ThermoFisher SCIENTIFIC

FINISHED PRODUCT TECHNICAL DATA SHEET

Universal Polystyrene Containers 30ml

Product Code	128A/FS	128B/FS	128B/50*	128C/FS	128BBAC/FS#	128BBAC/50#*
Description	No Label	Printed Label	Printed Label	Plain Label	Boric Acid, Printed Label	Boric Acid, Printed Label

	Product Code	128AFS/1	128BFS/1	128BR/1/IRR**	128CFS/50*
	Description	No Label Tray packed	Printed Label Tray packed	Printed Label Red cap Tray Packed	Plain Label
1	Dimensions		OD (mm)	Height (mm) with a cap	
			31	93	

		Bag Quantity*	Carton Quantity	Tray Quantity
2	Packaging	50	400	50

3	Material composition	Container: General Purpose Polystyrene (PS) White Cap: Polypropylene (PP) & Thermoplastic Vulcanizate (TV) Inner Red Cap: Polypropylene (PP)
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 Suitable for centrigugation at 3,800 x g 95kPa compliant at ambient temperatures #Contains boric acid - 0.4g ±0.02g ** Sterile to SAL 10^{-6} in accordance with BS EN ISO 11137-1
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 onIn-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". This product complies with the relevant requirements of Regulation 1935/2004/EC (Framework Regulation) as applicable to intermediate materials (e.g. plastic powders, plastic granules or plastic flakes). 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	Container & cap (PP+TV): This product do 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. Cap (PP): This product does not contain any of the Annex XIV candidate chemicals proposed to be Substances of Very High Concern (List as of June 15, 2015) above the 0.1% threshold as stated in REACH (Article 57, Regulation No. 1907/2006) determined either through (i) non-use of the substance, (ii) mass balance calculation, or (iii) specific testing.
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 (PP): Tallow derived additives may be used in the manufacture of this product. Tallow derived materials used in this product fullfill the requirements laid down in the Regulations 1069/2009/EC, 142/2011/EC, 1774/2002/EC Annex VI Chapter III, Directive 2000/6/EC and the "Note for Guidance EMEA/410/01, rev. 3".
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. Caps: 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	Phthalates are not used in the manufacture of or the formulation of this product.
16	Other information	Do not store in direct sunlight

Data sheet subject to change without notice