

Safety Data Sheet

IMPORTANT

Read this SDS before handling and disposing of this product and pass this information on to employees, customers and users of this product.

1. IDENTIFICATION

1.1 Product Identifier

Product Name	PoliFLEX Plus

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

Product Use	Professional dental use only.
Description	Dental Product

1.3 Supplier of the Safety Data Sheet

Company Name	Perfection Plus Ltd
Company Address	6 Westwood Court, Brunel Road, Totton, Hants. SO40 3WX. UK
Company Phone No.	+44 (0) 2380 866 677
Website	www.perfectionplus.com
Telephone	0044 (0) 2380 866677
Email	Regulatory@perfectionplus.com
Email address of	Regulatory@perfectionplus.com
Competent Person	

1.4 Emergency telephone number

Emergency telephone	0044 (0) 230 866 677
number	(8am – 5pm Monday to Friday)

2. HAZARDS IDENTIFICATION

2.1 Label Elements

Hazard Statement	No significant
2.2 Other hazards	
Other hazards	PBT. vPvB. Not applicable.

Further information

Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of regulation (EC) No 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

3. **COMPOSITION/INFORMATION ON INGREDIENTS**

3.1 Substances

<u>Component 1: Polyester film coated with aluminium oxide grains bonded with hardened Acrylate and Polyester resins</u>

Polyester film, (CAS Number 25038-59-9), a film manufactured from polyethylene terephthalate, coated with aluminium oxide grains (CAS Number 1344-28-1), bonded with hardened Acrylate and Polyester resins.

Component 2: Brass metal pressing Grade L63 CZ108 or equivalent

Brass metal pressing (CAS Number 63338-02-03) Grade L63, CZ108 or equivalent.

Raw Material Composition: (Typical values, can vary slightly)

	Chemical Analysis %	CAS Number	
Copper (Cu)	62.0 – 65%	7440-50-8	
Lead (Pb)	0.07% Max	7439-92-1	
Iron (Fe)	0.2% Max	7439-89-6	
Antimony (Sb)	0.005% Max	7440-36-0	
Bismuth (Bi)	0.002% Max	7440-69-9	
Phosphorous (P)	0.01% Max	7723-14-0	
Zinc (Zn)	Balance	7440-66-6	



Note:- Solvents Butyl Acetate and Xylene are used in the production process and are completely removed at the high temperature drying stage of production.

4. FIRST AID MEASURES

4.1 Description of first aid measures

Inhalation	Not applicable
Eye Contact	In case of accident or accidental contact with the moving instrument call a physician.
Skin contact	Do not use in case of a specific allergy. In case of permanent irritation, call a physician.
Ingestion	Accidental ingestion is not harmful, consult a physician if necessary.

4.2 Most important symptoms and effects, both acute and delayed

Inhalation	No data available
Eye Contact	No data available
Skin contact	No data available
Ingestion	No data available

Indication of any immediate medical attention and special treatment needed

Inhalation	No data available
Eye Contact	No data available
Skin contact	No data available
Ingestion	No data available

General information

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5. FIRE FIGHTING MEASURES

Extinguishing media

F.O. Consider	annuals outsing from the substance or mintrus
	Water spray, alcohol resistant foam, dry chemical, carbon dioxide.
	<u> </u>

Special hazards arising from the substance or mixture

Not applicable

5.3 Advice for firefighters

Not applicable

6. **ACCIDENTAL RELEASE MEASURES**

Personal precautions, protective equipment and emergency 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. 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

6.2 **Environmental precautions**

Not applicable

Methods and material for containment and cleaning up 6.3

May be swept up or mechanically collected

Reference to other sections

See section 13 for disposal information.

7. **HANDLING AND STORAGE**

7.1 Precautions for safe handling

There are no specific handling requirements, store in clean dry conditions at room
temperature (12-28°C) and away from light.

7.2 Conditions for safe storage, including any incompatibilities

None known.

7.3 Specific end use(S)

For professional use in dentistry only.



8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

8.2 Exposure controls

Provide adequate ventilation. Local exhaust at processing equipment to keep particulate below 15mg/m³

(OSHA limit for particulates not otherwise regulated).



