

safety data sheet

to product

Fix Adhesive

1. Identification of the substance / preparation and company

Emergency number:

Tox Info Suisse, Freiestrasse 16, 8032 Zürich; Tox-Info Suisse: 145 (24h-operation); info@toxinfo.ch;
In case of emergency: Tel. 145; (abroad: +41 44 251 51 51); information: +41 44 251 66 66

Company name:



abc dental ag

Gaswerkstrasse 6, 8952 Schlieren
Tel. 044 755 51 00, Fax 044 755 51 01



Condor Dental Research CO Sàrl

Ch. des Cibleries 2, CP 300, 1896 Vouvry
Tel. 024 482 61 61, Fax 024 482 61 69



Curaden AG Dentaldepot

Riedstrasse 12, 8953 Dietikon
Tel. 041 319 45 00, Fax 041 319 45 90



dema dent AG

Furtbachstrasse 16, 8107 Buchs
Tel. 044 838 65 65, Fax 044 838 65 66



Flexdental Services SA

Route de la Corniche 1, 1066 Epalinges
Tel. 0848 336 825, Fax 021 907 67 02



Jordi Röntgentechnik AG

Dammstrasse 70, 4142 Münchenstein
Tel. 061 417 93 93, Fax 061 417 93 94



Kaladent AG

Schachenstrasse 2, 9016 St. Gallen
Tel. 071 282 80 80, Fax 071 282 80 81



Lometral AG

Binzenholzstrasse 20, 5704 Egliswil
Tel. 062 775 05 05, Fax 062 775 33 07



Novadent AG

Sägereistrasse 17, 8152 Glattbrugg
Tel. 044 880 20 20, Fax 044 811 04 40



Smart Dentist AG

Verenastrasse 4b, 8832 Wollerau
Tel. 044 726 20 20, Fax 044 726 20 25

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

Printing date 23.01.2023

Version number 8 (replaces version 7)

Revision: 23.01.2023

Start

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

- **1.1 Product identifier**
- **Trade name: Fix Adhesive**
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the mixture** Tray Adhesive for Alginate Impression Materials
- **Uses advised against** No further relevant information available.
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Dentsply DeTrey GmbH
De-Trey-Str. 1
D-78467 Konstanz
GERMANY
Tel.: +49-(0)7531-583-0
Fax: +49-(0)7531-583-104
email: KonstanzDEU.info-sdb@dentsplysirona.com
- **Further information obtainable from:** Research and Development
- **1.4 Emergency telephone number:** +49-(0)7531-583-0 8:00 - 17:00 (GMT + 1:00)

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.
Skin Irrit. 2	H315	Causes skin irritation.
Eye Irrit. 2	H319	Causes serious eye irritation.
STOT SE 3	H335-H336	May cause respiratory irritation. May cause drowsiness or dizziness.
STOT RE 2	H373	May cause damage to the respiratory system through prolonged or repeated exposure.
Aquatic Chronic 3	H412	Harmful to aquatic life with long lasting effects.

- **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 GHS08

- **Signal word** Danger
- **Hazard-determining components of labelling:**
xylene (mix)
propan-2-ol
- **Hazard statements**

H225	Highly flammable liquid and vapour.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335-H336	May cause respiratory irritation. May cause drowsiness or dizziness.
H373	May cause damage to the respiratory system through prolonged or repeated exposure.
H412	Harmful to aquatic life with long lasting effects.

- **Precautionary statements**

P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P241	Use explosion-proof [electrical/ventilating/lighting] equipment.

(Contd. on page 2)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 23.01.2023

Version number 8 (replaces version 7)

Revision: 23.01.2023

Trade name: Fix Adhesive

(Contd. of page 1)

P303+P361+P353 **IF ON SKIN (or hair):** Take off immediately all contaminated clothing. Rinse skin with water [or shower].

P305+P351+P338 **IF IN EYES:** Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P405 Store locked up.

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

· **Additional information:**

As this product is a medical device in the meaning of Directive 93/42/EEC and regulation (EC) 2017/745 and intended for use by the end consumer and is applied in an invasive manner or body contact, it is exempt from the labelling requirements according to regulation (EC) 1272/2008.

