

E.C. – Safety Data Sheet (91/155/EEC) Quickmat Deluxe

POLYDENTIA SA Status 15.03.2012/AR Page 1 of 1

Quickmat kit MSDS composition:

- MSDS Quick ringsMSDS Re-Force insert
- MSDS Steel Matrices
- MSDS Wood Wedges
- MSDS Silicone Tubes Delta silicone tubes







E.C. – Safety Data Sheet (91/155/EEC) QUICK RINGS

POLYDENTIA SA Status 15.03.2012/AR Page 1 of 3

1.1 Identification of the substance/preparation and of the company

Information on the product:

Quick rings

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

CH-6805 Mezzovico-Vira 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
 CAS-No.

 Chrome
 7440-47-3

 Nickel
 7440-02-0

 Manganese
 7439-96-5

Traces of Carbon, Phosphorus, Sulphur, Silicium and Molybdenum

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







E.C. – Safety Data Sheet (91/155/EEC) QUICK RINGS

POLYDENTIA SA

Status 15.03.2012/AR Page 2 of 3

5. Fire fighting measures

Suitable extinguishing media: non applicable

Unsuitable extinguishing media for safety reasons: not applicable

Special exposure hazards: non 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: Round wire

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: Wire Ø1.5mm







E.C. – Safety Data Sheet (91/155/EEC) QUICK RINGS

POLYDENTIA SA

Status 15.03.2012/AR Page 3 of 3

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

16. Other information

Recommended use: for dental professional use only

Restriction of use: other than dental







E.C. – Safety Data Sheet (91/155/EEC) RE-FORCE INSERT

POLYDENTIA SA Status 15.03.2012/AR

Page 1 of 3

1.1 Identification of the substance/preparation and of the company

Information on the product:

"Re-Force Insert"

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 Strada Cantonale

CH-6805 Mezzovico-Vira

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

2. Composition (Substance)

HT-Polyamide Glass reinforced

3. Hazards identification

Physical and chemical hazards for people and environment: none

The preparation is not classified as dangerous according to Directive 1999/45/EC.

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: Hydrogen cyanide (HCN), Carbon monoxide (CO)

Banks: Banca dello Stato del Canton Ticino, Lugano Credit Suisse, Lugano

PostFinance

Protective equipment for fire fighting: No special measures required.

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.







E.C. – Safety Data Sheet (91/155/EEC) RE-FORCE INSERT

POLYDENTIA SA

Status 15.03.2012/AR Page 2 of 3

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 Odour: odourless Colour: Various Colors

Melting Point/Melting Range : 260 °C Boiling Point/Boiling Range : Not applicable

Flash point: not applicable

Lower explosion limit: not applicable Upper explosion limit: not applicable Vapour pressure: not applicable Density at 20°C: >1 g/cm3 Water solubility: insoluble

10. Stability and reactivity

Thermal decomposition / Condition to be avoided: No decomposition if used according to specifications Dangerous reactions: No dangerous reactions known

Dangerous products of decomposition: No dangerous decomposition products known

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.

Banks: Banca dello Stato del Canton Ticino, Lugano Credit Suisse, Lugano

PostFinance







E.C. – Safety Data Sheet (91/155/EEC) RE-FORCE INSERT

POLYDENTIA SA Status 15.03.2012/AR Page 3 of 3

12. Ecological information

Product not soluble and not hazardous for water.

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

Recommended use: for dental professional use Restriction of use: keep away from children

This Safety Data Sheet completes the Technical Data Sheet of the product, but it doesn't replace it. It is based on our present-day knowledge and has been issued according to the Safety Data Sheet of the raw material supplier.







E.C. – Safety Data Sheet (91/155/EEC) STEEL MATRICES

POLYDENTIA SA Status 15.03.2012/AR Page 1 of 3

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

CH-6805 Mezzovico-Vira 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
 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







E.C. – Safety Data Sheet (91/155/EEC) STEEL MATRICES

POLYDENTIA SA

Status 15.03.2012/AR Page 2 of 3

5. Fire fighting measures

Suitable extinguishing media: non applicable

Unsuitable extinguishing media for safety reasons: not applicable

Special exposure hazards: non 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







E.C. - Safety Data Sheet (91/155/EEC) STEEL MATRICES

POLYDENTIA SA

Status 15.03.2012/AR Page 3 of 3

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

16. Other information

Recommended use: for dental professional use only

Restriction of use: other than dental







E.C. – Safety Data Sheet (91/155/EEC) WOOD WEDGES

POLYDENTIA SA Status 15.03.2012/AR Page 1 of 3

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

CH-6805 Mezzovico-Vira 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

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)

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



Banks: Banca dello Stato del Canton Ticino, Lugano Credit Suisse, Lugano

PostFinance





E.C. – Safety Data Sheet (91/155/EEC) WOOD WEDGES

POLYDENTIA SA

Status 15.03.2012/AR Page 2 of 3

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, 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, 13mm green, 15mm yellow, 17mm white







E.C. – Safety Data Sheet (91/155/EEC) WOOD WEDGES

POLYDENTIA SA Status 15.03.2012/AR Page 3 of 3

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

16. Other information

Recommended use: for dental professional use only

Restriction of use: keep away from children







E.C. – Safety Data Sheet (91/155/EEC) SILICONE TUBES – DELTA SILICONE TUBES

POLYDENTIA SA

Status 15.03.2012/AR Page 1 of 3

1.1 Identification of the substance/preparation and of the company

Information on the product:

"Silicone tubes" and "Delta silicone tubes"

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 Strada Cantonale

CH-6805 Mezzovico-Vira

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 Emergence 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 Directive 1999/45/EC.

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.

Banks: Banca dello Stato del Canton Ticino, Lugano

Credit Suisse, Lugano

PostFinance

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.







E.C. – Safety Data Sheet (91/155/EEC) SILICONE TUBES – DELTA SILICONE TUBES

POLYDENTIA SA

Status 15.03.2012/AR Page 2 of 3

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).







E.C. - Safety Data Sheet (91/155/EEC) SILICONE TUBES - DELTA SILICONE TUBES

POLYDENTIA SA Status 15.03.2012/AR Page 3 of 3

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

Recommended use: for dental professional use Restriction of use: keep away from children

This Safety Data Sheet completes the Technical Data Sheet of the product, but it doesn't replace it. It is based on our present-day knowledge and has been issued according to the Safety Data Sheet of the raw material supplier.



