

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

Printing date 05.02.2024

Version number 11 (replaces version 10)

Revision: 05.02.2024

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

- **1.1 Product identifier**
- **Trade name:** Syntac Adhesive
- **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** Enamel-Dentin Bonding Agent
- **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**  
Acute Tox. 4      H302 Harmful if swallowed.  
Acute Tox. 3      H331 Toxic if inhaled.  
Skin Corr. 1B    H314 Causes severe skin burns and eye damage.  
Eye Dam. 1      H318 Causes serious eye damage.  
Resp. Sens. 1    H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
Skin Sens. 1     H317 May cause an allergic skin reaction.  
STOT SE 3       H335 May cause respiratory irritation.  
Aquatic Chronic 2 H411 Toxic 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 GB CLP regulation.

- **Hazard pictograms**



GHS05   GHS06   GHS08   GHS09

- **Signal word** Danger
- **Hazard-determining components of labelling:**  
glutaral  
polyethylene glycol dimethacrylate
- **Hazard statements**  
H302 Harmful if swallowed.  
H331 Toxic if inhaled.  
H314 Causes severe skin burns and eye damage.  
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

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*H317 May cause an allergic skin reaction.**H335 May cause respiratory irritation.**H411 Toxic to aquatic life with long lasting effects.***· Precautionary statements***P261 Avoid breathing dust/fume/gas/mist/vapours/spray.**P280 Wear protective gloves/protective clothing/eye protection/face protection.**P304+P341 IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.**P333+P313 If skin irritation or rash occurs: Get medical advice/attention.**P342+P311 If experiencing respiratory symptoms: Call a POISON CENTER/doctor.***· 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 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 Mixtures****· Description:** Mixture of substances listed below with nonhazardous additions.**· Dangerous components:**

CAS: 25852-47-5 Reg.nr.: 17-2119401310-65-XXXX	polyethylene glycol dimethacrylate Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	25-50%
CAS: 111-30-8 EINECS: 203-856-5	glutaral Acute Tox. 3, H301; Acute Tox. 2, H330; Resp. Sens. 1, H334; Skin Corr. 1B, H314; Eye Dam. 1, H318; Aquatic Acute 1, H400; Aquatic Chronic 1, H410; Skin Sens. 1A, H317; STOT SE 3, H335, EUH071 Specific concentration limit: STOT SE 3; H335: C ≥ 0.5 %	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:** Immediately rinse with water.**· After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.**· After swallowing:** Do not induce vomiting; call for medical help immediately.**· 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.*

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- **For safety reasons unsuitable extinguishing agents:** Water with full jet
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** Mouth respiratory protective device.
- **Additional information** Cool endangered receptacles with water spray.

### 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:**  
Dilute with plenty of water.  
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).  
Dispose contaminated material as waste according to section 13.  
Ensure adequate ventilation.
- **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.  
Ensure good ventilation/exhaustion at the workplace.  
Prevent formation of aerosols.
- **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:** 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:**

**CAS: 111-30-8 glutaral**

WEL	Short-term value: 0.2 mg/m <sup>3</sup> , 0.05 ppm
	Long-term value: 0.2 mg/m <sup>3</sup> , 0.05 ppm
Sen	

· **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.

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*Immediately remove all soiled and contaminated clothing**Wash hands before breaks and at the end of work.**Keep away from foodstuffs, beverages and feed.**Do not inhale gases / fumes / aerosols.**Avoid contact with the eyes and skin.***· Respiratory protection:***Not necessary if room is well-ventilated.**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.***· 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***· 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)

**· Body protection: Protective work clothing**

## SECTION 9: Physical and chemical properties

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

<b>· Colour:</b>	Colourless
<b>· Odour:</b>	Characteristic
<b>· Odour threshold:</b>	Not determined.
<b>· Melting point/freezing point:</b>	Undetermined.
<b>· Boiling point or initial boiling point and boiling range</b>	Undetermined.
<b>· Flammability</b>	Not applicable.
<b>· Lower and upper explosion limit</b>	
<b>· Lower:</b>	Not determined.
<b>· Upper:</b>	Not determined.
<b>· Flash point:</b>	Not applicable.
<b>· pH</b>	Not determined.
<b>· Viscosity:</b>	
<b>· Kinematic viscosity</b>	Not determined.
<b>· Dynamic:</b>	Not determined.
<b>· Solubility</b>	
<b>· water:</b>	Fully miscible.
<b>· Partition coefficient n-octanol/water (log value)</b>	Not determined.
<b>· Vapour pressure:</b>	Not determined.

