



Memorandum

Date: May 30, 2003

From: Kelly M. Randolph, D.V.M., M.P.H. (HFS-275)

Subject: Food Contact Substance Notification FCN No. 000338

To: Administrative File, Food Contact Substance Notification FCN No. 000338

AD



This memorandum is in reference to FCN 000338 received April 21, 2003, from DuPont Chemical Solutions Enterprise and submitted in accordance with section 409(h) of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 348(h)).

Background Information:

This food contact substance (FCS) was the subject of two previous food contact notifications (FCN 206 and FCN 311). FCN 206 covers the use of (b) (4) as an oil and grease resistant treatment for paper and paperboard at levels not to exceed 0.18 wt.% of fluorine based on paper, for use in contact with all types of food under conditions of Use B-H. FCN 206 became effective June 12, 2002. FCN 311 covers the use of (b) (4) as an oil and grease resistant treatment for paper and paperboard intended for single service use in microwave heat-susceptor packaging; the FCS is intended to contact all food types and will not exceed 0.18 wt. % of flourine based on the weight of the paper.

This notification (FCN 338) is for the same use of the subject fluorinated copolymers in FCN 206, but at a higher use level in paper and paperboard. The data and information in FCN 206 and FCN 311 is incorporated by reference into FCN 338.

Notifier: DuPont Chemical Solutions Enterprise

FCS: Copolymers of 2-perfluoroalkyethyl acrylate, 2-N,N-diethylaminoethyl methacrylate, and glycidyl methacrylate.

Trade Name (b) (4)

CAS#: 247047-61-6

Intended Use: For use as an oil and grease resistant treatment for paper and paperboard intended for food-contact use.

Specifications/Limitations: The food-contact substance (FCS) is intended to contact all food types under Conditions of Use B through H. The maximum level of the FCS will not exceed 0.37 wt.% fluorine (0.69 wt. % of the FCS) based on the weight of the paper.

Regulatory Status of Food Contact Substance:

FCN 206 and FCN 311

Regulatory Status of all reagents, monomers, solvents, catalyst, and purification aids:

2-perfluoroalkyl acrylate (ZFAN) CAS# 65605-70-1, FCN 206, FCN311

2-propenoic acid, 2-methyl-, 2-(diethylamino)ethyl ester (DEAM) CAS# 105-16-8; FCN 206 and FCN 311

glycidyl methacrylate (GMA) CAS # 106-91-2; FCN 206 and FCN 311, 21 CFR 176.180, 175.300 cross linking agent

(b) (4)



Impurities

2-perfluoroalkylethyl acrylate (ZFAN) CAS# 65605-70-1; FCN 206 and FCN 311

2-propenoic acid, 2-methyl-,2-(diethylamino)ethyl ester (DEAM) CAS# 105-16-8; FCN 206 and FCN 311

glycidyl methacrylate (GMA) CAS# 106-91-2;FCN 206 & FCN 311, 176.180, 175.300 cross linking agent

Telomer BA CAS Registry Numbers and regulations:

1,1,2,2-Tetrahydroperfluoro-1-Hexanol CAS Reg. 2043-47-2

1,1,2,2-Tetrahydroperfluoro-1-Octanol CAS Reg. 647-42-7

1,1,2,2-Tetrahydroperfluoro-1-Decanol CAS Reg. 678-39-7

1,1,2,2-Tetrahydroperfluoro-1-Dodecanol CAS Reg. 865-86-1

1,1,2,2-Tetrahydroperfluoro-1-Dodecanol Tetradecanol CAS Reg. 39239-77-5

1,1,2,2-Tetrahydroperfluoro-1-Hexadecanol CAS Reg. 60699-51-6

1,1,2,2-Tetrahydroperfluoro-1-Octadecanol CAS Reg. 65104-67-8

1,1,2,2-Tetrahydroperfluoro-1-Eicosanol Cas Reg. 65104-65-6

(b) (4)

Diethylaminoethanol (DEAE)

•Telomer BA has been allowed in FCN 206 and FCN 311

I. Chemistry Review

This Notification is for use of the subject fluorinated copolymers as an oil and grease resistant treatment for paper and paperboard for use in contact with all types of food under Conditions of Use B through H. The only difference between this FCN and FCN 206 is that this notification seeks what K&H refer to as "a slightly higher" use level for the food-contact substance. It is essentially doubled. Specifically, the copolymers are intended for use at levels not to exceed 0.37 wt. % of fluorine based on paper (instead of 0.18%); because the fluorine content of the copolymer is 53.6 ± 3 wt. %, the intended use level is 0.69 ± 0.01 wt. % of (b) (4) copolymer based on paper. This higher treatment level is needed to achieve the appropriate effect in certain specialty paper and paperboard applications, such as molded pulp. The requested clearance is otherwise identical to the clearance provided by FCN 206. The requested clearance will have no effect on the clearance for the microwave use provided by FCN 311.

