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DuPont Legal

13p.

Andrea V. Malinowski

Corporate Counsel

DuPont Legal D-7078

1007 Market Street

Wilmington, Delaware 19898

Phone: 302-774-6443

Fax: 302-774-4812

E-mail: Andrea.V.Malinowski@usa.dupont.com

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VIA OVERNIGHT MAIL

CONTAINS NO CBI

Mr. Richard H. Hefter

Chief

High Production Volume Chemicals Branch (7403M))

Office of Pollution Prevention and Toxics

U.S. Environmental Protection Agency

1201 Constitution Avenue, NW

Washington, DC 20004-3302

Re: FYI Submission



Dear Mr. Hefter:

During discovery in a class action lawsuit against DuPont, plaintiffs' counsel recently provided DuPont with what appear to be three versions of an abstract for a paper authored by James Dahlgren, et al. These three abstracts are enclosed. We understand that Dr. Dahlgren undertook this work on behalf of plaintiffs in the lawsuit. DuPont does not know whether plaintiffs' counsel has already submitted these abstracts to EPA.

DuPont is submitting these abstracts for informational purposes only, and because DuPont recognizes EPA's interest in and desire to obtain as much information as possible on perfluorinated compounds. DuPont's submission of the attached abstracts is not intended to imply that, nor should it be construed that, DuPont believes the information contained in them is in any way indicative of any actual risk, or that the information meets EPA's criteria for reporting under TSCA Section 8(e).

The limited information reported in the abstracts cannot reasonably support any conclusion of risk, for many reasons. For example, the abstracts' authors conclude only

that the information that they collected via questionnaire "*suggests*" that exposure "*may*" cause an effect. EPA guidance on Section 8(e) states that information that only "*may suggest*" a concern does not require reporting. In EPA's 1978 TSCA Section 8(e) Statement of Interpretation and Enforcement Policy, EPA noted that the Agency was deleting proposed language that would have required reporting when a person obtains information that "*may suggest*" a substantial risk. EPA deleted this language in response to numerous comments pointing out that the Administrator lacked authority to compel reporting of information that only "*may suggest*" a substantial risk.¹ EPA's June 3, 2003 TSCA Section 8(e) Notification of Substantial Risk; Policy Clarification and Reporting Guidance (68 FR 33129) does not question or alter this longstanding Agency position.

DuPont also notes that the abstracts do not provide sufficient information to meaningfully evaluate or to reach any objective conclusion regarding the authors' statement that the results "*suggest*" an effect. For example, the results appear to be made from inappropriate rate comparisons and consequently reach erroneous conclusions. Plaintiffs' counsel has provided DuPont with what appears to be raw data from the questionnaires referenced in the abstracts. DuPont has asked plaintiffs' counsel to provide additional information and data necessary to interpret and analyze such raw data. Plaintiffs' counsel has not, as of this date, provided the requested information. DuPont suggests that EPA contact Dr. Dahlgren for more information, if the Agency believes that this survey is worth investigating further.

DuPont also understands that one of the abstracts was made public as a poster presentation at a conference of the Society of Environmental Toxicology and Chemistry (SETAC) conference in Prague, Czechoslovakia on April 19, 2004, and therefore EPA may already have received this abstract. It is our understanding that a hard copy of the abstracts was made available to all conference attendees and that the full manuscript would be made available upon request. The abstract (without the results Table) may be obtained through the SETAC website at www.setac.org. (specifically, at <http://www.zuova.cz/vc/index.php?a=topic&x=1329&>). Other abstracts presented at the conference and pertaining to perfluorinated chemicals are accessible through the SETAC website at <http://www.zuova.cz/vc/>.

If you need any additional information, please contact me directly.

Very truly yours,



Andrea V. Malinowski

Counsel for E. I. DuPont de Nemours and Company

¹ See Supplementary Information, Paragraph (3) from EPA's Statement of Interpretation and Enforcement Policy; Notification of Substantial Risk, 43 Fed. Reg. 11110 (March 16, 1978).

Attachments (3 abstracts)

cc: Document Processing Center (7407M)
Attn: FYI Submission
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460-0011

ATTACHMENTS

1. Abstract: Cancer Prevalence in Subjects Exposed to Perfluorooctanoic Acid (PFOA) - 3 pages [LE 1806 – LE 1808]
2. Abstract: Cancer Prevalence in Subjects Exposed to Alkylated Substances (PFAS) – 3 pages [LE 1824 – LE 1826]
3. Abstract: Cancer Prevalence in Subjects Exposed to Alkylated Substances (PFAS) – 3 pages [LE1828 – LE1830]