EDF submitted a Freedom of Information Act (FOIA) request to the Food and Drug Administration (FDA) in October 2017 seeking documents related to 31 Food Contact Substance Notifications that FDA approved for 19 unique per- and poly-fluorinated alkyl substances (PFAS) from six companies between 2002 and 2016. To minimize delays and the burden of FDA, EDF agreed in early 2018 to narrow the request to those documents generated by the agency. Those documents generally consist of evaluations of the: 1) chemistry and exposure; 2) toxicology; and 3) environmental impacts.

For each of the 31 FCNs below, we provide the FDA's staff review memo of the environmental impact of the chemicals followed by relevant portions of the application submitted by the company to that the agency used to inform its decisions. The links for the FCN go to FDA's Inventory of Effective Food Contact Substance (FCS) Notifications webpage where the agency describes the chemicals and its approved uses.

For more information, contact Tom Neltner at 202-572-3263 or tneltner@edf.org.

Memorandum

Date: November 19, 2014

From: Biologist, Regulatory Team 2, Division of Biotechnology and GRAS Notice Review (HFS-255)

Subject: FCN - 2-Propenoic acid, 2-methyl-, 2-(dimethylamino)ethyl ester, polymer with 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl 2-methyl-2-propenoate, N-oxides, acetates (CAS Reg. No. 1440528-04-0) for use in the manufacture of paper and paperboard and will either be added to the pulp slurry at the wet-end of paper production or applied to the paper surface by size-press impregnation or coating. The FCS will be used at levels up to 0.26 mg polymer solids per square inch of paper and paperboard surface area. The finished paper and paperboard may be used in contact with all food types under FDA's Condition of Use B through H

Notifier: Archroma Management GmBH

To: Paul Honigfort, Ph.D., Division of Food Contact Notifications (HFS-275)

Through: Suzanne Hill, Environmental Team Lead, Office of Food Additive Safety (HFS-255)____

Suzanne Hill -A

Digitally signed by Suzanne Hill -A
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Suzanne Hill -A, 0.9.2342.19200300.100.1.1=2001511836
Date: 2014.11.19 13:39:33 -05'00'

We have reviewed the claim of categorical exclusion for the above referenced notification and have concluded that the categorical exclusion is warranted. As a part of our review, we have confirmed that that a) the FCS is stable and will remain with the paper (i.e. in order to achieve its technical effect), b) the FCS will be present at less than 5% by weight of the dry paper, and c) that non-substantive components make up significantly less than 5% of the FCS.

The claim of categorical exclusion cites the section, 21 CFR 25.32(i), under which categorical exclusion is warranted, states compliance with the categorical exclusion criteria, and states that no extraordinary circumstances exist that require the submission of an environmental assessment.

Please let us know if there is any change in the identity or use of the food-contact substance.

Talia A. Lindheimer -S

Digitally signed by Talia A. Lindheimer -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2001000001, cn=Talia A. Lindheimer -S
Date: 2014.11.19 12:56:52 -05'00'

Talia A. Lindheimer

cc: HFS-255 Lindheimer

File: FCN No. 1493

Part IV - ENVIRONMENTAL INFORMATION (21 CFR Part 25)

All FCN submissions must contain either a claim of categorical exclusion under 21 CFR 25.32 or an environmental assessment (EA) under 21 CFR 25.40.

A - CLAIM OF CATEGORICAL EXCLUSION

1. Cite the specific section(s) of the CFR under which the categorical exclusion is claimed:

☒ **21 CFR 25.32 (i)**

a. Is the FCS a component of a coating? ☐ Yes ☒ No

b. If no, the % of the FCS in the finished food-contact article is < 5% and

c. The % of the total market volume that remains with the food-contact articles is > 95%

☐ **21 CFR 25.32 (j)**

Is the FCS a component of a:

a. Repeat-use article? ☐ Yes ☐ No

b. Permanent or semi-permanent food-contact surface? ☐ Yes ☐ No

☐ **21 CFR 25.32 (k)**

☐ **21 CFR 25.32 (q)**

a. Is current FIFRA label attached? ☐ Yes ☐ No

b. Is the requested use essentially the same as the label? ☐ Yes ☐ No

If current FIFRA label has limitation on food-contact uses, provide a draft copy of a revised label you intend to submit to EPA to include food-contact uses.

☐ **21 CFR 25.32 (r)**

2. Does your proposed food-contact use comply with the categorical exclusion criteria? ☐ Yes ☒ No

If no, go to section B below.

3. To the best of your knowledge, are there any extraordinary circumstances that would require your submission of an EA? (see 21 CFR 25.21)

If yes, go to section B below ☐ Yes ☒ No

B - ENVIRONMENTAL ASSESSMENT

See Environmental Recommendations

1. If an EA is required, state that an EA has been prepared under 21 CFR 25.40, and is attached.

2. Environmental assessments are public documents and should not contain confidential information. Such information should be included in a separate section of the FCN, labeled confidential and summarized to the extent possible in the EA.

We note that FDA has previously agreed with our conclusion regarding the applicability of 21 C.F.R. § 25.32(i) where a grease-resistant agent is employed at the wet-end of the paper making process. *See, e.g.,* May 20, 2006 letter to FDA regarding FCN No. 628, explaining that Clariant, Archroma's predecessor company, has concluded that > 95% of the polymer remains with the paper when used in the wet-end because the functionality of the FCS is dependent on it remaining in the finished paper, and Kit Test results show the functionality of the polymer in paper; *see also* FDA Memorandum of Conference by Dr. Layla Batarseh re prenotification consultation (PNC) 435 and Part II. Section D.3 above for Kit Test results demonstration the functionality of the FCS when applied at the wet-end of the paper making process.

Part V - CERTIFICATION

The accuracy of the statements you make in this notice should reflect your best prediction of the anticipated facts regarding the chemical substance described herein. Any knowing and willful misinterpretation is subject to criminal penalty pursuant to 18 U.S.C. 1001.

The notifying party certifies that the information provided herein is accurate and complete to the best of his/her knowledge

SIGNATURE OF AUTHORIZED OFFICIAL OR AGENT

[redacted]

TITLE	DATE
Counsel for Archroma Management GmbH	8/29/2014

Memorandum

Date: March 20, 2006

From: Environmental Toxicologist, Environmental Review Group (ERG)
Division of Chemistry Research and Environmental Review (HFS-246)

Subject: FCN No. 599 – Copolymer of polyfluorooctyl methacrylate, 2-N,N-diethylaminoethylmethacrylate, 2- hydroxyethylmethacrylate, and 2,2'-ethylenedioxydiethyldimethacrylate

AD

AGC Chemicals America Inc.
229 East 22nd St.
Bayonne, NJ 07002-5002

To: Division of Food Contact Notifications (HFS-275)
Attention: Paul Honigfort, Ph.D.
Through: Layla Batarseh, Ph.D. LB

We have reviewed the claims of categorical exclusion for the above referenced notification and have concluded that categorical exclusion is warranted. The FCS is intended for use as an oil, grease, and water resistant treatment for paper and paperboard employed either prior to the sheet forming operation or at the size press. The notifier has proven that greater than 95% of the total market volume of the FCS will be incorporated into the paper and paperboard and will remain with the finished food packaging through use and disposal. The claim of categorical exclusion cites the section under which categorical exclusion is warranted, 21 *CFR* 25.32 (i), states compliance with the categorical exclusion criteria, and states that no extraordinary circumstances exist that require the submission of an environmental assessment.

Please let us know if there is any change in the identity or use of the food contact substance.

/s/
/s/

Annette M. McCarthy, Ph.D.

[redacted]

003122

Part IV — ENVIRONMENTAL IMPACT OF FOOD CONTACT SUBSTANCE (21 CFR part 25)

All FCN submissions must contain either a claim of categorical exclusion under 21 CFR 25.32 or an environmental assessment (EA) under 21 CFR 25.40.

A - CLAIM OF CATEGORICAL EXCLUSION

1. Cite the specific section of the CFR under which the categorical exclusion is claimed (21 CFR 25.32 (i), (j), (k), (q), or (r) **21 C.F.R. § 25.32 (l)**

2. Does your proposed food-contact use comply with the categorical exclusion criteria? ☒ Yes ☐ No

3. To the best of your knowledge are there any extraordinary circumstances that would require your submission of an EA? ☐ Yes ☒ No

B - ENVIRONMENTAL ASSESSMENT

If an EA is required, state that an EA has been prepared under 21 CFR 25.40, and is attached.

Although the categorical exclusion at 21 CFR § 25.32(l) should apply to the FCS, an EA has been prepared in the alternative. See Attachment 11.

Part V — CERTIFICATION

The accuracy of the statements you make in this notice should reflect your best prediction of the anticipated facts regarding the chemical substance described herein. Any knowing and willful misinterpretation is subject to criminal penalty pursuant to 18 U.S.C. 1001.

The notifying party certifies that the information provided herein is accurate and complete to the best of his/her knowledge.

Signature of Authorized Official or Agent /s/ [redacted]

Title Attorney / Agent for NGCCIA 23

Date 12/30/05

Memorandum

Date: April 17, 2006

AD

From: Environmental Toxicologist, Environmental Review Group (ERG)
Division of Chemistry Research and Environmental Review (HFS-246)

Subject: FCN No. 604 – Copolymer of polyfluorooctyl methacrylate, 2-N,N-diethylaminoethylmethacrylate, 2- hydroxyethylmethacrylate, and 2,2'-ethylenedioxydiethyldimethacrylate

AGC Chemicals America Inc.
229 East 22nd St.
Bayonne, NJ 07002-5002

To: Division of Food Contact Notifications (HFS-275)
Attention: Ken McAdams
Through: Layla Batarseh, Ph.D. LB

We have reviewed the claims of categorical exclusion for the above referenced notification and have concluded that categorical exclusion is warranted. The FCS is intended for use as an oil, grease, and water resistant treatment for paper and paperboard employed either prior to the sheet forming operation or at the size press. The finished food packaging will be used in contact with all types of food under microwave susceptor conditions. The notifier has proven that greater than 95% of the total market volume of the FCS will be incorporated into the paper and paperboard and will remain with the finished food packaging through use and disposal.

The claim of categorical exclusion cites the section under which categorical exclusion is warranted, 21 *CFR* 25.32 (i), states compliance with the categorical exclusion criteria, and states that no extraordinary circumstances exist that require the submission of an environmental assessment.

Please let us know if there is any change in the identity or use of the food contact substance.

/s/ [redacted]

Annette M. McCarthy, Ph.D.

[redacted]

000270

Part IV — ENVIRONMENTAL IMPACT OF FOOD CONTACT SUBSTANCE (21 CFR part 25)

All FCN submissions must contain either a claim of categorical exclusion under 21 CFR 25.32 or an environmental assessment (EA) under 21 CFR 25.40.

A - CLAIM OF CATEGORICAL EXCLUSION

1. Cite the specific section of the CFR under which the categorical exclusion is claimed (21 CFR 25.32 (i), (j), (k), (q), or (r) **21 C.F.R. § 25.32 (i)**

2. Does your proposed food-contact use comply with the categorical exclusion criteria? ☒ Yes ☐ No

3. To the best of your knowledge are there any extraordinary circumstances that would require your submission of an EA? ☐ Yes ☒ No

B - ENVIRONMENTAL ASSESSMENT

If an EA is required, state that an EA has been prepared under 21 CFR 25.40, and is attached.

Although the categorical exclusion at 21 CFR § 25.32(i) should apply to the FCS, an EA has been prepared in the alternative. See Attachment 3 to this Notification.

Part V — CERTIFICATION

The accuracy of the statements you make in this notice should reflect your best prediction of the anticipated facts regarding the chemical substance described herein. Any knowing and willful misinterpretation is subject to criminal penalty pursuant to 18 U.S.C. 1001.

The notifying party certifies that the information provided herein is accurate and complete to the best of his/her knowledge.

000025

Signature of Authorized Official or Agent

/s/ [redacted]

23 January 2006

Title: **Attorney/Agent for AGCCA**

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: June 18, 2012

From: Senior Science and Policy Staff (HFS-205)

Subject: FCN No. 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

AGC Chemicals Americas, Inc. ("AGCCA")
c/o Crowell & Moring LLP
1001 Pennsylvania Avenue, NW,
Washington, DC 20004

To: Division of Food Contact Notifications (HFS-275)
Attention: Kenneth McAdams, MS
Through: Annette McCarthy, Ph.D., Senior Science and Policy Staff _____

The FCS is intended to be used as oil, grease and water repellent for food-contact paper and paperboard articles in contact with all types of food, under conditions of use B through H at a level of 1.2% by weight. Proposed trade name of the 15% copolymer aqueous solution is (b) (4)

We have reviewed the claim of categorical exclusion under 21 CFR 25.32(i) and have concluded that the claim is warranted. The notifier cited the sections, 21 CFR 25.32(i) under which categorical exclusion is warranted, stated compliance with the categorical exclusion criteria, and stated that no extraordinary circumstances exist that require submission of an environmental assessment.

Please let us know if there is any change in the identity or use of the food-contact substance.

Berhane G. Girmay, PhD, PMP

cc:

HFS-205 Girmay
File: FCN No. 1186

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: June 18, 2012

From: Senior Science and Policy Staff (HFS-205)

Subject: FCN No. 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

AGC Chemicals Americas, Inc.
("AGCCA")
c/o Crowell & Moring LLP
1001 Pennsylvania Avenue, NW,
Washington, DC 20004

To: Division of Food Contact Notifications (HFS-275)
Attention: Kenneth McAdams, MS
Through: Annette McCarthy, Ph.D., Senior Science and Policy Staff AM'

The FCS is intended to be used as oil, grease and water repellent for food-contact paper and paperboard articles in contact with all types of food, under conditions of use B through H at a level of 1.2% by weight. Proposed trade name of the 15% copolymer aqueous solution is (b) (4) .

We have reviewed the claim of categorical exclusion under 21 CFR 25.32(i) and have concluded that the claim is warranted. The notifier cited the sections, 21 CFR 25.32(i) under which categorical exclusion is warranted, stated compliance with the categorical exclusion criteria, and stated that no extraordinary circumstances exist that require submission of an environmental assessment.

Please let us know if there is any change in the identity or use of the food-contact substance.

Berhane G. Girmay, PhD, PMP

cc:

HFS-205 Girmay
File: FCN No. 1186

ENVIRONMENTAL REVIEW

This memorandum may contain confidential or proprietary business information. It should be redacted before release to the public in response to a FOIA request.

FCN 1186

Phase I meeting: May 9, 2012

Environmental Reviewer: Berhane Girmay, PhD

Notifier: AGC Chemicals Americas, Inc. ("AGCCA")

Proposed Food Contact Substance (FCS): 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 as an oil, grease and water repellent for food-contact paper and paperboard articles. The proposed trade name of the FCS (15% copolymer aqueous solution) is AG-E080.

Intended Use:
The FCS will be used as an additive in paper and paperboard that may come into contact with all types of food, under conditions of use B-H. The copolymer is intended to impart oil, grease, and water resistance to treated articles at an intended use level of 1.2% by weight.

Related Submissions: The FCS is not currently regulated nor is there an effective FCN for the use of this material in contact with food. The notifier resubmitted environmental study data from FCN (b) [1]," which is chemically similar to (b) (4).

Environmental Submissions: Categorical exclusion statement and environmental assessment dated April 3, 2012 (Attachment 13). The notifier also provides confidential environmental information as a supplement to the public EA for environmental consideration.

The following documents were included under Exhibit 1 (Attachment 13):

1. (b) (4)
2. (b) (4)
3. (b) (4)

[1] 2-Propenoic acid, 2-methyl-, 1,2-ethanediylbis(oxy-2,l-ethanediyl) ester, polymer with 2-(diethylamino) ethyl 2-methyl propenoate, 2-hydroxyethyl-2-methyl-2-propenoatea,n d 3,3,4,4,5,5,6,6,7,7,8,8,8-trid~uorooctyl-2-methyl-2-prownoate (CAS Reg. No. 863408-19-9)

4. (b) (4)
5.
6.
7.
8.

Categorical Exclusion under 21 CFR 25.32(i):

The notifier presented study evidence that greater than 95% of the FCS introduced into the wet end pulp slurry is expected to be incorporated into and remain with the finished paper product. Also, the notifier asserts that there are no any extraordinary circumstances that would require the submission of an EA.

Environmental Assessment:

Description of the Proposed Action: The notifier requested clearance of the FCS (proposed trade name of the 15% copolymer aqueous solution is (b) (4)) to be used as an additive in paper and paperboard that may come into contact with all types of food, under conditions of use B-H. The copolymer is intended to impart oil, grease, and water resistance to treated articles at an intended use level of 1.2% by weight. The EA focuses on the use of (b) (4) in the wet end of paper production.

Introduction of substances into the Environment: The notifier does not manufacture the paper and paperboard that will contain the FCS. Instead, the notifier plans to market the FCS to companies that will use the product in the manufacture of food-contact paper and paperboard. The FCS is expected to be used in place of other oil, grease, and water resistant treatments that are currently used in the production of food contact paper and paperboard. Thus, the use of the FCS in place of these materials will not result in any adverse change in the nature or the amount of substances released into the environment. The FCS is manufactured abroad and imported into the United States and the EA does not discuss the manufacturing sites and potential impacts from the manufacturing process. Any of the FCS that is not incorporated into the finished product will be disposed of either by landfill at suitable sites or by incineration. Based on the evidence presented, the amount of the FCS that might leach in a landfill is expected to be very low. In addition, EPA regulations require new municipal solid waste landfills to implement composite liners and leachate collection systems and all landfills to monitor groundwater and to take

corrective action upon detection of a release. Therefore, there are no extraordinary circumstances in this case that indicate any adverse environmental impact.

Environmental Fate: The notifier estimated the maximum expected introduction concentration (EIC) of the FCS to be 0.23ppm to be released into the environment as a component of effluents from waste water treatment facilities. The expected environmental concentration (EEC), with a river dilution factor of 10, will be 0.023 ppm. The aquatic toxicity data for the use of the FCS[2] is 100 ppm, which is above the EEC. In addition, the FCS will be used in place of these materials and will not result in any significant adverse change in the nature or the amount of substances released into the environment.

Environmental Effects: The notifier submitted original study reports (listed above and included in Attachment 13) for the FCS (e.g., algal growth inhibition test, 48-hour acute immobilization test, 96-hour acute toxicity test), and a journal article bioconcentration and tissue distribution in *Oncorhynchus mykiss* (rainbow trout) as well as two pharmacokinetic studies looking at perfluorohexanoic acid and nonfluoro-1-butanesulfonic acid in both rats and cynomolgus monkeys. The notifier stated that the data submitted in FCN (b) (4) regarding the potential toxicity of (b) (4) to aquatic organisms is chemically quite similar to (b) (4)

The algal growth inhibition test[3], the 48-hour acute immobilization test[4], and the 96-hour acute toxicity test[5] were carried out using a dispersed suspension using a nominal concentration of 100mg/L and a control. At this concentration (100mg/L), the FCS was not dissolved and the exact concentration could not be determined. Therefore, the EL50 (Median Effective Loading), and the LL50 (Median Lethal Loading) defined as the concentration that causes 50% effect, or mortality, during the exposure were calculated. Although the usefulness of these tests was limited because of that fact that the tests were conducted above the solubility level, the no observed effect level ("NOEL") values for the tests discussed in the reports were determined to be greater than or equal to 100 ppm. Given the concerns with results of these studies, due to solubility of the FCS, the 96-hour LC50 (defined as the estimated lethal concentration that causes 50% mortality) was estimated from the bioconcentration study conducted in carp as being greater than 10ppm (Doudoroff method). The EEC of 0.023ppm is several orders of magnitude less than the NOEL from the carp test of 10ppm. At the EEC value of 0.023 ppm, and the results of the study that demonstrate the lack of toxicity to aquatic organisms[2-5], the potential release of

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[2] Martin J. Mabury S. et al., "Bioconcentration and Tissue Distribution of Perflourinated Acids in Rainbow Trout (*Oncorhyncus mykiss*)," Env. Toxicology and Chemistry Vol. 22., No. 1 pp. 196-204.

[3] (b) (4)

[4] (b) (4)

[5] (b) (4)

the FCS to the environment under the intended conditions of use will not lead to any significant adverse environmental impacts.

Use of Resources and Energy and Mitigation Measures: The production of food-contact paper and paperboard using the FCS is not expected to result in a net increase in the use of energy and resources. The FCS is intended to replace other fluorochemicals. Hence, its use is not reasonably expected to result in any new environmental problems requiring mitigation measures.

Alternatives to the Proposed Action: There are no potential adverse environmental effects identified in the EA, which would necessitate alternative actions to that proposed in this notification.

Conclusion and Recommendation:
We have reviewed the claim of categorical exclusion under 21 CFR 25.32(i) and the EA. The notifier cited the section 21 CFR 25.32(i) under which categorical exclusion is warranted, stated compliance with the categorical exclusion criteria, and stated that no extraordinary circumstances exist that require submission of an environmental assessment. The supporting information provided in the EA is consistent with the notifier's claim that there are no potential adverse environmental effects. We conclude that the claim of categorical exclusion under 21 CFR 25.32 (i) is warranted and the FCS was accepted for review based on environmental grounds. We also determined that the EA will not be needed as the basis of this Agency action and, therefore, the entire EA will not be releasable under FOIA.

Please let us know if there is any change in the identity or proposed use of the FCS.

Status: Effective

Part IV - ENVIRONMENTAL INFORMATION (21 CFR Part 25)

All FCN submissions must contain either a claim of categorical exclusion under 21 CFR 25.32 or an environmental assessment (EA) under 21 CFR 25.40.

A - CLAIM OF CATEGORICAL EXCLUSION

1. Cite the specific section(s) of the CFR under which the categorical exclusion is claimed

☒ **21 CFR 25.32 (i)**

a. Is the FCS a component of a coating? ☒ Yes ☐ No

b. If no, the % of the FCS in the finished food-contact article is 1.2% and

c. The % of the total market volume that remains with the food-contact articles is >95%

☐ **21 CFR 25.32 (j)**

Is the FCS a component of a:

a. Repeat-use article? ☐ Yes ☐ No

b. Permanent or semi-permanent food-contact surface? ☐ Yes ☐ No

☐ **21 CFR 25.32 (k)**

☐ **21 CFR 25.32 (q)**

a. Is current FIFRA label attached? ☐ Yes ☐ No

b. Is the requested use essentially the same as the label? ☐ Yes ☐ No

If current FIFRA label has limitation on food-contact uses, provide a draft copy of a revised label you intend to submit to EPA to include food-contact uses.

☐ **21 CFR 25.32 (r)**

2. Does your proposed food-contact use comply with the categorical exclusion criteria? If no, go to section B below. ☒ Yes ☐ No

3. To the best of your knowledge, are there any extraordinary circumstances that would require your submission of an EA? *(see 21 CFR 25.21)* If yes, go to section B below. ☐ Yes ☒ No

B - ENVIRONMENTAL ASSESSMENT

See Environmental Recommendations

1. If an EA is required, state that an EA has been prepared under 21 CFR 25.40, and is attached.

2. Environmental assessments are public documents and should not contain confidential information. Such information should be included in a separate section of the FCN, labeled confidential and summarized to the extent possible in the EA.

In addition to qualifying for the categorical exclusion described above, we have also prepared an EA for the food contact substance. See Attachment 13.

Part V - CERTIFICATION

The accuracy of the statements you make in this notice should reflect your best prediction of the anticipated facts regarding the chemical substance described herein. Any knowing and willful misinterpretation is subject to criminal penalty pursuant to 18 U.S.C. 1001.

The notifying party certifies that the information provided herein is accurate and complete to the best of his/her knowledge.

SIGNATURE OF AUTHORIZED OFFICIAL OR AGENT

(b) (6)

TITLE	DATE
Attorney/Agent for AGC Chemicals Americas Inc.	5 April 2012

Memorandum

Date: August 16, 2016

From: Biologist, Division of Biotechnology and GRAS Notice Review (HFS-255)

Subject: FCN No. 1676 – Use of 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] as an oil, grease, and water-resistant treatment for paper and paperboard intended for food contact use, except for use in contact with infant formula and breast milk.

Notifier: AGC Chemicals Americas, Inc.

To: Ken McAdams Consumer Safety Officer, Div. of Food Contact Notifications (HFS-275)
Through: Suzanne Hill, Environmental Supervisor, Office of Food Additive Safety (HFS-255)

Suzanne Hill -S

Digitally signed by Suzanne Hill -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Suzanne Hill -S, 0.9.2342.19200300.100.1.1=2001511836
Date: 2016.08.16 12:17:01 -04'00'

We have reviewed the claim of categorical exclusion under 21 CFR 25.32(i) for the above referenced notification and have concluded that the claim is warranted. The claim of categorical exclusion cites the section, 21 CFR 25.32(i), under which the categorical exclusion is warranted, states compliance with categorical exclusion criteria, and states that no extraordinary circumstances exist that require the submission of an environmental assessment.

Our analysis of this claim of categorical exclusion is summarized below.

25.32(i) Claim: As part of our review, we confirmed that the FCS will be present in finished food-packaging material applied as a coating, or at a use level not greater than 5 percent by weight when incorporated into paper/paperboard and will remain with finished food-packaging material through use by consumers.

The FCS functions as a coating when added at the size press in paper manufacturing. When added at the wet end of paper manufacturing the intended use level of the FCS is not to exceed 1.2 weight percent therefore meeting the 5% by-weight use level criterion.

Retention of the FCS in the finished food-packaging material through use by consumers is supported by retention study data demonstrating 96.8% and 98.8% FCS retention when added at size press and wet end steps of paper processing, respectively.

Further, we accept that paper and paperboard are food packaging.

Therefore, we find that the criteria of categorical exclusion under 21 CFR 25.32(i) are met.

Extraordinary Circumstances:

Recycling: Since similar fluorocarbon greaseproofing agents are currently authorized for use in paper and paperboard and because the notified use of the FCS is intended as a substitutional replacement, we have determined that the FCS would not impact the recyclability of the final end-use products.

Incineration: On August 1, 2016, the Council on Environmental Quality (CEQ) issued final guidance[1] to agencies regarding addressing greenhouse gas (GHG) emissions and climate change impacts in NEPA documents. This guidance is "intended to help Federal agencies ensure their analysis of potential GHG emissions and effect of climate change in an EA or EIS is commensurate with the extent of the effects of the proposed action." The GHG emissions resulting from the use and disposal of the FCS relate to the land disposal and/or incineration of articles containing the FCS in MSW landfills and/or MSW combustion facilities. Such facilities are regulated by the U.S. Environmental Protection Agency (U.S. EPA) under 40 CFR 98, which "establishes mandatory GHG reporting requirements for owners and operators of certain facilities that directly emit GHG." Part 2 of this regulation (40 CFR 98.2), describes the facilities that must report GHG emissions and sets an annual 25,000 metric ton carbon dioxide equivalent (CO2-e) emission threshold for required reporting.

We note that the FCS contains carbon, hydrogen, oxygen and fluorine and may be expected to form GHGs such as carbon dioxide (CO2) and fluorohydrocarbon gases when combusted after disposal by the consumer. Utilizing market volume (notifier supplied confidential data) and current municipal solid waste combustion rate (U.S. EPA 2015 Report #EPA530-R-15-002) information for paper and paperboard, we have confirmed that combustion of the FCS is expected to produce far less than 25,000 metric tons of carbon dioxide equivalent GHG emissions per year.

To evaluate the significance of the environmental impact of these GHG emissions, we refer to CEQ regulations under 40 CFR 1508.27, which defines 'significantly' as it relates to assessing the intensity of an environmental impact in NEPA documents. 40 CFR 1508.27(b)(10) states, that when evaluating intensity of an impact, one should consider "whether the action threatens a violation of Federal, State, or local law or requirements imposed for the protection of the environment." GHG emissions from MSW combustion facilities are regulated under 40 CFR 98.2. As the estimated GHG emissions are well below the threshold for mandatory reporting, we find that there are no extraordinary circumstances related to combustion of the FCS.

We conclude that the claim of categorical exclusion under 21 CFR 25.32(i) is warranted and that there are no extraordinary circumstances that would require preparation of an environmental assessment or environmental impact statement.

Please let us know if there is any change in the identity or use of the food contact substance.

