

STATEMENT ON COMPLIANCE

We assure that the raw material composition in **PRE-ELEC ESD 5000** is cleared by European and FDA current regulations for food-contact applications.

EC: According to the European Food Safety Authority (EFSA), PRE-ELEC ESD 5000 can be used in contact with dry foods as represented by Simulant E (poly(2,6- diphenyl-p-phenylene oxide) in Regulation (EU) 10/2011. The contact conditions should be at ambient temperature or below.

There is a specific migration limit of the low molecular weight oligomeric fraction <1000 daltons should in total not exceed 50 µg/kg food. This specific migration limit (SML) will not be exceeded with the maximum addition of 20% of PRE-ELEC ESD 5000.

FDA: FCN nr 839 (21.11.2008): For use as an antistatic agent in polymer films (compliant with existing authorizations) at levels not to exceed 20 weight percent of the finished article in contact with non-fatty, dry foods (i.e. dry solids with the surface containing no free fat or oil) under the following conditions.

- Room temperature filled and stored (no thermal treatment in container).
- Refrigerated storage (no thermal treatment in the container).
- Frozen storage (no thermal treatment in the container).

Compliance with the overall and specific migration limits as described above must be measured from the final packaging intended to come into contact with foodstuff by using real food or appropriate food simulants at the intended and foreseeable conditions of use as specified in Directive 82/711/EEC (as amended) and Annex III of Commission Regulation (EU) 2011/10. It is the responsibility of the converter as well as food packer to verify that the final packaging complies with the imposed overall and specific migration requirements.

PRE-ELEC ESD 5000 does not contain any substances which are authorized as food additives by Directive 89/107, 95/2 and their amendments.

PRE-ELEC ESD 5000 is free from heavy metals and is recyclable as regulated by Directive 94/62 (packaging and packaging waste), the sum of lead, cadmium, mercury and hexavalent chromium is below 100 ppm. PRE-ELEC ESD 5000 does not affect the recycling or burning of the plastics products it is part of. PRE-ELEC ESD 5000 also fulfills the requirements of CONEG (toxics in packaging) and OEHA proposition 65, 27.9.2013.

PRE-ELEC ESD 5000 is free from risk of transmission of BSE or TSE, EMEA/401/01 rev.3 (Note for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products)

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PRE-ELEC ESD 5000 has been manufactured in compliance with good manufacturing practice as regulated in the regulation no 1935/2004 (materials and articles intended to come into contact with food) and 2023/2006 (good manufacturing practice for materials and articles intended to come into contact with food).

Rajamäki, 09.03.2016

PREMIX OY

Heikki Ruuhonen
R&D Manager Manager

This certificate has been produced electronically and therefore does not contain a signature.

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