

MATERIAL SPECIFICATION AND SAFETY DATA

Product : PRB106, 110, 410, PRN010, 012, 030
Classification : Class 2a Medical Device

Schedule of Product (Ref):

JC/WNRA	JUNIOR CUP WHITE NYLON RA
JC/WNSC	JUNIOR CUP WHITE NYLON SCREW
JC/BBRA	JUNIOR CUP BLACK BRISTLE RA
JC/BBSC	JUNIOR CUP BLACK BRISTLE SCREW
JC/WBRA	JUNIOR CUP WHITE BRISLTE RA
JC/WBSC	JUNIOR CUP WHITE BRISTLE SCREW
JC/WGHRA	JUNIOR CUP WHITE GOAT HAIR RA
JC/HHRA	JUNIOR CUP WHITE HORSE HAIR RA
JC/PKNRA	JUNIOR CUP PINK NYLON RA
JC/PUNRA	JUNIOR CUP PURPLE NYLON RA
JC/PBNRA	JUNIOR CUP DARK BLUE NYLON RA
JC/PKNSC	JUNIOR CUP PINK NYLON SC
JC/PUNSC	JUNIOR CUP PURPLE NYLON SC
JC/PBNSC	JUNIOR CUP DARK BLUE NYLON SC
JC/WNGRA	JUNIOR CUP WHITE NYLON RA
JC/WNGSC	JUNIOR CUP WHITE NYLON SC

Description:

The Dental surgeon or Hygienist uses PRB106, 110, 410, PRN010, 012, 030 for the Prophy cleaning or polishing of natural teeth and filled surfaces in the mouth. They are generally 2-component products filled in a variety of manmade and natural materials including horsehair, black bristle, goat hair, white bristle and nylon.

Standard Packaging: Pack of 100 pieces.

Manufacturer:

Manufacturer/supplier: Made for UnoDent Ltd. Tel: 01376 500582
Address: 10 Perry Way, Witham, Essex Fax: 01376 500581
CM8 3SX, UK
Information sector: Technical Department Tel: 01376 500582
Emergency information: Technical Department
Emergency e-mail: info@unodent.com

Component 1

Metal Shank (Brass) RA

Ref: CTP003B

Description:

Turned and fine ground mandrels made from free cutting brass rod JIS H3250 C3604 BD, JIS H3250 C3604 or similar grade specification with RA shanks produced to conform with ISO1797: 1995 parts 1&2

Raw Material Composition:

Chemical Analysis %

COMPOUNDS	%
Cu	57.0 – 61.0 %
Pb	1.8 – 3.7 %
Fe	< 0.5 %
Sn + Fe	< 1.2 %
Zn	Remainder

Surface Treatment:

Bright Nickel Plated Nickel (Ni) Test Result 99.97%

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

Physical data:

Physical state: Solid
Colour: Natural bright metallic
Odour: None
Evaporation rate: Not applicable
Specific gravity: Not applicable
Solubility in water: Insoluble

Material Safety Data Sheet:

Metal Shank (Brass) RA

Ref: CTP003B

Stability and reactivity:

Chemical stability: Stable at normal temperature and storage conditions.

Incompatibility with other materials: None reasonable or foreseeable

Hazardous decomposition products: Decomposition will not occur

Hazardous polymerisation: Polymerisation will not occur.

Handling and Storage:

There are no specific handling requirements, store in clean dry conditions at room temperature.

Toxicology:

There is no toxicological data specific to this product.

Waste Disposal:

Waste is not harmful. The handling, storage, transportation and disposal are generally performed similarly to those of other general wastes designated by the nation or local government. Do not wash off with water or flush to drains because material is principally non-biodegradable.

This product may be Incinerated or landfill in compliance with local and national regulations. Recycling is recommended.

Fire and explosion data:

Flash point (method): Not applicable
Flash ignition temp: Not applicable,
Extinguishing media: Water, carbon dioxide foam, dry chemicals.
Special firefighting instructions: None

Health hazard information:

Brass in solid wire form is not hazardous to health.

