

**LABLABO – Compliance of compound PB651 to following regulatory requirements.**

|                              | NORM REGULATION   | CONTENT   | COMPLIANCE | COMMENTS  |
|------------------------------|-------------------|---|------------|---|
| <b>Food Contact</b>          | 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  |
| <b>REACH</b>                 | Reg n°1907/2006   | SVHC list   | Conform    | No substances listed in SVHC list and General compliance to the regulation  |
| <b>Dangerous substances</b>  | 2005/84/EC        | Phtalates in toys and childcare articles                      | Conform    | Less than 100 ppm of phtalate   |
| <b>Heavy Metals</b>          | 94/62/CE          | Heavy metals in EU Packaging and packaging waste              | Conform    | Within the limits defined by the directive 2000/53/CE   |
| <b>TSE/BSE</b>               | 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.<br>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 healths rules concerning animal by-products not intended for human consumption (Category 3 Material).<br>Based on the above, we are confident that our products are free of SRM (Specified Risk Material) |
| <b>Absence of substances</b> |                   | LATEX   | Conform    | Does not contain any product with Latex   |
|                              |                   | PVC   | Conform    | Does not contain any product with PVC   |
|                              |                   | Bisphenol A   |            | Substance no intentionnaly 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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