Mariellen Pfeil -S
Digitally signed by Mariellen Pfeil -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2001132721, cn=Mariellen Pfeil -S
Date: 2016.08.16 10:07:24 -04'00'

Mariellen Pfeil

cc: HFS-255 Pfeil
File: FCN No. 1676

[1] *Available at* https://www.whitehouse.gov/sites/whitehouse.gov/files/documents/nepa_final_ghg_guidance.pdf

PART IV – ENVIRONMENTAL INFORMATION (21 CFR Part 25)

All FCN submissions must contain either a claim of categorical exclusion under 21 CFR 25.32 or an environmental assessment (EA) under 21 CFR 25.40. See Environmental Recommendations

A - CLAIM OF CATEGORICAL EXCLUSION

Items 1, 2 and 3 below must be completed in order for your claim of categorical exclusion to be complete.

1. Mark (X) in the box next to the specific section(s) of the CFR under which the categorical exclusion is claimed, and complete the information below each section cited as directed:

☒ 21 CFR 25.32 (i)

a. Is the FCS expected to remain with finished food-packaging material? ☒ Yes ☐ No (if "No," then the claim is not valid);

b. Is the FCS a component of a coating of a finished food-packaging material? ☒ Yes ☐ No

c. Is the FCS a non-coating component in finished food-packaging material? ☐ Yes ☒ No

d. If the FCS is a non-coating component, what is the percentage of the FCS in finished food-packaging material? %
(If the FCS is a non-coating component contributing more than five percent by weight to finished food-packaging material, then the claim is not valid.)

☐ 21 CFR 25.32 (j)

a. Is the FCS a component of a repeat-use article? ☐ Yes ☐ No

b. Is the FCS a component of a permanent or semi-permanent food-contact surface? ☐ Yes ☐ No

☐ 21 CFR 25.32 (k)

☐ 21 CFR 25.32 (q)

a. Is the current FIFRA label attached? ☐ Yes ☐ No

b. Is the requested use essentially the same as that specified on the FIFRA label? ☐ Yes ☐ No
(If the current FIFRA label has a limitation on food-contact uses, then provide a draft copy of a revised label you intend to submit to EPA to include food-contact uses).

☐ See attachment number(s) _____ ☐ See other FDA file _____

☐ 21 CFR 25.32 (r)

2. a. Does your proposed food-contact use comply with the categorical exclusion criteria? ☒ Yes ☐ No (If "No," go to section B below.)

b. If compliance with the categorical exclusion criteria is not evidenced in other parts of the submission, FDA may request additional information *(See Section II.B of the Environmental Recommendations)*. If you have attached such information, indicate location.

☒ See attachment number(s) 55,56, ☐ See other FDA file _____

3. To the best of your knowledge, are there any extraordinary circumstances that would require your submission of an EA? *(see 21 CFR 25.21)* ☐ Yes ☒ No (If "Yes," go to section B below.)

B - ENVIRONMENTAL ASSESSMENT

See Environmental Recommendations

☐ An EA is required and has been prepared under 21 CFR 25.40 and is attached.

Note: An EA is a public document and should not contain confidential information. Such information should be included in a separate section of the FCN, labeled confidential and summarized to the extent possible in the EA.

☐ See attachment number(s) _____ ☐ See other FDA file _____

PART V – CERTIFICATION

The accuracy of the statements you make in this submission should reflect your best prediction of the anticipated facts regarding the chemical substance described herein. Any knowing and willful misinterpretation is subject to criminal penalty pursuant to 18 U.S.C. 1001. The notifying party certifies that the information provided herein is accurate and complete to the best of his/her knowledge.

Signature of Authorized Official or Agent	Printed Name and Title	Date (mm/dd/yyyy)
(b) (6)	Warren Lehrenbaum, Attorney	05/13/2016

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: May 19, 2009

From: Environmental Toxicologist, Environmental Review Team (ERT)
Office of Food Additive Safety (HFS-246)

Subject: FCN No. 885 - Perfluorochemical copolymer for use as an oil and grease resistant treatment for paper and paperboard.

DuPont Chemical Solutions
Enterprise, PO Box 80402
Wilmington, DE 19880-0402

To: Division of Food Contact Notifications (HFS-275)
Attention: Paul Honigfort, Ph.D.
Through: William H. Lamont, Ph.D., Acting Supervisor, ERT, _____

The food contact substance (FCS) is 2-propenoic acid, 2-methyl-, polymer with 2-(diethylamino)ethyl 2-methyl-2-propenoate, 2-propenoic acid and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl 2-methyl-2-propenoate, acetate.

We have reviewed the claim of categorical exclusion for the above referenced food contact notification and have concluded that categorical exclusion is warranted. The claim of categorical exclusion cites the section, 21 *CFR* 25.32 (j), under which categorical exclusion is warranted, states compliance with the categorical exclusion criteria, and states that no extraordinary circumstances exist that require the submission of an environmental assessment.

Please let us know if there is any change in the identity or use of the food-contact substance.

Ron C. Hardman, Ph.D.

cc:
HFS-246 File: FCN No. 885

HFS-246:RCHardman:rch: 6/22/2009 H:\FCN\FCN 000891\FCN885_E_CatEx.doc
FT: RCHardman:rch: 6/22/09 P:\EIS Documents\FCN\FCN 801-1000\FCN885_E_CatEx.doc

AD

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Attention: Paul Honigfort, Ph.D.
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The food contact substance (FCS) is 2-propenoic acid, 2-methyl-, polymer with 2-(diethylamino)ethyl 2-methyl-2-propenoate, 2-propenoic acid and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl 2-methyl-2-propenoate, acetate.

We have reviewed the claim of categorical exclusion for the above referenced food contact notification and have concluded that categorical exclusion is warranted. The claim of categorical exclusion cites the section, 21 *CFR* 25.32 (j), under which categorical exclusion is warranted, states compliance with the categorical exclusion criteria, and states that no extraordinary circumstances exist that require the submission of an environmental assessment.

Please let us know if there is any change in the identity or use of the food-contact substance.

(b) (6)

Ron C. Hardman, Ph.D.

cc:
HFS-246 File: FCN No. 885

HFS-246:RCHardman:rch: 5/19/2009 H:\FCN\FCN 000891\FCN885_E_CatEx.doc
FT: RCHardman:rch: 5/19/09 P:\EIS Documents\FCN\FCN 801-1000\FCN885_E_CatEx.doc

Part IV - ENVIRONMENTAL INFORMATION (21 CFR Part 25)

All FCN submissions must contain either a claim of categorical exclusion under 21 CFR 25.32 or an environmental assessment (EA) under 21 CFR 25.40.

A - CLAIM OF CATEGORICAL EXCLUSION

1. Cite the specific section(s) of the CFR under which the categorical exclusion is claimed:

☒ **21 CFR 25.32 (i)** When FCS is applied at the size-press

a. Is the FCS a component of a coating? ☒ Yes ☐ No When FCS is applied at the size-press

b. If no, the % of the FCS in the finished food-contact article is _____ and

c. The % of the total market volume that remains with the food-contact articles is _____

☐ **21 CFR 25.32 (j)**

Is the FCS a component of a:

a. Repeat-use article? ☐ Yes ☐ No

b. Permanent or semi-permanent food-contact surface? ☐ Yes ☐ No

☐ **21 CFR 25.32 (k)**

☐ **21 CFR 25.32 (q)**

a. Is current FIFRA label attached? ☐ Yes ☐ No

b. Is the requested use essentially the same as the label? ☐ Yes ☐ No

If current FIFRA label has limitation on food-contact uses, provide a draft copy of a revised label you intend to submit to EPA to include food-contact uses.

☐ 21 CFR 25.32 (r)

2. Does your proposed food-contact use comply with the categorical exclusion criteria? ☒ Yes ☐ No
If no, go to section B below.

3. To the best of your knowledge, are there any extraordinary circumstances that would require your submission of an EA? *(see 21 CFR 25.21)* ☐ Yes ☒ No
If yes, go to section B below..

B - ENVIRONMENTAL ASSESSMENT

See Environmental Recommendations

1. If an EA is required, state that an EA has been prepared under 21 CFR 25.40, and is attached.

2. Environmental assessments are public documents and should not contain confidential information. Such information should be included in a separate section of the FCN, labeled confidential and summarized to the extent possible in the EA.

As indicated above, DuPont is claiming a categorical exclusion for applications in which the FCS is added in the size press. With regard to applications in which the FCS is added in the wet-end, we note that an EA was submitted as part of DuPont's FCN Nos. 206, 311, and 338. Because the present FCN addresses a somewhat different FCS, we have prepared a new EA to address its environmental impact when used in the wet-end to make food-contact paper and paperboard. The EA is provided as **Attachment 21**.

Part V - CERTIFICATION

The accuracy of the statements you make in this notice should reflect your best prediction of the anticipated facts regarding the chemical substance described herein. Any knowing and willful misinterpretation is subject to criminal penalty pursuant to 18 U.S.C. 1001.

The notifying party certifies that the information provided herein is accurate and complete to the best of his/her knowledge.

SIGNATURE OF AUTHORIZED OFFICIAL OR AGENT

TITLE	DATE
COUNSEL FOR NOTIFIER	02-04-09

Attachment 21

Environmental Assessment

ENVIRONMENTAL ASSESSMENT

1. Date: February 3, 2009

2. Name of Applicant: DuPont Chemical Solutions Enterprise

3. Address:

Jackson Laboratory
Chambers Works
Deepwater, NJ 08023

All communications on this matter are to be sent in care of Counsel for Notifier:
George G. Misko
Keller and Heckman LLP
1001 G Street N.W., Suite 500 West
Washington, D.C. 20001
Telephone: (202) 434-4170
Facsimile: (202) 434-4646
E-mail: misko@khlaw.com

4. Description of the Proposed Action

The action requested in this submission is the notification of the use of a copolymer produced by the polymerization of methacrylic acid with acrylic acid, diethylaminoethyl methacrylate, and 2-(perfluorohexyl)ethyl methacrylate. The product is generally referred to herein as the "food contact substance" (FCS) or as the copolymer.

The subject fluorinated copolymer is intended for use as an additive in paper and paperboard that may contact all types of food under Conditions of Use B through H and in microwave susceptor applications. The copolymer is intended to function as an oil and grease resistant treatment at levels not to exceed 0.42 wt. % of polymer solids by weight of the paper.

DuPont does not manufacture the paper and paperboard that will use the FCS as an oil and grease resistant treatment. Rather, DuPont plans to market the copolymer to manufacturers who will, in turn, use the product as an oil and grease resistant treatment in the manufacture of paper and paperboard.

The FCS will be sold to manufacturers who will use it to treat food-contact paper and paperboard in both the size press and wet end of the manufacturing process. With respect to the size press, no environmental effects are expected because the FCS remains fully with the treated paper. Therefore, in keeping with guidance received from the FDA environmental

review staff in the context of previous Notifications, this EA discusses the use of the FCS in the wet-end of paper production only.

As discussed more fully below, it is expected that the great majority of the copolymer will be incorporated into, and remain a component of, the finished paper and paperboard. To the extent that a fraction of the FCS does not become incorporated into the paper, it is expected that most of the remaining copolymer will be present as a component of the solid wastes generated in the waste water treatment process. These wastes are expected to be disposed of by either landfill or incineration. Only very low levels of the copolymer are expected to be present in effluent from the on-site waste water treatment facility. Aquatic toxicity data provided herewith indicate a wide margin of safety relative to the estimated release concentrations.

Food-contact articles made with paper containing the copolymer will be utilized in patterns corresponding to the national population density and will be widely distributed across the country. Therefore, it is anticipated that disposal will occur nationwide, with about 80% of the materials ultimately being deposited in land disposal sites, and about 20% incinerated.[1] The types of environments present at and adjacent to the disposal locations are the same as for the disposal of any other food-contact material in current use. Consequently, there are no special circumstances regarding the environment surrounding either the use or disposal of food-contact materials prepared using the FCS.

5. Identification of Chemical Substance that is the Subject of the Proposed Action

Chemical Name:	Methacrylic acid copolymer with acrylic acid, diethylaminoethyl methacrylate, and 2-(perfluorohexyl)ethyl methacrylate, acetate
CAS Registry Number:	1071022-26-8
CAS Registry Name:	Propenoic acid, 2-methyl-, polymer with 2-(diethylamino)ethyl 2-methyl-2-propenoate, 2-propenoic acid and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl 2-methyl-2-propenoate, acetate

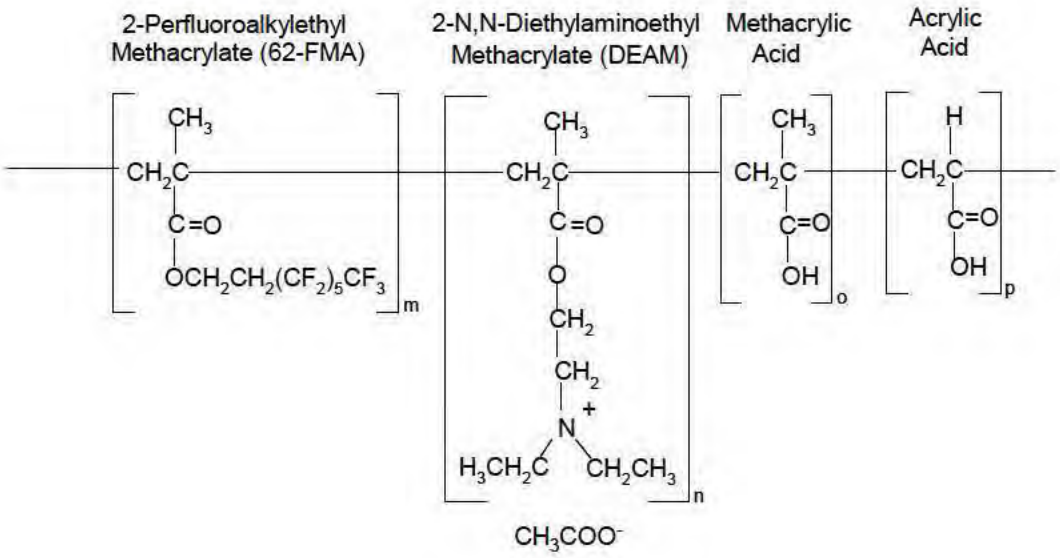
The starting monomers are further identified in the following table:

[1] "Characterization of Municipal Solid Waste in the United States, 1994 Update," EPA/530-S-94-042, U.S. Environmental Protection Agency, Washington, D.C. 20460.

CASRN	CAS Name	Common Name
2144-53-8	2-Propenoic acid, 2-methyl-, 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl ester	2-Perfluorohexylethyl methacrylate
105-16-8	2-Propenoic acid, 2-methyl-, 2-(diethylamino)ethyl ester	Diethylaminoethyl methacrylate
79-41-4	2-Propenoic acid, 2-methyl-	Methacrylic acid
79-10-7	2-Propenoic acid	Acrylic acid

The molecular formula is as follows: $(C_{12}H_9F_{13}O_2)_m\,(C_{10}H_{19}O_2N)_n\,(C_4H_6O_2)_o\,(C_3H_4O_2)_p$.

The structural formula for the copolymer is given below:



The quantitative composition of the copolymer is confidential and thus not provided here, but is set forth in Attachment 1 of this notification.

Analysis of representative samples of the copolymer by size exclusion chromatography (SEC) indicated weight-average molecular weights (Mw) of approximately (b) (4)

The copolymer is supplied in the form of an aqueous dispersion containing approximately 19.5% of polymer solids. Typical physical properties are included in the specifications set forth in Attachment 12.

6. Introduction of Substances into the Environment

1. Introduction of substances into the environment as a result of manufacture of the polymer

FDA has indicated that an EA ordinarily should focus on relevant environmental issues relating to the use and disposal from use, rather than the production, of FDA regulated articles. Moreover, information available to DuPont does not suggest that there are any extraordinary circumstances in this case indicative of any adverse environmental impact as a result of the manufacture of the copolymer. Consequently, information regarding the manufacturing site and compliance with the relevant emissions requirements is not provided here.

2. Introduction of substances into the environment as a result of use/disposal

As stated previously, based on available information, DuPont expects that the majority of the copolymer will be incorporated into, and remain a component of, finished paper produced using the product. To address the potential environmental introductions as a result of use of the FCS, we refer to information DuPont previously obtained from a paper manufacturer regarding typical manufacturing and waste treatment practices at paper mills that may use the FCS in the wet end. This information, which also was used in the Environmental Assessments for the Notifier's FCN Nos. 206, 311, 338, and 646, is expected to be representative of other mills that may apply the treatment in the wet end. Thus, the following discussion of environmental releases at the site of use of the FCS is based upon the information supplied by this company.

Based on substantial experience with the use of fluorochemicals as oil and grease resistant treatments for paper and paperboard, it is estimated that at least 88% of the copolymer introduced into the pulp slurry will become incorporated into the finished paper. This includes the amount of copolymer that becomes incorporated into the paper on the first pass, based on both laboratory and plant experiments, as well as that which is incorporated into the pulp in additional passes and copolymer that becomes adsorbed to fiber "fines" that initially do not become part of the paper. These fines typically are recovered from the white water via filtration and recycled back into the papermaking process. (The economics of the papermaking process demand such recycling of fines.) The total polymer retention level of 88% is equal to the retention rate achieved with competitive fluorochemicals; thus, substituting the FCS in place of the currently used fluorochemicals is not expected to result in a loss of retention of the treatment on the paper.

To the extent that the FCS copolymer is not incorporated into the finished paper, it will be present in the white water from the process. While the white water is typically recycled through the process, the water will ultimately be released to the waste water treatment facility. The frequency of such releases will vary from plant to plant. DuPont believes that all of the paper mills that will use the product operate on-site treatment facilities. It is further estimated, again based on DuPont's knowledge of similar chemicals, that at least 90% of the fluoropolymer will be removed from the waste water as a component of the solid

wastes, or sludge, from the waste water treatment process. This figure is based on several considerations. First, the waste water treatment will begin with a filtration step that will remove fines containing adsorbed copolymer. Second, following the filtration, the aqueous stream is biotreated. Based on general experience in biotreatment, DuPont's knowledge indicates that acrylate polymers, such as the FCS copolymer, tend to go predominantly with the sludge. A third point is that once neutralized, the copolymer has extremely low solubility in water; this further implies that the copolymer will tend to stay with the solids.

Thus, at least 90% of the copolymer going to the waste water is expected to be present in either the filtered solids or sludges recovered from the waste water. Based on DuPont's experience, these solid wastes are expected to be disposed of by means of either landfilling at suitable sites or by incineration, with the ash from the incinerator being disposed of via landfill.[2]

As for solid wastes from waste water treatment processes that are either directly disposed of by landfill or are incinerated followed by landfilling of the resultant ash, we expect that only very low levels of the subject food-contact substance will leach from the landfills containing these wastes. Moreover, even if a very small amount of the substance migrates from sludges disposed of in landfills, we expect extremely low quantities to actually enter the environment; this finding is based on the regulations of the Environmental Protection Agency (EPA) governing municipal solid waste landfills.[3]

The maximum level at which the FCS copolymer may be present in the waste water following treatment may be estimated based on the foregoing considerations as follows. First, we will assume that all of the 12% of the polymer that may not be incorporated into the paper in either multiple passes or recycling of fines will be initially present in the waste water. Of the resulting amount, we will assume that 10% will remain in the waste water after removal via the filtered solids and sludge.

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[2] Guidance previously provided by FDA suggests that environmental releases resulting from soil application of sludges containing the FCS should be considered. As noted in DuPont's previous EAs, DuPont is not aware of a paper manufacturer who disposes of solid wastes by this means, so DuPont does not have information specifically dealing with this potential introduction. However, in the event that such sludges are used for soil amendment purposes, it is expected that the FCS copolymer will largely adhere to pulp fibers and thus will not be directly released to the surrounding environment.

[3] These regulations require (1) the use of composite liners and leachate collection systems with new municipal solid-waste landfill units and lateral expansions of existing units to prevent leachate from entering the ground and surface water, and (2) groundwater monitoring systems. See 40 C.F.R. Part 258. Although owners and operators of existing active municipal solid-waste landfills that were constructed before October 9, 1993 are not required to retrofit liners and leachate collection systems, they are required to monitor groundwater and to take corrective action as appropriate.

The calculations are based further on the following information regarding a typical large-scale paper production process, again supplied by DuPont's customer. Specifically, a total of 750 metric tons (750 x 10^3 kg) of treated paper is typically produced by the mill per day. As stated in the notification, the paper is intended to be treated with the FCS at a maximum level corresponding to a copolymer content of 0.42% polymer solids by weight of the paper. If 88% of the copolymer is retained in finished paper, the actual level of the FCS copolymer added to the pulp slurry will need to be adjusted for the retention rate; the adjusted amount may be estimated, relative to the dry paper weight, as (0.42% ÷ 0.88), or 0.48%. Thus, the total amount of the FCS copolymer employed on a daily basis will be about 3600 kg.[4] If 12% of this amount does not become incorporated into the finished paper, a total of 432 kg will remain with the white water. Further, if 10% of this amount remains in the waste water after treatment, this will amount to approximately 43 kg of the copolymer.

In producing 750 metric tons of treated paper per day, the mill processes an estimated 18,000 gallons per minute (gpm) of waste water. This is equivalent to 26 million gallons per 24-hour day.[5] (This includes both the release of white water from the papermaking process and other aqueous plant wastes.) This is equivalent to 99 million liters (or kg) of water per day.[6] On this basis, if 43 kg of copolymer is present in the post-treatment waste water, the resulting concentration will be 0.43 part per million (ppm).[7]

It should be noted that the FCS is expected to be used in place of other oil and grease resistant treatments that are currently used in the production of food-contact paper and paperboard. Thus, the use of the copolymer in place of these materials will not result in any meaningful change in the nature or the amount of substances released into the environment upon the use of the product in the manufacture of food-contact paper and paperboard.

7. Fate of Emitted Substances in the Environment

As shown in Item 6 above, the primary means by which the FCS copolymer is expected to be released into the environment is as a component of effluents from waste water treatment facilities. The expected introduction concentration (EIC) is estimated to be 0.43 ppm.

This concentration, of course, will be greatly diluted once the effluent enters the receiving water. For the sake of conservatism, we will estimate the expected environmental concentration (EEC) using a river dilution factor of 10; that is, we will assume just a 10-fold dilution in the concentration of copolymer residues upon entering the receiving water. This will result in an EEC of 0.43 ppm ÷ 10 = 0.043 ppm, or 43 parts per billion (ppb).

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[4] 0.48% x 750 x 10^3 kg/day = 3600 kg/day.

[5] 18,000 gpm x 60 min/hr x 24 hr/day = 26 x 10^6 gal/day.

[6] 26 x 10^6 gal/day x 3.8 L/gal = 99 x 10^6 L/day.

[7] 43 kg polymer ÷ 99 x 10^6 kg water = 4.3 x 10^{-7} kg/kg = 0.43 ppm.

We respectfully submit that the concentration at which the copolymer may be released in effluent from waste water treatment facilities is so low as to warrant no substantive concern. The conclusion that there will be no significant adverse impact is further supported by the aquatic toxicity data discussed in Item 8 below.

8. Environmental Effects of Released Substances

The potential release of the FCS at the worst-case level calculated above is not expected to result in any significant environmental effects. This expectation is based on the low levels at which the product may be introduced into the environment and on available data, which indicate that the product is essentially non-toxic to aquatic organisms.

As documentation of this lack of toxicity, we refer to the reports of two acute toxicity studies conducted in aquatic organisms using a test substance that is closely related to the FCS.[8] Specifically, the studies were conducted on a copolymer of 2-(perfluoroalkyl)ethyl acrylate, 2-N,N-diethylaminoethyl methacrylate, and glycidyl methacrylate. That polymer was the subject of the Notifier's FCN No. 206, and the aquatic toxicity studies were submitted in support of the EA for that notification. See Attachment 19 to this FCN for a comparison of the polymer cleared under FCN 206 to the current FCS.

The first of the two previously submitted reports relates to a static, acute 96-hour screening test in fathead minnows. The 96-hour LC_{50} was found to be between 50 mg/L and 500 mg/L of the product. The second report relates to a static, acute 48-hour screening test in *Daphnia magna*. The LC_{50} was again found to be between 50 mg/L and 500 mg/L.

In addition to these previously submitted studies, the Notifier has conducted an acute aquatic toxicity study in *Daphnia magna* using the FCS described in this notification. The study demonstrated that the EC_{50} for the FCS is >120 mg/L. The report of this study is not provided with this Environmental Assessment because it contains confidential information; we are submitting it, however, for inclusion in the Notifier's Food Additive Master File No. 799.

DuPont advises that these toxicity values are based on the concentration of the product as delivered, that is, on the wet basis. DuPont advises further that the product tested in the previously submitted studies consists of 30% solids, whereas the FCS described in this notification is supplied as a 19.5% solids dispersion and was tested on this basis. Thus, the LC_{50} and EC_{50} values obtained on the tested formulations may be converted to the corresponding values on the polymer solids basis. For the studies on the similar product that were previously submitted in FCN 206, the LC_{50} on the solids basis is calculated by multiplying the reported value by 0.3. This results in an estimated LC_{50} in fathead minnows

[8] That polymer was the subject of the Notifier's FCN No. 206, and the aquatic toxicity studies were submitted in support of the EA for that notification. Note, however, that they contain confidential information that should not be disclosed.

and *Daphnia magna* of between 15 mg/L and 150 mg/L on the polymer solids basis.[9] For the FCS described herein, the EC_{50} on the polymer solids basis is >23.4 mg/L.[10]

As discussed in Item 7 above, the maximum concentration at which the FCS copolymer is expected to be present in the environment, or the EEC, is 0.043 ppm, equivalent to 0.043 mg/L. The lower end of the LC_{50} range calculated based on the previously submitted studies on the similar polymer, 15 mg/L, is about 350 times the EEC.[11] Moreover, the EC_{50} determined on the FCS itself is more than 540 times the EEC.[12] Thus, it may readily be concluded that the potential release of copolymer will not lead to any significant adverse environmental impacts. Moreover, as noted previously, this release will not represent a new environmental introduction of fluorochemical but, rather, a substitution for the corresponding release of other fluorochemicals that would otherwise be used for the same purpose. We respectfully submit, therefore, that no adverse environmental effects are expected as a result of this release.

9. Use of Resources and Energy

The notified use of the FCS copolymer is expected to compete with, and to some degree replace, other fluorochemicals that are already used in the manufacture of paper and paperboard. Other fluorochemicals that are specifically listed in Section 176.170 of the food additive regulations for this purpose include, *e.g.*, perfluoroalkyl acrylate copolymer (CAS Reg. No. 92265-81-1), in addition to the Notifier's products that are cleared under FCN Nos. 206, 311, 338, and 646. For this reason, the use of the FCS in the production of food-contact paper and paperboard is not expected to result in a net increase in the use of energy and resources.

10. Mitigation Measures

As discussed above, no significant adverse environmental impacts are expected to result from the manufacture of food-contact paper and paperboard using the FCS. This is largely due to the low levels at which the copolymer may be introduced into the environment and the available data indicating an absence of toxicity to organisms in the environment. This conclusion is further supported by the close similarity of the FCS to the fluorochemicals it is

---

[9] For studies submitted in FCN 206: (LC_{50} of 50-500 mg/L on liquid product basis) x (0.3 mg solids/mg liquid product) = LC_{50} of 15-150 mg/L on solids basis.

[10] For the study on the FCS described in this notification: (EC_{50} of >120 mg/L on liquid product basis) x (0.195 mg solids/mg liquid product) = EC_{50} of >23.4 mg/L on solids basis.

[11] LC_{50} of 15 mg/L (solids basis, as calculated in footnote 9) ÷ EEC of 0.043 mg/L = 349.

[12] EC_{50} of >23.4 mg/L (solids basis, as calculated in footnote 10) ÷ 0.043 mg/L = >544.

intended to replace. Thus, the use of the copolymer as proposed is not reasonably expected to result in any new environmental problem requiring mitigation measures of any kind.

11. Alternatives to the Proposed Action

No potential adverse environmental effects are identified herein which would necessitate alternative actions to that proposed in this request. Therefore, alternatives to the proposed action need not be considered.

12. List of Preparers

Holly H. Foley, Staff Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Washington, DC 20001.

Peter Schtur III, Technical Group Leader, DuPont Chemical Solutions Enterprise, Experimental Station – E402/5336A, Rt. 141 and Henry Clay, PO Box 80402, Wilmington, DE 19880-0402

13. Certification

The undersigned official certifies that the information presented is true, accurate, and complete to the best of his knowledge.

