

Safety Data Sheet

1907/2006/EU (Annex II, article 31) – 453/2010/EU
SILICONE TUBES – DELTA TUBES – DIAMOND24

POLYDENTIA SA

Status 15.05.2018/AR
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1.1 Identification of the substance/preparation and of the company

Information on the product:

“Silicone tubes” - “Delta tubes” – “Diamond 24”

Medical Device Class (according to 93/42/EEC): I – Rule 5

Main use of the product: **Option for Quick rings**

1.2 Information on the manufacturer:

Polydentia SA
Via Cantonale 47
6805 Mezzovico-Vira (Switzerland)
Phone: +41 (0) 91 946 29 48
Fax : +41 (0) 91 946 32 03
Email : info@polydentia.com

1.3 Information provided by:

Phone: +41 (0) 91 946 29 48

Emergency telephone: +41 (0) 91 946 29 48

2. Composition (Substance)

Polydimethylsiloxane with vinyl groups, auxiliary and pigments

3. Hazards identification

Physical and chemical hazards for people and environment: none

The preparation is not classified as dangerous according to EU Directive.

4. First aid measures

After inhalation: Material cannot be inhaled under normal conditions.
After contact with skin: No special measures required.
After contact with eyes: No special measures required.
After ingestion: No first aid necessary.

5. Fire fighting measures

Suitable extinguishing media: Extinguishing powder, foam, sand, CO2

Extinguishing media which must not be used for safety reasons: None known

Special hazards caused by the material, its products of combustion or flue gases: None known

Special protective equipment for fire fighting: Use respiratory protection independent of recirculated air and suitable protective garments.

Combustion products: Silicon dioxide, traces of carbon oxide, carbon dioxide and formaldehyde.

6. Accidental release measures

Personal precautions: No special measures required.

Environmental precautions: Avoid spreading and prevent the product from entering sewers or surface waters.

Methods for cleaning up: Sweep and scrap into a waste bin.

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7. Handling and storage

Handling

Precautions for safe handling: No special protective measures required.

Precautions against fire and explosion: No special precautions are required.

Storage

Conditions for storage rooms and vessels: None known

Advice for storage of incompatible materials: Not applicable

Further information for storage: Keep the pack tightly close

8. Exposure controls / Personal protection

Additional information about the technical concept of the product: None

Exposure limited and controlled: Not applicable

General protection and hygiene measures: None required

Respiratory protection: Non required

Eye protection: Not required

Skin protection: Not required

Soft oral tissue protection: Not required

9. Physical and chemical properties

Appearance: solid, elastic

Odour: odourless

Colour: according to product specification (transparent or in various colours)

Ignition temperature: >400 °C

Flash point: not applicable

Lower explosion limit: not applicable

Upper explosion limit: not applicable

Vapour pressure: not applicable

Density: 1,17 g/cm³

Water solubility: insoluble

Liposolubility: not applicable

pH-Value: not applicable

Viscosity: not applicable

10. Stability and reactivity

Stability: Product is stable under normal handling and storage.

Conditions to avoid: Remove all sources of ignition, avoid storing in moist and warm conditions.

Materials to avoid: None known.

Dangerous products of decomposition: Measurements have shown the formation of small amounts of formaldehyde at temperatures above about 400 °C (302 °F).

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11. Toxicological information

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

12. Ecological information

Product not soluble and not hazardous for water. No expected damaging effects to aquatic organisms. Material not biodegradable on the basis of its structure. Bioaccumulation is not expected to occur.

13. Disposal consideration

Avoid spreading and prevent the product from entering sewers or surface waters.
Used products can be discharged into a waste bin, according to any national or regional provisions which may be in force.

14. Transport information

Land ADR/RID: No hazardous material
Sea: INO/IMDG: No hazardous material
Air transport ICAO-II/IATA-DGR: No hazardous material
UN regulation: - /

Customs Harmonized Tariff No. 9018.4900

15. Regulatory information

None of the ingredients is listed.
Mark as ECC-guideline / Not necessary to mark
National regulations / Classification as VFB / Not subordinated

Warning Label:

R sets: none

S sets: none

16. Other information**FOR PROFESSIONAL USE ONLY**

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.
The receiver of this product must take responsibility for observing existing laws and national regulations.

POLYDENTIA SA is not held liable for any damage resulting from handling or contact with above mentioned products.

