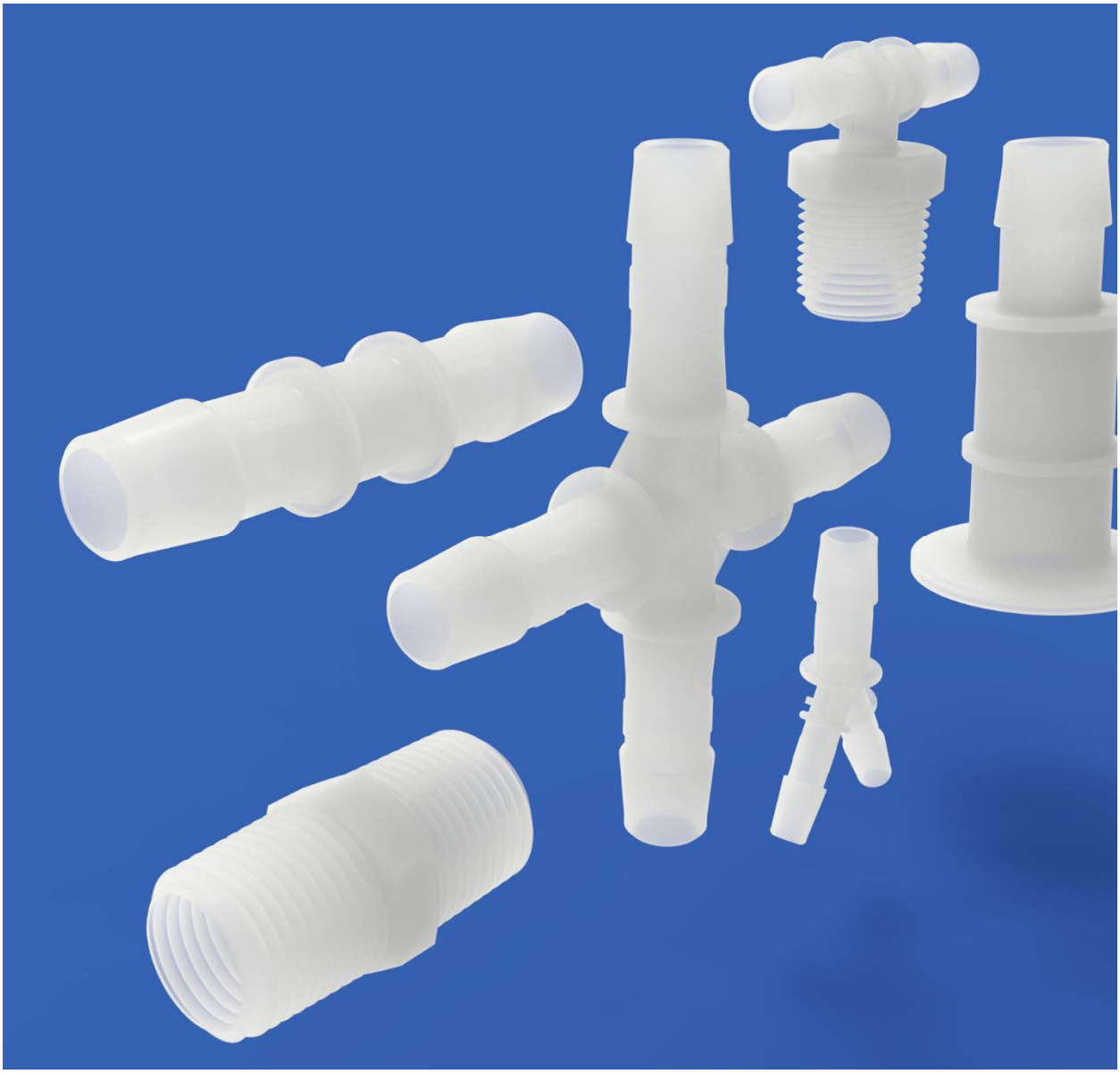
ELDON JAMES

Validation Guide

KYNAR® 740 PVDF (NK7)



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1. VALIDATION GUIDE OVERVIEW

1.1. Introduction

The purpose of this validation guide is to document the testing and results of the Kynar 740 PVDF (NK7) fitting line. It will provide users with the information necessary to assess the suitability of these products for use in their intended applications. The testing and results to follow will detail the mechanical, material, performance, environmental, leachables and extractables, and other USP tests required to provide users with the information necessary to assess the suitability of these products for use in their intended applications.

