

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

Printing date 20.11.2023

Version number 11 (replaces version 10)

Revision: 20.11.2023

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

- **1.1 Product identifier**
- **Trade name:** **SR Link**
- **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** Lab-composite 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**
Flam. Liq. 2 H225 Highly flammable liquid and vapour.
Acute Tox. 4 H332 Harmful if inhaled.
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 GB CLP regulation.
- **Hazard pictograms**
 
GHS02 GHS07
- **Signal word** Danger
- **Hazard-determining components of labelling:**
2-methylpropan-2-ol
urethane dimethacrylate
4-methylpentan-2-one
methacrylated phosphoric acid ester
- **Hazard statements**
H225 Highly flammable liquid and vapour.
H332 Harmful if inhaled.
H319 Causes serious eye irritation.
H317 May cause an allergic skin reaction.
H335 May cause respiratory irritation.

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· **Precautionary statements**

- P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
 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.
 P337+P313 If eye irritation persists: Get medical advice/attention.
 P403+P233 Store in a well-ventilated place. Keep container tightly closed.

· **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: 75-65-0 EINECS: 200-889-7	2-methylpropan-2-ol Flam. Liq. 2, H225; Acute Tox. 4, H332; Eye Irrit. 2, H319; STOT SE 3, H335	50-100%
CAS: 108-10-1 EINECS: 203-550-1 Reg.nr.: 01-2119473980-30-XXXX	4-methylpentan-2-one Flam. Liq. 2, H225; Acute Tox. 4, H332; Eye Irrit. 2, H319; STOT SE 3, H335, EUH066 ATE: LC50/4 h inhalative: 11 mg/l	20-25%
CAS: 72869-86-4 EINECS: 276-957-5	urethane dimethacrylate Eye Irrit. 2, H319; Skin Sens. 1, H317; Aquatic Chronic 3, H412	2.5-<10%
CAS: 85590-00-7	methacrylated phosphoric acid ester Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	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**

- **General information:** Immediately remove any clothing soiled by the product.
 · **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 wash with water and soap and rinse thoroughly.
 · **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.
 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:** CO₂, sand, extinguishing powder. Do not use water.

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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:**
 - Wear self-contained respiratory protective device.
 - 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:** 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:**
 - Keep ignition sources away - Do not smoke.
 - Protect against electrostatic charges.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:**
 - Store in a cool location.
 - Store only in the original receptacle.
- **Information about storage in one common storage facility:**
 - Store away from oxidising agents.
 - Store away from reducing agents.
- **Further information about storage conditions:**
 - Keep container tightly sealed.
 - Store in cool, dry conditions in well sealed receptacles.
 - Protect from heat and direct sunlight.
- **7.3 Specific end use(s)** No further relevant information available.

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SECTION 8: Exposure controls/personal protection

· 8.1 Control parameters

· Ingredients with limit values that require monitoring at the workplace:

CAS: 75-65-0 2-methylpropan-2-ol

WEL Short-term value: 462 mg/m³, 150 ppm
Long-term value: 308 mg/m³, 100 ppm

CAS: 108-10-1 4-methylpentan-2-one

WEL Short-term value: 416 mg/m³, 100 ppm
Long-term value: 208 mg/m³, 50 ppm
Sk, BMGV

· Ingredients with biological limit values:

CAS: 108-10-1 4-methylpentan-2-one

BMGV 20 µmol/L
Medium: urine
Sampling time: post shift
Parameter: 4-methylpentan-2-one

· 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.

Remove contaminated clothing and wash before reuse.

Keep away from foodstuffs, beverages and feed.

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.

· Recommended filter device for short term use:

Filter A1

Filter A2

Filter A3

· Hand protection



Protective gloves (EN 374)

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

After use of gloves apply skin-cleaning agents and skin cosmetics.

· Material of gloves

Butyl rubber, BR

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.

