

## Declaration of compliance PTFE material Acoflon 212 intended to come into direct contact with food

Name of company                      Acoplastic A/S  
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We have made this declaration concerning the *material* Acoflon 212 Polytetrafluoroethylene (PTFE) with 10% E-carbon. The material is semi-finished and the declaration does not necessarily cover the finished product.

The material has been manufactured in accordance with the rules for good manufacturing practice, EC/2023/2006<sup>1</sup>, and there is a traceability system according to EC/1935/2004<sup>1</sup>.

The material complies with the following regulations and standards:

- ✓ EU 10/2011. The monomer tetrafluoroethylene (FCM no. 281) is approved for use in direct contact with food with a SML of 0.05 mg/kg. The final product or article should be tested for global and specific migration.
- ✓ US regulation FDA CFR 21 §177.1550<sup>2</sup>. PTFE may be safely used as articles intended to contact food

The material is manufactured exclusively from the raw material and no other substances have intentionally been added.

The material is suited for repeated use with aqueous, acidic, alcoholic and fatty foods.

It is the responsibility of the customer to determine whether the finished product and its intended use comply with the laws and regulations.

### Specific details regarding filler materials:

The carbon filler used in this compound is heat treated graphitized carbon at temperature range of 2500-3000 deg C over a period of more than 24 hours. Due to this procedure the carbon fillers consists neither organic substances nor other extractable amounts of material. Based on this there is no reasonable expectation for this filler to be used as a component for food applications coming into contact with food.

The FDA-conformity can be derived with the status of “No Migration” and “Nil exposure”.

### Reach Supplier Declaration

Regarding REACH and Substances of Very High Concern (SVHC), (substances on The Candidate List) Regulation No. EU 1907/2006<sup>1</sup>, the supplier declares **no** use of SVHC substances in the article.

### Heavy metals in wrapping

The supplier declares compliance with directive 94/62/EC<sup>1</sup> and subsequent amendments. The added concentration of lead, cadmium, mercury and hexavalent chromium in the wrapping does not exceed 100 ppm.

Best regards,

  
Ejvind Nyholm Nielsen

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<sup>1</sup>Updated versions of Regulations etc. can be found at the website of European Union Law, EUR-Lex: [EUR-Lex](http://eur-lex.europa.eu)

<sup>2</sup>Updated versions of Resolutions can be found at the website of the FDA website <http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=33a3eb25a700d389973404798273cf16&rgn=div8&view=text&node=21:3.0.1.1.8.2.1.31&idno=21>