Memorandum

Date: December 1, 2009

From: Division of Food Contact Notifications, HFS-275
Chemistry Team 1
Sharon Elyashiv-Barad, Ph.D.

Subject: **FCN 933:** Keller and Heckman on behalf of Daikin America (Daikin). Use of 2-propenoic acid, 2-methyl-, polymer with 2-hydroxyethyl 2-methyl-2-propenoate, α-(l-oxo-2-propen-l-yl)-ω-hydroxypoly(oxy-l,2-ethanediyl) and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl 2-propenoate, sodium salt as a grease-proofing agent in food-contact paper and paperboard. Submission received September 1, 2009.

To: Division of Food Contact Notifications, HFS-275
Regulatory Team 1
Attention: K. Randolph, D.V.M., M.P.H.

Keller and Heckman on behalf of Daikin America (Daikin) submitted this food contact notification (FCN) for use of 2-propenoic acid, 2-methyl-, polymer with 2-hydroxyethyl 2-methyl-2-propenoate, α-(l-oxo-2-propen-l-yl)-ω-hydroxypoly(oxy-l,2-ethanediyl) and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl 2-propenoate, sodium salt as a grease-proofing agent for food-contact paper and paperboard employed at the size press or wet-end in contact with all foods under Conditions of Use A through H and J (including microwave susceptor applications). The food-contact substance (FCS) will be used at a level not to exceed 0.8 weight-percent (wt.-%) of the finished food-contact paper and paperboard. (b) (4)

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Background

The FCS is not currently regulated under 21 CFR 170-199 nor is it the subject of any effective FCNs. There are numerous perfluoro-based grease-proofing agents regulated or authorized for use in contact with food. The FCSs identified in Daikin's FCNs 820[1] (effective July 31, 2008), 827[2] (effective September 9, 2008) and 888[3] (effective June 18, 2009) are prepared from the same or similar perfluoroalkylethylacrylate monomers:

1. FCN 820- 2-propenoic acid, 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl ester, polymer with α-(1-oxo-2-propen-1-yl)- ω -hydroxypoly(oxy-1,2-ethanediyl) as an oil and grease-proofing agent for food-contact paper and paperboard employed at the size press at levels not to exceed (NTE) 0.2 wt.-% of the finished food-contact paper.
2. FCN 827- 2-propenoic acid, 2-hydroxyethyl ester, polymer with α-(l-oxo-2-propen-l-yl)-ω-hydroxypoly(oxy-l,2-ethanediyl), α-(1-oxo-2-propen-l-yl)-ω-[(l-oxo-2-propen-l-yl)oxy]-poly

[1] Chemistry memorandum for FCN 820 dated July 1, 2008 (K. Arvidson to M. Hepp).
[2] Chemistry memorandum for FCN 827 dated July 31, 2008 (K. Arvidson to P. Honigfort).
[3] Memorandum to the File for FCN 888 dated May 27, 2009 (P. Honigfort).

(oxy-l,2-ethanediyl) and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl 2-propenoate as a grease-proofing agent for food-contact paper and paperboard employed at the size press, at levels NTE 0.4 wt.-%, under Conditions of Use A through H.

3. FCN 888- expanded FCN 827 to include use in microwave susceptor applications (Condition of Use J).

FCNs 820 and 827 were initially submitted for use of the FCS in food-contact paper and paperboard employed at the size press or wet-end. (b) (4) (b) (4)

Chemistry information is contained in FDA Form 3480 and Attachments 2 (IR spectrum), 3 (certificates of analysis for reagents), 4 (manufacturing diagram), 5 (test results for potential impurities in the FCS), 6 (test results for residual (b) (4), 7 (test results for residual (b) (4) 8 (test results for residual (b) (4) (b) (4), 9 (analysis of volatile compounds released from fluoropolymer heated in a microwave oven), 10 (molecular weight distribution. MWD, data), 11 (technical data sheet), 12 (thermogravimetric analysis, TGA, of the FCS), 13 (exposure calculations). The suggested language for the FCN is provided in Attachment 21.

Identity

Information on the identity of the FCS is contained in Form 3480, Sections II.A and II.C, and Attachments 2, 3 and 10.

