

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

Printing date 20.04.2015

Version number 9

Revision: 18.02.2015

**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  
FL-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, FL-9494 Schaan, Liechtenstein)

**SECTION 2: Hazards identification**

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
Skin Irrit. 2 H315 Causes skin irritation.  
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.

- **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**



GHS05 GHS07 GHS08

- **Signal word** Danger
- **Hazard-determining components of labelling:**  
glutaral  
polyethylene glycol dimethacrylate
- **Hazard statements**  
H315 Causes skin irritation.  
H318 Causes serious eye damage.  
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
H317 May cause an allergic skin reaction.  
H335 May cause respiratory irritation.
- **Precautionary statements**  
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.  
P280 Wear protective gloves/protective clothing/eye protection/face protection.

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P342+P311 If experiencing respiratory symptoms: Call a POISON CENTER/doctor.

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.

· **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: 25852-47-5	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. 3, H331; Resp. Sens. 1, H334; Skin Corr. 1B, H314; Aquatic Acute 1, H400; Skin Sens. 1, H317	3-<10%

· **Additional information:** For the wording of the listed risk 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.

· **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.

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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:**  
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 item 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

- **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:**

**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
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- **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.  
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.

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· **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

*The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.*

*Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.*

*Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation*

· **Material of gloves**

*The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.*

· **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:**

<b>Form:</b>	Fluid
<b>Colour:</b>	Colourless
<b>Odour:</b>	Characteristic
<b>Odour threshold:</b>	Not determined.

· **pH-value:** Not determined.

· **Change in condition**

<b>Melting point/Melting range:</b>	Undetermined.
<b>Boiling point/Boiling range:</b>	Undetermined.

· **Flash point:** Not applicable.

· **Flammability (solid, gaseous):** Not applicable.

· **Self-igniting:** Product is not selfigniting.

· **Danger of explosion:** Product does not present an explosion hazard.

· **Explosion limits:**

<b>Lower:</b>	Not determined.
<b>Upper:</b>	Not determined.

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· <b>Vapour pressure:</b>	Not determined.
· <b>Density at 20 °C:</b>	1.38 g/cm <sup>3</sup>
· <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** 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 toxicological effects**
- **Acute toxicity:**

· **LD/LC50 values relevant for classification:**

**111-30-8 glutaral**

Oral	LD50	134 mg/kg (rat)
Dermal	LD50	2560 mg/kg (rabbit)

- **Primary irritant effect:**
- **on the skin:** Irritant to skin and mucous membranes.
- **on the eye:** Strong irritant with the danger of severe eye injury.
- **Sensitisation:**
- Sensitisation possible through inhalation.
- Sensitisation possible through skin contact.
- **Additional toxicological information:** No further relevant information available.

### 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.

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- **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.
- **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

- |   |  |
|---|--|
| · <b>14.1 UN-Number</b>   |  |
| · <b>ADR, ADN, IMDG, IATA</b>   | Void   |
| · <b>14.2 UN proper shipping name</b>   |  |
| · <b>ADR, ADN, IMDG, IATA</b>   | Void   |
| · <b>14.3 Transport hazard class(es)</b>  |  |
| · <b>ADR, ADN, IMDG, IATA</b>   |  |
| · <b>Class</b>  | Void   |
| · <b>14.4 Packing group</b>   |  |
| · <b>ADR, IMDG, IATA</b>  | Void   |
| · <b>14.5 Environmental hazards:</b>  |  |
| · <b>Marine pollutant:</b>  | No   |
| · <b>14.6 Special precautions for user</b>  | Not applicable.  |
| · <b>14.7 Transport in bulk according to Annex II of MARPOL73/78 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>   | -  |

### SECTION 15: Regulatory information

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

*H301 Toxic if swallowed.*

*H314 Causes severe skin burns and eye damage.*

*H315 Causes skin irritation.*

*H317 May cause an allergic skin reaction.*

*H319 Causes serious eye irritation.*

*H331 Toxic 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.*

· **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)*

*LC50: Lethal concentration, 50 percent*

*LD50: Lethal dose, 50 percent*

*Acute Tox. 3: Acute toxicity, Hazard Category 3*

*Skin Corr. 1B: Skin corrosion/irritation, Hazard Category 1B*

*Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2*

*Eye Dam. 1: Serious eye damage/eye irritation, Hazard Category 1*

*Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2*

*Resp. Sens. 1: Sensitisation - Respirat., Hazard Category 1*

*Skin Sens. 1: Sensitisation - Skin, Hazard Category 1*

*STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3*

*Aquatic Acute 1: Hazardous to the aquatic environment - AcuteHazard, Category 1*

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

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