

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

Printing date 16.04.2013


Version number 2

Revision: 16.04.2013

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

- **1.1 Product identifier**
- **Trade name: Delton FS+ Pit & Fissure Sealant**
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the preparation** Dental sealing material
- **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@dentsply.com
- **Further information obtainable from:**
 - Departement Analytical Research / 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)

2 Hazards identification

- **2.1 Classification of the substance or mixture**
 - **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
Xi; Irritant
R36/37/38: Irritating to eyes, respiratory system and skin.
Xi; Sensitising
R43: May cause sensitisation by skin contact.
 - **Information concerning particular hazards for human and environment:**
The product has to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.
 - **Classification system:**
The classification is according to the latest editions of the EU-lists, and extended by company and literature data.
 - **2.2 Label elements**
 - **Labelling according to EU guidelines:**
The product has been classified and marked in accordance with EU Directives / Ordinance on Hazardous Materials
 - **Code letter and hazard designation of product:**
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Xi Irritant
- **Hazard-determining components of labelling:**
Dimethacrylat Resin mixture
 - **Risk phrases:**
36/37/38 Irritating to eyes, respiratory system and skin.
43 May cause sensitisation by skin contact.
 - **Safety phrases:**
23 Do not breathe gas/fumes/vapour/spray (appropriate wording to be specified by the manufacturer).

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- 24 Avoid contact with skin.
- 26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
- 37 Wear suitable gloves.
- 60 This material and its container must be disposed of as hazardous waste.

- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition/information on ingredients

- **3.2 Chemical characterization: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**

	Dimethacrylat Resin mixture ☒ Xi R36/37/38; ☒ Xi R43 ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335	25-50%
CAS: 7681-49-4 EINECS: 231-667-8	sodium fluoride ☒ T R25; ☒ Xi R36/38 R32 ⚠ Acute Tox. 3, H301; ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319	≤ 2.5%

- **Additional information** For the wording of the listed risk phrases refer to section 16.

4 First aid measures

- **4.1 Description of first aid measures**
- **After inhalation** 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.
- **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **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.

6 Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Wear protective clothing.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.

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- **6.3 Methods and material for containment and cleaning up:** 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.

7 Handling and storage

- **7.1 Precautions for safe handling** Observe normal care for working with chemicals.
- **Handling** Product is intended for dental use only.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage**
- **Requirements to be met by storerooms and receptacles:** Store only in the original receptacle.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Keep receptacle tightly sealed.
- **7.3 Specific end use(s)** No further relevant information available.

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:**

7681-49-4 sodium fluoride

WEL	Long-term value: 2.5 mg/m ³ as F
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- **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:** 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.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- **Material of gloves**

Natural rubber, NR

Recommended thickness of the material: ≥ 0.12 mm

Permeation: Level ≥ 1

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:**

Safety glasses



Tightly sealed goggles.

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

9 Physical and chemical properties

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

- **General Information**

- **Appearance:**

Form:

Pasty

Colour:

Different according to colouring

- **Odour:**

Characteristic

- **Odour threshold:**

Not determined.

- **pH-value:**

Not applicable.

- **Change in condition**

Melting point/Melting range:

undetermined

Boiling point/Boiling range:

undetermined

- **Flash point:**

Not applicable

- **Flammability (solid, gaseous)**

Not determined.

- **Ignition temperature:**

Decomposition temperature:

Not determined.

- **Self-igniting:**

Product is not selfigniting.

- **Danger of explosion:**

Product does not present an explosion hazard.

- **Explosion limits:**

Lower:

Not determined.

Upper:

Not determined.

- **Vapour pressure:**

Not applicable.

- **Density:**

Not determined

- **Relative density**

Not determined.

- **Vapour density**

Not applicable.

- **Evaporation rate**

Not applicable.

- **Solubility in / Miscibility with**

Water:

Insoluble

- **Partition coefficient (n-octanol/water):** Not determined.

- **Viscosity:**

dynamic:

Not applicable.

kinematic:

Not applicable.

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· Solvent content:	
Organic solvents:	0.0 %
· Solids content:	
	55.0 %
· 9.2 Other information	
	No further relevant information available.

10 Stability and reactivity

- **10.1 Reactivity**
- **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

11 Toxicological information

- **11.1 Information on toxicological effects**

- **Acute toxicity:**

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

7681-49-4 sodium fluoride

Oral	LD50	52 mg/kg (rat)
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- **Primary irritant effect:**

- **on the skin:**

Irritant to skin and mucous membranes.

The unpolymerized product may be irritant to the skin for susceptible persons.

- **on the eye:** Irritating effect.

- **Sensitization:**

Sensitization possible through skin contact.

Repeated or prolonged contact with the not polymerized product may cause sensitization for acrylates / methacrylates.

- **Additional toxicological information:**

The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.

Irritant

12 Ecological information

- **12.1 Toxicity**

- **Aquatic toxicity:**

7681-49-4 sodium fluoride

LC50/96h	>100 mg/l (fish)
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- **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.

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- **Additional ecological information:**
- **General notes:**
At present there are no ecotoxicological assessments.
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

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 dangerous substances

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

14 Transport information

- | | |
|---|-----------------|
| · 14.1 UN-Number | Void |
| · ADR, ADN, IMDG, IATA | Void |
| · 14.2 UN proper shipping name | Void |
| · ADR, ADN, IMDG, IATA | Void |
| · 14.3 Transport hazard class(es) | Void |
| · ADR, ADN, IMDG, IATA | Void |
| · Class | Void |
| · 14.4 Packing group | Void |
| · ADR, IMDG, IATA | Void |
| · 14.5 Environmental hazards: | |
| · Marine pollutant: | No |
| · 14.6 Special precautions for user | Not applicable. |
| · 14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | Not applicable. |

15 Regulatory information

- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

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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

- H301 Toxic if swallowed.
- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H319 Causes serious eye irritation.
- H335 May cause respiratory irritation.
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- R25 Toxic if swallowed.
- R32 Contact with acids liberates very toxic gas.
- R36/37/38 Irritating to eyes, respiratory system and skin.
- R36/38 Irritating to eyes and skin.
- R43 May cause sensitisation by skin contact.

- **Department issuing MSDS:** Analytical Research
- **Contact:** HotLine for urgent technical support: +49-7531-583-333
- *** Data compared to the previous version altered.**

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