ThermoFisher SCIENTIFIC

FINISHED PRODUCT TECHNICAL DATA SHEET

Polystyrene Containers 60ml

Product Code	**125AM***	**125BM***	**125CM***	**125AP**	**125BP**	**125CP**
Description	No Label Metal Cap	Printed Label Metal Cap	Plain Label Metal Cap	No Label Plastic Cap	Printed Label Plastic Cap	Plain Label Plastic Cap
1	**Dimensions**		**OD (mm)***	**Height (mm)***	**OD (mm)**	**Height (mm)**
			44.5	**61**	**35**	**61**



2	**Packaging**	**Carton Quantity** **300**
3	**Material composition**	Container: General Purpose Polystyrene (PS) Cap: Tin Plated Steel (TPS) Cap: High Density Polyethylene (HDPE)
4	**Sterility**	Aseptically manufactured: manufactured in an ISO Class 7 environment in accordance with BS EN ISO 14644-1
5	**Quality**	Leak tested in accordance with BS EN 14254 Annex D * 95kPa compliant at ambient temperatures
6	**Autoclavability**	Not suitable
7	**Chemical Resistance**	Dilute acids, bases, alcohols, oils & minerals
8	**Shelf Life**	5 years from date of manufacture
9	**CE Marking**	Meets the Essential Requirements of Directive 98/79/EC of the European Parliament on In-Vitro Diagnostic Medical Devices
10	**Regulatory**	The composition and traceability of the product complies with the relevant requirements of Articles 3 & 17 of Regulation (EC) No 1935/2004, provided the end-use restrictions are met under normal conditions of use. This product complies with the relevant requirements of Regulation 2023/2006/EC (GMP). If present, the monomers and additives used to produce this product are listed in the Union List of Authorized Substances of Regulation 10/2011/EC. The composition of the product complies with the requirements of the 21 CFR 177.1640 "Polystyrene and rubber modified polystyrene". The sum of lead, cadmium, chromium-VI and mercury does not exceed the maximum value of 100 ppm (i.e. 0.01%) as required by the CONEG (Coalition of North Eastern Governors) for the January 1, 1994. Thus, also the maximum value for these elements laid down in Directive 94/62/EC as last amended by Regulation (EC) No 219/2009 is met.
11	**REACH**	This product does not contain as intentionally added additives or ingredients any of the substances of very high concern (SVHC) above a limit of 0.1 % w/w according to the candidate list, article 59 (1, 10) of the European REACH regulation No.1907/2006/EC (effective 15.06.2015), which is published on the ECHA homepage.
12	**BSE / TSE**	Container: All resin raw materials currently used in the manufacture of the above products(s) are either not manufactured from animal derived substances, or, if animal-derived, are from animal raw material obtained from suppliers who certify that their products are produced according to EC regulations and guidelines (e.g. 2000/418/EC). Moreover the production process for the manufacture of the resin involves using high temperatures (>200°C), being under pressure and long periods of time (>20 minutes, usually several hours). The extrusion process used in the manufacture of the pipettes also involves high temperatures (>250°C). The EU TSE Note for Guidance EMEA/410/01 Rev. 3 (published as EU Decision 2011/C 73/01) has been reviewed and, based on the above supplier information; our resin supplier states that the relevant section 6.4 "Tallow Derivatives" is complied with in terms of "rigorous process". As stated, tallow derivatives manufactured according to these conditions are unlikely to present any TSE risk and shall therefore be considered compliant with this note for guidance. Cap (TPS & HDPE): Substances of animal origin are not intentionally used in this product.
13	**Cytotoxicity**	Container: Resin passed biocompatibility testing according to USP class VI. In addition, in vitro cytotoxicity testing was conducted on resin following ISO 10993-5 protocol: Biological Evaluation of Medical Devices, Part 5: The test extract showed no evidence of causing cell lysis or toxicity. Cap (TPS & HDPE): Not tested.
14	**Latex rubber**	No materials containing latex or natural rubber are used in the manufacturing, handling and packaging processes for this product.
15	**Phthalates**	Container & Cap (HDPE): Phthalates are not used in the manufacture of or the formulation of this product. Cap (TPS): Phthalates are contained in the cap liner - migration limits are in accordance with Regulation 10/2011/EC.
16	**Other information**	Do not store in direct sunlight

Data sheet subject to change without notice

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