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

Printing date 11.04.2019 Version number 6 Revision: 11.04.2019

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

· **1.1 Product identifier**

· **Trade name:** **Fix Adhesive Aerosol**
· **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)

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SECTION 2: Hazards identification

· **2.1 Classification of the substance or mixture**
· **Classification according to Regulation (EC) No 1272/2008**

Aerosol 1	H222-H229	Extremely flammable aerosol. Pressurised container: May burst if heated.
Skin Irrit. 2	H315	Causes skin irritation.
Eye Irrit. 2	H319	Causes serious eye irritation.
STOT SE 3	H336	May cause drowsiness or dizziness.
STOT RE 2	H373	May cause damage to the respiratory system through prolonged or repeated exposure.
Asp. Tox. 1	H304	May be fatal if swallowed and enters airways.

· **2.2 Label elements**
· **Labelling according to Regulation (EC) No 1272/2008**
Labelling of aspiration hazard (Asp. Tox. 1 H304) is not required for aerosols and containers with sealed spray attachment (Regulation (EC) no. 1272/2008, Annex. 1, 1.3.3).
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
ethylbenzene
· **Hazard statements**
H222-H229 Extremely flammable aerosol. Pressurised container: May burst if heated.
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H336 May cause drowsiness or dizziness.
H373 May cause damage to the respiratory system through prolonged or repeated exposure.

(Contd. on page 2)

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

Printing date 11.04.2019 Version number 6 Revision: 11.04.2019

Trade name: Fix Adhesive Aerosol

(Contd. of page 1)

· **Precautionary statements**

P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P251	Do not pierce or burn, even after use.
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.
P410+P412	Protect from sunlight. Do not expose to temperatures exceeding 50 °C/122 °F.
P501	Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Additional information:**
Buildup of explosive mixtures possible without sufficient ventilation.

· **2.3 Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

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SECTION 3: Composition/information on ingredients

· **3.2 Chemical characterisation: Mixtures**

· **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**

CAS: 106-97-8 EINECS: 203-448-7	butane Flam. Gas 1, H220; Press. Gas (Comp.), H280	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: 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	≥ 10 – < 25%
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	≥ 10 – < 20%
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%

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

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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**
In case of unconsciousness place patient stably in side position for transportation.
Supply fresh air; consult doctor in case of complaints.

· **After skin contact** Immediately wash with water and soap and rinse thoroughly.

· **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.

(Contd. on page 3)

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

Printing date 11.04.2019 Version number 6 Revision: 11.04.2019

Trade name: Fix Adhesive Aerosol

(Contd. of page 2)

· **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.
· **For safety reasons unsuitable extinguishing agents**
Water with full jet.
Water.
· **5.2 Special hazards arising from the substance or mixture**
Formation of toxic gases is possible during heating or in case of fire.
· **5.3 Advice for firefighters**
· **Protective equipment:** Self-contained 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:**
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.
Observe normal care for working with chemicals.

· **Handling** Product is intended for dental use only.
· **Information about fire - and explosion protection:**
Do not spray onto a naked flame or any incandescent material.

Keep ignition sources away - Do not smoke.

Keep respiratory protective device available.
Pressurised container: protect from sunlight and do not expose to temperatures exceeding 50°C, i.e. electric lights. Do not pierce or burn, even after use.

· **7.2 Conditions for safe storage, including any incompatibilities**
· **Storage**
· **Requirements to be met by storerooms and receptacles:**
Observe official regulations on storing packagings with pressurised containers.
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:**
Keep receptacle tightly sealed.
Protect from heat and direct sunlight.
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 11.04.2019 Version number 6 Revision: 11.04.2019

Trade name: Fix Adhesive Aerosol

(Contd. of page 3)

· **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: 106-97-8 butane	
WEL	Short-term value: 1810 mg/m³, 750 ppm Long-term value: 1450 mg/m³, 600 ppm Carc (if more than 0.1% of buta-1.3-diene)
CAS: 67-63-0 propan-2-ol	
WEL	Short-term value: 1250 mg/m³, 500 ppm Long-term value: 999 mg/m³, 400 ppm
CAS: 1330-20-7 xylene (mix)	
WEL	Short-term value: 441 mg/m³, 100 ppm Long-term value: 220 mg/m³, 50 ppm Sk; BMGV
CAS: 100-41-4 ethylbenzene	
WEL	Short-term value: 552 mg/m³, 125 ppm Long-term value: 441 mg/m³, 100 ppm Sk

· **Regulatory information** WEL: EH40/2018

· **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

(Contd. on page 5)

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

Printing date 11.04.2019 Version number 6 Revision: 11.04.2019

Trade name: Fix Adhesive Aerosol

(Contd. of page 4)

· **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.

