

Declaration of Compliance

Identification of Supplier:

Company name	Ahlsell Danmark A/S
Address	Jydekrogen 2A, DK – 2625 Vallensbæk Denmark
E-mail	produktsikkerhed@ahlsell.dk
Website	www.ahlsell.dk
Is registered at The Danish Veterinary and Food Administration: http://www.findsmiley.dk/da-DK/Searching/DetailsView.htm?virk=10957106	

Conformity:

Ahlsell DK hereby declare that the products complies with the European regulations:	
(EC) No 1935/2004:	Materials and articles intended to come into contact with food.
(EU) No 10/2011:	Plastic materials and articles intended to come into contact with food.
(EC) No 2023/2006:	Good manufacturing practice for materials and articles intended to come into contact with food.
(DK) 681/2020:	Regulation 681/2020 for materials and articles intended to come into contact with food.

Products covered by this DoC:

Danish:	Teflonslange PTFE iht. næste side
English:	Teflonhose PTFE according to the next page
Please refer to the supplier DoC (next page) for area of application and technical information.	

Date:	Sign:
04.02.2025	
	Head of Product safety Dot Sør

TECHNICAL STATEMENT

FDA & EU-2011 COMPLIANCE

FDA AND EU FOOD COMPLIANCE IN TUBING MANUFACTURED FROM PTFE

- Teflon® 641XT X - ASTM D4895, Type I, Grade 1, Class C
- Teflon® T62 / Fluon® CD086 / Inoflon® MGN 7045 - ASTM D4895. Type 1, Grade 4, Class B
- Teflon® T62 XT - ASTM D4895, Type 1, Grade 3, Class D

Kongsberg Automotive confirm that, certain hose products manufactured using the above-named fluorocarbons, may be used as articles or components of articles intended to make contact with food in compliance with the following regulations:

EU FOOD COMPLIANCE

Compliant with European Regulation (EU) n° 10/2011

FDA COMPLIANCE

Reference: 21 CFR 177.1550 Perfluorocarbon Resins

U.S. Federal Food and Drug Administration (FDA) regulations governing the use of fluoropolymers as articles or components of articles intended for use in contact with food.

With reference to the PTFE hose liners, the following product lines manufactured by Kongsberg Automotive are suitable for food use

Natural PTFE: All PTFE Hose Product Lines

Carbon Anti-Static Lined PTFE: PTFE Hose Products with the following part number structures

TSRLXX-XB01: SAE 100 R14 Conductive lined Hoses
TSLGLXX-XB25: Pressureflex® Conductive Lined Hoses
TSHLXX-XB25: Pressureflex® Conductive Lined Hoses

Carbon Anti-Static Filled PTFE: PTFE Hose Products with “TCMF” & “SBCF” Prefixes ONLY

TCMF: ConvoFlex® Conductive Filled Hoses
SBCF: UltiFlex® Conductive Filled Hoses

Representative samples have been taken from the above product lines and have been externally tested by an accredited laboratory. The outcome of the testing is as follows:



TEST IN ACCORDANCE WITH REGULATION (EU) N.10 / 2011

On the basis of the performed tests, in the indicated terms of use, the materials of the samples in object don't release potentially hazardous substances for human health according to Reg. (EU) n.10/2011. Therefore, the products are suitable for food contact according to Reg. (CE) 1935/2004 art. 3 a) and b).

TEST IN ACCORDANCE WITH FDA REGULATION

On the basis of the performed tests, the materials of the samples in object comply according to U.S. Food and Drug Administration 21CFR Part 177.1550 clause (e) (3i) and (e) (3ii).

