



Safety Data Sheet

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

HY-DROP FORTE

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 Forte”

Medical Device Class: I – Rule 1 (according to 93/42/EEC)

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)

-PEI (Polyetherimide)

Preparation based on Polyetherimide plus colorants. No harmful classified ingredients, no Cadmium, no Lead, no Chrom-VI- no Diaryl-Pigments. Fulfils the EC-Directives RoHS 2002/95/EC and its amendments 2005/618/EC.

-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.

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5. Fire-Fighting Measures/Instructions:

At Fire: Suitable extinguishing media: Water, Foam, Dry extinguishing media or CO₂.

Specific hazards: At temperatures above +420°C it can emit CO, CO₂, SO₂ and SO₃. Under specific fire conditions traces of other toxic substances are possible. The formation of further decomposition and oxidation products depends on the fire environment conditions. Dispose of fire debris and contaminated extinguishing water in accordance to local regulations.

6. Accidental release measures

Personal precautions: No special measures required.

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

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

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

Eye protection: Not required

Skin protection: Not required

Soft oral tissue protection: Not required

9. Physical and Chemical Properties:

Appearance / Colour / Odour: Solid / Black / Odourless

Ignition temperature: +580°C - + 600°C

Softening point: + 190°C

Density: 1,25 up to 1,40 g/cm³

Solubility in Water: Insoluble in aqueous solutions

Fast thermal decomposition: +420°C

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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/ Additional Information:

Based on our experience and the information available, no adverse health effects are expected if the product is handled as recommended with suitable precautions for designated uses. No negative effects known to our experience of today.

12. Ecological Information:

No eco-toxicological negative effects known. Other advices: None.

13. Disposal Considerations:

Check for possible material recycling. Waste can be disposed in normal waste land field in observation of the local regulations, or can be incinerated in plants with scrubber. Waste-key: none

14. Transport Information:

Not classified as hazardous under international transport regulations.

15. Regulatory Information:

Product does not require a hazard warning label in accordance to European Union (EC) labelling Directives.

No substances on the US State hazardous lists added. None water pollution hazardous classification.

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.