

MANUFACTURING COMPANY LIMITED

BLACKHORSE ROAD, LETCHWORTH, HERTS, SG6 1HB, ENGLAND Tel: + 44 (0) 1462 686221 www.stoddard.co.uk Fax: + 44 (0) 1462 480711

PRODUCT SAFETY DATA SHEET

<u>Product: Junior Cup Brush RA and Screw Shanks (1.72 Universal Thread)</u> Classification: Class 2a Medical Device

Schedule of Product (Ref):

Concadic of Froduct (Itel).	
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
JC/ORNRA	JUNIOR CUP ORANGE NYLON RA
JC/YNRA	JUNIOR CUP YELLOW NYLON RA
JC/SDRA	JUNIOR CUP STAIN DEVIL NYLON RA
JC/WFRA	JUNIOR CUP WHITENING FILAMENT RA

Description: The Dental surgeon or Hygienist uses Stoddard Prophylaxis polishing Junior Cup brushes for the Prophy cleaning or polishing of natural teeth and filled surfaces in the mouth. They are generally 4-component products filled in a variety of manmade and natural materials including horsehair, black bristle, goat hair, white bristle and nylon.

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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 Insoluble

Stability and reactivity:

Chemical stability: Stable at normal temperature and storage conditions.

Incompatibility with other materials:

Hazardous decomposition products:

None reasonable or foreseeable

Decomposition will not occur

Hazardous polymerisation: Polymerisation will not occur.

<u>Handling and Storage</u>: 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, dry chemicals.

Special fire fighting instructions: None

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Health hazard information:

Brass in solid wire form is not hazardous to health.

Ingestion: Not a probable route of exposure

Inhalation: Not respirable

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

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

Stability and reactivity:

Chemical stability: Stable at normal temperature and storage conditions.

Incompatibility with other materials:

Hazardous decomposition products:

None reasonable or foreseeable
Decomposition will not occur

Hazardous polymerisation: Polymerisation will not occur.

<u>Handling and Storage</u>: 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.

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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

Health hazard information:

Brass in solid wire form is not hazardous to health. Ingestion: not a probable route of exposure

Inhalation: not respirable

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 heath.

Ingestion: Accidental ingestion is not harmful or a probable route of exposure

Inhalation: Not respirable

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, dry chemicals

Special fire fighting instructions: None

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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 local Regulations. Recycling is recommended.

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

containers dry.

Component (fill material):

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:
Solubility in water:
Evaporation rate:
Specific gravity:

Not applicable
Insoluble
Not applicable
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, dry chemicals

Special fire fighting instructions: None

Health hazard information:

Nylon is not a hazardous material.

Ingestion: Not a probable route of exposure

Inhalation: Not respirable

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 local regulations

Special protection information:

Ventilation: local exhaust at processing equipment to keep particulate below 15mg/m³ (OSHA limit for

particulates not otherwise regulated)

Personal protection equipment:

Eyes: Safety glasses

Gloves: None under normal processing

Respirator: Not applicable

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Component (fill material):

Material description: Stain Devil filament

Specification: Chemical name:

TPE Thermoplastic Elastomer
PBT Polybutylene Terephthalate

master batch colourants

Physical data: Melting point: 223°C

Boiling point:
Solubility in water:
Evaporation rate:
Not applicable
Insoluble
Not applicable

Fire and explosion data:

Flash point (method): Not applicable

Extinguishing media: Water, carbon dioxide, dry chemicals

Special fire fighting instructions: None

Health hazard information:

TPE & PBT are not classified as hazardous materials.

Ingestion:

Not a probable route of exposure

Inhalation: Not respirable

Hazardous reactivity:

Stability: Stable

Conditions to avoid: Heating above 300°C

Incompatibility: Strong acids, hydrogen peroxide

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 local regulations

Special protection information:

Ventilation: local exhaust at processing equipment to keep particulate below 15mg/m³

Personal protection equipment:

Eyes: Safety glasses

Gloves: None under normal processing

Respirator: Not applicable

Component (fill material):

Material description: Whitening Nylon filament with calcium carbonate

Specification: Chemical name:

Polyamide 6.12

Calcium carbonate (CaCO3) particle size 31µm mohrs hardness:3

Master batch colourants

Physical data: Melting point: 208-215°C

Boiling point: Not applicable
Solubility in water: Insoluble
Evaporation rate: Not applicable

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Fire and explosion data:

Flash point (method): Not applicable

Flash ignition temp: 400°C (ASTM D1929) Extinguishing media: Water, carbon dioxide

Special fire fighting instructions: None

Health hazard information:

Polyamid 6.12 & calcium carbonate are not hazardous materials.

Ingestion: Not a probable route of exposure and levels well below the recommended range of

1.2-1.5g daily for an adult of calcium carbonate

Inhalation: Not respirable

Hazardous reactivity:

Stability: Stable

Conditions to avoid: Heating above 340°C

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 local regulations

Special protection information:

Ventilation: local exhaust at processing equipment to keep particulate below 15mg/m³

Personal protection equipment:
Eyes: Safety glasses

Gloves: None under normal conditions

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 applicableBoiling point:Not applicableSolubility in water:InsolubleEvaporation rate:Not applicable

Odour: Mild Eventual declared toxicity: None

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

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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.

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 respirable

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.

Contact with eyes: In case of accident or accidental contact with the moving instrument call for physician.

In case of permanent irritation, call for physician.

Fire and explosion data: Reaction of fire: combustible.

Extinguishing media: Atomised water jet, carbon dioxide, dry chemicals

Special fire fighting 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: lincinerate 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 2 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 applicableBoiling point:Not applicableSolubility in water:InsolubleEvaporation rate:Not applicable

Odour: Mild Eventual declared toxicity: None

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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 not less than 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 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 respirable

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, and dry chemicals

Special fire fighting 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 Goat hair

Specification: Processed to standard GB8211-87 and boiled for not less than 2 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

PH: Neutra
Physical state: Solid

Melting point:Not applicableBoiling point:Not applicableSolubility in water:InsolubleEvaporation rate:Not applicable

Odour: Mild Eventual declared toxicity: None

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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 not less than 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 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.Anthraces was found.

Ingestion: Accidental ingestion is not harmful or a probable route of exposure

Inhalation: Not respirable

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, and dry chemicals

Special fire fighting 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.

The materials contained in this product are non-hazardous or non-hazardous at the levels of inclusion.

Investigation into the suitability of Chemical and Physical Properties for materials including contaminates, residues and corrosion was conducted in accordance with BS EN 1639 Dentistry – Medical devices for dentistry – Instruments and BS EN ISO 10271 Dentistry – Corrosion test methods for metallic materials.

DISCLAIMER OF LIABILITY

The information in this PSDS was obtained from sources, which we believe are reliable. However, the information is provided without any warranty, express or implied, regarding its correctness.

The conditions or methods of handling, storage, use 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 PSDS was prepared and is to be used only for this product. If the product is used as a component in another product, this PSDS information may not be applicable.

Emergency Phone No: (0044) 1462 686221

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