· **Penetration time of glove material**
The exact break trough 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:	Aerosol
Colour:	Pink
· **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:	≥ -0.5 °C
· **Flash point:**	≥ -60 °C (Butane)
· **Flammability (solid, gaseous)**	Not applicable.
· **Ignition temperature:**	≥ 325 °C
· **Decomposition temperature:**	Not determined.
· **Auto-ignition temperature:**	Product is not selfigniting.
· **Explosive properties:**	Not determined.
· **Explosion limits:**	
Lower:	≥ 1 Vol %
Upper:	≤ 13.4 Vol %
· **Vapour pressure at 20 °C:**	≤ 2,100 hPa
· **Density at 20 °C:**	0.54133 g/cm³
· **Relative density**	Not determined.
· **Vapour density**	Not determined.
· **Evaporation rate**	Not applicable.
· **Solubility in / Miscibility with**	
Water:	Not miscible or difficult to mix
· **Partition coefficient: n-octanol/water:**	Not determined.
· **Viscosity:**	
dynamic:	Not determined.
kinematic:	Not determined.

(Contd. on page 6)

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

Printing date 11.04.2019 Version number 6 Revision: 11.04.2019

Trade name: Fix Adhesive Aerosol

(Contd. of page 5)

· **Solvent content:**	
Organic solvents:	81.5 %
Solids content:	0.0 %
· **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**
Danger of receptacles bursting because of high vapour pressure when heated
· **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

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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	11,333 mg/kg (rabbit)
Inhalative	LC50/4 h	550 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 (carcinogenity, 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 drowsiness or dizziness.
· **STOT-repeated exposure**
May cause damage to the respiratory system through prolonged or repeated exposure.

(Contd. on page 7)

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

Printing date 11.04.2019 Version number 6 Revision: 11.04.2019

Trade name: Fix Adhesive Aerosol

(Contd. of page 6)

· **Aspiration hazard**
May be fatal if swallowed and enters airways.

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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.
· **Additional ecological information:**
· **General notes:**
Do not allow product to reach ground water, water course or sewage system.
Danger to drinking water if even small quantities leak into the ground.
· **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**	
16 05 04*	gases in pressure containers (including halons) containing hazardous substances
HP 3	Flammable
HP 4	Irritant - skin irritation and eye damage
HP 5	Specific Target Organ Toxicity (STOT)/Aspiration Toxicity

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

(Contd. on page 8)

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

Printing date 11.04.2019 Version number 6 Revision: 11.04.2019

Trade name: Fix Adhesive Aerosol

(Contd. of page 7)

SECTION 14: Transport information

· **14.1 UN-Number**	
· **ADR, IMDG, IATA**	UN1950
· **14.2 UN proper shipping name**	
· **ADR**	1950 AEROSOLS
· **IMDG**	AEROSOLS
· **IATA**	AEROSOLS, flammable
· **14.3 Transport hazard class(es)**	
· **ADR**	

· **Class**	2 5F Gases.
· **Label**	2.1
· **IMDG, IATA**	

· **Class**	2.1
· **Label**	2.1
· **14.4 Packing group**	
· **ADR, IMDG, IATA**	Void
· **14.5 Environmental hazards:**	Not applicable.
· **14.6 Special precautions for user**	Warning: Gases.
· **Danger code (Kemler):**	-
· **EMS Number:**	F-D,S-U
· **Stowage Code**	SW1 Protected from sources of heat. SW22 For AEROSOLS with a maximum capacity of 1 litre: Category A. For AEROSOLS with a capacity above 1 litre: Category B. For WASTE AEROSOLS: Category C, Clear of living quarters.
· **Segregation Code**	SG69 For AEROSOLS with a maximum capacity of 1 litre: Segregation as for class 9. Stow "separated from" class 1 except for division 1.4. For AEROSOLS with a capacity above 1 litre: Segregation as for the appropriate subdivision of class 2. For WASTE AEROSOLS: Segregation as for the appropriate subdivision of class 2.
· **14.7 Transport in bulk according to Annex II of Marpol and the IBC Code**	Not applicable.
· **Transport/Additional information:**	
· **ADR**	
· **Limited quantities (LQ)**	1L
· **Excepted quantities (EQ)**	Code: E0 Not permitted as Excepted Quantity
· **Transport category**	2
· **Tunnel restriction code**	D
· **IMDG**	
· **Limited quantities (LQ)**	1L

(Contd. on page 9)

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

Printing date 11.04.2019 Version number 6 Revision: 11.04.2019

Trade name: Fix Adhesive Aerosol

(Contd. of page 8)

· **Excepted quantities (EQ)**	Code: E0 Not permitted as Excepted Quantity
· **UN "Model Regulation":**	UN 1950 AEROSOLS

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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** P3a FLAMMABLE AEROSOLS
· **Qualifying quantity (tonnes) for the application of lower-tier requirements** 150 t
· **Qualifying quantity (tonnes) for the application of upper-tier requirements** 500 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.

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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**
H220 Extremely flammable gas.
H225 Highly flammable liquid and vapour.
H226 Flammable liquid and vapour.
H280 Contains gas under pressure; may explode if heated.
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. Gas 1: Flammable gases – Category 1
Aerosol 1: Aerosols – Category 1
Press. Gas (Comp.): Gases under pressure – Compressed gas
Flam. Liq. 2: Flammable liquids – Category 2

(Contd. on page 10)

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

Printing date 11.04.2019 *Version number 6* *Revision: 11.04.2019*

Trade name: Fix Adhesive Aerosol

(Contd. of page 9)

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.***