

Thermo Fisher Scientific hereby certifies that the product identified below is manufactured and/or distributed according to the requirements of product and quality specifications as maintained in our quality management system which is compliant to ISO 13485 (BSI Certificate Number: FM 653694) or ISO 9001 (BSI Certificate Number: FM 743358) in Rochester, NY, USA.

Alan E Hatch

Alan E. Hatch
Sr. Quality Manager
04/17/2025

The following information represents Product Certification for: Item#: **2197-0032**

Description: **BTL,W/M,FLUOR,HDPE;32 OZ**

Lot#: **7452354010**

Manufactured: **02/26/2025**

Part Number	Description	Common Name	DMF#	Cytotoxicity	USP Class VI	FDA Compliance - 21 CFR
1-0622-70	BTL,1000ML,RND,W/M,FLPE,R/F FLUOR	COMPONENT PART				
8-0042-31	RESIN,HDPE,IBM,EBM,EXT	HIGH-DENSITY POLYETHYLENE	3310	PASSED	PASSED	177.1520 (c) 3.2a
1-1811-11	CLOS,63/415,PP,NAT,NALGE,16- CAV	COMPONENT PART				
8-0071-06	Resin,PP,Inj	POLYPROPYLENE, INJECTION	9988	PASSED	PASSED	177.1520(a)(1)(i), (c)1.1a,177.1520(b), (use conditionsA-H)

If N/A appears in any of the columns above it means the information is not available. Any item listed as "COMPONENT PART" will show blank in the DMF#, Cytotoxicity, USP Class VI, and FDA Compliance Information columns.

If the word "PASSED" appears in the USP Class VI column next to the resin listing, this material has passed USP Class VI requirements, latest Volume, as part of our initial test approval protocol.

If the word "PASSED" appears in the Cytotoxicity column next to the resin listing, this material was tested and shown to be non-cytotoxic as part of our initial test approval protocol, using either mouse fibroblast L929 cells or the more sensitive human diploid lung cell lines WI-38 or MRC-5.

The inside and outside surfaces of these bottles/closures have been exposed to fluorine gas under controlled temperature and pressure conditions.

ANIMAL DERIVED MATERIALS (BSE/TSE) - All resins and colorants used at the manufacturing site comply with the latest revision of EMA/410/01 section 6.4.