· **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: 68139-75-3 EC number: 614-310-4	Fatty acids, C18-unsatd., dimers, polymers with diethylenetriamine and tall-oil fatty acids ----- Skin Irrit. 2, H315; Eye Irrit. 2, H319; Aquatic Chronic 3, H412	25 – 50%
CAS: 67-63-0 EINECS: 200-661-7	propan-2-ol ----- Flam. Liq. 2, H225; Eye Irrit. 2, H319; STOT SE 3, H336	25 – 50%
CAS: 1330-20-7 EINECS: 215-535-7	xylene (mix) ----- Flam. Liq. 3, H226; STOT RE 2, H373; Asp. Tox. 1, H304; Acute Tox. 4, H312; Acute Tox. 4, H332; Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	≥ 20 – ≤ 25%
CAS: 100-41-4 EINECS: 202-849-4	ethylbenzene ----- Flam. Liq. 2, H225; STOT RE 2, H373; Asp. Tox. 1, H304; Acute Tox. 4, H332	≥ 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; consult doctor in case of complaints.

· **After skin contact**

Immediately wash with water and soap and rinse thoroughly.

If skin irritation continues, consult a doctor.

· **After eye contact**

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

· **After swallowing** If symptoms persist consult doctor.

· **Information for doctor** No further relevant information available.

· **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.

GB

(Contd. on page 3)

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

Printing date 23.01.2023

Version number 8 (replaces version 7)

Revision: 23.01.2023

Trade name: **Fix Adhesive**

(Contd. of page 2)

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents** CO₂, sand, extinguishing powder. Do not use water.
- **For safety reasons unsuitable extinguishing agents**
Water with full jet.
Water.
- **5.2 Special hazards arising from the substance or mixture**
During heating or in case of fire poisonous gases are produced.
- **5.3 Advice for firefighters**
- **Protective equipment:** Mount respiratory protective device.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Mount respiratory protective device.
Wear protective equipment. Keep unprotected persons away.
- **6.2 Environmental precautions:**
Do not allow product to reach sewage system or any water course.
Prevent seepage into sewage system, workpits and cellars.
- **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.
Do not flush with water or aqueous cleansing agents
- **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**
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
Observe normal care for working with chemicals.
- **Information about fire - and explosion protection:**



Keep ignition sources away - Do not smoke.

- Protect against electrostatic charges.
Keep respiratory protective device available.
- **Handling** Product is intended for dental use only.
- **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.
- **Further information about storage conditions:**
Keep receptacle tightly sealed.
Store in cool, dry conditions in well sealed receptacles.

(Contd. on page 4)

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

Printing date 23.01.2023

Version number 8 (replaces version 7)

Revision: 23.01.2023

Trade name: **Fix Adhesive**

(Contd. of page 3)

· 7.3 **Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

· 8.1 Control parameters

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

CAS: 67-63-0 **propan-2-ol**

WEL	Short-term value: 1250 mg/m ³ , 500 ppm Long-term value: 999 mg/m ³ , 400 ppm
-----	--

CAS: 1330-20-7 **xylene (mix)**

WEL	Short-term value: 441 mg/m ³ , 100 ppm Long-term value: 220 mg/m ³ , 50 ppm Sk; BMGV
-----	--

CAS: 100-41-4 **ethylbenzene**

WEL	Short-term value: 552 mg/m ³ , 125 ppm Long-term value: 441 mg/m ³ , 100 ppm Sk
-----	---

· **Regulatory information** WEL: EH40/2020

· **Ingredients with biological limit values:**

CAS: 1330-20-7 **xylene (mix)**

BMGV	650 mmol/mol creatinine Medium: urine Sampling time: post shift Parameter: methyl hippuric acid
------	--

· **Regulatory information** BMGV: EH40/2011· **Additional information:** The lists valid during the making were used as basis.

· 8.2 Exposure controls

· **Appropriate engineering controls** No further data; see item 7.· **Individual protection measures, such as personal protective equipment**· **General protective and hygienic measures**

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.

Not necessary if room is well-ventilated.

· **Hand protection**

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.

(Contd. on page 5)

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

Printing date 23.01.2023

Version number 8 (replaces version 7)

Revision: 23.01.2023

Trade name: Fix Adhesive

(Contd. of page 4)

- **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/face protection**



Tightly sealed goggles.