Date: 02-04-09

George G. Misko
Counsel for DuPont Chemical Solutions Enterprise

14. References

None

15. Attachments

None

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: February 12, 2010

From: Acting Supervisor, Environmental Review Team (ERT)
Office of Food Additive Safety (HFS-246)

Subject: FCN No. 940 – Fluoropolymer-based oil-repellent, not to exceed 0.18 percent-by-weight and added at either the size press or prior to sheet formation, in paper and paperboard.

DuPont Chemical Solutions Enterprise
PO Box 80402
Wilmington, DE 19880-0402

To: Division of Food Contact Notifications (HFS-275)
Attention: Paul Honigfort, Ph.D.

The food-contact substance (FCS) is hexane, 1,6-diisocyanato-, homopolymer, 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluoro-1-octanol-blocked. A claim for categorical exclusion under 21 CFR 25.32 (i) was made for the notified use of the FCS at size press operations, where there is little opportunity for loss of the FCS, in the manufacture of paper products. The claim was made on the basis that the FCS was used as a component of a coating, which is inconsistent with the nature of its use as a grease-and-oil resistant treatment for paper products. Nonetheless, the claim is otherwise still applicable on the basis that the FCS is used at not more than five percent-by-weight and is expected to remain in the treated finished paper products.

We have reviewed the claim of categorical exclusion for the above referenced notification and have concluded that categorical exclusion is warranted based on the information provided in the notification. The claim of categorical exclusion cites the section, 21 *CFR* 25.32 (i), under which categorical exclusion is warranted, states compliance with the categorical exclusion criteria, and states that no extraordinary circumstances exist that require the submission of an environmental assessment.

Please let us know if there is any change in the identity or use of the food-contact substance.

William H Lamont

cc:

HFS-246 Lamont
File: FCN No. 940

Memorandum

Date: February 12, 2010

From: Acting Supervisor, Environmental Review Team (ERT)
Office of Food Additive Safety (HFS-246)

Subject: FCN No. 940 – Fluoropolymer-based oil-repellent, not to exceed 0.18 percent-by-weight and added at either the size press or prior to sheet formation, in paper and paperboard.

DuPont Chemical Solutions Enterprise
PO Box 80402
Wilmington, DE 19880-0402

To: Division of Food Contact Notifications (HFS-275)
Attention: Paul Honigfort, Ph.D.

The food-contact substance (FCS) is hexane, 1,6-diisocyanato-, homopolymer, 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluoro-l-octanol-blocked. A claim for categorical exclusion under 21 CFR 25.32 (i) was made for the notified use of the FCS at size press operations, where there is little opportunity for loss of the FCS, in the manufacture of paper products. The claim was made on the basis that the FCS was used as a component of a coating, which is inconsistent with the nature of its use as a grease-and-oil resistant treatment for paper products. Nonetheless, the claim is otherwise still applicable on the basis that the FCS is used at not more than five percent-by-weight and is expected to remain in the treated finished paper products.

We have reviewed the claim of categorical exclusion for the above referenced notification and have concluded that categorical exclusion is warranted based on the information provided in the notification. The claim of categorical exclusion cites the section, 21 *CFR* 25.32 (i), under which categorical exclusion is warranted, states compliance with the categorical exclusion criteria, and states that no extraordinary circumstances exist that require the submission of an environmental assessment.

Please let us know if there is any change in the identity or use of the food-contact substance.

William H Lamont

cc:

HFS-246 Lamont
File: FCN No. 940

Part IV - ENVIRONMENTAL INFORMATION (21 CFR Part 25)

All FCN submissions must contain either a claim of categorical exclusion under 21 CFR 25.32 or an environmental assessment (EA) under 21 CFR 25.40.

A - CLAIM OF CATEGORICAL EXCLUSION

1. Cite the specific section(s) of the CFR under which the categorical exclusion is claimed:

☒ **21 CFR 25.32 (i)** When FCS is applied at the size-press

a. Is the FCS a component of a coating? ☒ Yes ☐ No When FCS is applied at the size-press

b. If no, the % of the FCS in the finished food-contact article is _____ and

c. The % of the total market volume that remains with the food-contact articles is _____

☐ **21 CFR 25.32 (j)**

Is the FCS a component of a:

a. Repeat-use article? ☐ Yes ☐ No

b. Permanent or semi-permanent food-contact surface? ☐ Yes ☐ No

☐ **21 CFR 25.32 (k)**

☐ **21 CFR 25.32 (q)**

a. Is current FIFRA label attached? ☐ Yes ☐ No

b. Is the requested use essentially the same as the label? ☐ Yes ☐ No

If current FIFRA label has limitation on food-contact uses, provide a draft copy of a revised label you intend to submit to EPA to include food-contact uses.

☐ 21 CFR 25.32 (r)

2. Does your proposed food-contact use comply with the categorical exclusion criteria? ☒ Yes ☐ No
If no, go to section B below.

3. To the best of your knowledge, are there any extraordinary circumstances that would require your submission of an EA? *(see 21 CFR 25.21)* ☐ Yes ☒ No
If yes, go to section B below..

B - ENVIRONMENTAL ASSESSMENT

See Environmental Recommendations

1. If an EA is required, state that an EA has been prepared under 21 CFR 25.40, and is attached.
2. Environmental assessments are public documents and should not contain confidential information. Such information should be included in a separate section of the FCN, labeled confidential and summarized to the extent possible in the EA.

As indicated above, DuPont is claiming a categorical exclusion for applications in which the FCS is added in the size press. An EA that addresses the use of the FCS in the wet-end of paper production is provided as **Attachment 17**.

Part V - CERTIFICATION

The accuracy of the statements you make in this notice should reflect your best prediction of the anticipated facts regarding the chemical substance described herein. Any knowing and willful misinterpretation is subject to criminal penalty pursuant to 18 U.S.C. 1001.

The notifying party certifies that the information provided herein is accurate and complete to the best of his/her knowledge.

SIGNATURE OF AUTHORIZED OFFICIAL OR AGENT

(b)(6) [redacted]

TITLE	DATE
Partner	9/30/09

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: November 18, 2010

From: Biologist, Environmental Review Team (ERT)
Office of Food Additive Safety (HFS-246)

Subject: FCN No. 1027 – Fluorochemical copolymer as an oil and grease resistant treatment employed either prior to or after the sheet forming operation for paper and paperboard.

DuPont Chemicals and Fluoroproducts
E402/4313A – PO Box 80402
Wilmington, DE 19880

To: Division of Food Contact Notifications (HFS-275)
Attention: Paul Honigfort, Ph.D.
Through: William H Lamont, Acting Supervisor, ERT

The food contact substance (FCS) is 2-propenoic acid, 2-methyl-, polymer with 2-(diethylammonium)ethyl 2-methyl-2-propenoate, 2-propenoic acid and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl 2-methyl-2-propenoate, acetate.

The notifier submitted a claim of categorical exclusion under 21 CFR 25.32(i) for the proposed use of the FCS at the size press in production of finished food-packaging paper products. We have reviewed the claim of categorical exclusion and have concluded that categorical exclusion is warranted. The claim of categorical exclusion cites the section—21 CFR 25.32(i)—under which categorical exclusion is warranted, states compliance with the categorical exclusion criteria, and states that no extraordinary circumstances exist that require the submission of an environmental assessment.

Also, the notifier submitted an environmental assessment for the proposed use of the FCS added in production operations prior to formation of paper sheet. We have reviewed the environmental assessment, and we have prepared the attached Finding of No Significant Impact (FONSI) for FCN 1027. After this notification becomes effective, copies of this FONSI and the notifier's environmental assessment, dated September 9, 2010, may be made available to the public. We shall post digital transcriptions of the FONSI and the environmental assessment on the agency's public website.

Please let us know if there is any change in the identity or use of the food-contact substance.

Hoshing W. Chang

Attachment:
Finding of No Significant Impact

cc:
HFS-246 Chang
File: FCN No. 1027

FINDING OF NO SIGNIFICANT IMPACT
FOR

A food contact notification (FCN No. 1027), submitted by DuPont Chemicals and Fluoroproducts, to provide for the safe use of 2-propenoic acid, 2-methyl-, polymer with 2-(diethylammonium)ethyl 2-methyl-2-propenoate, 2-propenoic acid and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl 2-methyl-2-propenoate, acetate as an oil and grease resistant treatment for paper and paperboard employed either prior to or after the sheet forming operation.

The Environmental Review Team has determined that allowing this notification to become effective will not significantly affect the quality of the human environment and, therefore, will not require the preparation of an environmental impact statement. This finding is based on information, submitted by the notifier, in an environmental assessment, dated September 9, 2010, and other information known to the agency.

Prepared by _____Date: November 18, 2010
Hoshing W Chang, Ph.D.
Environmental Review Team
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Approved by _____Date: November 18, 2010
William H. Lamont, Acting Supervisor
Acting Supervisor, Environmental Review Team
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

ENVIRONMENTAL REVIEW

This memorandum may contain confidential or proprietary business information. It should be redacted before release to the public in response to a FOIA request.

FCN 1027

Phase I meeting: 10/6/2010

Environmental Reviewer: Hoshing Chang

Notifier: DuPont Chemicals and Fluoroproducts

Proposed FCS: 2-Propenoic acid, 2-methyl-, polymer with 2-(diethylamino)ethyl 2-methyl-2-propenoate, 2-propenoic acid and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl 2-methyl-2-propenoate, acetate

Proposed Use of the FCS: In item II.D.1, "The FCS copolymer is intended for use as an oil and grease resistant treatment for paper and paperboard used in contact with food. The polymer is currently cleared under FCN 885 for use either in the wet-end or at the size press at levels not to exceed 0.42 wt.% of polymer solids by weight of the paper." The notifier seeks the extension of usage rate in the wet-end of paper production up to 0.8 wt. % of polymer solids by weight of the paper.

Environmental Submission: A claim under 21 CFR 25.32 (i) (the notifier declared that the FCS is a componant of "coating," although the FCS is better described as a surface treatment after sheet formation) and an environmental assessment (EA), dated September 9, 2010.

Related Submissions: FMF799; FCN885

Environmental Review: The notifier declares that no environmental introduction is expected during the paper press manufacture process because all FCS remains with the treated paper. Therefore, the discussions in the EA focus chiefly on the potential environmental impacts of the FCS resulting from use and disposal from use in the wet-end paper production.

POTENTIAL ENVIRONMENTAL ROUTES OF ENTRY.

- Eighty-eight percent of the FCS is incorporated in paper and paperboard, based on provided information. The FCS contained in paper and paperboard is anticipated to be disposed in landfills or to be combusted.
- Twelve percent of the FCS, which is not incorporated in the paper and paperboard, is anticipated to be discharged in whitewater and subjected to on-site wastewater treatment. Ninety percent of the FCS in the whitewater, thus 10.8% of the FCS used, is absorbed by sludge in the on-site wastewater treatment plants. The FCS contained in the sludge, after treatment, is disposed by landfilling or by incinerating, with the ash from the incinerator disposed in landfills. Ten percent of the FCS in whitewater,

thus 1.2% of the FCS used, might enter the aquatic environment after the on-site wastewater treatment.

EXPECTED ENVIRONMENTAL EFFECTS. The FCS in solid wastes from wastewater sludge or incinerator ashes is managed in landfills so that no significant environmental entry is likely to occur that would pose environmental impacts.

The notifier estimated that the environmental introduction concentration (EIC) in the aquatic environment is 0.83 ppm and the expected environmental concentration (EEC) is 83 ppb, which is substantially lower than concentrations having observable eco-toxicity effects for aquatic organisms, based on information reported in attachment 4 of FMF799. Therefore, the environmental impacts due to disposal of the FCS through on-site wastewater treatment plants are anticipated to be insignificant.

Additionally, the FCS substitutes for other similar substances in the same use. Therefore, no significant cumulative impacts on the environment are anticipated.

Environmental Review Conclusion: We have reviewed the EA, dated September 9, 2010, and have concluded the FCN is acceptable for review as a notification on environmental grounds. We have reviewed the claim of categorical exclusion under 21 CFR 25.32 (i) and have concluded that the categorical exclusion is also warranted.

Please let us know if there is a change in the identity or proposed use of the FCS.

Status: Effective (January 12, 2011)

Part IV - ENVIRONMENTAL INFORMATION (21 CFR Part 25)

All FCN submissions must contain either a claim of categorical exclusion under 21 CFR 25.32 or an environmental assessment (EA) under 21 CFR 25.40.

A - CLAIM OF CATEGORICAL EXCLUSION

1. Cite the specific section(s) of the CFR under which the categorical exclusion is claimed:

☒ **21 CFR 25.32 (i)** When FCS is applied after sheet formation

a. Is the FCS a component of a coating? ☒ Yes ☐ No When FCS is applied after sheet formation

b. If no, the % of the FCS in the finished food-contact article is _____ and

c. The % of the total market volume that remains with the food-contact articles is _____

☐ **21 CFR 25.32 (j)**

Is the FCS a component of a:

a. Repeat-use article? ☐ Yes ☐ No

b. Permanent or semi-permanent food-contact surface? ☐ Yes ☐ No

☐ **21 CFR 25.32 (k)**

☐ **21 CFR 25.32 (q)**

a. Is current FIFRA label attached? ☐ Yes ☐ No

b. Is the requested use essentially the same as the label? ☐ Yes ☐ No

If current FIFRA label has limitation on food-contact uses, provide a draft copy of a revised label you intend to submit to EPA to include food-contact uses.

☐ 21 CFR 25.32 (r)

2. Does your proposed food-contact use comply with the categorical exclusion criteria?
If no, go to section B below. ☒ Yes ☐ No

3. To the best of your knowledge, are there any extraordinary circumstances that would require your submission of an EA? *(see 21 CFR 25.21)*
If yes, go to section B below.. ☐ Yes ☒ No

B - ENVIRONMENTAL ASSESSMENT
See Environmental Recommendations

1. If an EA is required, state that an EA has been prepared under 21 CFR 25.40, and is attached.

2. Environmental assessments are public documents and should not contain confidential information. Such information should be included in a separate section of the FCN, labeled confidential and summarized to the extent possible in the EA.

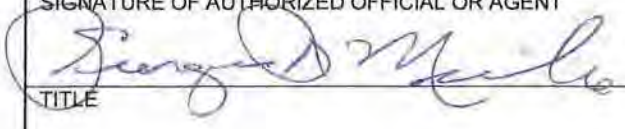
As indicated above, DuPont is claiming a categorical exclusion for applications in which the FCS is applied after sheet formation. An EA was previously submitted as part of DuPont's FCN 885 to address applications in which the FCS is used in the wet-end, *i.e.*, prior to sheet formation. A new EA is provided as **Attachment 10** of this notification to address the higher use level for the FCS proposed herein. Note that the test reports and literature references previously provided in support of the EA for FCN 885 are not attached to the new EA but are incorporated by reference.

Part V - CERTIFICATION

The accuracy of the statements you make in this notice should reflect your best prediction of the anticipated facts regarding the chemical substance described herein. Any knowing and willful misinterpretation is subject to criminal penalty pursuant to 18 U.S.C. 1001.

The notifying party certifies that the information provided herein is accurate and complete to the best of his/her knowledge.

SIGNATURE OF AUTHORIZED OFFICIAL OR AGENT



TITLE	DATE
	09-10-10

Attachment 10
Environmental Assessment

ENVIRONMENTAL ASSESSMENT

1. Date: September 9, 2010

2. Name of Applicant: DuPont Chemicals and Fluoroproducts

3. Address:

Experimental Station Laboratory
Bldg 402
Wilmington, DE 19880-0402

All communications on this matter are to be sent in care of Counsel for Notifier:
George G. Misko
Keller and Heckman LLP
1001 G Street N.W., Suite 500 West
Washington, D.C. 20001
Telephone: (202) 434-4170
Facsimile: (202) 434-4646
E-mail: misko@khlaw.com

4. Description of the Proposed Action

The action requested in this submission is the notification of the use of a copolymer produced by the polymerization of methacrylic acid with acrylic acid, diethylaminoethyl methacrylate, and 2-(perfluorohexyl)ethyl methacrylate. The product is generally referred to herein as the "food contact substance" (FCS) or as the copolymer.

The subject fluorinated copolymer is currently cleared under FCN 885 for use as an additive in paper and paperboard that may contact all types of food under Conditions of Use B through H and in microwave susceptor applications. The copolymer is intended to function as an oil and grease resistant treatment and may be added at either the wet-end or at the size press at levels not to exceed 0.42 wt. % of polymer solids by weight of the paper. The purpose of this notification is to increase the maximum treatment level to 0.8 wt. % of polymer solids by weight of paper when the polymer is added in the wet-end.

DuPont does not manufacture the paper and paperboard that will use the FCS as an oil and grease resistant treatment. Rather, DuPont plans to market the copolymer to manufacturers who will, in turn, use the product as an oil and grease resistant treatment in the manufacture of paper and paperboard.

The FCS will be sold to manufacturers who will use it to treat food-contact paper and paperboard in both the size press and wet end of the manufacturing process. With respect to the size press, no environmental effects are expected because the FCS remains fully with the

treated paper. Therefore, in keeping with guidance received from the FDA environmental review staff in the context of previous Notifications, the EA submitted with FCN 885 discussed the use of the FCS in the wet-end of paper production only. As the increase in use level proposed herein relates to the use of the FCS in the wet-end, this EA has been prepared to consider the impact of this increased application rate on environmental introductions as a result of the polymer's use.

As discussed more fully below, it is expected that the great majority of the copolymer will be incorporated into, and remain a component of, the finished paper and paperboard. To the extent that a fraction of the FCS does not become incorporated into the paper, it is expected that most of the remaining copolymer will be present as a component of the solid wastes generated in the waste water treatment process. These wastes are expected to be disposed of by either landfill or incineration. Only very low levels of the copolymer are expected to be present in effluent from the on-site waste water treatment facility. Aquatic toxicity data provided herewith indicate a wide margin of safety relative to the estimated release concentrations.

Food-contact articles made with paper containing the copolymer will be utilized in patterns corresponding to the national population density and will be widely distributed across the country. Therefore, it is anticipated that disposal will occur nationwide, with about 80% of the materials ultimately being deposited in land disposal sites, and about 20% incinerated.[1] The types of environments present at and adjacent to the disposal locations are the same as for the disposal of any other food-contact material in current use. Consequently, there are no special circumstances regarding the environment surrounding either the use or disposal of food-contact materials prepared using the FCS.

5. Identification of Chemical Substance that is the Subject of the Proposed Action

Chemical Name:	Methacrylic acid copolymer with acrylic acid, diethylaminoethyl methacrylate, and 2-(perfluorohexyl)ethyl methacrylate, acetate
CAS Registry Number:	1071022-26-8
CAS Registry Name:	Propenoic acid, 2-methyl-, polymer with 2-(diethylamino)ethyl 2-methyl-2-propenoate, 2-propenoic acid and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl 2-methyl-2-propenoate, acetate

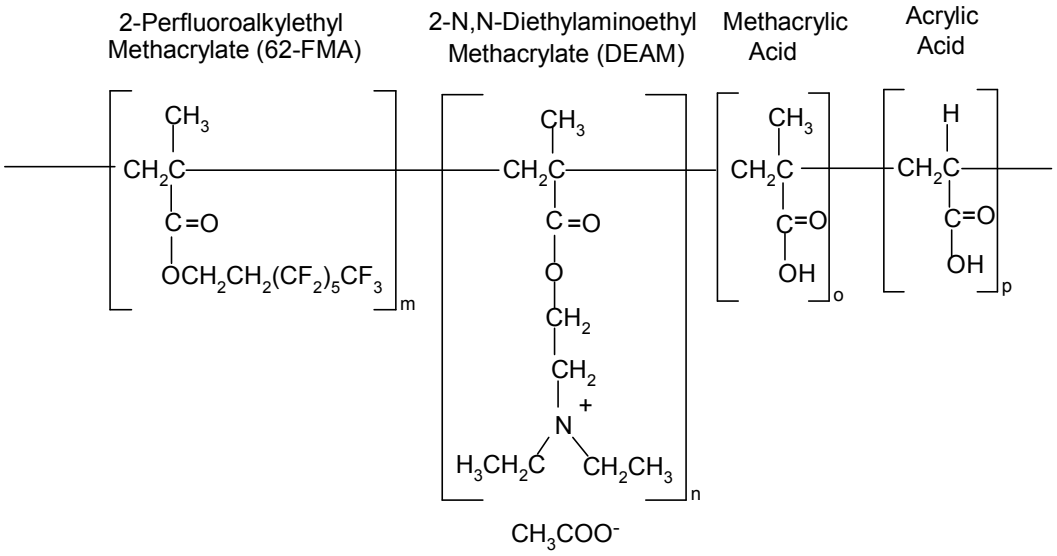
The starting monomers are further identified in the following table:

[1] "Characterization of Municipal Solid Waste in the United States, 1994 Update," EPA/530-S-94-042, U.S. Environmental Protection Agency, Washington, D.C. 20460.

CASRN	CAS Name	Common Name
2144-53-8	2-Propenoic acid, 2-methyl-, 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl ester	2-(perfluorohexyl)ethyl methacrylate
105-16-8	2-Propenoic acid, 2-methyl-, 2-(diethylamino)ethyl ester	Diethylaminoethyl methacrylate
79-41-4	2-Propenoic acid, 2-methyl-	Methacrylic acid
79-10-7	2-Propenoic acid	Acrylic acid

The molecular formula is as follows: $(C_{12}H_9F_{13}O_2)_m\ (C_{10}H_{19}O_2N)_n\ (C_4H_6O_2)_o\ (C_3H_4O_2)_p$.

The structural formula for the copolymer is given below:



The quantitative composition of the copolymer is confidential and thus not provided here, but is set forth in **Attachment 1** of this notification.

Analyses of representative samples of the copolymer by size exclusion chromatography (SEC) included in FCN 885 indicated weight-average molecular weights (Mw) of approximately 1.6 million, 1.8 million, and 577,000 Da, and number-average molecular weights (Mn) of approximately 80,000, 92,000, and 83,000 Da. Additional data submitted herewith indicate Mw values of 2.2 and 2.6 million and Mn values of 171,000 and 132,600 for more recently produced polymer samples.

The copolymer is supplied in the form of an aqueous dispersion containing approximately 19.5 wt.% to 25 wt.% of polymer solids. Data concerning the typical

concentrations of manufacturing impurities in the finished product is set forth in **Attachments 3-4** of this FCN. Typical physical properties are included in the specifications set forth in Attachment 12 of FCN 885.

6. Introduction of Substances into the Environment

1. Introduction of substances into the environment as a result of manufacture of the polymer

FDA has indicated that an EA ordinarily should focus on relevant environmental issues relating to the use and disposal from use, rather than the production, of FDA regulated articles. Moreover, information available to DuPont does not suggest that there are any extraordinary circumstances in this case indicative of any adverse environmental impact as a result of the manufacture of the copolymer. Consequently, information regarding the manufacturing site and compliance with the relevant emissions requirements is not provided here.

2. Introduction of substances into the environment as a result of use/disposal

As stated previously, based on available information, DuPont expects that the majority of the copolymer will be incorporated into, and remain a component of, finished paper produced using the product. To address the potential environmental introductions as a result of use of the FCS, we refer to information DuPont previously obtained from a paper manufacturer regarding typical manufacturing and waste treatment practices at paper mills that may use the FCS in the wet end. This information, which also was used in the Environmental Assessments for the Notifier's FCN Nos. 206, 311, 338, 646, and 885 is expected to be representative of other mills that may apply the treatment in the wet end. Thus, the following discussion of environmental releases at the site of use of the FCS is based upon the information supplied by this company. Note that the relevant calculations have been revised as appropriate to specifically address the FCS that is the subject of this notification.

Based on substantial experience with the use of fluorochemicals as oil and grease resistant treatments for paper and paperboard, it is estimated that at least 88% of the copolymer introduced into the pulp slurry will become incorporated into the finished paper. This includes the amount of copolymer that becomes incorporated into the paper on the first pass, based on both laboratory and plant experiments, as well as that which is incorporated into the pulp in additional passes and copolymer that becomes adsorbed to fiber "fines" that initially do not become part of the paper. These fines typically are recovered from the white water via filtration and recycled back into the papermaking process. (The economics of the papermaking process demand such recycling of fines.) The total polymer retention level of 88% is equal to the retention rate achieved with competitive fluorochemicals; thus, substituting the FCS in place of the currently used fluorochemicals is not expected to result in a loss of retention of the treatment on the paper.

To the extent that the FCS copolymer is not incorporated into the finished paper, it will be present in the white water from the process. While the white water is typically recycled through the process, the water will ultimately be released to the waste water treatment facility. The frequency of such releases will vary from plant to plant. DuPont believes that all of the paper mills that will use the product operate on-site treatment facilities. It is further estimated, again based on DuPont's knowledge of similar chemicals, that at least 90% of the copolymer will be removed from the waste water as a component of the solid wastes, or sludge, from the waste water treatment process. This figure is based on several considerations. First, the waste water treatment will begin with a filtration step that will remove fines containing adsorbed copolymer. Second, following the filtration, the aqueous stream is biotreated. Based on general experience in biotreatment, DuPont's knowledge indicates that acrylate polymers, such as the FCS copolymer, tend to go predominantly with the sludge. A third point is that once neutralized, the copolymer has extremely low solubility in water, as shown in Section 7 below; this further implies that the copolymer will tend to stay with the solids.

Thus, at least 90% of the copolymer going to the waste water is expected to be present in either the filtered solids or sludges recovered from the waste water. Based on DuPont's experience, these solid wastes are expected to be disposed of by means of either landfilling at suitable sites or by incineration, with the ash from the incinerator being disposed of via landfill.[2]

The maximum level at which the FCS copolymer may be present in the waste water following treatment may be estimated based on the foregoing considerations as follows. First, we will assume that all of the 12% of the polymer that may not be incorporated into the paper in either multiple passes or recycling of fines will be initially present in the waste water. Of the resulting amount, we will assume that 10% will remain in the waste water after removal via the filtered solids and sludge.

The calculations are based further on the following information regarding a typical large-scale paper production process, again supplied by DuPont's customer. Specifically, a total of 750 metric tons (750×10^3 kg) of treated paper is typically produced by the mill per day. As stated in the notification, the paper is intended to be treated with the FCS at a maximum level corresponding to a copolymer content of 0.8% polymer solids by weight of the paper. If 88% of the copolymer is retained in finished paper, the actual level of the FCS copolymer added to the pulp slurry will need to be adjusted for the retention rate; the adjusted amount may be estimated, relative to the dry paper weight, as (0.8% ÷ 0.88), or 0.91%. Thus,

[2] Guidance previously provided by FDA suggests that environmental releases resulting from soil application of sludges containing the FCS should be considered. As noted in DuPont's previous EAs, DuPont is not aware of a paper manufacturer who disposes of solid wastes by this means, so DuPont does not have information specifically dealing with this potential introduction. However, in the event that such sludges are used for soil amendment purposes, it is expected that the FCS copolymer will largely adhere to pulp fibers and thus will not be directly released to the surrounding environment.

the total amount of the FCS copolymer employed on a daily basis will be about 6825 kg.[3] If 12% of this amount does not become incorporated into the finished paper, a total of 819 kg will remain with the white water. Further, if 10% of this amount remains in the waste water after treatment, this will amount to approximately 82 kg of the copolymer per day.

In producing 750 metric tons of treated paper per day, the mill processes an estimated 18,000 gallons per minute (gpm) of waste water. This is equivalent to 26 million gallons per 24-hour day.[4] (This includes both the release of white water from the papermaking process and other aqueous plant wastes.) This is equivalent to 99 million liters (or kg) of water per day.[5] On this basis, if 82 kg of copolymer is present in the post-treatment waste water, the resulting concentration will be 0.83 part per million (ppm).[6]

It should be noted that the FCS is expected to be used in place of other oil and grease resistant treatments that are currently used in the production of food-contact paper and paperboard. Thus, the use of the copolymer in place of these materials will not result in any meaningful change in the nature or the amount of substances released into the environment upon the use of the product in the manufacture of food-contact paper and paperboard. In this regard, life-cycle studies of fluorotelomer-based products in North America including emissions from manufacture, use, and disposal concluded that the life cycle was only a minor (about 1%) contributor to total historic environmental emissions of PFCAs (Yarwood, 2007).

