Auer.Charles@epamail.epa.gov on 04/11/2000 01:40:35 PM

To: Dan C. Hakes/US-Corporate/3M/US
cc: Hernandez.Oscar@epamail.epa.gov
patel.neil@epamail.epa.gov
Penberthy.Ward@epamail.epa.gov
Subject: follow-up on perfluorochemicals request

Attn: Bill Weppner and Dan Hakes, 3M

Dear Bill and Dan,

I found yesterday's phone call useful in helping to sharpen and clarify some of our priority needs for submission of test data in 3M?s possession or control on the perfluorochemicals as discussed in my email message of April 7, 2000. As we discussed:

>3M need not resubmit copies of studies already provided to EPA (e.g., under TSCA §8(e), 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 must 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 will take a close look at the white paper on exposure previously provided by 3M and get back to you with additional points where relevant.

Tab 362

>Regarding PFOS, we request that 3M by April 24, 2000, send full copies of studies relating to reproductive toxicity, developmental toxicity, pharmacokinetics (including the results of the 2-generation study analysis), and human bio- and occupational monitoring (especially details of analytical chemistry methods and study protocols to allow us to evaluate studies already provided). Per our discussion the date for submission of the other information on PFOS as outlined in my April 7 email message will be extended to April 28, 2000.

>Regarding other sulfonated perfluorochemicals appearing in Table 1 of 3M?s March 1, 2000 white paper (as discussed in my April 7 email), 3M is asked to provide the requested information by May 19, 2000.

>Information on PFOA, a carboxylated perfluorochemical, is requested to be provided by May 26, 2000 (rather than May 19 as indicated in my April 7 email message), and should be submitted as supplements to your company?s prior submissions under TSCA 8(e) 394 (not 8(e) 373/374 as otherwise discussed in my April 7 email message).

Except as discussed above, the requests and guidance provided in may April 7, 2000 email continue to apply to this request by EPA for information. 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

Tab 362