

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
 Sr. Quality Manager
 01/10/2025

The following information represents Product Certification for: Item#: **312085-0016**

Description: **BTL PKG N/M AMBER HDPE;16OZ**

Lot#: **1416431**

Manufactured: **10/22/2024**

Part Number	Description	Common Name	DMF#	Cytotoxicity	USP Class VI	FDA Compliance - 21 CFR
1-0424-93P	BTL,500ML,RND,N/M,HDPE,AMB,PKG	COMPONENT PART				
8-0042-45P	RESIN,HDPE,AMBER,IBM,EBM,1.5:100	COMPONENT PART				
8-0042-31	RESIN,HDPE,IBM,EBM,EXT	HIGH-DENSITY POLYETHYLENE	3310	PASSED	PASSED	177.1520 (c) 3.2a
8-0097-17	COLOR,AMBER, MULTI	COLORANT, OPAGUE, AMBER	24299	PASSED	PASSED	177.1520, 177.1350,178.3297, 181.28
1-1811-84	CLOS,28/415,PP,AMB,ANON	COMPONENT PART				
8-0071-14P	RESIN,PP,AMB,INJ	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)
8-0097-17	COLOR,AMBER, MULTI	COLORANT, OPAGUE, AMBER	24299	PASSED	PASSED	177.1520, 177.1350,178.3297, 181.28

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.

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.