Declaration of Compliance



Company Endress+Hauser SE+Co. KG, Hauptstrasse 1, 79689 Maulburg

being the manufacturer, declares that the "process-wetted parts" of the product

Product Liquiphant

FTL43

Material group	Material	Order codes	Process-wetted parts
Metals	316L ¹	090: **	Fork, fork base
		110: ***	Process connection
Rubber	EPDM ²	105: NC	Gasket
		<u>or</u> 620: PP	
	EPDM ²		
	EPDIM	620: PF, PH	
	Silicone ³	620: PJ	
	Silicone ⁴	620: PF, PH, PP	
Plastics	PTFE ⁵	110: 4AJ	Gasket

^{**} all order codes except YY

are in conformity with following European Regulations:

Regulations

Regulation (EC) No. 1935/2004, on materials and articles intended to come into contact with food. Regulation (EC) No. 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food.

1) Stainless Steel:

meets at least the EDQM (European Directorate for the Quality of Medicines & HealthCare) guide from the Council of Europe for metals and alloys used in food contact materials and articles *-1st edition* (2013).

2) EPDM:

The EPDM material passed the migration and sensory requirements of the LFGB (*Lebensmittel- und Futtermittelgesetzbuch /* German food and feed code), the German BfR (*Bundesinstitut für Risikobewertung /* federal agency for risk assessment) recommendations XXI, Category 1, and Article 3 of Regulation (EC) 1935/2004 for aqueous, acidic, alcoholic and fatty food.

3) Silicone:

The silicone material complies with the German BfR recommendations XV.

⁴⁾ Silicone:

The silicone material complies with the German BfR recommendations XV (in respect to ingredients).

5) PTFE:

Regulation (EU) 10/2011 on plastic materials and articles intended to come into contact with food.

HE 01952 02.24 1/3

^{***} all order codes except 9YY

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People for Process Automation

• Overall Migration Test:

Test conditions:

Simulant	Temperature	Time
10 % ethanol	100℃	4 h
Olive oil	175℃	2 h

Test Results:

Simulant	Limit	Result		
10 % ethanol	10 mg/dm²	passed		
10 % ethanor	60 mg/kg food	passed		
Olive oil	10 mg/dm ²	passed		
Olive oil	60 mg/kg food	passed		

• Specific Migration Test:

Test conditions:

Simulant	Temperature	Time
10 % ethanol	100℃	4 h
Olive oil	175 ℃	2 h

Test Results:

Substances with restrictions set out in Annex I (Regulation (EU) 10/2011) are used in production of this polymer. The results of specific migration tests comply with the respective SML (Specific Migration Limit).

Sensory Tests

No sensory tests were performed on the product with food simulants. It is recommended that the operator performs sensory tests with the applicable food or food simulant.

• Non-intentionally added substances (NIAS):

To the best of our knowledge, no NIAS are present in the product. Furthermore, our evaluation shows no production processes that add or yield not regulated substances or NIAS in a relevant and/or harmful amount. However, we cannot rule out the presence of NIAS in principle.

HE 01952 02.24 2/3

Declaration of Compliance



- According to the raw material manufacturer, no dual-use additives according to regulation (EC) No 1333/2008 and (EC) No 1334/2008 are used during polymerization or in any step of production.
- Functional barrier:
 The material is not a multilayer material and therefore does not contain a functional barrier.

Additional information:

The product must be cleaned before use, as appropriate for the application. This declaration of conformity emphasizes that the customer is obliged to test the product regarding its suitability in the application. This declaration of conformity is exclusively valid for the listed products as supplied to customer and without any further modification. Since the conditions of use are beyond Endress+Hauser's control, Endress+Hauser makes no warranties, expressed or implied, and assumes no liability in connection with any use of this declaration.

This declaration of compliance refers to the compliance of the mentioned materials with the listed regulations. No further suitability of the products for a specific purpose shall be derived from this.

Maulburg, 2024-10-02 Endress+Hauser SE+Co. KG

i.V. Thorsten Springmann Dept. Manager R&D Devices Level Limit

i.V. Stefan Jäger Dept. Manager R&D Quality Management/FSM

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HE 01952 02.24 3/3