Informace o výrobku

Polystone® P HG EHS

extruded products

This information relates to following semi-finished products, extruded and purchased from Röchling Industrial Lahnstein SE & Co. KG, located in 56112 Lahnstein/Germany:

Výrobky		
Polystone® P HG EHS hnědá	Polystone® P HG EHS modrý	Polystone® P HG EHS zelená
Polystone® P HG EHS šedý	Polystone® P HG EHS žlutá	

To produce the above-mentioned semi-finished products made of Polypropylene Homopolymer, only resins from qualified manufacturers and suppliers (hereinafter “supplier”) are used. The recommendations of the raw material producers are considered during the manufacturing and handling process. This material is not approved for human implants.

Resin compliance

Suppliers provides documents including but not limited to the following information regarding the compositional compliance of the resin:

- Polypropylene Homopolymer (CAS No.9003-07-0) as well as colorants and/or additives
- Classification according to Regulation EC No. 1272/2008 [CLP]: None
- Phthalates / Endocrine Disruptors / CMR substances: None
- Animal origin, TSE/BSE: no materials of biological origin, compliant with the European Union note for guidance “EMA/410/01 rev.3, 2011” and are free from BSE-(Bovine Spongiform Encephalopathy) and TSE-(Transmissible Spongiform Encephalopathy).
- REACh Registration / SVHC / ANNEX XIV / ANNEX XVII: compliant
- ABSENCE OF SUBSTANCES

  following substances are not intentionally added:

  - Biocides according to Regulation (EU) No 528/2012

  - Substances of animal origin

- Genetically modified organisms and their productso Latex
- Esters of phthalic acid (phthalates, all types)

· ROHS (EC) No. 2011/65/EU, No. 2015/863/EU: compliant

· PAK, Latex, Silicon free

· Biocompatibility: ISO 10993-5: The Type Testing was performed in support of ISO 10993 Type A medical device applications with a limited contact duration of less than 24 hours.

· FDA food contact compliant / EU 10/2011 compliant

· Country of Origin – Europe

Process / incoming goods

Our risk management process ensures that within the framework of the incoming goods inspection of the raw material the cytotoxicity test according to DIN EN ISO 10993-5 is carried out by an accredited institute on a representative delivery lot of the semi-finished product processed by Röchling Industrial Lahnstein SE & Co. KG out of the raw material. All the above-mentioned products have been successfully tested on the semi-finished product to ISO 10993-5 accordingly and therefore released.

Manufacturing process

No additional additives, plasticizers, or processing aids are added in the manufacturing process. Furthermore, the products listed above contains of no recycled, reconstituted, regrind, recovered or reprocessed resin.

To reduce possible internal stresses after extrusion, the semi-finished products can be subjected to an annealing process. Planning, sawing and milling operations are carried out without the use of cooling lubricants. This product information encompasses the working steps planning, sawing and milling – all without the use of cooling lubricants. All medical grade semi-finished products are ultrasonically tested and found to be void free.

Identification and traceability

Our Healthcare Grade (HG) materials are marked respectively given a sticker on each item and therefore fully traceable through their batch number up to the used resin lot number.

Compliance

All the above listed products are focused on ISO 10993 Type A “medical” applications with less than 24 hours exposure. The Healthcare Grades (HG) are not intended to be used for medical application in accordance with the Regulation (EU) 2017/745. Our Healthcare Grade semi-finished products are manufactured exclusively at our Lahnstein site with certified management systems in accordance with EN ISO 9001:2015 and in compliance with GMP Regulation No. 2023/2006 (EC).

Röchling Industrial conduct on a defined regular basis biocompatibility test directly on semi-finished products manufactured by Röchling; however, not each batch number – this is optional and upon request available.

Please note that the responsibility for the evaluation of the end product for the intended use and compliance with the applicable relevant legal requirements lies exclusively with the user/processor as well as the distributor of the respective product/end product. We do not recommend or support use of these products in specific medical and sensitive end-use applications. The manufacturer or seller of parts and articles made out the above-mentioned products have to take the full responsibility regarding applicable legal

requirements.

This information was provided by machine and requires therefore no signature.

Röchling Industrial Lahnstein SE & Co. KG

Advice: This product information serves alone for informative purposes. Warranties, assurances and guarantees cannot be derived from this.

Important: This information is accurate as of the date of issue based on the most recent version of any applicable manufacturer's instructions, regulations or standards, unless otherwise stated above. This information should not be construed as a promise or guarantee of specific properties of the products described or their suitability for a particular application. The suitability of Röchling Industrial Lahnstein SE & Co. KG products in a given end-use environment is dependent upon various conditions including, without limitation, chemical compatibility, temperature, part design, sterilization method, residual stresses, and external loads. It is the sole responsibility of the manufacturer of the final product to assess and determine the suitability of all components to ensure that the final product is safe for its intended use (Fit for Use) as well as all applicable legal or other regulatory requirements.

Röchling Industrial Lahnstein SE & Co. KG
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