


ThermoFisher SCIENTIFIC		FINISHED PRODUCT TECHNICAL DATA SHEET				
		"Quickstart" Universal Polystyrene Containers 30ml				
Product Code	128A*	128B*	128C*	128BBAC*	128A/IRR**	128AR/IRR**
Description	No Label	Printed Label	Plain Label	Boric Acid, Printed Label	No Label, Irradiated	No Label, Red Cap, Irradiated
1	Dimensions	OD (mm)	Height (mm)			
		31	94			
2	Packaging		Bag Quantity	Carton Quantity		
			50	400		
3	Material composition		Container: General Purpose Polystyrene (PS) Cap: High density polyethylene (HDPE)			
4	Sterility		* Aseptically manufactured: manufactured in an ISO Class 7 environment in accordance with BS EN ISO 14644-1 ** Sterile to SAL 10 ⁻⁶ in accordance with BS EN ISO 11137-1			
5	Quality		Leak tested in accordance with BS EN 14254 Annex D Suitable for centrifugation at 3,800 x g 95kPa compliant at ambient temperatures Contains boric acid (128BBAC) - 0.4g ±0.02g			
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 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.			
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: 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: Resin 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						
Information contained within this document is confidential and proprietary to ThermoFisher Scientific. This document must not be reproduced. All rights of design, and copyright are reserved						