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)

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.
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:

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:

- **butane**
  - CAS: 106-97-8
  - EINECS: 203-448-7
  - Flam. Gas 1, H220; Press. Gas (Comp.), H280
  - 25 – 50%

- **propan-2-ol**
  - CAS: 67-63-0
  - EINECS: 200-661-7
  - Flam. Liq. 2, H225; Eye Irrit. 2, H319; STOT SE 3, H336
  - 25 – 50%

- **2,2'-iminodiyethyamine**
  - CAS: 68139-75-3
  - EC number: 614-310-4
  - Skin Irrit. 2, H315; Eye Irrit. 2, H319; Aquatic Chronic 3, H412
  - 10 – 25%

- **xylene (mix)**
  - CAS: 1330-20-7
  - EINECS: 215-535-7
  - 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 – 25%

- **ethylbenzene**
  - CAS: 100-41-4
  - EINECS: 202-849-4
  - Flam. Liq. 2, H225; STOT RE 2, H373; Asp. Tox. 1, H304; Acute Tox. 4, H332
  - ≥ 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

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. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.

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:

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.

Information for doctor:

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.
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:

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.
Do not spray onto a naked flame or any incandescent material.

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.
Store in cool, dry conditions in well sealed receptacles.
Protect from heat and direct sunlight.
### 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

**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...
**Trade name:** Fix Adhesive Aerosol

- **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**

<table>
<thead>
<tr>
<th>9.1 Information on basic physical and chemical properties</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>General Information</strong></td>
</tr>
<tr>
<td><strong>Appearance:</strong></td>
</tr>
<tr>
<td>Form: Aerosol</td>
</tr>
<tr>
<td>Colour: Pink</td>
</tr>
<tr>
<td>Odour: Product specific</td>
</tr>
<tr>
<td>Odour threshold: Not determined.</td>
</tr>
<tr>
<td>pH-value: Not determined.</td>
</tr>
</tbody>
</table>

- **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.
Trade name: Fix Adhesive Aerosol

<table>
<thead>
<tr>
<th>· Solvent content:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Organic solvents:</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Solids content:</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>· 9.2 Other information</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

(Contd. of page 5)

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: Carbon monoxide and carbon dioxide

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:

<table>
<thead>
<tr>
<th>ATÉ (Acute Toxicity Estimate)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dermal LD50</td>
</tr>
<tr>
<td>Inhalative LC50/4 h</td>
</tr>
<tr>
<td>CAS: 67-63-0 propan-2-ol</td>
</tr>
<tr>
<td>Oral LD50</td>
</tr>
<tr>
<td>Dermal LD50</td>
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<td>CAS: 1330-20-7 xylene (mix)</td>
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</tr>
<tr>
<td>Oral LD50</td>
</tr>
<tr>
<td>Dermal LD50</td>
</tr>
</tbody>
</table>

· 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 drowsiness or dizziness.
· STOT-repeated exposure
  May cause damage to the respiratory system through prolonged or repeated exposure.

(Contd. on page 7)
6.0.18

Aspiration hazard
May be fatal if swallowed and enters airways.

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity:

<table>
<thead>
<tr>
<th>CAS: 67-63-0 propan-2-ol</th>
</tr>
</thead>
<tbody>
<tr>
<td>LC50/96h 1,400 mg/l (Fish acute toxicity study)</td>
</tr>
<tr>
<td>EC50/48h 13,299 mg/L (daphnia magna)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAS: 100-41-4 ethylbenzene</th>
</tr>
</thead>
<tbody>
<tr>
<td>LC50/48h 16.2 mg/l (daphnia magna)</td>
</tr>
<tr>
<td>LC50/96h 80 mg/l (Fish acute toxicity study)</td>
</tr>
<tr>
<td>EC50/48h 4.75 mg/L (daphnia magna)</td>
</tr>
<tr>
<td>EC50/72h 5 mg/l (Alg)</td>
</tr>
</tbody>
</table>

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.

SECTION 14: Transport information

14.1 UN-Number

ADR, IMDG, IATA

UN1950

14.2 UN proper shipping name

ADR

1950 AEROSOLS
### Safety data sheet

**Trade name:** Fix Adhesive Aerosol

<table>
<thead>
<tr>
<th>IMDG</th>
<th>AEROSOLS</th>
<th>IMDG, IATA</th>
<th>AEROSOLS, flammable</th>
</tr>
</thead>
</table>

### 14.3 Transport hazard class(es)

- **ADR**
  - Class: 2
  - Label: 5F Gases.

- **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

- **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
  - **Transport category:** 2
  - **Tunnel restriction code:** D

- **IMDG**
  - **Limited quantities (LQ):** 1L
  - **Excepted quantities (EQ):** Code: E0
  - Not permitted as Excepted Quantity

- **UN "Model Regulation":** UN 1950 AEROSOLS, 2.1
SECTION 15: Regulatory information

- 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, 40

- 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
  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.

- 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
  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.