

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

Printing date 24.01.2019

Version number 7

Revision: 24.01.2019

### 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:**

- *Departement Research & Development for technical information*

- *Departement Marketing & Sales for distribution of the safety data sheets*

· **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 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.*

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P241 Use explosion-proof [electrical/ventilating/lighting] equipment.

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 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 Chemical characterisation: 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**

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 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.

· **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.

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

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- **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** CO<sub>2</sub>, 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.
- **Handling** Product is intended for dental use only.
- **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.
- **Further information about storage conditions:**  
Keep receptacle tightly sealed.

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- Store in cool, dry conditions in well sealed receptacles.  
· **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:**

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

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

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

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

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

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

- **Regulatory information** WEL: EH40/2011

· **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**
- **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.
- **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**

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.

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- **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.

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

## SECTION 9: Physical and chemical properties

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

- **General Information**

- **Appearance:**

**Form:** Solution

**Colour:** Red

- **Odour:** Product specific

- **Odour threshold:** Not determined.

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

- **Change in condition**

**Melting point/freezing point:** undetermined

**Initial boiling point and boiling range:** 88 °C

- **Flash point:** 11 °C (Abel c.c.)

- **Flammability (solid, gaseous)** Not applicable.

- **Ignition temperature:** 325 °C

- **Decomposition temperature:** Not determined.

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

- **Explosive properties:** Product is not explosive. However, formation of explosive air/vapour mixtures are possible.

- **Explosion limits:**

**Lower:** 1 Vol %

**Upper:** 13.4 Vol %

- **Vapour pressure at 20 °C:** 43 hPa

- **Density at 20 °C:** 0.87 g/cm<sup>3</sup>

- **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.

- **Viscosity:**

**dynamic:** Not determined.

**kinematic at 40 °C:** 80.65 mm<sup>2</sup>/s (ASTM D7042)

- **Solvent content:**

**Organic solvents:** 61.0 %

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· **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**
- **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 toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.

· **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)

- **Primary irritant effect:**
- **Skin corrosion/irritation**  
Causes skin irritation.
- **Serious eye damage/irritation**  
Causes serious eye irritation.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **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. May cause drowsiness or dizziness.
- **STOT-repeated exposure**  
May cause damage to the respiratory system through prolonged or repeated exposure.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

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### 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.

##### · Ecotoxicological 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

· **12.5 Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

· **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.

##### · European waste catalogue

18 01 06\* chemicals consisting of or containing hazardous substances

HP 3 Flammable

HP 4 Irritant - skin irritation and eye damage

HP 5 Specific Target Organ Toxicity (STOT)/Aspiration Toxicity

HP 6 Acute Toxicity

HP 14 Ecotoxic

· **Uncleaned packaging:**

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

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### SECTION 14: Transport information

· 14.1 UN-Number · ADR, IMDG, IATA	UN1993
· 14.2 UN proper shipping name · ADR · IMDG, IATA	1993 FLAMMABLE LIQUID, N.O.S. (ISOPROPANOL (ISOPROPYL ALCOHOL), XYLENES) 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 · Danger code (Kemler): · EMS Number: · Stowage Category	Warning: Flammable liquids. 33 F-E,S-E B
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· Transport/Additional information:	
· ADR · Limited quantities (LQ) · Excepted quantities (EQ)	1L Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· Transport category · Tunnel restriction code	2 D/E
· IMDG · Limited quantities (LQ) · Excepted quantities (EQ)	1L 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

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### 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
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3
- **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 the respiratory system through prolonged or repeated exposure.
- H412 Harmful to aquatic life with long lasting effects.
- **Classification according to Regulation (EC) No 1272/2008** Calculation method
- **Department issuing SDS:** Research & Development
- **Contact:** HotLine for urgent technical support: +49-7531-583-350
- **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)
- 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
- 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.**