Informace o výrobku

Health Grade semi-finished products

This information relates to following semi-finished products, pressed and planed Röchling Industrial SE & Co. KG:

Výrobky		
Polystone® P HG EHS bílá stisknuto	Polystone® P HG EHS černý	Polystone® P HG EHS šedý stisknuto
Polystone® P HG HI černý	Polystone® P HG přírodní	

The recommendations of the raw material manufacturers are followed in the manufacture and handling of the above-mentioned polypropylene (PP) semi-finished products. Please get in touch with us if you have special requirements for your application. In general, our Röchling Industrial portfolio is not suitable neither for medical devices in risk class III, for those with permanent oral or dental contact, nor for the manufacturing of medical implants.

Regulatory

Based on previous tests and our years of good experience with the raw material, we would like to inform you that the above delivered products comply with the following regularities:

1. Animal Free Origin (AFO)

We hereby confirm that the material stated above does not contain any animal-derived substances (e.g. glycerol, fatty acids, tallow, etc.). The product is manufactured in compliance with EMA/410/01 Rev. 3 and does not pose any TSE/BSE risk. No animal-derived materials are used or come into contact with the product during manufacturing. EU Class 1 solvents are not used in production or downstream cleaning operations. Trace substances that may be detectable at very low levels due to environmental ubiquity are not covered by this declaration.

2. REACh

Our products listed above comply with the REACH Regulation. They do not contain any substances listed in the SVHC list, Annex XIV, or Annex XVII.

3. RoHs

The products listed above comply with the RoHS Directive. They do not contain any restricted substances in accordance with the applicable limits set forth in the Directive.

4. USP <88> Class VI (70°/24h)

Our product meets the requirements of USP Class VI in accordance with USP 42, NF 37, 2019, <88> “Biological Reactivity Tests, In Vivo.” Therefore, a sample is regularly taken from the processed raw material and tested at an external, accredited testing laboratory.

5. ISO 10993-5, 2009 (37°/24h)

Our product fulfils the requirements of ISO 10993-5, 2009; Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity. Therefore, a sample is regularly taken from the processed raw material and tested at an external, accredited testing laboratory

6. FDA/CFR 177

Code of Federal Regulations, Title 21, §177.1520 „Olefin Polymers“ of the Food and Drug Administration / USA (FDA), Edition from April 2011. as well as, if applicable, further specific FDA regulations for additives or colorants contained (e.g. FDA 21 CFR 178.3297 Colorants for polymers).

Risk process / incoming goods

Our risk management process ensures that, as part of the incoming inspection of raw materials, a cytotoxicity test in accordance with DIN EN ISO 10993-5 and USP Class VI is performed by an accredited institute on a representative batch of the semi-finished product manufactured by Röchling Industrial SE & Co. KG from the raw material.

The raw materials used for the products have passed internal qualification with the result “non-cytotoxic,” which is a prerequisite for the release of the semi-finished product. However, the cytotoxicity test is not part of continuous production control and is performed at regular intervals.

Manufacturing process

No plasticizers are added during manufacturing. Furthermore, the products listed above do not contain any recycled, reconstituted, regrind, reclaimed, or reprocessed raw materials.

To reduce internal stresses after pressing, the semi-finished products undergo an annealing process. All Healthcare Grade (HG) semi-finished products are ultrasonically tested and are verifiably pore-free. This product

information covers the steps of planing, sawing, and milling – all without the use of cooling lubricants.

Compliance

The Healthcare Grades (HG) are not intended to be used for medical devices in accordance with the Regulation (EU) 2017/745. Therefore, those products are not suitable for the manufacture of medical implants, critical components of medical devices with direct contact to the human body, fluids and/or tissue respectively bones, permanent oral or dental contact. The distributor, processor and user of the respective product, manufactured from our semi-finished products, are exclusively responsible for evaluating the end product's compliance with applicable legal requirements and its intended use.

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 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