

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

Printing date 11.03.2020

Version number 1

Revision: 06.03.2020

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

- **1.1 Product identifier**
- **Trade name:** **Lithium-Ion-Batteries or Lithium-Polymer-Batteries for Bluephase LED polymerization lights**
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture** Auxiliary for manufacture of dental prothesis
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Ivoclar Vivadent AG  
Bendererstrasse 2  
9494 Schaan  
PRINCIPALITY OF LIECHTENSTEIN  
  
Tel: +423 235 35 35  
Fax: +423 235 33 60
- **Further information obtainable from:**  
Regulatory Affairs  
sds@ivoclarvivadent.com
- **1.4 Emergency telephone number:** +423 / 235 33 13 (Ivoclar Vivadent AG, 9494 Schaan, Liechtenstein)

**SECTION 2: Hazards identification**

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
The product is not classified, according to the CLP regulation.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

**SECTION 3: Composition/information on ingredients**

- **3.2 Chemical characterisation: Mixtures** Rechargeable Lithium-Ion-Batteries or Lithium-Polymer-Batteries
- **Description:**  
The materials contained in the battery may only become a hazard if the battery or the cell is damaged or if the battery is physically or electrically abused.
- **Dangerous components:** Void

**SECTION 4: First aid measures**

- **4.1 Description of first aid measures**
- **General information:**  
In case of contact with the materials from a damaged or ruptured cell or battery see the following first aid measures:

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- **After inhalation:**  
Supply fresh air or oxygen; call for doctor.  
In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact:**  
Rinse with water.  
If skin irritation continues, consult a doctor.
- **After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.
- **After swallowing:**  
Rinse out mouth and then drink plenty of water.  
Seek medical treatment.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

### SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**  
Fire-extinguishing powder  
Carbon dioxide
- **5.2 Special hazards arising from the substance or mixture**  
Toxic gases will be formed if cells or battery are involved in a fire. Cells or battery may flame or leak potentially hazardous organic vapor if exposed to excessive heat, fire or over-voltage conditions. Damaged or opened cells or batteries may result in rapid heat and the release of flammable vapors.
- **5.3 Advice for firefighters**
- **Protective equipment:** Wear self-contained respiratory protective device.

### SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**  
Should a battery unintentionally be crushed, thus releasing its contents, rubber gloves must be used to handle all battery components. Avoid inhalation of any vapors that may be emitted.
- **6.2 Environmental precautions:** No special measures required.
- **6.3 Methods and material for containment and cleaning up:**  
The material contained within the batteries would only be expelled under abusive conditions.  
Spilled substances with dry sand or vermiculite.
- **6.4 Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

### SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**  
Only adequately trained personnel should handle this product.  
For use in dentistry only.  
Do not store batteries in a manner that allows terminals to short circuit.
- **Information about fire - and explosion protection:**  
Please note that lithium-polymer batteries may react with explosion, fire, and smoke development if handled improperly or mechanically damaged.

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- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:**  
Do not store at temperatures above 40 °C / 104 °F (or 60 °C / 140 °F for a short period).
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Protect from heat and direct sunlight.
- **7.3 Specific end use(s)** No further relevant information available.

### SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**  
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** Under normal conditions release of ingredients does not occur.

#### 8.2 Exposure controls

- **Personal protective equipment:**
- **General protective and hygienic measures:**  
Usual hygienic measures for dental practice and dental laboratories.
- **Respiratory protection:**  
Not required.  
If the battery is damaged:  
In case of battery rupture and fumes, use self-contained full-face respiratory equipment.
- **Protection of hands:**  
Not required.  
If the battery is damaged:



Protective gloves

- **Material of gloves**  
Butyl rubber, BR  
Fluorocarbon rubber (Viton)  
Chloroprene rubber, CR
- **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:**  
Not required.  
If the battery is damaged:



Tightly sealed goggles

Wear safety goggles or glasses with side shields if handling a leaking or ruptured battery.

