AR 226 - 0634

2PP

Barbara Leczynski
08/17/2000 06:45 PM

To: Karen Lannon/DC/USEPA/US@EPA
cc:
Subject: request for information on perfluorochemicals

---------- Forwarded by Barbara Leczynski/DC/USEPA/US on 08/17/2000 06:34 PM ----------

Charles Auer
04/19/2000 08:42 AM

To: gerald.l.kennedy@usa.dupont.com
cc: Oscar Hernandez/DC/USEPA/US@EPA, Neil Patel/DC/USEPA/US@EPA, Barbara Leczynski/DC/USEPA/US@EPA
Subject: request for information on perfluorochemicals

Dear Gerry,

As discussed on April 13 by phone, EPA needs to review complete copies of final reports and any other relevant information in your possession or control on carboxylated and sulfonated perfluorochemicals, with initial focus on PFOA (perfluoro octanoic acid). The requested information includes health effects studies (including pharmacokinetics), environmental effects studies, environmental fate studies and information, and human and environmental exposure studies and information, including monitoring. If final reports are not available, we request that you clarify the status of any ongoing studies with regard to projected completion date and provide us with the latest and most complete version of any preliminary reports in your possession or control.

We request that you provide us with the above information on PFOA by May 26, 2000. Regarding the sulfonated perfluorochemicals, our initial interest is focused on perfluorooctyl sulfonic acid (PFOS) and we request that you provide the above information on PFOS by April 28, 2000.

If you have any of the above information on other carboxylated or sulfonated perfluorochemicals , we request that, by April 28, 2000, you initially identify the chemicals to allow us to confirm our interest, and then provide the requested information in your possession or control on other sulfonated perfluorochemicals by May 19, 2000 and on other carboxylated perfluorochemicals by a week later, May 26, 2000. The information on these additional chemicals can most usefully be provided in chemical specific increments as they are completed, with completion of the full submissions by the dates requested.

A few points of clarification regarding this request:

>duPont need not resubmit copies of studies already provided to EPA (e.g., under TSCA §8(e),

as FYIs, under FIFRA) although we do request that you provide a comprehensive bibliography of the studies already submitted so we can check this against our holdings.

>copies of acute systemic toxicity studies can be limited to the key or critical studies as described in the Data Adequacy and robust summary guidance developed for the HPV Challenge Program. Under this approach all studies will be cited in a bibliographic listing although full copies can be limited to studies which (1) serve to identify lowest (i.e., most toxic) lethal dose values by different routes or (2) report observed effects which differ from those seen in studies (using the same route) submitted under (1).

>skin and eye irritation studies can be handled in a manner consistent with that outlined for acute systemic toxicity (i.e., submit copies of the key or critical studies which serve to set out the irritation potential of the chemical and other irritation studies which show effects which differ from those reported in submitted studies).

>the initial request is generally limited to studies conducted during or after 1976. For studies conducted prior to 1976, we ask for a bibliography listing all studies and for full copies of studies in the following endpoint areas: genetic toxicity; subchronic toxicity; reproductive toxicity; developmental toxicity; immunotoxicity; uptake/metabolism; chronic toxicity/carcinogenicity; neurotoxicity.

>regarding exposure information, we are most interested in receiving information and data of the types found in the Use and Exposure Information Profile (UEIP; the UEIP has been used to support SIDS assessments in the US) and information on results of exposure or monitoring studies (human and environmental), including full copies of studies where available and including details on procedures and methods used for sampling and analysis. We are also interested in studies relating to the ultimate environmental fate and distribution of these chemicals.

In order to maintain the integrity of your submissions, please submit all information on a given chemical as a separate "For Your Information" (FYI) submission. You may also submit the information as supplements to any prior submissions by your company under TSCA §8(e) relating to these chemicals. As always, any CBI must be submitted in accordance with applicable procedures. If you have any questions with regard to the submission procedures, or you wish to work out the arrangements in advance, please contact Terry O'Bryan (202-260-3483).

If you have any general questions regarding this request, please contact me by email or phone (202-260-3749). I thank you in advance for your cooperation.

Charles M. Auer, Director
Chemical Control Division
Office of Pollution Prevention and Toxics/OPPTS/EPA