Rather than reiterate the identity and manufacturing details from the previous submissions, please review relevant memoranda.¹

Exposure

The exposures to the FCS and its components are summarized in the table below. The cumulative estimated daily intake (CEDI) assumes a daily diet of 3000 grams of food per person per day. The dietary concentrations (DCs) from the current submission are essentially double the values we determined for FCN 206 with the exception of the oligomers which increased by .9 ppb (FCN 206 oligomers 7ppb) (FCN 338 oligomers 7.9 ppb). The FCN 206 uses are subsumed by the uses proposed in the current submission.

Chemical Name	DC (ppb)		DC, total (ppb)	CEDI (µg/p/day)
	FCN 338 ³	FCN 311		

¹ FCN 206, memorandum from K. Arvidson to J. Smith dated 6-10-02; FCN 311, memorandum from K. Smeds to K. Williams dated 2-20-03.

² Less than 1000 Daltons.

³ Includes FCN 206 applications.

Oligomers ²	7.9	0.13	8.0	24
ZFAN	2.9	0.023	2.9	8.7
DEAM	0.14	0.001	0.14	0.42
GMA	0.009	0.00008	0.009	0.027
Telomer BA	3.8	0.21	4.0	12
DEAE	36	0.05	36	110

Conclusion

Our preliminary exposure estimates, summarized above, are essentially double the exposures determined for FCN 206, consistent with the proposed use in the current FCN that is double the value of the proposed use in FCN 206.

Final Chemistry Comments

We have no questions.

II. Toxicology Review

Toxicity of FCS: No data have been provided on the toxicity of the food contact substance itself. In FCN 206 the dietary concentration (DC) for Zonyl 9464 oligomers was estimated to be 7 ppb.

**Table I
Constituents / Impurities**

Chemical Name (C.A.S. #)	Function	DC ppb	Existing Reg. 21 CFR	Notifier Literature Search ?
Oligomers		7.9		No
perfluoroalkylethyl acrylate (ZFAN) (65605-70-1)	monomer	2.9		No (data, FCN 206)
2-N,N-diethyl aminoethyl methacrylate (DEAM) (105-16-8)	monomer	0.14		Yes (FCN 206)
glycidyl methacrylate (GMA) (106-91-2)	monomer	0.009	176.180 175.300	Yes (FCN 206)
Telomer BA (perfluoroalkylethanol)	hydrolysis product	3.8		No (data, FCN 206)

(b) (4)

Chemical Name (C.A.S. #)	Function	DC ppb	Existing Reg. 21 CFR	Notifier Literature Search ?
Diethylaminoethanol (DEAE) (100-37-8)	hydrolysis product	36		Yes (FCN 206)

III. Toxicity Information Provided

A. Safety Narrative - (*Chemicals discussed, brief summary of effects, lowest NOEL*)

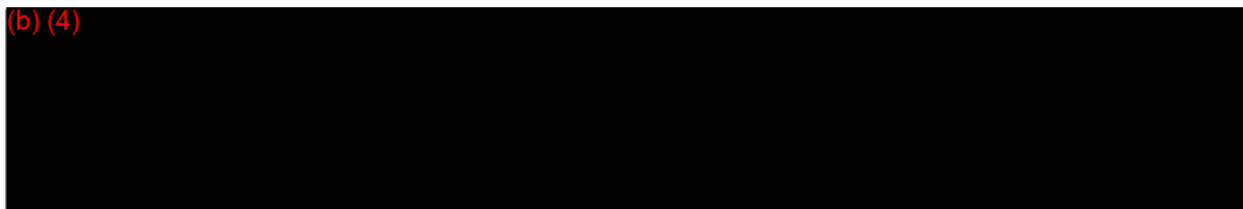
A short safety narrative was provided citing data provided in FCN 206 and FCN 311. Since migrating polymer constituents and CEDIs are only slightly higher than previously accepted for FCN 206 and FCN 311 combined, the Notifier claims that no additional safety questions arise in the present FCN (338).

B. List of Publications / Unpublished Studies Provided with Submission for Substances listed in Table I.

No additional safety data provided beyond citation of FCN 206 and FCN 311.

C. Discussion of Safety Submission Deficiencies:

(b) (4)



IV. Safety Submission Conclusion

Toxicology has no further questions

References

Sheu, C. (2002) FCN 206 - Final Review. FDA / CFSAN / DFCNSR