

Material Safety Data Sheet

(Annex II of Regulation (UE) 2020/878 – modifying annexe II (EC) 1907/2006 - CLP Regulation N°1272/2008)

1. Identification of the substance/mixture and the company**1.1 Product identifier**

Product name Endoneedle
Type of product Canulas for root canal irrigation
Product reference ED27-30, ED27-100, ED30-100, ED30-30, ED23-100, ED23-30

1.2 Relevant identified uses of the substance or mixture and uses advised against:
Identified use(s)**1.3 Details of the supplier of the safety data sheet:**

Name **G-PHARMA**
Address 35, avenue du Gros Chêne - ZI des Bellevues
95220 Herblay - France
Email elsodent@elsodent.com
Phone + 33 (0)1 30 37 75 75

1.4 Emergency telephone number

ORFILA + 33 (0)1 45 42 59 59

2. Hazards Identification

The mixture meets the classification criteria of Regulation No 1272/2008 amending and repealing Directives 67/548/EEC and 1999/45/EC and amending Regulation No 1907/2006/EC (CLP Regulation). The mixture requires a safety data sheet in accordance with the requirements.

2.1 Classification of the substance or mixture**2.1.1 Classification according to Regulation (EC) No 1272/2008 (CLP)**

This product has no classification under CLP.

2.1.3 Additional information

The full wording of the hazard classes and categories, hazard statements H and R phrases is mentioned in section 2.2.

2.2 Label elements

Labeling in accordance with Regulation (EC) No 1272/2008 (CLP) and its derogations from article 17 (relating to labeling and packaging requirements) for products with a capacity of less than 125 ml (Annex I to Regulation 1.5.2.1).

Pictogram

GHS07

Signal word

Warning

Hazard statement**H302** – Harmful if swallowed.Precautionary advices**P103** – Read label before use (always attached the canula to a luer lock syringe to avoid risk if ingestion of the canula).**P301** – IF SWALLOWED: Seek for medical advice to retrieve the cannula under endoscopy.Additional information on hazards:

None

2.3 Other hazards:

Not listed

3. Composition / Information on ingredients**3.1 Product**

EC Designation Not applicable
Classification according to Regulation Class I
(EU) MDR 2017/745

3.2 Mixtures

Index CE	Chemical name	% Mass	Classification according to (CLP) N°1272/2008 (CE)	Generic threshold
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CAS				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

Note: The full text of H statements and R phrases is listed in section 2.2.

4. First aid measures

4.1 Description of first aid measures

Inhalation

Not applicable

Skin contact

Not applicable

Eye contact

Seek for medical advice in case irritation.

Ingestion

Seek for medical advice to retrieve the cannula under endoscopy.

4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

For the possibility of consulting a physician, refer to section 4.1.

5. Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media: Not applicable

Flammability: Not applicable

Auto-ignition temperature: Not applicable

Unsuitable extinguishing media: Not applicable

Explosive Limit in Air: Not applicable

Flash point: Fusion point: Not applicable

5.2 Special hazards arising from the substance or mixture

Not applicable

5.3 Tips for firefighters

Not applicable

6. Accidental release measures

6.1 Personal precautions, protective equipment, and emergency procedures

Not applicable

6.2 Environmental precautions

Not applicable

6.3 Methods and materials for containment and cleaning up

Not applicable

6.4 References to other sections

Not applicable

7. Handling and Storage

7.1 Precautions for safe handling

None

7.2 Conditions for safe storage, including any incompatibilities

none

7.3 Specific end use(s)/ Dental professional use only

8. Exposure controls / personal protection

8.1 Control parameters

Always attached the cannula to a luer lock syringe to avoid risk if ingestion of the cannula.

Appropriate technical controls

Personal protective measures, such as personal protective equipment

Not applicable

Eye/face protection

Wear goggles, mask, gloves and blouse.

Avoid contact with eyes.

Skin/hand protection

Not applicable

Respiratory protection

Not applicable

8.2 Exposure parameters

Not applicable

9. Physical & Chemical properties**9.1 Information on basic physical and chemical properties****Appearance**

Physical state	Solid
Color	Metallic

Specific Physical Form: Not applicable

Odor

Odor threshold	Not applicable
pH	Not applicable
Boiling point	Not applicable
Melting point	Not applicable
Flash point	Not applicable
Evaporation rate	Not applicable
Flammability (solid, gas)	Not applicable
Flammability Limits (LEL)	Not applicable
Flammability Limits (UEL)	Not applicable
Vapor Pressure	Not applicable

Vapor density (air = 1)

Not applicable

Density

Not applicable

Specific gravity

Not applicable

Solubility in water

Not applicable

Solubility-non-water

Not applicable

Reactivity in water

Not applicable

Partition coefficient: n-octanol/water Not applicable**Decomposition temperature**

Not applicable

Autoignition Temperature

Not applicable

9.2 Other information**9.2.1 Information on physical hazard classes**

No important information available.

9.2.2 other safety characteristics

None.

10. Stability & reactivity

10.1 Reactivity	Not applicable
10.2 Chemical stability	Not applicable
10.3 Possibility of hazardous reactions	Not applicable
10.4 Conditions to avoid	Not applicable
10.5 Incompatible materials	Not applicable
10.6 Hazardous decomposition products	Not applicable
10.7 Uncontrolled polymerization	Not applicable

11. Toxicological information**11.1 Information on toxicological effects**

Not applicable

11.2 Other information

None

12. Ecological information

12.1 Toxicity	Not applicable
12.2 Persistence and degradability	Not applicable
12.3 Bioaccumulative potential	Not applicable
12.4 Mobility in soil	Not applicable
12.5 Results of PBT and vPvB assessment	Not applicable
12.6 Endocrine-disrupting properties	Not applicable
12.7 Other adverse effects	Not applicable

13. Disposal measures**13.1 Waste treatment methods**

Large quantities: disposal according to applicable national, federal, regional or local laws. Do not pour into the sink.

13.2 Uncleaned packaging

Disposal must be in accordance to all federal, national and local

14. Transport information

Substances/mixtures not classified as hazardous for transportation. No restriction for the road, boat or plane transportation.
This information regarding the transportation follows the international transportation requirements.

15. Regulation

15.1 Safety, health and environmental regulations / legislation specific for the substance or mixture

Class I medical device according to Regulation (EU) MDR 2017/745.

15.2 Chemical Safety Assessment

Not applicable

16. Other information

Abbreviations and acronyms:

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

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