MEDICAL DEVICE
TECHNICAL DATA SHEET

POLO MB OISTERWIJK BV

Product name:
PoloDent Pasteless Occlusal Brushes Cup RA

Product specification

Product name: PoloDent® Pasteless Occlusal Brushes Cup RA

Article number(s): 74 36 40

CE Class: IIa Medical Device

Company: Polo MB Oisterwijk BV
Laarakkerweg 5
5061 JR Oisterwijk
The Netherlands
www.polodent.com

Description

Silicon carbide loaded filament pencil brushes for occlusal polishing of composite, compomer and ceramic surfaces, without using polishing paste.

Component 1: Metal Shank Ferrule (Brass) Right Angle

Description

Turned and fine ground mandrels made from free cutting brass rod CUZN39PB3 or similar grade specification with Right Angle shanks produced to conform dimensionally with ISO1797 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. PoloDent polishers are proven to function together correctly by historical use with no adverse reports.

Raw Material Composition

(Approximate, varies between grades)

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

Material hardness

Vickers: HV151, megapascal 510MPa.

Surface Treatment: Bright Nickel Plated (Ni) Test Result 99.97% CAS Number 7440-02-0

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

MEDICAL DEVICE
TECHNICAL DATA SHEET

POLO MB OISTERWIJK BV

Product name:
PoloDent Pasteless Occlusal Brushes Cup RA

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.

MEDICAL DEVICE
TECHNICAL DATA SHEET

POLO MB OISTERWIJK BV

Product name:
PoloDent Pasteless Occlusal Brushes Cup RA

Component 2: Junior Cup Ferrule Metal Cup, Nickel Plated

Description

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

Raw Material Composition

(Approximate, varies between grades)

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

Surface Treatment: Bright Nickel Plated (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.
This Cup has a plating coat to this cup component of 0.001 mm to 0.002 mm of pure Gold.

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.

MEDICAL DEVICE
TECHNICAL DATA SHEET

POLO MB OISTERWIJK BV

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PoloDent Pasteless Occlusal Brushes Cup RA

Component 3: Junior Ring

Description

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

Raw Material Composition

(Approximate, varies between grades)

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

MEDICAL DEVICE
TECHNICAL DATA SHEET

POLO MB OISTERWIJK BV

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PoloDent Pasteless Occlusal Brushes Cup RA

Component: Fill material

Material Description

Silicon carbide filaments (SiC).

Composition

Filament of solid polymer composed principally of Poly (isophthaloyl chloride/mphenylenediamine) carbon, loaded with Silicon Carbide abrasive grit.

Composition: (Aramid)

Material	Existing chemical substances No. (LERMCS*)	Content:	CAS No.
- Poly(isophthaloyl chloride/m-phenylenediamine)	7-1972	93%	25765-47-3
- Water	None	3%	7732-18-5
- Grain: Silicon carbide (SiC) abrasive		4%	409-21-2

Filament 0.24mm diameter of solid polymer composed principally of Poly (isophthaloyl chloride/mphenylenediamine) (meta-aramid polymer)carbon, loaded with 4% Silicon Carbide abrasive grit size 3000.

Physical and chemical characteristics

Odour: Mild

Specific gravity: 1.39 g/cm^3

Vapour density: Not applicable.

Vapour pressure: Not applicable.

Boiling point: Not applicable.

Solubility in water: Insoluble

Melting point: Begins to thermally degrade rapidly above 430ºC.

Colour Type of no grain: Grey, green grey.

Form: Solid with a wide range of denier and cut length.

Stability and reactivity

Chemical stability: Stable at normal temperature and storage conditions.

Incompatibility with other materials: None reasonable or foreseeable.

Hazardous decomposition products: Begins to thermally degrade rapidly above 275ºC.
The thermal degradation rate increases with temperature.

Hazardous polymerisation

Polymerisation will not occur.

MEDICAL DEVICE
TECHNICAL DATA SHEET

POLO MB OISTERWIJK BV

Product name:
PoloDent Pasteless Occlusal Brushes Cup RA

OTHER INFORMATION

Special protection information

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

Toxicological information

Eye: Untested for eye irritancy. As with other particles, dust entering into the eye may cause physical irritation.

Skin: Allergic reaction has not been observed by patch tests on the skin of animals and humans.

Acute oral effects: Very low toxicity by ingestion. Oral acute toxicity LD50 (rats)>5,000 mg/kg
(l) NIOSH, "Registry of Toxic Effects of Chemical Substances", US.DHHS, 1993.1 update.

Acute inhalation effects: Does not generate fibrils in ordinary environment.

Chronic effects: It is improbable to cause any influence on the lung by the inhalation of small amount of dust over a long period.

