

# SAFETY DATA SHEET (GHS)

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|-----------------------|------------|
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# 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE/PRODUCT AND MANUFACTURER/IMPORTER

1.1 Product identifier:-**Product name:** Telio CS C&B (Base) Product number: Void 1.2 Other means of identification:-Not applicable. Recommended use of the chemical and restrictions on use:-1.3 Not applicable. Identified uses: Self-curing temporary c&b material Details of the manufacturer and importer:-1.4 Manufacturer: Ivoclar Vivadent AG Bendererstrasse 2 FL-9494 Schaan PRINCIPALITY OF LIECHTENSTEIN Importer: Ivoclar Vivadent Pty Ltd 1-5 Overseas Drive Noble Park North VIC 3174 Tel: + 61 3 9795 9599 Fax: + 61 3 9795 9645 Email: info@ivoclarvivadent.com 1.5 13 11 26 **Emergency phone number:** Poisons Hotline (24 hours / 7 days)

# 2. HAZARD(S) IDENTIFICATION

# 2.1 GHS Classification:-

Aquatic Chronic 4 H413 May cause long lasting harmful effects to aquatic life.

| 2.2 | GHS Label elements, including precautio   | elements, including precautionary statements:- |  |  |  |
|-----|---|--|--|--|--|
|     | Hazard Pictogram:   | Void   |  |  |  |
|     | Signal word:<br>Hazard-determining components of<br>labelling:<br>Hazard statements:<br>Precautionary statements: |  | ng lasting harmful effects to aquatic life<br>to the environment |  |  |

**2.3** Additional information: 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 Regulation (EC) No 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

| Other hazards:-                     | Void  |                 |
|-------------------------------------|-------|-----------------|
| Results of PBT and vPvB assessment; | PBT:  | Not applicable. |
|                                     | vPvB: | Not applicable. |

# 3 COMPOSITION/INFORMATION ON INGREDIENTS

Mixture of substances listed below with nonhazardous additions. Description:

| Ingredient name | CAS No.        | Classification          | Concentration |
|-----------------|----------------|-------------------------|---------------|
| 41637-38-1      | ethyoxylated   | Aquatic Chronic 4, H413 | 50-100%       |
|                 | bisphenol A    |                         |               |
|                 | dimethacrylate |                         |               |
|                 |                |                         |               |

## 4. FIRST AID MEASURES

4.1 Description of necessary first aid measures:-



|           |  |                 |            | I  | p                                   | assion vision innovation |
|-----------|--|-----------------|------------|--|-------------------------------------|--------------------------|
|           | If inhaled:  |                 |            |  | usness place patie                  |                          |
|           | In case of skin c<br>In case of eye co   |                 |            |  | several minutes under running water | under running water.     |
|           | If swallowed:  |                 |            | If symptoms persist,<br>If symptoms persist of   |                                     |                          |
| 4.2       | Symptoms caus  |                 | :-         | No further relevant in                           |                                     | -                        |
| 4.3       | Medical attention treatment:-  | n and special   |            | No further relevant in                           | formation available                 | le.                      |
| 5.<br>5.1 | FIRE FIGHTING MEASURES Suitable extinguishing equipment:-  |                 |            |  |                                     |                          |
|           | Suitable extingu   | ishing media:   |            | CO2, powder or wate                              |                                     | ger fires with water     |
|           | Unsuitable extin   | quishing media  | :          | spray or alcohol resis<br>No further relevant in |                                     | le.                      |
| 5.2       | Specific hazards   | arising from th |            | No further relevant in                           |                                     |                          |
| 5.3       | substance/mixtu  |                 | nd precaut | tions for fire fighters:                         | _                                   |                          |
| 5.5       | Special persona  |                 |            | No further relevant in                           |                                     | le                       |
|           | Precautions:   |                 |            | No further relevant in                           | formation availab                   | le                       |
| 6.<br>6.1 | ACCIDENTAL RELEASE MEASURES<br>Personal precautions, protective equipment and emergency procedures:-<br>Not required |                 |            |  |                                     |                          |
| 6.2       | Environmental precautions:-  |                 |            |  |                                     |                          |
| 6.3       | Do not allow to enter sewers/ surface or ground water.<br>Methods and materials for containment and cleaning up:-    |                 |            |  |                                     |                          |
| 0.0       | Pick up mechanically.  |                 |            |  |                                     |                          |
|           | See Section 7 for information on safe handling.<br>See Section 8 for information on personal protection equipment.   |                 |            |  |                                     |                          |
|           | See Section 13 fc  |                 |            | olection equipment.                              |                                     |                          |
| 7         |  |                 |            |  |                                     |                          |
| 7.<br>7.1 | 7. HANDLING AND STORAGE<br>7.1 Precautions for safe handling:-   |                 |            |  |                                     |                          |
|           | Only adequately trained personnel should handle this product.  |                 |            |  |                                     |                          |
| 7.2       | For use in dentistry only. 2 Conditions for safe storage, including any incompatibilities:-                          |                 |            |  |                                     |                          |
|           | Store only in the original receptacle  |                 |            |  |                                     |                          |
|           | Protect from heat<br>Keep container tig  |                 | ght.       |  |                                     |                          |
|           | Reep container ti  | giniy sealed.   |            |  |                                     |                          |
| 8.<br>8.1 |  |                 |            |  |                                     |                          |
|           | Component  | CAS No.         |            | Value  | Parameters                          | Basis                    |
|           | -  |                 |            |  |                                     |                          |

