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3M

CERTIFIED MAIL
Document Processing Center (7407)
ATTN: Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
US Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

Re: TSCA 8(e) Notice for Perfluorooctane Sulfonyl Fluoride-based Production Processes

Dear Sir:

Pursuant to Section 8(e) of the Toxic Substances Control Act, 3M is reporting the draft results of an update of a retrospective cohort mortality study of workers at the Decatur, Alabama manufacturing facility. The study update was performed by the University of Minnesota's Division of Environmental and Occupational Health and included workers with at least one year of cumulative employment at the plant prior to December 31, 1997. The cohort of 2,083 employees was followed from 1961 through 1998.

This mortality study was originally initiated as part of an ongoing monitoring program of fluorochemical production workers that began in the late 1970's. Previous study results showed a healthy worker effect and no statistically significant elevations of standard mortality ratios for any cause among fluorochemical production workers at Decatur [Mandel, 1995]. In addition, testing done through regular medical monitoring has not associated abnormal clinical chemistry results with Decatur employees' serum levels for perfluorooctane sulfonate [Olsen, 1999].

In the current update of this cohort mortality study, the cohort was divided into three exposure categories based on job titles in the employee's work history and knowledge of serum PFOS levels generally found in employees with that job title - no workplace exposure to perfluorooctanesulfonyl fluoride (POSF)-based chemistries; low potential workplace exposure to POSF-based chemistries; and ever had job with high potential workplace exposure to POSF-based chemistries. There were fewer than expected deaths from all causes (145 v. 230 expected) and from all cancers (39 v. 54 expected) in the overall cohort. In the highest exposed group, there were fewer than expected overall deaths (65 v. 93 expected) and deaths from cancer (18 v. 21 expected). The basis of this section 8(e) report is that the study did find a statistically significantly elevated standard morality ratio (SMR) for bladder cancer (coded as malignant neoplasm of the bladder and other urinary organs) in the high exposure group. The SMR for this cause in the high potential exposure group was 16.1 (3 observed, 0.2 expected, 95% confidence interval 3.3-47.1). All three employees who died from bladder cancer worked in the facility beginning in the 1960's and the last retired by 1989. One died prior to 1992 and the other two died between 1992 and 1998.

Although the study shows an association between workers ever employed in jobs with high exposure to POSF-based fluorochemicals at Decatur and bladder cancer, existing toxicology data indicate it is unlikely that POSF chemistry exposure is related to these tumors. Perfluorooctane sulfonate and N-ethyl-perfluorooctanesulfomamidoethanol have both been extensively studied. Neither is genotoxic in multiple studies. Two-year bioassays on both compounds, in rats, are nearing completion. Preliminary information shows no tumors of the urinary bladder in the high dose group of either study. (Final reports pending.) No acute or subchronic study for either compound has shown any bladder or urinary tract toxicity. Other possible explanations for the study finding are chance, exposure to other chemicals in the work environment and personal risk factors such as smoking or recurrent urinary tract stones or infection. In general, the exposure stratification used in this study would apply to exposure to most chemicals used on the site, not just POSF-based chemistries. We are currently investigating whether there has been historical use of known or suspected bladder carcinogens at this location.

The liver has been the target organ in animal studies done with perfluorooctane sulfonate and N-ethyl-perfluorooctanesulfonamidoethanol. The two-year feeding study of N-ethyl-perfluorooctanesulfonamidoethanol resulted in a significant increase in benign liver adenomas in high dose female rats. (Supplemental 8(e) notice dated December 4, 2000) In this mortality study there were two cases of death from liver cancer - one in the low exposure group and one in the high exposure group (SMR = 3.1, observed = 2, expected = .65, 95% confidence interval = 0.4-11.1). In one of these cases, there is still uncertainty as to whether the death of this 85-year-old male was related to a primary liver cancer or a metastatic process to the liver. In the other case, the employment duration was brief (one year) and the worker was young (36 years), raising the possibility of another causative explanation (viral).

The final report will be forwarded to you when available from the University of Minnesota.

Please contact Dr. Larry Zobel, 3M Medical Director at 651-733-5181 if you have any questions concerning this filing.

Sincerely,

Charles Reich
Executive Vice President

References:

Mandel J, Johnson R. Mortality study of employees at 3M plant in Decatur, Alabama. Division of Environmental and Occupational Health, School of Public Health, University of Minnesota, Minneapolis, Minnesota, 1995.

Olsen GW, Burris JM, Mandel JH, Zobel LR. Serum perfluorooctane sulfonate and hepatic and lipid clinical chemistry tests in fluorochemical production employees. Journal of Occupational and Environmental Medicine 1999; 41(9): 799-806.