Carcinogenicity: No carcinogenicity was noticeable by animal experiments. None of the components present in these materials at concentrations equal to or greater than 0.1% are listed by IARC(2), NTP(3), OSHA(4), Labour safety and Sanitation Law (Japan), and Japan Association on Industrial Health. Some grades contain carbon black (classified into the group 2B (5) of IARC) in an amount of 0.05%.
(2) IARC = International Agency for Research on Cancer.
(3) NTP = National Toxicology Program issuing "Annual Report on Carcinogens".
(4) OSHA = Occupational Safety and Health Administration, US Department of Labour OSHA shows a list of the minimum standard of carcinogenicity and restricts the substances listed on the carcinogenicity lists of IARC and NTP as the carcinogenic substances.
(5) Group 2B = Substances possibly carcinogenic to humans by toxicity test.

First aid measures

Market evaluation for 26 years has revealed that this raw material is harmless to the human body and environment.
Burning may release toxic or irritating gases depending on the burning conditions.
Non-biodegradable and non-toxic to aquatic life, and usually pose no environmental hazard in a spill or fire.

Inhalation: If large amounts of dust are inhaled, expose to fresh air, if persistent cough or other symptoms develop consult physician.

Skin contact: Wash with soap and water. Use hand cream to soothe irritated skin and get medical attention if irritation persists.

Eye contact: In case of eye contact, immediately rinse with plenty of water for at least 15 minutes. Consult physician if the irritation persists.

Ingestion: In case of erroneous ingestion, consult physician.

Fire fighting measures

This product is inherently flame resistant. Product dust does not present an explosion hazard. The product can ignite, but burning will stop when the ignition source is removed.

Flash point: Not applicable.

Explosive limits: Not applicable.

Auto-ignition temperature: Not available.
Inherently flame resistant but can be ignited (LOI=28 to 32). Burning spontaneously stops when the ignition source is removed.
Fibre dust does not present an explosion hazard.

Fire hazards: Burning produces carbon monoxide, carbon dioxide, nitrogen oxides and small amounts of hydrogen cyanide, ammonia, aliphatic hydrocarbons and other toxic gases depending on conditions of burning.

Fire extinguishing measures: Use water, foam, carbon dioxide or dry chemical as extinguishing media.

Fire fighting instructions: Keep personnel removed and upwind of fire. Wear breathing apparatus. Wear full protective equipment.

Handling and Storage

Degraded by ultraviolet light. Do not store in direct sunlight. Fluorescent lighting will cause discolouration but will not affect fibre mechanical properties.

MEDICAL DEVICE
TECHNICAL DATA SHEET

POLO MB OISTERWIJK BV

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PoloDent Pasteless Occlusal Brushes Cup RA

Control of working environment and personal protective equipment

Use only with adequate exhaustion or ventilation equipment. Avoid dust generation. Do not consume food, drink or use tobacco in the areas where they may become contaminated with this material.

Engineering controls: Isolation, enclosures, exhausts, ventilation, dust collecting systems etc are effective for controlling suspending dusts. Smoke and suspending dusts from laser cutting or machining of fabrics should be removed by an exhaustion equipment.

Personal protective equipment

Protection with mask: Use a disposable face mask where there is potential for irritation of the nasal passage or throat.

Eye protection: Wear safety glasses with side shields.

Skin protection: None required.

Exposure guidelines: There is not exposure guidelines by OSHA (4)/PEL (6), ACGIH (7)/TLV (8), Labour Safety and Sanitation Law (Japan) and Japan Association on Industrial Health.
(6)PEL = Permissible Exposure Limit defined by OSHA showing the upper limit of the time average concentration or the maximum concentration.
(7)ACGIG = American Conference of Government Industrial Hygienists.
(8) TLV = Threshold Limit Value defining the upper limits on chemical substances or substances exerting physical actions.

Environmental Influence

Hazard to environment: Principally non-biodegradable and does not destruct the ecosystems of the flora and fauna.

Disposal procedures

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.

Information on transportation

Covering laws: There is no particular law in Japan and other countries restricting.

Information on restrictions

EPA (9): Clean Air Act Amendments of 1990: products and their packaging and production processes do not contain the Class 1 substances (chlorofluorocarbons, halons, carbon tetrachloride and methyl chloroform) and the Class 2 substances (hydro chlorofluorocarbons) registered in the amendments as ozonosphere destructing substances.

FDA (10)/USDA: Not approved for uses repeatedly containing with foods. See appendix I.

(9) EPA = US Environmental Protection Agency
(10) FDA = US Food and Drug Administration

Other information

Warning: This material is suitable for transient use but should not be permanently implanted into the human body.

Food Additive Regulations

This MONO FILAMENT has been qualified for Japanese Food Hygiene Law (regulated in 1959 and enforced by announcement No.370 by Public Welfare Ministry).

Waste disposal procedures

Waste is not harmful. 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. Do not wash off with water or flush to drains because material is principally non-biodegradable.

This TDS 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.

Notes: This TDS concerns exclusively the substances shown in the sheet and does not concern the combinations with other substances or other processes.

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.