

# DECLARATION OF COMPLIANCE



EC 1935/2004 & FDA 21 CFR Part 177

09  
10/04 2024

## E569

### DECLARATION OF COMPLIANCE TO REGULATIONS ON MATERIALS INTENDED TO COME INTO CONTACT WITH FOOD as per Article 16 of REGULATION (EC) N° 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) N° 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) N° 1935/2004, dated 27/10/2004
- REGULATION (EC) N° 2023/2006, dated 22/12/2006

This declaration is based on test references n° 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 conditions	Migration of substances	Limit	Units
D1	50% Ethanol	3x2 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

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## 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	≤ 1	mg/kg
B	Acetic acid 3%	3x2 hours, 40°C Cycle 3	Baryum	≤ 1.2	mg/kg
B	Acetic acid 3%	3x2 hours, 40°C Cycle 3	Copper	≤ 4	mg/kg

## 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	Peroxydes	No positive reaction	

## Determination of heavy metals

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

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

Simulants	Simulant Media	Contact conditions	Migration of substances	Limit	Units
B	Acetic acid 3%	2 hours, 40°C Cycle 3	N-nitrosamines and N-Nitrosatable substances	According to the norm	
D1	50% Ethanol	2 hours, 40°C 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 <sup>2</sup> )
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 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 aqueous or alcoholic food and dairy product or oil in water emulsions in all the cases for foods with pH ≥ 4,5.