



SUMMARY VALIDATION GUIDE

Food and Beverage hose products

Bioflex Ultra, Pharmaline N, Pharmaline X, FaBLINE

Executive Summary

This is a validation guide for Aflex Hose products suitable for the Food and Beverage industry.

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1. Introduction

Aflex Hose is based in West Yorkshire, UK, and manufactures PTFE lined hose products. The facility manufactures from raw materials (e.g. PTFE granulated powder, braid wire, stock bar) to produce end-products in the form of hose assemblies. Aflex Hose is known for its excellent quality and innovative products that provide superior flexibility, kink resistance, cleanability and PTFE lined end fittings.

Products that are intended for food and beverage applications are:

- **Bioflex Ultra**
- **Pharmaline N**
- **Pharmaline X**
- **FaBLINE**

The PTFE liners are available in both natural PTFE and anti-static (static dissipative) versions and are manufactured from materials compliant with FDA CFR 21 177.1550 and FDA CFR 21 178.3297. All products are suitable for autoclave sterilisation. Aflex Hose operates an ISO 9001 quality management system.

Hose assemblies have the following features:

- **Individual build serial number for full traceability of materials of construction and manufacturing processes.**
- **PTFE raw materials are free from PFOA and PFOS.**
- **PTFE liners have extremely low extractable results, are non-toxic and free from animal derived content.**
- **Both PTFE lined and standard non-lined fittings are available. Lined fittings have superior cleanability and smooth flow to connecting pipework.**
- **PTFE exhibits outstanding chemical resistance and cleanability due to the hydrophobic nature of the material.**
- **High temperature and good vacuum resistance**
- **Kink resistance.**
- **Excellent flexibility**

2. Conditions of use

Full details of the usage conditions are available within the product brochure.

3. Chemical compatibility

PTFE exhibits superior chemical compatibility over many polymer, ceramic and metallic materials. Aflex Hose can provide support to assess specific applications. Some chemicals can permeate through PTFE, such as Halides (chlorine / bromine / fluorine containing media are typical) and could corrode external components such as stainless steel braid. Contact Aflex Hose for more application specific information.



4. Materials, manufacturing and regulatory compliance statements

4a Materials of construction

Hose liners are smooth bore and externally convoluted to provide flexibility. The liner is manufactured from PTFE in compliance with FDA CFR 21 177.1550. Anti-static PTFE liners contain high purity furnace black in compliance with FDA CFR 21 178.3297 and 3A 62-02 requirements.

The liner has an outer stainless steel 316 helix wire wound into the external convolutions to provide additional hoop strength and kink resistance.

Metallic support braid is stainless steel 316. A polypropylene braid is available for the Bioflex Ultra product, but this cannot be supplied with a cover.

External covers are platinum-cured silicone or blue EPDM.

The external covers (EPDM & SI) on FaBLINE are compliant with FDA 177.2600.

End fittings are stainless steel 316L, unless otherwise specified.

4b Manufacturing environment

Aflex operate a Quality Management System certified to ISO 9001. Additionally, Aflex are certified to ISO 45001, ISO 14001. If applicable the hoses will be dual marked with CE (Pressure Equipment Directive 2014/68/EU & UKCA (Pressure Equipment (Safety) Regulations SI 2016 No 1105).

4c Country of origin

Aflex hose and fittings are manufactured in the UK. Assemblies may be put together in other countries – please consult the local supplier of assemblies for further information.

4d Compliance declaration summary

Please see table below

Named substance/compliance statement	Raw material	Manufacturing process	Final product
Animal Derived Content	–	–	–
Conflict materials (tin, tantalum, tungsten, gold) which are sourced from DRC or adjoining countries.	–	–	–
Gluten	–	–	–
Bisphenol A	–	–	–
Melamine	–	–	–
Latex/Dry Natural rubber	–	–	–
Phthalates	–	–	–
Nitrosamines or Nitrosamine precursors	–	–	–

4e REACH legislation

All raw materials, compounds used in the manufacturing process and the final Aflex Hose products comply with the REACH regulations. None of the chemicals used in the manufacture of Aflex Hose products are on the candidate list or the list of substances of very high concern (SVHC).

