

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  
 02/06/2025

The following information represents Product Certification for: Item#: **362830-0118**

Description: **CLOS, MPV, PURPLE CODER, HDPE; 11MM** Lot#: **1421543**

Manufactured: **01/21/2025**

Part Number	Description	Common Name	DMF#	Cytotoxicity	USP Class VI	FDA Compliance - 21 CFR
1-3828-86	COLOR CODER,PURPLE,PKG VIAL	COMPONENT PART				
8-0077-19P	RESIN,PS,HIGH IMPACT,BOYSN,INJ	COLOR MIX	N/A	N/A	N/A	N/A
8-0077-13	RESIN,PS,HIGH IMPACT,INJ	POLYSTYRENE	1623	PASSED	PASSED	177.1640
8-0099-15	COLOR,BOYSENBERRY	COLORANT, BOYSENBERRY	N/A	N/A	N/A	177.1350, 1520, 1580, 1620,178.2010, 3297, 181.28,184.1210 use conditions B-H
1-3828-90	CLOS,HDPE,PACKAGING VIAL	COMPONENT PART				
8-0042-02	RESIN,HDPE,HF,INJ	HIGH DENSITY POLYETHYLENE	1646	PASSED	PASSED	176.170(c), 177.1520(c)3.2a

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.