

Declaration of compliance for Acoflon M 100 / TFM 1610 intended to come into direct contact with food

Name of company Acoplastic A/S
Address Løvdalsvej 5, DK-3000 Helsingør, Denmark

We have made this declaration concerning the *material* Acoflon M 100/TFM 1610 made of Polytetrafluoroethylene (PTFE). 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, and there is a traceability system according to EC/1935/2004.

The material complies with the following regulations and statements:

- ✓ EU/10/2011¹ – The monomer tetrafluoroethylene (FCM number 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 §177.1550² – material may be safely used as articles intended to contact food.
- ✓ US 3A Sanitary Standard for multiple-use plastic materials No 20-27.
- ✓ USP Class VI

The material is manufactured exclusively from the raw material and no other substances have intentionally been added. The above mentioned product is animal derived components free (ADCF).

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.

Reach Supplier Declaration

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

Heavy metals in wrapping

The supplier declares compliance with directive 94/62/EC¹ and subsequent amendments. The added concentration of lead, cadmium, mercury and chrome in the wrapping does not exceed 100 ppm.

Best regards,



Ejvind Nyholm Nielsen

Managing Director at Acoplastic A/S

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

²Updated 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>