

Test Report

Report No.: 2302098 / 22299 / 2H **Date:** 2024-09-04

Client: UNI GASKET SRL
Via Lombardia 16
IT - 24060 Villongo (BG)

Material Producer: Gujarat Fluorochemicals

Product Manufacturer: UNIGASKET S.R.L.

Subject: PTFE Tube 4x6 mm made of INOFLON® MGN 7045

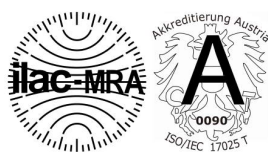
Task: Test according to EN 16421:2015, method 2 “Influence of materials on water for human consumption — Enhancement of microbial growth (EMG)” with formulation assessment according to KTW-BWGL “Evaluation Criteria for plastics and other organic materials in contact with drinking water, Issue 2022-03-07”

Order: Order of 2023-09-21

Date of sampling: 2024-04-08

Location of sampling: 24060 Villongo (BG) , Italy

Receipt of samples: 2024-04-22



Nicht akkreditierte Verfahren sind als solche gekennzeichnet.
Non-accredited procedures applied have been named as such.

1 SCOPE OF WORK

As ordered the samples taken during inspection – with consideration of existing test a/o inspection results from accredited laboratories – were tested for fulfilment of the requirements given by the EN 16421:2015. Further, a formulation assessment according to KTW-BWGL was performed.

2 SCOPE OF APPLICATION

The results given in this Test Report have been obtained under the specific conditions of the individual tests. As a rule, they are not the only criteria for assessing the product in question and its suitability for a specific purpose of application.

The test report may only be used by the client within the scope of the agreed right of use. Further rights, in particular the right to modify or edit, even in part, are not transferred to the client. This Test Report shall only be used for internal information of the client and shall not be used as a basis for decision-taking by third parties. OFI shall give its consent before this test report or its contents are passed on to third parties. Publication or reproduction, even in part, is prohibited in any case and always requires the prior written consent of the OFI.

3 SAMPLE MATERIAL

The following sample was provided by the client:

Table 1: Sample material description

| Sample No. | Sample description | Manufacturing process |
|------------|--|-----------------------|
| 3 | PTFE Tube 4x6 mm made of INOFLON® MGN 7045 | Extrusion |

4 TESTS

Testing took place from 2024-06-05 to 2024-09-02.

The tests were carried out in the individual technical departments within the scope of competence of the authorized signatories according to the OFI QM manual.

The specified test conditions, the used methods and the used devices are given in the following tables.

Submitted external test / inspection results:

- None

Table 2: Test conditions

| Test period | Tested surface | Flow rate | Exposure period | Test water |
|------------------|-------------------------|------------|-----------------|--------------------------|
| 1-month sample | 2 x 800 cm ² | 20 ± 2 L/h | 3 x 28 days | De-chlorinated tap water |
| 2-month sample | | | 56 days | |
| 3-month sample | | | 84 days | |
| Positive control | 1 x 800 cm ² | | 3 x 28 days | |
| Negative control | | | 3 x 28 days | |

5 RESULTS

The results of all tests are shown in Table 3 and Table 4.

Table 3: Summary of general results

| Parameter | Test |
|---|--|
| Composition Requirements according to KTW-BWGL, chapter 5.2 | tested and fulfilled ¹ |
| Check for microbial growth according to EN 16421, Method 2, chapter 5.6.7 | Microbial growth detectable ² |

Table 4: Results in mL surface growth per 800 cm² surface

| Duration | 1-month sample [mL/800cm ²] | | | 2 -month sample [mL/800cm ²] | 3-month sample [mL/800cm ²] |
|------------------|--|------------------|------------------|---|--|
| | 4 weeks | 8 weeks | 12 weeks | 8 weeks | 12 weeks |
| 1. Determination | < 0,01 | < 0,01 | < 0,01 | < 0,01 | < 0,01 |
| 2. Determination | < 0,01 | < 0,01 | < 0,01 | < 0,01 | < 0,01 |
| Mean | < 0,01 | < 0,01 | < 0,01 | < 0,01 | < 0,01 |
| Negative control | < 0,01 | < 0,01 | < 0,01 | < 0,01 | < 0,01 |
| Positive control | 1,7 | 1,5 | 2,0 | 1,8 | 2,2 |

