Perspective on U.S. Food and Drug Administration regulation of PFAS uses in contact with food

Maricel V. Maffini, Ph.D.

Independent Consultant

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Disclosure

- Clients include public interest organizations, food additives and food service companies
- Co-authored food additive petitions requesting FDA revoke approval for food contact substances such as long-chain perfluoroalkyl substances, perchlorate, ortho-phthalates and carcinogenic flavors
- This work was done in collaboration with the Environmental Defense Fund. Opinions are my own.

How do PFAS get into the food supply?

- U.S. Food and Drug Administration (FDA) approval of food additive petition; publication in Code of Federal Regulation
- Manufacturer self-determination that the use is ‘generally recognized as safe’ or GRAS; bypasses FDA review. Unknown substance, uses and safety
- FDA review of food contact notifications (FCN) submitted by manufacturer; FDA publishes decision in website Inventory of Effective Food Contact Substance Notifications

FCN Records Search

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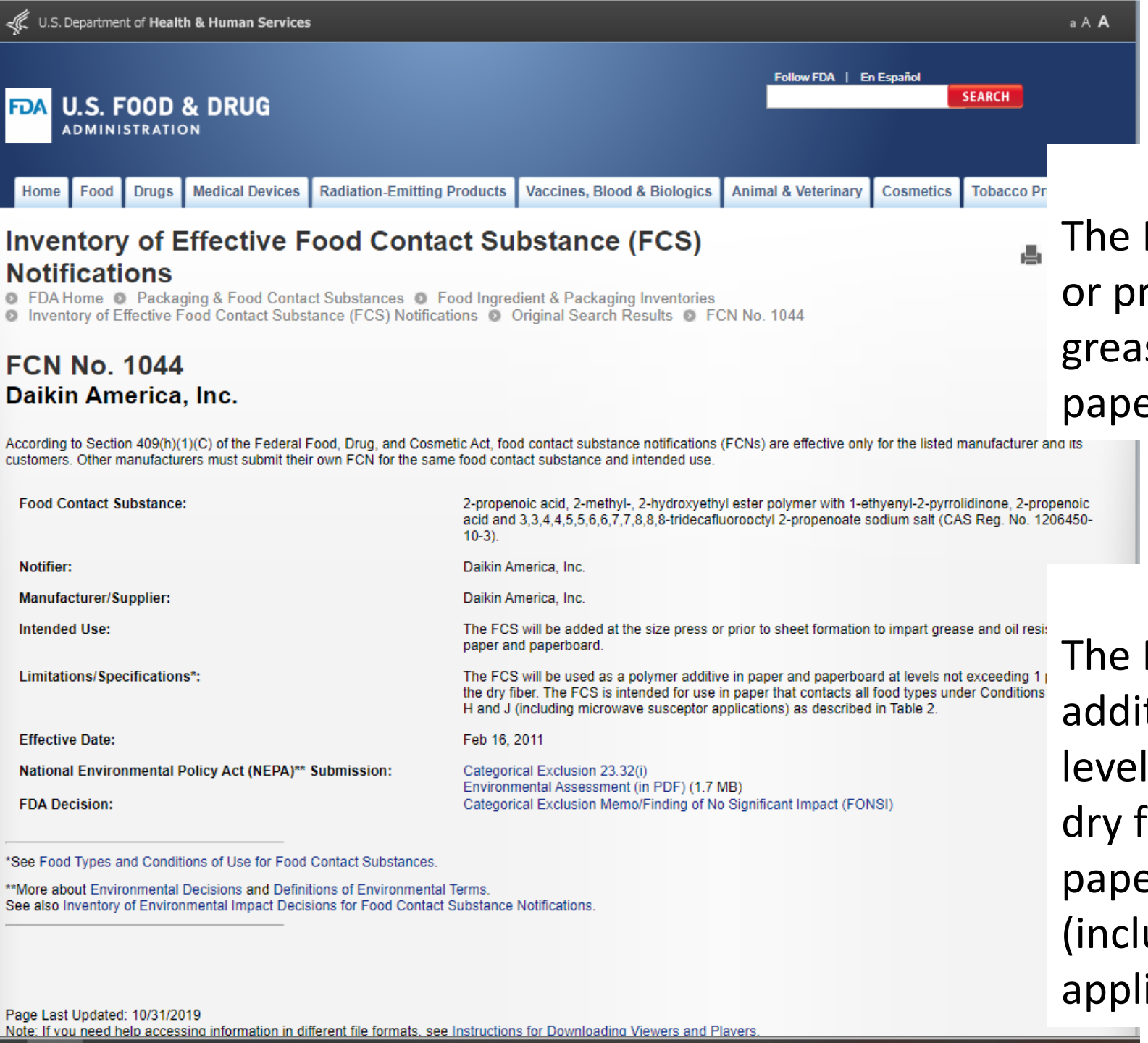
Search: fluoro Show Items Clear Search within these results

