

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 22.09.2016

Version number 7

Revision: 22.09.2016

SECTION 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**
- **Application of the substance / the mixture** Polishing paste
- **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**
Acute Tox. 4 H302 Harmful if swallowed.
Eye Irrit. 2 H319 Causes serious eye irritation.
- **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**



GHS07

- **Signal word** Warning
- **Hazard-determining components of labelling:**
sodium fluoride
Silicic acid, sodium salt
- **Hazard statements**
H302 Harmful if swallowed.
H319 Causes serious eye irritation.
- **Precautionary statements**

P280	Wear protective gloves/protective clothing/eye protection/face protection.
P264	Wash thoroughly after handling.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P301+P312	IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
P337+P313	If eye irritation persists: Get medical advice/attention.
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 1272/2008.

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- **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: 56-81-5 EINECS: 200-289-5	glycerol substance with a Community workplace exposure limit	25-50%
CAS: 7681-49-4 EINECS: 231-667-8	sodium fluoride ⚠ Acute Tox. 3, H301; ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319	2.5-<3%
CAS: 1344-09-8 EINECS: 215-687-4	Silicic acid, sodium salt ⚠ Eye Dam. 1, H318; ⚠ Acute Tox. 4, H302; Skin Irrit. 2, H315	2.5-<3%

- **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**
- **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**
Rinse out mouth and then drink plenty of water.
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.
- **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, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **For safety reasons unsuitable extinguishing agents** Water with full jet.
- **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.

SECTION 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.
Dispose contaminated material as waste according to item 13.
- **6.4 Reference to other sections**
See Section 7 for information on safe handling
See Section 8 for information on personal protection equipment.

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See Section 13 for disposal information.

SECTION 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.

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: 56-81-5 glycerol

WEL Long-term value: 10 mg/m³
CAS: 7681-49-4 sodium fluoride

WEL Long-term value: 2.5 mg/m³
as F

- **Regulatory information** WEL: 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**
Avoid contact with the eyes and skin.
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.

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SECTION 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.

· 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: 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:	Slightly soluble
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· Partition coefficient (n-octanol/water): Not determined.

· Viscosity:

dynamic:	Not applicable.
kinematic:	Not applicable.

· Solvent content:

Organic solvents:	30.0 %
· 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 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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SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Harmful if swallowed.

LD/LC50 values relevant for classification:

ATE (Acute Toxicity Estimates)

Oral	LD50	1878 mg/kg (rat)
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CAS: 56-81-5 glycerol

Oral	LD50	12600 mg/kg (rat)
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Dermal	LD50	> 18700 mg/kg (rabbit)
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CAS: 7681-49-4 sodium fluoride

Oral	LD50	52 mg/kg (rat)
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CAS: 1344-09-8 Silicic acid, sodium salt

Oral	LD50	1960 mg/kg (rat)
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Dermal	LD50	>4640 mg/kg (rabbit)
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Primary irritant effect:

• **Skin corrosion/irritation** Based on available data, the classification criteria are not met.

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** Based on available data, the classification criteria are not met.

• **STOT-repeated exposure** Based on available data, the classification criteria are not met.

• **Aspiration hazard** Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity:

CAS: 56-81-5 glycerol

LC50/24h	> 5000 mg/l (Fish acute toxicity study)
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EC50/24h	> 10000 mg/L (daphnia magna)
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CAS: 7681-49-4 sodium fluoride

LC50/96h	>100 mg/l (Fish acute toxicity study)
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CAS: 1344-09-8 Silicic acid, sodium salt

LC50/48h	378 mg/l (daphnia magna)
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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.

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.

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· 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 07	chemicals other than those mentioned in 18 01 06
HP 4	Irritant - skin irritation and eye damage
HP 6	Acute Toxicity

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

SECTION 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: | Not applicable. |
| · 14.6 Special precautions for user | Not applicable. |
| · 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| · UN "Model Regulation": | Void |

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.
- 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

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of the product is given in the DFU.

• **Relevant phrases**

H301 Toxic if swallowed.

H302 Harmful if swallowed.

H315 Causes skin irritation.

H318 Causes serious eye damage.

H319 Causes serious eye irritation.

• **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

Acute Tox. 3: Acute toxicity – Category 3

Acute Tox. 4: Acute toxicity – Category 4

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Dam. 1: Serious eye damage/eye irritation – Category 1

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

• *** Data compared to the previous version altered.**

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