¹ Refer to OFI formulation assessment No. ES-177-2023

² Slap-on test "HYCON Contact Slide TC" (by Company Millipore)

6 SUPPLEMENTARY STATEMENT ON THE TEST RESULTS

Based on these test results and considering chapter 5.6.3 of the KTW-BWGL, the material:

“INOFLON® MGN 7045”

is suitable for direct contact with drinking water with respect to microbial growth– on condition of professional processing with respect to its application (M1).

The “Recommendation for attestation of conformity of product hygiene suitability for drinking water” (Issued 2021-07-29) says that the test according to EN 16421 shall be repeated once every five years. Therefore, a new test according to EN 16421 should be done before 2029-09-02.

This Test Report No. **2302098 / 22299 / 2H** comprises
6 sheets with 4 table(s), 0 figure(s) and 0 appendix(es).

Any test results relate only to the samples tested. All tests applied are subject to a quality assurance program according to EN ISO/IEC 17025:2017. The test report may only be used by the client within the scope of the agreed right of use. Publication or reproduction, even in part, always requires the prior written consent of the OFI.

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Daniela Posselt
Testing engineer

Filip Petrovic, MSc
Director in charge

Test Report

| | | |
|------------------------------|--|-------------------------|
| Report No.: | 2302098 / 22299 / 3H | Date: 2024-09-17 |
| Client: | UNI GASKET SRL Via Lombardia 16 IT - 24060 Villongo (BG) | |
| Material Producer: | Gujarat Fluorochemicals | |
| Product Producer: | UNI GASKET SRL | |
| Sample Producer: | UNI GASKET SRL | |
| Subject: | PTFE TUBE 4x6 mm made of PTFE INOFLON® MGN 7045 | |
| Task: | Type test according to KTW-BWGL "Evaluation Criteria for plastics and other organic materials in contact with drinking water, Issue 2022-03-07" | |
| Order: | Order of 2023-09-21 | |
| Date of sampling: | 2023-11-29 and 2024-04-08 | |
| Location of sampling: | 24060 Villongo (BG), Italy | |
| Receipt of samples: | 2023-12-01 (sample No. 1) 2024-04-22 (sample No. 3) | |



Nicht akkreditierte Verfahren sind als solche gekennzeichnet.
Non-accredited procedures applied have been named as such.

1 SCOPE OF WORK

As ordered the samples taken during inspection – with consideration of existing test a/o inspection results from accredited laboratories – were tested for fulfilment of the requirements given by the KTW-BWGL.

2 SCOPE OF APPLICATION

The results given in this Test Report have been obtained under the specific conditions of the individual tests. They shall serve as proof for the client of the conformity of the samples tested to the requirements of the product standard(s) given.

The test report may only be used by the client within the scope of the agreed right of use. Further rights, in particular the right to modify or edit, even in part, are not transferred to the client. This Test Report shall only be used for internal information of the client and shall not be used as a basis for decision-taking by third parties. OFI shall give its consent before this test report or its contents are passed on to third parties. Publication or reproduction, even in part, is prohibited in any case and always requires the prior written consent of the OFI.

3 SAMPLE MATERIAL

At the inspection on 2023-11-29 and 2024-04-08 at company UNI GASKET SRL located in 24060 Villongo (BG), Italy the samples listed in Table 1 were taken by Mr. Rumpold as auditor of the OFI.

Table 1: Sample material description

| Sample No. | Sample description | Manufacturing process |
|------------|---|-----------------------|
| 1 | PTFE TUBE 4x6 mm made of PTFE INOFLON® MGN 7045 | Extrusion |
| 3 | PTFE TUBE 4x6 mm made of PTFE INOFLON® MGN 7045 | Extrusion |

4 TESTS

Testing took place from 2024-02-19 to 2024-09-17.

The tests were carried out in the individual technical departments within the scope of competence of the authorized signatories according to the OFI QM manual.