Records Found: 70 Show All Page 1 of 2

FCN No. (sorted Z-A)	Food Contact Substance	Manufacturer/Supplier	Effective Date
1958	Fluorocarbon cured elastomer produced by copolymerizing tetrafluoroethylene (CAS Reg. No. 116-14-3) and propylene (CAS Reg. No. 115-07-1) and subsequent curing with triallylisocyanurate (CAS Reg. No. 1025-15-6) or triallylcyanurate (CAS Reg. No. 101-37-1) and 2,2'-bis(*tert*-butylperoxy)diisopropylbenzene (CAS Reg. No. 25155-25-3).	AGC Chemicals Americas, Inc.	Jul 17, 2019
1914	Tetrafluoroethylene-ethylene-3,3,4,4,5,5,6,6,6-nonafluoro-1-hexene terpolymer (CAS Reg. No. 68258-85-5).	Asahi Glass Co., Ltd. AGC Chemicals Europe	Dec 13, 2018
1825	Siloxanes and silicones, methyl-phenyl, methyl-3,3,3-trifluoropropyl (CAS Reg. No. 1643944-25-5).	Dow Silicones Corporation DDP Specialty Electronic Materials US 9, LLC	Dec 1, 2017
1805	A polymer produced from tetrafluoroethylene (CAS Reg. No. 116-14-3) and 1,1,2,2-tetrafluoro-2-((1,2,2-trifluoroethenyl)oxy)ethanesulfonyl fluoride (CAS Reg. No. 29514-94-1). The polymer is hydrolyzed and may optionally be further neutralized to its ammonium salt.	Solvay Specialty Polymers USA, LLC	Dec 20, 2017
1723	1-hexene, 3,3,4,4,5,5,6,6,6-nonafluoro-, polymer with 1,1,2,2-tetrafluoroethene (CAS Reg. No. 82606-24-4). **REPLACES FCN 1065**	Asahi Glass Co., Ltd. AGC Chemicals Europe AGC Chemicals Americas, Inc.	Jan 13, 2017
1676	2-propenoic acid, 2-methyl-, 2-hydroxyethyl ester, polymer with 2-propenoic acid and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl 2-methyl-2-propenoate, sodium salt (CAS Reg. No. 1878204-24-0).	Asahi Glass Co., Ltd. AGC Chemicals Americas, Inc.	Sep 21, 2016
1674	2,4,4'-Trifluorobenzophenone (TFBP) (CAS Reg. No. 80512-44-3).	Victrex Plc	Sep 2, 2016
1661	D-Glucitol, 1-deoxy-1-(methylamino)-, reaction products with 4-ethenylphenol homopolymer and formaldehyde, 1-hydroxyethylidene-1,1-diphosphonic acid, manganous oxide, phosphate, fluorotitanic and fluorozirconic salts. **REPLACES FCN 1472**	Henkel Adhesive Technologies	Jul 20, 2016
1601	2,3,3,4,4,5,5-Heptafluoro-1-pentene polymer with ethene and tetrafluoroethene (CAS Reg. No.. 94228-79-2) .	Daikin Industries, LTD	Mar 5, 2016
1560	Vinylidene fluoride-hexafluoropropene copolymer (CAS Reg. No. 9011-17-0).	Arkema, Inc.	Sep 18, 2015
1493	Copolymer of 2-(dimethylamino) ethyl methacrylate with 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl methacrylate, N-oxide, acetate (CAS Reg. 1440528-04-0)	Archroma Management GmbH	Dec 31, 2014
1451	2-Propenoic acid, 2-methyl-, 2-(dimethylamino)ethyl ester, polymer with 1-ethenyl-2-pyrrolidinone and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl 2-propenoate, acetate (CAS Reg. No. 1334473-84-5).	Daikin America, Inc.	Sep 4, 2014
1448	Vinylidene fluoride-hexafluoropropene copolymer (CAS Reg. No. 9011-17-0).	Arkema, Inc.	Aug 28, 2014
1360	2-Propenoic acid, 2-methyl-, 2-(dimethylamino)ethyl ester, polymer with 1-ethenyl-2-pyrrolidinone and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl 2-propenoate, acetate (CAS Reg. No. 1334473-84-5).	Daikin America, Inc.	Feb 21, 2014
1255	Copolymer of vinylidene fluoride and hexafluoropropene (CAS Reg. No. 9011-17-0).	3M	Apr 12, 2013
1186	Butanedioic acid, 2-methylene-, polymer with 2-hydroxyethyl, 2-methyl-2-propenoate, 2-methyl-2-propenoic acid and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl 2-methyl-2-propenoate, sodium salt	Asahi Glass Co., Ltd. AGC Chemicals Americas,	Sep 21, 2012



U.S. Department of Health & Human Services

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FDA U.S. FOOD & DRUG ADMINISTRATION

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Inventory of Effective Food Contact Substance (FCS) Notifications

FDA Home ● Packaging & Food Contact Substances ● Food Ingredient & Packaging Inventories
Inventory of Effective Food Contact Substance (FCS) Notifications ● Original Search Results ● FCN No. 1044

FCN No. 1044
Daikin America, Inc.

According to Section 409(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act, food contact substance notifications (FCNs) are effective only for the listed manufacturer and its customers. Other manufacturers must submit their own FCN for the same food contact substance and intended use.