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· Eye/face protection



Tightly sealed goggles (EN 166)

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Colour:	According to product specification
· Odour:	Characteristic
· Odour threshold:	Not determined.
· Melting point/freezing point:	Undetermined.
· Boiling point or initial boiling point and boiling range	83 °C
· Flammability	Not applicable.
· Lower and upper explosion limit	
· Lower:	1.7 Vol %
· Upper:	9.0 Vol %
· Flash point:	11 °C
· Auto-ignition temperature:	460 °C
· pH	Not applicable.
· Viscosity:	
· Kinematic viscosity	Not determined.
· Dynamic:	Not determined.
· Solubility	
· water:	Partly soluble.
· Partition coefficient n-octanol/water (log value)	Not determined.
· Vapour pressure at 20 °C:	40 hPa
· Density and/or relative density	
· Density at 20 °C:	0.825 g/cm ³
· Relative density	Not determined.
· Vapour density	Not determined.

· 9.2 Other information

· Appearance:	
· Form:	Fluid
· Important information on protection of health and environment, and on safety.	
· Ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product is not explosive. However, formation of explosive air/vapour mixtures are possible.
· Change in condition	
· Evaporation rate	Not determined.

· Information with regard to physical hazard classes

· Explosives	Void
· Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Highly flammable liquid and vapour.
· Flammable solids	Void

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|---|------|
| · Self-reactive substances and mixtures | Void |
| · Pyrophoric liquids | Void |
| · Pyrophoric solids | Void |
| · Self-heating substances and mixtures | Void |
| · Substances and mixtures, which emit flammable gases in contact with water | Void |
| · Oxidising liquids | Void |
| · Oxidising solids | Void |
| · Organic peroxides | Void |
| · Corrosive to metals | Void |
| · Desensitised explosives | 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**
 Reacts with strong oxidising agents.
 Reacts with reducing agents.
- **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 inhaled.

· LD/LC50 values relevant for classification:

CAS: 75-65-0 2-methylpropan-2-ol

Oral	LD50	3500 mg/kg (rat)
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CAS: 108-10-1 4-methylpentan-2-one

Oral	LD50	2080 mg/kg (rat)
Dermal	LD50	16000 mg/kg (rab)
Inhalative	LC50/4 h	8.3-16.6 mg/l (rat)

- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **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.
- **Additional toxicological information:** No further relevant information available.

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· **11.2 Information on other hazards**· **Endocrine disrupting properties**

None of the ingredients is listed.

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 1 (German Regulation) (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

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

· **14.1 UN number or ID number**· **ADR/RID/ADN, IMDG, IATA**

UN1993

· **14.2 UN proper shipping name**· **ADR/RID/ADN**

1993 FLAMMABLE LIQUID, N.O.S. (BUTANOLS, METHYL ISOBUTYL KETONE)

· **IMDG, IATA**

FLAMMABLE LIQUID, N.O.S. (BUTANOLS, METHYL ISOBUTYL KETONE)

· **14.3 Transport hazard class(es)**· **ADR/RID/ADN**· **Class**

3 (F1) Flammable liquids.

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· Label	3
· IMDG, IATA	
	
· Class	3 Flammable liquids.
· Label	3
· 14.4 Packing group	
· ADR/RID/ADN, IMDG, IATA	II
· 14.5 Environmental hazards:	
· Marine pollutant:	No
· 14.6 Special precautions for user	Warning: Flammable liquids.
· Hazard identification number (Kemler code):	33
· EMS Number:	F-E, S-E
· 14.7 Maritime transport in bulk according to IMO instruments	Not applicable.
· Transport/Additional information:	
· ADR/RID/ADN	
· Limited quantities (LQ)	1L
· Transport category	2
· Tunnel restriction code	D/E
· UN "Model Regulation":	UN1993, FLAMMABLE LIQUID, N.O.S. (BUTANOLS, METHYL ISOBUTYL KETONE), 3, II

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** 5000 t
- **Qualifying quantity (tonnes) for the application of upper-tier requirements** 50000 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**
- H225 Highly flammable liquid and vapour.
- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H319 Causes serious eye irritation.
- H332 Harmful if inhaled.
- H335 May cause respiratory irritation.

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H412 Harmful to aquatic life with long lasting effects.

EUH066 Repeated exposure may cause skin dryness or cracking.

· 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 relatif au transport international 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

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Flam. Liq. 2: Flammable liquids – Category 2

Acute Tox. 4: Acute toxicity – Category 4

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

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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