

**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**

I, the undersigned , Gérald SOULAGNET

Company: TRELLEBORG CLERMONT-FERRAND 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 materials intended to come into contact with food and entering into the composition of the article referenced as **BIOVAST**, belong to the category of materials RUBBER.

I declare that our product complies with the requirements of:

- Regulation (EC) No 1935/2004 of 27th October 2004 modified.
- Regulation (EC) No 2023/2006 of 22nd December 2006 modified.
- Regulation (EC) No 2024/3190 of 19th December 2024;
- French Regulation dated 2020/08/05 on rubber materials

Compliance is declared:

- Subject to compliance with 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 analysis according to French Regulation dated 2020/08/05 on rubber materials, category D, 3x2h at 40°C

Simulants list:

- B: Acetic acid 3%
- Ethanol 70% (Covering simulants A, C & D1)
- Isooctane - Ethanol 95% (as a substitute of the D2 simulant as stipulated 10/2011 modified)

- Analysis of substances subject to limitation (including specific migration) according to French Regulation dated 2020/08/05 on rubber materials, category D, 3x2h at 40°C.

Simulants list:

- B: Acetic acid 3%
- D2: vegetable oil

**For reasons of confidentiality, we do not specify substances and associated LMS.**

This declaration is valid on the date of delivery of the material or article. It must 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.

**In addition to, and not as a substitute for, compliance with the requirements of regulations (EC) No. 1935/2004 and No. 2023/2006**, the material in contact with foodstuffs complies with the requirements of the following regulations:

#### Germany

- BfR Category 2 Recommendation XXI; Commodities based on natural and synthetic rubber.

#### United States

- FDA CFR 21 § 177.2600 (e), Rubber articles intended for repeated use.

Furthermore, I confirm that this hose complies, without restriction, to the latest REACH regulation and contains

- no phthalate
- no bisphenol A
- no MOAH or MOSH
- no animal derived ingredients, no ethyl alcohol or intoxicant, ethyl alcohol has not been used in the manufacturing process, it is not manufactured on equipment used for manufacturing of products containing ingredients of animal origin and is not stored together with products containing ingredients of animal origin.

Clermont-Ferrand, 01/02/2025  
R&D Material Manager  
Gérald SOULAGNET

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