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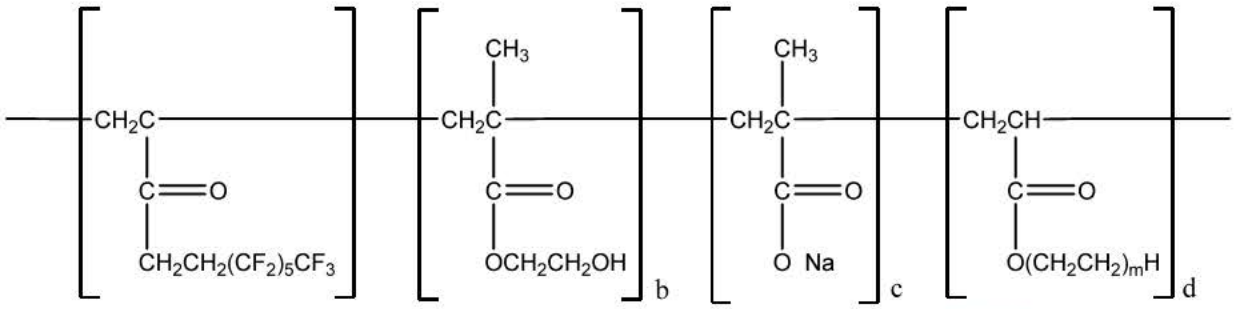
CAS name:	2-propenoic acid, 2-methyl-, polymer with 2-hydroxyethyl 2-methyl-2-propenoate, α-(l-oxo-2-propen-l-yl)-ω-hydroxypoly(oxy-l,2-ethanediyl) and 3,3,4,4,5,5,6,6,7,7,8,8,8 -tridecafluorooctyl 2-propenoate, sodium salt
CAS Reg. No.:	1158951-86-0
Other names:	Copolymer of C-6 fluoroacrylate, 2-hydroxyethyl methacrylate, polyethylene glycol monoacrylate and methacrylic acid
Trade names:	(b) (4)
Structure:	The structure of the FCS, as taken from Section II.A.5, is shown below.

P fluo oh xyl thyl c yl t (13F)

2-Hyd oxy thyl th c yl t (HEM)

M th c ylic cid (MM)

Poly thyl n lycol ono c yl t (PEGM)



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Monomer mole ratios:

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FCS specifications: In Section II.C, the notifier provided specifications for the FCS (solids content, pH, specific gravity and % solvent in the FCS). Attachment 3 contains the method used for determining the amount of solvent in the product.

FCS Analysis: Attachment 2 contains an IR spectrum that supports the structure of the FCS.

Molecular weight distribution (MWD)

Attachment 10 contains gel permeation chromatography (GPC) data for four batches (dry) of the commercial product.

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We would like to note that for the FCS, Toxicology typically requests that we calculate exposure to the fraction of oligomers <1000 Daltons. In reviewing the chemistry memoranda for various FCNs for other perfluorinated grease-proofing agents we have previously provided toxicology with exposure values based on the MW fractions with <1000, 2200 and 2500 D. In addition, there have been a number of discussions regarding the relative size of these perfluorinated oligomers versus their hydrocarbon analogs and how that might affect absorption in the gut. While chemistry cannot speak to the bioavailability of these perfluorinated species compared to their hydrocarbon analogs, we can provide some insight into their relative size. Using Chem3D Ultra5 version 6.0, we have determined the solvent-excluded volume and MW of a representative repeat unit in the FCS and the analogous hydrocarbon version of that same repeat unit.

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We have no questions on the identity of the FCS.

Manufacture

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[4] Chemistry memorandum for FCN 885 dated May 14, 2009 (S. Elyashiv-Barad to P. Honigfort). FCN 885 was submitted by DuPont Chemical Solutions Enterprise for use of a perfluoroalkylethyl methacrylate copolymer as an oil and grease resistant treatment for paper and paperboard intended for use under Conditions of Use B through H and J (microwave susceptor applications).

Table 1: Materials used to manufacture the FCS

Reagants	CAS Reg. #	Function	Amount used (kg)
Perfluorohexylethyl acrylate (13FA)	17527-29-6	Monomer	(b) (4)
2-Hydroxyethyl methacrylate (HEMA)	868-77-9	Monomer	(b) (4)
Polyethylene glycol monoacrylate (PEGMA or AE200)	26403-58-7	Monomer	(b) (4)
Methacrylic acid (MMA)	79-41-4	Monomer	(b) (4)
(b) (4)			

(b) (4)

Impurities

(b) (4)

Attachment 5: Determination of residual polymerization aids, solvents and impurities in the "dry" commercial product by GC-MS

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The typical residual levels of impurities in the FCS on a dry basis, as taken from Section II.B.3, are summarized in Table 2, below.

Table 2: Summary of impurities in the "dry" commercial product

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We have no questions on the manufacture of the FCS or impurities in the FCS.

