B572 - DECLARATION OF COMPLIANCE TO REGULATONS 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 **B572** 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 02604630-27, carried out on Abril-26, in an external Laboratory according to specifications of "Arrêté du 5 août 2020" of France:

Positive list:

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

Simulants	Simulant Media	Contact condictions	Migration of substances	Limit	Units
A	10% Ethanol	3x2 hours, 40ºC	Overall migration	≤ 10	mg/dm^2
D2	Vegetal oil	2 / 4 / 6 hours, 40ºC	Overall migration	≤ 10	mg/dm^2

Specific migrations of primary aromatics amines

Simulants	Simulant Media	Contact condictions	Migration of substances	Limit	Units
A	10% Ethanol	3x2 hours, 40ºC Cylcle 1	Primary aromatics amines	< 0.002	mg/kg

Specific migrations of metals and metalloides in simulant

Simulants	Simulant Media	Contact condictions	Migration of substances	Limit	Units
A	10% Ethanol	3x2 hours, 40ºC Cylcle 3	Aluminium Barium Copper Zinc	According to the norm	

Specific migrations of formaldehyde and hexamethylenetetramine

Simulants	Simulant Media	Contact condictions	Migration of substances	Limit	Units
A	10% Ethanol	3x2 hours, 40ºC Cylcle 3	Formaldehyde Hexamethlylenetetramine Formaldehyde + hexamethylenetetramine	According to the norm	

Specific migration of formaldehyde

Simulants	Simulant Media	Contact condictions	Migration of substances	Limit	Units
A	10% Ethanol	3x2 hours, 40ºC, Cylcle 3	Formaldehyde	≤ 3	mg/kg

Volatils organic substances and Residual Peroxydes

Material content	Contact condictions	Migration of substances	Limit	Units
Volatil organic substances	4 hours, 105ºC	Average FVOS	≤ 0,5	%
Residual peroxides	French Pharmacopeia Xth ed	Peroxides	No positive reaction	

Determination of heavy metals

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

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

Simulants	Simulant Media	Time Temperature	Migration of substances	Limit	Units
A	10% Ethanol	2 hours, 40ºC 3rd cycle	N-Nitrosamines N-Nitrosables	According to the norm	

Additionally, **B572** 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 D18-03-0827 carried out on 19/07/2018, in an external Laboratory.

Extraction test condition CFR 21&177.2600:

Test	Limit (mg/in^2)
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

For information, we confirm furthermore that these materials contain no phthalate and no bispehnol A.

B572 is free of Animal Derived Ingredients (ADI).