Food Contact Substance:	2-propenoic acid, 2-methyl-, 2-hydroxyethyl ester polymer with 1-ethyenyl-2-pyrrolidinone, 2-propenoic acid and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl 2-propenoate sodium salt (CAS Reg. No. 1206450-10-3).
Notifier:	Daikin America, Inc.
Manufacturer/Supplier:	Daikin America, Inc.
Intended Use:	The FCS will be added at the size press or prior to sheet formation to impart grease and oil resi paper and paperboard.
Limitations/Specifications*:	The FCS will be used as a polymer additive in paper and paperboard at levels not exceeding 1 the dry fiber. The FCS is intended for use in paper that contacts all food types under Conditions H and J (including microwave susceptor applications) as described in Table 2.
Effective Date:	Feb 16, 2011
National Environmental Policy Act (NEPA) Submission:**	Categorical Exclusion 23.32(i) Environmental Assessment (in PDF) (1.7 MB)
FDA Decision:	Categorical Exclusion Memo/Finding of No Significant Impact (FONSI)

*See Food Types and Conditions of Use for Food Contact Substances.

**More about Environmental Decisions and Definitions of Environmental Terms.
See also Inventory of Environmental Impact Decisions for Food Contact Substance Notifications.

Page Last Updated: 10/31/2019
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

FCN Records

Intended use

The FCS will be added at the size press or prior to sheet formation to impart grease and oil resistance to paper and paperboard

Limitations/Specifications

The FCS will be used as a polymer additive in paper and paperboard at levels not exceeding 1 percent of the dry fiber. The FCS is intended for use in paper that contacts all food types (including microwave susceptor applications)

Freedom of Information Act request

ASKED

- 31 FCNs (2002-2016)
- 19 distinct chemical mixtures (FCSs), mostly polymers
- 14 FCS used to coat paper and carboard
- 6 chemical companies
  - Archroma
  - Asahi
  - Chemours
  - Daikin
  - Solenis
  - Solvay

RECEIVED

- Form 3480 (FCN)
- FDA review memos
  - ENVIRONMENTAL
  - TOXICOLOGY
  - CHEMISTRY AND EXPOSURE
- Company's support information
  - Analytical methods
  - Toxicity testing
  - Exposure assessment
- FDA correspondence with notifier

http://blogs.edf.org/health/files/2018/05/EDF-PFAS-FDA-FCN-Environmental-Assessments-Full-5-17-18.pdf

Chemistry Information

- Section A: Identification for the FCS
- Section B: Manufacture
- Section C: Impurities
- Section D: Intended use
- Section E: Stability of the FCS
- Section F: Migration levels into food
- Section G: Estimated daily intake

Part II — CHEMISTRY INFORMATION

Section A - IDENTIFICATION OF THE FOOD CONTACT SUBSTANCE

See Chemistry Recommendations Sections II.A.1 through 4.

1. Chemical Abstracts Service (CAS) name

2-Propen-1-ol, reaction products with pentafluoroiodoethane-tetrafluoroethylene telomer, dehydroiodinated, reaction products with epichlorohydrin and triethylenetetramine

2. CAS Registry Number

484178-90-3

3. Trade or Common Name

4. Other Chemical Names (IUPAC, etc.)

n/a

Pentafluoroiodoethane-tetrafluoroethylene telomer

5. Description

Provide a description of the FCS, including chemical formula(e), structure(s) and molecular weight(s). For FCSs that cannot be represented by a discrete chemical structure, such as new polymers, provide a representative chemical structure(s) and the M_w and M_n. For new copolymers, also provide the ratio of monomer units in the copolymer.

See FCN No. 314, Attachment 1 for chemical structure. The chemical formula is:

$H\text{-}(C_2H_5N)_{x1}\text{-}(C_5H_{11}NO_2)_{x2}\text{-}(C_5H_{10}NOCl)_{x3}\text{-}(C_5H_9NOCl)_{x4}\text{-}(C_5H_{10}NON\text{-x link})_{x5}\text{-}(C_{11\text{-}23}H_{10}NOF_{13\text{-}37})_{x6}\text{-}(C_8H_{17}NO_3Cl)_{x7}\text{-}C_{12\text{-}24}H_{12}N\text{-x link}F_{13\text{-}37}$

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Mw = 3,067,499 Daltons
Mn = 24,368 Daltons

6. Characterization

Attach data, such as infrared (IR) data for identification of the FCS

^{13}C NMR and ^1H NMR spectra are inc

FDA FORM 3480 (Rev. 11/02)

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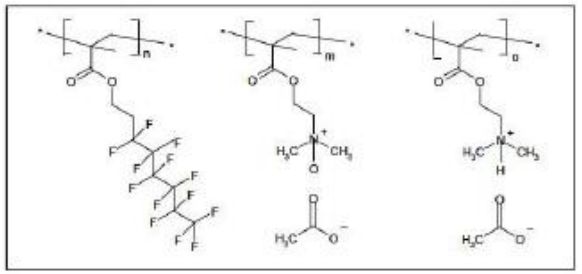
5. Description

Provide a description of the FCS, including chemical formula(s), structure(s) and molecular weight(s). For FCSs that cannot be represented by a discrete chemical structure, such as new polymers, provide a representative chemical structure(s) and the M_w and M_n. For new copolymers, also provide the ratio of monomer units in the copolymer.

