

Safety Data Sheet

IMPORTANT

Read this SDS 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	Prophy+ Polishing Bristle Brush RA and Screw in
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1.2 Relevant identified uses of the substance of mixture and uses advised against

Product Use	Professional dental use only.
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 Label Elements

Hazard Statement	No significant
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2.2 Other hazards

Other hazards	PBT. vPvB. Not applicable.
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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

3.1 Substances

Component 1: Fill material

Bristle Filament: Natural bristle white

Processed to standard GB8211-87 and boiled for more than 2 hours. Certified by the relevant Commodity Inspection Bureau.

100% Natural bristle is animal (pig, hog or boar) hair composed primarily of the protein Keratin which contains a disulphide bond with trace elements of hydrogen, nitrogen and oxygen. These trace elements are non-hazardous or non-hazardous at the levels of inclusion.

Component 2: Brass Ferrule

CuZn30 – bright nickel plating

Typical values, can vary slightly

Chemical Analysis		
Chemical Name	CAS No.	CONC. (%w/w)
Copper Cu	7440-50-8	69.00-71.00
Tin Sn	7440-31-5	0.00 – 0.02
Iron Fe	7439-89-6	0.00-0.05

Aluminium Al	7429-90-5	0.00-0.02
Zinc Zn	7440-66-6	Balance
Nickel Ni	7440-02-0	0.00 – 0.10
Lead Pb	7439-92-1	0.00-0.02

Surface Treatment: Bright Nickel-Plated (Ni). 2 treatments are used, either:

1. e-plate Ni (Bright) (electrodeposited Nickel Bright) composition:

Material	CAS Number
0.0-0.1% Carbon(C)	7440-44-0
0.0-0.1% Nitrogen (N)	7727-37-9
0.05-0.1% Sulphur (S)	7704-34-9
Balance 99.825% Nickel (Ni)	7740-02-0

2. Autocatalytic Nickel-Phosphorous coatings which has the following composition:

Material	CAS Number
90.75% Nickel (Ni)	7740-02-0
9.25% Phosphorous (P)	7723-14-0

This product may also contain trace elements, which are non-hazardous or non-hazardous at the levels of inclusion.

Component 3: Brass RA (Right Angle) and Screw in Shank

Brass Shank CuZn39PB3 or similar, bright nickel plating.

Typical values, can vary slightly

Chemical Analysis		
Chemical Name	CAS No.	CONC. (%w/w)
Copper Cu	7440-50-8	57.0 -59.0
Cadmium Cd	7440-43-9	Max 0.0075
Iron Fe	7439-89-6	0.1 – 0.3
Lead Pb	7439-92-1	2.5 – 3.5
Nickel Ni	7440-02-0	0.04 – 0.3
Tin Sn	7440-31-5	0.2 – 0.3
Zinc Zn	7440-66-6	Balance
Aluminium Al	7429-90-5	Max 0.05

Surface Treatment: Bright Nickel-Plated (Ni). 2 treatments are used, either:

1. e-plate Ni (Bright) (electrodeposited Nickel Bright) composition:

Material	CAS Number
0-0.1% Carbon(C)	7440-44-0
0.0-0.1% Nitrogen (N)	7727-37-9
0.05-0.1% Sulphur – S	7704-34-9
Balance 99.825% Nickel (Ni)	7740-02-0

2. Autocatalytic Nickel-Phosphorous coatings which has the following composition:

Material	CAS Number
90.75% Nickel (Ni)	7740-02-0
9.25% Phosphorous (P)	7723-14-0

This material may also contain trace elements, which are non-hazardous or non-hazardous at the levels of inclusion.

Material hardness: Vickers : HV151, megapascal 510MPa.

Component 4: Brass Ring

Brass Ring CuZn37.

Typical values, can vary slightly

Chemical Analysis		
Chemical Name	CAS No.	CONC. (%w/w)
Copper (Cu)	7440-50-8	62.00 - 64.00
Tin (Sn)	7440-31-5	0.00 – 0.01
Iron (Fe)	7439-89-6	0.00 – 0.01
Aluminium (Al)	7429-90-5	0.00-0.05
Zinc (Zn)	7440-66-6	Balance
Nickel (Ni)	7440-02-0	0.00 – 0.30
Lead (Pb)	7439-92-1	0.00 - 0.01

This material may also contain trace elements, which are non-hazardous or non-hazardous at the levels of inclusion.

4. FIRST AID MEASURES

4.1 Description of first aid measures

Inhalation	Not applicable
Eye Contact	In case of accident or accidental contact with the moving instrument call a physician.
Skin contact	Do not use in case of specific allergy. In case of permanent irritation, call physician
Ingestion	Accidental ingestion is not harmful, consult a physician if necessary.

4.2 Most important symptoms and effects, both acute and delayed

Inhalation	No data available
Eye Contact	No data available
Skin contact	No data available
Ingestion	No data available

4.3 Indication of any immediate medical attention and special treatment needed

Inhalation	No data available
Eye Contact	No data available
Skin contact	No data available
Ingestion	No data available

General information

	If you feel unwell, seek medical advice (show the label where possible).
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5. FIRE FIGHTING MEASURES

Component 1

5.1 Extinguishing media

	Water spray, alcohol resistant foam, dry chemical, carbon dioxide.
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5.2 Special hazards arising from the substance or mixture

	Not applicable
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5.3 Advice for firefighters

	Not applicable
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5.4 Reaction of fire

	Combustible
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Component 2, 3 and 4

4.1 Extinguishing media

	Water spray, dry chemical, carbon dioxide.
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4.2 Special hazards arising from the substance or mixture

	Not applicable
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4.3 Advice for firefighters

