

LABLABO – Compliance of compound PB651 to following regulatory requirements.

	NORM REGULATION	CONTENT	COMPLIANCE	COMMENTS
Food Contact	FDA CFR 21	US Requirement for food contact	Conform	The composition is in accordance with the positive list of Chapter 1772600, 1771210 or GRAS list
	10/2011/EC	European directive for plastics material in contact with food		Not applicable to rubber compounds
REACH	Reg n°1907/2006	SVHC list, Annex XIV and Annex XVII	Conform	No substances listed in SVHC list in rate > 0,1 % and General compliance to the regulation
Heavy Metals	94/62/CE	Heavy metals in EU Packaging and packaging waste	Conform	Within the limits defined by the directive 2000/53/CE
TSE/BSE	EMEA/410/01, rev3	Statement on transmissible bovine spongiform encephalopathy	Conform	1/ Most additives that go into the composition of our products are not animal derived. 2/ Whilst the others could derive from tallow/lard, the suppliers have stated that they are in compliance with the monographs of the European Directorate for the Quality of Medicines (EDQM) and/or with the note for guidance on minimizing the risk of transmitting animal Encephalopathy agents via human and veterinary medicinal products. Tallow derivatives and/or with the regulation 1774/2002/EC laying down health rules concerning animal by-products not intended for human consumption (Category 3 Material). Based on the above, we are confident that our products are free of SRM (Specified Risk Material)
Absence of substances		LATEX	Conform	Does not contain any product with Latex
		PVC	Conform	Does not contain any product with PVC
		Bisphenol A		Substance no intentionally introduced

Note: Furthermore it is necessary to check in the framework of the final application:

- Any additional requirement related to regulations
- The material compatibility with fluids in contact, the operating conditions
- The neutrality for products in contact



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