Disposal by the ultimate consumer of food-contact materials containing the subject substance will be primarily by sanitary landfill or incineration. The FCS consists of carbon, fluorine, oxygen, nitrogen, and hydrogen. These are elements that are commonly found in municipal solid waste. Based on the proposed use of the FCS, we have concluded that the FCS will make up a very small portion of the total municipal solid waste currently combusted, the FCS will not significantly alter the emissions from properly operating municipal solid waste combustors, and incineration of the FCS will not cause municipal waste combustors to threaten a violation of applicable emissions laws and regulations (40 C.F.R. Part 60 and/or relevant state and local laws).

In further regard to incineration emissions, studies of the thermal degradation of fluorotelomer-treated articles have demonstrated that such materials are destroyed under municipal incineration conditions and do not release any detectable perfluorocarboxylic acid or other volatile organic fluorine byproducts (Yamada, 2005).

Only extremely small amounts, if any, of the subject substance are expected to enter the environment as a result of the landfill disposal of food-contact articles. Leaching of the polymer to the environment is not anticipated considering the low solubility of the FCS in

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[3] 0.91% x 750 x 10^3 kg/day = 6825 kg/day.

[4] 18,000 gpm x 60 min/hr x 24 hr/day = 26 x 10^6 gal/day.

[5] 26 x 10^6 gal/day x 3.8 L/gal = 99 x 10^6 L/day.

[6] 82 kg polymer ÷ 99 x 10^6 kg water = 8.3 x 10^{-7} kg/kg = 0.83 ppm.

water. The likelihood of the FCS entering the environment due to leaching from either manufacturing wastes or disposal of food-contact materials is further diminished by consideration of EPA's regulations governing municipal solid waste landfills. EPA's regulations require new municipal solid-waste landfill units and lateral expansions of existing units to have composite liners and leachate collection systems to prevent leachate from entering ground and surface water, and to have groundwater monitoring systems. (40 C.F.R. Part 258.) Although owners and operators of existing active municipal solid waste landfills that were constructed before October 9, 1993 are not required to retrofit liners and leachate collection systems, they are required to monitor groundwater and to take corrective action as appropriate.

7. Fate of Emitted Substances in the Environment

The subject FCS is a high molecular weight polymer. The low levels of polymer that may be released to the environment thus are not expected to volatilize out of aqueous or terrestrial compartments. The polymer has been shown to be essentially non-soluble in water; experiments in which the solid polymer was ground and extracted with water at 20ºC resulted in no detectable polymer in the aqueous extract at a sensitivity equivalent to 6 mg polymer per liter of water. Based on the mass of sample extracted and volume of water, the water-extractable fraction of the polymer was less than 0.59 mg/g polymer.

FCS polymer released to the environment is not expected to readily degrade. In theory, polymer degradation through hydrolysis of side-chains could result in release of perfluorohexylethyl alcohol (62-FTOH), which could in turn be degraded to yield perfluorohexanoic acid (PFHxA) and / or perfluoropentanoic acid (PFPA). A conceptual degradation pathway of the copolymer is shown in Figure 1.

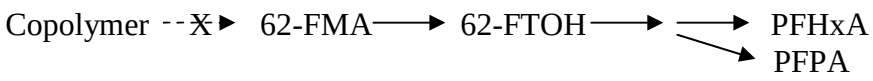

Figure 1. Conceptual environmental degradation pathway for FCS copolymer

In actuality, the polymer does not appear to break down to any significant extent. Studies of the biodegradation potential of fluoroacrylate polymer similar to the FCS in aerobic soils for two years indicate that the polymer is largely stable, and that degradation results in only minimal amounts of perfluorinated carboxylic acids (PFCAs) (Russell, 2008). Notably, as the FCS contains only 6-carbon perfluorinated alkyl chains, it cannot degrade to form perfluorooctanoic acid (PFOA) or other C8 or longer-chain perfluorinated species.

Physical/chemical/environmental properties of 62-FMA monomer, 62-FTOH, and PFHxA are summarized in Table 1 below.

Table 1. Physical, chemical and environmental properties of 62-FMA, 62-FTOH and PFHxA

Phys/Chm/Env Property	62-FMA	62-FTOH	PFHxA
Molecular weight	432.2	364.1	314.1
Boiling point (ºC @ 760 mm Hg)	--	171	157
Vapor pressure (mm Hg@ 25ºC)	10.5 @ 20ºC	0.2	1.98 (acid) $6x10^{-7}$ (salt)
Aqueous solubility (mg/L)	12	18.8	Soluble (salt)
Log Koa	ND	3.56, 5.26	Not measurable
Log Kaw	ND	-0.56	Negligible (salt)
Partition coefficient, Koc (mL/g)	ND	260	< 100 (est)
pKa	--	--	< 1 (est)
Degradation half-life, aerobic soil (d)	10-30 (est)	10-30	stable

The 62-FMA monomer was assessed for biodegradation using the Closed-Bottle Test (OECD guideline 301D). The test substance reached a maximum biodegradation of 15% during the 28 day period of the test. The test substance is not readily biodegradable. The report of this study is not provided with this Environmental Assessment because it contains confidential information; we have submitted it, however, for inclusion in the Notifier's Food Additive Master File No. 799.[7]

The monomer was also assessed for biodegradation using the Modified Strum Test (OECD guideline 301B). The test substance reached a maximum biodegradation of 3% during the 28 day period of the test, indicating that the test substance is not readily biodegradable. The report of this study has been submitted for inclusion in the Notifier's Food Additive Master File No. 799.

Experimental studies with 82-FTOH and 62-FTOH indicate that fluorotelomer alcohols are rapidly degraded aerobically to form perfluorcarboxylic acids with essentially complete conversion in a matter of weeks to months. The aerobic biodegradation of 62-FTOH in aerobic soil yields PFHxA and PFPA (Wang et al, 2005a; Wang et al, 2005b; Wang et al, 2009).

Available data on perfluorochemical (PFC) concentrations measured at a wastewater treatment plant (WWTP) indicate that activated carbon treatment yields variable results for different PFC contaminants. While treatment brought about a 79% reduction in PFOA concentration, perfluorohexanoic acid (PFHxA) levels were not decreased by activated carbon treatment at the 3M Cottage Grove facility (Oliaei et al., 2006). Higher concentrations of all detected PFCAs were found in effluent water samples taken at the main metro WWTP in St. Paul, Minnesota than in influent. (The C6 acid, PFHxA, was between 6 and 15 ppt in influent

[7] The studies referenced in this EA were previously referenced in the April 22, 2009 EA submitted in support of FCN 885; the study reports and literature citations are not attached here but were submitted at that time to FAMF 799 or attached to the EA for FCN 885. We incorporate the prior submission by reference.

and 22 ppt in effluent.) Sludge samples from the WWTP contained far higher concentrations of PFCs, including 10.3 ppb of PHFxA. (Oliaei, id.) On the other hand, fluorotelomer alcohols (FTOHs) have been shown to be partially broken down by microbial biodegradation in activated sludge, yielding shorter fluorinated carbon metabolites (Wang et al., 2005). Strong adsorption to the activated sludge and subsequent transformation greatly reduced partitioning of 82-FTOH or transformation products to air.

Modeling using the EpiSuite Volume 3.20 software predicted the following fate distribution for PFHxA in a wastewater treatment facility:

STP Overall Chemical Mass Balance:

	g PFHxA/h	mol PFHxA/h	percent
Influent	1.00E+01	3.2E-02	100.00
Primary sludge	2.89E+00	9.2E-03	28.95
Waste sludge	1.05E+00	3.3E-03	10.45
Primary volatilization	6.36E-00	2.0E-04	0.64
Settling volatilization	8.81E-02	2.8E-04	0.88
Aeration off gas	3.14E+00	1.0E-02	31.42
Primary biodegradation	9.33E-03	3.0E-05	0.09
Settling biodegradation	1.42E-03	4.5E-06	0.01
Aeration biodegradation	1.87E-02	6.0E-05	0.19
Final water effluent	2.74E+00	8.7E-03	27.37
Total removal	7.26E+00	2.3E-02	72.63
Total biodegradation	2.95E-02	9.4E-05	0.30

This indicates that over 72% of the PFHxA entering a wastewater treatment facility is projected to be removed from the effluent, largely due to binding to sludge and to off-gas.

A field study at a municipal WWTP to determine the mass flows of selected fluorochemicals demonstrated that activated sludge treatment decreased the mass flow of PFHxA, while mass flows were unchanged for PFOA and 6-2 fluorotelomer sulfonate, indicating that conventional wastewater treatment is not effective for removal of the latter compounds (Schultz et al., 2006).

PFHxA has very low biopersistence, does not bioaccumulate, and is not bioaccumulative according to global regulatory criteria. The half-life in the blood of monkeys is less than 24 hours for PFHxA (Chang, 2008; Noker 2001). Biopersistence screening studies that have been conducted on perfluorohexanoate and short-chain fluorotelomer alcohols are described in a Product Stewardship Detail brochure prepared by the Notifier for certain fluorotelomer-based products.[8] These studies indicate that the clearance time for the

[8] The Product Stewardship Detail Brochure is available on DuPont web site at http://www2.DuPont.com/Capstone/en_US/assets/downloads/DuPont_Capstone_Product_Stewardship_Detail_Document_072910.pdf

C6 compounds is dramatically less than longer-chain homologues (Figures 6a-6d). Moreover, published studies have shown that PFCAs with less than eight total carbon atoms, including PFHxA, are not bioaccumulative (Martin, 2003a, 2003b; Conder, 2008).

As shown in Item 6 above, the primary means by which the FCS copolymer is expected to be released into the environment is as a component of effluents from waste water treatment facilities. The expected introduction concentration (EIC) is estimated to be 0.83 ppm. This concentration, of course, will be greatly diluted once the effluent enters the receiving water. For the sake of conservatism, we will estimate the expected environmental concentration (EEC) using a river dilution factor of 10; that is, we will assume just a 10-fold dilution in the concentration of copolymer residues upon entering the receiving water. This will result in an EEC of 0.83 ppm ÷ 10 = 0.083 ppm, or 83 parts per billion (ppb).

We respectfully submit that the concentration at which the copolymer may be released in effluent from waste water treatment facilities is so low as to warrant no substantive concern. The conclusion that there will be no significant adverse impact is further supported by the aquatic toxicity data discussed in Item 8 below.

8. Environmental Effects of Released Substances

The potential release of the FCS at the worst-case level calculated above is not expected to result in any significant environmental effects. This expectation is based on the low levels at which the product may be introduced into the environment and on available data, which indicate that the product is essentially non-toxic to aquatic organisms.

As documentation of this lack of toxicity, we refer to the report of an acute aquatic toxicity study in *Daphnia magna* using the FCS described in this notification. The study demonstrated that the EC_{50} for the FCS is >120 mg/L. The report of this study is not provided with this Environmental Assessment because it contains confidential information; we have submitted it, however, for inclusion in the Notifier's Food Additive Master File No. 799.

DuPont advises that the EC_{50} is based on the concentration of the product as delivered, that is, on the wet basis. DuPont advises further that the FCS described in this notification is supplied as a 19.5% solids dispersion and was tested on this basis. Thus, the EC_{50} value obtained on the tested formulation may be converted to the corresponding value on the polymer solids basis. This results in an estimated LC_{50} in *Daphnia magna* of >23.4 mg/L.[9]

As discussed in Item 7 above, the maximum concentration at which the FCS copolymer is expected to be present in the environment, or the EEC, is 0.083 ppm, equivalent to 0.083 mg/L. The minimum LC_{50} calculated above, 23.4 mg/L, is more than 280 times the EEC.[10] Thus, it may readily be concluded that the potential release of copolymer will not lead

[9] (EC_{50} of >120 mg/L on liquid product basis) x (0.195 mg solids/mg liquid product) = EC_{50} of >23.4 mg/L on solids basis.

[10] EC_{50} of >23.4 mg/L (solids basis, as calculated in footnote 9) ÷ 0.083 mg/L = >280.

to any significant adverse environmental impacts. Moreover, as noted previously, this release will not represent a new environmental introduction of fluorochemical but, rather, a substitution for the corresponding release of other fluorochemicals that would otherwise be used for the same purpose. We respectfully submit, therefore, that no adverse environmental effects are expected as a result of this release.

In addition to the study discussed above, the 62-FMA monomer has been determined to have a 48-hour EC_{50} in *Daphnia magna* > 120 mg/L (based on nominal concentrations). The report of this study is not provided with this Environmental Assessment because it contains confidential information; we have submitted it, however, for inclusion in the Notifier's Food Additive Master File No. 799.

In addition to the studies conducted on the FCS polymer and starting fluoromethacrylate monomer, a large volume of ecotoxicity data are available on two related C6 perfluorinated compounds, PFHxA and 62-FTOH. These studies are summarized as follows:

Ecotoxicity Values for Perfluorohexanoic Acid

Fish:

- 96-hour LC50 (species not specified) > 100 mg/L (AGC Data, n.d.).
- NOEC (species not specified) > 100 mg/L (AGC Data, n.d.).
- 96-hour LC50 (fish, acid) = 13.8 mg/L (>estimated water solubility of the acid) (value modeled using EpiSuite Volume 3.20 software).
- 96-hour LC50 (fish, sodium salt) = 5623 mg/L (value modeled using EpiSuite Volume 3.20 software).

Invertebrates:

- 24-hour EC50 (*Daphnia magna*) > 100 mg/L (AGC Data, n.d.).
- 48-hour EC50 (*Daphnia magna*) > 100 mg/L (AGC Data, n.d.).
- NOEC (*Daphnia magna*) > 100 mg/L (AGC Data, n.d.)
- 48-hour LC50 (daphnids, acid) = 17.4 mg/L (>estimated water solubility of the acid) (value modeled using EpiSuite Volume 3.20 software).
- 48-hour LC50 (daphnids, sodium salt) = 5455 mg/L (value modeled using EpiSuite Volume 3.20 software).

Other:

- 72-hour EbC50 (algae) = 90 mg/L (AGC Data, n.d.).
- 0-72 hour ErC50 (algae) = 86 mg/L (AGC Data, n.d.).
- NOEC (algae) = 50 mg/L (AGC Data, n.d.)
- 96-hour EC50 (green algae, acid) = 12.5 mg/L (>estimated water solubility of the acid) (value modeled using EpiSuite Volume 3.20 software).
- 96-hour EC50 (green algae, sodium salt) = 3139 mg/L (value modeled using EpiSuite Volume 3.20 software).
- Flow cytometric measurements were used to investigate the toxic effect of perfluorobutanoic sulfonate (PFBS), perfluorooctane sulfonate (PFOS), perfluorohexanoic acid (PFHxA), perfluorooctanoic acid (PFOA), perfluorododecanoic acid (PFDoA) and perfluorotetradecanoic acid (PFTeA) on some membrane systems of the freshwater alga species *Scenedesmus obliquus*. Among the test compounds, PFOS, PFDoA and PFTeA inhibited algal growth rate in a concentration-dependent manner while PFBS, PFHxA and PFOA did not inhibit algal growth within the test concentration ranges. (Liu et al., 2008).

Ecotoxicity Values for 62-Fluorotelomer Alcohol

Fish

- 96-hour LC_{50} (*Pimephales promelas*) = 4.84 mg/L

Invertebrates

- 48-hour EC_{50} (*Daphnia magna*) = 7.84 mg/L

Other

- 72-hour EC_{50} [50% inhibition of growth (biomass)] in green algae *Pseudokirchneriella subcapitata* = 4.52 mg/L

These data confirm that C6 perfluoroalkyl compounds generally present a low concern level with respect to potential toxicity to organisms in the environment. The ecotoxicity values above are all multiple orders of magnitude greater than the EEC for the FCS of 0.083 mg/L. The reports of these studies are not provided with this Environmental

Assessment because they contain confidential information; however, we have submitted them for inclusion in the Notifier's Food Additive Master File No. 799.

In addition to the ecotoxicity data discussed above, the Comprehensive Toxicology Profile submitted in Attachment 22 of FCN 885 provides a large volume of data relevant to the mammalian oral toxicity and the genotoxic activity of the FCS and several potential impurities/degradation products of the FCS. An updated CTP is submitted as **Attachment 9** of this notification. The most directly relevant data are summarized below. Please see Attachment 22 of FCN 885 and **Attachment 9** of this notification for additional data regarding other FCS-related compounds.

Toxicity Studies on the FCS Polymer

- Acute oral toxicity: LD_{50} >5000 mg/kg for female rats.
- Bacterial mutagenicity: No evidence of mutagenic activity in *Salmonella typhimurium* strains TA98, TA100, TA1535 and TA1537 and *Escherichia coli* strain WP2uvrA in the absence and presence of metabolic activation
- Genotoxicity in mammalian cells *in vitro*: The FCS did not induce structural or numerical chromosome aberrations in the *in vitro* mammalian chromosome aberration test in human peripheral blood lymphocytes in either non-activated or S9-activated test systems.

Toxicity Studies on 2-Perfluorohexylethyl methacrylate (62-FMA) Monomer

- Acute oral toxicity: LD_{50} >5000 mg/kg for female rats.
- Bacterial mutagenicity: No evidence of mutagenic activity in *Salmonella typhimurium* strains TA98, TA100, TA1535 and TA1537 and *Escherichia coli* strain WP2uvrA in the absence and presence of metabolic activation
- Mutagenicity in mammalian cells *in vitro*: No evidence of mutagenic activity in the presence and absence of S9 metabolic activation in the L5178Y/TK+/- Mouse Lymphoma Mutagenesis Assay.
- Genotoxicity in mammalian cells *in vitro*: 62-FMA was found to induce structural aberrations in the *in vitro* mammalian chromosome aberration test in human peripheral blood lymphocytes in the absence of metabolic activation. 62-FMA did not induce structural aberrations in the presence of activation, and did not induce numerical aberrations in either non-activated or S9-activated test systems.
- Genotoxicity *in vivo*: 62-FMA did not induce a significant increase in micronuclei or structural or numerical chromosome aberrations in bone marrow of male or female ICR mice. 62-FMA was concluded to have no

genotoxic/clastogenic potential, and was concluded to be negative in this *in vivo* study.

In sum, the data summarized above regarding the FCS polymer and other C6-based fluorinated compounds indicates that the FCS is not expected to have adverse environmental impacts at the low levels at which it may be introduced into the environment as a result of its use in the production of food-contact paper and paperboard.

9. Use of Resources and Energy

The notified use of the FCS copolymer is expected to compete with, and to some degree replace, other fluorochemicals that are already used in the manufacture of paper and paperboard. Other fluorochemicals that are specifically listed in Section 176.170 of the food additive regulations for this purpose include, *e.g.*, perfluoroalkyl acrylate copolymer (CAS Reg. No. 92265-81-1), in addition to the Notifier's products that are cleared under FCN Nos. 206, 311, 338, and 646. For this reason, the use of the FCS in the production of food-contact paper and paperboard is not expected to result in a net increase in the use of energy and resources.

10. Mitigation Measures

As discussed above, no significant adverse environmental impacts are expected to result from the manufacture of food-contact paper and paperboard using the FCS. This is largely due to the low levels at which the copolymer may be introduced into the environment and the available data indicating low toxicity to organisms in the environment with regard to the polymer itself and related C6 fluorinated compounds. This conclusion is further supported by the similarity of the FCS to the fluorochemicals it is intended to replace. Thus, the use of the copolymer as proposed is not reasonably expected to result in any new environmental problem requiring mitigation measures of any kind.

11. Alternatives to the Proposed Action

No potential adverse environmental effects are identified herein which would necessitate alternative actions to that proposed in this request. Therefore, alternatives to the proposed action need not be considered.

12. List of Preparers

Holly H. Foley, Staff Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Washington, DC 20001.

John C. Sworen, Senior Research Chemist, DuPont Chemicals and Fluoroproducts, Experimental Station – E402/4313A, Rt. 141 and Henry Clay, PO Box 80402, Wilmington, DE 19880-0402.

13. Certification

The undersigned official certifies that the information presented is true, accurate, and complete to the best of his knowledge.

Date: 09-10-10

George G. Misko
Counsel for DuPont Chemical Solutions Enterprise

14. References

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15. Attachments

Copies of the references cited above are attached to the April 22, 2009 EA for FCN 885.

Memorandum

Date: June 24, 2008

From: Chemist, Environmental Review Team (ERT)
Office of Food Additive Safety (HFS-246)

Subject: FCN No. 820 – Copolymer of perfluorohexylethyl acrylate and polyethylene glycol monoacrylate as an oil or grease resistant treatment of paper and paperboard intended for food-contact use.

Daikin America, Inc.
PO Box 2252
Decatur, AL 35609

To: Division of Food Contact Notifications (HFS-275)
Attention: Mark A. Hepp, Ph.D.
Through: Layla I. Batarseh, Ph.D., Supervisor, ERT _____

The food contact substance (FCS) is 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). The FCS is applied following the sheet forming operation during manufacture of the paper products.

We have reviewed the claim of categorical exclusion for the above referenced notification and have concluded that categorical exclusion is warranted. The claim of categorical exclusion cites the section, 21 *CFR* 25.32 (i), under which categorical exclusion is warranted, states compliance with the categorical exclusion criteria, and states that no extraordinary circumstances exist that require the submission of an environmental assessment.

Please let us know if there is any change in the identity or use of the food-contact substance.

William H Lamont

cc:

HFS-246 Lamont
File: FCN No. 820

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

AD

Date: June 24, 2008

From: Chemist, Environmental Review Team (ERT)
Office of Food Additive Safety (HFS-246)

Subject: FCN No. 820 – Copolymer of perfluorohexylethyl acrylate and polyethylene glycol monoacrylate as an oil or grease resistant treatment of paper and paperboard intended for food-contact use.

Daikin America, Inc.
PO Box 2252
Decatur, AL 35609

To: Division of Food Contact Notifications (HFS-275)
Attention: Mark A. Hepp, Ph.D.
Through: Layla I. Batarseh, Ph.D., Supervisor, ERT (b)(6) [redacted]

The food contact substance (FCS) is 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). The FCS is applied following the sheet forming operation during manufacture of the paper products.

We have reviewed the claim of categorical exclusion for the above referenced notification and have concluded that categorical exclusion is warranted. The claim of categorical exclusion cites the section, 21 *CFR* 25.32 (i), under which categorical exclusion is warranted, states compliance with the categorical exclusion criteria, and states that no extraordinary circumstances exist that require the submission of an environmental assessment.

Please let us know if there is any change in the identity or use of the food-contact substance.

(b)(6) [redacted]
William H Lamont

cc:

HFS-246 Lamont
File: FCN No. 820

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ENVIRONMENTAL REVIEW

This memorandum may contain confidential or proprietary business information. It should be redacted before release to the public in response to a FOIA request.

FCN 820

Date: April 30, 2008

Notifier: Daikin America, Inc.
PO Box 2252
Decatur, AL 35609

Proposed food contact substance (FCS): 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). (b) (4) [redacted]

Proposed use of FCS: As an oil-repellent, at a concentration not to exceed 0.2 percent-by-weight, for use in paper and paperboard.

Environmental submission: Claim of categorical exclusion under 21 CFR 25.32 (i).

Environmental history: None for the specific FCS.

(b) (4) [redacted]

[1] Attachment 9 and other disclosures in the notification show that the FCS is formulated as a 20 percent-by-weight aqueous solution.

[2] See the cover letter, dated April 1, 2008, prepared by the legal counsel representing Daikin America.

(b) (4) [redacted]

(b) (4)

[redacted]

We recognize that fluorochemicals are expensive. It follows also that to be effective as a repellent a fluorochemical must be essentially substantive to the fibers forming the finished paper. Nonetheless, we also know from prior environmental reviews of other (expensive and effective) fluorochemicals used similarly that substantial losses to water do occur even in cases where the substantivity is chemically enhanced.

The FCS has two functional components. The perfluorocarbon moiety provides the repellency, and the polyethylene glycol moiety provides the water solubility. (b) (4)

[redacted]

We understand the underlying intent of the notifier's admission that the FCS may be used in paper-based repeat-use articles although they are not aware of any such use but do not want to preclude such a possibility. Of course, a hypothetical use does not pose a significant environmental impact.

(b) (4)

[redacted]

Oil-repellent fluorochemicals in paper are not an impediment to recycling of paper. However, we believe that recycling of oil-repellent paper following disposal from uses in contact with food is not likely. Paper-based packaging containing residues of oily and fatty food are not acceptable for recycling regardless of whether oil-repellent fluorochemicals are present. Only clean paper-based products are accepted in collection programs for recycling of paper.

Incineration of waste paper treated with fluorochemicals is not expected to pose a significant impact on emissions into the atmosphere. To impart repellency, fluorochemical treatments are usually applied to paper at very low concentrations, which are not reasonably expected to cause or threaten to cause violation of air emission standards when the paper waste is subsequently incinerated.

(b) (4)

Please let us know if there is a change in the identity or proposed use of the FCS.

William H Lamont

Date: June 6, 2008

Comment: The legal counsel acting on behalf of the notifier informed the agency in a letter, dated June 5, 2008, (b) (4) for application of the FCS only at the size press following formation of the paper sheet.

The notifier's response regarding our environmental request to clarify use of the FCS is adequate.

William H Lamont

Status: Effective

Part IV - ENVIRONMENTAL INFORMATION (21 CFR Part 25)

All FCN submissions must contain either a claim of categorical exclusion under 21 CFR 25.32 or an environmental assessment (EA) under 21 CFR 25.40.

A - CLAIM OF CATEGORICAL EXCLUSION

1. Cite the specific section(s) of the CFR under which the categorical exclusion is claimed:

☒ **21 CFR 25.32 (i)**

a. Is the FCS a component of a coating? ☐ Yes ☒ No

b. If no, the % of the FCS in the finished food-contact article is 0.2% dry weight basis and

c. The % of the total market volume that remains with the food-contact articles is 100%

☐ **21 CFR 25.32 (j)**

Is the FCS a component of a:

a. Repeat-use article? ☐ Yes ☐ No

b. Permanent or semi-permanent food-contact surface? ☐ Yes ☐ No

☐ **21 CFR 25.32 (k)**

☐ **21 CFR 25.32 (q)**

a. Is current FIFRA label attached? ☐ Yes ☐ No

b. Is the requested use essentially the same as the label? ☐ Yes ☐ No

If current FIFRA label has limitation on food-contact uses, provide a draft copy of a revised label you intend to submit to EPA to include food-contact uses.

☐ 21 CFR 25.32 (r)

2. Does your proposed food-contact use comply with the categorical exclusion criteria? ☒ Yes ☐ No
If no, go to section B below.

3. To the best of your knowledge, are there any extraordinary circumstances that would require your submission of an EA? *(see 21 CFR 25.21)* ☐ Yes ☒ No
If yes, go to section B below.

B - ENVIRONMENTAL ASSESSMENT

See Environmental Recommendations

1. If an EA is required, state that an EA has been prepared under 21 CFR 25.40, and is attached.

2. Environmental assessments are public documents and should not contain confidential information. Such information should be included in a separate section of the FCN, labeled confidential and summarized to the extent possible in the EA.

Part V - CERTIFICATION

The accuracy of the statements you make in this notice should reflect your best prediction of the anticipated facts regarding the chemical substance described herein. Any knowing and willful misinterpretation is subject to criminal penalty pursuant to 18 U.S.C. 1001.

The notifying party certifies that the information provided herein is accurate and complete to the best of his/her knowledge.

SIGNATURE OF AUTHORIZED OFFICIAL OR AGENT [redacted]

Devon Wm. Hill

TITLE	DATE
Partner, Keller and Heckman LLP	4-1-08

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: July 31, 2008

From: Environmental Toxicologist/Environmental Review Team (ERT)
Office of Food Additive Safety (HFS-246)

Subject: FCN No. 827 – Copolymer of perfluorohexylethyl acrylate, and other acrylates for use as an oil or grease resistant treatment of paper and paperboard intended for food-contact use.

Daikin America, Inc.
P. O. Box 2252
Decatur, AL 35609

To: Division of Food Contact Notifications (HFS-275)
Attention: Paul Honigfort, Ph.D.
Through: Layla I. Batarseh, Ph.D., Supervisor, ERT _____

The food-contact substance (FCS) is 1-propenoic acid, 2-hydroxyethyl ester, polymer with α-(1-oxo-2-propen-1-yl)-ω-hydroxypoly(oxy-1,2-ethanediyl), α -(1-oxo-2-propen-1-yl)-ω-[(1-oxo-2-propen-1-yl)oxy]poly(oxy-1,2-ethanediyl) and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl 2-propenoate. The FCS is applied at the size press.

