected of causing cancer. Route of exposure: Inhalation.

- **Precautionary statements**

Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.
Avoid breathing dust/fume/gas/mist/vapors/spray
Contaminated work clothing must not be allowed out of the workplace.
Wear protective gloves/protective clothing/eye protection/face protection.
If on skin: Wash with plenty of water.
If exposed or concerned: Get medical advice/attention.
Specific treatment (see on this label).
If skin irritation or rash occurs: Get medical advice/attention.
Wash contaminated clothing before reuse.
Store locked up.
Dispose of contents/container in accordance with local/regional/national/international regulations.

- **National regulations:**

- **Other regulations, limitations and prohibitive regulations**

The product is a medical device according to Regulation 2017/745 on Medical Devices (MDR).
This product is classified as a medical device under US and Canadian regulations and has been reviewed by the US Food and Drug Administration and Health Canada.

- **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.

- **Contact:**

- **Date of preparation / last revision** 02/21/2024

- **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
DOT: US Department of Transportation
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)
NFPA: National Fire Protection Association (USA)
HMIS: Hazardous Materials Identification System (USA)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
NIOSH: National Institute for Occupational Safety
OSHA: Occupational Safety & Health
TLV: Threshold Limit Value
PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit
Sensitization - Skin 1: Skin sensitisation – Category 1
Carcinogenicity 2: Carcinogenicity – Category 2

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

US