

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 25.06.2013

Version number 5

Revision: 25.06.2013

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

- **1.1 Product identifier**
- **Trade name:** *Nupro Prophylaxis Pastes with Fluoride*
- **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** *Polishing paste*
- **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** *not applicable*
- **Information concerning particular hazards for human and environment:**
The product does not have 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:**
Observe the general safety regulations when handling chemicals
The product is not subject to identification regulations under EU Directives and the Ordinance on Hazardous Materials (German GefStoffV).
- **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:**

CAS: 56-81-5 EINECS: 200-289-5	glycerol substance with a Community workplace exposure limit	25-50%
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Trade name: Nupro Prophylaxis Pastes with Fluoride

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CAS: 7681-49-4 EINECS: 231-667-8 Index number: 009-004-00-7	sodium fluoride T R25; Xi R36/38 R32 Acute Tox. 3, H301; Skin Irrit. 2, H315; Eye Irrit. 2, H319	2.5-10%
CAS: 1344-09-8 EINECS: 215-687-4	Silicic acid, sodium salt Xi R36/37/38 Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	2.5-10%

· **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**
- **General information** No special measures required.
- **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.
- **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.
Use fire extinguishing methods suitable to surrounding conditions.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

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.
- **6.3 Methods and material for containment and cleaning up:** Pick up mechanically.
- **6.4 Reference to other sections**
No dangerous substances are released.
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**
No special measures required.
Observe normal care for working with chemicals.
- **Handling** Product is intended for dental use only.

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- **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:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.
- **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:**

56-81-5 glycerol

WEL	Long-term value: 10 mg/m ³
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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

The usual precautionary measures are to be adhered to when handling chemicals.

- **Respiratory protection:** Not necessary if room is well-ventilated.

Protection of hands:

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.

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

- **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: According to product specification

- **Odour:** Product specific

- **Odour threshold:** Not determined.

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· pH-value:	9-10
· Change in condition	
Melting point/Melting range:	undetermined
Boiling point/Boiling range:	undetermined
· Flash point:	Not applicable
· Flammability (solid, gaseous)	Not determined.
· Ignition temperature:	400 °C (Glycerol)
· Decomposition temperature:	Not determined.
· Self-igniting:	Product is not selfigniting.
· Danger of explosion:	Product does not present an explosion hazard.
· Explosion limits:	
Lower:	2.6 Vol % (Glycerol)
Upper:	11.3 Vol % (Glycerol)
· Vapour pressure at 20 °C:	23 hPa
· 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.
· Solvent content:	
Organic solvents:	30.0 %
Water:	12.0 %
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

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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)

- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**

The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.

When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

12 Ecological information

- **12.1 Toxicity**

- **Aquatic toxicity:**

7681-49-4 sodium fluoride		
LC50/96h	>100 mg/l	(fish)

- **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 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** Smaller quantities can be disposed of with household waste.

- **European waste catalogue**

18 01 07	chemicals other than those mentioned in 18 01 06
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- **Uncleaned packaging:**

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

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14 Transport information

· 14.1 UN-Number · ADR, ADN, IMDG, IATA	Void
· 14.2 UN proper shipping name · ADR, ADN, IMDG, IATA	Void
· 14.3 Transport hazard class(es) · ADR, ADN, IMDG, IATA · Class	Void
· 14.4 Packing group · 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.

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.

H302 Harmful if swallowed.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

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.

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

- **1.1 Product identifier**
- **Trade name:** Nupro Prophylaxis Pastes without Fluoride
- **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** Polishing paste
- **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** not applicable
- **Information concerning particular hazards for human and environment:**
The product does not have 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:**
Observe the general safety regulations when handling chemicals
The product is not subject to identification regulations under EU Directives and the Ordinance on Hazardous Materials (German GefStoffV).
- **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:**

CAS: 56-81-5 EINECS: 200-289-5	glycerol substance with a Community workplace exposure limit	25-50%
CAS: 1344-09-8 EINECS: 215-687-4	Silicic acid, sodium salt Xi R36/37/38 Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	2.5-10%

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· **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**
- **General information** No special measures required.
- **After inhalation** Void
- **After skin contact** Immediately rinse with water
- **After eye contact** Rinse opened eye for several minutes under running water.
- **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** Use fire extinguishing methods suitable to surrounding conditions.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

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.
- **6.3 Methods and material for containment and cleaning up:** Pick up mechanically.
- **6.4 Reference to other sections** No dangerous substances are released.

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:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.
- **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.

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· **8.1 Control parameters**

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

56-81-5 glycerol

WEL Long-term value: 10 mg/m³

· **Additional information:** The lists valid during the making were used as basis.

· **8.2 Exposure controls**

· **Personal protective equipment**

· **General protective and hygienic measures**

The usual precautionary measures are to be adhered to when handling chemicals.

· **Respiratory protection:** Not necessary if room is well-ventilated.

· **Protection of hands:**

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.

· **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

· **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: According to product specification

· **Odour:** Characteristic

· **pH-value at 20 °C:** 9.5

· **Change in condition**

Melting point/Melting range: undetermined

Boiling point/Boiling range: 100 °C

· **Flash point:** 160 °C (Glycerol)

· **Ignition temperature:** 400 °C (Glycerol)

· **Self-igniting:** Product is not selfigniting.

· **Danger of explosion:** Product does not present an explosion hazard.

· **Explosion limits:**

Lower: 2.6 Vol % (Glycerol)

Upper: 11.3 Vol % (Glycerol)

· **Vapour pressure at 20 °C:** 23 hPa

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· Density:	<i>Not determined</i>
· Solubility in / Miscibility with Water:	<i>Insoluble</i>
· Viscosity:	
dynamic:	<i>Not applicable.</i>
kinematic:	<i>Not applicable.</i>
· Solvent content:	
Organic solvents:	<i>30.0 %</i>
Water:	<i>12.0 %</i>
Solids content:	<i>58.0 %</i>
· 9.2 Other information	<i>No further relevant information available.</i>

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:**
- **Primary irritant effect:**
- **on the skin:** *No irritant effect.*
- **on the eye:** *No irritating effect.*
- **Sensitization:** *No sensitizing effects known.*
- **Additional toxicological information:**
The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.
When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

12 Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** *No further relevant information available.*
- **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.*

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· **12.6 Other adverse effects** No further relevant information available.

13 Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation** Smaller quantities can be disposed of with household waste.

· **European waste catalogue**

18 01 07	chemicals other than those mentioned in 18 01 06
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- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- | | |
|---|-----------------|
| · 14.1 UN-Number
· ADR, ADN, IMDG, IATA | Void |
| · 14.2 UN proper shipping name
· ADR, ADN, IMDG, IATA | Void |
| · 14.3 Transport hazard class(es)
· ADR, ADN, IMDG, IATA
· Class | Void |
| · 14.4 Packing group
· 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.

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**
- H302 Harmful if swallowed.
- H315 Causes skin irritation.
- H319 Causes serious eye irritation.

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H335 May cause respiratory irritation.

R36/37/38 Irritating to eyes, respiratory system and skin.

- **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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