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### SECTION 9: Physical and chemical properties

#### · 9.1 Information on basic physical and chemical properties

##### · General Information

##### · Appearance:

· Form:	Solid
· Colour:	Not determined.
· Odour:	Odourless
· Odour threshold:	Not determined.

· pH-value: Not applicable.

##### · Change in condition

· Melting point/freezing point:	Not applicable.
· Initial boiling point and boiling range:	Not applicable.

· Flash point: Not applicable.

· Flammability (solid, gas): Product is not flammable.

· Decomposition temperature: Not determined.

· Auto-ignition temperature: Not determined.

· Explosive properties: Product does not present an explosion hazard.

##### · Explosion limits:

· Lower:	Not determined.
· Upper:	Not determined.

· Vapour pressure: Not applicable.

· Density: Not applicable.

· Relative density: Not determined.

· Vapour density: Not applicable.

· Evaporation rate: Not applicable.

##### · Solubility in / Miscibility with water:

Not applicable.

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

##### · Viscosity:

· Dynamic:	Not applicable.
· Kinematic:	Not applicable.

##### · Solvent content:

· Solids content: 100.0 %

· 9.2 Other information: No further relevant information available.

### SECTION 10: Stability and reactivity

· 10.1 Reactivity: No further relevant information available.

· 10.2 Chemical stability: Stable under normal handling and storage conditions.

##### · Thermal decomposition / conditions to be avoided:

Do not short circuit battery.

Do not store at temperatures above 40 °C / 104 °F (or 60 °C / 140 °F for a short period).

· 10.3 Possibility of hazardous reactions: No dangerous reactions known.

· 10.4 Conditions to avoid: No further relevant information available.

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- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:**  
The electrolytes and electrolyte fumes released during explosion, fire, and smoke development are toxic and corrosive.  
None under normal conditions of storage and use.

### SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

### SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **Other information:**  
When properly used or disposed rechargeable Lithium-Ion/Polymer-Batteries do not present environmental hazard.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:** Not hazardous for water.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

### SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**  
Disposal must be made according to official regulations.  
May explode if disposed of in fire.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

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### SECTION 14: Transport information

· 14.1 UN-Number · ADR/RID/ADN, IMDG, IATA	UN3480
· 14.2 UN proper shipping name · ADR/RID/ADN · IMDG, IATA	3480 LITHIUM ION BATTERIES LITHIUM ION BATTERIES
· 14.3 Transport hazard class(es) · ADR/RID/ADN	
	
· Class · Label	9 (M4) Miscellaneous dangerous substances and articles. 9
· IMDG, IATA	
	
· Class · Label	9 Miscellaneous dangerous substances and articles. 9A
· 14.4 Packing group · ADR/RID/ADN, IMDG, IATA	Void
· 14.5 Environmental hazards: · Marine pollutant:	No
· 14.6 Special precautions for user · Hazard identification number (Kemler code): · EMS Number:	Warning: Miscellaneous dangerous substances and articles. - F-A,S-I
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· Transport/Additional information:	The batteries meets all the requirements of special provisions ADR 188, IMDG 188 and IATA DGR packaging instructions 965 Section IB.
· ADR/RID/ADN · Limited quantities (LQ) · Excepted quantities (EQ)	0 Code: E0 Not permitted as Excepted Quantity
· Transport category · Tunnel restriction code	2 E
· IMDG · Limited quantities (LQ) · Excepted quantities (EQ)	0 Code: E0 Not permitted as Excepted Quantity

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· UN "Model Regulation": UN 3480 LITHIUM ION BATTERIES, 9

### **SECTION 15: Regulatory information**

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- Directive 2012/18/EU
- Named dangerous substances - ANNEX I None of the ingredients is listed.
- 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

### **SECTION 16: Other information**

*This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.*

· **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)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

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Printing date 25.03.2019



Version number 5

Revision: 23.01.2019

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

- **1.1 Product identifier**
- **Trade name: Adhese Universal**
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture** Light-curing, single-component dental adhesive
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Ivoclar Vivadent AG  
Bendererstrasse 2  
9494 Schaan  
PRINCIPALITY OF LIECHTENSTEIN
- **Tel:** +423 235 35 35  
**Fax:** +423 235 33 60
- **Further information obtainable from:**  
Regulatory Affairs  
sds@ivoclarvivadent.com
- **1.4 Emergency telephone number:** +423 / 235 33 13 (Ivoclar Vivadent AG, 9494 Schaan, Liechtenstein)

