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TEMPORARY CERTIFICATE OF COMPLIANCE
For films, non-woven and laminated materials according to PERLAZID®

Dear Sirs,

We herewith declare, that the material mentioned above was checked by an external, accredited laboratory. The results are confirm according to the guidelines of the official test methods for direct contact concerning direct contact with food and drugs.

The above material complies with

- The American regulation: FDA 21 CFR 177.1990,
- The US standards: 21 CFR 175.300,
- The EU Directive: 2002/72/EC (overall migration), 94/62/EC, 2007/19/EC (regarding waste and heavy metals), 78/142/EEC (regarding vinylmonomer content),
- The (EC) 1935/2004 (articles 8 (release of materials), 15 (labelling, Symbols), 17 (Call Back Scenario) and 26 (in addition to RL 80/590 EWG & 89/109 EW) into contact with food)
- There is no substance of animal origin being used,
- The European Pharmacopoeia, 6th edition, chapter 3.1.11 , 3.2.2 and 3.1.3 as well,
- ISO 9001:2000, ISO 14001 (Environment), ISO 15378:2006 (GMP) and the current BRC/IoP directives,
- EC Commission Regulation (EC) on good manufacturing practice according to ISO 15378:2006,
- Cytotoxical investigations according to ISO 10993, chapter 4, 5, 10 & 11 were also accomplished successfully.

It further complies with the official Food Control Authority of Canton Lucerne, Switzerland and with the guidelines of the Federal Institute of Risk Assessment BfR (Bundesinstitut für Risikobewertung).

Our declaration only applies to the manufactured product and cannot cover a material, whose characteristics have been modified due to inappropriate conditions of use.

We declare that it is the user's responsibility to check the compatibility and the interactions between the complex and the content and the organoleptic properties.

Yours faithfully,
Perlen Packaging

Dr. Stefan Bokorny
Head of Business Development

Johannes Giessler
Director Sales & Marketing