

Safety Data Sheet

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

HY-DROP

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:

"Hy-Drop"

Medical Device Class (according to 93/42/EEC): I – Rule 1 Main use of the product: **Hygienic liquid dispenser**

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)

-PSU (Polysulfone)

-Parts in stainless steel

-Parts in silicone

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: Class UL94 V-O without alogens Special hazards caused by the material, its products of combustion or flue gases: Low lever of 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.







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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: Not required

Respiratory protection: Not required

Eve 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: 121°C to 163°C

Mold temperature: 190 °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

Water solubility: insoluble

Presence of little pipe in stainless steel and a membrane in silicone.

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







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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.

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.



