

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

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

Product **Micropilot Radar**
FMR43

Material group	Material	Order codes	Process-wetted parts
Metals	316L ¹	105: A1, I1	Process connection
		105: X1 with 620: R* or QI	Process connection with adaptor
Plastics	PTFE ²	210: FA, FC	Antenna
	PEEK ³	210: FB	
Rubber	EPDM ⁴	200: G	Gasket
	FKM ^{5 or 6}	200: D	

R* = RA/RB/RD/RE/RF/RI/RL/RM/RR/RS/RT

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⁾ PTFE:

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

- Overall Migration Test:

Test conditions:

Simulant	Temperature	Time
10 % ethanol	100 °C	2 h
4 % acetic acid	100 °C	2 h
Olive oil	175 °C	2 h

Test Results:

Simulant	Limit	Result
10 % ethanol	10 mg/dm ²	passed
	60 mg/kg food	passed
4 % acetic acid	10 mg/dm ²	passed
	60 mg/kg food	passed
Olive oil	10 mg/dm ²	passed
	60 mg/kg food	passed

- Specific Migration Test:

Test conditions:

Simulant	Temperature	Time
95 % ethanol	60 °C	6 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.
- 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.

³⁾ PEEK:

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

- Overall Migration Test:

Test conditions:

Simulant	Temperature	Time
10 % ethanol	100 °C	2 h
4 % acetic acid	100 °C	2 h
Olive oil	175 °C	2 h

Test Results:

Simulant	Limit	Result
10 % ethanol	10 mg/dm ²	passed
	60 mg/kg food	passed
4 % acetic acid	10 mg/dm ²	passed
	60 mg/kg food	passed
Olive oil	10 mg/dm ²	passed
	60 mg/kg food	passed

- Specific Migration Test:

Test conditions:

Simulant	Temperature	Time
95 % ethanol	60 °C	6 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.

- 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:
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.
- According to the raw material manufacturer, the polymer contains substances listed in Commission Regulation (EC) No 1333/2008 defined as dual-use additive, but which are not expected to change the properties of food as specified in Commission Regulation (EU) No 1935/2004.
- Functional barrier:
The material is not a multilayer material and therefore does not contain a functional barrier.

⁴⁾ EPDM:

The EPDM material complies with the German BfR (*Bundesinstitut für Risikobewertung* / federal agency for risk assessment) recommendations XXI. The material is suitable for all watery, acidic and alcoholic foods as well as dairy products.

⁵⁾ FKM compound 1: The FKM material complies with the German BfR recommendations XXI.

⁶⁾ FKM compound 2: The FKM material complies with the FDA 21 CFR 177.2600 and is suitable for contact with food according to Resolution ResAP (2004) "Rubber Products intended to come into contact with foodstuffs" of CoE (Council of Europe)

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, 2024-05-14
Endress+Hauser SE+Co. KG

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