The FCS is a copolymer produced from reaction of the following starting monomers, followed by partial oxidation of the dimethylaminoethyl methacrylate groups:

Chemical Name	CAS Reg. No.	Chemical Formula
2-Dimethylaminoethyl methacrylate	2867-47-2	$C_8H_{15}NO_2$
1H,1H,2H,2H-Perfluorooctyl methacrylate	2144-53-8	$C_{12}H_9F_{13}O_2$

The structure of the polymer may be represented as follows:



Part II - CHEMISTRY INFORMATION

SECTION A - IDENTIFICATION OF THE FOOD CONTACT SUBSTANCE

See Chemistry Recommendations, Sections II.A.1 through 4.

1. Chemical Abstracts Service (CAS) name

2-Propenoic acid, 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl ester, polymer with alpha-(1-oxo-2-propen-1-yl)-omega-hydroxypoly(oxy-1,2-ethanediyl)

2. CAS Registry Number

3. Trade or Common Name

(b) (4)

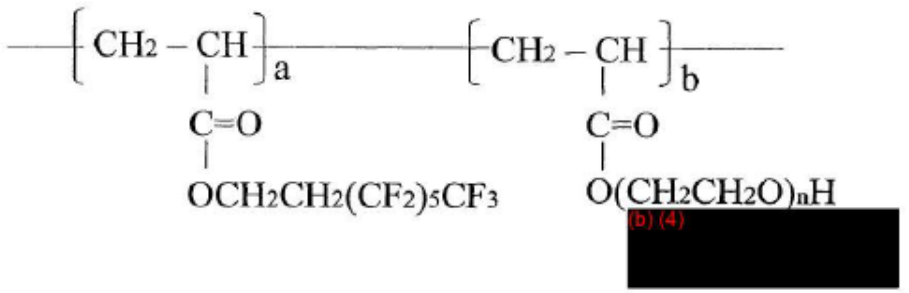
4. Other Chemical Names (*IUPAC, etc.*)

Perfluorohexylethyl acrylate-polyethylene glycol monoacrylate copolymer

Perfluorohexylethyl acrylate

5. Description

Provide a description of the FCS, including chemical formula(s), structure(s) and molecular weight(s). For FCSs that cannot be represented by a discrete chemical structure, such as new polymers, provide a representative chemical structure(s) and the M_w and M_n. For new copolymers, also provide the ratio of monomer units in the copolymer.



(b) (4)

Relative monomer weight percentages:

(b) (4)

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box if you attach a continuation sheet. Enter the attachment name and number in Section VI of this form.

uch as infrared (IR), ultraviolet (UV), nuclear magnetic resonance (NMR), mass spectra, or other similar data for identification of

um of the FCS is available in Attachment 2.

box if you attach a continuation sheet. Enter the attachment name and number in Section VI of this form.

FORM FDA 3480 (9/05)

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Examples of polymeric food contact substances

Archroma FCN 1493 was approved by FDA in 2014. The company described the FCS as a copolymer of 2-(dimethylamino)ethyl methacrylate with 3,3,4,4,5,5,6,6,7,7,8,8,8-trideacfluorooctyl methacrylate, N-oxide, acetate in the manufacture of food-contact paper and paperboard. The commercial FCS is a liquid formulation containing approximately 18% of the polymer with 82% impurities and reagents.

Asahi FCN 1186 was approved by FDA in 2012. The company described the FCS as butanedioic acid, 2-methylene-, polymer with 2-hydroxyethyl, 2-methyl-2-propenoate, 2-methyl-2-propenoic acid and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl 2-methyl-2-propenoate, sodium salt. The commercial FCS is available in a 15% solution in water with 85% expected to be reagents and impurities.

List of all reagents monomers, solvents, etc.

SECTION B - MANUFACTURE

See Chemistry Recommendations, Sections II.A.4.a through d.

1. List all reagents monomers, solvents, catalyst systems, purification aids, etc. used to manufacture the FCS. Include chemical name, CAS Reg. No., and function in the manufacture of the FCS.

CHEMICAL NAME	CAS REG. NO.	FUNCTION	Is residual expected to remain in the final food contact material?
1H,1H,2H,2H-Perfluorooctyl methacrylate	2144-53-8	Monomer	☒ Yes ☐ No
2-Dimethylaminoethyl methacrylate	2867-47-2	Monomer	☒ Yes ☐ No
(b) (4)			☐ Yes ☒ No
			☐ Yes ☒ No
			☐ Yes ☒ No
			☐ Yes ☒ No
			☐ Yes ☒ No
			☒ Yes ☐ No

† If yes, include in Table II.B.3. If no, support this conclusion in the manufacturing process description (#2).

Is residual expected to remain in the final food contact material?

PFAS found in FDA-tested commercial papers

Table 3. Concentrations of FCS and PFCAs in commercial papers.

