# **SAFETY DATA SHEETS**

# This SDS packet was issued with item:

077144561

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

077093065 077144520 077144538 077144546 077144553 077144579 077144587



Printing date 07/12/2011 Version number 3 Reviewed on 07/12/2011

# 1 Identification of the substance/mixture and of the company/undertaking

- · Product identifier
- · Trade name: Variolink Veneer
- · Relevant identified uses of the substance or mixture and uses advised against
- · Application of the substance / the preparation

Light-curing dental luting composite suitable for ceramic and composite restorations

- · 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.

2785 Skymark Avenue, Unit 1, Mississauga, Ontario L4W4Y3

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Tel. +1 800 263 8182 Fax +1 905 238 5711

- · 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 MSDS Assistance: US: 1-800-533-6825 Canada: 1-800-263-8182

### 2 Composition/information on ingredients

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

| · Dangerous components: |            |                              |                          |         |
|-------------------------|------------|------------------------------|--------------------------|---------|
|                         | 72869-86-4 | urethane dimethacrylate      | ♦ H319; H317; H402; H412 | 25-50%  |
|                         | 6701-13-9  | decamethylene dimethacrylate | <b>♦</b> H319; H317      | 2.5-10% |

# 3 Hazards identification

- · Classification of the substance or mixture
- · Classification according to Directive 67/548/EEC or Directive 1999/45/EC



X Irritant

Irritating to eyes. May cause sensitisation by skin contact.

Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

· Classification system:

The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

- · Label elements
- · Labelling according to EU guidelines:

Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Dangerous Substance Directive 1999/45/EWG usually if they are in the finished state and intended for the final user.

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- USA

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Trade name: Variolink Veneer

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· Code letter and hazard designation of product:



Irritant

· Hazard-determining components of labelling:

urethane dimethacrylate decamethylene dimethacrylate

· Risk phrases:

Irritating to eyes.

May cause sensitisation by skin contact.

Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

· Safety phrases:

Avoid contact with skin.

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Wear suitable gloves.

This material and its container must be disposed of as hazardous waste.

Avoid release to the environment. Refer to special instructions/safety data sheets.

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



Health = 1Fire = 0Reactivity = 0

· HMIS-ratings (scale 0 - 4)



1 Health = 1 Fire = 0

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

# 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.
- · After eye contact:

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

- · After swallowing: 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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Trade name: Variolink Veneer

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## 5 Firefighting 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 Not required.
- 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.

### 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.

Keep receptacle tightly sealed.

 $\cdot$  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:

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:
- $\cdot \textit{General protective and hygienic measures:} \\$

Usual hygienic measures for dental practice.

Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

Keep away from foodstuffs, beverages and feed.

· Breathing equipment: Not required.

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-USA

Printing date 07/12/2011 Version number 3 Reviewed on 07/12/2011

Trade name: Variolink Veneer

· Protection of hands:

(Contd. of page 3)



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

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

### · Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

### · Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eye protection: Safety glasses

| Physical and chemical propert        | ies   |  |  |
|--------------------------------------|---|--|--|
| Information on basic physical and ci | hemical properties                            |  |  |
| · General Information                |   |  |  |
| · Appearance:                        |   |  |  |
| Form:                                | Pasty   |  |  |
| Color:                               | According to product specification            |  |  |
| · Odor:                              | Characteristic                                |  |  |
| · Odour 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.                               |  |  |
| Vapour density                       | Not determined.                               |  |  |
| Evaporation rate                     | Not determined.                               |  |  |
| Solubility in / Miscibility with     |   |  |  |
| Water:                               | Nearly insoluble.                             |  |  |
| Segregation coefficient (n-octonol/w | ater): Not determined.                        |  |  |
| Viscosity:                           |   |  |  |
| Dynamic:                             | Not determined.                               |  |  |
| Kinematic:                           | Not determined.                               |  |  |

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Trade name: Variolink Veneer

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

# 12 Ecological information

- · Toxicity
- · Acquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- · Behavior in environmental systems:
- $\cdot \textit{Bioaccumulative potential No further relevant information available}.$
- · *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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– USA

Printing date 07/12/2011 Version number 3 Reviewed on 07/12/2011

Trade name: Variolink Veneer

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

# 14 Transport information

- · DOT regulations:
- · Hazard class:
- · Land transport ADR/RID (cross-border):
- · ADR/RID class:
- · Maritime transport IMDG:
- · IMDG Class:
- · Marine pollutant: No
- · Air transport ICAO-TI and IATA-DGR:
- · ICAO/IATA Class: -
- · Special precautions for user Not applicable.
- · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code Not applicable.