4f RoHS

In compliance with the restriction of hazardous substances (RoHS) directives, no listed substances are used in the manufacture of Aflex Hose products.

4g Material certification to EN10204-3.1

Material certification to EN10204-3.1 is available upon request.

Storage conditions

The storage periods quoted assume that all components are stored in a manner to optimise the storage periods.

- Products must be fully protected from contact with all chemicals, including any incidental contact – e.g cleaning fluid
- All products must be protected against physical damage including abrasion, kinking and crushing.
- Temperature does not exceed 25 °C
- Humidity of the atmosphere does not exceed 70%
- Protected from direct sunlight and UV exposure
- Protected from all sources of ionising radiation
- Protected from exposure to ozone.

Material certificates are retained by Aflex Hose Ltd for 10 years from receipt of material.

5. Food testing compliance

5a 1935/2004 Taint and odour testing. Samples: PTFE hose liner natural and anti-static

Test articles were externally convoluted and internally smoothbore PTFE hose liners in both natural and anti-static versions. These liners are assessed for organoleptic properties according to EN1230-2 (taint) and EN1230-1 (odour). Taint is assessed through boiling water exposure, leave to cool for four hours, which are the repeat use conditions.

Results: No significant difference in taste or odour and substances have not been transferred to the test food.

5b 1935/2004 EU 10/2011 Overall migration testing. Samples: PTFE hose liner natural and anti-static

Test articles were final sintered PTFE tubing in both natural and anti-static material version. The hose liner was subjected to EU 10/2011 test protocols for overall migration testing OM6 and OM7. The OM6 testing extracted test articles with Ethanol 10 % v/v (Simulant A) at 100 °C over 4 hours and Acetic Acid 3 % w/v (Simulant B) over 4 hours. The OM7 testing extracted test articles with vegetable oil (Simulant D2) at 175 °C for 2 hours.

OM6 relates to “Any food contact conditions with food simulants A, B or C at temperature exceeding 40 °C” Note that simulant C is Ethanol 20%, but is not required to satisfy “articles in contact with all types of food.”

OM7 relates to “High temperature applications with fatty foods exceeding the conditions of OM5”, which therefore exceed 121 °C.

Results: The requirements of EU 10/2011 overall migration limits for Natural and Anti-static PTFE hose liner were met for OM6 and OM7. Therefore, the PTFE liners are suitable for repeated use and contact with all types of food at temperatures exceeding 121 °C.

5c 1935/2004 EU 10/2011 Specific migration limit testing. Samples: PTFE hose liner natural and anti-static

Test articles were externally convoluted and internally smooth bore PTFE hose liners in both natural and anti-static versions. These were removed from a “Pharmaline R” product, but the externally convoluted and internally smooth bore form of the hose liner is

consistent in general form to that used in Bioflex Ultra, Pharmaline N, Pharmaline X and FaBLINE.

Specific Migration Limit (SML) testing for PTFE assessed for extraction of Tetrafluoroethylene (TFE – Union list #281), Perfluoropropylvinylether (PPVE – Union list #423) and Hexafluoropropylene (HFP – Union list #282). Extractions on immersed test articles was carried out using a 50 % Ethanol solution (simulant D1) at 70 °C for 6 hours.

Results: The requirements of EU 10/2011 specific migration limits for Natural and Anti-static PTFE hose liner were met. The limit for TFE and PPVE are 0.05 mg/kg and results were below this and below the limit of detection. The limit for HFP was not detectable with a limit of detection of 0.01mg/kg.

5d 1935/2004 EU 10/2011 Annex 1, Table 1 (Union list) substances

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

Anti-static PTFE contains high purity carbon black (CAS 1333-86-4, FCM substance 411). This material is compliant and specifically tested by the material supplier to ensure continuous compliance to the 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 amendments, concerning Plastics coming into contact with food. Aflex Hose products intended for food use contain less than 1.5 % w/w of carbon black and well below the maximum allowable limit of 2.5 % w/w.

5e Chinese food standard testing protocol GB 4806.7 - 2016. Samples: PTFE hose liner natural and anti-static

“Sense” is tested through colour, luster, odour and dirt. A soaked solution is checked for turbidity, sedimentation and foreign odour. Overall migration at 40 °C with 4 % Acetic acid, 20 % Alcohol, 95 % Alcohol. Potassium permanganate consumption in water at 60 °C for 2hrs. Heavy metals fraction through 4% Acetic acid at 60 °C for 2hrs. Decolonisation test using Alcohol (65+35), Vegetable oil and soak solution.

