

**DECLARATION OF COMPLIANCE TO REGULATIONS ON MATERIALS AND ARTICLES INTENDED TO COME INTO CONTACT WITH FOOD as per article 16 of REGULATION (EC) No 1935/2004 & ANVISA (Brazil)**

I, the undersigned, Mr G rald SOULAGNET

Company: **TRELLEBORG INDUSTRIE SAS**

Address: ZI La Combaude - Rue de Chantemerle CS 10725- 63050 Clermont-Ferrand Cedex 2, acting in the capacity of: R&D Material Manager

Hereby declare that the article referenced as follows: **CHEMIKLER PTFE**, is composed of strongly bound layers of rubber and plastic.

The material intended to come into contact with food entering into the composition of this product belongs to the Plastics category.

I declare that our product complies with the requirements of:

- Regulation (EC) No 1935/2004 of 27<sup>th</sup> October 2004 modified;
- Regulation (EC) No 2023/2006 of 22<sup>nd</sup> December 2006 modified;
- Regulation EC N  10/2011 of 14th January 2011 modified
- RDC 326/2019
- Regulation (EC) No 2024/3190 of 19th December 2024.

Compliance is declared:

- subject to respect of the storage, handling and usage conditions specified by Trelleborg, subject to the use of original spare parts, and taking into account the specific characteristics of our product.
- with the following restrictions, where applicable:
  - In the case of modification of the physicochemical properties of the food in contact with the material, modification of the said food, modification of the contact conditions (temperature, length of time, etc.) and in the case of modification of the process or cleaning and disinfection conditions as defined by Trelleborg, the recipient of this declaration must check the continuing fitness for use of the material or article referred to herein.
  - Any changes in the material or article or its use must be submitted for reassessment of compliance.

This declaration of compliance is based on the following:

- Declaration(s) of the suppliers of materials
- Overall migration tests  
Inertia's examination of a material intended to come into contact with foodstuffs.

Simulants list:

- B : Acetic acid 3%
- D1 : Ethanol 50%
- D2 : Vegetable oil

Test conditions: 2 hours at reflux temperature / 121 C for D2

This material contains no substance with specific migration limit.

This declaration is valid on the date of delivery of the material or article. It will be renewed whenever compliance to above is no longer ensured (change of material or change in regulations before delivery of the material or article).

We keep all appropriate documentation in support of the said compliance at the disposal of the relevant authorities.

We also confirm that our inner layer complies with requirements of these countries:

#### **United States**

- FDA CFR 21 § 177.1520 and § 175.300 (for aqueous, fatty and alcoholics products). Test report IANESCO n° RE-11/14500, dated 28/10/2011 (Institut Français de Poitiers),
- Pharmacopeia USP Class VI,

#### **Brazil**

RDC (Resolução de Diretoria Colegi )326/2019 December 4, published by the Brazilian National Health Surveillance Agency (Agência Nacional de Vigilância Sanitária, ANVISA)): a positive list of additives for food contact plastics and polymeric coatings with restriction regarding metals and phthalates content.

For information, we confirm furthermore that this hose, as all our hoses rubber intended for the food contact, contains no phthalate and no bisphenol A.

Clermont-Ferrand, 01/02/2025

R&D Material Manager  
Gérald SOULAGNET

