

Safety Data Sheet

According to Regulation (EU) 2015/830

IMPORTANT

Read this MSDS before handling and disposing of this product and pass this information on to employees, customers and users of this product.

1. IDENTIFICATION

1.1 Product Identifier

Product Name	ProphyPLUS
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1.2 Relevant identified uses of the substance of mixture and uses advised against

Product Use	(SU22) professional uses: Public domain (administration, education, entertainment, services, craftsmen); (SU20) Health services;
Restricted Use	(SU21) Consumer Uses: Private households (=general public = consumers);
Description	Dental Product

1.3 Supplier of the Safety Data Sheet

Company Name	Perfection Plus Ltd
Company Address	6 Westwood Court, Brunel Road, Totton, Hants. SO40 3WX. UK
Company Phone No.	+44 (0) 2380 866 677
Website	www.perfectionplus.com
Telephone	0044 (0) 2380 866677
Email	Regulatory@perfectionplus.com
Email address of Competent Person	Regulatory@perfectionplus.com

1.4 Emergency telephone number


Emergency telephone number	0044 (0) 230 866 677 (8am – 5pm Monday to Friday)
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2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

2.1.2. Classification - EC 1272/2008	H302 - Acute Oral Toxicity Category 4 H315 – Skin Irritant Category 3 H320 – Eye irritant Category 2B
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2.2 Label Elements

Hazard Pictograms	
Signal Word	Warning
Hazard Statement	H302 - Acute Oral Toxicity Category 4 – Harmful if swallowed H315 – Skin Irritant Category 3 – Causes skin irritation H320 – Eye irritant Category 2B – Causes eye irritation
Precautionary Statement: Prevention	P264 – Wash thoroughly after handling P270- Do not eat, drink or smoke when using this product P280 - Wear protective gloves/protective clothing/eye protection/face protection.
Precautionary Statement: Response	P301+P312- IF SWALLOWED: Call a POISON CENTRE or doctor/physician IF you feel unwell. P302+P352 – IF ON SKIN: Wash with plenty of soap and water. P305+P351+P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P321 – See section 4 for specific treatment. P330 – Rinse Mouth. P332+P313 – If skin irritation occurs: Get medical advice/attention. P337+P313 – if eye irritation persists: Get medical advice/attention.

	P362 – Take of contaminated clothing and wash before reuse. P501 – Dispose of contents and container in accordance with local and national regulations.
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2.3 Other hazards

Other hazards	None known.
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2.4 Unknown acute toxicity

	No data available.
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Further information

Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of regulation (EC) No 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

EC 1272/2008

Chemical Name	Index No.	CAS No.	EC No.	REACH Registration Number	CONC. (%w/w)	Classification
Sodium Fluoride		7681-49-4	231-667-8		1-10%	Acute Oral Tox. 3: H301 Skin Irrit. 2: H315 Eye Irrit. 2: H319

4. FIRST AID MEASURES

4.1 Description of first aid measures

Inhalation	Not applicable
Eye Contact	Immediately flush victim's eye with large quantities of water for several minutes, holding the eyelids apart. Get medical attention if irritation persists.
Skin contact	Remove contaminated clothing. Wash skin thoroughly with soap and water. If irritation develops, get medical attention. Wash clothes before reuse.
Ingestion	If more than the normal amount used for cleaning is swallowed, drink 1-2 glasses of milk. Get immediate medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Not expected to present a significant hazard under anticipated conditions or normal use.

Inhalation	Not applicable.
Eye Contact	May cause irritation to eyes.
Skin contact	May cause irritation to skin.
Ingestion	May be harmful if swallowed.

4.3 Indication of any immediate medical attention and special treatment needed

Inhalation	Seek medical attention if irritation or symptoms persist.
Eye Contact	Seek medical attention if irritation or symptoms persist.
Skin contact	Seek medical attention if irritation or symptoms persist.
Ingestion	Seek medical attention in case of high quantities of ingestion.

General information

	Note to physicians (Treatment, Testing and Monitoring): Treat symptomatically.
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5. FIRE FIGHTING MEASURES

5.1 Extinguishing media

	Use Chemical Foam, CO2, Dry Chemical Powder, or Water spray. NOTE: Water may be ineffective in extinguishing the fire.
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5.2 Special hazards arising from the substance or mixture

	Not determined.
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5.3 Advice for firefighters

	Wear suitable respiratory and protective equipment when necessary.
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6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

	Remove all ignition sources such as open flames, spark producing equipment, pilot lights etc. Avoid contact with skin, eyes or clothing. Wear appropriate protective clothing as described in Section 8.
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6.2 Environmental precautions

	Prevent entry into sewers and waterways. Report releases as required by local, state and national authorities. Avoid contact with skin, eyes and clothing. Wear appropriate protective clothing as described in Section 8.
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6.3 Methods and material for containment and cleaning up

	Clean up with absorbent material and remove residue with alcohol damp wipe. Rinse spill area with water. Use non-sparking tools and equipment.
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6.4 Reference to other sections

	See section 13 for disposal information. See section 8 for exposure controls/personal protection.
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7. HANDLING AND STORAGE

7.1 Precautions for safe handling

	Avoid contact with eyes, skin and clothing. Wear protective clothing and equipment as described in Section 8. Wash thoroughly after handling. Keep away from heat, sparks, flames and other sources of ignition.
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7.2 Conditions for safe storage, including any incompatibilities

	Keep in a cool, dry, well-ventilated area away from heat, direct sunlight and all sources of ignition. Store away from incompatible materials. Keep containers tightly closed to prevent contamination.
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7.3 Specific end use(S)

