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PRODUCT SAFETY DATA SHEET

Product: Junior Cup Bristle Brush Right Angle (RA) and Screw Type (SC) Shanks
Classification: Class 2a Medical Device

GMDN Code	GMDN Term	Basic UDI-DI	Medical Device	MD Class
64015	Dental Professional Prophylaxis Brush, single use	5051717DP01TU	JC, Junior Cup Brushes	IIa

Schedule of Product (Ref):

JC/WBRA JC/WBSC	Junior Cup, White Bristle, RA Junior Cup, White Bristle, Screw	WHITE BRISTLE	**Component (fill material):** Natural Bristle White
		Right Angle / Screw Type Shank	**Component 1:** Right Angle (RA) and Screw Type (SC) Brass Shank: CuZn39PB3 or equivalent, bright nickel plating
		Junior Cup Ferrule	**Component 2:** Brass Ferrule: CuZn30, bright nickel plating
		Junior Ring	**Component 3:** Brass Ring: CuZn37 – CW508L – C27400

Description: Stoddard Junior Cup brushes are used for the prophy cleaning or polishing of natural teeth and filled surfaces in the mouth. They are generally 4-component products filled with white bristle filaments.

Component 1: Metal Shank (Brass) Right Angle RA and Screw Type (SC) Shanks (1.72 universal thread)

Description: Turned and fine ground shanks made from free cutting brass rod CUZN39PB3 to EN12164 (Copper and Copper Alloys – Rod for free machining purposes) and EN12166 (Copper and Copper Alloys – wire for general purposes) or equivalent grade specification with Right Angle shanks produced to conform dimensionally with ISO1797 and Screw type shanks are produced to M1.8 x 0.35 DIA 1.70/1.78 universal type thread.

The strength of the alloy used in these devices has been selected for good tensile strength in combination with mechanical hardness. Proof of the suitability and durability of these materials is borne out by the exemplary performance record over a considerable number of years. There is no evidence of a shank failure due to material selection during this time. Stoddard brushes are proven to function correctly by historical use with no adverse reports.

Raw Material Composition: (Approximate, varies between grades)

Chemical Analysis %

COMPOUNDS	%	CAS Number
Copper – Cu	57.0 to 59.0%	CAS Number 7440-50-8
Cadmium – Cd	Max 0.0075%	CAS Number 7440-43-9
Iron – Fe	0.1 to 0.3%	CAS Number 7439-89-6
Lead – Pb	2.5 to 3.5%	CAS Number 7439-92-1
Nickel – Ni	0.04 to 0.3%	CAS Number 7440-02-0
Tin – Sn	0.2 to 0.3%	CAS Number 7440-31-5
Zinc – Zn	Remainder	CAS Number 7440-66-6
Aluminium – Al	Max 0.05%	CAS Number 7429-90-5

Material hardness: Vickers: HV151, megapascal 510MPa.

Surface Treatment: Bright Nickel-Plated Nickel (Ni). Two processes are currently used, and their constituents are listed below: - (typical values, can vary slightly)

1) e-plate Ni (Bright) (electrodeposited Nickel Bright) which has the following composition:
   0,0 – 0,1% Carbon - C — CAS Number 7440-44-0
   0,0 – 0,1% Nitrogen - N — CAS Number 7727-37-9
   0,05 – 0,1% Sulphur - S — CAS Number 7704-34-9
   Remainder – 99,825% Nickel - Ni — CAS Number 7440-02-0

2) Autocatalytic Nickel-Phosphorous coatings which has the following composition:
   90,75% Nickel - Ni — CAS Number 7440-02-0
   9,25% Phosphorous - P — CAS Number 7723-14-0

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

Fire and explosion data:

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

Hazardous reactivity:

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

Health hazard information:

Brass in solid wire form is not hazardous to health. Do not use in a case of a specific allergy.

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

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

Component 2: Junior Cup Ferrule Brass Cup, Nickel Plated

Description: The component part Cup Ferrule is a metal pressing composed of brass CuZn30 to BS EN1652 – Copper and Copper Alloys. Plate, sheet, strip and circles for general purposes and surface treatment bright nickel-plated.

Raw Material Composition: (Approximate, varies between grades)

Chemical Analysis %

COMPOUNDS	%	CAS Number
Copper – Cu	69.00 – 71.00 %	CAS Number 7440-50-8
Tin – Sn	0.00 – 0.02 %	CAS Number 7440-31-5
Iron - Fe	0.00 – 0.05 %	CAS Number 7439-89-6
Aluminium – Al	0.00 – 0.02 %	CAS Number 7429-90-5
Zinc - Zn	Remainder	CAS Number 7440-66-6
Nickel - Ni	0.00 – 0.10 %	CAS Number 7440-02-0
Lead – Pb	0.00 – 0.02 %	CAS Number 7439-92-1

