

DISPOSABLE PLASTIC INSTRUMENTS

MATERIAL SAFETY DATA SHEET

Product: various disposable instruments made of High Impact Polystyrene some of them with additional stainless steel. Sterile or Non-Sterile.

Ref: 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 Hamlacha 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 high impact polystyrene as in E.P, U.S.P, B.P. Part of the instruments, like Razors, Scalpels, armllets 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: Polystyrene may melt in direct flames or heat over 100°C. Metal may twist at temperatures over 850°C.

Upper: ND

Lower: ND

Auto ignition temperature: ND

Extinguishing media: Direct flames or heat over 100°C.

Hazardous combustion Products: ND

Fire and Exposure Hazards: Polymerization may occur on temperatures over 120°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°C wait till temperature rises 10°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: Polystyrene 100° C, stainless steel 850° C

pH: 7 ± 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 ETO or gamma rays or chemical agents that do not melt polystyrene.

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, turned into CO₂, H₂O. (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 7th, 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.