FCS	Conc. on paper (mg kg^{-1})	PFCA Conc. on paper (μg kg^{-1})						
		PFHxA	PFHpA	PFOA	PFNA	PFDA	PFUnDA	PFDoDA
PAA								
Mean	2250	717	1180	2220	1000	1430	624	824
RSD (%)		19.6	15.7	17.8	29.6	24.0	32.6	19.7
PAPs								
Mean	5530	870	1320	1360	941	1030	716	698
RSD (%)		19.7	10.9	11.1	14.6	11.4	17.3	19.3

Note: FCS, food contact substance; PAA, di-perfluoro-alkyloxy-amino-acid; PAPs, polyfluoroalkyl phosphate surfactants; PFCAs, perfluorocarboxylic acids; PFDoDA, perfluorododecanoic acid; PFHpA, perfluoroheptanoic acid; PFHxA, perfluorohexanoic acid; PFDA, perfluorodecanoic acid; PFNA, perfluorononanoic acid; PFOA, perfluorooctanoic acid; PFUnDA, perfluoroundecanoic acid.

Concentration of the FCS (mixture)

Concentration of individual PFAS within the FCS (mixture)

Xu Y et al. Food Additives & Contaminants: Part A, 2013. 30:899

PFAS MONOMER	SYNONYM	CASRN
3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl 2-methyl-2-propenoate	2-propenoic acid, 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl ester; Perfluorohexylethyl acrylate	17527-29-6
1, 1-difluoroethylene		75-38-7
Hexafluoropropene	Hexafluoropropylene	116-15-4
Tetrafluoroethylene		29118-24-9
Trifluoromethyl trifluorovinyl ether		1187-93-5
4-bromo-3,3,4,4-tetrafluoro-l-butene		18599-22-9
3,3,3-trifluoropropene		11514-82-5
3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluoro-1-octanol		647-42-7
1,1,2-trifluoro-2-(1,1,2,2,2-pentafluoroethoxy)ethane	Perfluoroethyl vinyl ether	10493-43-3
Pentafluoroiodoethane-tetrafluoroethylene telomer		Not found
1,1,1,2,2,3,3,4,4,5,5,6,6-tridecafluoro-6-iodohexane		355-43-1
Perfluoropolyether dicarboxylic acid		Not found
Perfluoropolyether diol		Not found

List of impurities

Part II - CHEMISTRY INFORMATION *(continued)*

SECTION B - MANUFACTURE *(continued)*

See Chemistry Recommendations, Sections II.A.4.a through d.

3. List impurities in the FCS including: the chemical names, CAS Reg. Nos., and typical and maximum residual levels (percent weight) in the FCS as it will be marketed. For FCSs that are polymers, include typical and maximum residual monomer concentrations. Provide supporting data including analytical methods and validation information.

CHEMICAL NAME	CAS REG. NO.	TYPICAL RESIDUAL (%)	MAXIMUM RESIDUAL (%)	Is residual expected to migrate from the final food contact material?
1H,1H,2H,2H-Perfluorooctyl methacrylate	2144-53-8	(b) (4)		☒ Yes ☐ No
2-Dimethylaminoethyl methacrylate	2867-47-2			☒ Yes ☐ No
(b) (4)		281 ppm	< 1600 ppm	☒ Yes ☐ No
		163 ppm	< 300 ppm	☒ Yes ☐ No
		334 ppm	< 400 ppm	☒ Yes ☐ No
		< 27 ppm	< 1600 ppm	☒ Yes ☐ No
		Not detected (< 0.2 ppm)	Not detected (< 0.2 ppm)	☐ Yes ☒ No
		2.2 ppm	< 10 ppm	☒ Yes ☐ No

Impurities in the FCS remaining in the coated paper

Table 2: Exposure Estimates for Impurities in the FCS

Impurity	Typical residual (dry basis, mg/kg)	Basis of Exposure	DC (ppb) FCN 518	EDI (ug/p/d) FCN 518	EDI (µg/p/d) FCN 487	EDI (ug/p/d) FCN 314
FCS oligomers		From Microwave use	0.2	0.6	1.5	1.5
C_6-C_{18} Fluorinated telomer iodides (FTI)	<184(total)	100% of residual	0.0048	0.014	0.69	<0.008
Allyl alcohol	1853	LOD of method	0.05	0.15	0.81	0.021
C_6-C_{18} Fluorinated iodohydrins (FI)	<61 (total)	100% of residual	0.0016	0.005	0.23	<0.003
Tetramethyl succinonitrile (TMSN) Breakdown product from AIBN	171		-	AIBN Regulated in § 176.170		
C_6-C_{18} Fluorinated epoxides (FE)	<61 (total)	100% of residual	0.0016	0.005	0.23	<0.003
C_6-C_{18} Fluorinated alcohols (FA)	2989	Migration results FCN 518	0.1	0.3	0.17	0.12
ECH	2.3	100% of residual	0.00006	0.0002	0.009	0.0001
2,3-Dichloro-1-propanol (2,3-DCP)	8.2	100% of residual	0.00021	0.0006	0.03	0.0003
1,3-Dichloro-1-propanol (1,3-DCP)	9484	Migration results from FCN 518	0.0088	0.03	0.012	0.004
3-Chloro-1,2-propanediol (3-CPD)	3355	Migration results from FCN 518	0.014	0.04	0.13	0.03
TETA	<84	Residual level from 518	0.0022	0.007	0.15	0.08
Perfluorooctanoic acid (PFOA)	57	100% of residual	0.0015	0.005	0.2	Not determined
Perfluoroacid congeners	114	2 x PFOA residual level	0.003	0.009	0.4	Not determined
Perfluorinated alkanes		Migration Results FCN 518	0.1	0.3	-	-
Sodium hypophosphite monohydrate				Essentially zero	Essentially zero	Essentially zero
Sodium metabisulfite				Essentially zero	Essentially zero	Essentially zero
Sodium sulfate				Essentially zero	Essentially zero	Essentially zero

