Certificate
Quality Department

R642

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 **R642** 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 and O2301035-12, carried out in October 2021 and January 2023, in an external Laboratory according to specifications of "Arrêté du 5 août 2020" of France:

Positive list:

Compound R642 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
E	modified polyphenylene oxide (MPPO) Tenax®	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 Cylcle 1	Primary aromatics amines	< 0.002	mg/kg

Specif migrations of metals and metalloides in simulant

Simulants	Simulant Media	Contact condictions	Migration of substances	Limit	Units
B	Acetic acid 3%	3x2 hours, 40ºC Cylcle 3	Aluminium	≤ 1	mg/kg
B	Acetic acid 3%	3x2 hours, 40ºC Cylcle 3	Baryum	≤ 1.2	mg/kg
B	Acetic acid 3%	3x2 hours, 40ºC Cylcle 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 Cylcle 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 Cylcle 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 Xth 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 Cylcle 3	N-nitrosamines and N-Nitrosatable substances	According to the norm	
D1	50% Ethanol	2 hours, 40ºC Cylcle 3	N-nitrosamines and N-Nitrosatable substances	According to the norm	

Additionally, **R642** 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 P12-13460-4 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

R642 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 and dry foods or which can be considered to have a dry surface (e.g. unpeeled fruits, frozen foods).