Surface Treatment: Bright Nickel-Plated Nickel (Ni). Two processes are currently used, and their constituents are listed below: - (Typical values, can vary slightly)

1) e-plate Ni (Bright) (electrodeposited Nickel Bright) which has the following composition:
   0,0 – 0,1% Carbon - C CAS Number 7440-44-0
   0,0 – 0,1% Nitrogen - N CAS Number 7727-37-9
   0,05 – 0,1% Sulphur - S CAS Number 7704-34-9
   Remainder – 99,825% Nickel - Ni CAS Number 7440-02-0

2) Autocatalytic Nickel-Phosphorous coatings which has the following composition:
   90,75% Nickel - Ni CAS Number 7440-02-0
   9,25% Phosphorous - P CAS Number 7723-14-0

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

Fire and explosion data:

Flash point (method):	Not applicable, Flash ignition temp: not applicable,
Extinguishing media:	Water, carbon dioxide, dry chemicals
Special fire fighting instructions:	None

Hazardous reactivity:

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

Health hazard information:

This instrument is not considered hazardous to heath. Do not use in a case of a specific allergy.

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

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

Component 3: Junior Ring

Description: The component part Junior Ring is a metal pressing composed of brass CuZn37 to BS EN1652 – Copper and Copper Alloys. Plate, sheet, strip and circles for general purposes.

Raw Material Composition: (Approximate, varies between grades)

Chemical Analysis %

COMPOUNDS	%	CAS Number
Copper – Cu	62.00 – 64.00 %	CAS Number 7440-50-8
Tin – Sn	0.00 – 0.1 %	CAS Number 7440-31-5
Iron - Fe	0.00 – 0.1 %	CAS Number 7439-89-6
Aluminium – Al	0.00 – 0.05 %	CAS Number 7429-90-5
Zinc - Zn	Remainder	CAS Number 7440-66-6
Nickel - Ni	0.00 – 0.30 %	CAS Number 7440-02-0
Lead – Pb	0.00 – 0.1 %	CAS Number 7439-92-1

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

Fire and explosion data:

Extinguishing media:	Atomised water jet, carbon dioxide, dry chemicals
Special fire fighting instructions:	None

Hazardous reactivity:

Stability:	Stable
Incompatibility:	Strong acids, oxidising agents

Health hazard information:

Components not considered hazardous to heath. Do not use in a case of a specific allergy.

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

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

Component (fill material): Natural bristle (White).

Specification: Stoddard bristle brushes contain materials of an animal origin which are quality checked, disinfected and veterinary certified by the Peoples Republic of China Commodity Inspection Bureau and Certified by Official Veterinarian Officer of regional Entry-Exit Inspection & Quarantine Bureau the Peoples Republic of China. All component natural bristle is supplied boiled and is certified as having been disinfected at 100°c for not less than 2 hours.

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
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.

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

Fire and explosion data:
Reaction of fire: combustible.
Extinguishing media: Atomised water jet, carbon dioxide, dry chemicals
Special fire fighting instructions: None

Hazardous reactivity:
Stability: Stable
Incompatibility: Strong acids, oxidising agents

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. Do not use in a case of a specific allergy.
Ingestion: Accidental ingestion is not harmful or a probable route of exposure
Inhalation: Not respirable
Allergy: Low risk from transient use.

These devices do not incorporate and/or utilise tissues of an animal origin associated with TSE – Tissue Spongiform Encephalopathy.

Transmissible Spongiform Encephalopathles (TSE) is certified as not being present in the bristle by the veterinary certificate supplied in accordance with the World Health Organisation risk category which does not list TSE as occurring in pigs. We do not use any bovine-derived materials in our products.

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

First aid measures (in case of):

Inhalation:	Not applicable
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.

Personal protection equipment:

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

Accidental dispersion: May be swept up or mechanically collected.

Toxicology: There is no toxicological data specific to this product in its moulded state.

Transportation: The product should be transported in original containers to avoid damage or leakage. Keep containers dry.

Disposal procedures:

Aquatic toxicity:	Not applicable
Spill or leak:	Sweep up to prevent slipping hazard
Waste disposal:	Industrial recycling is recommended. Incinerate or landfill in compliance with National & local regulations.

Waste disposal 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. 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.

This PSDS was prepared and is to be used only for the above product Ref(s).

The instructions for conditions of storage or methods of safe handling, use or disposal of the product must be followed, but maybe beyond our control. We do not assume responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected with the improper handling, storage, use or disposal of the product.

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.

The following rule confirms the classification of these devices as Class IIa as they are intended only to come into contact with intact skin.

Annex VIII, Rule 18
All devices manufactured utilising tissues or cells of human or animal origin, or their derivatives, which are non- viable or rendered non-viable, are classified as class III, unless such devices are manufactured utilising tissues or cells of animal origin, or their derivatives, which are non-viable or rendered non-viable and are devices intended come into contact with intact skin only.

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