

Safety Data Sheet

1907/2006/EU (Annex II, article 31) - 453/2010/EU

WOOD WEDGES

POLYDENTIA SA

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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 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)

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:

After contact with skin:

After contact with skin:

no need for first aid is anticipated no need for first aid is anticipated 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

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.



