

Product/material: NBR 70 COMPOUND 366470

Date of declaration: 05-02-2021

We confirm that the above mentioned material is compliant to the below mentioned regulation and legislations.

To European legislation EC 1935/2004 EU10/2011

The safety of this material has been verified by testing migration requirements as described in EU 10/2011 and are tested in accordance with EN1186. The material has been manufactured from monomers, polymers and additives that are authorized on either one of the positive lists of 'Warenwetregeling verpakkingen en gebruiksartikelen', 'Arrêté du 9 novembre 1994 relatif aux matériaux et objets en caoutchouc au contact des denrées, produits et boissons alimentaires' or 'FDA 21 CFR 177.2600'.

**Overall Migration test results EU10/2011 (EN1186)**

Simulant	Simulant media	Type of food	Time/Temperature	Ratio S/V	Result
A	Ethanol 10%	Aqueous food	24 hours at 60°C	6	PASS
B	Acetic Acid 3%	Foods with pH <4,5	4 hours at 70°C	6	PASS
C	Ethanol 20%	Alcoholic beverages <= 20% alcohol	1 hour at 70°C	6	PASS
D1	Ethanol 50%	Alcoholic beverages >20% alcohol and oil in water emulsions	1 hour at 70°C	6	PASS
D2	Iso Octane	Free fat on the surface	1 hour at 60°C	0.5	PASS
F	Distilled water	Aqueous food	24 hours at 70°C	6	PASS

No specific migrations test have been carried out, no results available

Conditions of use

This material can only be used considering the indicated conditions, the Surface to Volume factor and relevant types of food as per simulants listed in above table.

The material is suitable for repeated use.

ERIKS guarantees that all products of this material are produced according the directive for GMP (Good Manufacturing Practice) 2023/2006/EC, which is part of the Framework regulation EC1935/2004. The traceability of the products derived from this material is secured and the regulations for documentation and labelling protocol have been fulfilled.

To FDA regulation 21 CFR 177.2600

This material formulation has been evaluated according to the requirements of FDA 21 CFR 177.2600 (a-d) and extraction tested according to FDA 21 CFR 177.2600 (e-f).

**Extraction test results FDA 21 CFR 177.2600 (e-f)**

Test	Requirements	Result
Extraction Hexane 7 hours	Max. 175 mg/inch ²	PASS
Extraction Hexane 2 hours	Max. 4 mg/inch ²	PASS
Extraction in boiling water 7 hours	Max. 20 mg/inch ²	PASS
Extraction in boiling water 2 hour supplementary	Max. 1 mg/inch ²	PASS

Conditions of use

This material can be used for aqueous and fatty foods as per 21 CFR 177.2600.