DECLARATION OF COMPLIANCE ａａｇ

EC 1935/2004 & FDA 21 CFR Part 177

E569

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 **E569** 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 O21101395-25-2, carried out in October 2021, in an external Laboratory according to specifications of "Arrêté du 5 août 2020" of France:

Positive list:

Compound **E569** 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 condictions	Migration of substances	Limit	Units
D1	50% Ethanol	3x2 hours, 40ºC	Overall migration	≤ 10	mg/dm^2

Specific migrations of primary aromatics amines

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

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Specific migrations of metals and metalloides in simulant

Simulants	Simulant Media	Contact condictions	Migration of substances	Limit	Units
B	Acetic acid 3%	3x2 hours, 40ºC Cycle 3	Aluminium	≤ 1	mg/kg
B	Acetic acid 3%	3x2 hours, 40ºC Cycle 3	Baryum	≤ 1.2	mg/kg
B	Acetic acid 3%	3x2 hours, 40ºC Cycle 3	Copper	≤ 4	mg/kg

Specific migrations of formaldehyde and hexamethylenetetramine

Simulants	Simulant Media	Contact condictions	Migration of substances	Limit	Units
B	Acetic acid 3%	3x2 hours, 40ºC Cycle 3	Formaldehyde Hexamethlylenetetramine Formaldehyde + hexamethylenetetramine	According to the norm	

Specific migration of formaldehyde

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

FVOS and Peroxydes

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

Determination of heavy metals

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

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

Simulants	Simulant Media	Contact condictions	Migration of substances	Limit	Units
B	Acetic acid 3%	2 hours, 40ºC Cycle 3	N-nitrosamines and N-Nitrosatable substances	According to the norm	
D1	50% Ethanol	2 hours, 40ºC Cycle 3	N-nitrosamines and N-Nitrosatable substances	According to the norm	

Additionally, **E569** is in compliance with FDA 21 CFR Part 177.2600 according to migration analysis, using as simulants Distilled Water for Aqueous Food. Test Reference is P12-13460 carried out on 02/03/12, 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

E569 is free of Animal Derived Ingredients (ADI) and do not contain phthalate neither bispehnol A.

According to "Arrêté du 5 août 2020" and regulation (EU) nº 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 aqueous or alcoholic food and dairy product or oil in water emulsions in all the cases for foods with pH ≥ 4,5.

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