EU N.10/2011 OVERALL MIGRATION & SPECIFIC MIGRATION TEST SUMMARY

TEST	CONTACT PERIOD CONTACT TEMPERATURE	REPEATED USE	OVERALL MIGRATION SIMULANTS / CONTACT PERIOD / TEMPERATURE / N.MIGRATION	SPECIFIC MIGRATION SIMULANTS / CONTACT PERIOD / TEMPERATURE / N.MIGRATION	TEST RESULTS	CONCLUSION
Reg. (EU) n.10/2011 Reg. 1245/2020 Migration tests SUITABILITY FOR PLASTIC FOOD CONTACT	OM6: Any food contact conditions with food simulants A, B or C, at temperature exceeding 40°C. OM7: High temperature applications with fatty foods exceeding the conditions of OM5	Yes	Ethanol 10% / 4h / 100°C / N3 Acetic acid 3% / 4h / 100°C / N3 Vegetable oil / 2h / 175°C / N3 Isooctane(2) / 4h / 60°C / N3	Ethanol 10% / 30 min / 100°C / N3 Acetic acid 3% / 30 min / 100°C / N3 Vegetable Oil / 5 min / 225°C / N3	Samples do not release potentially hazardous substances for human health according to Reg. (EU) n.10/2011	PTFE Liners of this type are suitable for food contact according to (EC) 1935/art. 3 a) and b).

FDA 21 CFR 177.1550 TOTAL EXTRACTION AND FLUORINATED EXTRACTION TEST SUMMARY

TEST	TOTAL EXTRACT SIMULANTS / CONTACT PERIOD	FLUORINATED EXTRACTS SIMULANTS / CON- TACT PERIOD	TEST RESULTS	CONCLUSION
FDA Extraction test 21CFR Part 177,1550 Clause (e)(3i) and (e)(3ii)	Distilled water / 2h Ethanol 50% / 2h n-heptane / 2h Ethyl acetate / 2h	Distilled water / 2h Ethanol 50% / 2h n-heptane / 2h Ethyl acetate / 2h	Samples comply according to U.S. Food and Drug Administration 21CFR Part 177,1550 Clause (e)(3i) and (e)(3ii)	PTFE Liners of this type are suitable for food contact according to FDA 21CFR Part 177,1550 Clause (e)(3i) and (e)(3ii)

APPROVED BY:

Technical Department

Kongsberg Automotive

DECLARATION OF COMPLIANCE EU-2011 COMPLIANCE

DECLARATION OF COMPLIANCE TO COMMISSION REGULATION (EU) NO 10/2011 ON PLASTIC MATERIALS AND ARTICLES INTENDED TO COME INTO CONTACT WITH FOOD IN ACCORDANCE WITH ARTICLE 15 AND ANNEX IV

Kongsberg Automotive is the business operator which manufactures the PTFE lined hose products, including the control of intermediate stages of manufacture of the materials

The business address relating to the manufacture of the PTFE lined hose products is:

Kongsberg Automotive
Euroflex Centre
Foxbridge Way
Normanton
West Yorkshire
WF6 1TN

The date of this declaration is 5th July 2022

Kongsberg Automotive confirm that, PTFE hose liners in Natural, Anti-static lined and Anti-static filled meet the relevant requirements laid down in the Regulation (EC) No 10/2011 and in Article 3, 11(5), 15 and 17 of Regulation (EC) No 1935/2004. In addition, (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food.

Natural PTFE does not contain any additional substances noted within Annex 1 of EU 10/2011 regulation

The grade of carbon black used is compliant and is specifically tested to ensure continuous compliance with carbon black (CAS 1333-86-4, FCM Substance No 411) purity requirements and specific restrictions/specifications mentioned in Annex I of the Commission Regulation (EU) No 10/2011 (replacing Dir. 2002/72/EC) and its current amendment, concerning plastics coming into contact with food.

Commission Regulation (EU) No 10/2011 authorises and regulates the use/ manufacture/importation of food contact plastic materials and articles compliant with this legislation and containing a maximum of 2.5 % carbon black.

Overall Migration testing has been carried out on PTFE lined hose products in order to verify compliance against the following criteria

OM6: Any food contact conditions with food simulants A, B or C, at temperature exceeding 40 °C.

OM7: High temperature applications with fatty foods exceeding the conditions of OM5.

There are no restrictions to the type or types of food for which the PTFE lined hose products are intended to be put in contact with

There are no known restrictions on time and temperature of treatment and storage in contact with food

The food contact surface area to volume ratio used to verify compliance was 6 dm²/l

with reference to Functional barrier layers, for carbon lined or carbon filled PTFE liners, Kongsberg Automotive confirm that these articles comply with the requirements in accordance with Article 13(2), (3) and (4) or Article 14(2) and (3) of this Regulation.

APPROVED BY:

Technical Department
Kongsberg Automotive

