

Certificate of quality

Thermo Fisher Scientific certifies that this product meets the following criteria

Thermo Scientific™ Banded Analytical Membranes for Dispensers

Table 1. Catalog Numbers

Membrane	Pore Size	Color	Cat. No.
Mixed Cellulose Esters (MCE)	0.2 µm	White	DS0600-0102
Mixed Cellulose Esters (MCE)	0.2 µm	Black	DS0600-0202
Mixed Cellulose Esters (MCE)	0.45 µm	White	DS0600-0145
Mixed Cellulose Esters (MCE)	0.45 µm	Black	DS0600-0245
Mixed Cellulose Esters (MCE)	0.8 µm	White	DS0600-0108
Mixed Cellulose Esters (MCE)	0.8 µm	Black	DS0600-0208

Product criteria

Non-Fiber releasing membrane

This product was manufactured using a mixed cellulose esters microporous membrane which meets the criteria for “non-fiber” releasing filters as defined in 21 CFR 210.3 (b) (6) of the Food Additive Amendment of the U.S. Federal Food and Drug Acts.

Membrane gravimetric extractable

The extractable level of the membrane was less than 1.0 weight percent of the membrane.

Water quality testing

The product has been tested for bacterial recovery as described in Standard Methods for Examination of Water and Wastewater [23rd Ed., Part 9020, Section 5i] established by the American Public Health Association (APHA), American Water Works Association (AWWA) and the Water Environment Federation (WEF). Filters have been tested for microbiological recovery in accordance with ISO 7704 procedures and exceed the requirements of the standard.

Sterilizing grade

0.2µm achieves log⁷ reduction of B. Dimunta per ASTM F838

Microbial recovery

0.2µm meets ISO 7704:1985 for recovery of E. coli (ATCC™ 8739)

0.2µm meets ISO 7704:1985 for recovery of E.aerogenes (ATCC™ 49701)

0.45µm meets ISO 7704:1985 for recovery of E.aerogenes (ATCC™ 49701)

0.45µm meets ISO 7704:1985 for recovery of E. coli (ATCC™ 8739)

0.8µm meets ISO 7704:1985 for recovery of S. cerevisiae (yeast)

Audit criteria

Audit criteria tests are conducted on a routine basis as appropriate for each product configuration manufactured.

Sterilization validation

Product has been Gamma sterilized and acceptance released per Sterility Assurance Level (SAL) of 10⁻⁶ as defined in ISO 11137-1:2006.

Note: These filter products are designed for analytical and research purposes only and are not intended for the sterilization of liquids, manufacturing, or clinical applications. This product is not intended for use in direct patient care or diagnostic procedures.

Manufactured under an ISO 9001:2015 registered quality management system.

Learn more at thermofisher.com/filtration

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