

Product Stewardship Document

Products: Highflow Tetpor II Filter Range

This statement covers all filters with the following part codes prefix: **ZHFT**

Parker Biosciences Engineering and Filtration Division manufacture the filters for use with life-science applications. These assemblies are constructed from mainly polymeric or metallic materials sourced from component and material suppliers. These products are manufactured and packed in the UK.

The Highflow Tetpor II filter range is intended for gas filtration applications and is not approved for use in any other applications.

Requirement	Compliant	Comments
Additives	Yes	The following substances are not intentionally used or added during manufacturing at Parker: Latex, lactose, gluten, epoxy derivatives, plasticisers, phthalates (DEHP), polychlorinated biphenyl (PCB), asbestos, preservatives, antioxidants, talc, corn starch, jatropa. This product contains trace amounts of phthalates which are used as a catalyst during the manufacture of one of the materials of construction.
Allergens	Yes	The following substances are not intentionally used or added during manufacturing at Parker: Peanuts, eggs, milk, tree nuts, wheat, soya, bean, sesame seeds, seafood, sulphites, mustard, celeriac, celery, lupin, palm oil, glycerin.
BSE/TSE	Yes	Some materials of construction used contain small quantities (less than 0.05% by weight) of tallow-based additives. This is of bovine source. It has been rendered inactive during manufacturing according to the requirements of EMA 410/01 rev 3.
Biocompatibility	Yes	The polymeric materials of construction within this product have been tested to and meet the requirements of USP<88> Class VI plastics at 121 °C.
Bisphenol A		This product does not contain bisphenol A.
Cytotoxicity	N/A	Cytotoxicity testing to USP<87> has not been performed on the materials of construction.
EU Food Contact	Yes	This product complies with the requirements of EU 10/2011. Using information provided by the material supplier, this product contains substances listed with SMLs. Independent tested was conducted and the migration levels were below the permitted level. Information on the substance may be

		provided upon request.
GMO	Yes	This product or materials of construction do not contain any genetically modified materials.
Halal	Yes	This product is approved for Halal use.
Kosher	Yes	This product is approved for Kosher use.
Melamine	Yes	Melamine is not intentionally added to the product or materials of construction.
Nitrosamines	Yes	Nitrosamines are not intentionally added or used during manufacturing of this product.
REACH	Yes	No Substances of Very High Concern (SVHC), as defined to the current ECHA candidate list, are intentionally added to this product.
RoHS	Yes	This product conforms to the RoHS Directive (2011/65/EU including amendment EU 2015/863). This product does not contain heavy metals (lead, mercury, cadmium, hexavalent chromium), PBB, PBDE, DEHP, BBP, DBP& DIBP above 0.1%.
Recycled Materials	Yes	No recycled materials used in this product.
US Food Contact	Yes	This product complies with FDA regulations: 21 cfr 177.1520 (Olefin Polymers). 21 cfr 177.1550 (Perfluorocarbon Resins). 21 cfr 177.2600 (Rubber Articles)

Information to support product claims has been provided by the material suppliers. Unless stated otherwise in the table above, no verification testing has been performed conducted by Parker or an independent laboratory.

This document and other information from Parker-Hannifin Corporation, its subsidiaries and authorized distributors provide product or system options for further investigation by users having technical expertise.

The user, through its own analysis and testing, is solely responsible for making the final selection of the system and components and assuring that all performance, endurance, maintenance, safety and warning requirements of the application are met. The user must analyze all aspects of the application, follow applicable industry standards, and follow the information concerning the product in the current product catalogue and in any other materials provided from Parker or its subsidiaries or authorized distributors.

To the extent that Parker or its subsidiaries or authorized distributors provide component or system options based upon data or specifications provided by the user, the user is responsible for determining that such data and specifications are suitable and sufficient for all applications and reasonably foreseeable uses of the components or systems.



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