





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

- **Product identifier**
- **Trade name:** Syntac Adhesive
- **Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the preparation** *Enamel-Dentin Bonding Agent*
- **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
msds@ivoclarvivadent.com*
- **Emergency telephone number:** +423 / 235 33 13

2 Hazards identification

- **Classification of the substance or mixture**
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
-  *Xn; Harmful*
R20/22: Harmful by inhalation and if swallowed.
-  *Xn; Sensitising*
R42/43: May cause sensitisation by inhalation and skin contact.
-  *Xi; Irritant*
R37/38-41: Irritating to respiratory system and skin. Risk of serious damage to eyes.
- **Classification system:**
The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

- **Label elements**
- **Labelling according to EU guidelines:**
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 Dangerous Substance Directive 1999/45/EC usually if they are in the finished state and intended for the final user.
- **Code letter and hazard designation of product:**
-  *Xn Harmful*
- **Risk phrases:**
*20/22 Harmful by inhalation and if swallowed.
37/38 Irritating to respiratory system and skin.
41 Risk of serious damage to eyes.
42/43 May cause sensitisation by inhalation and skin contact.*
- **Safety phrases:**
*23 Do not breathe fumes/aerosol.
24 Avoid contact with skin.*

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- 26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
37/39 Wear suitable gloves and eye/face protection.
45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
60 This material and its container must be disposed of as hazardous waste.
- **Other hazards**
 - **Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.

3 Composition/information on ingredients

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

· **Dangerous components:**

CAS: 25852-47-5	polyethylene glycol dimethacrylate  Xi R36/37/38	25-50%
CAS: 111-30-8 EINECS: 203-856-5	glutaral  T R23/25;  C R34;  Xn R42/43;  N R50	2.5-10%

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

4 First aid measures

- **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.
- **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 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **For safety reasons unsuitable extinguishing agents:** Water with full jet
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** Mouth respiratory protective device.
- **Additional information** Cool endangered receptacles with water spray.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
- **Environmental precautions:**
Dilute with plenty of water.
Do not allow to enter sewers/ surface or ground water.

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- **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.
- **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.
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
- **Information about fire - and explosion protection:** No special measures required.
- **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.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **Control parameters**

- **Ingredients with limit values that require monitoring at the workplace:**

111-30-8 glutaral

WEL ()	Short-term value: 0.2 mg/m ³ , 0.05 ppm Long-term value: 0.2 mg/m ³ , 0.05 ppm Sen
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- **Additional information:** The lists valid during the making were used as basis.
- **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.
Do not inhale gases / fumes / aerosols.
Avoid contact with the eyes and skin.
Keep away from foodstuffs, beverages and feed.
- **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

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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.

- **Eye protection:**



Tightly sealed goggles

9 Physical and chemical properties

- **Information on basic physical and chemical properties**

- **General Information**

- **Appearance:**

Form:	Fluid
Colour:	Colourless
Odour:	Characteristic
Odour threshold:	Not determined.

- **pH-value:** Not determined.

- **Change in condition**

Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	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:**

Lower:	Not determined.
Upper:	Not determined.

- **Vapour pressure:** Not determined.

Density at 20°C:	1.38 g/cm ³
Relative density	Not determined.
Vapour density	Not determined.
Evaporation rate	Not determined.

- **Solubility in / Miscibility with water:** Fully miscible.

- **Segregation coefficient (n-octanol/water):** Not determined.

- **Viscosity:**

Dynamic:	Not determined.
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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.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **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:**

· **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.

· **Sensitization:**

- Sensitization possible through inhalation.
- Sensitization possible through skin contact.

· **Additional toxicological information:**

The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:

Harmful
Irritant

12 Ecological information

· **Toxicity**

- **Acquatic 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 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.

· **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

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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
· ADR, ADN, IMDG, IATA | Void |
| · UN proper shipping name
· ADR, ADN, IMDG, IATA | Void |
| · Transport hazard class(es)
· ADR, ADN, IMDG, IATA
· Class | Void |
| · Packing group
· ADR, IMDG, IATA | Void |
| · Environmental hazards:
· Marine pollutant: | No |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | Not applicable. |

15 Regulatory information

- **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 EC-directive 93/42/EEC.
- **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**
R23/25 Toxic by inhalation and if swallowed.
R34 Causes burns.
R36/37/38 Irritating to eyes, respiratory system and skin.
R42/43 May cause sensitisation by inhalation and skin contact.
R50 Very toxic to aquatic organisms.