Ingestion: Not a probable route of exposure
Inhalation: Not respiratory

Hazardous reactivity:

Stability: Stable
Conditions to avoid: Heating above 340°C
Incompatibility: Strong acids, bases and oxidising agents.

Component: 2**Junior Cup Ferrule****Ref: CTP001A****Description:**

The component part Cup Ferrule is a metal pressing composed of brass CuZn30 and surface treatment bright nickel-plated.

Raw Material Composition Ref: CTP001A

Copper:	0.00 – 71.00 %
Tin:	0.00 – 0.10 %
Iron:	0.00 – 0.05 %
Aluminium:	0.00 – 0.02 %
Zinc:	0.00 – 31.00 %
Nickel:	0.00 – 0.30 %
Lead:	0.00 – 0.05 %

Surface Treatment:

Bright Nickel Plated Nickel (Ni) Test Result 99.97%, 1.0 – 2.0 microns.

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

Physical data:

Physical state:	Solid
Colour:	Natural bright metallic
Odour:	None
Evaporation rate:	Not applicable
Specific gravity:	Not applicable
Solubility in water:	Insoluble
Hardness:	HV 080

Material Safety Data Sheet:**Junior Cup Ferrule****Ref: CTP001A****Stability and reactivity:**

Chemical stability: Stable at normal temperature and storage conditions.

Incompatibility with other materials: None reasonable or foreseeable

Hazardous decomposition products: Decomposition will not occur

Hazardous polymerisation: Polymerisation will not occur.

Handling and Storage:

There are no specific handling requirements, store in clean dry conditions at room temperature.

Toxicology:

There is no toxicological data specific to this product.

Waste Disposal:

Waste is not harmful. The handling, storage, transportation and disposal are generally performed similarly to those of other general wastes designated by the nation or local government. Do not wash off with water or flush to drains because material is principally non-biodegradable.

This product may be incinerated or landfill in compliance with local and national regulations. Recycling is recommended.

Fire and explosion data:

Flash point (method): Not applicable

Flash ignition temp: Not applicable,

Extinguishing media: Water, carbon dioxide foam, dry chemicals.

Special firefighting instructions: None

Health hazard information:

Brass in solid wire form is not hazardous to health.

Ingestion: Not a probable route of exposure

Inhalation: Not respiratory

Hazardous reactivity:

Stability: Stable

Conditions to avoid: Heating above 340°C

Incompatibility: Strong acids, bases and oxidising agents.

Component: 3
Junior Ring
Ref: CTP002

Description:

The component part Junior Ring is a metal pressing composed of brass CuZn37

Raw Material Composition Ref:
CTP002

Copper:	63.69 %
Iron:	0.02 %
Zinc:	Rem
Lead:	0.010 %

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

Physical data:

Physical state:	Solid
Colour:	Natural metallic
Odour:	None
Evaporation rate:	Not applicable
Specific gravity:	Not applicable
Solubility in water:	Insoluble
Hardness:	HV 174.0 – 179.0

Health hazard information:

Components not considered hazardous to health.

Ingestion:	Accidental ingestion is not harmful or a probable route of exposure
Inhalation:	Not respiratory
Allergy:	Low risk from transient use.

Hazardous reactivity:

Stability:	Stable
Incompatibility:	Strong acids, bases oxidising agents.

First aid measures (in case of):

Inhalation:	There are no poisoning risks.
Skin contact:	Do not use in case of a specific allergy. In case of permanent irritation, call for physician
Contact with eyes:	In case of accident or accidental contact with the moving instrument call for physician.

Fire and explosion data:

Extinguishing media:	Atomised water jet, carbon dioxide foam, dry chemicals
Special firefighting instructions:	None

Accidental dispersion:

May be swept up or mechanically collected.

Handling and Storage:

Store dry at room temperature away from light. Avoid temperature > 70°

Disposal procedures:

Aquatic toxicity: Very low toxicity
Spill or leak: Sweep up to prevent slipping hazard
Waste disposal: Incinerate or landfill in compliance with federal, state & local Regulations. Recycling is recommended.

