






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

- **Product identifier**
- **Trade name:** Virtual Tray Adhesive
- **Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the preparation** Custom tray material
- **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**
R20/21-48/20-63-65: Harmful by inhalation and in contact with skin. Harmful: danger of serious damage to health by prolonged exposure through inhalation. Possible risk of harm to the unborn child. Harmful: may cause lung damage if swallowed.
-  **Xi; Irritant**
R38: Irritating to skin.
-  **F; Highly flammable**
R11: Highly flammable.
- **Information concerning particular hazards for human and environment:**
The product has to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.
- **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:**
The product has been classified and marked in accordance with EU Directives / Ordinance on Hazardous Materials.
- **Code letter and hazard designation of product:**
-   **Xn Harmful**
F Highly flammable
- **Hazard-determining components of labelling:**
toluene
xylene

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· **Risk phrases:**

- 11 Highly flammable.
- 20/21 Harmful by inhalation and in contact with skin.
- 38 Irritating to skin.
- 48/20 Harmful: danger of serious damage to health by prolonged exposure through inhalation.
- 63 Possible risk of harm to the unborn child.
- 65 Harmful: may cause lung damage if swallowed.

· **Safety phrases:**

- 9 Keep container in a well-ventilated place.
- 16 Keep away from sources of ignition - No smoking.
- 23 Do not breathe gas/fumes/vapour/spray (appropriate wording to be specified by the manufacturer).
- 25 Avoid contact with eyes.
- 36/37 Wear suitable protective clothing and gloves.
- 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: 1330-20-7 EINECS: 215-535-7	xylene	☒ Xn R20/21; ☒ Xi R38 R10	25-50%
CAS: 108-88-3 EINECS: 203-625-9	toluene	☒ Xn R48/20-63-65; ☒ Xi R38; ☒ F R11 R67	10-25%
CAS: 67-63-0 EINECS: 200-661-7	propan-2-ol	☒ Xi R36; ☒ F R11 R67	≤ 2.5%

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

4 First aid measures

· **Description of first aid measures**· **General information:**

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

· **After inhalation:**

Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.

In case of unconsciousness place patient stably in side position for transportation.

· **After skin contact:**

Immediately 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:** Seek medical treatment.· **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 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:** Do not allow to enter sewers/ surface or ground water.
- **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.
Do not flush with water or aqueous cleansing agents
- **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**
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
- **Information about fire - and explosion protection:**
Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store in a cool location.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**
Keep container tightly sealed.
Store in cool, dry conditions in well sealed receptacles.
Store receptacle in a well ventilated area.
- **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.

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· **Control parameters**· **Ingredients with limit values that require monitoring at the workplace:****1330-20-7 xylene**

WEL Short-term value: 441 mg/m³, 100 ppm
Long-term value: 220 mg/m³, 50 ppm
Sk; BMGV

108-88-3 toluene

WEL Short-term value: 384 mg/m³, 100 ppm
Long-term value: 191 mg/m³, 50 ppm
Sk

67-63-0 propan-2-ol

WEL Short-term value: 1250 mg/m³, 500 ppm
Long-term value: 999 mg/m³, 400 ppm

· **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.
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.

· **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.

Filter AX

· **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**

Butyl rubber, BR
Fluorocarbon rubber (Viton)
PVA 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.

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· Eye protection:



Tightly sealed goggles

9 Physical and chemical properties

· Information on basic physical and chemical properties

· General Information

· Appearance:

Form:	Fluid
Colour:	Blue
· 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: < 21°C

· Self-igniting: Product is not selfigniting.

· Danger of explosion: Product is not explosive. However, formation of explosive air/vapour mixtures are possible.

· Explosion limits:

Lower:	Not determined.
Upper:	Not determined.

· Vapour pressure: Not determined.

· Density at 20°C:	0.9 g/cm ³
· Relative density	Not determined.
· Vapour density	Not determined.
· Evaporation rate	Not determined.

· Solubility in / Miscibility with water:

Not miscible or difficult to mix.

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

· Viscosity:

Dynamic:	Not determined.
Kinematic:	Not determined.

· Solvent content:

Organic solvents: 55.5 %

· 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.

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· **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:****1330-20-7 xylene**

Oral	LD50	4300 mg/kg (rat)
Dermal	LD50	2000 mg/kg (rabbit)

108-88-3 toluene

Oral	LD50	5000 mg/kg (rat)
Dermal	LD50	12124 mg/kg (rabbit)
Inhalative	LC50/4 h	5320 mg/l (mouse)

· **Primary irritant effect:**· **on the skin:** Irritant to skin and mucous membranes.· **on the eye:** No irritating effect.· **Sensitization:** No sensitizing effects known.· **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 2 (German Regulation) (Self-assessment): hazardous for water

Do not allow product 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**

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· **Uncleaned packaging:**· **Recommendation:** Disposal must be made according to official regulations.

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14 Transport information

· Land transport ADR/RID (cross-border)



- ADR/RID class: 3 (F1) Flammable liquids.
- Danger code (Kemler): 33
- UN-Number: 1133
- Packaging group: II
- Hazard label: 3
- UN proper shipping name: 1133 ADHESIVES
- Tunnel restriction code D/E

· Maritime transport IMDG:



- IMDG Class: 3
- UN Number: 1133
- Label: 3
- Packaging group: II
- EMS Number: F-E,S-D
- Marine pollutant: No
- Proper shipping name: ADHESIVES

· Air transport ICAO-TI and IATA-DGR:



- ICAO/IATA Class: 3
- UN/ID Number: 1133
- Label: 3
- Packaging group: II
- Proper shipping name: ADHESIVES

- Special precautions for user Warning: Flammable liquids.
- 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.

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· Relevant phrases

R10 Flammable.

R11 Highly flammable.

R20/21 Harmful by inhalation and in contact with skin.

R36 Irritating to eyes.

R38 Irritating to skin.

R48/20 Harmful: danger of serious damage to health by prolonged exposure through inhalation.

R63 Possible risk of harm to the unborn child.

R65 Harmful: may cause lung damage if swallowed.

R67 Vapours may cause drowsiness and dizziness.

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