- **Body protection: Protective work clothing.**

SECTION 9: Physical and chemical properties

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

- **General Information**

- **Physical state**

Fluid

- **Colour:**

Red

- **Odour:**

Product specific

- **Odour threshold:**

Not determined.

- **Melting point/freezing point:**

undetermined

- **Boiling point or initial boiling point and boiling range**

≥ 82 °C (CAS: 67-63-0 propan-2-ol)

- **Flammability**

Not applicable.

- **Lower and upper explosion limit**

- **Lower:**

≥ 1 Vol % (CAS: 68139-75-3 Fatty acids, C18-unsatd., dimers, polymers with diethylenetriamine and tall-oil fatty acids)

- **Upper:**

≤ 13.4 Vol % (CAS: 67-63-0 propan-2-ol)

- **Flash point:**

≥ 12 °C (CAS: 67-63-0 propan-2-ol)

- **Ignition temperature:**

≥ 325 °C (CAS: 68139-75-3 Fatty acids, C18-unsatd., dimers, polymers with diethylenetriamine and tall-oil fatty acids)

- **Decomposition temperature:**

Not applicable

- **pH**

Not determined.

- **Viscosity:**

Not determined.

- **Kinematic viscosity at 40 °C**

80.65 mm²/s

- **dynamic:**

Not determined.

- **Solubility**

- **Water:**

Not miscible or difficult to mix

- **Partition coefficient n-octanol/water (log value)**

Not determined.

- **Vapour pressure at 20 °C:**

≤ 43 hPa (CAS: 67-63-0 propan-2-ol)

- **Density and/or relative density**

- **Density at 20 °C:**

0.87565 g/cm³

- **Relative density**

Not determined.

- **Vapour density**

Not determined.

- **9.2 Other information**

- **Appearance:**

Solution

- **Form:**

- **Important information on protection of health and environment, and on safety.**

- **Auto-ignition temperature:**

Product is not selfigniting.

- **Explosive properties:**

Product is not explosive. However, formation of explosive air/vapour mixtures are possible.

- **Solvent content:**

- **Organic solvents:**

61.0 %

- **Solids content:**

0.0 %

(Contd. on page 6)

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

Printing date 23.01.2023

Version number 8 (replaces version 7)

Revision: 23.01.2023

Trade name: Fix Adhesive

(Contd. of page 5)

- **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
- **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**
- **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:** No dangerous decomposition products known

SECTION 11: Toxicological information

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity**

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

ATE (Acute Toxicity Estimate)

Dermal	LD50	7,391 mg/kg (rabbit)
Inhalative	LC50/4 h	275 mg/l

CAS: 67-63-0 propan-2-ol

Oral	LD50	5,045 mg/kg (rat)
Dermal	LD50	12,800 mg/kg (rab)

CAS: 1330-20-7 xylene (mix)

Oral	LD50	4,300 mg/kg (rat)
Dermal	LD50	1,700 mg/kg (rabbit)
Inhalative	LC50/4 h	21.7 mg/l (rat)

CAS: 100-41-4 ethylbenzene

Oral	LD50	3,500 mg/kg (rat)
Dermal	LD50	17,800 mg/kg (rabbit)
Inhalative	LC50/4 h	11 mg/l (ATE)

(Contd. on page 7)

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

Printing date 23.01.2023

Version number 8 (replaces version 7)

Revision: 23.01.2023

Trade name: Fix Adhesive

(Contd. of page 6)

- **Skin corrosion/irritation** Causes skin irritation.
- **Serious eye damage/irritation** Causes serious eye irritation.
- **STOT-single exposure** May cause respiratory irritation. May cause drowsiness or dizziness.
- **STOT-repeated exposure**
May cause damage to the respiratory system through prolonged or repeated exposure.
- **11.2 Information on other hazards**

- **Endocrine disrupting properties**

None of the ingredients is listed.

SECTION 12: Ecological information

- **12.1 Toxicity**

- **Aquatic toxicity:**

- **CAS: 67-63-0 propan-2-ol**

LC50/96h	1,400 mg/l (Fish acute toxicity study)
EC50/48h	13,299 mg/L (daphnia magna)

- **CAS: 1330-20-7 xylene (mix)**

LC50/48h	8.5 mg/l (daphnia magna)
LC50/96h	15.7 mg/l (Fish acute toxicity study)

- **CAS: 100-41-4 ethylbenzene**

LC50/48h	16.2 mg/l (daphnia magna)
LC50/96h	80 mg/l (Fish acute toxicity study)
EC50/48h	4.75 mg/L (daphnia magna)
EC50/72h	5 mg/l (Alg)

- **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**

The product does not contain substances with endocrine disrupting properties.