**SECTION 2: Hazards identification**

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
Flam. Liq. 3 H226 Flammable liquid and vapour.  
Skin Irrit. 2 H315 Causes skin irritation.  
Eye Irrit. 2 H319 Causes serious eye irritation.  
Skin Sens. 1 H317 May cause an allergic skin reaction.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**  
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms**
- 


GHS02 GHS07
- **Signal word** Warning
- **Hazard-determining components of labelling:**  
2-hydroxyethyl methacrylate  
Bis-GMA  
1,10-decandiol dimethacrylate  
methacrylated phosphoric acid ester  
2-dimethylaminoethyl methacrylate
- **Hazard statements**  
H226 Flammable liquid and vapour.  
H315 Causes skin irritation.  
H319 Causes serious eye irritation.  
H317 May cause an allergic skin reaction.

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· **Precautionary statements**

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

· **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.

· **2.3 Other hazards**

· **Results of PBT and vPvB assessment**

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

### SECTION 3: Composition/information on ingredients

· **3.2 Chemical characterisation: Mixtures**

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

· **Dangerous components:**

CAS: 868-77-9 EINECS: 212-782-2	2-hydroxyethyl methacrylate Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	10-25%
CAS: 36425-15-7 NLP: 500-089-0	Bis-GMA Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	10-25%
CAS: 64-17-5 EINECS: 200-578-6	ethanol Flam. Liq. 2, H225	10-25%
CAS: 6701-13-9 EINECS: 229-745-1	1,10-decandiol dimethacrylate Eye Irrit. 2, H319; Skin Sens. 1, H317	≥2.5-<10%
CAS: 85590-00-7	methacrylated phosphoric acid ester Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	≥2.5-<10%
CAS: 10373-78-1	camphorquinone Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	<2.5%
CAS: 2867-47-2 EINECS: 220-688-8	2-dimethylaminoethyl methacrylate Acute Tox. 2, H330; Acute Tox. 4, H302; Acute Tox. 4, H312; Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	≥1-<2.5%

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

### SECTION 4: First aid measures

· **4.1 Description of first aid measures**

· **After inhalation:**

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

### SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**  
CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

### SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**  
Wear protective equipment. Keep unprotected persons away.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **6.4 Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

### SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**  
Only adequately trained personnel should handle this product.  
For use in dentistry only.
- **Information about fire - and explosion protection:**  
Keep ignition sources away - Do not smoke.  
Protect against electrostatic charges.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store only in the original receptacle.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**  
Protect from exposure to the light.  
Keep container tightly sealed.
- **7.3 Specific end use(s)** No further relevant information available.

### SECTION 8: Exposure controls/personal protection

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

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· **8.1 Control parameters**· **Ingredients with limit values that require monitoring at the workplace:****CAS: 64-17-5 ethanol****WEL** Long-term value: 1920 mg/m<sup>3</sup>, 1000 ppm· **Additional information:** The lists valid during the making were used as basis.· **8.2 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.

· **Respiratory protection:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

· **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

**SECTION 9: Physical and chemical properties**· **9.1 Information on basic physical and chemical properties**· **General Information**· **Appearance:****Form:** Liquid**Colour:** Yellow· **Odour:** Characteristic· **Odour threshold:** Not determined.· **pH-value:** Not applicable.· **Change in condition****Melting point/freezing point:** Undetermined.**Initial boiling point and boiling range:** Undetermined.· **Flash point:** 36 °C (ASTM D7094)

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· <b>Auto-ignition temperature:</b>	Product is not selfigniting.
· <b>Explosive properties:</b>	Product does not present an explosion hazard.
· <b>Explosion limits:</b>	
<b>Lower:</b>	Not determined.
<b>Upper:</b>	Not determined.
· <b>Vapour pressure:</b>	Not determined.
· <b>Density:</b>	Not determined.
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not determined.
· <b>Evaporation rate</b>	Not determined.
· <b>Solubility in / Miscibility with water:</b>	Fully miscible.
· <b>Partition coefficient: n-octanol/water:</b>	Not determined.
· <b>Viscosity:</b>	
<b>Dynamic:</b>	Not determined.
<b>Kinematic:</b>	Not determined.
· <b>9.2 Other information</b>	No further relevant information available.

