

# **DISPOSABLE REINFORCED POLYAMIDE INSTRUMENTS**

## **MATERIAL SAFETY DATA SHEET**

**Product:** various disposable instruments, named **Europias<sup>®</sup>**, made of reinforced polyamide some of them with additional stainless steel. Sterile or Non-Sterile.

**Ref:** 01001 - 01082 (Not including 01013 - 01020)

### **Product and Company Identification**

**Product name:** Various disposable instruments.

**Intended Use:** To be used in medical procedures on humans and other mammals.

### **Manufacturer:**

Pollak (International) Ltd

20 Hamelacha Street, New Industrial Zone, Afek, Rosh Ha'ayin 48091 Israel.

Tel: 972 3 9022885 Fax: 972 3 9024531

### **Composition/Information on Ingredients:**

Various molded instruments made of reinforced polyamide as in E.P, U.S.P, B.P. Part of the instruments, like scissors, forceps and clamps include stainless steel metal parts of 316 or 430 series, same as stainless steel instruments used in other medical procedures.

### **Hazards Identification:**

**Emergency Overview:** No Hazards to Incidental or Prolonged Exposures.

### **Signs and Symptoms of Overexposure**

No Hazards to Incidental or Prolonged Exposures.

Inhalation or other body cavities: No Hazards to Incidental or Prolonged Exposures.

Effects of Chronic Exposure: ND

Medical Conditions Aggravated: ND

### **First Aid Measures**

No identified risks. Same as other plastic or stainless steel instruments. Because of density and shape these products are X-Ray detectable.

### **Fire Fighting Measures**

Flash point and Method: ND

Flammable Limits: Polyamide may melt in direct flames or heat over 250<sup>0</sup>C. Metal may twist at temperatures over 850<sup>0</sup>C.

Upper: ND

Lower: ND

Auto-ignition temperature: ND

Extinguishing media: Direct flames or heat over 250<sup>0</sup>C.

Hazardous combustion Products: ND

Fire and Exposure Hazards: Polymerization may occur on temperatures over 250<sup>0</sup>C.

Special Firefighting Instruction: None.

### **Accidental Release Measures:** NE

### **Handling and Storage**

Refer to specification product labeling for storage conditions. Keep dry, avoid dust and high humidity. If storage temperature decreases below 10<sup>0</sup>C wait till temperature rises 10<sup>0</sup>C for at least 24 hours. If exposed to high humidity over 80% or wetness, wait at least 48 hours in humidity of 40% ± 20%. If humidity storage decreased 20% for over 48 hours keep product at least 48 hours in humidity of 40% ± 20%.

### **Exposure Control/Personal Protection**

No hazards exist requiring exposure control or protection

### **Physical and Chemical Properties**

Physical state: Solid.

Appearance: If not otherwise requested the polyamide is Pantone 341 or similar green.

Odor: None.

Solubility in water: None.

Absorbency:  $\pm 2\%$  of its own weight.

Melting Point: Polyamide 250° C, stainless steel 850° C

pH:  $7 \pm 0.2$

### **Stability and Reactivity**

Hazardous Polymerization will not occur

Good compatibility with other materials used in medical procedures including light acids or light alkalis.

### **Toxicological Information:**

No known toxicological effects.

Materials are known for proven biocompatibility.

Colors comply with the FDA regulation 21 CFR 177.2470.

### **Sterile Position:**

Product can be supplied sterile, being sterilized by steam of up to 137° C, or ETO or gamma rays or chemical agents or high heat of 185° C.

After steam sterilization wait 48 hours in humidity of  $40\% \pm 20\%$ .

After ETO sterilization, verify residues of ETO not to exceed the permitted levels for the required medical procedures.

**Ecological Information:** NE, when discarded or burned, polyamide material will turn into CO<sub>2</sub>, H<sub>2</sub>O and quartz. (Negligible residues of nitrogen may be released during burning).

### **Disposal Considerations:**

Dispose or incinerate in accordance with all applicable regulations for disposed medical products.

### **Transportation Information:**

No specific requirements to be met; not regulated as a hazardous material.

**Regulatory Information:** NE.

### **Other Information:**

Legends: NA= not applicable NE = Not Established ND = Not Determined

Approved by:

POLLAK (INTERNATIONAL) LTD – Quality Assurance

Approval Date September 7<sup>th</sup>, 1996:

*Note: The information on this MSDS represents our current data and best opinion as to the proper use in handling of these products under the normal conditions of their use. Any use of these products which is not in conformance with the data sheet or product labeling, or which involves the product in combination with any other material or processes or interactions is the responsibility of the user. This information should not be construed as a legal contract or guaranteeing any specific property of the product.*