Produktinformation

Medical Device Regulation (EU) 2017/745

Annex I, Chapter II, paragraphs 10.4.1-3 and 10.13

This document is to confirm that the substances within the scope of the EU Medical Device Regulation (MDR) EU 2017/745 (CMR (carcinogenic, mutagenic or toxic to reproduction), endocrine disrupting and animal origin substances as well as phthalates), updated through ATP 18 (EU) 2021/849, have not been intentionally added or used in the manufacturing processes of the listed Medical Grade (MG) products below:

Produkte		
SustaPEEK MG blau BL	SustaPEEK MG gelb YL	SustaPEEK MG grün GN
SustaPEEK MG natur	SustaPEEK MG rot RD	SustaPEEK MG schwarz
SustaPEI MG natur	Sustason® PPSU MG blau	Sustason® PPSU MG bone NT15
Sustason® PPSU MG braun	Sustason® PPSU MG gelb	Sustason® PPSU MG grau
Sustason® PPSU MG grün	Sustason® PPSU MG orange	Sustason® PPSU MG rot
Sustason® PPSU MG schwarz	Sustason® PSU MG natur	

Please be advised that these grades are compliant with the referenced sections of the regulation, as well as the raw materials used in our formulations.

Substances within the scope of the EU MDR (EU) 2017/745 Annex I, Chapter II, Sections 10.4.1a & b:

- (a) Substances which are carcinogenic, mutagenic, or toxic to reproduction ('CMR'), of category 1A or 1B, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council, or

- (b) Substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified either in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council (REACH) or, once a delegated act has been adopted by the Commission pursuant to the first subparagraph of Article 5(3) of Regulation (EU) No 528/2012 of the European Parliament and the Council(Biocidal Products), in accordance with the criteria that are relevant to human health amongst the criteria established therein.

Substances as outlined in Sections 10.4.1 a & b are not contained at concentrations above 0.1% (w/w).

This information relies on manufacturer data's given by our suppliers. However, we do not conduct any analyses to determine if any impurities exist.

No additional additives, plasticizers, animal origin substances or processing aids are added in the manufacturing process. We do not use any recycled, reconstituted, regrind, recovered or reprocessed resin in any of the production for these items.

The biocompatibility of the above-mentioned products was tested by means of a cytotoxicity test in accordance with ISO 10993-5 on semi-finished products. Ubiquitous trace impurities (e.g., due to technical and natural conditions) cannot be completely ruled out. We reserve the right to update/revise the statements made here if updated information from our suppliers on the raw materials used becomes available.

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.

The current candidate list of Substance of Very High Concern (SVHC) can be found: https://echa.europa.eu/candidate-list-table, with substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health specified as “Endocrine disrupting properties (Article 57(f) – human health)”

Advice: This document has been printed automatically and is valid without any signature. 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.

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