

MEDICAL DEVICE**TECHNICAL DATA SHEET**

POLO MB OISTERWIJK BV

Product name:

PoloDent Pasteless Occlusal Br. Pencil+Point RA

Product specification

Product name:	PoloDent® Pasteless Occlusal Brushes	
Article number(s):	74 36 41	Pencil RA
	74 36 42	Point RA
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 shanks made from free cutting brass rod CUZN39PB3, CZ121 or CW614N or similar grade specification with RA shanks produced to conform dimensionally with ISO1797.

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

(Typical values, can vary slightly)

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% Covered with pure Gold.

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

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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

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.

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Component: Fill material**Material Description**

Silicon carbide filaments (SiC).

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 430°C.
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 275°C. The thermal degradation rate increases with temperature.

Hazardous polymerisation

Polymerisation will not occur.

MEDICAL DEVICE

TECHNICAL DATA SHEET

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Component 2: Epoxy Adhesive, suitable for use in the assembly of disposable medical devices

Description

Epoxy adhesive, Amber-beige in appearance which when fully cured offers superior thermal shock resistance, excellent mechanical properties and withstands exposure to a wide variety of solvents and chemicals.

Raw Material Composition

(Values given by Manufacturer, note * Exact contents are considered a trade secret and not available)

Component	%*	CAS Number
Amine Adduct	60 to 100 %	Proprietary
Tetraethylene pentaamine	10 to 30 %	112-57-2
Triethylenetetramine	5 to 10 %	112-24-3

Product is proven to be inert once fully cured and has a Certificate of compliance, project number 11-4211 with ISO 10993 Biological Tests, dated 24th October 2011 and conducted by Toxikon Corporation, 15 wiggins Avenue, Bedford, MA 01730. USA.

Physical Data

Physical state:	Solid
Colour:	Amber beige.
Odour:	None
Evaporation rate:	Not applicable.
Specific gravity:	1.07
Solubility in water:	Insoluble

Hazardous reactivity

Stability:	Stable
Conditions to avoid:	Contact with oxidising agents and acids
Incompatibility:	Acids, oxidising agents.

Health hazard information

This Epoxy adhesive in solid form is inert and not hazardous to health.

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

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OTHER INFORMATION

PoloDent Diamond loaded filament These products are intended for use by trained Dental professionals only.

These PoloDent polishers are produced from Polyamide 612 nylon containing Diamond particles, bonded with a medical grade epoxy adhesive into a Gold and Nickel plated brass shank.

There is a marginal risk posed by the separation of the polisher from the handpiece. These risks are controlled by:

- The use of designs incorporating careful material selection with dimensions able to withstand the stresses of normal use.
- Testing to ensure that the mechanical strength is sufficient.

The following hazards have been identified

- Use by unskilled personnel
- Use by untrained personnel
- Human error

Special protection information

Ventilation: Local exhaust at processing equipment to keep particulate below 15mg/m³ (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: Untested for skin irritancy.

Acute oral effects: Very low toxicity by ingestion.

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

Flash point: Not applicable.

Explosive limits: Not applicable.

Auto-ignition temperature: Not available.

Inherently flame resistant but can be ignited. Burning spontaneously stops when the ignition source is removed.

Fibre dust does not present an explosion hazard.

Fire hazards: Burning produces carbon monoxide, traces of ammonia 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

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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: Allowable concentration. (Japan Society for Occupational Health (2007))
 Type III dust

Total dust: 8 mg/cubic metre

Respirable dust: 2 mg/cubic metre

Allowable concentration. (ACGIH (edition in 2007) TLV/TWA: Silicon Carbide)

Non-fibrous: 10 mg/cubic metre (inhalable fraction, E)
 3 mg/cubic metre (inhalable fraction, E)

E; Particulate matter containing no less than 1% crystalline fibrous (whiskers included): 0.1f/cc (Respirable fibres), less than 5 microns in length, aspect ratio \leq 3:1

Environmental Influence

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

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

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

Other information

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

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.