- **12.7 Other adverse effects**

- **Remark:** Harmful to fish

- **Additional ecological information:**

- **General notes:**

Do not allow product to reach ground water, water course or sewage system.

Harmful to aquatic organisms

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.

(Contd. on page 8)

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

Printing date 23.01.2023

Version number 8 (replaces version 7)

Revision: 23.01.2023

Trade name: Fix Adhesive

(Contd. of page 7)

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

SECTION 14: Transport information

- **14.1 UN number or ID number**
- **ADR, IMDG, IATA**

UN1993

- **14.2 UN proper shipping name**
- **ADR**

1993 FLAMMABLE LIQUID, N.O.S. (ISOPROPANOL (ISOPROPYL ALCOHOL), XYLENES)

- **IMDG, IATA**

FLAMMABLE LIQUID, N.O.S. (ISOPROPANOL (ISOPROPYL ALCOHOL), XYLENES)

- **14.3 Transport hazard class(es)**

- **ADR**



- **Class**
- **Label**

3 (F1) Flammable liquids.

3

- **IMDG, IATA**



- **Class**
- **Label**

3 Flammable liquids.

3

- **14.4 Packing group**

- **ADR, IMDG, IATA**

II

- **14.5 Environmental hazards:**

Not applicable.

- **14.6 Special precautions for user**

Warning: Flammable liquids.

- **Hazard identification number (Kemler code):**

33

- **EMS Number:**

F-E,S-E

- **Stowage Category**

B

- **14.7 Maritime transport in bulk according to IMO instruments**

Not applicable.

- **Transport/Additional information:**

- **ADR**

- **Limited quantities (LQ)**

1L

- **Excepted quantities (EQ)**

Code: E2

Maximum net quantity per inner packaging: 30 ml

Maximum net quantity per outer packaging: 500 ml

- **Transport category**

2

- **Tunnel restriction code**

D/E

- **IMDG**

- **Limited quantities (LQ)**

1L

(Contd. on page 9)

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

Printing date 23.01.2023

Version number 8 (replaces version 7)

Revision: 23.01.2023

Trade name: Fix Adhesive

(Contd. of page 8)

· Excepted quantities (EQ)	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· UN "Model Regulation":	UN 1993 FLAMMABLE LIQUID, N.O.S. (ISOPROPANOL (ISOPROPYL ALCOHOL), XYLENES), 3, II

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 P5c FLAMMABLE LIQUIDS**
- **Qualifying quantity (tonnes) for the application of lower-tier requirements** 5.000 t
- **Qualifying quantity (tonnes) for the application of upper-tier requirements** 50.000 t
- **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.

The attached safety data sheet covers the dangers and measures to be taken when large quantities of material are released, for example due to accidents during transport or storage by the dealer.

For quantities of material typically used in clinical practice, information necessary for safe use and storage of the product is given in the DFU.

- **Relevant phrases**
- H225 Highly flammable liquid and vapour.
- H226 Flammable liquid and vapour.
- H304 May be fatal if swallowed and enters airways.
- H312 Harmful in contact with skin.
- H315 Causes skin irritation.
- H319 Causes serious eye irritation.
- H332 Harmful if inhaled.
- H335 May cause respiratory irritation.
- H336 May cause drowsiness or dizziness.
- H373 May cause damage to organs through prolonged or repeated exposure.
- H412 Harmful to aquatic life with long lasting effects.
- **Department issuing SDS:** Research & Development
- **Contact:** HotLine for urgent technical support: +49-7531-583-350
- **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
- Flam. Liq. 3: Flammable liquids – Category 3
- 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

(Contd. on page 10)

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

Printing date 23.01.2023

Version number 8 (replaces version 7)

Revision: 23.01.2023

Trade name: Fix Adhesive

(Contd. of page 9)

*STOT SE 3: Specific target organ toxicity (single exposure) – Category 3**STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2**Asp. Tox. 1: Aspiration hazard – Category 1**Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3***· * Data compared to the previous version altered.**

GB