Food contact substance (FCS) 2-propen-1-ol, reaction products with pentafluoroiodoethane-tetrafluoroethylene telomer, dehydroiodinated, reaction products with epichlorohydrin and triethylenetetramine (CAS Reg. No 464178-90-3). Food Contact Notification 518

DC: Dietary concentration
EDI: Estimated daily intake

List of impurities

Part II - CHEMISTRY INFORMATION *(continued)*

SECTION B - MANUFACTURE *(continued)*

See Chemistry Recommendations, Sections II.A.4.a through d.

3. List impurities in the FCS including: the chemical names, CAS Reg. Nos., and typical and maximum residual levels (percent weight) in the FCS as it will be marketed. For FCSs that are polymers, include typical and maximum residual monomer concentrations. Provide supporting data including analytical methods and validation information.

CHEMICAL NAME	CAS REG. NO.	TYPICAL RESIDUAL (%)	MAXIMUM RESIDUAL (%)	Is residual expected to migrate from the final food contact material?
1H,1H,2H,2H-Perfluorooctyl methacrylate	2144-53-8	(b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4)		☒ Yes ☐ No
2-Dimethylaminoethyl methacrylate	2867-47-2			☒ Yes ☐ No
(b) (4)		281 ppm	< 1600 ppm	☒ Yes ☐ No
		163 ppm	< 300 ppm	☒ Yes ☐ No
		334 ppm	< 400 ppm	☒ Yes ☐ No
		< 27 ppm	< 1600 ppm	☒ Yes ☐ No
		Not detected (< 0.2 ppm)	Not detected (< 0.2 ppm)	☐ Yes ☒ No
		2.2 ppm	< 10 ppm	☒ Yes ☐ No

Is residual expected to migrate from the final food contact material?

PFAS migration from food packaging

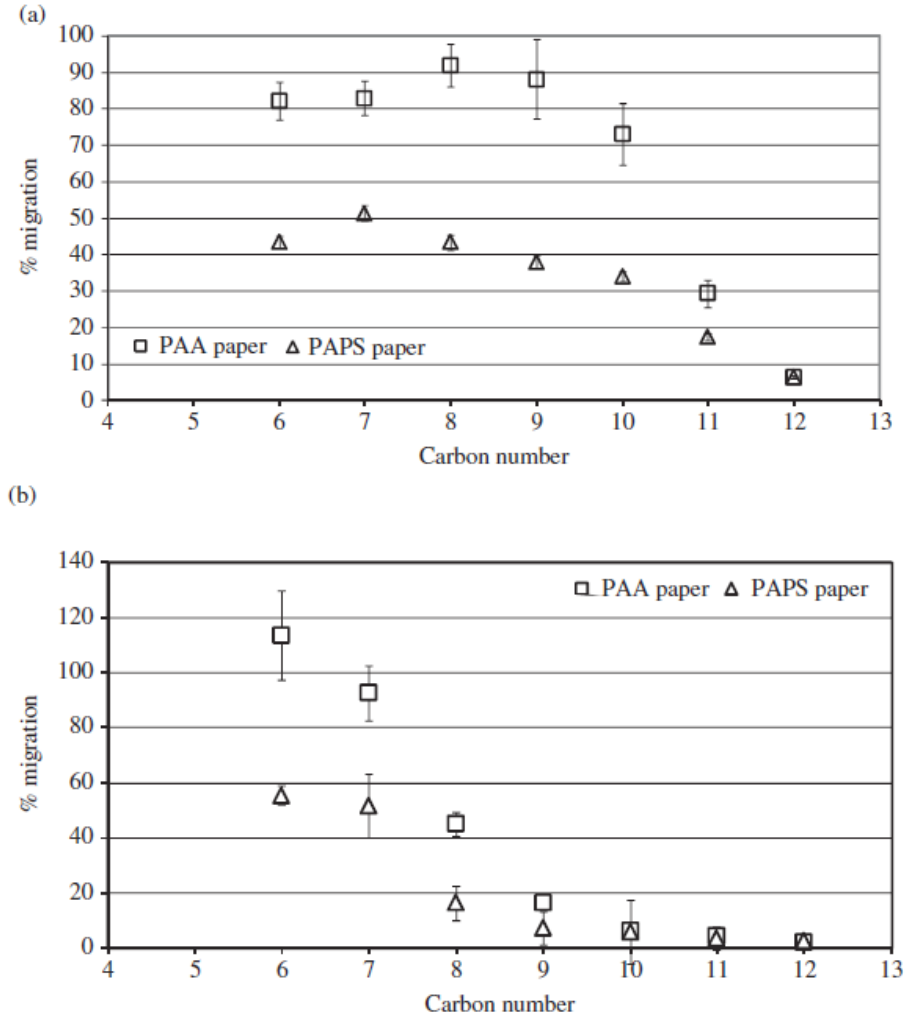

Figure 7. Migration of PFCAs from the PAA and PAPs papers into (a) 10% ethanol and (b) 3% acetic acid after 10 days at 40°C. PAA, di-perfluoro-alkyloxy-amino-acid; PAPs, polyfluoroalkyl phosphate surfactants; PFCA, perfluorocarboxylic acid.