Transportation:

The product should be transported in original containers to avoid damage or Leakage. Keep containers dry.

MEDICAL DEVICES DIRECTIVE 93/42/EEC**MATERIAL DATA SHEET****Material description:**

Nylon filament.

Specification:

Chemical name: Polyhexamethylene Dodecanamide (nylon)
CAS No. 26098-55-5
Less than 1% colorants

Physical data:

Melting point: 208-215°C
Boiling point: Not applicable
Solubility in water: Insoluble
Evaporation rate: Not applicable
Specific gravity: 1.05-1.07

Fire and explosion data:

Flash point (method): Not applicable
Flash ignition temp: 400°C (ASTM D1929)
Extinguishing media: Water, carbon dioxide foam, dry chemicals
Special firefighting instructions: None

Health hazard information:

Nylon is not a hazardous material.

Ingestion: Not a probable route of exposure
Inhalation: Not respiratory

Hazardous reactivity:

Stability: Stable
Conditions to avoid: Heating above 340°C
Incompatibility: Strong acids, bases oxidising agents
Decomposition products: Carbon monoxide, ammonia, aldehydes

Disposal procedures:

Aquatic toxicity:	Very low toxicity
Spill or leak:	Sweep up to prevent slipping hazard
Waste disposal:	Incinerate or landfill in compliance with federal state & local regulations

Special protection information:

Ventilation:	Local exhaust at processing equipment to keep particulate below 15mg/m ³ (OSHA limit for particulates not otherwise regulated)
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Personal protection equipment:

Eyes:	Safety glasses
Gloves:	None under normal processing
Respirator:	Not applicable

Component (fill material):**Material description:**

Natural bristle (Black and White).

Specification:

Processed to standard GB8211-87 and boiled for not less than 2 hours. Certified by the relevant Commodity Inspection Bureau.

Composition:

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

Physical data:

Colour:	Bleached white, black, spotty, grey and natural white.
Kind of animal:	Hog, pig or boar.
Part of animal used:	Hair from back.
PH:	Neutral.
Physical state:	Solid
Melting point:	Not applicable
Boiling point:	Not applicable
Solubility in water:	Insoluble
Evaporation rate:	Not applicable
Odour:	Mild
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 at least 2 Hours.

Handling and Storage:

Store dry at room temperature away from light. Avoid temperature > 70° keep in original sealed polythene sleeves to prevent moth damage

Health hazard information:

Non-hazardous to health – hair derived from pigs which on inspection were certified to be healthy before and after slaughter, originated from non-epizootic area and when tested no evidence of B.Anthraces was found.

Ingestion: Accidental ingestion is not harmful or a probable route of exposure
Inhalation: Not respiratory
Allergy: Low risk from transient use.

Hazardous reactivity:

Stability: Stable
Incompatibility: Strong acids, bases oxidising agents

First aid measures (in case of):

Inhalation: There are no poisoning risks.
Skin contact: Do not use in case of a specific allergy.
In case of permanent irritation, call for physician
Contact with eyes: In case of accident or accidental contact with the moving instrument call for physician.

Fire and explosion data:

Reaction of fire: Combustible.
Extinguishing media: Atomised water jet, carbon dioxide foam, dry chemicals
Special firefighting instructions: None

Accidental dispersion:

May be swept up or mechanically collected.

Disposal procedures:

Aquatic toxicity: Very low toxicity
Spill or leak: Sweep up to prevent slipping hazard
Waste disposal: Incinerate or landfill in compliance with local Regulations. Recycling is recommended.

Component (fill material):**Material description:**

Natural Horsehair

Specification:

Processed to standard GB8211-87 and boiled for not less than 4 hours. Certified by the relevant Commodity Inspection Bureau.

Composition:

100 % Natural Horsehair is animal (Horse) hair primarily composed of the protein Keratin which contains a disulphide bond (two atoms of sulphur) with trace elements of hydrogen,

oxygen, and nitrogen. These trace elements are non-hazardous or non-hazardous at the levels of inclusion.

