



DECLARATION OF COMPLIANCE TO REGULATIONS ON RUBBER MATERIAL INTENDED TO COME INTO CONTACT WITH FOODSTUFFS.

I undersigned Domenico Scopolino
Company: Alfagomma Industrial S.p.A.
Address: Via Attilio Di Sante, snc - Nucleo Industriale - 64100 Sant'Atto (TE) ITALY
Function: R&D rubber compound manager

Object: Inner layer rubber material belonging to the NBR family used in the Alfagomma hose 405LE Fat Food S&D 10 bar (150 psi)

DECLARES

that the above-mentioned rubber material, intended for repeated use contact with food, complies with the following regulations:

- (EC) N. 1935/2004 of 27 October 2004 modified
- (EC) N. 2023/2006 of 22 December 2006 modified
- French Regulation: Arrêté du 05 Août 2020
- Italian Regulation: DM 21 March 1973
- USA: FDA – CFR 21 – Parts 170 to 199 – Item 177.2600
- USA: 3A Sanitary Standard 18-03 Class II

The above compliance is established on basis of the following test conditions:

French regulation:

- Overall Migration testing according to French Regulation: Arrête du 5 Août 2020 Cat D:

Simulant	Time	Temperature
B - Acetic Acid 3%	3 X 2h	40°C
Ethanol 95%	3 X 2h	40°C
D2 - Vegetable oil	3 X 2h	40°C

- Specific Migration Testing according to French Regulation: Arrête du 5 Août 2020 Cat D:

Simulant	Time	Temperature
B- Acetic Acid 3%	3 X 2h	40°C

(IANESCO: tests report n°E23-10200 – 25/05/2023)

Italian Regulation:

The resulting values comply with the requirements defined in the DM 21 March 1973

(CERISIE: test report 780 ^{supp.1}/2023 – 26/01/2924)

ALFA GOMMA INDUSTRIAL S.p.A.

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Capitale Sociale € 4.672.000,32 i.v. - REA Teramo N° 92225 - C.F. e P.IVA N° IT 00730430675



United States of America Regulations:

The resulting values comply with the requirements defined in the FDA-Title 21 Parts 170 to 199 Item 177.2600 (a), (b), (c), (e), (f).

(CERISIE: test report 744-B/2023 – 31/10/2023.).

The resulting values comply with the requirements defined in the 3A Sanitary Standard 18-03 Class II

(CERISIE: test report 744-A/2023 – 31/10/2023)

The rubber material object of this declaration is suitable for Aqueous foods, Acidic foods, Alcoholic foods and Fatty foods according to the certificates test conditions.

In addition, we declare that the rubber material of 405LE Fat Food S&D 10 bar (150 psi):

- Complies with Regulation 2011/65/UE of the European Parliament 08/June 2011 (ROHS)
- Complies with Regulation (EC) No. 1907/2006 of the European Parliament -18 December 2006 (REACH)
- Does not contain Phthalate
- Does not contain Bisphenol A

The hose shall be cleaned according to the following recommendations:

CLEANING BEFORE FIRST USE

Prewash	Media	Max Concentration	Max temperature	Max Exposure Time	Final Wash
Drinking Water 80 °C - 2 h	Steam		130 °C	30 min	Drinking Water 80 °C 15 min
	Sodium Hydroxide	2%	40 °C	30 min	
		5%	20 °C	30 min	

STANDARD CLEANING

Media	Max Concentration	Max temperature	Max Exposure Time	Final Wash
Steam		130 °C	30 min	Drinking Water 80 °C 15 min
Sodium Hydroxide	2%	40 °C	30 min	
	5%	20 °C	30 min	

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Any change of the hose or modification of its use shall be submitted to the reassessment of the compliance.

This declaration is valid from the date indicated below and will be replaced earlier if there are changes to the production process, formulation of the rubber material, or if the legislative references that necessitate a new compliance assessment.

The documentation supporting this declaration of compliance is maintained by Alfagomma Industrial S.p.A. and is available at disposal to the relevant Authorities upon request.

Teramo,
10/12/2024

R&D rubber compound manager

A handwritten signature in black ink, reading 'Domenico Sepino'.

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