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 1907/2006/EU (Annex II, article 31) – 453/2010/EU
LumiContrast – Sectional Matrices

POLYDENTIA SA
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1.1 Identification of the substance/preparation and of the company

Information on the product:

LumiContrast – Sectional Matrices
 (various types, forms and thicknesses)

Medical Device Class (according to 93/42/EEC):

I - Rule 5

Main use of the product:

As a help for dental fillings

1.2 Information on the manufacturer:

Polydentia SA
 Via Cantonale 47
 6805 Mezzovico-Vira (Switzerland)
 Phone: 0041 (0) 91 946 29 48
 Fax : 0041 (0) 91 946 32 03
 Email: info@polydentia.com

1.3 Information provided by:

Phone: +41 (0) 91 946 29 48

Emergence telephone: +41 (0) 91 946 29 48

2. Composition (Substance) – Stainless Steel

Substance	CAS-No.
Chrome	7440-47-3
Nickel	7440-02-0
Manganese	7439-96-5
Traces of Carbon, Phosphorus, Sulphur, Silicium and Molybdenum, Chromium Oxide	

3. Hazards identification

Physical and chemical hazards for people and environment: **none**
 The product is not classified as dangerous according to EU Directive

4. First aid measures

General information:	No special measures necessary
After inhalation:	Material cannot be inhaled under normal conditions
After contact with skin:	No special measures required
After contact with eyes:	No special measures required
After ingestion:	No first aid necessary

5. Fire fighting measures

Suitable extinguishing media:	not applicable
Extinguishing media which must not be used for safety reasons:	not applicable
Special hazards caused by the material, its products of combustion or flue gases:	not applicable
Special protective equipment for fire fighting:	not applicable
Combustion products:	not applicable

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6. Accidental release measures

Precautionary measures related to people:	not applicable
Environmental protective measures:	not required
Methods for cleaning up:	mechanical

7. Handling and storage

Handling

Precautions for safe handling:	No special protective measures required
Precautions against fire and explosion:	No special precautions are required

Storage

Conditions for storage rooms and vessels:	None known
Advice for storage of incompatible materials:	Not applicable
Further information for storage:	Keep the pack tightly close

8. Exposure controls / Personal protection

Additional information about the technical concept of the product:	None
Exposure limited and controlled:	Not applicable
General protection and hygiene measures:	None required
Respiratory protection:	Non required
Eye protection:	Not required
Skin protection:	Not required
Soft oral tissue protection:	Not required

9. Physical and chemical properties

Appearance:	flexible bands of various forms, sizes and thicknesses
Thickness:	0.025mm, 0.04mm
Odour:	odourless
Colour:	dark blue
Ignition temperature:	not applicable
Flash point:	not applicable
Lower explosion limit:	not applicable
Upper explosion limit:	not applicable
Vapour pressure:	not applicable
Density:	8 g/cm ³
Water solubility:	insoluble
Liposolubility:	not applicable
pH-Value:	not applicable
Viscosity:	not applicable

10. Stability and reactivity

Shelf life:	not applicable
Stability:	Product is stable under normal handling and storage
Conditions to avoid:	storage near acids
Materials to avoid:	acidic solution
Dangerous products of decomposition:	not applicable



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11. Toxicological information

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

12. Ecological information

Product not soluble and not hazardous for water. No expected damaging effects to aquatic organisms. Material not biodegradable on the basis of its structure. Bioaccumulation is not expected to occur.

13. Disposal consideration

Recycling of the metals

N.B. Respect any national or regional provisions which may be in force.

14. Transport information

Land ADR/RID: No hazardous material
Sea IMO/IMDG: No hazardous material
Air transport ICAO-II/IATA-DGR: No hazardous material

Customs Harmonized Tariff: 9018.4900

15. Regulatory information

None of the ingredients is listed
Mark as ECC-guideline / Not necessary to mark
National regulations / Classification as VFB / Not subordinated

Warning Label:

R sets: none

S sets: none

16. Other information

FOR PROFESSIONAL USE ONLY

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WOOD WEDGES

POLYDENTIA SA

Status 09.04.2015/AR

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1.1 Identification of the substance/preparation and of the company

Information on the product:

Interdental Wood Wedges POLYDENTIA

(various types and lengths, plain or colour coded)

Medical Device Class I (according to 93/42/EEC) – Rule 5

Main use of the product: help for cavity preparation during restorative procedures

1.2 Information on the manufacturer:

Polydentia SA
 Via Cantonale 47
 6805 Mezzovico-Vira (Switzerland)
 Phone: 0041 (0) 91 946 29 48
 Fax : 0041 (0) 91 946 32 03
 Email : info@polydentia.com

1.3 Information provided by:

Phone: +41 (0) 91 946 29 48

Emergency telephone: +41 (0) 91 946 29 48

2. Composition

Substances

CAS Nr.

