UnoDent Ltd, 10 Perry Way, Witham, Essex, United Kingdom, CM8 3SX.
(01376) 500582 feedback@unodent.com

Please note that the text of this Product Safety Data Sheet makes reference to Stoddard polishers. Stoddard are the Original Equipment Manufacturers (OEM) of the Unodent products therefore there is direct equivalence of the information stated in this document to Unodent Polishers.

PRODUCT SAFETY DATA SHEET

Product: Prophy Cups RA Shanks with Ring
Classification: Class 2a Medical Device

Schedule of Products (Ref):

PRA001 PRA002 PRA003 TPR003 EPR003	Prophy Cup RA 6 Web Ring Pink Soft Prophy Cup RA 6 Web Ring Purple Medium Prophy Cup RA 6 Web Ring Blue Hard Prophy Cup RA 6 Web Ring Mint Medium Prophy Cup RA 6 Web Ring Mint Medium	ELASTOMER POLYMER	**Component 1:** Thermoplastic Elastomer (Polymer) – (100 % latex free) with Colour Masterbatch CAS Number - 308079-71-2
		Right Angle Shank	**Component 2:** Right Angle (RA) Brass Shank: CuZn39PB3 or JIS H3250 C3604 or similar, bright nickel plating
		Polypropylene	**Component 3:** Polypropylene Polypropylene PPR 7220 or Polypropylene RE420MO CAS Number – 9010-79-1
		Silicon Rubber Ring	**Component 4:** Silicon Rubber Ring CAS Number – 63394-02-5

Description: Stoddard prophy cups with Ring are four component products produced by moulding a Bi-material latex free, synthetic polymer to metal shanks with the inclusion of Polypropylene as a material utilised to ensure a secure join between the parts and a silicon rubber ring fitted to the shank which acts as a handpiece bearing protector. They are single use, Class IIa medical devices for the prophylaxis polishing of natural teeth, gold, and amalgam fillings.

Component 1: Thermoplastic Elastomer (Polymer) – (100 % latex free) with Colour Masterbatch.
CAS Number - 308079-71-2

Stoddard polishers are produced from Thermoplastic Elastomer compound based on Styrene block Copolymers.

Thermoplastic Elastomers, sometimes referred to as Thermoplastic Rubbers, are a polymer from an independent group of materials sitting between Thermoplastics and Elastomers.

In order to qualify as a Thermoplastic Elastomer, the materials used have 3 essential characteristics: -

- The ability to be stretched to moderate elongations and, upon removal of the stress, return to something close to its original shape.
- Processable as a melt at elevated temperatures.
- Absence of significant creep.

There are 3 different grades used in the Stoddard process to produce the properties of the soft, medium, and hard polishers. Their differential is shown in the shore A hardness as indicated below: -

Soft – 45 Shore A, Medium – 54 Shore A and Hard – 65 Shore A.

To this Thermoplastic Elastomer is added approximately 2 to 4% of a colour Masterbatch just for the colouring and identification of the product. (Note, Quantities vary depending on colour)

Masterbatch is a solid additive used for colouring plastics. Masterbatch is a concentrated mixture of pigments and/or additives encapsulated during a heat process into a carrier resin which is then cooled and cut into a granular shape.

This material may also contain trace elements, which are non-hazardous or non-hazardous at the levels of inclusion.

Component 2: **Metal Shank (Brass, Nickel plated) RA**

Description: Turned mandrels made from free cutting brass rod CUZN39PB3 or JIS H3250 C3604 or similar grade specification 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. Stoddard polishers are proven to function correctly by historical use with no adverse reports.

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

Chemical Analysis %

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

Material hardness: Vickers: HV151, megapascal 510MPa.

Surface Treatment: Bright Nickel Plated (Ni) CAS Number 7440-02-0

This material may also contain trace elements, which are non-hazardous or non-hazardous at the levels of inclusion.

Component 3: **Polypropylene**

Polypropylene, also known as polypropene, is a thermoplastic polymer used in a wide variety of applications. It is produced via chain-growth polymerisation from the monomer propylene. It belongs to the group of polyolefins and is partly crystalline and non-polar.
There are two grades used, depending on availability, Polypropylene PPR 7220 or Polypropylene RE420MO.

CAS Number – 9010-79-1

Typical properties: -

Density	902 to 905 Kg/m³
Melt Flow rate (230°C/2,16 Kg)	10 to 13 g/10min
Flexural modulus	1.150 to 1200 MPa
Tensile modulus (1 mm/min)	1.100 to 1.300 MPa
Tensile strength at yield (50 mm/min)	28 to 29MPa
Charpy impact strength, notched (23°C)	6 to 7 KJ/m²

This material may also contain trace elements, which are non-hazardous or non-hazardous at the levels of inclusion.

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Component 4: **Silicone Rubber Ring.**

Silicone Rubber is an elastomer composed of Silicone, which is itself a polymer containing silicon together with Carbon, Hydrogen and Oxygen. In its uncured state, silicone rubber is a highly adhesive gel or liquid and in order to convert it to a solid it must be cured, vulcanised or catalysed.
Silicon Rubber is generally non-reactive, stable and resistant to extreme environments and temperatures while still retaining its useful properties.

CAS number - 63394-02-5

Typical properties: -

Hardness	60 – 70 Shore A
Density	1.18 g/cm³
Tensile strength	7 – 11 MPa
Tear strength	25 – 30 KN/m

Physical data:

Physical state:	Solid
Solubility in water:	Insoluble
Evaporation rate:	Not applicable
Density (working part):	0.89g/cm³
Colour (working part):	various
Odour (working part):	Mild
Evaporation rate:	Not applicable
Solubility in water:	Insoluble

Warning: For professional use only. This instrument is for use by or under the supervision of a qualified dental professional. This product is manufactured in accordance with the dimensional requirements of ISO 1797 and should only be used in conjunction with rotary handpieces that conform with ISO 14457. The product must be correctly installed in the handpiece prior to commencement of procedure.

Health hazard information:

Ingestion:	Accidental ingestion is not harmful, consult physician if necessary.
Contamination of single use device:	Do not re-use, sterilise before single use, consult Sterilisation and Instructions for use.

Other information:
Stoddard Prophy cups.

These products are intended for use by trained Dental professionals only.

These Stoddard prophy polishing cups with ring are produced from Thermoplastic elastomer, bonded with Polypropylene to a nickel plated brass shank and fitted with a Silicone Rubber Ring.

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

a) The use of designs incorporating careful material selection with dimensions able to withstand the stresses of normal use.
b) 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

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

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

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First aid measures (in case of):

Inhalation:	Not applicable
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.

Personal protection equipment:

Eyes:	Safety glasses
Gloves:	None under normal processing
Respirator:	Not applicable

Accidental dispersion: May be swept up or mechanically collected.

Toxicology: There is no toxicological data specific to this product in its moulded state.

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

Handling and Storage: There are no specific handling requirements, store in clean dry conditions at room temperature and away from light.

Disposal procedures:

Aquatic toxicity:	Not applicable
Spill or leak:	Sweep up to prevent slipping hazard
Waste disposal:	Industrial recycling is recommended. Incinerate or landfill in compliance with National & local regulations.

Waste disposal 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. 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.

This PSDS 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.

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.

Emergency Phone No: (0044) 1462 686221

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