

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, hose products manufactured using the above named fluorocarbons, may be used as articles or components of articles intended to contact food in compliance with the following regulations:

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.

EU FOOD COMPLIANCE

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





FDA AND EU FOOD COMPLIANCE IN TUBING MANUFACTURED FROM NATURAL & CARBON FILLED PTFE ONLY, NOT CARBON LINED.

CABOT MONARCH ® 4750 CARBON BLACK (FILLER MATERIAL ≤ 2.5%)

Kongsberg Automotive confirm that hose product manufactured using the above named carbon filler when used in conjunction with the above PTFE resins, may be used as articles or components of articles intended to contact food in compliance with the following regulations:

FDA COMPLIANCE*

Reference: 21 CFR 178. 3297 Colorants for Polymers.

Maximum 2.5 % carbon black in the final application.

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

EU FOOD COMPLIANCE

This grade 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.

***NOTE**

As stated in a Food Contact Notification (FCN No. 1789) submitted by Cabot Corporation to the FDA, Monarch 4750 is not for use in contact with infant formula and human milk.

APPROVED BY:

Technical Department
Kongsberg Automotive



DISCLAIMER: To the best of our knowledge, the information contained herein is accurate and reliable as of the date of publication; however, we do not assume any liability whatsoever for the accuracy and completeness of the enclosed information. Kongsberg Automotive ASA and its affiliates and subsidiaries make no warranties for the information's fitness for any intended use or merchantability. It is the customers' responsibility to inspect and to test our products in order to satisfy themselves as to the suitability of the products to their particular purpose. In particular, all hose assemblies must be leak tested by the customer prior to be put in use / service.

COMPLIANCE STATEMENT

(EU) 2017/1000 PFOA COMPLIANCE

The EU has taken measures to regulate PFOA, its salts and PFOA-related compounds in a wide range of products under:

- Annex XVII of EU REACH, Commission Regulation (EU) 2017/1000
- Annex I to Regulation (EU) 2019/1021 (EU Persistent Organic Pollutants Regulation) (as adopted on April 8, 2020 and with an enforcement date of July 4, 2020)

These regulations require, subject to certain exceptions, that from July 4, 2020, mixtures and articles placed on the market in the European Union will require:

- Concentration of ≤ 25 ppb of PFOA, including its salts,
- ≤ 1000 ppb of one or a combination of PFOA-related compounds.

We declare to the best of our knowledge, that all Raw materials and processing chemicals used in the manufacture of hose products from the Kongsberg Automotive Normanton facility comply to the above regulation

Company Name: KONGSBERG AUTOMOTIVE

Address: Euroflex Centre,
Foxbridge Way,
Normanton,
West Yorkshire,
WF6 1TN

Date: 16th June 2020

APPROVED BY:

Technical Department
Kongsberg Automotive

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Technical Statement:-

FDA and EU Food Compliance in Tubing Manufactured from PTFE

Teflon® T62N X PTFE (polytetrafluoroethylene)

Kongsberg Automotive confirm that the above named fluorocarbon, may be used as articles or components of articles intended to contact food in compliance with the following regulations:

Inoflon® MGN7045, 7055, 7065 (polytetrafluoroethylene)

Kongsberg Automotive confirm that the above named fluorocarbon, may be used as articles or components of articles intended to contact food in compliance with the following regulations:

Fluon® CD086 PTFE (polytetrafluoroethylene)

Kongsberg Automotive confirm that the above named fluorocarbon, may be used as articles or components of articles intended to contact food in compliance with the following regulations:

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

EU Food Compliance

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

FDA and EU Food Compliance in Carbon Filled PTFE Tubing

Cabot Monarch® 4750 carbon black (filler material ≤ 2.5%)

Kongsberg Automotive confirm that the above named carbon filler when used in conjunction with the above PTFE, may be used as articles or components of articles intended to contact food in compliance with the following regulations:

FDA Compliance

Reference: 21 CFR 178. 3297 Colorants for Polymers.

Maximum 2.5 % carbon black in the final application.

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

EU Food Compliance

This grade 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.

Sam. Vidal

Applications Engineer | Fluid Transfer

TECHNICAL STATEMENT

USP CLASS VI COMPLIANCE

DECLARATION OF COMPLIANCE FOR USP CLASS VI IN RESINS USED TO MANUFACTURE PTFE TUBING

**KONGSBERG AUTOMOTIVE CONFIRM THAT ALL GRADES OF PTFE RESIN
USED IN THE MANUFACTURE OF TUBING HAVE BEEN:**

- Tested by the resin manufacturer for biocompatibility in accordance with USP Biocompatibility Testing (class VI) protocol.
- Meet the requirements of a USP Class VI (121°C) plastic.

Testing of the finished article is the responsibility of the manufacturer or seller of the finished product if certification that it meets USP standards is required.

These products are not intended for use in applications that involve permanent implantation with the human body.

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