

Safety Data Sheet 1907/2006/EU (Annex II, article 31) – 453/2010/EU **Hemo – Wedges** POLYDENTIA SA Status 09.04.2015/AR Page 1 of 3

1.1 Identification of the substance/preparation and of the company

Information on the product: **Hemo - Wedges POLYDENTIA**(various types and lengths)

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 -

7% wt Aluminium potassium sulphate dodecahydrate 7784-24-9

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: Rinse opened eye for several minutes under running water

After ingestion: consult with a physician.

Other recommendations: none







Safety Data Sheet 1907/2006/EU (Annex II, article 31) – 453/2010/EU **Hemo – Wedges** POLYDENTIA SA Status 09.04.2015/AR Page 2 of 3

5. Fire fighting measures

Suitable extinguishing media: CO2, powder or water spray

Unsuitable extinguishing media for safety reasons: none

Special exposure hazards: Sulfur Oxides (SOx) - Potassium oxides

Special protective equipment for fire fighting: Do not inhale gases in case or fire or combustion

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: Store in cool place. Keep original container tightly closed in a dry and well-ventilated place 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 protection: not required not required skin protection: not required not required soft oral tissue protection: not required

9. Physical and chemical properties

Appearance: solid (wedge)
Odour: odourless
Colour: white

pH: not applicable

Flammability: yes

Solubility: not applicable not applicable pensity: not applicable Melting point: not applicable poiling point: not applicable not applicable not applicable

Other data: Five lengths 11mm, 12mm, 13mm, 15mm, 17mm







Safety Data Sheet 1907/2006/EU (Annex II, article 31) – 453/2010/EU **Hemo – Wedges** POLYDENTIA SA Status 09.04.2015/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

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

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

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.