8.2.1 Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday

8.2.2 Individual protection measures

Eye/face protection	Wear eye / face protection equipment. Safety glasses with side-shields, conforming to EN 166.
Skin protection – Hand protection	None under normal processing
Respiratory protection	Not applicable.

8.2.3 Environmental exposure controls

Not applicable.

This product should be used in conjunction with rotary handpieces that conform with ISO 14457.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance	Flexible polyester disc with	Flammability	Not determined
	abrasive layer, Brass metal	Upper/Lower levels	
	pressing		
Colour	Various	Vapour pressure	Not determined
Odour	None	Vapour density	Not determined
Odour threshold	Not determined	Relative density	Not determined
рН	Not determined	Explosive properties	Not determined
Melting/freezing point	Not determined	Oxidising properties	Not determined
Boiling point	Not determined	Evaporation rate	Not determined
Flash Point	<150°C	Solubility in water	Insoluble

10. STABILITY AND REACTIVITY

10.1 Reactivity

	No data available.
10.2 Chemical stability	
	Stable under recommended storage conditions and normal temperature.

10.3 Possibility of hazardous reactions

No dangerous reactions known

10.4 Conditions to avoid

Heating above 150°C

10.5 Incompatible materials

Strong acids, oxidising agents

10.6 Hazardous decomposition products

Decomposition will not occur.

Hazardous polymerisation will not occur

11. TOXICOLOGICAL INFORMATION



11.1 Information on toxicological effects

Acute toxicity	Based on available data, no risks are known
Skin corrosion/irritation	Based on available data, no risks are known
Serious eye	Based on available data, no risks are known
damage/irritation	
Respiratory of skin	Based on available data, no risks are known
sensitisation	
Germ cell mutagenicity	Based on available data, no risks are known
Carcinogenicity	Based on available data, no risks are known
Reproductive toxicity	Based on available data, no risks are known
STOT-single exposure	Based on available data, no risks are known
STOT-repeated exposure	Based on available data, no risks are known
Aspiration hazard	Based on available data, no risks are known
Repeated or prolonged	Based on available data, no risks are known
exposure	

11.1.4 Toxicological Information

No specific data available to this product in its moulded state.

12. ECOLOGICAL INFORMATION

12.1 Toxicity

Aqua	ntic	Very low toxicity	
12.2	12.2 Persistence and degradability		
		No data is available on this product.	
12.3	12.3 Bio accumulative potential		
		No data is available on this product.	
12.4	12.4 Mobility in soil		
		No data is available on this product.	
12.5	12.5 Results of PBT and vPvB assessment		
		No data is available on this product.	
12.6	12.6 Other adverse effects		
		No data is available on this product.	

13. <u>DISPOSAL CONSIDERATIONS</u>

13.1 Waste treatment methods

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.

General information

18 WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (except kitchen and restaurant wastes not arising from immediate health care). 18 01 wastes from natal care, diagnosis, treatment or prevention of disease in humans. 18 01 06 chemicals consisting of or containing dangerous substances.

Disposal Methods

For disposal within the EC, the appropriate code according to the European Waste Catalogue (EWC) should be used.

14. TRANSPORT INFORMATION

No specific instruction.

14.1 UN number

n/a



14.2 UN proper shipping name

n/a		
14.3 Environmental hazards		
Environmental haz	ards	No
Marine pollutant No		No
14.4 Special precautions for user		
	Read	safety instructions, SDS and emergency procedures before handling.
14.5 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code		
	No da	ta available.

15. REGULATORY INFORMATION

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

Regulations	These instruments are considered manufactured 'articles' and as such are exempt from 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 to them.	
15.2 Chemical Safety Assessment		
	No data available.	

16. OTHER INFORMATION

Other information

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.

Further information

This product is manufactured by Stodddard Manufacturing Ltd, Blackhorse Road, Letchworth Garden City, Herts, SG16 1HB, UK and the contained SDS information is supplied by them.

The information used in this SDS is believed to be correct however, the information is provided without any warranty, neither expressed nor implied, regarding its correctness.

This SDS is relevant for large quantities of product, the instructions for safe use of quantities typically used during a normal procedure is as referenced in the Instructions for Use.

The conditions or methods for handling, storage, lone use and/or in combination with other products and disposal are beyond our control.

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 SDS was prepared and is to be used only for this product. If the product is used as a component in or in combination with another product, this SDS information may not be applicable.