# Certificate – E569
## Food grade quality

## 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<br>Hexamethlylenetetramine<br>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<br>Cadminum<br>Antimony<br>Mercury<br>Arsenic | ≤ 1 | mg/kg |

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**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 bisphenol 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.