

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

Printing date 12.11.2020


Version number 4

Revision: 12.11.2020

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

- **1.1 Product identifier**
- **Trade name: *ProArt Print Splint***
- **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** Splint material for stereolithography
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Ivoclar Vivadent AG
Bendererstrasse 2
9494 Schaan
FÜRSTENTUM 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, 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 Irrit. 2 H319 Causes serious eye irritation.
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**
- 
- GHS07
- **Signal word** Warning
- **Hazard-determining components of labelling:**
triethylene glycol dimethacrylate
urethane dimethacrylate
Bis-GMA
- **Hazard statements**
H315 Causes skin irritation.
H319 Causes serious eye irritation.
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.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

(Contd. on page 2)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 12.11.2020

Version number 4

Revision: 12.11.2020

Trade name: ProArt Print Splint

(Contd. of page 1)

P337+P313 If eye irritation persists: Get medical advice/attention.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

- **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: 72162-39-1	urethane acrylate oligomer Skin Irrit. 2, H315; Eye Irrit. 2, H319	25-50%
CAS: 109-16-0 EINECS: 203-652-6 Reg.nr.: 01-2119969287-21-XXXX	triethylene glycol dimethacrylate Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335	25-50%
CAS: 72869-86-4 EINECS: 276-957-5 Reg.nr.: 01-2120751202-68-XXXX	urethane dimethacrylate Eye Irrit. 2, H319; Skin Sens. 1, H317; Aquatic Chronic 3, H412	10-<25%
CAS: 36425-15-7 NLP: 500-089-0	Bis-GMA Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	2.5-<10%
CAS: 75980-60-8 EINECS: 278-355-8 Reg.nr.: 01-2119972295-29-XXXX	diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide Repr. 2, H361f	0.1-<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:**
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:**
Rinse out mouth and then drink plenty of water.
Seek medical treatment.
- **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:**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.

(Contd. on page 3)

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

Printing date 12.11.2020

Version number 4

Revision: 12.11.2020

Trade name: **ProArt Print Splint**

(Contd. of page 2)

- **5.3 Advice for firefighters**
- **Protective equipment:** Mouth respiratory protective device.

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:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **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.
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.
Protect from exposure to the light.
Protect from heat and direct sunlight.
- **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:**
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**
- **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.
Remove contaminated clothing and wash before reuse.
Avoid contact with the eyes and skin.
- **Respiratory protection:**
Not necessary if room is well-ventilated.

(Contd. on page 4)

-GB-

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

Printing date 12.11.2020

Version number 4

Revision: 12.11.2020

Trade name: **ProArt Print Splint**

(Contd. of page 3)

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

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 protection:**



Tightly sealed goggles

SECTION 9: Physical and chemical properties

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

· **General Information**

· **Appearance:**

Form:	Viscous
Colour:	Yellowish
Odour:	Characteristic
Odour threshold:	Not determined.

· **pH-value:** Not applicable.

· **Change in condition**

Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	Undetermined.

· **Flash point:** >107 °C (ISO 13736)

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

· **Auto-ignition temperature:** Product is not selfigniting.

· **Explosive properties:** Product does not present an explosion hazard.

· **Vapour pressure:** Not determined.

· **Density:** Not determined.

· **Relative density** Not determined.

· **Vapour density** Not determined.

· **Evaporation rate** Not determined.

· **Solubility in / Miscibility with water:**

Not miscible or difficult to mix.

· **Partition coefficient: n-octanol/water:** Not determined.

(Contd. on page 5)

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

Printing date 12.11.2020

Version number 4

Revision: 12.11.2020

Trade name: **ProArt Print Splint**

(Contd. of page 4)

- **Viscosity:**
- Dynamic:** Not determined.
- Kinematic:** Not determined.
- **9.2 Other information** No further relevant information available.

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
Photoreactive (Danger of polymerization).
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**
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 toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **Skin corrosion/irritation**
Causes skin irritation.
- **Serious eye damage/irritation**
Causes serious eye irritation.
- **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**
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.

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.
- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
Do not allow product to reach ground water, water course or sewage system.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

(Contd. on page 6)

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

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Version number 4

Revision: 12.11.2020

Trade name: **ProArt Print Splint**

(Contd. of page 5)

· **12.6 Other adverse effects** No further relevant information available.**SECTION 13: Disposal considerations**· **13.1 Waste treatment methods**· **Recommendation**

Must not be disposed together with household garbage. Do not allow product to reach sewage system.
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**· **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 Transport in bulk according to Annex II of Marpol and the IBC Code**

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**· **Named dangerous substances - ANNEX I** None of the ingredients is listed.· **Seveso category O1** Substances or mixtures with hazard statement EUH014· **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3· **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**

None of the ingredients is listed.

· **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

GB

(Contd. on page 7)

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

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Version number 4

Revision: 12.11.2020

Trade name: ProArt Print Splint

(Contd. of page 6)

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.

H361f Suspected of damaging fertility.

H412 Harmful 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:**

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)

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

Repr. 2: Reproductive toxicity – Category 2

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

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

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