	No specific end use other than that mentioned in Section 1.2.
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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

	No additional information available.
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8.2 Exposure controls

	 
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8.2.1 Appropriate engineering controls

	None required under normal product handling conditions.
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8.2.2 Individual protection measures

Eye/face protection	Chemical safety goggles should be worn if needed to avoid eye contact.
Specific Skin protection	Wear impervious gloves such as natural rubber or neoprene if needed to avoid skin contact. Consult glove supplier for thickness and breakthrough times.
Specific Respiratory protection	None should be needed under normal use. If exposure limits are exceeded an approved respirator or supplied air respirator appropriate should be used. Respirator selection and use should be based on contaminant type, form and concentration. Follow applicable regulations and good Industrial Hygiene practice.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state	Paste	Relative density	1.50 to 2.00g/cc @25°C/77°F
Appearance	Uniform Paste	Melting point	Not determined
Odour	Characteristic	Initial boiling point	Not determined
Odour threshold	No data available	Solubility in water	Partially soluble
pH	7.50 - 9.50	Other data	Not applicable

9.2. Other information

Conductivity	No data available
Surface tension	No data available
Gas group	No data available
Benzene content	No data available
Lead content	No data available
VOC (Volatile organic compounds)	No data available

10. STABILITY AND REACTIVITY
10.1 Reactivity

	Stable at ambient temperature and under normal conditions of use.
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10.2 Chemical stability

	Stable at standard temperature and pressure.
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10.3 Possibility of hazardous reactions

	None known.
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10.4 Conditions to avoid

	Keep away from heat, sparks, incompatible materials, flames and other sources of ignition.
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10.5 Incompatible materials

	High temperatures, strong oxidising agents. Keep away from sunlight and open flames.
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10.6 Hazardous decomposition products

	None known.
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11. TOXICOLOGICAL INFORMATION
11.1 Information on toxicological effects

Sodium Fluoride	Acute Oral Toxicity Rat LD50: 52 mg/kg	Acute Dermal Toxicity Rat LD50: 175 mg/kg
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12. ECOLOGICAL INFORMATION
12.1 Toxicity

Sodium Fluoride	Oncorhynchus Mykiss – LC50 static - 96h: 38-68 mg/L Lepomis macrochirus – LC50 semi static – 96h: 830 mg/L Pimephales promelas – LC50 semi static – 96h: 180mg/L Lepomis macrochirus – LC50 semi static – 96h: 530mg/L Pseudokirchneriella subcapitata – EC50 – 96h: 272 mg/L Desmodemus subspicatus – EC50 static- 72h: 850 mg/L Daphnia magna – EC50 static – 48h: 98mg/L Daphnia magna – EC50 - 48h: 338 mg/l
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12.2 Persistence and degradability

	No data is available on this product.
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12.3 Bio accumulative potential

	No data is available on this product.
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12.4 Mobility in soil

	No data is available on this product.
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12.5 Results of PBT and vPvB assessment

	No data is available on this product.
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12.6 Other adverse effects

	No data is available on this product.
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13. DISPOSAL CONSIDERATIONS
13.1 Waste treatment methods

Regulations	Dispose of in compliance with all local and national regulations.
Households	Product used in household may be disposed of in refuse or sewer.
Properties (Physical/Chemical) Affecting disposal	None currently known

Waste treatment recommendations	Dispose in accordance with national and local regulations.
US EPA	This material is not considered a hazardous waste under the United States Resource Conservation and Recovery Act when disposed.

General information

	18 WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (except kitchen and restaurant wastes not arising from immediate health care). 18 01 wastes from natal care, diagnosis, treatment or prevention of disease in humans. 18 01 06 chemicals consisting of or containing dangerous substances.
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Disposal Methods

	Do not empty in to drains. For disposal within the EC, the appropriate code according to the European Waste Catalogue (EWC) should be used.
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Disposal of packaging

	Do NOT reuse empty canisters. Empty containers can be sent for disposal or recycling.
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14. TRANSPORT INFORMATION
14.1 UN number

	This product is not classified as dangerous for carriage.
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14.2 UN proper shipping name

	This product is not classified as dangerous for carriage.
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14.3 Transport hazard class(es)

	This product is not classified as dangerous for carriage.
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14.4 Packing group

	This product is not classified as dangerous for carriage.
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14.5 Environmental hazards

	This product is not classified as dangerous for carriage.
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14.6 Special precautions for user

	This product is not classified as dangerous for carriage.
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14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

	This product is not classified as dangerous for carriage.
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15. REGULATORY INFORMATION
15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Regulations	COMMISSION REGULATION (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.
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15.2 Chemical Safety Assessment

	No data available.
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16. OTHER INFORMATION
HMIS Hazard Rating

Health: 1	Flammability: 0	Reactivity: 0
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Other information

Text of Hazard Statements in Section 3	H301 – Acute Oral Toxicity, Category 3 H305 – Acute Oral Toxicity, Category 4 H315 – Skin corrosion/irritation, Category 2 H319 – Serious eye damage/eye irritation, Category 2A H320 – Serious eye damage/eye irritation, Category 2B
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Further information

This product is manufactured by Dental Technologies, Inc., 6901 N. Hamlin Avenue, Lincolnwood, IL 60712, USA and the contained SDS information is supplied by them.

The information used in this SDS is believed to be correct however, the information is provided without any warranty, neither expressed nor implied, regarding its correctness.

The conditions or methods of handling, storage, use alone or in combination with other products, or disposal of the product are beyond our control and may be beyond our knowledge.

For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the product.

This SDS was prepared and is to be used only for this product. If the product is used as a component in or in combination with another product, this SDS information may not be applicable.