	Not applicable
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5. ACCIDENTAL RELEASE MEASURES

5.1 Personal precautions, protective equipment and emergency procedures

	Used rotary instruments should be considered as contaminated and appropriate handling precautions should be taken following a clinical procedure and during disposal. Gloves, eye protection and a mask should be worn.
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5.2 Environmental precautions

	Not applicable
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5.3 Methods and material for containment and cleaning up

	Sweep up to prevent slipping hazard.
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5.4 Reference to other sections

	See section 13 for disposal information.
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6. HANDLING AND STORAGE
6.1 Precautions for safe handling

	Store at room temperature away from light. Avoid temperature >70°C keep in original sealed polythene sleeves to prevent moth damage.
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6.2 Conditions for safe storage, including any incompatibilities

	None known.
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6.3 Specific end use(S)

	For professional use in dentistry only.
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7. EXPOSURE CONTROLS/PERSONAL PROTECTION
7.1 Control parameters
7.2 Exposure controls

Provide adequate ventilation.

	
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7.2.1 Appropriate engineering controls

	Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday
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7.2.2 Individual protection measures

Eye/face protection	Wear eye / face protection equipment. Safety glasses with side-shields, conforming to EN 166.
Skin protection – Hand protection	Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. For permanent contact in work areas without heightened risk of injury (e.g. laboratory) gloves made of the following material are suitable: PVC, neoprene, rubber. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.
Respiratory protection	Not applicable.

7.2.3 Environmental exposure controls

	Not applicable.
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This product should be used in conjunction with rotary handpieces that conform with ISO 14457.

8. PHYSICAL AND CHEMICAL PROPERTIES
9.1. Information on basic physical and chemical properties
Component 1-Bristle

Appearance	Bleached white bristle	pH	Neutral
Animal	Hog, pig or boar	Boiling point	Not applicable
Part of animal used	Hair from back	Melting Point	Not applicable

Solubility in water	Insoluble	Odour	Mild
Evaporation rate	Not applicable	Eventual declared toxicity	None

Disinfection and veterinary certified: By chief veterinarian of relevant regional Import and Export Inspection Bureau.

Sterilisation: All component bristle is supplied boiled and is certified as having been disinfected by boiling at 100°C for not less than 2 hours.

Component 2, 3 and 4 Brass elements

Appearance	Solid	Density	Not applicable
Colour	Natural bright metallic	Solubility in water	Insoluble
Odour	None	Evaporation rate	Not applicable

9. STABILITY AND REACTIVITY

9.1 Reactivity

	No data available.
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9.2 Chemical stability

	Stable under normal temperature under recommended storage conditions.
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9.3 Possibility of hazardous reactions

	No data available.
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9.4 Conditions to avoid

	Heating above 340°C.
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9.5 Incompatible materials

	Strong acids, oxidising agents
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9.6 Hazardous decomposition products

	Decomposition will not occur
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9.7 Hazardous Polymerisation

	Polymerisation will not occur
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10. TOXICOLOGICAL INFORMATION

10.1 Information on toxicological effects

Acute toxicity	No data available.
Skin corrosion/irritation	No data available.
Serious eye damage/irritation	No data available.
Respiratory of skin sensitisation	No data available.
Germ cell mutagenicity	No data available.
Carcinogenicity	No data available.
Reproductive toxicity	No data available.
STOT-single exposure	No data available.
STOT-repeated exposure	No data available.
Aspiration hazard	No data available.
Repeated or prolonged exposure	No data available.

11.1.4 Toxicological Information

	No specific data available to this product in its moulded state.
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12. ECOLOGICAL INFORMATION

12.1 Toxicity

	No data available
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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

	Used rotary instruments should be considered as contaminated and appropriate handling precautions should be taken following a clinical procedure and during disposal. Gloves, eye protection and a mask should be worn. Handling, storage, transportation, and disposal are generally performed similarly to those of other biological wastes designated by the national or local government regulations. Incinerate or landfill in compliance with local and national regulations.
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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

	For disposal within the EC, the appropriate code according to the European Waste Catalogue (EWC) should be used.
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14. TRANSPORT INFORMATION

No specific instruction.

14.1 UN number

	n/a
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14.2 UN proper shipping name

	n/a
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14.3 Environmental hazards

Environmental hazards	No
Marine pollutant	No

14.4 Special precautions for user

	Read safety instructions, SDS and emergency procedures before handling. The product should be transported in containers to avoid damage or leakage. Keep containers dry.
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14.5 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

	No data available.
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15. REGULATORY INFORMATION
15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Regulations	These instruments are considered manufactured 'articles' and as such are exempt from Safety Data Sheet requirements. These products are considered non-hazardous when used according to accepted practices for the intended use. As a courtesy to our customers this document is to provide basic guidance for safe handling, use, storage, transportation and disposal. The information is not to be considered a warranty or detailed quality specification and relates only to the specific instrument and materials designated to them.
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15.2 Chemical Safety Assessment

	No data available.
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16. OTHER INFORMATION

Other information

Articles as defined in OSHA Hazard Communication Standard, Section 1910.1200. These instruments are considered manufactured "articles" and, as such are exempt from Material Safety Data Sheet requirements. These products are considered non-hazardous when used according to accepted practices for the intended use. As a courtesy to our customers this document is to provide basic guidance for safe handling, use, storage, transportation, and disposal. The information is not to be considered a warranty or detailed quality specification and relates only to the specific instrument and materials designated herein.

Further information

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.

This SDS is relevant for large quantities of product, the instructions for safe use of quantities typically used during a normal procedure is as referenced in the Instructions for Use.

The conditions or methods for handling, storage, lone use and/or in combination with other products and disposal are beyond our control.

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.