

## Safety Data Sheet according to WHS Regulations

Printing date 24.10.2023

Version number 1

Revision: 24.10.2023

Hazardous according to criteria of Australian Safety and Compensation Council.

### 1 Identification

· **Product identifier**

· **Trade name:** ***Tetric plus Fill***

· **Relevant identified uses of the substance or mixture and uses advised against**

No further relevant information available.

· **Application of the substance / the mixture** Polymer-based dental restorative material (intraoral light-curing)

· **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

**Importer:**

Ivoclar Vivadent Pty. Ltd.

1- 5 Overseas Drive

Noble Park North VIC 3174

Tel: + 61 3 9795 9599 / Fax: + 61 3 9795 9645

· **Further information obtainable from:**

Regulatory Affairs

sds@ivoclar.com

· **Emergency telephone number:** 131 126 (Poisons Information Centre - 24 hours / 7 days)

### 2 Hazard(s) Identification

· **Classification of the substance or mixture**

Serious eye damage/irritation – Category 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 labelled according to the Globally Harmonised System (GHS).

· **Hazard pictograms**



GHS07

· **Signal word** Warning

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

urethane dimethacrylate

aromatic aliphatic urethane dimethacrylate

tricyclodecane dimethanol dimethacrylate

· **Hazard statements**

Causes serious eye irritation.

May cause an allergic skin reaction.

· **Precautionary statements**

Avoid release to the environment.

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

**IF ON SKIN:** Wash with plenty of water.

**IF IN EYES:** Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

If eye irritation persists: Get medical advice/attention.

Wash contaminated clothing before reuse.

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

### 3 Composition and Information on Ingredients

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

· **Dangerous components:**

CAS: 72869-86-4	urethane dimethacrylate Serious eye damage/irritation – Category 2A, H319; Skin Sens. 1, H317	2.5-10%
CAS: 13760-80-0	ytterbium trifluoride Skin Irrit. 2, H315; Serious eye damage/irritation – Category 2A, H319; STOT SE 3, H335	2.5-10%
CAS: 1219495-43-8	aromatic aliphatic urethane dimethacrylate Skin Sens. 1, H317	2.5-10%
CAS: 43048-08-4	tricyclodecane dimethanol dimethacrylate Skin Sens. 1B, H317	<2.5%
CAS: 139096-43-8	N-(2-Methacryloyloxyethyl)carbaminsäure-(2-methacryloyloxyethyl)ester Skin Sens. 1, H317	<2.5%
CAS: 10287-53-3	ethyl p-dimethylaminobenzoate Repr. 1B, H360	<2.5%

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

### 4 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.
- **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

- **Suitable extinguishing agents:** CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray.
- **Special hazards arising from the substance or mixture** No further relevant information available.

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- **Protective equipment:** No special measures required.

### 6 Accidental Release Measures

- **Personal precautions, protective equipment and emergency procedures**  
Wear protective equipment. Keep unprotected persons away.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:** Pick up mechanically.
- **Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

### 7 Handling and Storage

- **Handling:**
- **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.
- **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.
- **Specific end use(s)** No further relevant information available.

### 8 Exposure controls and personal protection

- **Additional information about design of technical facilities:** No further data; see section 7.
- **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.
- **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.  
Remove contaminated clothing and wash before reuse.  
Avoid contact with the skin.
- **Respiratory protection:** Not required.
- **Protection of hands:**



Protective gloves (EN 374)

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

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· **Penetration time of glove material**

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

· **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 (EN 166)

## 9 Physical and Chemical Properties

· **General Information**

· **Appearance:**

· **Form:**

Pasty

· **Colour:**

According to product specification

· **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:**

Not applicable.

· **Flammability (solid, gas):**

Not applicable.

· **Decomposition temperature:**

Not determined.

· **Ignition temperature:**

Product is not selfigniting.

· **Explosive properties:**

Product does not present an explosion hazard.

· **Explosion limits:**

· **Lower:**

Not determined.

· **Upper:**

Not determined.

· **Vapour pressure:**

Not determined.

· **Density at 20 °C:**

1.895 g/cm<sup>3</sup>

· **Relative density**

Not determined.

· **Vapour density**

Not determined.

· **Evaporation rate**

Not determined.

· **Solubility in / Miscibility with**

· **water:**

Nearly insoluble.

· **Partition coefficient: n-octanol/water:**

Not determined.

· **Viscosity:**

· **Dynamic:**

Not determined.

· **Kinematic:**

Not determined.

· **Other information**

No further relevant information available.

## 10 Stability and Reactivity

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

· **Chemical stability**

Photoreactive (Danger of polymerization).

Stable under normal handling and storage conditions.

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

· **Possibility of hazardous reactions** No dangerous reactions known.

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- **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** 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** 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.

### 12 Ecological Information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Ecotoxicological effects:**
- **Remark:** Harmful to fish
- **Additional ecological information:**
- **General notes:**  
Water hazard class 1 (German Regulation) (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.  
Harmful to aquatic organisms
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

### 13 Disposal considerations

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

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### 14 Transport information

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

### 15 Regulatory information

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

· Australian Inventory of Industrial Chemicals

CAS: 72869-86-4 urethane dimethacrylate

CAS: 10287-53-3 ethyl p-dimethylaminobenzoate

· Standard for the Uniform Scheduling of Medicines and Poisons

None of the ingredients is listed.

· Australia: Priority Existing Chemicals

None of the ingredients is listed.

· GHS label elements

The product is classified and labelled according to the Globally Harmonised System (GHS).

· Hazard pictograms



GHS07

· Signal word Warning

· Hazard-determining components of labelling:

urethane dimethacrylate

aromatic aliphatic urethane dimethacrylate

tricyclodecane dimethanol dimethacrylate

· Hazard statements

Causes serious eye irritation.

May cause an allergic skin reaction.

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· **Precautionary statements**

*Avoid release to the environment.*

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

*IF ON SKIN: Wash with plenty of water.*

*IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.*

*If eye irritation persists: Get medical advice/attention.*

*Wash contaminated clothing before reuse.*

· **Directive 2012/18/EU**

· **Named dangerous substances - ANNEX I** None of the ingredients is listed.

· **National regulations:**

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

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

· **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.*

· **Relevant phrases**

*H315 Causes skin irritation.*

*H317 May cause an allergic skin reaction.*

*H319 Causes serious eye irritation.*

*H335 May cause respiratory irritation.*

*H360 May damage fertility or the unborn child.*

· **Contact:**

· **Abbreviations and acronyms:**

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

*IMDG: International Maritime Code for Dangerous Goods*

*IATA: International Air Transport Association*

*EINECS: European Inventory of Existing Commercial Chemical Substances*

*ELINCS: European List of Notified Chemical Substances*

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

*PBT: Persistent, Bioaccumulative and Toxic*

*vPvB: very Persistent and very Bioaccumulative*

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

*Serious eye damage/irritation – Category 2A: Serious eye damage/eye irritation – Category 2A*

*Skin Sens. 1: Skin sensitisation – Category 1*

*Skin Sens. 1B: Skin sensitisation – Category 1B*

*Repr. 1B: Reproductive toxicity – Category 1B*

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