



Zeta Plus™ HT SERIES FILTER CARTRIDGES

Declaration of Compliance for Food Contact

This document is the declaration of compliance within the meaning of Article 16(1) of Regulation (EC) No. 1935/2004.

1) Manufacturer

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2) Product Descriptions Covered by this Document

Zeta Plus	Diameter (in)	Cartridge Design	O-ring Material	Grade	Grade
Z	08	P – Plug in 7 cells D – Standard 8 cells	A – Silicone B – Fluorocarbon C – EPR D – Nitrile E – PTFE	003 8 015 050 080 150	HT
	12	C – 9 cells B – Special pre-coat 12 cells D – Standard 16 cells S – Special 7 cells			
	16	M – Standard diffusion netting 14 cells D – Standard 15 cells S – Special pre-coat 9 cells			

3) Composition

Filter media	Cellulose pulp, inorganic filter aid, cationic resin
Plastic parts	Polypropylene & filled polypropylene
Metal binders	Stainless Steel
O-Rings/Gaskets	As 'Product Description' table above

4) Compliance with Regulation (EC) 1935/2004

Hereby we declare the product(s) comply with the legal requirements as laid down in Regulation (EC) 1935/2004 as amended.

They are manufactured from materials that are suitable for contact with foodstuffs according to the following European specific measures or other recognized standards where specific measures have yet to be defined;

Plastic Parts

The plastic components of the product have been manufactured only with authorised monomers, other starting substances, additives and polymer production aids that are listed in Annex I of Regulation (EC) 10/2011. Migration testing according to Article 17 and 18 of Regulation (EC) 10/2011 in conjunction with Annex V shows that when used as specified the overall migration is below 10 mg/dm².

The product may contain the following substances that are subject to a specific migration limit (SML).

Substance	CAS#	SML/QM/QMA
Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	2082-79-3	6 mg/kg
1,3,5-tris(3,5-di-tert-butyl-4-hydroxybenzyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione	27676-62-6	5 mg/kg
Methyl-4-isothiazolin-3-one	2682-20-4	0.05 mg/kg
Triisopropanolamine	122-20-3	5 mg/kg
Ethylene oxide	75-21-8	ND
Barium sulphate	7727-43-7	1 mg/kg
Zinc sulphide	1314-98-3	25 mg/kg
Triethanolamine	102-71-6	0.05 mg/kg

Migration testing according to Article 17 and 18 of Regulation (EC) 10/2011 and migration modelling in conjunction with Annex V shows that when used as specified the specific migration is below the allowed limits.

The product may contain the following substances that are also approved as food additives, dual use additives.

E470A Calcium salt of fatty acid

The product may contain the following non-intentionally added substances (NIAS).

Polyolefin materials may contain trace levels of phthalates as impurities. According to information from 3M Purification's suppliers the maximum amount of these phthalate impurities in their product is 15ppm in total but typically much less. Specific migration testing of several similar products has shown these phthalates to be non-detectable.

There is no functional barrier present.

Metal Parts

The metal binders are made from a food grade stainless steel; EN 1.4404 (316L), that is compliant with the compositional requirements of the French order of 13th January 1976.

Rubber Parts

In the absence of any European harmonized standard compliance for the rubber gaskets is based upon the following standards:

FDA CFR21

Silicone	177.2600
Fluorocarbon	177.2600
EPR	177.2600
Nitrile	177.2600

USP <88> Class VI Biological Reactivity Tests for Plastics - All gasket materials used in this product meet the requirements of the USP guidelines for plastics Class VI.

Filter Media

The inorganic filter aids are compliant with the specifications of the US Food Chemicals Codex and are compliant with FDA CFR Title 21 Part 182.90 or listed as GRAS.

The cellulose pulp is compliant with BfR Recommendation XXXVI Paper and board for food contact and FDA CFR21 186.1673.

The cationic resin is compliant with BfR Recommendation XXXVI Paper and board for food contact and Council of Europe resolution AP (2002) 1 on paper and board materials and articles intended to come into contact with foodstuffs.

In the absence of any European harmonized standard compliance with Article 3 of 1935/2004 for the media is based upon a total exhaustive extraction of representative samples of Zeta Plus HT Series media and subsequent risk analysis. The Zeta Plus HT series filter media may properly be considered to be "generally recognized as safe" (GRAS) when used as specified.

The product may contain the following non-intentionally added substances NIAS that are present as impurities in the cationic resin:

Substance	CAS #
1,3-Dichloro-2-propanol (DCP)	96-23-1
3-monochloro-1,2-Propanediol (3-MCDP)	96-24-2

Conditions of Use

Food types: All food types.

Contact time and temperature: Any long term storage at room temperature or below, including heating up to 70 °C for up to 2 hours, or heating up to 100 °C for up to 15 minutes.

Ratio of food contact surface area to volume used to establish compliance: 1 dm²/kg

Use restrictions: A minimum required pre-conditioning flush of the Zeta Plus HT series filter product of 54 L/m² with water, or other suitable fluid, prior to exposure to the customer product.

5) Good Manufacturing Practice

The product(s) are manufactured at an ISO 9001:2008 certified facility in accordance with good manufacturing practice as required by Regulation (EC) No.2023/2006. The product(s) have fully documented traceability throughout the manufacturing process that is identifiable by the means of a lot number printed on the product label or quality documentation supplied with the product.

The information provided in this document related to material content represents 3M Purification's knowledge and belief as of the date it is provided which may be based in whole or in part on information provided by suppliers to 3M.

In the event any Product is proven not to conform with 3M's certification, then to the extent permitted by law, 3M's entire liability and Buyer's exclusive remedy, will be at 3M's option either: (i) replacement of Product with a conforming product, or (ii) refund of the purchase price paid by Buyer for each non-conforming Product, within a reasonable time after written notification of said non-conformance and return of said Product to 3M. 3M shall not under any circumstances be liable for direct, incidental, special, or consequential damages (including but not limited to loss of profits, revenue, or business) related to or arising out of this certification, including, the use, misuse or inability to use the Product. Unless stated otherwise in writing, the foregoing language cannot be waived, modified, or supplemented in any manner whatsoever.

Certified by:



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Product Responsibility Liaison I&TB

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This document remains valid for a period of 1 year from the date of issue.