

Thermo Fisher Scientific hereby certifies that the product identified below is manufactured according to the requirements of product and quality specifications as maintained in our quality management system which is compliant to ISO 13485:2003 (BSI Certificate Number: FM 653694) in Monterrey Mexico.



Ana Martinez
 Quality Manager

The following information represents Product Certification for: Item#: **295-4545**

Certificate issued: **02/27/2019**

Description: **BTLTOPPES,45MM,500ML,75M;45U**

Lot#: **1250479**

Use Before: **02/28/2024**

Manufactured: **02/15/2019**

| Part Number | Description | Common Name | DMF# | Cytotoxicity | USP Class VI | FDA Compliance - 21 CFR |
|-------------|--------------------------------|-----------------------------|------|--------------|--------------|--|
| 1-0014-86 | COLLAR,FLT,45/75,MF75,HIPS,BLU | COMPONENT PART | | | | |
| 8-0077-18P | RESIN,PS,HIGH IMPACT,BLU,INJ | COLOR MIX | N/A | PASSED | PASSED | N/A |
| 8-0077-13 | RESIN,PS,HIGH IMPACT,INJ | POLYSTYRENE | 1623 | PASSED | PASSED | 177.1640 |
| 8-0099-74 | COLOR,BLUE,MULTI | COLORANT, BLUE, MULTI-RESIN | N/A | PASSED | PASSED | 177.1350, 1520, 1580, 1620,178.2010, 3297, 181.28,184.1210 |
| 1-0014-95 | ADP,FLT,Q/D,LDPE,WHT,MF-75 | COMPONENT PART | | | | |
| 8-0049-14P | RESIN,LDPE,WHT,INJ | COLOR MIX (LDPE, WHT, INJ) | N/A | N/A | N/A | N/A |
| 8-0049-01 | RESIN,LDPE,INJ | LOW-DENSITY POLYETHYLENE | 9522 | PASSED | PASSED | 177.1520(a)(2)(i) |
| 8-0099-26 | COLOR,WHT,OLF | COLORANT, WHITE | N/A | N/A | N/A | 178.3297, 170.39, use C-G, notfor articles used for holdingfood during cooking |
| 1-0014-44 | COV,FLT,500mL,THERMO | COMPONENT PART | | | | |
| 8-0077-12 | RESIN,PS,INJ,IBM | POLYSTYRENE | 1623 | PASSED | PASSED | 177.1640 |
| 1-0014-90 | UPPER,FLT,500 ML, MF-75, PS | COMPONENT PART | | | | |
| 8-0077-12 | RESIN,PS,INJ,IBM | POLYSTYRENE | 1623 | PASSED | PASSED | 177.1640 |
| 1-0014-95 | ADP,FLT,Q/D,LDPE,WHT,MF-75 | COMPONENT PART | | | | |
| 8-0049-14P | RESIN,LDPE,WHT,INJ | COLOR MIX (LDPE, WHT, INJ) | N/A | N/A | N/A | N/A |
| 8-0049-01 | RESIN,LDPE,INJ | LOW-DENSITY POLYETHYLENE | 9522 | PASSED | PASSED | 177.1520(a)(2)(i) |
| 8-0099-26 | COLOR,WHT,OLF | COLORANT, WHITE | N/A | N/A | N/A | 178.3297, 170.39, use C-G, notfor articles used for holdingfood during cooking |

Thermo Fisher Scientific hereby certifies that the product identified below is manufactured according to the requirements of product and quality specifications as maintained in our quality management system which is compliant to ISO 13485:2003 (BSI Certificate Number: FM 653694) in Monterrey Mexico.

The following information represents Product Certification for: Item#: **295-4545**



Ana Martinez
Quality Manager

Certificate issued: **02/27/2019**

Description: **BTLOPPES,45MM,500ML,75M;45U**

Lot#: **1250479**

Use Before: **02/28/2024**

Manufactured: **02/15/2019**

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.

Product was Gamma Irradiation Sterilized. Product was dosimetric released per ANSI/AAMI/ISO 11137 guidelines. Product was determined to be non-pyrogenic at a level < 0.25 EU/ml per USP < 85 > .