Xu Y et al. Food Additives & Contaminants: Part A, 2013. 30:899

PFAS migration from commercial paper bowls

Table 2. Migration Efficiencies (%) of FTOHs and PFCAs from Paper Bowls to Food Simulants

chemicals	paper bowl (ng/cm^2)	water	10% ethanol	30% ethanol	50% ethanol	oil
6:2 FTOH	7.10 (0.56[a])	0.24 (0.017)	0.24 (0.012)	2.79 (0.18)	13.0 (1.46)	1.07 (0.16)
8:2 FTOH	96.4 (9.4)	0.008 (0.001)	0.006 (0)	0.79 (0.16)	9.47 (0.74)	2.28 (0.30)
10:2 FTOH	90.9 (9.4)	0.007 (0)	0.005 (0)	0.044 (0.003)	7.33 (0.30)	0.64 (0.02)
12:2 FTOH	63.2 (6.2)	0.006 (0)	0.004 (0)	0.011 (0.001)	2.84 (0.12)	0.16 (0.01)
14:2 FTOH	35.4 (4.1)	0.005 (0)	0.004 (0)	0.010 (0.001)	0.46 (0.06)	0.05 (0)
16:2 FTOH	6.36 (0.82)	0.004 (0)	0.004 (0)	0.009 (0)	0.06 (0.02)	0.04 (0)
PFBA	0.064 (0.006)	18.3 (2.03)	18.1 (2.39)	21.4 (2.09)	28.7 (2.76)	–[b]
PFPeA	0.075 (0.008)	11.6 (1.51)	9.56 (1.14)	15.1 (1.38)	30.1 (4.56)	–
PFHxA	0.39 (0.05)	5.81 (0.63)	5.72 (0.72)	11.5 (1.77)	32.5 (3.45)	–
PFHpA	0.21 (0.02)	2.08 (0.31)	2.33 (0.18)	5.98 (0.70)	31.7 (2.41)	–
PFOA	1.58 (0.18)	0.83 (0.06)	1.06 (0.07)	2.43 (0.13)	28.7 (2.59)	–
PFNA	0.26 (0.03)	0.24 (0.02)	0.38 (0.05)	1.20 (0.01)	26.7 (2.00)	–
PFDA	1.18 (0.12)	0.097 (0.010)	0.24 (0.026)	1.05 (0.08)	10.5 (0.48)	–
PFUnDA	0.21 (0.02)	0.021 (0.003)	0.083 (0.004)	0.29 (0.02)	9.81 (0.23)	–
PFDoDA	1.00 (0.10)	0.005 (0.001)	0.034 (0.005)	0.20 (0.02)	4.76 (0.08)	–
PFTriDA	0.084 (0.010)	–	–	0.17 (0.01)	1.74 (0.08)	–
PFTeDA	0.63 (0.06)	–	–	0.056 (0.004)	0.71 (0.06)	–
PFPeDA	0.04 (0.01)	–	–	0.010 (0.001)	0.41 (0.03)	–
PFHxDA	0.17 (0.02)	–	–	–	0.26 (0.03)	–
PFHpDA	0.012 (0.002)	–	–	–	0.28 (0.03)	–
PFODA	0.063 (0.011)	–	–	–	0.19 (0.01)	–

[a]Standard deviation. [b]Migration efficiencies could not be calculated because the chemical was not detected in the food stimulants.

Yuan G et al. Env Sci and Tech, 2016. 50:942

Exposure estimates

SECTION G - ESTIMATED DAILY INTAKE (EDI) *(continued)*
See Chemistry Recommendations, Sections II.E and Appendix IV

3. SUMMARY OF THE CHEMISTRY INFORMATION

Summarize the values for weight-average migration (<M>), dietary concentration (DC), and EDI for the FCS and any migrants, including oligomeric species and breakdown products, as appropriate. Provide cumulative EDI (CEDI) to include this use, where appropriate.