We have reviewed the claim of categorical exclusion for the above referenced food contact notification and have concluded that the categorical exclusion is warranted. The claim of categorical exclusion cites the section under which categorical exclusion is warranted, 21 *CFR* 25.32 (i), states compliance with the categorical exclusion criteria, and states that no extraordinary circumstances exist that would require the submission of an environmental assessment.

Please let us know if there is any change in the identity or use of the food-contact substance.

Kiros Hailemariam, Ph.D.

I have reviewed this document and accept it as final:

_____

Layla I. Batarseh, Ph.D. Date: July 31, 2008
Environmental Review Team/Supervisor
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

cc:
HFS-246 File: FCN No. 827

HFS-246: KHailemariam: khm: 7/18/08 H:\EIS Docs\FCN\FCN827_E_CatEx.doc
FT: KHailemariam: khm: 7/31/08 P:\EIS Documents\FCN\FCN 801-1000\FCN827_E_CatEx.doc

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: July 31, 2008

AD

From: Environmental Toxicologist/Environmental Review Team (ERT)
Office of Food Additive Safety (HFS-246)

Subject: FCN No. 827 – Copolymer of perfluorohexylethyl acrylate, and other acrylates for use as an oil or grease resistant treatment of paper and paperboard intended for food-contact use.

Daikin America, Inc.
P. O. Box 2252
Decatur, AL 35609

To: Division of Food Contact Notifications (HFS-275)
Attention: Paul Honigfort, Ph.D.
Through: Layla I. Batarseh, Ph.D., Supervisor, ERT _____

The food-contact substance (FCS) is 1-propenoic acid, 2-hydroxyethyl ester, polymer with α-(1-oxo-2-propen-1-yl)-ω-hydroxypoly(oxy-1,2-ethanediyl), α -(1-oxo-2-propen-1-yl)-ω-[(1-oxo-2-propen-1-yl)oxy]poly(oxy-1,2-ethanediyl) and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl 2-propenoate. The FCS is applied at the size press.

We have reviewed the claim of categorical exclusion for the above referenced food contact notification and have concluded that the categorical exclusion is warranted. The claim of categorical exclusion cites the section under which categorical exclusion is warranted, 21 *CFR* 25.32 (i), states compliance with the categorical exclusion criteria, and states that no extraordinary circumstances exist that would require the submission of an environmental assessment.

Please let us know if there is any change in the identity or use of the food-contact substance.

(b) (6) [redacted]
Kiros Hailemariam, Ph.D.

I have reviewed this document and accept it as final:

(b) (6) [redacted]

Layla I. Batarseh, Ph.D.
Environmental Review Team/Supervisor
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Date: July 31, 2008

cc:
HFS-246 File: FCN No. 827

HFS-246: KHailemariam: khm: 7/18/08 H:\EIS Docs\FCN\FCN827_E_CatEx.doc
FT: KHailemariam: khm: 7/31/08 P:\EIS Documents\FCN\FCN 801-1000\FCN827_E_CatEx.doc

Part IV - ENVIRONMENTAL INFORMATION (21 CFR Part 25)

All FCN submissions must contain either a claim of categorical exclusion under 21 CFR 25.32 or an environmental assessment (EA) under 21 CFR 25.40.

A - CLAIM OF CATEGORICAL EXCLUSION

1. Cite the specific section(s) of the CFR under which the categorical exclusion is claimed:

☒ **21 CFR 25.32 (i)**

a. Is the FCS a component of a coating? ☐ Yes ☒ No

b. If no, the % of the FCS in the finished food-contact article is 0.4% dry weight basis and

c. The % of the total market volume that remains with the food-contact articles is 100%

☐ **21 CFR 25.32 (j)**

Is the FCS a component of a:

a. Repeat-use article? ☐ Yes ☐ No

b. Permanent or semi-permanent food-contact surface? ☐ Yes ☐ No

☐ **21 CFR 25.32 (k)**

☐ **21 CFR 25.32 (q)**

a. Is current FIFRA label attached? ☐ Yes ☐ No

b. Is the requested use essentially the same as the label? ☐ Yes ☐ No

If current FIFRA label has limitation on food-contact uses, provide a draft copy of a revised label you intend to submit to EPA to include food-contact uses.

☐ 21 CFR 25.32 (r)

2. Does your proposed food-contact use comply with the categorical exclusion criteria? ☒ Yes ☐ No
If no, go to section B below.

3. To the best of your knowledge, are there any extraordinary circumstances that would require your submission of an EA? *(see 21 CFR 25.21)* ☐ Yes ☒ No
If yes, go to section B below..

B - ENVIRONMENTAL ASSESSMENT

See Environmental Recommendations

1. If an EA is required, state that an EA has been prepared under 21 CFR 25.40, and is attached.

2. Environmental assessments are public documents and should not contain confidential information. Such information should be included in a separate section of the FCN, labeled confidential and summarized to the extent possible in the EA.

Part V - CERTIFICATION

The accuracy of the statements you make in this notice should reflect your best prediction of the anticipated facts regarding the chemical substance described herein. Any knowing and willful misinterpretation is subject to criminal penalty pursuant to 18 U.S.C. 1001.

The notifying party certifies that the information provided herein is accurate and complete to the best of his/her knowledge.

SIGNATURE OF AUTHORIZED OF[redacted]

Devon Wm. Hill

TITLE

Partner, Keller and Heckman LLP

DATE

5-08-08

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: March 24, 2009

From: Chemist, Environmental Review Team (ERT)
Office of Food Additive Safety (HFS-246)

Subject: FCN No. 888 – Copolymer of perfluorohexylethyl acrylate and other acrylates as an oil and grease resistant treatment of paper and paperboard intended for single-use food-contact articles.

Daikin America, Inc.
PO Box 2252
Decatur, AL 35609

To: Division of Food Contact Notifications (HFS-275)
Attention: Paul Honigfort, Ph.D.
Through: Layla I. Batarseh, Ph.D., Supervisor, ERT _____

The food-contact substance (FCS) is 2-propenoic acid, 2-hydroxyethyl ester, polymer with α-(1-oxo-2-propen-1-yl)-ω-hydroxypoly(oxy-1,2-ethanediyl), α-(1-oxo-2-propen-1-yl)-ω-[(1-oxo-2-propen-1-yl)oxy]poly(oxy-l,2-ethanediyl), and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl 2-propenoate. The FCS is applied following the sheet forming operation during manufacture of the paper products.

We have reviewed the claim of categorical exclusion for the above referenced notification and have concluded that categorical exclusion is warranted. The claim of categorical exclusion cites the section, 21 *CFR* 25.32 (i), under which categorical exclusion is warranted, states compliance with the categorical exclusion criteria, and states that no extraordinary circumstances exist that require the submission of an environmental assessment.

Please let us know if there is any change in the identity or use of the food-contact substance.

William H Lamont

cc:

HFS-246 Lamont
File: FCN No. 888

HFS-246:WHLamont:whl:3/24/09 H:\FCN\FCN888_E_CatEx.doc
FT:WHLamont:whl:3/24/09 P:\EIS Documents\FCN\FCN801-1000\FCN888_E_CatEx.doc

Memorandum

Date: March 24, 2009

From: Chemist, Environmental Review Team (ERT)
Office of Food Additive Safety (HFS-246)

Subject: FCN No. 888 – Copolymer of perfluorohexylethyl acrylate and other acrylates as an oil and grease resistant treatment of paper and paperboard intended for single-use food-contact articles.

Daikin America, Inc.
PO Box 2252
Decatur, AL 35609

To: Division of Food Contact Notifications (HFS-275)
Attention: Paul Honigfort, Ph.D.
Through: Layla I. Batarseh, Ph.D., Supervisor, ERT LIB

The food-contact substance (FCS) is 2-propenoic acid, 2-hydroxyethyl ester, polymer with α-(1-oxo-2-propen-1-yl)-ω-hydroxypoly(oxy-1,2-ethanediyl), α-(1-oxo-2-propen-1-yl)-ω-[(1-oxo-2-propen-1-yl)oxy]poly(oxy-1,2-ethanediyl), and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl 2-propenoate. The FCS is applied following the sheet forming operation during manufacture of the paper products.

We have reviewed the claim of categorical exclusion for the above referenced notification and have concluded that categorical exclusion is warranted. The claim of categorical exclusion cites the section, 21 *CFR* 25.32 (i), under which categorical exclusion is warranted, states compliance with the categorical exclusion criteria, and states that no extraordinary circumstances exist that require the submission of an environmental assessment.

Please let us know if there is any change in the identity or use of the food-contact substance.

(b) (4) [redacted]

William H Lamont

cc:

HFS-246 Lamont
File: FCN No. 888

HFS-246:WHLamont:whl:3/24/09 H:\FCN\FCN888_E_CatEx.doc
FT:WHLamont:whl:3/24/09 P:\EIS Documents\FCN\FCN801-1000\FCN888_E_CatEx.doc

ENVIRONMENTAL REVIEW

This memorandum may contain confidential or proprietary business information. It should be redacted before release to the public in response to a FOIA request.

FCN 888

Date: March 11, 2009

Notifier: Daikin America, Inc.
Post Office Box 2252
Decatur, AL 35609

Proposed food contact substance (FCS): 2-Propenoic acid, 2-hydroxyethyl ester, polymer with α-(1-oxo-2-propen-1-yl)-ω-hydroxypoly(oxy-1,2-ethanediyl), α-(1-oxo-2-propen-1-yl)-ω-[(1-oxo-2-propen-1-yl)oxy]poly(oxy-l,2-ethanediyl), and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl 2-propenoate.

Proposed use of FCS: As an additive, at a concentration not to exceed 0.4 percent-by-weight, to impart grease and oil resistance to paper and paperboard that will be used in food-contact applications with microwave susceptors.

Environmental submission: Claim of categorical exclusion citing 21 CFR 25.32 (i).

Environmental history: FCN 827 directly preceded this notification and provided for the use of the FCS under Conditions of Use A through H. The FCS is once again notified to expand its use to microwave susceptor applications, which is included under Condition of Use J. (b) (4) [redacted]

Environmental review: The FCS belongs to a class of fluorochemicals that have longstanding uses to impart water, oil, and grease resistance to materials such as paper. As water- and oil-repellent agents, these fluorochemicals are effective at low concentrations and are adaptable to water-based methods of manufacturing paper. Specifically, the FCS is made adaptable to processes for manufacturing paper by incorporating into the polymeric composition a non-ionic hydrophilic component, which makes the fluorochemical soluble in water.

(b) (4) [redacted]

(b) (4)

(b) (4)

The notifier stipulated that the intended use of the FCS would occur at a stage in the paper manufacturing process where the FCS would be applied to an essentially finished paper. Treatment of the nearly finished paper has the environmental advantage that the application of the FCS is directly controlled with little opportunity for loss during its use.

We understand that the notifier's intent to propose that the FCS might be used in paper-based repeat-use articles serves only to intensify dietary exposure for the purpose of demonstrating a margin of food safety. Although such use is unknown to the notifier by admission, the notifier does not want to preclude such a possibility.

"Between the idea
And the reality
…
Falls the Shadow"
(TS Eliot, *The Hollow Men*)

We do not dwell on this point. A hypothetical use does not pose a significant environmental impact.

Oil-repellent fluorochemicals in paper are not an impediment to recycling of paper. However, we believe that recycling of oil-repellent paper following disposal from uses in contact with food is not likely. Paper-based packaging containing residues of oily and fatty food are not acceptable for recycling regardless of whether oil-repellent fluorochemicals are present. Only clean paper-based products are accepted in collection programs for recycling of paper.

Incineration of waste paper treated with fluorochemicals is not expected to pose a significant impact on emissions into the atmosphere. To impart repellency, fluorochemical treatments are usually applied to paper at very low concentrations, which are not reasonably expected to cause or threaten to cause violation of air emission standards when the paper waste is subsequently incinerated.

To be effective as a repellent, a fluorochemical must be essentially substantive to the fibers forming the finished paper. Consequently, the FCS is expected to remain with the finished food-packaging material through use by consumers. Moreover, we believe that such packaging

would be discarded into landfills and that introduction, if any, of the FCS, its decomposition products, and lixiviated impurities into the environment following disposal from use is not anticipated to pose a significant environmental impact due to the very small quantities of emissive substances and regulation controlling landfill effluents.

The notifier cited section 25.32 (i) of 21 CFR under which categorical exclusion was claimed, stated compliance with the criteria for categorical exclusion, and stated that no extraordinary circumstances exist that require submission of an environmental assessment.

Conclusion: We have reviewed the claim of categorical exclusion under 21 CFR 25.32 (i) for the above referenced notification, and we have concluded that the categorical exclusion is warranted.

Please let us know if there is a change in the identity or proposed use of the FCS.

William H Lamont

Status: Effective June 18, 2009.

would be discarded into landfills and that introduction, if any, of the FCS, its decomposition products, and lixiviated impurities into the environment following disposal from use is not anticipated to pose a significant environmental impact due to the very small quantities of emissive substances and regulation controlling landfill effluents.

The notifier cited section 25.32 (i) of 21 CFR under which categorical exclusion was claimed, stated compliance with the criteria for categorical exclusion, and stated that no extraordinary circumstances exist that require submission of an environmental assessment.

Conclusion: We have reviewed the claim of categorical exclusion under 21 CFR 25.32 (i) for the above referenced notification, and we have concluded that the categorical exclusion is warranted.

Please let us know if there is a change in the identity or proposed use of the FCS.

(b) (6)
[redacted]

William H Lamont

Status: Effective June 18, 2009.

Part IV - ENVIRONMENTAL INFORMATION (21 CFR Part 25)

All FCN submissions must contain either a claim of categorical exclusion under 21 CFR 25.32 or an environmental assessment (EA) under 21 CFR 25.40.

A - CLAIM OF CATEGORICAL EXCLUSION

1. Cite the specific section(s) of the CFR under which the categorical exclusion is claimed:

☒ **21 CFR 25.32 (i)**

a. Is the FCS a component of a coating? ☐ Yes ☒ No

b. If no, the % of the FCS in the finished food-contact article is 0.4% dry weight basis and

c. The % of the total market volume that remains with the food-contact articles is 100%

☐ **21 CFR 25.32 (j)**

Is the FCS a component of a:

a. Repeat-use article? ☐ Yes ☐ No

b. Permanent or semi-permanent food-contact surface? ☐ Yes ☐ No

☐ **21 CFR 25.32 (k)**

☐ **21 CFR 25.32 (q)**

a. Is current FIFRA label attached? ☐ Yes ☐ No

b. Is the requested use essentially the same as the label? ☐ Yes ☐ No

If current FIFRA label has limitation on food-contact uses, provide a draft copy of a revised label you intend to submit to EPA to include food-contact uses.

☐ 21 CFR 25.32 (r)

2. Does your proposed food-contact use comply with the categorical exclusion criteria? ☒ Yes ☐ No
If no, go to section B below.

3. To the best of your knowledge, are there any extraordinary circumstances that would require your submission of an EA? *(see 21 CFR 25.21)* ☐ Yes ☒ No
If yes, go to section B below..

B - ENVIRONMENTAL ASSESSMENT

See Environmental Recommendations

1. If an EA is required, state that an EA has been prepared under 21 CFR 25.40, and is attached.

2. Environmental assessments are public documents and should not contain confidential information. Such information should be included in a separate section of the FCN, labeled confidential and summarized to the extent possible in the EA.

Part V - CERTIFICATION

The accuracy of the statements you make in this notice should reflect your best prediction of the anticipated facts regarding the chemical substance described herein. Any knowing and willful misinterpretation is subject to criminal penalty pursuant to 18 U.S.C. 1001.

The notifying party certifies that the information provided herein is accurate and complete to the best of his/her knowledge.

SIGNATURE OF AUTHORIZED OFFICIAL OR AGENT

(b) (6) [redacted]

Devon Wm. Hill

TITLE

Partner, Keller and Heckman LLP

DATE

2-13-09

Memorandum

Date: October 28, 2009

From: Acting Supervisor, Environmental Review Team (ERT)
Office of Food Additive Safety (HFS-246)

Subject: FCN No. 933 - Fluorochemical copolymer as an oil and grease resistant treatment for paper and paperboard.

Daikin America, Inc.
905 State Docks Road
Decatur, AL 35601

To: Division of Food Contact Notifications (HFS-275)
Attention: Kelly Randolph, D.V.M., M.P.H.

The food contact substance (FCS) is 2-propenoic acid, 2-methyl-, polymer with 2-hydroxyethyl 2-methyl-2-propenoate, α-(1-oxo-2-propen-1-yl)-ω-hydroxypoly(oxy-1,2-ethanediyl), and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl 2-propenoate, sodium salt. The FCS is employed at the size press or is added prior to sheet formation in the production of paper and paperboard.

The notifier submitted a claim of categorical exclusion under 21 CFR 25.32(i) for the proposed use of the FCS at the size press in production of paper products. We have reviewed the claim of categorical exclusion and have concluded that categorical exclusion is warranted. The claim of categorical exclusion cites the section—21 CFR 25.32(i)—under which categorical exclusion is warranted, states compliance with the categorical exclusion criteria, and states that no extraordinary circumstances exist that require the submission of an environmental assessment for the proposed use of the FCS at the size press.

Also, the notifier submitted an environmental assessment for the proposed use of the FCS added in production operations prior to formation of paper sheet. We have reviewed the environmental assessment, and we have prepared the attached Finding of No Significant Impact (FONSI) for FCN 933. After this notification becomes effective, copies of this FONSI and the notifier's environmental assessment, dated August 31, 2009, may be made available to the public. We shall post digital transcriptions of the FONSI and the environmental assessment on the agency's public website.

Please let us know if there is any change in the identity or use of the food-contact substance.

William H. Lamont

Attachment:
Finding of No Significant Impact

(b) (5)

Memorandum

Date: October 28, 2009

From: Acting Supervisor, Environmental Review Team (ERT)
Office of Food Additive Safety (HFS-246)

Subject: FCN No. 933 - Fluorochemical copolymer as an oil and grease resistant treatment for paper and paperboard.

Daikin America, Inc.
905 State Docks Road
Decatur, AL 35601

To: Division of Food Contact Notifications (HFS-275)
Attention: Kelly Randolph, D.V.M., M.P.H.

The food contact substance (FCS) is 2-propenoic acid, 2-methyl-, polymer with 2-hydroxyethyl 2-methyl-2-propenoate, α-(1-oxo-2-propen-1-yl)-ω-hydroxypoly(oxy-1,2-ethanediyl), and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl 2-propenoate, sodium salt. The FCS is employed at the size press or is added prior to sheet formation in the production of paper and paperboard.

The notifier submitted a claim of categorical exclusion under 21 CFR 25.32(i) for the proposed use of the FCS at the size press in production of paper products. We have reviewed the claim of categorical exclusion and have concluded that categorical exclusion is warranted. The claim of categorical exclusion cites the section—21 CFR 25.32(i)—under which categorical exclusion is warranted, states compliance with the categorical exclusion criteria, and states that no extraordinary circumstances exist that require the submission of an environmental assessment for the proposed use of the FCS at the size press.

Also, the notifier submitted an environmental assessment for the proposed use of the FCS added in production operations prior to formation of paper sheet. We have reviewed the environmental assessment, and we have prepared the attached Finding of No Significant Impact (FONSI) for FCN 933. After this notification becomes effective, copies of this FONSI and the notifier's environmental assessment, dated August 31, 2009, may be made available to the public. We shall post digital transcriptions of the FONSI and the environmental assessment on the agency's public website.

Please let us know if there is any change in the identity or use of the food-contact substance.

William H. Lamont

Attachment:
Finding of No Significant Impact

(b) (5)

FINDING OF NO SIGNIFICANT IMPACT
FOR

A food contact notification (FCN No. 933), submitted by Daikin America, Inc., to provide for the safe use of 2-propenoic acid, 2-methyl-, polymer with 2-hydroxyethyl 2-methyl-2-propenoate, α-(1-oxo-2-propen-1-yl)-ω-hydroxypoly(oxy-1,2-ethanediyl), and 3,3,4,4,5,5,6,6,7,7,8,8,8-trideca-fluorooctyl 2-propenoate, sodium salt, as an oil and grease resistant treatment for paper and paperboard.

The Environmental Review Team has determined that allowing this notification to become effective will not significantly affect the quality of the human environment and, therefore, will not require the preparation of an environmental impact statement. This finding is based on information, submitted by the notifier, in an environmental assessment, dated August 31, 2009, and other information known to the agency.

Prepared by _____Date: October 28, 2009

William H. Lamont, Chemist
Acting Supervisor, Environmental Review Team
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

FINDING OF NO SIGNIFICANT IMPACT
FOR

A food contact notification (FCN No. 933), submitted by Daikin America, Inc., to provide for the safe use of 2-propenoic acid, 2-methyl-, polymer with 2-hydroxyethyl 2-methyl-2-propenoate, α-(1-oxo-2-propen-1-yl)-ω-hydroxypoly(oxy-1,2-ethanediyl), and 3,3,4,4,5,5,6,6,7,7,8,8,8-trideca-fluorooctyl 2-propenoate, sodium salt, as an oil and grease resistant treatment for paper and paperboard.

The Environmental Review Team has determined that allowing this notification to become effective will not significantly affect the quality of the human environment and, therefore, will not require the preparation of an environmental impact statement. This finding is based on information, submitted by the notifier, in an environmental assessment, dated August 31, 2009, and other information known to the agency.

Prepared by _____ Date: October 28, 2009
William H. Lamont, Chemist
Acting Supervisor, Environmental Review Team
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

ENVIRONMENTAL ASSESSMENT

1. **Date:** August 31, 2009

2. **Name of Applicant:** Daikin America, Inc.

3. **Address:** Post Office Box 2252
Decatur, Alabama 35609

All communications on this matter are to be sent in care of Counsel for the Notifier:
Devon Wm. Hill
Keller and Heckman LLP
1001 G Street, N.W., Suite 500 West
Washington, D.C. 20001
Telephone: 202-434-4279
Facsimile: (202) 434-4646
E-mail: Hill@khlaw.com

4. Description of the Proposed Action

The subject Food Contact Notification (FCN) seeks clearance for copolymers produced by the polymerization of perfluorohexylethyl acrylate, 2-hydroxyethyl methacrylate, polyethylene glycol monoacrylate, and methacrylic acid, for use as grease proofing agents for food-contact paper and paperboard at levels of up to 0.8% (by weight of dry paper), added at either the size press or prior to sheet formation. In this Environmental Assessment (EA), the term "FCS" is used to refer to the product as it is sold by Daikin, which is a water based dispersion. The dry copolymer is referred to as the "perfluoroacrylate copolymer" or simply "copolymer" in this EA.

No environmental effects are expected as a result of the addition of the FCS at the size press, because the copolymer will fully remain with the treated paper. Therefore, this EA only discusses the use of the FCS prior to sheet formation. When the FCS is added prior to sheet formation, it is expected that most of the copolymer will be incorporated into the finished paper and paperboard and will remain a component of the paper and paperboard. In the event that a small amount of copolymer is not incorporated into the paper, it is expected that it will become a component of solid wastes generated by the waste water treatment process, which will be disposed of by either landfill or incineration. Only a minimal amount of the fluoroacrylate copolymer is expected to be present in effluent from the on-site waste water treatment facility.

Food-contact articles made with paper containing the copolymer will be utilized in patterns corresponding to the national population density and will be widely distributed across the country. Therefore, it is anticipated that disposal will occur nationwide, with about 80% of the materials ultimately being deposited in land disposal sites, and about

20% incinerated.[1] The types of environments present at and adjacent to the disposal locations are the same as for the disposal of any other food-contact material in current use. Consequently, there are no special circumstances regarding the environment surrounding either the use or disposal of food-contact paper prepared using the FCS.

5. Identification of Chemical Substance that is the Subject of the Proposed Action

Chemical Name: Copolymer of fluorohexylethyl acrylate, 2-hydroxyethyl methacrylate, polyethylene glycol monoacrylate and methacrylic acid.

CAS Registry Number: 1158951-86-0

CAS Name: 2-Propenoic acid, 2-methyl-, polymer with 2-hydroyethyl 2-methyl-2-propenoate, α-(1-oxo-2-propen-1-yl)-ω-hydroxypoly(oxy-1,2-ethanediyl) and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl 2-propenoate, sodium salt.

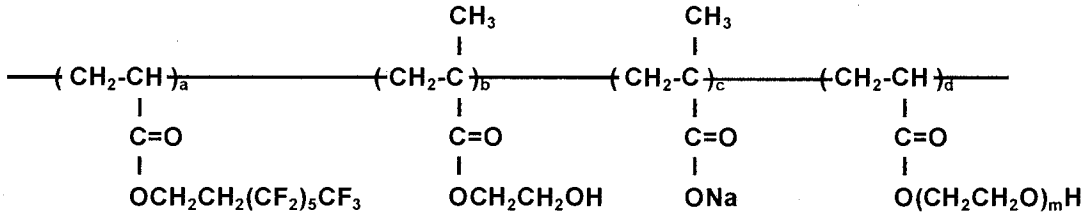
The starting monomers are shown in the following table:

Chemical Name	CAS Registry Number
Perfluorohexylethyl acrylate	17527-29-6
2-Hydroxyethyl methacrylate	868-77-9
Polyethylene glycol monoacrylate	26403-58-7
Methacrylic acid	79-41-4

The molecular formula of the copolymer is:

$$(C_{11}H_7F_{13}O_2)_a(C_6H_{10}O_3)_b(C_4H_5O_2Na)_c((C_2H_4O)_mC_3H_4O_2)_d$$

The structural formula for the fluoroacrylate copolymer is given below:



[1] "Characterization of Municipal Solid Waste in the United States, 1994 Update," EPA/530-S-94-042, U.S. Environmental Protection Agency, Washington, D.C. 20460.

The weight average molecular weight, as determined by gel permeation chromatography on 4 batch samples, was 53800 ± 5597; the number average molecular weight was 25725 ± 2417.

Physical properties are shown in the following table:

Physical Properties of the FCS

Property	Typical Value or Range
Solids Content (wt. %)	19-21%
pH (25°C)	7-9
Specific Gravity	1.00-1.15

6. Introduction of Substances into the Environment

a. Introduction of substances into the environment as a result of manufacture of the polymer

Under 21 C.F.R. § 25.40(a), an environmental assessment ordinarily should focus on relevant environmental issues relating to the use and disposal from use, rather than production, of FDA-regulated substances. In addition, information available to the Notifier does not suggest that there are any extraordinary circumstances here that would indicate any adverse environmental impact as a result of the manufacture of the FCS. Consequently, information regarding the manufacturing site and compliance with the relevant emissions requirements is not provided here.

b. Introduction of substances into the environment as a result of use/disposal

As discussed above, the Notifier expects that most of the copolymer will be incorporated into the finished paper and will remain a component of the paper. If this were not the case, addition of the FCS prior to sheet formation would not be financially viable. We discuss below the possible introduction into the environment of the fraction of the FCS that may be present in the effluent water from the paper making process.

Based on experience with the use of such fluoropolymers as oil and grease resistant treatments for paper and paperboard, Daikin estimates that at least 85-90% of the copolymer introduced prior to sheet formation will become incorporated into the finished paper. This estimation is based on actual information generated in duplicate fashion from both the Notifier and our the Notifier's customers by testing of the paper made during pilot trials. The total polymer retention for fluoropolymers such as the copolymer is similar throughout the industry, and it is not expected that replacement of competitive products with the FCS will result in any loss of retention to the paper.

Copolymer not incorporated into the finished paper will remain in the white water. After multiple recycling steps, the water will eventually be released to the waste water treatment facility. It is Daikin's understanding that all of the major paper mills operate on-site treatment facilities. FDA has previously reviewed and utilized information regarding the removal of fluoroacrylate copolymers from the paper mill waste water (as solid wastes or sludge).[2] This information, which is publicly available on the Agency's website, indicates that about 90% of the fluoroacrylate copolymer will be removed from the waste water as solid wastes or sludge. Waste water treatment typically begins with a filtration step to remove fines, which will contain adsorbed copolymer. Subsequent biotreatment results in solids that precipitate from the water, and fluoropolymers will be adsorbed to the polymer. Any free polymer remaining will likely precipitate as pH is lowered to neutral conditions.