Maple wood, Birch wood, Lime wood

If colour coded, food dyes:

Pink: E-124	2611-82-7
Blue: E-131	20262-76-4
Green: E-104 + E-131	8004-92-0 & 20262-76-4
Yellow: E-104	8004-92-0 (95193-83-2)
Orange: E-110	2783-94-0
Plain: -	-

3. Hazards identification

To man: Irritation in case of hard contact with oral tissues

To environment: No anticipated hazard to environment

4. First aid measures

After inhalation:	no need for first aid is anticipated
After contact with skin:	no need for first aid is anticipated
After contact with tissue contact:	no need for first aid is anticipated
After contact with eyes:	get medical attention
After ingestion:	consult with a physician.
Other recommendations:	none



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5. Fire fighting measures

Suitable extinguishing media: Water spray

Unsuitable extinguishing media for safety reasons: none

Special exposure hazards: none

Special protective equipment for fire fighting: none

6. Accidental release measures

Precautionary measures related to people: not applicable

Environmental protective measures: not required

Methods for cleaning up: sweep

7. Handling and storage

Handling: -

Storage: in well closed original container, at room temperature

Further information about storage: not required

8. Exposure controls / Personal protection

Precautionary measures to be taken during use: usual in dental practice

Respiratory protection: not required

Hand protection: not required

Eye protection: not required

Skin protection: not required

Soft oral tissue protection: not required

9. Physical and chemical properties

Appearance: solid (wedge)

Odour: odourless

Colour: plain, pink, blue, green, yellow, orange, white

pH: not applicable

Flammability: yes

Solubility: not applicable

Insolubility: not applicable

Density: not applicable

Melting point: not applicable

Boiling point: - not applicable

Other data: Five lengths 11mm pink, 12mm blue/orange, 13mm green, 15mm yellow, 17mm white



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10. Stability and reactivity

Stability: stable

Conditions to avoid: humidity, all sources of ignition

Material to avoid: none

Hazardous decomposition products: none

11. Toxicological information

Not reported

12. Ecological information

Not determined

N.B. Information relevant to the environment is provided, in case of need, in other section of the data sheet.

13. Disposal consideration

Dustbin

N.B. Respect any national or regional provisions which may be in force.

14. Transport information

Land ADR/RID : No hazardous material

Sea: INO/IMDG : No hazardous material

Air transport ICAO-II/IATA-DGR : No hazardous material

UN regulation: - /

Customs Harmonized Tariff No. 9018.4900

15. Regulatory information

Mark as ECC-guideline

Not necessary to mark

National regulations

Classification as VFB

Not subordinated

R sets: none

S sets: none



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16. Other information

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STEEL MATRICES

POLYDENTIA SA

Status 09.04.2015/AR

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1.1 Identification of the substance/preparation and of the company

Information on the product:

Stainless Steel Matrices POLYDENTIA

(various types, forms and thicknesses)

Medical Device Class I (according to 93/42/EEC) – Rule 5

Main use of the product: as a help for dental fillings

1.2 Information on the manufacturer:

Polydentia SA

Via Cantonale 47

6805 Mezzovico-Vira (Switzerland)

Phone: 0041 (0) 91 946 29 48

Fax : 0041 (0) 91 946 32 03

Email: info@polydentia.com

1.3 Information provided by:

Phone: +41 (0) 91 946 29 48

Emergency telephone: +41 (0) 91 946 29 48

2. Composition

Substance	CAS-No.
Chrome	7440-47-3
Nickel	7440-02-0
Manganese	7439-96-5
Traces of Carbon, Phosphorus, Sulphur and Silicium	

3. Hazards identification

Special hazards information for human and environment: not applicable

4. First aid measures

General information: no special measures necessary

Inhalation: not applicable

Contact with skin: not applicable

Contact with eyes: not applicable

Ingestion: Consult with a physician

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5. Fire fighting measures

Suitable extinguishing media: not applicable

Unsuitable extinguishing media for safety reasons: not applicable

Special exposure hazards: not applicable

Special protective equipment for fire fighting: not applicable

6. Accidental release measures

Precautionary measures related to people: not applicable

Environmental protective measures: not required

Methods for cleaning up: mechanical

7. Handling and storage

Handling: -

Storage: at room temperature, avoiding contact with acidic vapours

Further information about storage: not required

8. Exposure controls / Personal protection

Precautionary measures to be taken during use: usual in dental practice

Respiratory protection: not required

Hand protection: not required

Eye protection: not required

Skin protection: not required

Soft oral tissue protection: not required

9. Physical and chemical properties

Appearance: flexible bands of various forms, sizes and thicknesses

Odour: none

Colour: brilliant steel

pH: not applicable

Flammability: not applicable

Solubility: not applicable

Insolubility: not applicable

Density: not applicable

Melting point: not applicable

Boiling point: not applicable

Thickness: 0.025mm, 0.03mm, 0.04mm, 0.05mm



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STEEL MATRICES

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10. Stability and reactivity

Shelf life: not applicable

Conditions to avoid: storage near acids

Material to avoid: acidic solution

Hazardous decomposition products: not applicable

11. Toxicological information

Not applicable; there are none unhealthy effects.

12. Ecological information

Not applicable

13. Disposal consideration

Recycling of the metals

N.B. Respect any national or regional provisions which may be in force.

14. Transport information

Land ADR/RID: No hazardous material

Sea IMO/IMDG: No hazardous material

Air transport ICAO-II/IATA-DGR: No hazardous material

Customs Harmonized Tariff: 9018.4900

15. Regulatory information

Mark as ECC-guideline

Not necessary to mark

National regulations

Classification as VFB

Not subordinated

R sets: none

S sets: none

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