

# MEDICAL DEVICE

## SAFETY DATA SHEET

POLO MB OISTERWIJK BV

Product name:

PoloDent PoloFlex Pop-On & Snap-On discs

### Document History Summary

Summary of changes	Version No.
<ul style="list-style-type: none"><li>First issue according to Stoddard's SDS Issue 2 dated 04/2016</li></ul>	1.0

### Approvals

Managing Director: Pieter van Lieshout		QA Manager: Naomi Claasen	
Signature	Date	Signature	Date

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### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1 Product identifier

<b>Product name:</b>	PoloDent® PoloFlex Pop-On & Snap-On Discs		
<b>Article number:</b>	72 94 05	PoloFlex Pop-On assortment, 240 pcs	
	72 94 10	PoloFlex Pop-On 10 mm x-fine	72 94 30 PoloFlex Pop-On 14 mm x-fine
	72 94 15	PoloFlex Pop-On 10 mm fine	72 94 35 PoloFlex Pop-On 14 mm fine
	72 94 20	PoloFlex Pop-On 10 mm medium	72 94 40 PoloFlex Pop-On 14 mm medium
	72 94 25	PoloFlex Pop-On 10 mm coarse	72 94 45 PoloFlex Pop-On 14 mm coarse
	72 94 55	PoloFlex Snap-On assortment, 240 pcs	
	72 94 60	PoloFlex Snap-On 10 mm x-fine	72 94 80 PoloFlex Snap-On 14 mm x-fine
	72 94 65	PoloFlex Snap-On 10 mm fine	72 94 85 PoloFlex Snap-On 14 mm fine
	72 94 70	PoloFlex Snap-On 10 mm medium	72 94 90 PoloFlex Snap-On 14 mm medium
	72 94 75	PoloFlex Snap-On 10 mm coarse	72 94 95 PoloFlex Snap-On 14 mm coarse

#### 1.2 Relevant identified uses of the substance or mixture and uses advised against

**Use of substance/mixture:** Finishing and polishing of composite restorations.

#### 1.3 Details of the supplier of the safety data sheet

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

### SECTION 2: Hazards identification

#### Hazards identification

Direct contact may cause eye irritation during polishing.

### SECTION 3: Composition/information on ingredients

#### Composition

**Chemical characterisation:** Aluminium oxide, acrylic polymer binder, plastic, brass, food dyes, silicon rubber

**Hazardous components:** None

**Further information:** None

### SECTION 4: First aid measures

#### 4.1 Description of first aid measures

**Eye contact:** Use glasses or goggles for protection.

**Skin and tissue contact:** Not hazardous.

**Ingestion:** No special precautions.

**Inhalation:** No special precautions.

**Further information:** None

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### SECTION 5: Fire-fighting measures

#### 5.1 Extinguishing media

Extinguishing media:	Does not apply.
Extinguishing media to avoid:	None known.
Further information:	None

### SECTION 6: Accidental release measures

#### 6.3 Methods and material for containment and cleaning up

Clean-up procedures:	Clean up mechanically. Dispose of, according to local and national regulations.
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### SECTION 7: Handling and storage

#### 7.1 Precautions for safe handling

Handling requirements:	Trained personnel should handle this product. Keep out of reach of children.
Industrial hygiene:	Usual Hygienic measures are necessary, do not eat or drink.

#### 7.2 Conditions for safe storage, including any incompatibilities

Storage conditions:	Store at room temperature (12-28°C).
Place of storage:	Avoid exposure to direct light.
Fire- & explosion Protection:	Not required.

### SECTION 8: Exposure controls/personal protection

#### 8.2 Exposure controls

Technical equipment:	Provide adequate local ventilation.
Control of threshold limits:	None established.
Respiratory protection:	Provide adequate local ventilation.
Hand protection:	Not necessary.
Eye protection:	Use glasses or goggles for protection.
Other:	None

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### SECTION 9: Physical and chemical properties

#### 9.1 Information on basic physical and chemical properties

<b>Appearance:</b>	Flexible plastic disc with abrasive layer.
<b>Colour:</b>	Various
<b>Odour:</b>	Odourless
<b>Change in physical stat:</b>	Test method: ---
<b>Density:</b>	Not determined.
<b>Vapour pressure:</b>	Not applicable.
<b>Viscosity:</b>	Not determined.
<b>Solubility in water:</b>	None
<b>pH-value:</b>	Not determined.
<b>Flash point (°C):</b>	> 150°C
<b>Ignition temperature:</b>	Not determined.
<b>Autoflammability (°C):</b>	No data available.
<b>Explosion limits:</b>	Not applicable.

#### 9.2 Other information

**Other information:** None

### SECTION 10: Stability and reactivity

#### 10.2 Chemical stability

**Thermal decomposition:** None, if used in accordance to instructions.

#### 10.3 Possibility of hazardous reactions

**Hazardous reactions:** None

#### 10.6 Hazardous decomposition products

**Hazardous decomposition products:** None

#### 10.7 Other information

**Further information:** Avoid exposure of product to direct light and excess humidity.

### SECTION 11: Toxicological information

#### 11.1 Information on toxicological effects

<b>Acute toxicity:</b>	None
<b>Subacute / chronic toxicity:</b>	None
<b>Further information:</b>	None

### SECTION 12: Ecological information

#### Ecological information

No ecological problems to be anticipated if properly handled and used.

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### SECTION 13: Disposal considerations

#### 13.1 Waste treatment methods

<b>Disposal operations:</b>	Take to a waste incineration plant, under conditions approved by the local authority.
<b>EC waste key:</b>	-
<b>Swiss waste code:</b>	-
<b>Origin:</b>	-

### SECTION 14: Transport information

#### Transport information

Product is not classified for any mode of transportation.

### SECTION 15: Regulatory information

#### 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

<b>Specific regulations:</b>	Class IIa according to the Medical Devices Directive (93/42/EEC).
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### SECTION 16: Other information

#### 16.1 Other information

<b>Other information:</b>	No other information.
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#### **Articles as defined in OSHA Hazard Communication Standard, Section 1910.1200**

These instruments are considered manufactured "articles" and, as such are exempt from Product 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 and not to its use in combination with any other materials or in any process.

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 contaminants, 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.

<b>Legal disclaimer:</b>	The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. This company shall not be held liable for any damage resulting from handling or from contact with the above product.
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