Ingredients with biological limit values:

# 8.2

Biological monitoring:-The lists valid during the making were used as basis. Exposure controls / Personal protective equipment / 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 eves and skin. Keep away from foodstuffs, beverages and feed.

- 8.3 **Control banding:-**Void
- 8.4 **Engineering controls:-**Void
- 8.5 Individual protection measures include PPE:-Eye/face protection: Safety glasses



Skin protection:



Respiratory protection:



Not required

- PHYSICAL/CHEMICAL PROPERTIES 9.
- Information on physical/chemical properties:-9.1
- Appearance/Form: a)
- Colour: b)
- Odour: c)
- **Odour threshold:** d)
- pH-value (10 g/l) at 20 °C: e)
- Melting point/melting range: f)
- Boiling point/boiling range: a)
- Flash point: h)
- Ignition temperature: i)

Pasty According to product specification Characteristic Not determined. Not determined. Not determined. Not determined. Not determined. Not determined.

### Required Use tightly fitting safety glasses as per Australian Standard AS 1336 and AS/NZS 1337.

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.

- j) Self-igniting:
- **k**) **Danger of explosion**:
- I) Upper/lower flammability or explosive limits:
- m) Vapour pressure 20°C:
- n) Density at 20°C:
- o) Relative density:
- p) Vapour density:
- q) **Evaporation rate**:
- r) Solubility in/miscibility with water:
- s) **Partition coefficient: n- octanol/water:**
- t) Viscosity:
- u) Solids content:

# Product is not self-igniting.Not determined.LowerNot determinedUpperNot determined.Not determined.

1.55 g/cm<sup>3</sup> Not determined. Not applicable. Not applicable. Nearly insoluble. Not determined. Dynamic | Not applicable. Kinematic | Not applicable. Not determined.

- 10. STABILITY AND REACTIVITY
- 10.1 Reactivity:-No further relevant information available.
  10.2 Chemical stability:-
- Total stability: Stable under normal handling and storage conditions.
   Thermal decomposition / conditions to be avoided:
   No decomposition if used according to specifications
- 10.3 Possibility of hazardous reactions:-No further relevant information available.
  10.4 Conditions to avoid:-
- 10.4 Conditions to avoid:-Keep away from heat and direct sunlight
- **10.5** Incompatible materials:-No further relevant information available.
- **10.6 Hazardous decomposition products:-**None under normal conditions of storage and use.

# 11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects:-Acute toxicity / Values relevant for classification:

| Skin corrosion/irritation:                          | Irritant to skin and mucous membranes.     |
|---|--|
| Serious eye damage/eye irritation:                  | Irritating effect                          |
| Respiratory or skin sensitization:                  | No sensitising effects known               |
| Germ cell mutagenicity:                             | No further relevant information available. |
| Carcinogenicity:                                    | No further relevant information available. |
| Reproductive toxicity:                              | No further relevant information available. |
| Specific target organ toxicity - single exposure:   | No further relevant information available. |
| Specific target organ toxicity - repeated exposure: | No further relevant information available. |
| Aspiration hazard:                                  | No further relevant information available. |
| Additional information:                             | No further relevant information available. |
| Information on possible routes of expos             |  |

 11.2
 Information on possible routes of exposure: 

 Short Term (Acute) Exposure:
 No further relevant information available.

 Swallowed:
 No further relevant information available.

 Eyes:
 No further relevant information available.

 Skin:
 No further relevant information available.

 Inhaled:
 No further relevant information available.

 Long Term (Chronic) Exposure:
 No further relevant information available.





