

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	/	Peroxides	≤ 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



Certificate of Conformity

Date	20/11/14
Page	1 / 1

SUBJECT: FDA 21 CFR Part. 177

Trelleborg Izarra, S.A.U. hereby certifies our compliance with materials and articles intended for repeated use for contact with aqueous food or with aqueous food and with fatty food, according to FDA 21 CFR Part. 177. Indirect Food Additives: Polymers. Sec 177.2600

Rubber recipes: R642, R448, R320, RE02, E569, E669

We declare that our products produced with above rubber recipes comply with the requirements of :

FDA 21 CFR Part. 177. Indirect Food Additives: Polymers. Sec 177.2600 Rubber articles intended for repeated use, for contact with aqueous food

Rubber recipes: B571, BF07,V732

We declare that our products produced with above rubber recipes comply with the requirements of :

FDA 21 CFR Part. 177. Indirect Food Additives: Polymers. Sec 177.2600 Rubber articles intended for repeated use for contact with aqueous food and with fatty food.

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

Izarra, 20/11/14
Quality Department
Ignacio Irazabal