1.2. Scope

NK7 fittings are manufactured from a high purity, semi-opaque, thermoplastic material that contains no animal derived materials, plasticizers, natural rubber latex, vinyl acetate, melamine, or residual solvents. It can be used in food, beverage, bioprocess, and medical device applications, to name a few. NK7 isa highly chemically resistant fluoropolymers providing excellent corrosion and chemical resistance at both ambient and elevated temperatures. It is also inherently UV stable, exhibits high mechanical toughness, and abrasion and flame resistant. Due to its inherent chemical resistance and high purity, applications involving contact with high purity water, acids, chlorine, halogenated solvents, and petrochemical mixtures are possible.

It is biocompatible, has excellent chemical and corrosion resistance, is RoHS and REACH compliant, and is Animal Derivative (ADF) free. It is temperature stable from -35°C to 135°C (-31°F to 275°F) and can be sterilized by autoclave, ethylene oxide or e-beam.

NK7 exhibits very low extractables and does not contain phthalates or halogens. It is manufactured according to GMP and meets USP Class VI requirements. With respect to downstream processing, it is ultrasonically weldable.

1.3. Effective Date

The information contained within this document is current as of August 2023.

1.4. Country of Origin

NK7 fittings are manufactured in the U.S.A.

1.5. Product Manufacturer

NK7 fittings are manufactured by:

Eldon James Corporation
3486 Precision Drive
Fort Collins, CO 80528

Eldon James Corporation
3420 Precision Drive
Fort Collins CO 80528

1.6. Manufacturing Environment

NK7 fittings are manufactured in both non-cleanroom and ISO Class 7 cleanroom environments within a facility certified to both ISO 9001:2015 and ISO 13485:2016. Cleanroom manufactured product is designated with a QC suffix.

1.7. Summary of Material Specifications

Mechanical	
Density	1.78 gr/cm^3
Water Absorption	
Saturation, 73°F (23°C)	0.030%
Equilibrium, 73°F (23°C), 50% RH	0.015%
Thermal	
Continuous Service Temperature	-35°F to +275°F (-31°C to +135°C)
Glass Transition Temperature	-40°F (-40°C)
Vicat Softening Temperature	275°F (135°C)
Deflection Temperature Under Load	
66 psi (0.45 MPa), Unannealed	275°F (135°C)
264 psi (1.8 MPa), Unannealed	221°F (105°C)
Application Specific	
Steam Autoclavable	121 °C, 132 °C, and 134 °C cycles
Radiation	≤50 kGy (Gamma and E-beam)
EtO	Standard cycle 7 and 8
Flammability Classification	
0.03 in (0.8 mm)	V-0
0.06 in (1.6 mm)	V-0
Oxygen Index	43%

Table 1.8: Summary of Material Specifications

2. REGULATORY INFORMATION

2.1. United States of America Standards

2.1.1. Food Contact Status (USA)

NK7 raw materials fully comply with the US Federal Food, Drug, and Cosmetic Act (CFR 177-2510) and all applicable food additive regulations with no known Threshold of Regulation (TOR) restrictions.

CFR 177-2510 specifies requirements for food packaging contact and is intended for repeated use applications. Final article compliance may require that extraction testing be performed on the final article. It is the responsibility of the customer to determine the applicability of this regulation in the development of the finished food contact article.

This product can be used in compliance with the above FDA regulations if predicated on the assumption that the chemical composition will not be altered or adulterated by the addition of other unregulated substances, and that the food contact surfaces will be manufactured and employed in accordance with Good Manufacturing Practices outlined in 21 CFR 174.5 and the general provisions applicable to indirect food additives listed there.

2.1.2. **California Proposition 65 (PROP65)**

Based on the final composition of the NK7 fitting raw material, no known PROP65 substances defined in Proposition 65 of the California Safe Drinking Water and Toxic Enforcement Act of 1986 and its amendments have been identified.

2.1.3. **US Pharmacopeia (USP) <88>**

USP <88> is a series of three tests that evaluate biological reactivity of animals to polymeric material: systemic toxicity, intracutaneous reactivity and implantation.

The Systemic Injection Test and the Intracutaneous Test are designed to determine the systemic and local, respectively, biological responses of animals to plastics and other polymers by the single dose injection of specific extracts prepared from a sample. The Implantation Test is designed to evaluate the reaction of living tissue to the plastic and other polymers by the implantation of the sample itself into animal tissue.

This product meets guideline requirements and as such has been certified as a USP Class VI Plastic (USP<88>, Biological Reactivity Tests, In Vivo). Tests were conducted on the material pellets, not the product itself. Eldon James does not use additional additives or compounds when manufacturing the product.