### SECTION 10: Stability and reactivity

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

### SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **Skin corrosion/irritation**  
Causes skin irritation.
- **Serious eye damage/irritation**  
Causes serious eye irritation.
- **Respiratory or skin sensitisation**  
May cause an allergic skin reaction.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

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### SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**  
Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water  
Do not allow product to reach ground water, water course or sewage system.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

### SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
  - **Recommendation**  
Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.
  - **European waste catalogue**
- |           |  |
|-----------|--|
| 18 01 06* | chemicals consisting of or containing dangerous substances |
|-----------|--|
- **Uncleaned packaging:**
  - **Recommendation:** Disposal must be made according to official regulations.

### SECTION 14: Transport information

- |   |  |
|---|--|
| · <b>14.1 UN-Number</b>   |  |
| · <b>ADR/RID/ADN, IMDG, IATA</b>  | UN1170   |
| · <b>14.2 UN proper shipping name</b>   |  |
| · <b>ADR/RID/ADN</b>  | 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION) |
| · <b>IMDG</b>   | ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)      |
| · <b>IATA</b>   | ETHANOL SOLUTION                               |
| · <b>14.3 Transport hazard class(es)</b>  |  |
| · <b>ADR/RID/ADN</b>  |  |
|  |  |
| · <b>Class</b>  | 3 (F1) Flammable liquids.                      |
| · <b>Label</b>  | 3  |

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· **IMDG, IATA**

· **Class** 3 Flammable liquids.  
· **Label** 3

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

· **14.5 Environmental hazards:**  
· **Marine pollutant:** No

· **14.6 Special precautions for user** Warning: Flammable liquids.  
· **Danger code (Kemler):** 30  
· **EMS Number:** F-E,S-D

· **14.7 Transport in bulk according to Annex II of Marpol and the IBC Code** Not applicable.

· **Transport/Additional information:**

· **ADR/RID/ADN**  
· **Limited quantities (LQ)** 5L  
· **Excepted quantities (EQ)** Code: E1  
Maximum net quantity per inner packaging: 30 ml  
Maximum net quantity per outer packaging: 1000 ml

· **Transport category** 3  
· **Tunnel restriction code** D/E

· **IMDG**  
· **Limited quantities (LQ)** 5L  
· **Excepted quantities (EQ)** Code: E1  
Maximum net quantity per inner packaging: 30 ml  
Maximum net quantity per outer packaging: 1000 ml

· **UN "Model Regulation":** UN1170, ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION), 3, III

\* **SECTION 15: Regulatory information**

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

· **Directive 2012/18/EU**

· **Qualifying quantity (tonnes) for the application of lower-tier requirements** 5.000 t

· **Qualifying quantity (tonnes) for the application of upper-tier requirements** 50.000 t

· **REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction:** 3

· **National regulations:**

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

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.

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**SECTION 16: Other information**

*This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.*

· **Relevant phrases**

H225 Highly flammable liquid and vapour.

H302 Harmful if swallowed.

H312 Harmful in contact with skin.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H330 Fatal if inhaled.

H335 May cause respiratory irritation.

