

Certificate Quality Department

V735

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 **V735** 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 D23-02-0508, carried out in April 2023, in an external Laboratory according to specifications of "Arrêté du 5 août 2020" of France:

Positive list:

Compound V735 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	3x 10 days, 40°C	Overall migration	≤ 10	mg/dm ²

Specific migrations of primary aromatics amines

Simulants	Simulant Media	Contact conditions	Migration of substances	Limit	Units
B	Acetic acid 3%	3x 10 days, 40°C Cycle 2	Primary aromatics amines	According to the norm	

Specific migrations of metals and metalloides in simulant

Simulants	Simulant Media	Contact conditions	Migration of substances	Limit	Units
B	Acetic acid 3%	3x 10 days, 40°C Cycle 2	Aluminium	≤ 1	mg/kg
B	Acetic acid 3%	3x 10 days, 40°C Cycle 2	Baryum	≤ 1.2	mg/kg
B	Acetic acid 3%	3x 10 days, 40°C Cycle 2	Copper	≤ 4	mg/kg
B	Acetic acid 3%	3x 10 days, 40°C Cycle 2	Zinc	≤ 5	mg/kg

Specific migrations of formaldehyde and hexamethylenetetramine

Simulants	Simulant Media	Contact conditions	Migration of substances	Limit	Units
B	Acetic acid 3%	3x 10 days, 40°C Cycle 2	Hexamethylenetetramine	According to the norm	

Specific migration of formaldehyde

Simulants	Simulant Media	Contact conditions	Migration of substances	Limit	Units
B	Acetic acid 3%	3x 10 days, 40°C Cycle 2	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	Internal method (iodométrie)	Peroxides	≤ 0,08	%

Determination of heavy metals

Material content	Contact conditions		Limit	Units
Lead Cadmium Antimony Mercury Arsenic	3x 10 days, 40°C Cycle 2	ICP-MS immersion CVAAS immersion (for Hg)	According to the norm	

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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%	3x 10 days, 40°C	N-nitrosamines and N-Nitrosatable substances	According to the norm	

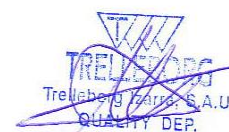
Additionally, **V735** is prepared according to the list of ingredients included in the recommendations of the Code of Federal Regulations 21 FDA 177.2600.

V735 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 \geq 4,5.



María Gutiérrez-Cortines
Izarra, 25/09/2023
Quality Department