2.1.4. **ISO 10993-4**

ISO 10993-4 provides general requirements for evaluating the interactions of medical devices with blood. It describes a classification of medical and dental devices that are intended for use in contact with blood, based on the intended use and duration of

contact as defined in ISO 10993-1. It covers the fundamental principles governing the evaluation of the interaction of devices with blood, the rationale for structured selection of tests according to specific categories, together with the principles and scientific basis of these tests.

This product meets guideline requirements and as such has been certified as a non-hemolytic plastic (ISO 10993-4, 2002, Direct Contact and Extraction Methods). Tests were conducted on the material pellets, not the product itself. Eldon James does not use additional additives or compounds when manufacturing the product.

2.1.5. **ISO 10993-5**

This test is a common cytotoxicity assessment designed to assess the toxicity to cells of leachable components of the material. The material is extracted in cell culture media (Minimum Essential Medium, or “MEM”). Extracts are placed in contact with a monolayer of L-929 mouse fibroblast cells. Cells are incubated at controlled

temperature and CO_2 level for an additional period (72 hrs), after which they are examined microscopically for indications of cytotoxicity including malformation, degeneration, and lysis.

This product meets elusion test guideline requirements and as such has been certified as a non-cytotoxic plastic (ISO 10993-5, 1999). Tests were conducted on the material pellets, not the product itself. Eldon James does not use additional additives or compounds when manufacturing the product.

2.1.6. **Substance Reviews**

2.1.6.1. Glycol Ethers

2-Methoxyethanol 0.001	109-86-4	Not Present
Butyldiglycol	112-34-5	Not Present
Diethylene glycol dimethyl ether (DEGDME)	111-96-6	Not Present
Diethylene glycol methyl ether (DEGME)	111-77-3	Not Present
Ethyldiethyleneglycol	111-90-0	Not Present
Ethylene glycol dimethyl ether (EGDME)	110-71-4	Not Present
Ethylene glycol ethyl ether acetate (EGEEA)	111-15-9	Not Present
Ethylene glycol methyl ether acetate (EGMEA)	110-49-6	Not Present
Ethylene glycol monobutyl ether (EGBE)	111-76-2	Not Present
Ethylene glycol monoethyl ester 0.001	110-80-5	Not Present
Triethylene glycol dimethyl ether (TEGDME)	112-49-2	Not Present

2.1.6.2. Bisphenols and Phthalates

1,2-Benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10-rich (DIDP)	68515-49-1	Not Present
1,2-Benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10-rich (DINP)	68515-48-0	Not Present
Benzyl butyl phthalate (BBP)	85-68-7	Not Present
Bis(2-ethyl-1-hexyl)tetrabromophthalate	26040-51-7	Not Present
Bis(2-ethylhexyl)phthalate (DEHP)	117-81-7	Not Present
Bis(2-methoxyethyl) phthalate	117-82-8	Not Present
Bisphenol A (BPA)	80-05-7	Not Present
Bisphenol AF	1478-61-1	Not Present
Bisphenol B	77-40-7	Not Present

Bisphenol F (BPF)	620-92-8	Not Present
Bisphenol F (BPF)	87139-40-0	Not Present
Bisphenol S	80-09-1	Not Present
Dibutyl phthalate (DBP)	84-74-2	Not Present
Dicyclohexyl phthalate	84-61-7	Not Present
Diethyl phthalate	84-66-2	Not Present
Diisobutyl phthalate	84-69-5	Not Present
Diisodecyl phthalate (DIDP)	26761-40-0	Not Present
Diisohexyl phthalate (DIHxP)	71850-09-4	Not Present
Diisononyl phthalate (DINP)	28553-12-0	Not Present
Diisopentylphthalate	605-50-5	Not Present
Di-n-hexyl phthalate (DNHP)	84-75-3	Not Present
Di-n-octyl phthalate (DNOP)	117-84-0	Not Present
Di-n-pentyl phthalate	131-18-0	Not Present
Mono-n-butyl phthalate	131-70-4	Not Present
Phthalic anhydride	85-44-9	Not Present

2.1.6.3. Natural Rubber and Rubber Latex

cis 1,4 Polyisoprene	Not Present
Natural Rubber	Not Present
Polyisoprene, cis	Not Present

2.1.6.4. Halogenated (Cl and Br) Organic Compounds

Epichlorohydrin	Not Present
Polybrominated Biphenyls (PBBs)	Not Present
Polybrominated Diphenyl Ethers (PBDEs and DecaBDE)	Not Present
Polybrominated Terphenyls (PBTs)	Not Present
Polychlorinated biphenyls (PCB)	Not Present
Polychlorinated naphthalenes (PCN)	Not Present
Polychlorinated terphenyls (PCT)	Not Present
Short Chain Chlorinated paraffins (SCCP)	Not Present
Tris(2-chloroethyl) phosphate 0.005	Not Present

2.2. European Union Standards

The composition of this product complies with the formulary provisions (inclusion in Union list in Table I of Annex I) of Regulation (EU) No. 10/2011 involving plastic materials intended to come into contact with food.