## 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 ingredients are 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.

· IARC (International Agency for Research on Cancer)

7631-86-9 silicon dioxide, chemically prepared

3

· NTP (National Toxicology Program)

None of the ingredients is listed.

· TLV (Threshold Limit Value established by ACGIH)

13760-80-0 ytterbium trifluoride

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USA

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Trade name: Variolink Veneer

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

None of the ingredients is listed.

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

None of the ingredients is listed.

#### · Product related hazard informations:

Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Dangerous Substance Directive 1999/45/EWG usually if they are in the finished state and intended for the final user.

#### · Hazard symbols:



Irritant

### · Hazard-determining components of labelling:

urethane dimethacrylate decamethylene dimethacrylate

### · Risk phrases:

Irritating to eyes.

May cause sensitisation by skin contact.

Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

#### · Safety phrases:

Avoid contact with skin.

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Wear suitable gloves.

This material and its container must be disposed of as hazardous waste.

Avoid release to the environment. Refer to special instructions/safety data sheets.

### · National regulations:

# · Other regulations, limitations and prohibitive regulations

The product is a medical device according to the EC-directive 93/42/EEC.

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.

- USA



Printing date 05/07/2015 Version number 4 Reviewed on 03/16/2015

## 1 Identification

- · Product identifier
- · Trade name: Variolink Veneer
- · Relevant identified uses of the substance or mixture and uses advised against

No further relevant information available.

· Application of the substance / the mixture

Light-curing dental luting composite suitable for ceramic and composite restorations

- · Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

Ivoclar Vivadent Inc.

175 Pineview Drive, Amherst, N.Y. 14228

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L5T 2Y2

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Phone: +1 905 670 8499

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- · Information department: Quality Assurance / Regulatory Affairs
- · Emergency telephone number:

+423 / 235 33 13

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 Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2A H319 Causes serious eye irritation.

Skin Sens. 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



- · Signal word Warning
- · Hazard-determining components of labeling: urethane dimethacrylate

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# Trade name: Variolink Veneer

(Contd. of page 1)

1,10-decandiol dimethacrylate

#### · Hazard statements

Causes skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

#### · Precautionary statements

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

Wash contaminated clothing before reuse.

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

If eye irritation persists: Get medical advice/attention.

#### · Additional information:

Medical devices are exempt from the labeling provisions of GHS according to the Hazard Communication Standard (HCS).

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



Health = 1Fire = 0Reactivity = 0

· HMIS-ratings (scale 0 - 4)



Health = 1Fire = 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: |                               |        |
|---|-------------------------|-------------------------------|--------|
| ſ | 72869-86-4              | urethane dimethacrylate       | 25-50% |
|   | 6701-13-9               | 1,10-decandiol dimethacrylate | 1-<10% |

### 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.
- · After eye contact:

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

- · After swallowing: If symptoms persist consult doctor.
- · Information for doctor:
- · Most important symptoms and effects, both acute and delayed No further relevant information available.

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Trade name: Variolink Veneer

(Contd. of page 2)

· 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 Not required.
- 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.

# 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.

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:

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.

(Contd. on page 4)

Printing date 05/07/2015 Version number 4 Reviewed on 03/16/2015

Trade name: Variolink Veneer

(Contd. of page 3)

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

Remove contaminated clothing and wash before reuse.

Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

Keep away from foodstuffs, beverages and feed.