CHEMICAL NAME	CAS REG. NO.	<M> (ppb)	DC (ppb)	EDI (mg/person/day)	CDC (ppb)
Low molecular weight oligomers (<2000 daltons) of FCS	1440528-04-0	3.48 ppb	0.174 ppb	0.52 µg/p/d	0.174 ppb
(b) (4)	(b) (4)	31.1 ppb	1.56 ppb	4.67 µg/p/d	
1H,1H,2H,2H-Perfluorooctyl methacrylate	2144-53-8	43 ppb	2.15 ppb	6.45 µg/p/d	
2-Dimethylaminoethyl methacrylate	2867-47-2	7.9 ppb	0.40 ppb	1.2 µg/p/d	
(b) (4)		43 ppb	2.15 ppb	6.45 µg/p/d	
		5.8 ppb	0.29 ppb	0.87 µg/p/d	
		0.029 ppb	0.0015 ppb	0.0044 µg/p/d	
		1.4 ppb	0.070 ppb	0.21 µg/p/d	

DC: Dietary concentration

EDI: Estimated daily intake

Daikin FCN 820: Exposure estimates of impurities

Table 1. Tentative Exposure Estimates

	Residual level	DC (ppb)	EDI (µg/p/d)
FCS (oligomers below 1600 Daltons)	1.7 wt-%	0.5	1.5
13FA monomer	50 µg/g FCS	0.002	0.006
Polyethylene glycol monoacrylate	133 µg/g FCS	0.004	0.01
(b) (4)	248 µg/g FCS	0.007	0.02
	1000 µg/g FCS	0.03	0.09
	50 µg/g FCS	0.002	0.006
	20 µg/g FCS	0.0006	0.002
	5000 µg/g FCS	0.2	0.6
	0.009 µg/g FCS	$3x10^{-07}$	$9x10^{-07}$
	0.005 µg/g FCS	$2x10^{-07}$	$6x10^{-07}$
		Regulated	176.170
		Regulated	176.170

FDA review called the exposure estimates “vanishingly small”

Daikin FCN 820 Toxicology Review

- Main focus: genotoxicity of PFAS monomer and impurities
- Cursory review of the data submitted
- Review the literature for additional information
- **Refers to Chemistry's exposure assessment**

Daikin America, Inc. has notified for the use of 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl ester, polymer with alpha-(1-oxo-2-propen-1-yl)-omega-hydroxypoly(oxy-1,2-ethanediyl) as a grease-proofing additive in the manufacture of food contact paper and paperboard. The FCS will be used at no more than 0.2 wt-% of finished paper or paperboard in contact with all food types under conditions of use A-H, as described in Chemistry's final memorandum. Toxicology has no questions regarding the safety of proposed use of the FCS, based on the exposure estimates and the toxicological evaluation of the available data as indicated above.

What have we learned from the FOIA request?

Some shortcomings in FDA's reasoning

- Safety is driven by exposure estimates
- If PFAS monomer is not genotoxic, then
  - Oligomers are assumed not genotoxic
  - Dietary concentration of <50 ppb of PFAS monomer or low molecular weight oligomer is **assumed of no safety concern**
  - 50 ppb in the diet corresponds to 150 µg PFAS/person-day
- Dietary concentration estimates are for individual food contact substances and its impurities
- Toxicity tests other than genotoxicity assays are rare for PFAS monomers and oligomers

More shortcomings in FDA's reasoning

- Assumption: short-chain PFAS (≤ C6) don't bioaccumulate
- There aren't estimates of collective, cumulative exposure through the diet that includes other PFAS (e.g., environmental contamination)
- Not fulfilling its responsibility to assess PFAS as a class of chemicals
  - By law, it must assess the cumulative effects of chemically- and pharmacologically-related substances in the diet – Class approach

PFAS FCS MONOMERS APPROVED	PFAS FDA TESTED IN FOOD
3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl 2-methyl-2-propenoate	Perfluoro-n-butanoic acid
1, 1-difluoroethylene	Perfluoro-n-pentanoic acid
Hexafluoropropene	Perfluoro-n-hexanoic acid
Tetrafluoroethylene	Perfluoro-n-heptanoic acid
Trifluoromethyl trifluorovinyl ether	Perfluoro-n-octanoic acid
4-bromo-3,3,4,4-tetrafluoro-l-butene	Perfluoro-n-nonanoic acid
3,3,3-trifluoropropene	Perfluoro-n-decanoic acid
3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluoro-1-octanol	K Perfluoro-1-butanesulfonate
1,1,2-trifluoro-2-(1,1,2,2,2-pentafluoroethoxy)ethane	Na Perfluoro-1-pentanesulfonate
Pentafluoroiodoethane-tetrafluoroethylene telomer	Na Perfluoro-1-hexanesulfonate
1,1,1,2,2,3,3,4,4,5,5,6,6-tridecafluoro-6-iodohexane	Na Perfluoro-1-heptanesulfonate
Perfluoropolyether dicarboxylic acid	Na Perfluoro-1-octanesulfonate
Perfluoropolyether diol	Na Dodecafluoro-3H-4,8-dioxanonanoate
	Tetrafluoro-2-(heptafluoropropoxy)propanoic acid
	K 9-Chlorohexadecafluoro-3-oxanonane-1-sulfonate
	K 11-Chloroeicosafluoro-3-oxaundecane-1-sulfonate

Summary

- Low exposures are of no concern
- Estimates of cumulative exposures to PFAS in the diet are lacking
- Toxicity testing is lacking
- Absorption, distribution, metabolism, excretion (ADME) and bioaccumulation data are lacking
- Rationale for some assumptions are unclear
- Analytical methods to measure PFAS monomers at low levels lacking
- FDA continue to approve PFAS uses in contact with food

Thank you!

drmvma@gmail.com