Intended Use and Technical Effect

Information on the intended use and technical effect of the FCS is contained in Form 3480, Section

II.D., and Attachment 11

The FCS is intended to be used as a grease-proofing agent for food-contact paper and paperboard employed either prior to the sheet forming operation (aka wet-end) or at the size press. The FCS is used at a level not to exceed 0.8 wt.-% dry weight of the food-contact paper and paperboard (b) (4) (b) (4) The FCS may contact all foods under Conditions of Use A through H and J (microwave heat-susceptor packaging).

The notifier provided a technical data sheet for the commercial product in Attachment 11. The suggested language for the FCS is contained in Attachment 21. We concur with this language.

We have no questions on the intended use and technical effect of the FCS.

Stability

Information on the stability of the FCS is contained in Sections II.E, II.F, and Attachments 9 and 12. The notifier states that the FCS is stable under the proposed use and notes that the thermogravimetric analysis (TGA) curve submitted in Attachment 12 supports the stability of the FCS.

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We have no questions on the stability of the FCS under the proposed conditions of use.

Consumer Exposure

The notifier did not carry out migration studies to support of the proposed use. Rather, in Form 3480, Section II.F.2, the notifier calculated migration of FCS oligomers and impurities separately for Conditions of Use A through H and J based on the assumption of 100% migration to food, the residual levels of impurities (from Section II.B.3), volatiles (from Section F.1.c) or the quantity of oligomers (b) (4) combined with the maximum requested application rate of the FCS at the size press (0.8 wt.-% of dry paper).

For Conditions of Use A through H, the notifier used FDA's standard assumption for the average basis weight of all food-contact paper and paperboard (0.05 g paper/in^2), the assumption that 10 g of food contacts 1 in^2 of food packaging, and a consumption factor (CF) of 0.05 for specialty paper. For Condition of Use J, the notifier used FDA's standard assumption for the average basis weight of all food-contact paper and paperboard (0.023 g paper/in^2), the assumption that 5 g of food contacts 1 in^2 of microwave susceptor packaging, and the CF for microwave susceptor packaging (0.001). Exposure estimates were provided in Attachment 13, and are summarized in Tables 4 and 5, below. We note that the notifier did not estimate exposure to non-volatile migrants under Conditions of Use J. As can be seen in Table 4, exposures from Condition of Use J were negligible in comparison. As such, we concur with the notifier's approach and exposure estimates.

A sample exposure calculation for LMWOs is provided below.

LMWOs: Condition of Use A-H

$$< M >_{Oligomers,\,A-H} = \frac{0.004\ g\ LMWO}{100\ g\ FCS}\ x\ \frac{0.8\ g\ FCS}{100\ g\ paper}\ x\ \frac{0.05\ g\ paper}{in^2}\ x\ \frac{in^2}{10\ g\ food} = 1.6\ \mu g\ LMWO / kg\ food$$

$$DC_{Oligomers,\,A-H} = 0.05\ x\ 1.6\ \mu g\ LMWO / kg\ food = 0.08\ \mu g\ LMWO / kg\ food = 0.08\ ppb$$

LMWOs: Condition of Use J

$$< M >_{Oligomers,\,J} = \frac{0.004\ g\ LMWO}{100\ g\ FCS}\ x\ \frac{0.8\ g\ FCS}{100\ g\ paper}\ x\ \frac{0.023\ g\ paper}{in^2}\ x\ \frac{in^2}{5\ g\ food} = 1.5\ \mu g\ LMWO / kg\ food$$

$$DC_{Oligomers,\,J} = 0.001\ x\ 1.5\ \mu g\ LMWO / kg\ food = 1.5\ ng\ LMWO / kg\ food = 1.5\ pptr$$

LMWOs: Total exposure

$$DC_{Oligomers,\,total} = DC_{Oligomers,\,A-H} + DC_{Oligomers,\,J} = 0.8\ ppb + 1.5\ pptr = 0.8\ ppb$$

Table 4: Exposure estimates to non-volatile migrants (Conditions of Use A-H and J)

(b) (4)

Table 5: Exposure estimates to volatile migrants

(b) (4)

(b) (4)

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We have no questions on consumer exposure.

Notification Language

The acknowledgment letter, signed off by Chemistry on September 30, 2009, is appropriate as written.

Conclusion

We have no questions on this FCN.

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(b) (5)

Table 5: Exposure estimates to volatile migrants

(b) (4)

[redacted]

(b) (4)

[redacted]

We have no questions on consumer exposure.

Notification Language

The acknowledgment letter, signed off by Chemistry on September 30, 2009, is appropriate as written.

Conclusion

We have no questions on this FCN.

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(b) (5)

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