Monomers, additives, and polymer production aids (PPA) used to manufacture this product are included in the Union list within the regulation and comply with any applicable restrictions and limitations. In addition, listed below are substance(s) within this product that have a restriction or limitation:

2.2.1. Food Contact Status (EU)

Raw material testing has provided evidence that NK7 fittings contain only substances authorized by Regulation (EU) No 10/2011, August 8th, 2019. No additional process additives are used when processing NK7 fittings.

It is the responsibility of the customer who brings a finished product to the market to verify compliance with Regulation (EC) No 1935/2001 with emphasis on Article 3 or with Regulation (EU) No 10/2011 and amendments in force of the date of this statement.

2.2.2. Food Contact Materials

2.2.2.1. Monomers and Additives

The following restrictions are noted with respect to Monomers and Additives used in the manufacturing process:

Ethylene Oxide	**75-21-8**
FCM #:	129
Material #:	17020
Migration Restrictions: SML = ND. The specific migration limit is non-detectable (ND). A detection limit of 0.01mg substance per kg food is applicable unless specified differently for an individual substance.	
Specifications: 1 mg/kg in final product	
Compliance Verification Note: Verification of compliance by residual content per food contact surface area (QMA) in case of	
Vinylidene Fluoride	**75-38-7**
FCM #:	132

Material #:	26140
Migration Restrictions: SML = 5 mg/kg	
Propylene Oxide	**75-56-9**
FCM #:	135
Material #:	24010
Migration Restrictions: SML = ND. The specific migration limit is non-detectable (ND). A detection limit of 0.01mg substance per kg food is applicable unless specified differently for an individual substance.	
Specifications: 1 mg/kg in final product	

Table 2.2.2.1: EU Food Contact Restrictions – Monomers and Additives

2.2.2.2. Aids to Polymerization

NK7 fittings only contain Aids to Polymerization (AP) authorized by Regulation (EU) No 10/2011 and Resolution AP (92) 2 of the Council of Europe on Aids to Polymerization.

2.2.2.3. Pigments and Colorants

NK7 fittings do not contain any pigments or colorants.

2.2.3. **REACH 235 Substances (June 14th, 2023)**

Based on the information provided to Eldon James from Arkema and their formulation reviews, this product does not contain SVHC Candidate List Annex XIV materials (in accordance with Article 59 of the European Regulation 1907/2006) above the declaration threshold (0.1%) as updated by the European Chemical Agency as of June 14th 2023 (235 substances).

2.2.4. **Restriction of Hazardous Substances (RoHS)**

EU Directive 2015/863/EU (RoHS 3 Directive)

Restriction on use of: lead, mercury, hexavalent chromium, polybrominated biphenyl (PBB) and polybrominated diphenyl ether (PBDE) flame retardants, at levels of greater than 0.1%; cadmium, at levels greater than 0.01%; and Pentabromodiphenylether, Octabromodiphenylether, and Decabromodiphenyl oxide, in concentrations higher than 0.1%; and HBCDD, Bis(2-ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP), Diisobutyl phthalate (DIBP) in concentrations greater than 0.1%.

Based on the information provided by our resin suppliers and their formulation reviews, they have found that the product listed above does not contain RoHS substances above listed concentrations and would therefore be in compliance with substance restrictions per RoHS 3 Directive 2015/863/EU and amendments in force.

2.2.5. **Heavy Metals (ELV Directive 2000/53/EC)**

Coalition of Northeastern Governors (CONEG)

Model Toxins in Packaging Legislation (CONEG) concerns restrictions on the use of certain hazardous substances in packaging or packaging components. It restricts the sum of the incidental concentration levels of lead, mercury, cadmium, and hexavalent chromium present in the product to a level equal to or less than 100 parts per million (ppm) by weight.

Based on material supplier data of the final composition, the base resin does not contain CONEG substances at or above the 100 ppm reporting threshold. As such, NK7 fittings meets requirements of the Model Toxics in Packaging Legislation developed in 1989 by the CONEG (Coalition of Northeastern Governors, USA).

