

Declaration of Compliance

ERIKS

Product/material **SILICONE BLUE 131402**

Date of declaration 17-03-2020

To European legislation **EC 1935/2004**
To FDA regulation **CFR 21§177.2600**



We confirm that the above mentioned material is compliant to the above mentioned regulations and legislations. Products from this material are intended for repeated use in contact with the below listed type of foods.

This material has been evaluated according to the requirement of the of the Regulation EC 1935/2004, Annex I. Materials intended to come into contact, directly or indirectly, with food.

This material first enters the European market in Germany. Based on German recommendations for Silicone materials, BfR XV, the material complies to the regulation EC 1935/2004.

To further ensure the material can be used safely in direct contact with food, the material has also been tested according to Dutch legislation.

Based on the Dutch legislation "Warenwetregeling verpakkingen en gebruiksartikelen" the safety of this material has been verified by testing against the migration requirements as described in EU 10/2011 and in accordance with EN1186.

This material has been tested following the FDA regulation on extraction.

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 guideline EC 1935/2004.

The traceability of the products derived from this material is secured and the regulations for documentation and labelling protocol have been fulfilled.

Overall migration test results (OML) - EU 10/2011 (EN1186) - test performed on base material

Simulant	Simulant media	Type of food	Time/temperature	Ratio S/V
A	10% Ethanol	Aqueous food	24 hours reflux	0,5
B	3% Acetic acid	Acidic food with pH <4,5	4 hours reflux	0,5
D1	50% Ethanol	alcoholic foods above 20 % or oil in water emulsions	1 hour reflux	0,5
Extra	Distilled water	Aqueous food	24 hours reflux	0,5

Extraction test results **CFR 21§177.2600**

Test	Requirements
Extraction Hexane 7 hours	Max. 175 mg/inch ²
Extraction Hexane 2 hours	Max. 4 mg/inch ²
Extraction in demi water 7 hours	Max. 20 mg/inch ²
Extraction in demi water 2 hours supplementary	Max. 1 mg/inch ²

Dual use additives: No dual use additives are used.

Functional barrier: No functional barrier is used

Active or intelligent components of packaging material: No active/intelligent components are used

The material can be used in repeated contact with the types of food relevant for above simulants. Please refer to EU 10/2011 for a complete list. The material should not be used in contact with lipophilic substances, or foods that are assigned to simulants other than the tested simulants. Suitability for use in applications with longer exposure times or higher temperatures than stated above must be verified before use.

For more information phone +31 72 514 15 14 or E-mail info@eriks.nl

This declaration is not intended as technical documentation, the suitability of this product for a specific application should be verified with ERIKS. This declaration is valid until revocation or renewal.