Solid wastes containing the fluoroacrylate copolymer are disposed of by placement in landfills or by incineration. The ash resulting from incineration is also disposed into landfills. Due to EPA regulations, only minimal quantities of fluoroacrylate copolymer is expected to leach into the environment. EPA regulations require the use of composite liners and leachate collection systems with new municipa solid-waste landfill units and lateral expansions of existing units to prevent leachate from entering the ground and surface water, and (2) groundwater monitoring systems.[3]

The level at which the fluoroacrylate copolymer might be present in the waste water following treatment may be calculated using standard assumptions:

1. Between 85-90% of the added fluoropolymers remains with the paper. Thus, an average of 88% of the added fluoropolymer remains with the paper, the remainder will be present in wastewater.

2. A total of 750 MT (750 x 10^3 kg) of paper coated with fluoropolymers are typically produced in paper mill per day. A typical volume of waste water produced per day is 18,000 gallons per minute, or 26 million gallons per 24 hours, or 99 million (M) liters per day, given 3.8 L/gal. Assuming a density of 1.0 kg/L, 99 M liters is 99 million kg.

This information is consistent with the Notifier's knowledge of the paper making process and disposal of solid wastes and sludge. Thus, because the finished paper will contain fluoroacrylate copolymer at 0.8% (dry paper weight), and if 88% of the added fluoropolymer remains with the paper, the actual level of copolymer added to the pulp slurry must be adjusted for the retention rate to achieve the desired 0.8% level. The

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[2] *See* Inventory of Final Environmental Impact Decisions for Food Contact Notifications, Notifier's Environmental Assessment for FCN 646 (copy available at: http://www.fda.gov/downloads/Food/FoodIngredientsPackaging/EnvironmentalDecisions/UCM143321.pdf), and Environmental Decision Memorandum, available at: http://www.fda.gov/Food/FoodIngredientsPackaging/EnvironmentalDecisions/ucm155295.htm.

[3] 40 C.F.R. Part 258.

quantity actually added to the slurry would be 0.91%.[4] Therefore, the total quantity of copolymer added per day would be:

$$(0.0091)(750 \times 10^3 \text{ kg/day}) = 6.82 \times 10^3 \text{ kg}_{\text{fluoroacrylate}}/\text{day}$$

If 88% becomes incorporated into the paper, the remaining fluoroacrylate copolymer remaining in the slurry would be:

$$(0.12)(6.82 \times 10^3 \text{ kg}_{\text{fluoroacrylate}}/\text{day}) = 820 \text{ kg}$$

If 90% of this quantity is precipitated as solids and sludge, 82 kg of copolymer would remain. The concentration in 99 M kg wastewater would be 0.83 ppm.[5] We believe that this concentration is typical in the industry, so there should be no significant increase in concentration when the FCS replaces another product.

7. Fate of Emitted Substances in the Environment

As explained above, the primary means in which the fluoroacrylate copolymer is expected to be released into the environment is through effluents from wastewater treatment facilities. The expected concentration in these effluents would be 0.83 ppm. Once the effluent enters the receiving water, the concentration will be greatly diluted. If we assume a river dilution factor of 1000, which likely is extremely conservative, the concentration expected in the water would be 0.83 part per billion (ppb). As discussed in the Form 3480 of the FCN, the fluoroacrylate copolymer contains a very low amount of low molecular weight oligomers. Using the confidential information provided in the Form 3480 regarding the percentage of low molecular weight oligomers, we can conclude that the concentration of fluoroacrylate that could be absorbed by mammals, including humans, is less than 50 parts per trillion (ppt), a negligible concentration.

8. Environmental Effects of Release Substances

Due to the extremely low levels of fluoroacrylate copolymer that might be released, as calculated above, as well as the much lower percentage of the oligomers that are the potentially toxic components, no significant environmental effects are expected.

The Notifier has not performed ecotoxicity studies on the FCS. However, tests on similar copolymers strongly suggest that the fluoroacrylate copolymer will pose no safety concern to aquatic organisms. The Notifier sponsored acute toxicity studies on *Daphnia magna* and *Pimephales promelas* using a related product. The active ingredient of the related product is a copolymer of perfluorohexylethyl acrylate, 2-hydroxyethyl acrylate, polyethylene glycol monoacrylate and polyethylene glycol diacrylate. Thus, two of the monomers in the FCS are the same as two of the monomers in the related product, *i.e.*,

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[4] (0.8%)/(0.88) = 0.91%

[5] (82 kg)/(99 x 10^6 kg) = 0.83 x 10^{-7} $\text{kg}_{\text{fluoroacrylate}}$/kg, or 0.83 ppm

perfluorohexylethyl acrylate and polyethylene glycol monoacrylate. 2-Hydroxyethyl methacrylate has replaced 2-hydroxyethyl acrylate, and methacrylic acid has replaced polyethylene glycol diacrylate.

Based on range finding tests, 48 hour EC_{50} values (static non renewal) were determined in 4 definitive static tests on *Daphnia magna.* EC_{50} values averaged 9.14±0.32%

Based on range finding tests, 3 definitive 96 hour acute tests (static renewal) were carried out on *Pimephales promelas* (fathead minnows). The LC_{50} values averaged 8.56±0.78%.

The product tested consisted of 20% solids, the EC_{50} and LC_{50} values, so the above values, would be one fifth of the amount based on solids. Nevertheless, based on these results, the product tested, as well as the FCS, are expected to have no noticeable adverse affect on the aquatic community of the water to which these products may be discharged.

These acute toxicity percentages are far higher than the estimated maximum concentration in water for the fluoroacrylate copolymer of 0.83 ppb. Although the actual FCS was not tested, the margin of exposure at the lower end of the range, 1.6% as active solid, is over seven orders of magnitude higher than the estimated concentration of the fluoroacrylate copolymer. Even accounting for differences between the two copolymers, we believe it is clear that there will be no adverse environmental impacts due to possible release of the FCS.

9. Use of Resources and Energy

The notified use of the FCS copolymer is expected to compete with, and to some degree replace, other fluorochemicals that are already used in the manufacture of paper and paperboard, which are either specifically listed in Section 176.170 of the food additive regulations or cleared under other FCNs. For this reason, the use of the FCS in the production of food-contact paper and paperboard is not expected to result in a net increase in the use of energy and resources.

10. Mitigation Measures

As discussed above, no significant adverse environmental impacts are expected to result from the manufacture of food-contact paper and paperboard using the FCS. This is largely due to the low levels at which the copolymer may be introduced into the environment and the available data indicating low toxicity to organisms in the environment with regard to related compounds. Thus, the use of the copolymer as proposed is not reasonably expected to result in any new environmental problem requiring mitigation measures of any kind.

11. Alternatives to the Proposed Action

No potential adverse environmental effects are identified herein which would necessitate alternative actions to that proposed in this request. Therefore, alternatives to the proposed action need not be considered.

12. List of Preparers

Michael T. Flood, Staff Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Washington, DC 20001.

13. Certification

The undersigned official certifies that the information presented is true, accurate, and complete to the best of his knowledge.

Date: 8-31-09

Devon Wm. Hill
Counsel for Daikin America, Inc.

ENVIRONMENTAL REVIEW

This memorandum may contain confidential or proprietary business information. It should be redacted before release to the public in response to a FOIA request.

FCN 1044

Phase 1 meeting: 11/10/10

Reviewer: Leah Proffitt

Notifier: Daikin America, Inc.

Proposed FCS: 2-Propenoic acid, 2-methyl-, 2-hydroxyethyl ester, polymer with 1-ethenyl-2-pyrrolidinone, 2-propenoic acid and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl 2-propenoate, sodium salt

Proposed Use: As a grease-proofing agent for food-contact paper and paperboard at levels of up to 1.0% b.w. added at either the size press or before sheet formation. The notifier also indicated possible repeat use applications of the FCS.[1]

Related Submissions: (b) (4) [redacted]

Environmental Submission: The notifier submitted a claim of categorical exclusion under 21 CFR 25.32 (i) for the size press application, and references an environmental assessment (EA), dated (b) (4) [redacted], submitted with (b) (4) [redacted], for application before sheet formation.

Environmental Review: This FCS was previously the subject of (b) (4) [redacted]

Environmental Review Conclusion: We have reviewed the claim of categorical exclusion and the EA for (b) (4) [redacted]. We have concluded that the claim of categorical exclusion for application of the FCS at the size press for single-use articles is warranted. The notifier cited the section, 21 CFR 25.32(i), under which categorical exclusion is warranted, stated compliance with the categorical exclusion criteria, and stated that no extraordinary circumstances exist that require submission of an environmental assessment.

Furthermore, the EA is adequate for review on environmental grounds.

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[1] Form 3480, page 7, Part II Section D – Intended Use
[2] See note in Form 3480, Part IV, Section B. 2

Although Part II, Section D – Intended use, of the application form indicates repeat use (by incorporation from [redacted]), the notifier states that they are not aware of any existing repeat-use applications, but do not want to preclude any such future applications. Because the repeat use statement reflects a hypothetical situation, we do not, at this time, request an environmental component to be consistent with such a hypothetical use (e.g., categorical exclusion 20 CFR 25.32(j) was not claimed by the notifier).

Status: Effective

Part IV - ENVIRONMENTAL INFORMATION (21 CFR Part 25)

All FCN submissions must contain either a claim of categorical exclusion under 21 CFR 25.32 or an environmental assessment (EA) under 21 CFR 25.40.

A - CLAIM OF CATEGORICAL EXCLUSION

1. Cite the specific section(s) of the CFR under which the categorical exclusion is claimed:

☒ **21 CFR 25.32 (i)**

a. Is the FCS a component of a coating? ☐ Yes ☒ No

b. If no, the % of the FCS in the finished food-contact article is 1.0% and

c. The % of the total market volume that remains with the food-contact articles is 100%

☐ **21 CFR 25.32 (j)**

Is the FCS a component of a:

a. Repeat-use article? ☐ Yes ☐ No

b. Permanent or semi-permanent food-contact surface? ☐ Yes ☐ No

☐ **21 CFR 25.32 (k)**

☐ **21 CFR 25.32 (q)**

a. Is current FIFRA label attached? ☐ Yes ☐ No

b. Is the requested use essentially the same as the label? ☐ Yes ☐ No

If current FIFRA label has limitation on food-contact uses, provide a draft copy of a revised label you intend to submit to EPA to include food-contact uses.

☐ 21 CFR 25.32 (r)

2. Does your proposed food-contact use comply with the categorical exclusion criteria?
If no, go to section B below. ☒ Yes ☐ No

3. To the best of your knowledge, are there any extraordinary circumstances that would require your submission of an EA? *(see 21 CFR 25.21)*
If yes, go to section B below. ☐ Yes ☒ No

B - ENVIRONMENTAL ASSESSMENT

See Environmental Recommendations

1. If an EA is required, state that an EA has been prepared under 21 CFR 25.40, and is attached.

2. Environmental assessments are public documents and should not contain confidential information. Such information should be included in a separate section of the FCN, labeled confidential and summarized to the extent possible in the EA.

Although the application of the FCS at the size press complies with the categorical exclusion noted above, we understand that FDA requires an Environmental Assessment for application of the FCS prior to sheet formation. The EA has thus been prepared under 21 CFR 25.40 and is provided at **Attachment 21** of [redacted]

Part V - CERTIFICATION

The accuracy of the statements you make in this notice should reflect your best prediction of the anticipated facts regarding the chemical substance described herein. Any knowing and willful misinterpretation is subject to criminal penalty pursuant to 18 U.S.C. 1001.

The notifying party certifies that the information provided herein is accurate and complete to the best of his/her knowledge.

SIGNATURE OF AUTHORIZED OFFICIAL/OR AGENT [redacted]

TITLE
Partner

DATE
10-18-2016

ENVIRONMENTAL ASSESSMENT

1. Date: May 28, 2010

2. Name of Applicant: Daikin America, Inc.

3. Address: Post Office Box 2252
Decatur, Alabama 35609

All communications on this matter are to be sent in care of Counsel for the Notifier:
Devon Wm. Hill
Keller and Heckman LLP
1001 G Street, N.W., Suite 500 West
Washington, D.C. 20001
Telephone: 202-434-4279
Facsimile: (202) 434-4646
E-mail: Hill@khlaw.com

4. Description of the Proposed Action

The subject Food Contact Notification (FCN) seeks clearance for copolymers produced by the polymerization of perfluorohexylethyl acrylate, 2-hydroxyethyl methacrylate, 1-vinyl-2-pyrrolidone, and acrylic acid when used as a grease proofing agent for food-contact paper and paperboard at levels of up to 1.0% (by weight of dry paper), added at either the size press or prior to sheet formation. In this Environmental Assessment (EA), the term "FCS" is used to refer to the product as it is sold by Daikin, which is a water-based dispersion. The dry copolymer is referred to as the "perfluoroacrylate copolymer" or simply "copolymer" in this EA.

No environmental effects are expected as a result of the addition of the FCS at the size press, because the copolymer will fully remain with the treated paper. Therefore, this EA only discusses the use of the FCS prior to sheet formation. When the FCS is added prior to sheet formation, it is expected that most of the copolymer will be incorporated into the finished paper and paperboard and will remain a component of the paper and paperboard. In the event that a small amount of copolymer is not incorporated into the paper, it is expected that it will become a component of solid wastes generated by the waste water treatment process, which will be disposed of by either landfill or incineration. Only a minimal amount of the fluoroacrylate copolymer is expected to be present in effluent from the on-site waste water treatment facility.

Food-contact articles made with paper containing the copolymer will be utilized in patterns corresponding to the national population density and will be widely distributed across the country. Therefore, it is anticipated that disposal will occur nationwide, with about 80% of the materials ultimately being deposited in land disposal sites, and about

20% incincerated.[1] The types of environments present at and adjacent to the disposal locations are the same as for the disposal of any other food-contact material in current use. Consequently, there are no special circumstances regarding the environment surrounding either the use or disposal of food-contact paper prepared using the FCS.

5. Identification of Chemical Substance that is the Subject of the Proposed Action

Chemical Name:	Copolymer of fluorohexylethyl acrylate, 2-hydroxyethyl methacrylate, 1-vinyl-2-pyrrolidone and acrylic acid.
CAS Registry Number:	1206450-10-3
CAS Name:	2-Propenoic acid, 2-methyl-, 2-hydroxyethyl ester, polymer with 1-ethenyl-2-pyrrolidinone, 2-propenoic acid and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl 2-propenoate, sodium salt

The weight average molecular weight, as determined by gel permeation chromatography, was 1.04×10^6 daltons; the number average molecular weight was 2.9×10^5 daltons

Physical properties are shown in the following table:

Physical Properties of the FCS

Property	Typical Value or Range
Solids Content (wt. %)	19-21%
pH (25˚C)	6-9
Specific Gravity	1.00-1.15
Remaining Solvent (% in product)	<0.5 mass%

6. Introduction of Substances into the Environment

a. Introduction of substances into the environment as a result of manufacture of the polymer

Under 21 C.F.R. § 25.40(a), an environmental assessment ordinarily should focus on relevant environmental issues relating to the use and disposal from use, rather than production, of FDA-regulated substances. In addition, information available to the

[1] "Characterization of Municipal Solid Waste in the United States, 1994 Update," EPA/530-S-94-042, U.S. Environmental Protection Agency, Washington, D.C. 20460.

Notifier does not suggest that there are any extraordinary circumstances here that would indicate any adverse environmental impact as a result of the manufacture of the FCS. Consequently, information regarding the manufacturing site and compliance with the relevant emissions requirements is not provided here.

b. Introduction of substances into the environment as a result of use/disposal

As discussed above, the Notifier expects that most of the copolymer will be incorporated into the finished paper and will remain a component of the paper. If this were not the case, addition of the FCS prior to sheet formation would not be financially viable. We discuss below the possible introduction into the environment of the fraction of the FCS that may be present in the effluent water from the paper making process.

Based on experience with the use of such fluoropolymers as oil and grease resistant treatments for paper and paperboard, Daikin estimates that at least 85-90% of the copolymer introduced prior to sheet formation will become incorporated into the finished paper. This estimation is based on actual information generated in duplicate fashion from both the Notifier and our the Notifier's customers by testing of the paper made during pilot trials. The total polymer retention for fluoropolymers such as the copolymer is similar throughout the industry, and it is not expected that replacement of competitive products with the FCS will result in any loss of retention to the paper.

Copolymer not incorporated into the finished paper will remain in the white water. After multiple recycling steps, the water will eventually be released to the waste water treatment facility. It is Daikin's understanding that all of the major paper mills operate on-site treatment facilities. FDA has previously reviewed and utilized information regarding the removal of fluoroacrylate copolymers from the paper mill waste water (as solid wastes or sludge).[2] This information, which is publicly available on the Agency's website, indicates that about 90% of the fluoroacrylate copolymer will be removed from the waste water as solid wastes or sludge. Waste water treatment typically begins with a filtration step to remove fines, which will contain adsorbed copolymer. Subsequent biotreatment results in solids that precipitate from the water, and fluoropolymers will be adsorbed to the polymer. Any free polymer remaining will likely precipitate as pH is lowered to neutral conditions.

Solid wastes containing the fluoroacrylate copolymer are disposed of by placement in landfills or by incineration. The ash resulting from incineration is also disposed into landfills. Due to EPA regulations, only minimal quantities of fluoroacrylate copolymer is expected to leach into the environment. EPA regulations

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[2] *See* Inventory of Final Environmental Impact Decisions for Food Contact Notifications, Notifier's Environmental Assessment for FCN 646 (copy available at: http://www.fda.gov/downloads/Food/FoodIngredientsPackaging/EnvironmentalDecisions/UCM143321.pdf), and Environmental Decision Memorandum, available at: http://www.fda.gov/Food/FoodIngredientsPackaging/EnvironmentalDecisions/ucm155295.htm.

require the use of composite liners and leachate collection systems with new municipa solid-waste landfill units and lateral expansions of existing units to prevent leachate from entering the ground and surface water, and (2) groundwater monitoring systems.[3]

The level at which the fluoroacrylate copolymer might be present in the waste water following treatment may be calculated using standard assumptions:

1. Between 85-90% of the added fluoropolymers remains with the paper. Thus, an average of 88% of the added fluoropolymer remains with the paper, the remainder will be present in wastewater.

2. A total of 750 MT (750×10^3 kg) of paper coated with fluoropolymers are typically produced in paper mill per day. A typical volume of waste water produced per day is 18,000 gallons per minute, or 26 million gallons per 24 hours, or 99 million (M) liters per day, given 3.8 L/gal. Assuming a density of 1.0 kg/L, 99 M liters is 99 million kg.

This information is consistent with the Notifier's knowledge of the paper making process and disposal of solid wastes and sludge. Thus, because the finished paper will contain fluoroacrylate copolymer at 1.0% (dry paper weight), and if 88% of the added fluoropolymer remains with the paper, the actual level of copolymer added to the pulp slurry must be adjusted for the retention rate to achieve the desired 1.0% level. The quantity actually added to the slurry would be 1.1%.[4] Therefore, the total quantity of copolymer added per day would be:

$$(0.011)(750 \times 10^3 \text{ kg/day}) = 8.52 \times 10^3 \text{ kg}_{\text{fluoroacrylate}}/\text{day}$$

If 88% becomes incorporated into the paper, the remaining fluoroacrylate copolymer remaining in the slurry would be:

$$(0.12)(8.52 \times 10^3 \text{ kg}_{\text{fluoroacrylate}}/\text{day}) = 1022 \text{ kg}$$

If 90% of this quantity is precipitated as solids and sludge, 102.2 kg of copolymer would remain. The concentration in 99 M kg wastewater would be 1.03 ppm.[5] We believe that this concentration is typical in the industry, so there should be no significant increase in concentration when the FCS replaces another product.

7. Fate of Emitted Substances in the Environment

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[3] 40 C.F.R. Part 258.

[4] (1.0%)/(0.88) = 1.1%

[5] $(102.2 \text{ kg})/(99 \times 10^6 \text{ kg}) = 1.03 \times 10^{-6} \text{ kg}_{\text{fluoroacrylate}}/\text{kg}$, or 1.03 ppm

As explained above, the primary means in which the fluoroacrylate copolymer is expected to be released into the environment is through effluents from wastewater treatment facilities. The expected concentration in these effluents would be 1.03 ppm. Once the effluent enters the receiving water, the concentration will be greatly diluted. If we assume a river dilution factor of 1000, which likely is extremely conservative, the concentration expected in the water would be 1.03 part per billion (ppb). As discussed in the Form 3480 of the FCN, the fluoroacrylate copolymer contains a very low amount of low molecular weight oligomers. Using the confidential information provided in the Form 3480 regarding the percentage of low molecular weight oligomers, we can conclude that the concentration of fluoroacrylate that could be absorbed by mammals, including humans, is less than 50 parts per trillion (ppt), a negligible concentration.

8. Environmental Effects of Release Substances

Due to the extremely low levels of fluoroacrylate copolymer that might be released, as calculated above, as well as the much lower percentage of the oligomers that are the potentially toxic components, no significant environmental effects are expected.

The Notifier has not performed ecotoxicity studies on the FCS. However, tests on similar copolymers strongly suggest that the fluoroacrylate copolymer will pose no safety concern to aquatic organisms. The Notifier sponsored acute toxicity studies on *Daphnia magna* and *Pimephales promelas* using a related product. The active ingredient of the related product is a copolymer of perfluorohexylethyl acrylate, 2-hydroxyethyl acrylate, polyethylene glycol monoacrylate and polyethylene glycol diacrylate. The principal monomer in the FCS, perfluorohexylethyl acrylate, is the same as that in the related copolymer. Hydroxyethyl methacrylate has replaced 2-hydroxyethyl acrylate, and acrylic acid has replaced the polyethylene glycol mono- and diacrylates.

Based on range finding tests, 48 hour EC_{50} values (static non renewal) were determined in 4 definitive static tests on *Daphnia magna*. EC_{50} values averaged 9.14±0.32%

Based on range finding tests, 3 definitive 96 hour acute tests (static renewal) were carried out on *Pimephales promelas* (fathead minnows). The LC_{50} values averaged 8.56±0.78%.

The product tested consisted of 20% solids, the EC_{50} and LC_{50} values, so the above values, would be one fifth of the amount based on solids. Nevertheless, based on these results, the product tested, as well as the FCS, are expected to have no noticeable adverse affect on the aquatic community of the water to which these products may be discharged.

These acute toxicity percentages are far higher than the estimated maximum concentration in water for the fluoroacrylate copolymer of 1.03 ppb. Although the actual FCS was not tested, the margin of exposure at the lower end of the range, 1.6% as active solid, is over seven orders of magnitude higher than the estimated concentration of the

fluoroacrylate copolymer. Even accounting for differences between the two copolymers, we believe it is clear that there will be no adverse environmental impacts due to possible release of the FCS.

9. Use of Resources and Energy

The notified use of the FCS copolymer is expected to compete with, and to some degree replace, other fluorochemicals that are already used in the manufacture of paper and paperboard, which are either specifically listed in Section 176.170 of the food additive regulations or cleared under other FCNs. For this reason, the use of the FCS in the production of food-contact paper and paperboard is not expected to result in a net increase in the use of energy and resources.

10. Mitigation Measures

As discussed above, no significant adverse environmental impacts are expected to result from the manufacture of food-contact paper and paperboard using the FCS. This is largely due to the low levels at which the copolymer may be introduced into the environment and the available data indicating low toxicity to organisms in the environment with regard to related compounds. Thus, the use of the copolymer as proposed is not reasonably expected to result in any new environmental problem requiring mitigation measures of any kind.

11. Alternatives to the Proposed Action

No potential adverse environmental effects are identified herein which would necessitate alternative actions to that proposed in this request. Therefore, alternatives to the proposed action need not be considered.

12. List of Preparers

Michael T. Flood, Staff Scientist, Bethany M. Walls, Staff Scientist, Keller and Heckman LLP, 1001 G Street, NW, Ste. 500W, Washington, DC 20001.

13. Certification

The undersigned official certifies that the information presented is true, accurate, and complete to the best of his knowledge.

Date: May 28, 2010

(b) (6)

Devon Wm. Hill
Counsel for Daikin America, Inc.

Memorandum

Date March 6, 2003

From Environmental Toxicologist, Environmental Review Group (ERG)
Division of Chemistry Research and Environmental Review (HFS-246)

Subject FCN No. 314 – A polymer for use as an oil/grease resistant sizing agent employed prior to the sheet-forming operation in the manufacture of paper and paperboard

Hercules Incorporated
500 Hercules Road
Wilmington, DE 19808

To Division of Food Contact Substance Notification Review (HFS-275)
Attention: Vivian Gilliam
Through: Layla I. Batarseh, Ph.D., Supervisor, ERG (b) (4)

We have reviewed the claim of categorical exclusion under 21 *CFR* 25.32(i) for the above referenced notification and have concluded that the categorical exclusion is warranted. The food contact substance is 2-propen-1-ol, reaction products with pentafluoroiodoethane-tetrafluoroethylene telomer, dehydroiodinated, reaction products with epichlorohydrin and triethylenetetramine.

The claim of categorical exclusion cites the section under which the categorical exclusion is claimed, states compliance with the categorical exclusion criteria, and states that no extra-ordinary circumstances exist that require the submission of an environmental assessment.

Please let us know if there is any change in the identity or use of the food-contact substance.

(b) (4)

Tong Zhou, Ph.D.

(b) (4)

000730

Part IV — ENVIRONMENTAL IMPACT OF FOOD CONTACT SUBSTANCE (21 CFR part 25)

All FCN submissions must contain either a claim of categorical exclusion under 21 CFR 25.32 or an environmental assessment (EA) under 21 CFR 25.40.

A - CLAIM OF CATEGORICAL EXCLUSION

1 Cite the specific section of the CFR under which the categorical exclusion is claimed (21 CFR 25.32 (i), (j), (k), (q), or (r) 21 C.F.R. § 25.32(i).

2. Does your proposed food-contact use comply with the categorical exclusion criteria? ☒ Yes ☐ No

3. To the best of your knowledge are there any extraordinary circumstances that would require your submission of an EA? ☐ Yes ☒ No

B - ENVIRONMENTAL ASSESSMENT

If an EA is required, state that an EA has been prepared under 21 CFR 25.40, and is attached.

Part V — CERTIFICATION

The accuracy of the statements you make in this notice should reflect your best prediction of the anticipated facts regarding the chemical substance described herein. Any knowing and willful misinterpretation is subject to criminal penalty pursuant to 18 U.S.C. 1001.

The notifying party certifies that the information provided herein is accurate and complete to the best of his/her knowledge.

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(b)(4) [redacted]

Signature of Authorized Official or Agent

Partner, Keller and Heckman LLP

December 18, 2002

Title

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

AD

Date: April 11, 2005

From: Environmental Toxicologist, Environmental Review Group (ERG)
Division of Chemistry Research and Environmental Review (HFS-246)

Subject: FCN No. 487 – 2-propen-1-ol reaction products with pentafluoroiodoethane-tetrafluoroethylene telomer, dehydroiodinated, reaction products with epichlorohydrin and triethylenetramine for use as an oil/grease resistant sizing agent for paper and paperboard

Hercules Incorporated
500 Hercules Road
Wilmington, DE 19808
USA

To: Division of Food Contact Notifications (HFS-275)
Attention: Paul Honigfort, Ph.D.
Through: Layla I. Batarseh, Ph.D., Supervisor, ERG -S- -s-

We have reviewed the claim of categorical exclusion for the above referenced notification and have concluded that categorical exclusion is warranted. The claim of categorical exclusion cites the section under which categorical exclusion is warranted, 21 *CFR* 25.32 (i), states compliance with the categorical exclusion criteria, and states that no extraordinary circumstances exist that require the submission of an environmental assessment.

Please let us know if there is any change in the identity or use of the food contact substance.

-S- -s-

Annette M. McCarthy, Ph.D.

000413

Part IV — ENVIRONMENTAL IMPACT OF FOOD CONTACT SUBSTANCE (21 CFR part 25)

All FCN submissions must contain either a claim of categorical exclusion under 21 CFR 25.32 or an environmental assessment (EA) under 21 CFR 25.40.

