

Certificate Quality Department

R642 - 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 **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) N° 1935/2004, dated 27/10/2004
- REGULATION (EC) N° 2023/2006., dated 22/12/2006

This declaration is based on test references E17-04088, carried out on 21/03/2017, in an external Laboratory according to specifications of "l'article 7 de l'arrêté du 9 novembre 1994" of France:

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

Simulants	Simulant Media	Time Temperature	Migration of substances	Limit	Units
D1	50% Ethanol	3x2 hours, 40°C	Overall migration	≤ 10	mg/dm ²
B	3% Acetic Acid	3x2 hours, 40°C	Formaldehyde	≤ 3	mg/kg
			Primary Aromatic Amines	≤ 1	mg/kg
			n-nitrosamines	≤ 1	µg/dm ²
			n-nitrosables substances	≤ 10	µg/dm ²

FVOS and Peroxydes

Material content	Time Temperature	Migration of substances	Limit	Units
Free volatil organic substance	4 hours, 105°C	Average FVOS	≤ 0,5	%
Residual peroxides	/	Peroxydes	≤ 0,08	%

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/in²)
Extraction in distilled water 7 hours	≤ 20
Extraction in distilled water 2 hours supplementary	≤ 1

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

R642 is free of Animal Derived Ingredients (ADI).



María Gutiérrez-Cortines
Izarra, 11/12/2020
Quality Department