Safety Data Sheet
according to WHS Regulations

Printing date 24.03.2023 *Version number 2* *Revision: 24.03.2023*

Hazardous according to criteria of Australian Safety and Compensation Council.

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1 Identification

· **Product identifier**

· **Trade name:** **Tetric Prime**

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

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2 Hazard(s) Identification

· **Classification of the substance or mixture**

Skin Irrit. 2	H315 Causes skin irritation.
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
· **Hazard statements**
Causes skin irritation.
Causes serious eye irritation.
May cause an allergic skin reaction.

(Contd. on page 2)

Safety Data Sheet
according to WHS Regulations

Printing date 24.03.2023 Version number 2 Revision: 24.03.2023

Trade name: Tetric Prime

(Contd. of page 1)

· **Precautionary statements**
Wear protective gloves / eye protection / face protection.
If skin irritation or rash occurs: Get medical advice/attention.
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.

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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	10-25%
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: 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 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.
· **Information for doctor:**
· **Most important symptoms and effects, both acute and delayed** No further relevant information available.
· **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

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5 Fire Fighting Measures

· **Suitable extinguishing agents:**
CO2, 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.
· **Protective equipment:** Wear self-contained respiratory protective device.

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6 Accidental Release Measures

· **Personal precautions, protective equipment and emergency procedures** Wear protective clothing.

(Contd. on page 3)

Safety Data Sheet
according to WHS Regulations

Printing date 24.03.2023 Version number 2 Revision: 24.03.2023

Trade name: Tetric Prime

(Contd. of page 2)

· **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.
Protect from heat and direct sunlight.
Keep container tightly sealed.
· **Specific end use(s)** No further relevant information available.

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8 Exposure controls and personal protection

· **Additional information about design of technical facilities:** No further data; see item 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.
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.
Keep away from foodstuffs, beverages and feed.
· **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
· **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.

(Contd. on page 4)

Safety Data Sheet
according to WHS Regulations

Printing date 24.03.2023 Version number 2 Revision: 24.03.2023

Trade name: Tetric Prime

(Contd. of page 3)

· **Eye protection:**



Tightly sealed goggles (EN 166)

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9 Physical and Chemical Properties

· **General Information**	
· **Appearance:**	
· **Form:**	Pasty
· **Colour:**	Different according to colouring
· **Odour:**	Characteristic
· **Odour threshold:**	Not determined.
· **pH-value:**	Not determined.
· **Change in condition**	
· **Melting point/freezing point:**	Undetermined.
· **Initial boiling point and boiling range:**	Undetermined.
· **Flash point:**	Not applicable.
· **Auto-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:**	2.2 g/cm³
· **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**
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.

(Contd. on page 5)

Safety Data Sheet
according to WHS Regulations

Printing date 24.03.2023 Version number 2 Revision: 24.03.2023

Trade name: Tetric Prime

(Contd. of page 4)

· **Hazardous decomposition products:** None under normal conditions of storage and use.

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11 Toxicological Information

· **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.
· **Additional toxicological information:** No further relevant information available.

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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.
· **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.
· **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.

14 Transport information

· **UN-Number**
· **ADG, ADN, IMDG, IATA** Void

(Contd. on page 6)

Safety Data Sheet
according to WHS Regulations

Printing date 24.03.2023 Version number 2 Revision: 24.03.2023

Trade name: Tetric Prime

(Contd. of page 5)

· **UN proper shipping name**	
· **ADG**	Void
· **ADN, IMDG, IATA**	Void
· **Transport hazard class(es)**	
· **ADG, ADN, IMDG, IATA**	
· **Class**	Void
· **Packing group**	
· **ADG, IMDG, IATA**	Void
· **Environmental hazards:**	
· **Marine pollutant:**	No
· **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

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15 Regulatory information

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

· **Australian Inventory of Industrial Chemicals**

All ingredients are listed.

· **Standard for the Uniform Scheduling of Medicines and Poisons**

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
· **Hazard statements**
Causes skin irritation.
Causes serious eye irritation.
May cause an allergic skin reaction.
· **Precautionary statements**
Wear protective gloves / eye protection / face protection.
If skin irritation or rash occurs: Get medical advice/attention.
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.

(Contd. on page 7)

Safety Data Sheet
according to WHS Regulations

Trade name: Tetric Prime

(Contd. of page 6)

· **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.

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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
Repr. 1B: Reproductive toxicity – Category 1B
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
· *** Data compared to the previous version altered.**