· **Classification according to Regulation (EC) No 1272/2008**

*The classification of the mixture is generally based on the calculation method using substance data according to Regulation (EC) No 1272/2008.*

· **Abbreviations and acronyms:**

ADR: Accord 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

LATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

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

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Flam. Liq. 2: Flammable liquids – Category 2

Flam. Liq. 3: Flammable liquids – Category 3

Acute Tox. 4: Acute toxicity – Category 4

Acute Tox. 2: Acute toxicity – Category 2

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Skin Sens. 1: Skin sensitisation – Category 1

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

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

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

- **1.1 Product identifier**
- **Trade name: *Tetric PowerFlow***
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture** Light-curing, flowable, resin-based dental restorative
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Ivoclar Vivadent AG  
Bendererstrasse 2  
LI-9494 Schaan  
PRINCIPALITY OF LIECHTENSTEIN
- 
- Tel: +423 235 35 35  
Fax: +423 235 33 60
- **Further information obtainable from:**  
Regulatory Affairs  
sds@ivoclarvivadent.com
- **1.4 Emergency telephone number:** +423 / 235 33 13 (Ivoclar Vivadent AG, LI-9494 Schaan, Liechtenstein)

**SECTION 2: Hazards identification**

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
Skin Sens. 1      H317 May cause an allergic skin reaction.  
Aquatic Chronic 3      H412 Harmful to aquatic life with long lasting effects.

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

- **Hazard pictograms**



GHS07

- **Signal word** Warning
- **Hazard-determining components of labelling:**  
Bis-GMA  
tricyclodocane dimethanol dimethacrylate
- **Hazard statements**  
H317 May cause an allergic skin reaction.  
H412 Harmful to aquatic life with long lasting effects.
- **Precautionary statements**  
P273      Avoid release to the environment.  
P280      Wear protective gloves/protective clothing/eye protection/face protection.  
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.  
P363      Wash contaminated clothing before reuse.
- **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.

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

### SECTION 3: Composition/information on ingredients

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

- **Dangerous components:**

CAS: 41637-38-1	ethoxylated bisphenol A dimethacrylate Aquatic Chronic 4, H413	10-<25%
CAS: 36425-15-7 NLP: 500-089-0	Bis-GMA Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	2.5-<10%
CAS: 13760-80-0 EINECS: 237-354-2	ytterbium trifluoride Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	2.5-<10%
CAS: 43048-08-4 EINECS: 256-062-6	tricyclodocane dimethanol dimethacrylate Aquatic Chronic 2, H411; Skin Sens. 1B, H317	2.5-<10%

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

### SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **After inhalation:**  
Supply fresh air and to be sure call for a doctor.  
In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact:**  
Rinse with warm water.  
If skin irritation continues, consult a doctor.
- **After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.
- **After swallowing:**  
Rinse out mouth and then drink plenty of water.  
If symptoms persist consult doctor.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

### SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**  
CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

### SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.

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- **6.3 Methods and material for containment and cleaning up:** Pick up mechanically.
- **6.4 Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

### SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**  
Only adequately trained personnel should handle this product.  
For use in dentistry only.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store only in the original receptacle.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**  
Protect from exposure to the light.  
Protect from heat and direct sunlight.  
Keep container tightly sealed.
- **7.3 Specific end use(s)** No further relevant information available.

### SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**  
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists valid during the making were used as basis.
- **8.2 Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
Usual hygienic measures for dental practice and dental laboratories.  
Keep away from foodstuffs, beverages and feed.  
Wash hands before breaks and at the end of work.  
Avoid contact with the eyes and skin.
- **Respiratory protection:** Not required.
- **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.

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- **Not suitable are gloves made of the following materials:**  
Commercial medical gloves do not provide protection against the sensitizing effect of methacrylates.
- **Eye protection:** Safety glasses

### SECTION 9: Physical and chemical properties

#### · 9.1 Information on basic physical and chemical properties

##### · General Information

##### · Appearance:

- |                           |                                    |
|---------------------------|------------------------------------|
| · <b>Form:</b>            | Pasty                              |
| · <b>Colour:</b>          | According to product specification |
| · <b>Odour:</b>           | Characteristic                     |
| · <b>Odour threshold:</b> | Not determined.                    |

· <b>pH-value:</b>	Not applicable.
--------------------	-----------------

##### · Change in condition

- |   |               |
|---|---------------|
| · <b>Melting point/freezing point:</b>            | Undetermined. |
| · <b>Initial boiling point and boiling range:</b> | Undetermined. |

