ThermoFisher SCIENTIFIC

FINISHED PRODUCT TECHNICAL DATA SHEET

Tubes, Round Base, Polystyrene

			RT15*	RT20	RT25	RT30
	Product Code		RT15*	RT20	RT25	RT30
	Description		0.6mL tube	1.0 mL tube	2.7mL tube	4.9mL tube
1	Dimensions		H x OD (mm)	H x OD (mm)	H x OD (mm)	H x OD (mm)
			40 x 7	50 x 6	65 x 10	75 x 12
			RT15*	RT20	RT25	RT30
2	Packaging	Inner Pack	1000	1000	500	250
		Case Quantity	10,000	10,000	6000	3500
3	Material composition		General Purpose Polystyrene (PS)			
4	Sterility		Non sterile - manufactured in an unclassified environment			
5	Autoclavability		Not suitable			
6	Chemical Resistance		Dilute & concentrated acids, bases, alcohols			
7	Shelf Life		5 years from date of manufacture			
8	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.			
9	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.			
10	BSE / TSE		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. *RT15 -We can confirm that: 1) While Regulation (EC) No 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalophathies (TSE)does not apply to compronents od packaging materials, we can confirm that none of the components potentially present in the above-mentioned Product quality as Specified Risk Materials (SRMs) under said Regulation. 2)While Regulation(EC) No 1774/2002 laying down health rules concerning animal byproducts not intended for human consumption does not apply to tallow derivative components themselves, which do not qualify as animal by-products subject to the Regulation, we can confirm that any animal by-product used to manufacture the tallow from which tallow derivative components in the above-mentioned Product are derived are exclysively Category 3 materials processed in compliance with said Regulation.			
11	Cytotoxicity		No tests have been carried out			
12	Latex rubber		No materials containing latex or natural rubber are intentionally used in the manufacturing, handling and packaging processes for this product.			
13	Phthalates		Phthalates are not intentionally used in the manufacture of or the formulation of this product.			
14	Other information		Do not store in direct sunlight			

Data sheet subject to change without notice