YOUR CHOICE FOR FLUOROBASED PRODUCTS

GUARNIFLON®

DECLARATION OF COMPLIANCE FOR MATERIALS AND ARTICLES INTENDED TO COME INTO CONTACT WITH FOOD

Date : October 2024 (1)

Rev.8

We hereby confirm that the material :

PTFE G405

- **Comply with the requirements of the Regulation (EC) No. 1935/2004**
- **Comply with the relevant requirements of the Directive 2002/72/EC**
- **Is manufactured following the indications of Good Manufacturing Practice (GMP) as set out in Regulation (EC) No. 2023/2006**
- **Based on migration tests (overall migration as well as the specific migration) performed on material with simulants below identified according the Regulation (EC) No. 10/2011 and subsequent amendments (up to Reg. EU 2023/1627), the material can be used as specified below*.**
- **Is suitable to be used in contact with foodstuffs in accordance with U.S. legislation – FDA 21 CFR 177.1550 "Perfluorocarbon resins"**
- **Comply with Article 19 of 10/2011 : *Assessment of non intentionally added substances -NIAS* - not included in the Union list**
- **There are no dual-use additives present in the material.**

Specifications on the intended use :

- *Type(s) of food intended to come into repeated contact with the material : **Acqueous (Simulant A), Acidic (Simulant B) and Oily or Fatty (Simulant D2) foodstuffs.**
  This considering that :
  - when acqueous and fatty foodstuffs are used, considering a correction factor X/4 or above;
  - when acidic foodstuffs are used , considering the specific migration average value of aluminium without extended uncertainty

- *Type(s) of food not intended to come into repeated contact with the material **Not applicable**

GUARNIFLON SPA
(Società Soggetta all'attività di direzione e coordinamento ex art. 2497 bis C.C. da parte di Mazza Holding S.p.A.)

Sede Legale
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Phone +39.035.4494311

D-U-N-S ® Number: 429385180

- **Overall Migration + Colouring Migration + Specific Migration of Primary Aromatics Amines + Specific Migration Tetrafluoroethylene + Specific Migration of metals : Ba, Co, Mn, Zn, Cu, Fe, Li, Al, Ni, Sb, Hg*, As*, Cr*,Pb*, Cd*,La*, Eu*, Gd*,Tb*.**
  ***= according to Reg. EU 1245/20 (15th amendment)**

  Simulant A : Ethanol 10% v/v - 4 hours at 100°C
  Simulant B : Acetic Acid 3% W/v in aqueous solution - 4 hours at 100°C
  Simulant D2 : Rectified olive oil - 2 hours at 175°C
  Colouring Migration in Sunflower oil - 2 hours at 175°C

  Overall Migration test was carried out by **TOTAL IMMERSION**.
  SURFACE (dm^2): 1.0 (4 pieces)
  VOLUME (dl): 1
  LOD : 1 mg/dm^2

  With reference to Specific Migration, the compliance computation have been arranged assuming that 1 kg. of food comes in contact with 6 dm^2 of packaging material

- **Olfactory organoleptic test according to Reg. EC 1935/2004 following UNI 10192:2000**
  Score : 0,8 – Between "No perceivable smell" (0) and "little perceivable smell, very difficult to define" (1)

The following substances subject to restriction under Regulation EC No. 10/2011 are used in the material :

Chemical name of the substances	CAS No.	Restrictions
Tetrafluoroethylene	0000116-14-3	SML = 0,05 mg/kg

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Notes

(1) - This Declaration will expire 3 years after the date of this issue

It remains the responsibility of the customer use the plastic article manufactured from the product into the intended use, to assess the final suitability of the plastic material for the intended food contact application . i.e. checking if the physical properties of plastic material make it suitable for the intended application, checking compliance of the finished plastic article with the relevant migration limits, checking for possible influence of the plastic material on the composition and/or organoleptic properties of the contacting foodstuff, etc.

- Finished food contact articles shall be manufactured such that the surface skin(s) of semifinished product is (are) taken away.
- In accordance to GMP the food contact articles shall be thoroughly cleaned prior their first use in contact with food.
- It is the responsibility of the buyer to assure traceability of the material during any further downstream use up to and including the finished machined part as well as the equipment in which it is assembled.

Note No. 2 : The customer must always specify in the Orders when an approval / certification stated in this document is necessary. This because the approved material follow a different internal procedure with respect to the standard material.

Note No. 3 : the present declaration It is not valid unless accompanied by a certificate showing the identification (Lot No.) of material supplied

Rev. 0 – Date of First Issue - Released in December 2012 -
Rev. 1 – Released in April 2013 – FDA suitability added
Rev. 2 – Note No. 2 added
Rev. 3 – Note No. 3 added
Rev. 4 – Validity of Declaration prolonged up to Dec. 2018
Rev. 5 - Validity of Declaration prolonged up to September 2021
Rev. 6 – Tests updated according to Reg. EU 1245/20 (15th amendment of Reg. 10/2011)
Rev. 7 – NIAS and Dual-Use concepts added
Rev. 8 – Updating according amendment Reg, EU 2023/1627

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