· <b>Flash point:</b>	Not applicable.
-----------------------	-----------------

· <b>Flammability (solid, gas):</b>	Not determined.
-------------------------------------	-----------------

· <b>Auto-ignition temperature:</b>	Product is not selfigniting.
-------------------------------------	------------------------------

· <b>Explosive properties:</b>	Product does not present an explosion hazard.
--------------------------------	---

##### · Explosion limits:

- |                 |                 |
|-----------------|-----------------|
| · <b>Lower:</b> | Not determined. |
| · <b>Upper:</b> | Not determined. |

· <b>Vapour pressure:</b>	Not determined.
---------------------------	-----------------

· <b>Density at 20 °C:</b>	1.84 g/cm <sup>3</sup>
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· <b>Relative density</b>	Not determined.
---------------------------	-----------------

· <b>Vapour density</b>	Not determined.
-------------------------	-----------------

· <b>Evaporation rate</b>	Not determined.
---------------------------	-----------------

##### · Solubility in / Miscibility with water:

Nearly insoluble.
-------------------

· <b>Partition coefficient: n-octanol/water:</b>	Not determined.
--	-----------------

##### · Viscosity:

- |                     |                 |
|---------------------|-----------------|
| · <b>Dynamic:</b>   | Not determined. |
| · <b>Kinematic:</b> | Not determined. |

· <b>9.2 Other information</b>	No further relevant information available.
--------------------------------	--

### SECTION 10: Stability and reactivity

· <b>10.1 Reactivity</b>	No further relevant information available.
--------------------------	--

#### · 10.2 Chemical stability

Stable under normal handling and storage conditions.

Photoreactive (Danger of polymerization).

· <b>Thermal decomposition / conditions to be avoided:</b>	No decomposition if used according to specifications.
--	---

· <b>10.3 Possibility of hazardous reactions</b>	No dangerous reactions known.
--	-------------------------------

#### · 10.4 Conditions to avoid

Protect from exposure to the light.

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- Keep away from heat and direct sunlight.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** None under normal conditions of storage and use.

### SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation**  
May cause an allergic skin reaction.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

### SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**  
Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water  
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

### SECTION 13: Disposal considerations

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

### SECTION 14: Transport information

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

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· <b>14.2 UN proper shipping name</b> · ADR/RID/ADN, ADN, IMDG, IATA	Void
· <b>14.3 Transport hazard class(es)</b> · ADR/RID/ADN, ADN, IMDG, IATA · Class	Void
· <b>14.4 Packing group</b> · ADR/RID/ADN, IMDG, IATA	Void
· <b>14.5 Environmental hazards:</b>	Not applicable.
· <b>14.6 Special precautions for user</b>	Not applicable.
· <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b>	Not applicable.
· <b>Transport/Additional information:</b>	Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).
· <b>UN "Model Regulation":</b>	Void

### SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- Directive 2012/18/EU
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3
- **National regulations:**
- **Other regulations, limitations and prohibitive regulations**  
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.

### SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Relevant phrases**  
H315 Causes skin irritation.  
H317 May cause an allergic skin reaction.  
H319 Causes serious eye irritation.  
H335 May cause respiratory irritation.  
H411 Toxic to aquatic life with long lasting effects.  
H413 May cause long lasting harmful effects to aquatic life.
- **Classification according to Regulation (EC) No 1272/2008**  
The classification of the mixture is generally based on the calculation method using substance data according to Regulation (EC) No 1272/2008.
- **Abbreviations and acronyms:**  
ADR: Accord 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)

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*PBT: Persistent, Bioaccumulative and Toxic**vPvB: very Persistent and very Bioaccumulative**Skin Irrit. 2: Skin corrosion/irritation – Category 2**Eye Irrit. 2: Serious eye damage/eye irritation – Category 2**Skin Sens. 1: Skin sensitisation – Category 1**Skin Sens. 1B: Skin sensitisation – Category 1B**STOT SE 3: Specific target organ toxicity (single exposure) – Category 3**Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2**Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3**Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4*

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