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· <b>Density and/or relative density</b>	
· <b>Density at 20 °C:</b>	1.074 g/cm <sup>3</sup>
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not determined.
· <b>9.2 Other information</b>	
· <b>Appearance:</b>	
· <b>Form:</b>	Fluid
· <b>Important information on protection of health and environment, and on safety.</b>	
· <b>Ignition temperature:</b>	Product is not selfigniting.
· <b>Explosive properties:</b>	Product does not present an explosion hazard.
· <b>Solvent content:</b>	
· <b>Water:</b>	59.9 %
· <b>Solids content:</b>	0.0 %
· <b>Change in condition</b>	
· <b>Evaporation rate</b>	Not determined.
· <b>Information with regard to physical hazard classes</b>	
· <b>Explosives</b>	Void
· <b>Flammable gases</b>	Void
· <b>Aerosols</b>	Void
· <b>Oxidising gases</b>	Void
· <b>Gases under pressure</b>	Void
· <b>Flammable liquids</b>	Void
· <b>Flammable solids</b>	Void
· <b>Self-reactive substances and mixtures</b>	Void
· <b>Pyrophoric liquids</b>	Void
· <b>Pyrophoric solids</b>	Void
· <b>Self-heating substances and mixtures</b>	Void
· <b>Substances and mixtures, which emit flammable gases in contact with water</b>	Void
· <b>Oxidising liquids</b>	Void
· <b>Oxidising solids</b>	Void
· <b>Organic peroxides</b>	Void
· <b>Corrosive to metals</b>	Void
· <b>Desensitised explosives</b>	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.
- **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** No further relevant information available.
- **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**
- Harmful if swallowed.
- Toxic if inhaled.

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- **Skin corrosion/irritation**  
Causes severe skin burns and eye damage.
- **Serious eye damage/irritation**  
Causes serious eye damage.
- **Respiratory or skin sensitisation**  
May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
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**  
May cause respiratory irritation.
- **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.
- **11.2 Information on other hazards**

· <b>Endocrine disrupting properties</b>
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None of the ingredients is listed.
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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.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties** For information on endocrine disrupting properties see section 11.
- **12.7 Other adverse effects**
- **Additional ecological information:**
- **General notes:**  
Water hazard class 3 (German Regulation) (Self-assessment): extremely hazardous for water  
Do not allow product to reach ground water, water course or sewage system, even in small quantities.  
Danger to drinking water if even extremely small quantities leak into the ground.

### 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

- |   |      |
|---|------|
| · <b>14.1 UN number or ID number</b><br>· <b>ADR/RID/ADN, ADN, IMDG, IATA</b> | Void |
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· 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:	
· Marine pollutant:	No
· 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

#### 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 50 t
- Qualifying quantity (tonnes) for the application of upper-tier requirements 200 t
- 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**
  - H301 Toxic if swallowed.
  - H314 Causes severe skin burns and eye damage.
  - H315 Causes skin irritation.
  - H317 May cause an allergic skin reaction.
  - H318 Causes serious eye damage.
  - H319 Causes serious eye irritation.
  - H330 Fatal if inhaled.
  - H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
  - H335 May cause respiratory irritation.
  - H400 Very toxic to aquatic life.
  - H410 Very toxic to aquatic life with long lasting effects.
  - EUH071 Corrosive to the respiratory tract.
- **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.

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**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)*  
*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*  
*Acute Tox. 3: Acute toxicity – Category 3*  
*Acute Tox. 4: Acute toxicity – Category 4*  
*Acute Tox. 2: Acute toxicity – Category 2*  
*Skin Corr. 1B: Skin corrosion/irritation – Category 1B*  
*Skin Irrit. 2: Skin corrosion/irritation – Category 2*  
*Eye Dam. 1: Serious eye damage/eye irritation – Category 1*  
*Eye Irrit. 2: Serious eye damage/eye irritation – Category 2*  
*Resp. Sens. 1: Respiratory sensitisation – Category 1*  
*Skin Sens. 1: Skin sensitisation – Category 1*  
*Skin Sens. 1A: Skin sensitisation – Category 1A*  
*STOT SE 3: Specific target organ toxicity (single exposure) – Category 3*  
*Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1*  
*Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1*  
*Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2*

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

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