

**Safety Data Sheet**  
acc. to OSHA HCS

Printing date 05/19/2015

Version number 6

Reviewed on 04/09/2015


**1 Identification**

- **Product identifier**
- **Trade name: *Telio Add-On Flow***
- **Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture** Flowable temporary C&B add-on and repair material
- **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 Irrit. 2 H315 Causes skin irritation.  
Eye Irrit. 2A H319 Causes serious eye irritation.  
Skin Sens. 1 H317 May cause an allergic skin reaction.  
STOT SE 3 H335 May cause respiratory irritation.

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  - **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:**  
Bis-GMA  
ytterbium trifluoride

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urethane dimethacrylate  
triethylene glycol dimethacrylate

· **Hazard statements**

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

· **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 = 1  
Fire = 0  
Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**



Health = 1  
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:**

1565-94-2	Bis-GMA	10-<20%
13760-80-0	ytterbium trifluoride	10-<20%
72869-86-4	urethane dimethacrylate	10-<20%
109-16-0	triethylene glycol dimethacrylate	2.5-<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.  
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:**  
CO<sub>2</sub>, 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.

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· **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.*

*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.*

*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. 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

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

· **General Information**

· **Appearance:**

**Form:** *Pasty*

**Color:** *According to product specification*

· **Odor:** *Characteristic*

· **Odour 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.*

· **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 applicable.*

· **Density at 20 °C (68 °F):** *1.94 g/cm<sup>3</sup> (16.189 lbs/gal)*

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· <b>Relative density</b>	<i>Not determined.</i>
· <b>Vapour density</b>	<i>Not applicable.</i>
· <b>Evaporation rate</b>	<i>Not applicable.</i>
· <b>Solubility in / Miscibility with Water:</b>	<i>Nearly insoluble.</i>
· <b>Partition coefficient (n-octanol/water):</b>	<i>Not determined.</i>
· <b>Viscosity:</b>	
· <b>Dynamic:</b>	<i>Not applicable.</i>
· <b>Kinematic:</b>	<i>Not applicable.</i>
· <b>Other information</b>	<i>No further relevant information available.</i>

### 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:** *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**

- **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.*

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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.*

### 14 Transport information

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

### 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.*

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· **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**



GHS07

· **Signal word Warning**

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

Bis-GMA

ytterbium trifluoride

urethane dimethacrylate

triethylene glycol dimethacrylate

· **Hazard statements**

Causes skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

May cause respiratory irritation.

· **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.

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- **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.
- **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** 05/19/2015 / 5
- **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  
STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3
- **\* Data compared to the previous version altered.**

US