A - CLAIM OF CATEGORICAL EXCLUSION

1. Cite the specific section of the CFR under which the categorical exclusion is claimed (21 CFR 25.32 (i), (j), (k), (q), or (r) 21 C.F.R. § 25.32(i)
2. Does your proposed food-contact use comply with the categorical exclusion criteria? ☒ Yes ☐ No
3. To the best of your knowledge are there any extraordinary circumstances that would require your submission of an EA? ☐ Yes ☒ No

B - ENVIRONMENTAL ASSESSMENT

If an EA is required, state that an EA has been prepared under 21 CFR 25.40, and is attached.

Part V — CERTIFICATION

The accuracy of the statements you make in this notice should reflect your best prediction of the anticipated facts regarding the chemical substance described herein. Any knowing and willful misinterpretation is subject to criminal penalty pursuant to 18 U.S.C. 1001.

The notifying party certifies that the information provided herein is accurate and complete to the best of his/her knowledge.

000025

Signature of Authorized Official or Agent

Partner, Keller and Heckman LLP

Title

12/16/04

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: July 21, 2005

From: Environmental Toxicologist, Environmental Review Group (ERG)
Division of Chemistry Research and Environmental Review (HFS-246)

Subject: FCN No. 518 – A polymer for use as an oil/grease resistant sizing agent in the manufacture of paper and paperboard

Hercules Incorporated
500 Hercules Road
Wilmington, DE 19808

To: Division of Food Contact Notifications (HFS-275)
Attention: Vivian Gilliam
Through: Layla I. Batarseh, Ph.D., Supervisor, ERG LIB

We have reviewed the claim of categorical exclusion under 21 *CFR* 25.32(i) for the above referenced food contact notification. The food-contact substance (FCS) is 2-propen-1-ol, reaction products with pentafluoroiodoethane-tetrafluoroethylene telomer, dehydroiodinated, reaction products with epichlorohydrin and triethylenetetramine. The FCS is intended for use as an oil/grease resistant sizing agent employed either prior to the sheet forming operation or at the size press for paper and paperboard intended for use in microwave heat-susceptor packaging such as popcorn bags.

For the proposed use to meet the criteria for this exclusion, the FCS must be present in the finished food-packaging material at not greater than 5 percent-by-weight and more than 95% of the FCS (i.e., 95% of the total annual market volume) must remain with the finished food-packaging material through use and disposal by consumers. We believe that more than 95% of the FCS would remain with the food-packaging based on the following discussions:

(1) The FCN included substantivity data to demonstrate that the FCS is 100% substantive to the paper fiber. Therefore, we expect that the FCS will remain with the paper fiber when added in the wet-end of the paper making process.
(2) The data from the thermal gravimetric analysis (TGA) that the notifier submitted in attachment 2 of this notification showed that 8.8% of the FCS may be lost during uses of the packaging by consumers at 220°C (due to the breakdown of the FCS during microwave heating) and before disposal of the packaging in landfills or incineration. 220°C is the temperature that heat-susceptor packaging such as popcorn bags can reach during its intended use.[1] However, this study was conducted on pure FCS, rather than the polymer embedded in paper. We expect that under a typical use condition, the percentage of weight loss would be less than 5% because some heat would transfer to food and paper, and the FCS will be adhered to or embedded in the paper; thus, the heat actually transfer to the FCS would be significantly less at a given temperature. Moreover, we expect that the temperature would not reach 220°C for most part of the popcorn bag because only the oil-containing portion of the popcorn

[1] We believe that the microwave popcorn process would represent a worst-case scenario with the heating of hot oil in a closed bag at 220 °C.

000200

bag may reach 220 °C. This means that most of the FCS distributed in the food-contact side of the popcorn bag will not breakdown given the lower temperature that would reach in most part of the bag. We expect less than 5% weight loss of the FCS during uses of the packaging by consumers under a typical intended use condition.

We therefore have concluded that categorical exclusion is warranted. The claim of categorical exclusion cites the section under which categorical exclusion is warranted, 21 *CFR* 25.32(i), states compliance with the categorical exclusion criteria, and states that no extraordinary circumstances exist that require the submission of an environmental assessment.

Please let us know if there is any change in the identity or use of the food-contact substance.

[redacted]

Tong Zhou, Ph.D.

[redacted]

000201

Part IV — ENVIRONMENTAL IMPACT OF FOOD CONTACT SUBSTANCE (21 CFR part 25)

All FCN submissions must contain either a claim of categorical exclusion under 21 CFR 25.32 or an environmental assessment (EA) under 21 CFR 25.40.

A - CLAIM OF CATEGORICAL EXCLUSION

1. Cite the specific section of the CFR under which the categorical exclusion is claimed (21 CFR 25.32 (i), (j), (k), (q), or (r) **21** C.F.R. **§ 25.32(i).**

2. Does your proposed food-contact use comply with the categorical exclusion criteria? ☒ Yes ☐ No

3. To the best of your knowledge are there any extraordinary circumstances that would require your submission of an EA? ☐ Yes ☒ No

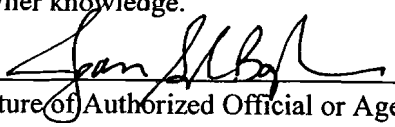
B - ENVIRONMENTAL ASSESSMENT

If an EA is required, state that an EA has been prepared under 21 CFR 25.40, and is attached.

Part V — CERTIFICATION

The accuracy of the statements you make in this notice should reflect your best prediction of the anticipated facts regarding the chemical substance described herein. Any knowing and willful misinterpretation is subject to criminal penalty pursuant to 18 U.S.C. 1001.

The notifying party certifies that the information provided herein is accurate and complete to the best of **his/her knowledge.**



ignature of Authorized Official or Agent

Partner, Keller and Heckman LLP — Title

April 25,2005 — Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: September 22, 2005

From: Environmental Review Group (ERG)/Supervisor
Division of Chemistry Research and Environmental Review (HFS-246)

Subject: FCN No. 542 – An oil/grease resistant sizing agent employed prior to sheet forming operation in the manufacture of paper and paperboard

Hercules Incorporated
c/o Keller and Heckman, LLP
Washington, D.C., USA

To: Division of Food Contact Notifications (HFS-275)
Attention: Paul Honigfort, Ph.D.

I have reviewed the claim of categorical exclusion for the above referenced notification and have concluded that categorical exclusion is warranted. The food contact substance is 2-Propen-1-ol, reaction products with 1,1,1,2,2,3,3,4,4,4,5,5,6,6-tridecafluro-6-iodohexane, dehydroiodinated, reaction products with epichlorohydrin and triethylenetetramine. The claim of categorical exclusion cites the section under which categorical exclusion is warranted, 21 *CFR* 25.32 (i), states compliance with the categorical exclusion criteria, and states that no extraordinary circumstances exist that would require the submission of an environmental assessment.

Please let me know if there is any change in the identity or use of the food contact substance.

[redacted]

Layl[redacted] Batarseh, Ph.D.

[redacted]

000444

Part IV — ENVIRONMENTAL IMPACT OF FOOD CONTACT SUBSTANCE (21 CFR part 25)

All FCN submissions must contain either a claim of categorical exclusion under 21 CFR 25.32 or an environmental assessment (EA) under 21 CFR 25.40.

A - CLAIM OF CATEGORICAL EXCLUSION

1. Cite the specific section of the CFR under which the categorical exclusion is claimed (21 CFR 25.32 (i), (j), (k), (q), or (r) 21 C.F.R. § 25.32(i).

2. Does your proposed food-contact use comply with the categorical exclusion criteria? ☒ Yes ☐ No

3. To the best of your knowledge are there any extraordinary circumstances that would require your submission of an EA? ☐ Yes ☒ No

B - ENVIRONMENTAL ASSESSMENT

If an EA is required, state that an EA has been prepared under 21 CFR 25.40, and is attached.

Part V — CERTIFICATION

The accuracy of the statements you make in this notice should reflect your best prediction of the anticipated facts regarding the chemical substance described herein. Any knowing and willful misinterpretation is subject to criminal penalty pursuant to 18 U.S.C. 1001.

The notifying party certifies that the information provided herein is accurate and complete to the best of his/her knowledge.

/p11 000025

Signature of Authorized Official or Agent

Partner, Keller and Heckman LLP — July 26, 2005

Title — Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: July 5, 2007

From: Environmental Review Team (ERT)/Supervisor
Office of Food Additive Safety (HFS-246)

Subject: FCN No. 746 – PPD D-37614 for use as an oil/grease resistant sizing agent in paper and paperboard in food-contact applications

Hercules Inc.
c/o Keller and Heckman, LLP
Washington, DC

To: Division of Food Contact Notifications (HFS-275)
Attention: Vanee Komolprasert, Ph.D., P.E.

The food contact substance, which is the subject of this FCN is 2-Propen-1-ol, reaction products with 1,1,1,2,2,3,3,4,4,4,5,5,6,6-tridecafluro -6-iodohexane, dehydroiodinated, reaction products with epichlorohydrin and triethylenetetramine.

I have reviewed the claim of categorical exclusion for the above referenced notification and have concluded that categorical exclusion is warranted. The claim of categorical exclusion cites the section under which categorical exclusion is warranted, 21 *CFR* 25.32 (i), states compliance with the categorical exclusion criteria, and states that no extraordinary circumstances exist that would require the submission of an environmental assessment.

Please let me know if there is any change in the identity or use of the food contact substance.

Layla I. Batarseh, Ph.D.

cc:
HFS-246 File: FCN No. 746

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Part IV - ENVIRONMENTAL INFORMATION (21 CFR Part 25)

All FCN submissions must contain either a claim of categorical exclusion under 21 CFR 25 32 or an environmental assessment (EA) under 21 CFR 25 40

A - CLAIM OF CATEGORICAL EXCLUSION

1 Cite the specific section(s) of the CFR under which the categorical exclusion is claimed

☒ **21 CFR 25.32 (i)**

a Is the FCS a component of a coating? ☐ Yes ☒ No

b If no, the % of the FCS in the finished food-contact article is 0.75% and

c The % of the total market volume that remains with the food-contact articles is approximately 100%

☐ **21 CFR 25.32 (j)**

Is the FCS a component of a

a Repeat-use article? ☐ Yes ☐ No

b Permanent or semi-permanent food-contact surface? ☐ Yes ☐ No

☐ **21 CFR 25.32 (k)**

☐ **21 CFR 25.32 (q)**

a Is current FIFRA label attached? ☐ Yes ☐ No

b Is the requested use essentially the same as the label? ☐ Yes ☐ No

If current FIFRA label has limitation on food-contact uses, provide a draft copy of a revised label you intend to submit to EPA to include food-contact uses

☐ 21 CFR 25 32 (r)

2 Does your proposed food-contact use comply with the categorical exclusion criteria? ☒ Yes ☐ No
If no, go to section B below

3 To the best of your knowledge, are there any extraordinary circumstances that would require your submission of an EA? *(see 21 CFR 25 21)* ☐ Yes ☒ No
If yes, go to section B below

B - ENVIRONMENTAL ASSESSMENT

See Environmental Recommendations

1 If an EA is required, state that an EA has been prepared under 21 CFR 25 40, and is attached

2 Environmental assessments are public documents and should not contain confidential information Such information should be included in a separate section of the FCN, labeled confidential and summarized to the extent possible in the EA

Part V - CERTIFICATION

The accuracy of the statements you make in this notice should reflect your best prediction of the anticipated facts regarding the chemical substance described herein Any knowing and willful misinterpretation is subject to criminal penalty pursuant to 18 U S C 1001

The notifying party certifies that the information provided herein is accurate and complete to the best of his/her knowledge

SIGNATURE OF AUTHORIZED OFFICIAL OR AGENT

Daniel Zaglin

000021

TITLE	DATE
Partner	6/4/07

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: December 17, 2007

From: Environmental Review Team (ERT)
Office of Food Additive Safety (HFS-246)

Subject: FCN No. 783 – PPD D-1435 for use as an oil/grease resistant agent in the manufacture of paper and paperboard.

Hercules Incorporated
c/o Keller and Heckman, LLP
Washington, DC 20001

To: Division of Food Contact Notifications (HFS-275)
Attention: Vanee Komolprasert, Ph.D., P.E.
Through: Layla I. Batarseh, Ph.D., Supervisor, ERT _____

The food contact substance for this notification is identified in the FCN as 2-propen-1-ol, reaction products with 1,l,1,2,2,3,3,4,4,5,5,6,6-tridecafluoro-6-iodohexane, dehydroiodinated, reaction products with epichlorohydrin and triethylenetetramine.

We have reviewed the claim of categorical exclusion for the above referenced food contact notification and have concluded that the categorical exclusion is warranted. The claim of categorical exclusion cites the section under which categorical exclusion is warranted, 21 *CFR* 25.32 (i), states compliance with the categorical exclusion criteria, and states that no extraordinary circumstances exist that would require the submission of an environmental assessment.

Please let us know if there is any change in the identity or use of the food-contact substance.

Kiros Hailemariam, Ph.D.

cc:
HFS-246 File: FCN No. 783

HFS-246:KHailemariam:khm: 12/17/07 H:\EIS Docs\FCN\FCN783_E_CatEx.doc
FT:KHailemariam:khm:12/17/07 P:\EIS Documents\FCN\FCN 601-800\FCN783_E_CatEx.doc

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

AD

Date: December 17, 2007

From: Environmental Review Team (ERT)
Office of Food Additive Safety (HFS-246)

Subject: FCN No. 783 – PPD D-1435 for use as an oil/grease resistant agent in the manufacture of paper and paperboard.

Hercules Incorporated
c/o Keller and Heckman, LLP
Washington, DC 20001

To: Division of Food Contact Notifications (HFS-275)
Attention: Vanee Komolprasert, Ph.D., P.E.
Through: Layla I. Batarseh, Ph.D., Supervisor, ERT LIB

The food contact substance for this notification is identified in the FCN as 2-propen-1-ol, reaction products with 1,1,1,2,2,3,3,4,4,5,5,6,6-tridecafluoro-6-iodohexane, dehydroiodinated, reaction products with epichlorohydrin and triethylenetetramine.

We have reviewed the claim of categorical exclusion for the above referenced food contact notification and have concluded that the categorical exclusion is warranted. The claim of categorical exclusion cites the section under which categorical exclusion is warranted, 21 *CFR* 25.32 (i), states compliance with the categorical exclusion criteria, and states that no extraordinary circumstances exist that would require the submission of an environmental assessment.

Please let us know if there is any change in the identity or use of the food-contact substance.

(b) (4) [redacted]

for Kiros Hailemariam, Ph.D.

cc:
HFS-246 File: FCN No. 783

HFS-246:KHailemariam:khm: 12/17/07 H:\EIS Docs\FCN\FCN783_E_CatEx.doc
FT:KHailemariam:khm:12/17/07 P:\EIS Documents\FCN\FCN 601-800\FCN783_E_CatEx.doc

Part IV - ENVIRONMENTAL INFORMATION (21 CFR Part 25)

All FCN submissions must contain either a claim of categorical exclusion under 21 CFR 25 32 or an environmental assessment (EA) under 21 CFR 25 40

A - CLAIM OF CATEGORICAL EXCLUSION

1 Cite the specific section(s) of the CFR under which the categorical exclusion is claimed

☒ **21 CFR 25.32 (i)**

a Is the FCS a component of a coating? ☒ Yes ☐ No ***(FCS may be used in coatings, and in base sheet.)***

b If no, the % of the FCS in the finished food-contact article is no more than 0.75% and

c The % of the total market volume that remains with the food-contact articles is 100%

☐ **21 CFR 25.32 (j)**

Is the FCS a component of a

a Repeat-use article? ☐ Yes ☐ No

b Permanent or semi-permanent food-contact surface? ☐ Yes ☐ No

☐ **21 CFR 25.32 (k)**

☐ **21 CFR 25.32 (q)**

a Is current FIFRA label attached? ☐ Yes ☐ No

b Is the requested use essentially the same as the label? ☐ Yes ☐ No

If current FIFRA label has limitation on food-contact uses, provide a draft copy of a revised label you intend to submit to EPA to include food-contact uses

☐ 21 CFR 25 32 (r)

2 Does your proposed food-contact use comply with the categorical exclusion criteria?
If no, go to section B below ☒ Yes ☐ No

3 To the best of your knowledge, are there any extraordinary circumstances that would require your submission of an EA? *(see 21 CFR 25 21)*
If yes, go to section B below ☐ Yes ☒ No

B - ENVIRONMENTAL ASSESSMENT

See Environmental Recommendations

1 If an EA is required, state that an EA has been prepared under 21 CFR 25 40, and is attached

2 Environmental assessments are public documents and should not contain confidential information Such information should be included in a separate section of the FCN, labeled confidential and summarized to the extent possible in the EA

Part V - CERTIFICATION

The accuracy of the statements you make in this notice should reflect your best prediction of the anticipated facts regarding the chemical substance described herein Any knowing and willful misinterpretation is subject to criminal penalty pursuant to 18 U S C 1001

The notifying party certifies that the information provided herein is accurate and complete to the best of his/her knowledge

SIGNATURE OF AUTHORIZED OFFICIAL OR AGENT

[redacted]

TITLE
Counsel for Hercules Incorporated

DATE 11/06/07

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

Date January 16, 2002

AD

From Environmental Scientist, Environmental Review Group (ERG)
Division of Chemistry Research and Environmental Review

Subject FCN No. 187 - Fluorinated polyurethane anionic resin for use as a water and oil repellant in the manufacture of paper and paperboard

Ausimont SpA
%Keller and Heckman LLP
Washington, DC 20001

To Division of Food Contact Substance Notification Review
Attention: Parvin Yasaei
Through: ERG Reviewer

We have reviewed the claim of categorical exclusion under 21 *CFR* 25.32(i) for the above referenced notification and have concluded that the categorical exclusion is warranted. The claim of categorical exclusion cites the section under which the categorical exclusion is claimed, includes a statement of compliance with the categorical exclusion criteria, and states that no extraordinary circumstances exist that require submission of an environmental assessment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Please let us know if there is any change in the identity or use of the food-contact substance.

Paul C. DeLeo, Ph.D.

000344

H. CLAIM OF CATEGORICAL EXCLUSION FROM THE NEED TO FILE AN ENVIRONMENTAL ASSESSMENT

The subject anionic polyurethane resins will chemically bind to and become a substantive part of the paper or paperboard. Thus, they will be present in finished food-contact paper and paperboard at a level not greater than 5 percent-by-weight and are expected to remain with finished food-packaging material through use by consumers. Consequently, this request qualifies for a categorical exclusion from the need to prepare an Environmental Assessment in accordance with 21 C.F.R. § 25.32(i). To the best of the Notifier's knowledge, no extraordinary circumstances exist that preclude a categorical exclusion under this section. *See* 21 C.F.R. § 25.15(d).

000037

DEPARTMENT OF HEALTH & HUMAN SERVICES

AD

Public Health Service

Food and Drug Administration
College Park, Maryland 20740

Date February 27, 2002

From Environmental Scientist, Environmental Review Group (ERG)
Division of Chemistry Research and Environmental Review

Subject FCN No. 195 - Phosphate ester of ethoxylated perfluoroether diol for use as a water and oil repellant in paper and paperboard

Ausimont SpA
% Keller and Heckman LLP
Washington, DC 20001

To Division of Food Contact Substance Notification Review (HFS-275)
Attention: Anna Shanklin, Ph.D.
Through: Supervisor, ERG LJB

We have reviewed the claim of categorical exclusion under 21 *CFR* 25.32(i) for the above referenced notification and have concluded that the categorical exclusion is warranted. The claim of categorical exclusion cites the section under which the categorical exclusion is claimed, includes a statement of compliance with the categorical exclusion criteria, and states that no extraordinary circumstances exist that require submission of an environmental assessment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Please let us know if there is any change in the identity or use of the food-contact substance.

Paul C. DeLeo, Ph.D.

000738

H. CLAIM OF CATEGORICAL EXCLUSION FROM THE NEED TO FILE AN ENVIRONMENTAL ASSESSMENT

The subject . resin will chemically bind to and become a substantive part of the paper and paperboard. Thus, it will be present in finished food-contact paper and paperboard at a level not greater than 5 percent-by-weight and is expected to remain with finished food-packaging material through use by consumers. Consequently, this request qualifies for a categorical exclusion from the need to prepare an Environmental Assessment in accordance with 21 C.F.R. § 25.32(i). To the best of the Notifier's knowledge, no extraordinary circumstances exist that preclude a categorical exclusion under this section. *See* 21 C.F.R. § 25.15(d).

February 12, 2004

Environmental Toxicologist, Environmental Review Group (ERG)
Division of Chemistry Research and Environmental Review (HFS-246)

FCN No. 398 – Perfluoropolyether dicarboxylic acid, ammonium salt as an oil and water repellent in the manufacture of food-contact paper and paperboard

Solvay-Solexis S.p.A.
Viale Lombardia 20
20021 Bollate (Milano) Italy

Division of Food Contact Notifications (HFS-275)
Attention: Paul Honigfort, Ph.D.
Through: Layla I. Batarseh, Ph.D., Supervisor, ERG ____

We have reviewed the claim of categorical exclusion for the above referenced food contact notification and have concluded that categorical exclusion is warranted. The claim of categorical exclusion cites the section under which categorical exclusion is claimed, 21 *CFR* 25.32(i), states compliance with the categorical exclusion criteria, and states that no extraordinary circumstances exist that require the submission of an environmental assessment.

Please let us know if there is any change in the identity or use of the food-contact substance.

Tong Zhou, Ph.D.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Memorandum

AD

Date: February 12, 2004

From: Environmental Toxicologist, Environmental Review Group (ERG)
Division of Chemistry Research and Environmental Review (HFS-246)

Subject: FCN No. 398 – Perfluoropolyether dicarboxylic acid, ammonium salt as an oil and water repellent in the manufacture of food-contact paper and paperboard

Solvay-Solexis S.p.A.
Viale Lombardia 20
20021 Bollate (Milano) Italy

To: Division of Food Contact Notifications (HFS-275)
Attention: Paul Honigfort, Ph.D.
Through: Layla I. Batarseh, Ph.D., Supervisor, ERG /s/

We have reviewed the claim of categorical exclusion for the above referenced food contact notification and have concluded that categorical exclusion is warranted. The claim of categorical exclusion cites the section under which categorical exclusion is claimed, 21 *CFR* 25.32(i), states compliance with the categorical exclusion criteria, and states that no extraordinary circumstances exist that require the submission of an environmental assessment.

Please let us know if there is any change in the identity or use of the food-contact substance.

/s/

Tong Zhou, Ph.D.

000477

Part IV — ENVIRONMENTAL IMPACT OF FOOD CONTACT SUBSTANCE (21 CFR part 25)

All FCN submissions must contain either a claim of categorical exclusion under 21 CFR 25.32 or an environmental assessment (EA) under 21 CFR 25.40.

A - CLAIM OF CATEGORICAL EXCLUSION

1. Cite the specific section of the CFR under which the categorical exclusion is claimed (21 CFR 25.32 (i), (j), (k), (q), or (r) 25.32 (i)

2. Does your proposed food-contact use comply with the categorical exclusion criteria? X Yes ☐ No

3. To the best of your knowledge are there any extraordinary circumstances that would require your submission of an EA? ☐ Yes X No

B - ENVIRONMENTAL ASSESSMENT

If an EA is required, state that an EA has been prepared under 21 CFR 25.40, and is attached.

Part V — CERTIFICATION

The accuracy of the statements you make in this notice should reflect your best prediction of the anticipated facts regarding the chemical substance described herein. Any knowing and willful misinterpretation is subject to criminal penalty pursuant to 18 U.S.C. 1001.

The notifying party certifies that the information provided herein is accurate and complete to the best of his/her knowledge.

/s/

000025

Signature of Authorized Official or Agent

Counsel for Solvay Solexis — Title

December 11, 2003 — Date

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

Date: July 1, 2004

From: Environmental Scientist, Environmental Review Group (ERG)
Division of Chemistry Research and Environmental Review (HFS-246)

AD

Subject: FCN No. 416 – Diphosphoric acid, polymers with ethoxylated reduced methyl esters of reduced polymerized oxidized tetrafluoroethylene

Solvay Solexis S.p.A.
20021 Bollate (Milano)
ITALY

To: Division of Food Contact Notifications (HFS-275)
Attention: Mark Hepp, Ph.D.
Through: Layla I. Batarseh, Ph.D., Supervisor, ERG LIB

We have reviewed the claim of categorical exclusion for the above referenced notification and have concluded that categorical exclusion is warranted. The claim of categorical exclusion cites the section under which categorical exclusion is claimed, 21 *CFR* 25.32(i), states compliance with the categorical exclusion criteria, and states that no extraordinary circumstances exist that require the submission of an environmental assessment.

The food-contact substance (FCS) is used as a water and oil repellant in the manufacture of paper and paperboard. This use of the FCS meets categorical exclusion criteria under 21 *CFR* 25.32(i) because essentially all of the market volume of the FCS is incorporated into finished paper and paperboard, the substance will be present in finished food-contact articles at not greater than 5% by weight, and the FCS will remain with food-contact articles through use by consumers. Specifically, the notifier indicated in the food-contact notification that FCS is fully substantive to paper and that it will be present at a level up to 1.5% by weight of paper and paperboard.

Please let us know if there is any change in the identity or use of the food-contact substance.

Jonathan L. Chappell

cc:
HFS-245 Diachenko
HFS-246 RF/Chappell
File: FCN No. 416

000127

HFS-246:JLChappell:jlc:6/27/04 H:\FCN\416\FCN416_E_CATEX.wpd
FT:JLChappell:sgm:07/01/04 p:\0pa\dpmu\eis\memos\FCN416_E_CatEx.doc

Part IV — ENVIRONMENTAL IMPACT OF FOOD CONTACT SUBSTANCE (21 CFR part 25)

All FCN submissions must contain either a claim of categorical exclusion under 21 CFR 25.32 or an environmental assessment (EA) under 21 CFR 25.40.

A - CLAIM OF CATEGORICAL EXCLUSION

1. Cite the specific section of the CFR under which the categorical exclusion is claimed (21 CFR 25.32 (i), (j), (k), (q), or (r) 25.32 (i)

2. Does your proposed food-contact use comply with the categorical exclusion criteria? X Yes ☐ No

3. To the best of your knowledge are there any extraordinary circumstances that would require your submission of an EA? ☐ Yes X No

B - ENVIRONMENTAL ASSESSMENT

If an EA is required, state that an EA has been prepared under 21 CFR 25.40, and is attached.

Part V — CERTIFICATION

The accuracy of the statements you make in this notice should reflect your best prediction of the anticipated facts regarding the chemical substance described herein. Any knowing and willful misinterpretation is subject to criminal penalty pursuant to 18 U.S.C. 1001.

The notifying party certifies that the information provided herein is accurate and complete to the best of his/her knowledge.

000024

Signature of Authorized Official or Agent

Counsel for Solvay Solexis S.p.A. — Title

25 March 2004 — Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: August 29, 2005

From: Environmental Toxicologist, Environmental Review Group (ERG)
Division of Chemistry Research and Environmental Review (HFS-246)

AD

Subject: FCN No. 538 – Perfluoropolyether dicarboxylic acid, ammonium salt for use as an oil and grease repellant in the manufacture of paper and paperboard

Solvay Solexis S.p.A.
20021 Bollate (Milano)
ITALY

To: Division of Food Contact Notifications (HFS-275)
Attention: Paul Honigfort, Ph.D.
Through: Layla Batarseh, Ph.D. Amc for LB

We have reviewed the claim of categorical exclusion for the above referenced notification and have concluded that categorical exclusion is warranted. The claim of categorical exclusion cites the section under which categorical exclusion is warranted, 21 *CFR* 25.32 (i), states compliance with the categorical exclusion criteria, and states that no extraordinary circumstances exist that require the submission of an environmental assessment.

Please let us know if there is any change in the identity or use of the food contact substance.

(b)(6)

Annette M. McCarthy, Ph.D.

cc:
HFS-246 McCarthy
File: FCN 538

HFS 246:AMcCarthy:amc:8/24/05 H:\FCN\FCN538_E_CatEx.doc
FT:AMcCarthy:amc:8/29/05 P:\EIS Documents\Memos\FCN538_E_CatEx.doc

000090

Part IV — ENVIRONMENTAL IMPACT OF FOOD CONTACT SUBSTANCE (21 CFR part 25)

All FCN submissions must contain either a claim of categorical exclusion under 21 CFR 25.32 or an environmental assessment (EA) under 21 CFR 25.40.