The specified test conditions, the used methods and the used devices are given in the following tables.

Submitted external test / inspection results:

- none

Table 2: Test conditions

| Test | Conversion factor F _c | S/V | Temp. | Migration- periods | Test water |
|-------------------|-------------------------------------|----------------------|-----------|-----------------------|----------------------------|
| Migration | 20 d/dm | 100 dm ⁻¹ | 23 ± 2 °C | 3 x 72 h | Ultra pure water MilliQ |
| Sensorial test | | 100 dm ⁻¹ | | | de-chlorinated tapwater |

Table 3: Used methods

| Test parameter | Method | Apparatus / OFI device |
|--|---|--|
| Migration | DIN EN 12873-1:2014 | --- |
| Total organic carbon (TOC) | DIN EN 1484:2019 | TOC-Analyser multi N/C pharma UV/1 # 3.372 |
| Sensorial test | DIN EN 1420:2016 DIN EN 1622:2006 | Paired comparison test |
| Turbidity | DIN EN 7027-1:2016 | Turbidimeter TL2360 # 3.309 |
| Colour | DIN EN 7887:2012 Method C | UV/VIS Lambda 35, Perkin Elmer / # 2.804 |
| Modelling of organic substances subject to confidentiality | DIN CEN/TR 16364:2012, non-accredited | SPECIFIC MIGRATION LIMITS Software (SML) Version 6.7 #3.491 |
| organic substances subject to confidentiality | OFI methods, non-accredited external testing, non-accredited | Dionex U3000 HPLC / #2.790 Agilent 7890A GC-MS / #2.665 Swiss quality testing services SAFE+Algorithmics GmbH |

5 RESULTS

The results of all tests are shown in Table 4 and Table 5.

Table 4: Summary of general results

| Parameter | Test |
|--|---|
| Composition Requirements according to chapter 5.2 | tested and fulfilled ¹ |
| Requirements for microbial growth according to chapter 5.6 | tested and fulfilled ² (M1) |

¹ Refer to OFI formulation check no: ES-177-2023

² Refer to OFI test report no. 2302098 / 22299 / 2H dated 2024-09-04

Table 5: Results cold water tests

| Parameter (<i>unit</i>) | 1. Mig. | 2. Mig. | 3. Mig. | Requirement ³ |
|--|----------------------|---------|---------|--------------------------|
| Foaming ⁴ | n.o. ⁵ | n.o. | n.o. | n.o. |
| Turbidity (<i>FNU</i>) ⁴ | 0,1 | < 0,1 | < 0,1 | ≤ 0,5 |
| Colour (<i>mg/L Pt</i>) ⁴ | < 2 | < 2 | < 2 | ≤ 10 |
| Threshold odour number (<i>TON</i>) ⁶ | 1 | 1 | 1 | ≤ 8 |
| Total organic carbon (<i>c_{tap} mg/L</i>) ⁴ | < 0,1 | < 0,1 | < 0,1 | ≤ 0,5 |
| Substances subject to restriction and confidentiality ⁶ | Migration limit kept | | | |

³ Requirement given by the KTW-BWGL for the 3rd migration period

⁴ Tested on sample No. 1

⁵ Not observed

⁶ Tested on sample No. 3

6 SUPPLEMENTARY STATEMENT ON THE TEST RESULTS

For the PTFE TUBE 4x6 mm made of PTFE INOFLON® MGN 7045 all tests needed for a type test according to the KTW-BWGL for the product group Pipes (P1) with ID < 80 mm in cold water 23 ± 2 °C were carried out.

The UBA recommendation “Conformity attestation of product hygiene suitability for drinking water”, issue 2021-06-29, states that a follow-up type test – on condition that material, manufacturing process and manufacturer do not change – should be done once every 5 years. Therefore, a follow-up type test on the PTFE TUBE 4x6 mm made of PTFE INOFLON® MGN 7045 should be done before 2029-09-17.

This Test Report No. **2302098 / 22299 / 1H** comprises
7 sheets with 5 table(s), 0 figure(s) and 0 appendix(es).

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Michael Schuster
Testing engineer

Filip Petrovic, MSc
Director in charge