- · Breathing equipment: Not required.
- · Protection of hands:



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

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

# · Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

### · Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eye protection: Safety glasses

# 9 Physical and chemical properties

| T C           | L        | 1        | 1     | . 1 1    |           |
|---------------|----------|----------|-------|----------|-----------|
| · Information | on vasic | pnysicai | ana d | спетісаі | properues |

· General Information

· Appearance:

Form: Pasty

Color: According to product specification

Odor: CharacteristicOdour threshold: Not determined.

· pH-value: Not determined.

· Change in condition

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

· Flash point: Not applicable.

· Flammability (solid, gaseous): 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.

(Contd. on page 5)

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Trade name: Variolink Veneer

(Contd. of page 4)

|                                    |                             | (Contd. of page 4) |
|------------------------------------|-----------------------------|--------------------|
| · Vapor pressure:                  | Not determined.             |                    |
| · Density:                         | Not determined.             |                    |
| · Relative density                 | Not determined.             |                    |
| Vapour density                     | Not determined.             |                    |
| · Evaporation rate                 | Not determined.             |                    |
| · Solubility in / Miscibility with | h                           |                    |
| Water:                             | Nearly insoluble.           |                    |
| · Partition coefficient (n-octar   | nol/water): Not determined. |                    |
| · Viscosity:                       |                             |                    |
| Dynamic:                           | Not determined.             |                    |
| Kinematic:                         | Not determined.             |                    |

No further relevant information available.

## 10 Stability and reactivity

· Other information

- · Reactivity No further relevant information available.
- · Chemical stability 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.

- $\cdot \textbf{Incompatible materials:} \ No \ further \ relevant \ information \ available.$
- · Hazardous decomposition products: None under normal conditions of storage and use.

# 11 Toxicological information

- · Information on toxicological effects
- · Acute toxicity:
- · Primary irritant effect:
- $\cdot$  on the skin: No irritant effect.
- · on the eye: Irritating effect.
- · Sensitization: Sensitization possible through skin contact.
- · Additional toxicological information: No further relevant information available.
- · 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.

(Contd. on page 6)

Printing date 05/07/2015 Version number 4 Reviewed on 03/16/2015

Trade name: Variolink Veneer

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- · 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.

| 4 Transport information  |  |
|--|--|
| · UN-Number<br>· DOT, ADR, ADN, IMDG, IATA                               | Void   |
| · UN proper shipping name<br>· DOT, ADR, ADN, IMDG, IATA                 | Void   |
| · Transport hazard class(es)   |  |
| · DOT, ADR, ADN, IMDG, IATA<br>· Class                                   | Void   |
| · Packing group<br>· DOT, ADR, IMDG, IATA                                | Void   |
| · Environmental hazards:<br>· Marine pollutant:                          | No   |
| · Special precautions for user   | Not applicable.  |
| · Transport in bulk according to Annex .<br>MARPOL73/78 and the IBC Code | <b>II of</b><br>Not applicable.  |
| · Transport/Additional information:                                      | Product is not classified as a dangerous good for transport (ADR, IMDG, IATA). |
| · UN ''Model Regulation'':   | -  |

# 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.

(Contd. on page 7)

Printing date 05/07/2015 Version number 4 Reviewed on 03/16/2015

Trade name: Variolink Veneer

(Contd. of page 6)

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

None of the ingredients is listed.

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

All ingredients are 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.

### · 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.

#### · GHS label elements

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

· Hazard pictograms



### · Signal word Warning

# · Hazard-determining components of labeling:

urethane dimethacrylate

1,10-decandiol dimethacrylate

### · Hazard statements

Causes skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

### · Precautionary statements

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

Wash contaminated clothing before reuse.

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 the Directive 93/42/EEC.

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.

(Contd. on page 8)

Printing date 05/07/2015 Version number 4 Reviewed on 03/16/2015

Trade name: Variolink Veneer

(Contd. of page 7)

· 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 05/07/2015 / 3
- · 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)

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2

Eye Irrit. 2A: Serious eye damage/eye irritation, Hazard Category 2A

Skin Sens. 1: Sensitisation - Skin, Hazard Category 1

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

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