

Declaration of Compliance

Product/material **CLIPPERLON 2115 FG**
Date of declaration 06-01-2020
To European legislation **EC 1935/2004 EU 10/2011**
To FDA regulation **CFR 21§177.1550**



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.

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 EU 10/2011 (EN1186) - test performed on base material, Ratio S/V 6

| Simulant | Simulant media | Type of food | Time/temperature | Result |
|----------|----------------|--------------------------|-------------------|--------|
| A | 10% Ethanol | Aqueous food | 4 hours at Reflux | PASS |
| B | 3% Acetic acid | Acidic food with pH <4,5 | 4 hours at Reflux | PASS |
| D2 | Iso Octane | Free fat on the surface | 6 hours at 60°C | PASS |

Specific migration limits

The monomer tetrafluoroethylene (PM/Ref 25120) used in this product is subject to a specific migration limit of 0.05mg/kg in food or food stimulants. The monomer perfluoropropyl perfluorvinyl ether (PM/Ref 22937) used in this product is subject to a specific migration limit of 0.05mg/kg in food or food stimulants.

The polymer production aid used in the manufacture of this product is listed in Annex I of Commission Regulation (EU) No 10/2011 with the restriction that it is only to be used in the polymerisation of fluoropolymers that are processed at temperatures higher than 300°C for at least 10 minutes. This is achieved during the production process of Clipperlon sheet material.

Extraction test results CFR 21§177.1550

| Test | Requirements - result |
|-------------------------------------|------------------------------------|
| Extraction in ethyl acetate 2 hours | Max. 3,1 mg/dm ² - PASS |
| Extraction in demi-water 2 hours | Max. 3,1 mg/dm ² - PASS |
| Extraction in n-heptane 2 hours | Max. 3,1 mg/dm ² - PASS |
| Extraction in ethanol 50% 2 hours | Max. 3,1 mg/dm ² - PASS |

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. 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 88 855 80 44 or E-mail gaskets@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.