Results: Sense tests were normal. Overall migration, Potassium permanganate consumption were well below the threshold of 10 mg/dm² (migration) and 10 mg/kg (Potassium permanganate). Heavy metals was below the limit of detection. Decolonisation results were negative.

5f EU 2016/1416 amending regulation EU 10/2011

Aflex Hose products and testing meet the requirements of the amendment EU 2016/1416 that applies to EU 10/2011.

5g 3-A sanitary standard

The Bioflex Ultra rubber covered, Pharmaline N, Pharmaline X and FaBLINE products, with particular end fitting configurations and appropriate ferrule seals comply with the 3-A 62-02 (hose assemblies) sanitary standard. Contact Aflex Hose for further details on the specific configurations that are covered by the 3-A certification.

5h Declaration of compliance to EU 10/2011 as required by article 15 and annex IV

Aflex Hose Ltd. Is the business operator issuing this declaration and the manufacturer of the hose products, which also include control of intermediate manufacturing stages. The business address for Aflex Hose is:- Aflex Hose Ltd, Dyson Wood Way, Bradley Business Park, Huddersfield, West Yorkshire, HD2 1GZ, UK.

The date of the declaration is the date of this validation guide document.

Aflex Hose Ltd declare that the PTFE hose liner in both Natural (GP) and Anti-Static (AS) versions meet

the relevant requirements laid down in the regulation (EC) No 10/2011 and (EC) No 1935/2004. In addition compliance with (EC) No 2016/1416 on materials and articles intended to come into contact with food, and (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food.

Testing for overall migration has been carried out to meet the following requirements:

- OM6 – “Any food contact conditions with food simulants A, B or C at temperature exceeding 40 °C” Note that simulant C is Ethanol 20 %, but is not required to satisfy “articles in contact with all types of food.
- OM7 – “High temperature applications with fatty foods exceeding the conditions of OM5” (Therefore exceeding 121 °C)

There are no restrictions to the types of food the PTFE liner materials can come into contact with. However, abrasive foodstuffs (e.g. blown powders, grains) may cause wear of the liner surface and material attrition. Aflex Hose can be consulted for advice and recommendation.

There are no know restrictions of time or temperature for food contact. The ratio of food contact surface area to volume used to establish the compliance of the PTFE liner articles was 6 dm²/Kg



6 EN 16643:2016 hose specification standard for non-adhesive bonded PTFE hose

Aflex Hose and hose assemblies meet the requirements of EN 16643:2016 Rubber and plastics hoses and hose assemblies — Non-bonded fluoroplastic lined (e.g. PTFE) hoses and hose assemblies for liquid and gaseous chemicals — specification. The term “non-bonded” relates to the hose layer construction, where adhesives are not used to bond adjacent layers of the construction.

Electrical properties of the hose and hose assembly are specified within EN 16643 and measured in accordance with the methods in EN ISO 8031 for both electrical continuity between end fittings and static dissipative properties.

Electrical continuity (EC) is measured on assemblies only and between the metallic end fittings. EC assemblies are marked “M” grade and the electrical resistance between end fittings is less than $10^2\Omega$ (100 Ω). The M-grade must be appropriate for the assembly construction.

The following are not EC:

- Bioflex Ultra tube only (TO)
- Pharmaline X
- Any assembly with non-EC fittings (e.g. Polypropylene fittings)

Anti-Static quality (AS) or static dissipative hose assemblies have an electrical resistance between $10^3\Omega$ to $10^8\Omega$ (1K Ω to 100M Ω), when measured between the liner or outer cover and the opposite end fitting.

Electro polished end fitting requirements:

Assemblies that include an electro polished Tri-clamp (or Tri-clover) non-lined stainless steel 316L fitting, or similar electro polished fitting, are electropolished and passivated to a surface finish of $\leq 15\mu\text{m Ra}$ ($\leq 0.4\mu\text{m}$).



FOOD AND BEVERAGE SOLUTIONS



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