FilmTec™ HSRO-4040-FF Element

USA FDA – Food Additive Status

When used unmodified and according to good manufacturing practices, these membranes will comply with the U.S. Food, Drug and Cosmetic Act as amended under Food Additive Regulation 21 CFR § 177.2550. These products may be used in processing liquid food and to purify water for food manufacturing in compliance with the mentioned regulatory citation.

Use of these products is subject to good manufacturing practices and any limitations which are part of the regulations. The regulations should be consulted for complete details.

Element parts or materials in contact with the potable water are compliant to 21 CFR § 170 to 199. Each has their own listing similar to the membranes.

European Union – Food Contact Status

The Declaration of Compliance for use in food contact applications is available upon request.

Hazard Analysis Critical Control Points (HACCP)

This product is manufactured utilizing a rigorous quality management system that includes the appropriate level of GMP for this product allowed applications. We do not have a formal HACCP program in place for the manufacture of this product.

Pretreatment

This product must be made ready before first use. Pre-treatment recommendations can be provided upon request by your sales or technical representative.

Allergen Status

This product has been evaluated for the source of the raw materials used in its production. Based on this evaluation:

- The production process does not use any raw materials, including additives, that are listed as allergens according to EU Directive 1169/2011/EC , FALCPA (Food Allergen Labelling and consumer Protection Act of 2004, FASTER (Food Allergy Safety, Treatment, Education, and Research Act of 2021) & Food Labelling (Declaration of Allergens) (England) Regulations 2008 No.1188 and their amendments that have their origin in cereals containing gluten, crustaceans, eggs, fish, peanuts, soybeans, milk, nuts, celery, mustard, sesame, molluscs, shellfish, wheat and/or lupin. Nor does the product contain sulphur dioxide or sulphites at concentrations of more than 10 mg/kg as SO_2.
- The production process does not use any raw materials, including additives, that are listed as allergen according to Food Labeling System (2015) based on Japan Food Sanitation Act. Within the Japan Food Sanitation Act, the Ministry of Health, Labour and Welfare has designated “Specified ingredients” as ingredients containing allergens. Specified ingredients include 28 items: shrimp, crab, wheat, buckwheat, eggs, dairy products, peanuts, almond, abalone, squid, salmon roe, oranges, cashew nut, kiwifruit, beef, walnuts, sesame, salmon, mackerel, soybeans, chicken, bananas, pork, matsutake mushrooms, peaches, yams, apples, gelatin.

Based on this evaluation of the raw materials and their sources, this product is expected to be free of the above-mentioned allergy stimulating substances. However, this product has not been tested for these substances.

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Bovine Spongiform Encephalopathy (BSE)/Transmissible Spongiform Encephalopathy (TSE)

This product is not manufactured using materials that are derived from animal sources. Bovine Spongiform Encephalopathy (BSE)/Transmissible Spongiform Encephalopathy (TSE) should not be a concern.

Declaration of Material Origin

This product is of synthetic origin. None of the raw materials used in the production are of animal, human, vegetal, or microbiological origin.

Genetically Modified Organisms (GMO)

This product is synthetic in origin. None of the raw materials used in the production are from Genetically Modified Organisms (GMO).

Dual Use Status

Based on the dual use review performed for this product, we concluded that this product is not listed as dual use product, according to Regulation (EC) 2021/821 and/or most updated Annex.

We believe this information to be reliable as of the date of this statement.

EU Directive 2011/65, amended by EU Directive 2015/863 - Restriction of Hazardous Substances (RoHS)

The RoHS Directives 2011/65/EC and 2015/863/EC contain restrictions on the following materials in electric and electronic equipment: lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB), polybrominated diphenyl ethers (PBDE), bis(2-Ethylhexyl) phthalate (DEHP), benzyl butyl phthalate (BBP), dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP).

While the RoHS Directives refer to electric and electronic equipment and not specific to reverse osmosis or nanofiltration membranes, based on raw material review, none of the restricted substances are intentionally added to this product.

CE Mark

The CE mark is a declaration by the manufacturer that the product meets all the appropriate provisions of the relevant legislations implementing certain European Directives. The CE mark must be affixed to a product if it falls under the scope of the relevant directives.

DuPont™ FilmTec™ Membranes are not in the scope of CE marking.

Irradiation

Irradiation is not part of the manufacturing process for this product.

Composition and Trace Analysis

The chemical materials listed below are not intentionally used in the manufacture of this product. However, this product has not been tested for these chemical materials:

- Melamine
- Cyanuric Acid
- Ammelide
- Ammeline
- Aflatoxins
- Fungi
- Mycoplasma
- Biocides
- Nitrites or its derivatives
- Palm Oil or its derivatives
- Partially Hydrogenated Oils
- Dioxins
- PCB´s
- Pesticides
- Phthalates
- Silicone
- Polytetrafluorethylene (PTFE)
- Natural Rubber
- Natural Latex
- Alklyating Agents e.g. Alkyl halides and sulphonates, sulphinates and sulphates
- Epoxides (and precursors)
- Aromatic nitro
- N-Nitroso
- Aromatic Azo
- Hydroperoxide
- Hydrazines
- Aziridines (and precursors)
- Primary Anilines
- Mesilate esters or alkyl mesilates e.g. methanesulphonic acid methyl esters and methanesulphonic acid ethyl esters, methanesulphonic acid
- Alkyl or aryl sulphonic ester contaminations e.g. (di)isetionates, besilates (benzenesulphonic acid esters) and tosilates (toluene-p-sulphonic acid esters).

Nitrosamines

DuPont has reviewed the raw materials used to produce this product. Nitrosamines are not intentionally added to this product. Specifically, for the NSF/ANSI/CAN61 certified elements, our certification agency measures a select number of nitrosamines in water treated with these elements. NSF consistently reports results as non-detectible, with a (normalized) detection limit of 0.05 ug/l.

Amines (secondary and/or tertiary) are used as raw materials in the production of this product. Low amounts of residual amines may be present in the water after treatment with this product. Additionally, reverse osmosis and or nanofiltration membranes may not – completely - reject (organic) amines present in the feed solution, strongly depending on the amine concentration in the feed solution, molecular weight of the amine, temperature and operating conditions. Nitrosamine formation requires the presence of both an amine and an oxidizing agent (for example disinfection agents, etc.). The potential for nitrosamine formation in the treated solution would depend on the concentration of amines (from all sources) and the oxidant.

We appreciate and value your business as we continue our commitment to provide high-quality products and service to our customers.

For further information, please consult your local DuPont representative or contact us via our website at https://www.dupont.com/water/contact-us.

Uma Kale

DuPont Water Solutions Global Product Steward

This document is valid until June 2024 unless earlier superseded by an updated version released on https://www.dupont.com/resource-center.html?BU=water or available upon request.

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Have a question? Contact us at:

www.dupont.com/water/contact-us

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