A - CLAIM OF CATEGORICAL EXCLUSION

1. Cite the specific section of the CFR under which the categorical exclusion is claimed (21 CFR 25.32 (i), (j), (k), (q), or (r) 25.32(i)

2. Does your proposed food-contact use comply with the categorical exclusion criteria? X Yes ☐ No

3. To the best of your knowledge are there any extraordinary circumstances that would require your submission of an EA? ☐ Yes X No

B - ENVIRONMENTAL ASSESSMENT

If an EA is required, state that an EA has been prepared under 21 CFR 25.40, and is attached.

Part V — CERTIFICATION

The accuracy of the statements you make in this notice should reflect your best prediction of the anticipated facts regarding the chemical substance described herein. Any knowing and willful misinterpretation is subject to criminal penalty pursuant to 18 U.S.C. 1001.

The notifying party certifies that the information provided herein is accurate and complete to the best of his/her knowledge.

(b)(4) [redacted]

000024

Signature of Authorized Official or Agent

Counsel for Solvay Solexis S.p.A. — Title

20 July 2005 — Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: March 1, 2010

From: Biologist, Environmental Review Team (ERT)
Office of Food Additive Safety (HFS-246)

Subject: FCN No. 962 – Diphosphoric acid, polymers with ethoxylated reduced methyl esters of reduced polymerized oxidized tetrafluoroethylene as a water and oil repellant for food-contact paper and paperboard.

Solvay Solexis, S.p.A.
10 Leonard Lane
Thorofare, NJ 08086

To: Division of Food Contact Notifications (HFS-275)
Attention: Mark A Hepp, Ph.D.
Through: William H Lamont, Acting Supervisor, ERT _____

The food-contact substance (FCS) is also known as phosphate esters of ethoxylated perfluoroether, prepared by reaction of ethoxylated perfluoroetherdiol with phosphorous pentoxide or pyrophosphoric acid. The FCS is added prior to sheet formation, or it is added at the size press in the production of paper and paperboard. Based on information provided for notified uses of the same FCS in prior food-contact notifications (FCN Nos. 195 and 416) and confirmed for the above referenced notification, the FCS is fully substantive to the paper product.

We have reviewed the claim of categorical exclusion for the above referenced notification and have concluded that categorical exclusion is warranted. The claim of categorical exclusion cites the section, 21 *CFR* 25.32 (i), under which the categorical exclusion is warranted, states compliance with the categorical exclusion criteria, and states that no extraordinary circumstances exist that require the submission of an environmental assessment.

Please let us know if there is any change in the identity or use of the food-contact substance.

Leah D. Proffitt

cc:

HFS-246 Proffitt
File: FCN No. 962

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: March 1, 2010

From: Biologist, Environmental Review Team (ERT)
Office of Food Additive Safety (HFS-246)

Subject: FCN No. 962 – Diphosphoric acid, polymers with ethoxylated reduced methyl esters of reduced polymerized oxidized tetrafluoroethylene as a water and oil repellant for food-contact paper and paperboard.

Solvay Solexis, S.p.A.
10 Leonard Lane
Thorofare, NJ 08086

To: Division of Food Contact Notifications (HFS-275)
Attention: Mark A Hepp, Ph.D.
Through: William H Lamont, Acting Supervisor, ERT wHL

The food-contact substance (FCS) is also known as phosphate esters of ethoxylated perfluoroether, prepared by reaction of ethoxylated perfluoroetherdiol with phosphorous pentoxide or pyrophosphoric acid. The FCS is added prior to sheet formation, or it is added at the size press in the production of paper and paperboard. Based on information provided for notified uses of the same FCS in prior food-contact notifications (FCN Nos. 195 and 416) and confirmed for the above referenced notification, the FCS is fully substantive to the paper product.

We have reviewed the claim of categorical exclusion for the above referenced notification and have concluded that categorical exclusion is warranted. The claim of categorical exclusion cites the section, 21 *CFR* 25.32 (i), under which the categorical exclusion is warranted, states compliance with the categorical exclusion criteria, and states that no extraordinary circumstances exist that require the submission of an environmental assessment.

Please let us know if there is any change in the identity or use of the food-contact substance.

(b)(6)

Leah D. Proffitt

cc:

HFS-246 Proffitt
File: FCN No. 962

Part IV - ENVIRONMENTAL INFORMATION (21 CFR Part 25)

All FCN submissions must contain either a claim of categorical exclusion under 21 CFR 25.32 or an environmental assessment (EA) under 21 CFR 25.40.

A - CLAIM OF CATEGORICAL EXCLUSION

1. Cite the specific section(s) of the CFR under which the categorical exclusion is claimed:

☒ **21 CFR 25.32 (i)**

a. Is the FCS a component of a coating? ☒ Yes ☐ No

b. If no, the % of the FCS in the finished food-contact article is _____ and

c. The % of the total market volume that remains with the food-contact articles is _____

☐ **21 CFR 25.32 (j)**

Is the FCS a component of a:

a. Repeat-use article? ☐ Yes ☐ No

b. Permanent or semi-permanent food-contact surface? ☐ Yes ☐ No

☐ **21 CFR 25.32 (k)**

☐ **21 CFR 25.32 (q)**

a. Is current FIFRA label attached? ☐ Yes ☐ No

b. Is the requested use essentially the same as the label? ☐ Yes ☐ No

If current FIFRA label has limitation on food-contact uses, provide a draft copy of a revised label you intend to submit to EPA to include food-contact uses.

☐ 21 CFR 25.32 (r)

2. Does your proposed food-contact use comply with the categorical exclusion criteria?
If no, go to section B below. ☒ Yes ☐ No

3. To the best of your knowledge, are there any extraordinary circumstances that would require your submission of an EA? *(see 21 CFR 25.21)*
If yes, go to section B below.. ☐ Yes ☒ No

B - ENVIRONMENTAL ASSESSMENT
See Environmental Recommendations

1. If an EA is required, state that an EA has been prepared under 21 CFR 25.40, and is attached.

2. Environmental assessments are public documents and should not contain confidential information. Such information should be included in a separate section of the FCN, labeled confidential and summarized to the extent possible in the EA.

Part V - CERTIFICATION

The accuracy of the statements you make in this notice should reflect your best prediction of the anticipated facts regarding the chemical substance described herein. Any knowing and willful misinterpretation is subject to criminal penalty pursuant to 18 U.S.C. 1001.

The notifying party certifies that the information provided herein is accurate and complete to the best of his/her knowledge.

SIGNATURE OF AUTHORIZED OFFICIAL OR AGENT

[redacted]

TITLE	DATE
Counsel for Solvay Solexis S.p.A.	1-7-10

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: June 22, 2005

From: Environmental Toxicologist, Environmental Review Group (ERG)
Division of Chemistry Research and Environmental Review (HFS-246)

Subject: FCN No. 510 – Copolymer of 1,1-difluoroethylene, hexafluoropropene, tetrafluoroethylene and a halogenated alkene

DuPont Dow Elastomers L.L.C.
Chestnut Run Plaza, PO Box 80713
Wilmington, DE 19880-0713

To: Division of Food Contact Notifications (HFS-275)
Attention: Julie Mayer

We have reviewed the claim of categorical exclusion for the above referenced notification and have concluded that categorical exclusion is warranted. The FCS is intended for use in the fabrication of molded parts intended for repeated use, such as o-rings and gaskets for food processing equipment. The claim of categorical exclusion cites the section under which categorical exclusion is warranted, 21 *CFR* 25.32 (j), states compliance with the categorical exclusion criteria, and states that no extraordinary circumstances exist that require the submission of an environmental assessment.

Please let us know if there is any change in the identity or use of the food contact substance.

Annette M. McCarthy, Ph.D.

cc:
HFS-246 McCarthy
File: FCN 510

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FT:AMcCarthy:amc:6/20/05 P:\EIS Documents\FCN510_E_CatEx.doc

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: June 22, 2005

From: Environmental Toxicologist, Environmental Review Group (ERG)
Division of Chemistry Research and Environmental Review (HFS-246)

Subject: FCN No. 510 – Copolymer of 1,1-difluoroethylene, hexafluoropropene, tetrafluoroethylene and a halogenated alkene

DuPont Dow Elastomers L.L.C.
Chestnut Run Plaza, PO Box 80713
Wilmington, DE 19880-0713

To: Division of Food Contact Notifications (HFS-275)
Attention: Julie Mayer

We have reviewed the claim of categorical exclusion for the above referenced notification and have concluded that categorical exclusion is warranted. The FCS is intended for use in the fabrication of molded parts intended for repeated use, such as o-rings and gaskets for food processing equipment. The claim of categorical exclusion cites the section under which categorical exclusion is warranted, 21 *CFR* 25.32 (j), states compliance with the categorical exclusion criteria, and states that no extraordinary circumstances exist that require the submission of an environmental assessment.

Please let us know if there is any change in the identity or use of the food contact substance.

(b) (6)

Annette M. McCarthy, Ph.D.

cc:
HFS-246 McCarthy
File: FCN 510

000237

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FT:AMcCarthy:amc:6/20/05 P:\EIS Documents\FCN510_E_CatEx.doc

Part IV — ENVIRONMENTAL IMPACT OF FOOD CONTACT SUBSTANCE (21 CFR part 25)

All FCN submissions must contain either a claim of categorical exclusion under 21 CFR 25.32 or an environmental assessment (EA) under 21 CFR 25.40.

A - CLAIM OF CATEGORICAL EXCLUSION

1. Cite the specific section of the CFR under which the categorical exclusion is claimed (21 CFR 25.32 (i), (j), (k), (q), or (r) 21 C.F.R. § 25.32(j)

2. Does your proposed food-contact use comply with the categorical exclusion criteria? ☒ Yes ☐ No

3. To the best of your knowledge are there any extraordinary circumstances that would require your submission of an EA? ☐ Yes ☒ No

B - ENVIRONMENTAL ASSESSMENT

If an EA is required, state that an EA has been prepared under 21 CFR 25.40, and is attached.

Part V — CERTIFICATION

The accuracy of the statements you make in this notice should reflect your best prediction of the anticipated facts regarding the chemical substance described herein. Any knowing and willful misinterpretation is subject to criminal penalty pursuant to 18 U.S.C. 1001.

The notifying party certifies that the information provided herein is accurate and complete to the best of his/her knowledge.

(b) (6)

Ralph A. Simmons

Signature of Authorized Official or Agent

000025

Title Partner

Date: 03/24/05

Memorandum

AD

Date: June 22, 2005

From: Environmental Toxicologist, Environmental Review Group (ERG)
Division of Chemistry Research and Environmental Review (HFS-246)

Subject: FCN No. 511 – Copolymer of 1,1-difluoroethylene, hexafluoropropene, trifluoromethyl trifluorovinyl ether and a halogenated alkene

DuPont Dow Elastomers L.L.C.
Chestnut Run Plaza, PO Box 80713
Wilmington, DE 19880-0713

To: Division of Food Contact Notifications (HFS-275)
Attention: Paul Honigfort, Ph.D.

We have reviewed the claim of categorical exclusion for the above referenced notification and have concluded that categorical exclusion is warranted. The FCS is intended for use in the fabrication of molded parts intended for repeated use, such as o-rings and gaskets for food processing equipment. The claim of categorical exclusion cites the section under which categorical exclusion is warranted, 21 *CFR* 25.32 (j), states compliance with the categorical exclusion criteria, and states that no extraordinary circumstances exist that require the submission of an environmental assessment.

Please let us know if there is any change in the identity or use of the food contact substance.

(b) (6)

Annette M. McCarthy, Ph.D.

cc:
HFS-246 McCarthy
File: FCN 511

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FT:AMcCarthy:amc:6/20/05 P:\EIS Documents\FCN511_E_CatEx.doc

000194

Part IV — ENVIRONMENTAL IMPACT OF FOOD CONTACT SUBSTANCE (21 CFR part 25)

All FCN submissions must contain either a claim of categorical exclusion under 21 CFR 25.32 or an environmental assessment (EA) under 21 CFR 25.40.

A - CLAIM OF CATEGORICAL EXCLUSION

1. Cite the specific section of the CFR under which the categorical exclusion is claimed (21 CFR 25.32 (i), (j), (k), (q), or (r) 21 C.F.R. § 25.32(j)

2. Does your proposed food-contact use comply with the categorical exclusion criteria? ☒ Yes ☐ No

3. To the best of your knowledge are there any extraordinary circumstances that would require your submission of an EA? ☐ Yes ☒ No

B - ENVIRONMENTAL ASSESSMENT

If an EA is required, state that an EA has been prepared under 21 CFR 25.40, and is attached.

000022

Part V — CERTIFICATION

The accuracy of the statements you make in this notice should reflect your best prediction of the anticipated facts regarding the chemical substance described herein. Any knowing and willful misinterpretation is subject to criminal penalty pursuant to 18 U.S.C. 1001.

The notifying party certifies that the information provided herein is accurate and complete to the best of his/her knowledge.

(b) (6) (for Jerome H. Heckman)

Signature of Authorized Official or Agent

Partner — Title

April 4, 2005 — Date

Memorandum

Date: September 23, 2005

From: Chemist, Environmental Review Group (ERG)
Division of Chemistry Research and Environmental Review (HFS-246)

AD

Subject: FCN No. 539 – Copolymer of 4-bromo-3,3,4,4-tetrafluoro-1-butene, ethylene, tetrafluoroethylene, and trifluoromethyl trifluorovinyl ether

DuPont Performance Elastomers LLC
Chestnut Run Plaza, PO Box 80713
Wilmington, DE 19880-0713

To: Division of Food Contact Notifications (HFS-275)
Attention: Kelly M. Randolph, D.V.M., M.P.H.
Through: Layla I. Batarseh, Ph.D. (b) (5)

We have reviewed the claim of categorical exclusion for the above referenced food contact notification and have concluded that categorical exclusion is warranted. The FCS is a copolymer of 4-bromo-3,3,4,4-tetrafluoro-1-butene, ethylene, tetrafluoroethylene, and trifluoromethyl trifluorovinyl ether, which is optionally cured with triallyl isocyanurate and 2,5-dimethyl-2,5-di(tert-butylperoxy)hexane. The claim of categorical exclusion cites the section under which categorical exclusion is warranted, 21 *CFR* 25.32(j), states compliance with the categorical exclusion criteria, and states that no extraordinary circumstances exist that require the submission of an environmental assessment.

Please let us know if there is any change in the identity or use of the food-contact substance.

(b) (5)

William H Lamont

cc:
(b) (5)

000223

Part IV — ENVIRONMENTAL IMPACT OF FOOD CONTACT SUBSTANCE (21 CFR part 25)

All FCN submissions must contain either a claim of categorical exclusion under 21 CFR 25.32 or an environmental assessment (EA) under 21 CFR 25.40.

A - CLAIM OF CATEGORICAL EXCLUSION

1. Cite the specific section of the CFR under which the categorical exclusion is claimed (21 CFR 25.32 (i), (j), (k), (q), or (r) 21 C.F.R. § 25.32(j)

2. Does your proposed food-contact use comply with the categorical exclusion criteria? ☒ Yes ☐ No

3. To the best of your knowledge are there any extraordinary circumstances that would require your submission of an EA? ☐ Yes ☒ No

B - ENVIRONMENTAL ASSESSMENT

If an EA is required, state that an EA has been prepared under 21 CFR 25.40, and is attached.

Part V — CERTIFICATION

The accuracy of the statements you make in this notice should reflect your best prediction of the anticipated facts regarding the chemical substance described herein. Any knowing and willful misinterpretation is subject to criminal penalty pursuant to 18 U.S.C. 1001.

The notifying party certifies that the information provided herein is accurate and complete to the best of his/her knowledge.

000025

Signature of Authorized Official or Agent

Title

Date 07/21/05

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

AD

Date: February 23, 2006

From: Environmental Toxicologist, Environmental Review Group (ERG)
Division of Chemistry Research and Environmental Review (HFS-246)

Subject: FCN No. 598 – Copolymer of propylene, tetrafluoroethylene and 3,3,3-trifluoropropene for repeat-use in the fabrication of molded parts

DuPont Performance Elastomers L.L.C.
Chestnut Run Plaza, PO Box 80713
Wilmington, DE 19880-0713

To: Division of Food Contact Notifications (HFS-275)
Attention: Vivian Gilliam
Through: Layla Batarseh, Ph.D. (b)(4) and/or (b)(6)

We have reviewed the claim of categorical exclusion for the above referenced notification and have concluded that categorical exclusion is warranted. The claim of categorical exclusion cites the section under which categorical exclusion is warranted, 21 *CFR* 25.32 (j), states compliance with the categorical exclusion criteria, and states that no extraordinary circumstances exist that require the submission of an environmental assessment.

Please let us know if there is any change in the identity or use of the food contact substance.

(b)(4) and/or (b)(6)

Annette M. McCarthy, Ph.D.

(b)(4) and/or (b)(6)

000577

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: January 13, 2010

From: Biologist, Environmental Review Team (ERT)
Office of Food Additive Safety (HFS-246)

Subject: FCN No. 947 – Copolymer of hexafluoropropylene, tetrafluoroethene and perfluoroethyl vinyl ether for use in repeat-use food-contact articles

E.I. du Pont de Nemours & Co.
Chestnut Run Plaza, Bldg. 713
Wilmington, DE 19880-0713

To: Division of Food Contact Notifications (HFS-275)
Attention: Elizabeth S. Furukawa, Ph.D.
Through: William H Lamont, Acting Supervisor, ERT _____

We have reviewed the claim of categorical exclusion for the above referenced notification and have concluded that categorical exclusion is warranted. The claim of categorical exclusion cites the section, 21 *CFR* 25.32 (j), under which the categorical exclusion is warranted, states compliance with the categorical exclusion criteria, and states that no extraordinary circumstances exist that require the submission of an environmental assessment.

Please let us know if there is any change in the identity or use of the food-contact substance.

Leah D. Proffitt

cc:

HFS-246 Proffitt
File: FCN No. 947

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: January 13, 2010

From: Biologist, Environmental Review Team (ERT)
Office of Food Additive Safety (HFS-246)

Subject: FCN No. 947 – Copolymer of hexafluoropropylene, tetrafluoroethene and perfluoroethyl vinyl ether for use in repeat-use food-contact articles

E.I. du Pont de Nemours & Co.
Chestnut Run Plaza, Bldg. 713
Wilmington, DE 19880-0713

To: Division of Food Contact Notifications (HFS-275)
Attention: Elizabeth S. Furukawa, Ph.D.
Through: William H Lamont, Acting Supervisor, ERT whl

We have reviewed the claim of categorical exclusion for the above referenced notification and have concluded that categorical exclusion is warranted. The claim of categorical exclusion cites the section, 21 *CFR* 25.32 (j), under which the categorical exclusion is warranted, states compliance with the categorical exclusion criteria, and states that no extraordinary circumstances exist that require the submission of an environmental assessment.

Please let us know if there is any change in the identity or use of the food-contact substance.

(b) (6)

Leah D. Proffitt

cc:

HFS-246 Proffitt
File: FCN No. 947

Part IV - ENVIRONMENTAL INFORMATION (21 CFR Part 25)

All FCN submissions must contain either a claim of categorical exclusion under 21 CFR 25.32 or an environmental assessment (EA) under 21 CFR 25.40.

A - CLAIM OF CATEGORICAL EXCLUSION

1. Cite the specific section(s) of the CFR under which the categorical exclusion is claimed:

☐ **21 CFR 25.32 (i)**

a. Is the FCS a component of a coating? ☐ Yes ☐ No

b. If no, the % of the FCS in the finished food-contact article is _____ and

c. The % of the total market volume that remains with the food-contact articles is _____

☒ **21 CFR 25.32 (j)**

Is the FCS a component of a:

a. Repeat-use article? ☒ Yes ☐ No

b. Permanent or semi-permanent food-contact surface? ☐ Yes ☐ No

☐ **21 CFR 25.32 (k)**

☐ **21 CFR 25.32 (q)**

a. Is current FIFRA label attached? ☐ Yes ☐ No

b. Is the requested use essentially the same as the label? ☐ Yes ☐ No

If current FIFRA label has limitation on food-contact uses, provide a draft copy of a revised label you intend to submit to EPA to include food-contact uses.

☐ 21 CFR 25.32 (r)

2. Does your proposed food-contact use comply with the categorical exclusion criteria?
If no, go to section B below. ☒ Yes ☐ No

3. To the best of your knowledge, are there any extraordinary circumstances that would require your submission of an EA? *(see 21 CFR 25.21)*
If yes, go to section B below.. ☐ Yes ☒ No

B - ENVIRONMENTAL ASSESSMENT

See Environmental Recommendations

1. If an EA is required, state that an EA has been prepared under 21 CFR 25.40, and is attached.

2. Environmental assessments are public documents and should not contain confidential information. Such information should be included in a separate section of the FCN, labeled confidential and summarized to the extent possible in the EA.

No EA is required.

Part V – CERTIFICATION

The accuracy of the statements you make in this notice should reflect your best prediction of the anticipated facts regarding the chemical substance descr bed herein. Any knowing and willful misinterpretation is subject to criminal penalty pursuant to 18 U.S.C. 1001.

The notifying party certifies that the information provided herein is accurate and complete to the best of his/her knowledge.

SIGNATURE OF AUTHORIZED OFFICIAL OR AGENT

TITLE	DATE
Counsel for Notifier, E. I. du Pont de Nemours and Company	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: January 13, 2010

From: Biologist, Environmental Review Team (ERT)
Office of Food Additive Safety (HFS-246)

Subject: FCN No. 948 – Ethene, 1,1,2,2-tetrafluoro-, polymer with 1,1,2-trifluoro-2-(1,1,2,2,2-pentafluoroethoxy)ethane for use in repeat-use food-contact articles

E.I. du Pont de Nemours & Co.
Chestnut Run Plaza, Bldg. 713
Wilmington, DE 19880-0713

To: Division of Food Contact Notifications (HFS-275)
Attention: Mark A. Hepp, Ph.D.
Through: William H Lamont, Acting Supervisor, ERT _____

We have reviewed the claim of categorical exclusion for the above referenced notification and have concluded that categorical exclusion is warranted. The claim of categorical exclusion cites the section, 21 *CFR* 25.32 (j), under which the categorical exclusion is warranted, states compliance with the categorical exclusion criteria, and states that no extraordinary circumstances exist that require the submission of an environmental assessment.

Please let us know if there is any change in the identity or use of the food-contact substance.

Leah D. Proffitt

cc:

HFS-246 Proffitt
File: FCN No. 948

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: January 13, 2010

From: Biologist, Environmental Review Team (ERT)
Office of Food Additive Safety (HFS-246)

Subject: FCN No. 948 – Ethene, 1,1,2,2-tetrafluoro-, polymer with 1,1,2-trifluoro-2-(1,1,2,2,2-pentafluoroethoxy)ethane for use in repeat-use food-contact articles

E.I. du Pont de Nemours & Co.
Chestnut Run Plaza, Bldg. 713
Wilmington, DE 19880-0713

To: Division of Food Contact Notifications (HFS-275)
Attention: Mark A. Hepp, Ph.D.
Through: William H Lamont, Acting Supervisor, ERT whl

We have reviewed the claim of categorical exclusion for the above referenced notification and have concluded that categorical exclusion is warranted. The claim of categorical exclusion cites the section, 21 *CFR* 25.32 (j), under which the categorical exclusion is warranted, states compliance with the categorical exclusion criteria, and states that no extraordinary circumstances exist that require the submission of an environmental assessment.

Please let us know if there is any change in the identity or use of the food-contact substance.

(b) (6) [redacted]

Leah D. Proffitt

cc:

HFS-246 Proffitt
File: FCN No. 948

ENVIRONMENTAL REVIEW

This memorandum may contain confidential or proprietary business information. It should be redacted before release to the public in response to a FOIA request.

FCN 948

Phase 1 meeting: 11/18/09

Reviewer: Leah Proffitt

Notifier: E. I. du Pont de Nemours and Company

Proposed FCS: Ethene, 1,1,2,2-tetrafluoro-, polymer with 1,1,2-trifluoro-2-(1,1,2,2,2-pentafluoroethoxy)ethane

Proposed Use: The food-contact substance (FCS) will be used in repeated-use food-contact applications, such as articles (tubing, tanks, and fittings for food equipment), coatings on metal bakeware and cookware, and coatings on metal pipe linings. The coatings will have a maximum thickness of 15 mils.

Related Submissions: None reported for the specific FCS.

Environmental Submission: The notifier submitted a claim of categorical exclusion under 21 CFR 25.32 (j).

Environmental Review Conclusion: We have reviewed the claim of categorical exclusion for FCN 947 and have concluded that the claim is warranted. The notifier cited the section, 21 CFR 25.32 (j), under which categorical exclusion is warranted, stated compliance with the categorical exclusion criteria, and stated that no extraordinary circumstances exist that require submission of an environmental assessment.

Please let us know if there is any change in the identity or proposed use of the FCS.

Status: Effective

ENVIRONMENTAL REVIEW

This memorandum may contain confidential or proprietary business information. It should be redacted before release to the public in response to a FOIA request.

FCN 948

Phase 1 meeting: 11/18/09

Reviewer: Leah Proffitt

Notifier: E. I. du Pont de Nemours and Company

Proposed FCS: Ethene, 1,1,2,2-tetrafluoro-, polymer with 1,1,2-trifluoro-2-(1,1,2,2,2-pentafluoroethoxy)ethane

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Related Submissions: None reported for the specific FCS.

Environmental Submission: The notifier submitted a claim of categorical exclusion under 21 CFR 25.32 (j).

Environmental Review Conclusion: We have reviewed the claim of categorical exclusion for FCN 947 and have concluded that the claim is warranted. The notifier cited the section, 21 CFR 25.32 (j), under which categorical exclusion is warranted, stated compliance with the categorical exclusion criteria, and stated that no extraordinary circumstances exist that require submission of an environmental assessment.

Please let us know if there is any change in the identity or proposed use of the FCS.

Status: Effective

Part IV - ENVIRONMENTAL INFORMATION (21 CFR Part 25)

All FCN submissions must contain either a claim of categorical exclusion under 21 CFR 25.32 or an environmental assessment (EA) under 21 CFR 25.40.

A - CLAIM OF CATEGORICAL EXCLUSION

1. Cite the specific section(s) of the CFR under which the categorical exclusion is claimed:

☐ **21 CFR 25.32 (l)**

a. Is the FCS a component of a coating? ☐ Yes ☐ No

b. If no, the % of the FCS in the finished food-contact article is _____ and

c. The % of the total market volume that remains with the food-contact articles is _____

☒ **21 CFR 25.32 (j)**

Is the FCS a component of a:

a. Repeat-use article? ☒ Yes ☐ No

b. Permanent or semi-permanent food-contact surface? ☐ Yes ☐ No

☐ **21 CFR 25.32 (k)**

☐ **21 CFR 25.32 (q)**

a. Is current FIFRA label attached? ☐ Yes ☐ No

b. Is the requested use essentially the same as the label? ☐ Yes ☐ No

If current FIFRA label has limitation on food-contact uses, provide a draft copy of a revised label you intend to submit to EPA to include food-contact uses.

☐ 21 CFR 25.32 (r)

2. Does your proposed food-contact use comply with the categorical exclusion criteria?
If no, go to section B below. ☒ Yes ☐ No

3. To the best of your knowledge, are there any extraordinary circumstances that would require your submission of an EA? *(see 21 CFR 25.21)*
If yes, go to section B below.. ☐ Yes ☒ No

B - ENVIRONMENTAL ASSESSMENT

See Environmental Recommendations

1. If an EA is required, state that an EA has been prepared under 21 CFR 25.40, and is attached.

2. Environmental assessments are public documents and should not contain confidential information. Such information should be included in a separate section of the FCN, labeled confidential and summarized to the extent possible in the EA.

No EA is required.

Part V - CERTIFICATION

The accuracy of the statements you make in this notice should reflect your best prediction of the anticipated facts regarding the chemical substance described herein. Any knowing and willful misinterpretation is subject to criminal penalty pursuant to 18 U.S.C. 1001.

The notifying party certifies that the information provided herein is accurate and complete to the best of his/her knowledge.

SIGNATURE OF AUTHORIZED OFFICIAL OR AGENT

(b) (6) [redacted]

TITLE	DATE
Counsel for Notifier, E. I. du Pont de Nemours and Company	10-26-09