



DECLARATION OF FOOD COMPLIANCE virgin PTFE paste extruded tubes to come into contact with food

TEST REPORT

We herewith confirms for the use of paste extruded tubes and machined parts thereof, that:

PTFE virgin complies with the Regulation (EC) No: 1935/2004 in conjunction with Regulation (EU) No. 10/2011 on materials and articles to come into contact with food. It also complies with the FDA 21 CFR 177.1550.

Furthermore we confirm that the semi-finished products (made by paste extrusion) and machined parts thereof are manufactured according to GMP (Good manufacturing Practices) as set out in

Regulation (EC) No. 2023/2006 in an controlled process.

1. Overall Migration

The overall migration has been performed as described in commission Regulation (EU) No. 10/2011 (and amendments) relating to plastic materials and articles intended to come into contact with food.

Test methods as described in:

- EN 1186-1: *Guide to the selection of conditions and test methods for overall migration*
- EN 1186-2: *Test methods for overall migration into olive oil by total immersion*
- EN 1186-3: *Test methods for overall migration into aqueous food simulants by total immersion.*

The samples were placed in contact with the food simulants and at the test conditions as mentioned below. These test conditions represent the worst of the foreseeable conditions of use for repeated use articles and have been agreed with the customer.

Simulant	Test condition*
3% acetic acid	4 hours at reflux temperature (OM6), repeated use (3 times)
10% ethanol	4 hours at reflux temperature (OM6), repeated use (3 times)
Olive oil	2 hours at 175°C (OM7), repeated use (3 times)

* References EU10/2011:

- To demonstrate compliance with the overall migration limit for all type of foods testing in distilled water or water of equivalent quality or food simulant A and food simulant B and simulant D2 shall be performed.
- OM6: Any food contact conditions with food simulants A, B or C, at temperature exceeding 40 °C.

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- OM7: High temperature applications with fatty foods exceeding the conditions of OM5.
- Test OM 7 covers also food contact conditions described for OM1, OM2, OM3, OM4, OM5. It represents the worst case conditions for fatty food simulants in contact with non-polyolefins.
- Test OM 6 covers also food contact conditions described for OM1, OM2, OM3, OM4 and OM5. It represents worst case conditions for food simulants A, B and C in contact with non-polyolefins.
- Where a material or article is intended to come into repeated contact with foods, the migration test shall be carried out three times on a single sample using another sample of the food simulant on each occasion. Its compliance shall be checked on the basis of the level of the migration found in the third test.

2. Specific migration

Specific migration tests are performed as described in Commission Regulation (EU) No 10/2011 (and amendments) relating to plastic materials and articles intended to come into contact with food. Tests are performed based on EN13130 and in-house methods

The substances mentioned below are subject to a specific migration set out in the Union list of the Commission Regulation (EU) No 10/2011.

Component	FCM	CAS	SML (mg/kg food)	Method
Tetrafluoroethylene	281	116-14-3	0.05	Residual on material by TD-GC-MS, incl. worst case calculation

Results

Tests performed 10th of March until 13th of April 2016.

1. Overall migration

Sample: PTFE tube 806a4*6c/RST
Contact area: 0.93 dm²

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Volume simulant: 100 ml

Method Replicates	EN 1186-2 Olive oil 2hr/175°C third simulation* (mg/dm ²)	EN 1186-3 10% ethanol 4hr/reflux third simulation (mg/dm ²)	EN 1186-3 3% acetic acid 4hr reflux third simulation (mg/dm ²)
1	< 2	< 0.5	< 0.5
2	< 2	< 0.5	< 0.5
3	< 2	< 0.5	< 0.5
4	< 2	-	< 0.5
Mean result	< 2	< 0.5	< 0.5

* Result for second simulation: < 2 mg/kg

Overall migration limit (OML) is 10 mg/dm² contact area.

2. Specific migration

Sample: PTFE tube 806a4*6c/RST

Component	SML (mg/kg food)	Residual content (mg/kg material)	Calculated migration* (mg/kg food)
Tetrafluoroethylene	0.05	< 0.05	< 0.01
		< 0.05	< 0.01
		< 0.05	< 0.01

* based on worst case calculation by mg/kg residual content, the standard EU ratio of 6 dm² per 1 kg of food, and the weight/inside surface area of 28.1g/dm²

Conclusion

The overall migration results obtained for **PTFE tube** were found **to be in compliance** with the restriction for the overall migration limit (< 10 mg/dm²) as defined in Commission Regulation (EU) No 10/2011 for food contact materials for the test under the above mentioned test conditions for repeated use articles.

The specific migration results of all components obtained of the **PTFE tube** were found **to be in compliance** with the restriction for the specific migration limits as defined in Commission Regulation (EU) 10/2011 for food contact materials for the tests under the above mentioned test conditions for repeated use articles.