2.3. Animal Derivative Content & Transmissible Spongiform Encephalitis (TSE/BSE) Risk

Bovine Spongiform Encephalopathy (BSE) and Transmissible Spongiform Encephalopathy (TSE) transmission risks are associated with substances derived from certain animal tissues sourced from risk regions as determined by The World Organization for Animal Health (OIE).

Based on material supplier data of the final composition, the base resin is not known or expected to contain substances which are animal derived or associated with BSE/TSE infectivity.

2.4 Per- and polyfluoroalkyl substances (PFAS)

The PFAS restriction proposal was prepared by authorities in Denmark, Germany, the Netherlands, Norway and Sweden and submitted to ECHA on 13 January 2023. It aims to reduce PFAS emissions into the environment and make products and processes safer for people.
As of the date listed on this document, PVDF Kynar 740 is not intentionally formulated with any Per- and polyfluoroalkyl substances.

3. PERFORMANCE TESTING

3.1. Sterilization

Sterilization using radiation, Gamma and E-Beam, has been shown safe up to 45kGy. At levels up to this limit, no mechanical property changes should occur. A slight yellowing which is purely visual may become present as the radiation level approaches 45 kGy. The customer should conduct testing for any sterilization method chosen to verify performance unique to the application.

- E-beam/Gamma ≤50 kGy, no deficiencies, may color shift at higher doses.
- EtO No issues. Can safely be used.
- Autoclave Up to 135°C.

3.2. Shelf-Life

NK7 fittings are molded from a thermoplastic formulation belonging to a particular product portfolio. The material supplier has provided guidance that in its resin pellet form, no processing issues or degradation of material performance will be expected within 50 years when stored at temperatures at or below 125°F (50°C). Other, similar chemistry formulations have been tested with respect to shelf-life for projects and products requiring FDA design history files and/or FDA submissions. Molded fitting shelf-life should be tested for each application and fluid contact but a minimum of five (5) years should be expected with aggressive, low and high pH fluids and a maximum of ten (10) years for more pH neutral fluids.

4. Extractables and Leachables

4.1. Introduction

The objective is to perform an extractables and leachables study for chemical characterization of NK7 fittings. Four test protocols will be executed with analysis methods below:

- GC/MS – Direct Injection
- GC/MS – Headspace
- LC/UV/MS
- ICP-OES

4.2. Test Setup

Three (3) solvents were used for the extraction samples.

- 1:1 EtOH:H_2O
- Acidic water (pH 3)
- Basic water (pH 10)

Fitting samples were covered with 34mL of each solvent and stored at 40°C for 21 days. After the storage period, sample extracts in glass containers were collected for GC/MS and

LC/UV/MS analyses and in polypropylene containers for ICP-OES analysis. Control solutions for each solvent and condition were prepared in the same manner as the sample preparations to ensure that no contamination from the labware or reagents used would be misinterpreted as an extractable compound. Both GC/MS solutions and LC/UV/MS solutions were stored at 2°C to 8°C until analysis and the ICP-OES solution was stored at room temperature.

4.3. Test Results

4.3.1. GC/MS – Direct Injection

In the direct injection GC/MS analysis, 2,5-dimethyl-1,4-dioxane was reportable in the 1:1 EtOH:water; acidic water, pH 3; and basic water, pH 10 extracts of the sample. In the 1:1 EtOH:water extracts, several unknowns, unknown alkanes, and unknown alcohols were also reportable.

As a reference standard, a sample of perfluorooctanesulfonic acid or PFOS was analyzed by direct injection GC/MS to compare with extracted ion analysis. Perfluorooctane

sulfonic acid (PFOS) cannot be recovered by direct inject analysis, but its analysis yielded 4 related compounds. These are likely degradants of the perfluorooctanesulfonic acid.

When comparing the extracts for the polymer tested, none of these 4 compounds were identified in any of the extracts of the sample. Therefore, no PFOS was detected in the extracts of component C.

4.3.2. GC/MS – Headspace

In the headspace GC/MS analysis, no compounds were reportable in the acidic water, pH 3 or the basic water, pH 10 extracts of the sample. In the 1:1 EtOH:water extracts alkanes and acetic acid ethyl ester were reportable. A perfluorooctanesulfonic acid standard was analyzed to determine spectra to perform extracted ion analysis. This compound cannot be recovered by headspace analysis and so no extracted ion analysis was performed for headspace.

4.3.3. LC/UV/MS

No reportable compounds were present in any extracts of the sample.

4.3.4. ICP-OES

No elements were reportable in any extracts of the sample.