

# Certificate Quality Department

## B571 - DECLARATION OF COMPLIANCE TO REGULATIONS ON MATERIALS INTENDED TO COME INTO CONTACT WITH FOOD as per Article 16 of REGULATION (EC) Nº 1935/2004

Trelleborg Izarra, S.A.U. hereby certifies our compliance with materials and articles intended to come into contact with food, as per article 16 of REGULATION (EC) Nº 1935/2004.

We hereby declare that the materials intended to come into contact with food entering into the composition of our products under reference **B571** belong to the category of materials RUBBER (as per Annex I of regulation EC 1935/2004)

We declare that our products comply with the requirements of:

- REGULATION (EC) Nº 1935/2004, dated 27/10/2004
- REGULATION (EC) Nº 2023/2006., dated 22/12/2006

This declaration is based on test references nº 021101395-25, carried out on October 2021, in an external Laboratory according to specifications of "Arrêté du 5 août 2020" of France:

### Positive list:

Compound B571 fulfil with "Arrêté du 5 août 2020" using only chemical included in the norm.

### Overall migration test result (OML) - EU 10/2011 (EN1186):

Simulants	Simulant Media	Contact conditions	Migration of substances	Limit	Units
A	10% Ethanol	3x2 hours, 40°C	Overall migration	≤ 10	mg/dm <sup>2</sup>
D2	Vegetal oil	2 / 4 / 6 hours, 40°C	Overall migration	≤ 10	mg/dm <sup>2</sup>

### Specific migrations of primary aromatics amines

Simulants	Simulant Media	Contact conditions	Migration of substances	Limit	Units
B	Acetic acid 3%	3x2 hours, 40°C Cycle 1	Primary aromatics amines	< 0.002	mg/kg

### Specific migrations of metals and metalloides in simulant

Simulants	Simulant Media	Contact conditions	Migration of substances	Limit	Units
B	Acetic acid 3%	3x2 hours, 40°C Cycle 3	Aluminium Barium Copper	According to the norm	

#### Specific migrations of formaldehyde and hexamethylenetetramine

Simulants	Simulant Media	Contact conditions	Migration of substances	Limit	Units
B	Acetic acid 3%	3x2 hours, 40°C Cycle 3	Formaldehyde Hexamethylenetetramine Formaldehyde + hexamethylenetetramine	According to the norm	

#### Specific migration of formaldehyde

Simulants	Simulant Media	Contact conditions	Migration of substances	Limit	Units
B	Acetic acid 3%	3x2 hours, 40°C Cycle 3	Formaldehyde	≤ 3	mg/kg

#### FVOS and Peroxydes

Material content	Contact conditions	Migration of substances	Limit	Units
Volatil organic substances	4 hours, 105°C	Average FVOS	≤ 0,5	%
Residual peroxides	French Pharmacopeia X <sup>th</sup> edition	Peroxides	No positive reaction	

#### Determination of heavy metals

Material content	Limit	Units
Cadmium Lead Antimony Mercury Arsenic	≤ 1	mg/kg

#### Specific migrations of N-Nitrosamines and N-Nitrosable substances in simulant

Simulants	Simulant Media	Time Temperature	Migration of substances	Limit	Units
B	Acetic acid 3%	2 hours, 40°C 3 <sup>rd</sup> cycle	N-Nitrosamines N-Nitrosables	According to the norm	

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Additionally, **B571** is in compliance with FDA 21 CFR Part 177.2600 according to migration analysis, using as simulants Distilled Water for Aqueous Food and n-Hexane for Fatty Food. Test Reference is P12-13967 carried out on 13/07/12, in an external Laboratory.

## Extraction test condition CFR 21&177.2600:

Test	Limit (mg/in <sup>2</sup> )
Extraction in distilled water 7 hours	≤ 20
Extraction in distilled water 2 hours supplementary	≤ 1
Extraction in n-Hexane 7 hours	≤ 175
Extraction in n-Hexane 2 hours supplementary	≤ 4

**B571** is free of Animal Derived Ingredients (ADI) and do not contain phthalate neither bisphenol A.

According to “Arrêté du 5 août 2020” and regulation (EU) n° 10/2011, this material can be recommended for application as:

Hoses, pipes and valve parts not remaining not under load (static and dynamic), membranes, gloves, conveyors belt, sleeves, rolls.

In contact with all types of food except for acidic foods with pH <4,5, as foods with hydrophilic character, aqueous food, oil, fat...



TRELLEBORG  
Trelleborg Izarra, S.A.U.  
QUALITY DEP.

María Gutiérrez-Cortines  
Izarra, 17/02/2023  
Quality Department