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

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

· **1.1 Product identifier**

· **Trade name: Evetric Bulk Fill**

· **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
9494 Schaan
PRINCIPALITY OF LIECHTENSTEIN

Tel: +423 235 35 35
Fax: +423 235 33 60

· **Further information obtainable from:**
Regulatory Affairs
sds@ivoclar.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**
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 GB CLP regulation.

· **Hazard pictograms**



GHS07

· **Signal word** Warning

· **Hazard-determining components of labelling:**
urethane dimethacrylate
tricyclodecane dimethanol dimethacrylate
· **Hazard statements**
H317 May cause an allergic skin reaction.
· **Precautionary statements**
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P337+P313 If eye irritation persists: Get medical advice/attention.
P363 Wash contaminated clothing before reuse.
· **Additional information:**
Medical devices as defined in Regulation (EU) 2017/745 (MDR) 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 (GB CLP/GHS) if they are in the finished state and intented for the final user.
· **2.3 Other hazards**
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.

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· **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

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

· **Dangerous components:**

CAS: 36425-15-7 NLP: 500-089-0 Reg.nr.: 01-2119485287-26	Bis-GMA	2.5-<10%
CAS: 13760-80-0 EINECS: 237-354-2 Reg.nr.: 17-2119404130-64-XXXX	ytterbium trifluoride Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	2.5-<10%
CAS: 72869-86-4 EINECS: 276-957-5 Reg.nr.: 01-2120751202-68-XXXX	urethane dimethacrylate Aquatic Chronic 2, H411; Skin Sens. 1, H317	2.5-<10%
CAS: 41637-38-1 EC number: 935-411-2 Reg.nr.: 01-2119980659-17-XXXX	Bis-EMA	<2.5%
CAS: 43048-08-4 EINECS: 256-062-6 Reg.nr.: 01-2120164868-39-XXXX	tricyclodecane dimethanol dimethacrylate Aquatic Chronic 2, H411; Skin Sens. 1B, 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:**
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.
· **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:** Use fire extinguishing methods suitable to surrounding conditions.
· **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.

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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:** 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

· **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**
· **Appropriate engineering controls** No further data; see section 7.
· **Individual protection measures, such as 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.
· **Hand protection**



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/face protection**



Tightly sealed goggles (EN 166)

SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**	
· **General Information**	
· **Colour:**	According to product specification
· **Odour:**	Characteristic
· **Odour threshold:**	Not determined.
· **Melting point/freezing point:**	Undetermined.
· **Boiling point or initial boiling point and boiling range**	Undetermined.
· **Flammability**	Not determined.
· **Lower and upper explosion limit**	
· **Lower:**	Not determined.
· **Upper:**	Not determined.
· **Flash point:**	Not applicable.
· **pH**	Not applicable.
· **Viscosity:**	
· **Kinematic viscosity**	Not determined.
· **Dynamic:**	Not determined.
· **Solubility**	
· **water:**	Nearly insoluble.
· **Partition coefficient n-octanol/water (log value)**	Not determined.
· **Vapour pressure:**	Not determined.
· **Density and/or relative density**	
· **Density at 20 °C:**	2.06 g/cm³
· **Relative density**	Not determined.
· **Vapour density**	Not determined.

· **9.2 Other information**	
· **Appearance:**	
· **Form:**	Pasty
· **Important information on protection of health and environment, and on safety.**	
· **Ignition temperature:**	Product is not selfigniting.
· **Explosive properties:**	Product does not present an explosion hazard.
· **Change in condition**	
· **Evaporation rate**	Not determined.

· **Information with regard to physical hazard classes**	
· **Explosives**	Void
· **Flammable gases**	Void
· **Aerosols**	Void
· **Oxidising gases**	Void

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· **Gases under pressure**	Void
· **Flammable liquids**	Void
· **Flammable solids**	Void
· **Self-reactive substances and mixtures**	Void
· **Pyrophoric liquids**	Void
· **Pyrophoric solids**	Void
· **Self-heating substances and mixtures**	Void
· **Substances and mixtures, which emit flammable gases in contact with water**	Void
· **Oxidising liquids**	Void
· **Oxidising solids**	Void
· **Organic peroxides**	Void
· **Corrosive to metals**	Void
· **Desensitised explosives**	Void

SECTION 10: Stability and reactivity

· **10.1 Reactivity** No further relevant information available.
· **10.2 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.
· **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 hazard classes as defined in Regulation (EC) No 1272/2008**
· **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.
· **11.2 Information on other hazards**

· **Endocrine disrupting properties**
None of the ingredients is listed.

SECTION 12: Ecological information

· **12.1 Toxicity**
· **Aquatic toxicity:** No further relevant information available.

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· **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.
· **12.5 Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **12.6 Endocrine disrupting properties**
The product does not contain substances with endocrine disrupting properties.
· **12.7 Other adverse effects**
· **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.

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 or ID number** · **ADR/RID/ADN, ADN, IMDG, IATA**	Void
· **14.2 UN proper shipping name** · **ADR/RID/ADN, ADN, IMDG, IATA**	Void
· **14.3 Transport hazard class(es)** · **ADR/RID/ADN, ADN, IMDG, IATA** · **Class**	Void
· **14.4 Packing group** · **ADR/RID/ADN, IMDG, IATA**	Void
· **14.5 Environmental hazards:**	Not applicable.
· **14.6 Special precautions for user**	Not applicable.
· **14.7 Maritime transport in bulk according to IMO instruments**	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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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.

· **National regulations:**
· **Other regulations, limitations and prohibitive regulations**
The product is a medical device according to Regulation 2017/745 on Medical Devices (MDR).
· **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.
· **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:**
IMO: International Maritime Organization
ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)
RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
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
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