Physical data:

Colour:	Natural white or black.
Kind of animal:	Horse.
Part of animal used:	Hair from back, mane or tail.
PH:	Neutral.
Physical state:	Solid
Melting point:	Not applicable
Boiling point:	Not applicable
Solubility in water:	Insoluble
Evaporation rate:	Not applicable
Odour:	Mild
Eventual declared toxicity:	None.

Disinfection and veterinary certified:

By chief veterinarian of relevant regional Import and Export Inspection Bureau .

Sterilisation:

All component bristle and hair is supplied boiled and is certified as having been disinfected by boiling at 100°C for at least 4 Hours.

Handling and Storage:

Store dry at room temperature away from light. Avoid temperature > 70° keep in original sealed polythene sleeves to prevent moth damage

Health hazard information:

Non hazardous to health – hair derived from horses which on inspection were certified to be healthy before and after slaughter, originated from non-epizootic area and when tested no evidence of B.Anthraces was found.

Ingestion:	Accidental ingestion is not harmful or a probable route of exposure
Inhalation:	Not respiratory
Allergy:	Low risk from transient use.

Hazardous reactivity:

Stability:	Stable
Incompatibility:	Strong acids, bases oxidising agents

First aid measures (in case of):

Inhalation:	There are no poisoning risks.
Skin contact:	Do not use in case of a specific allergy. In case of permanent irritation, call for Physician
Contact with eyes:	In case of accident or accidental contact with the moving instrument call for physician.

Fire and explosion data:

Reaction of fire:	Combustible.
Extinguishing media:	Atomised water jet, carbon dioxide foam, and dry chemicals
Special firefighting instructions:	None

Accidental dispersion:

May be swept up or mechanically collected.

Disposal procedures:

Aquatic toxicity: Very low toxicity
Spill or leak: Sweep up to prevent slipping hazard
Waste disposal: Incinerate or landfill in compliance with local Regulations. Recycling is recommended.

MATERIAL DATA SHEET**Component (fill material):****Material description:**

Natural Goat hair

Specification:

Processed to standard GB8211-87 and boiled for not less than 4 hours. Inspection by the relevant Commodity Inspection Bureau.

Composition:

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

Physical data:

Colour: Natural white or grey.
Kind of animal: Goat.
Part of animal used: Hair from back.
PH: Neutral.
Physical state: Solid
Melting point: Not applicable
Boiling point: Not applicable
Solubility in water: Insoluble
Evaporation rate: Not applicable
Odour: Mild
Eventual declared toxicity: None

Disinfection and veterinary certified:

By chief veterinarian of relevant regional Import and Export Inspection Bureau.

Sterilisation:

All component bristle and hair is supplied boiled and is certified as having been disinfected by boiling at 100°C for at least 4 Hours.

Handling and Storage:

Store dry at room temperature away from light. Avoid temperature > 70°. Keep in original sealed polythene sleeves to prevent moth damage.

Health hazard information:

Non-hazardous to health – hair derived from goats which on inspection were certified to be healthy before and after slaughter, originated from non-epizootic area and when tested no evidence of B.Anthraxes was found.

Ingestion: Accidental ingestion is not harmful or a probable route of exposure
Inhalation: Not respiratory
Allergy: Low risk from transient use.

Hazardous reactivity:

Stability: Stable
Incompatibility: Strong acids, bases oxidising agents

First aid measures (in case of):

Inhalation: There are no poisoning risks.
Skin contact: Do not use in case of a specific allergy.
In case of permanent irritation, call for physician
Contact with eyes: In case of accident or accidental contact with the moving instrument call for physician.

Fire and explosion data:

Reaction of fire: Combustible.
Extinguishing media: Atomised water jet, carbon dioxide foam, and dry chemicals
Special firefighting instructions: None

Accidental dispersion:

May be swept up or mechanically collected.

Disposal procedures:

Aquatic toxicity: Very low toxicity
Spill or leak: Sweep up to prevent slipping hazard
Waste disposal: Incinerate or landfill in compliance with local Regulations. Recycling is recommended.