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|-------------|---|--|
|             | Swallowed:                                    | No further relevant information available.                     |
|             | Eyes:   | No further relevant information available.                     |
|             | Skin:   | No further relevant information available.                     |
|             | Inhaled:                                      | No further relevant information available.                     |
| 11.3        | Early onset symptoms related to<br>exposure:- | No further relevant information available.                     |
| 11.4        | Delayed health effects from exposure:-        | No further relevant information available.                     |
| 11.5        | Exposure levels and health effects:-          | No further relevant information available.                     |
| 11.6        | Interactive effects:-                         | No further relevant information available.                     |
| 11.7        | Other:-                                       | No further relevant information available.                     |
| 12.         | <b>ECOLOGICAL INFORMATION</b>                 |  |
| 12.1        | Ecotoxicity:-                                 |  |
|             | No further relevant information available.    |  |
| 12.2        | Persistence/degradability:-                   |  |
|             | No further relevant information available.    |  |
| 12.3        | Bioaccumulative potential:-                   |  |
|             | No further relevant information available.    |  |
| 12.4        | Mobility in soil:-                            |  |
|             | No further relevant information available.    |  |
| 12.5        | Other adverse effects:-                       |  |
|             | No further relevant information available.    |  |
|             | Additional ecological information / Genera    |  |
|             |   | ties of it to reach ground water, water course or sewage       |
| 40.0        | system.                                       |  |
| 12.6        | Other adverse effects:-                       |  |
|             | No further relevant information available.    |  |
| 40          |   |  |
| 13.<br>13.1 | DISPOSAL CONSIDERATIONS                       |  |
| 13.1        | Disposal methods:-                            | ration plant, under conditions approved by the local           |
|             | authority.                                    | ration plant, under conditions approved by the local           |
|             | Uncleaned packaging:                          |  |
|             | • Recommendation: Disposal must be made       | according to official regulations                              |
| 14.         | TRANSPORT INFORMATION                         |  |
| 14.         |   | Void.  |
|             | UN proper shipping name or technical nam      |  |
|             | ADR:  | Void.  |
|             | IMDG, IATA:                                   | Void.  |
|             | Transport hazard class(es):                   | Void.  |
|             | Label:  | Void.  |
|             | Packaging group:                              | Void.  |
|             | Environmental hazards:                        | Not applicable.  |
|             | Special precautions for user:                 | Not applicable.  |
|             | Den non des                                   | \/-:-l   |
|             | Danger code:                                  | Void.  |
|             | EMS Number:                                   | Void.  |
|             | Transport in bulk according to Annex II       | Not applicable.  |
|             | of MARPOL73/78 and the IBC Code:              | Droduct is not clossified as a democratic model for the second |
|             | Transport/Additional information:             | Product is not classified as a dangerous good for transport    |
|             |   | (ADR, IMDG, IATA).   |
| 15.         | REGULATORYINFORMATION                         |  |
| 15.         |   |  |

# REGULATORY INFORMATION Safety, health and environmental regulations/legislation specific for the substance/mixture/product:-

The product is a medical device according to the Directive 93/42/EEC.



## 15.2 Chemical safety assessment:

A Chemical Safety Assessment has not been carried out.

## 16. OTHER INFORMATION

Key to abbreviations/acronyms used in SDS:-

H413 May cause long lasting harmful effects to aquatic life.

#### Key literature references/data sources used to compile SDS:-Void

# Copyright statement:-

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.

### 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.

IATA: International Air Transport Association.

GHS: Globally Harmonised System of Classification and Labelling of Chemicals.

EINECS: European Inventory of Existing Commercial Chemical Substances.

ELINCS: European List of Notified Chemical Substances.

CAS: Chemical Abstracts Service (division of the American Chemical Society).

LC50: Lethal concentration, 50 percent.

LD50: Lethal dose, 50 percent.

Flam. Liq. 2: Flammable liquids, Hazard Category 2.

Flam. Liq. 3: Flammable liquids, Hazard Category 3.

Acute Tox. 4: Acute toxicity, Hazard Category 4.

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

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

Repr. 2: Reproductive toxicity, Hazard Category 2.

STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3.

STOT RE 2: Specific target organ toxicity - Repeated exposure, Hazard Category 2.

Asp. Tox. 1: Aspiration hazard, Hazard Category 1.

\* Data compared to the previous version altered

## **Disclaimer:-**

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Users should rely on their own knowledge and inquiries and make their own determination as to the applicability of this information in relation to their particular purposes and specific circumstances. Each user should read this SDS and consider the information in the context of how the product will be handled and used in the workplace and in conjunction with other substances or products.

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