

3M

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July 1, 2004

AR226-1800

Document Processing Center
EPA East – Room 6428 Attn: Section 8(e)
Office of Pollution Prevention and Toxics
US EPA
1200 Pennsylvania Avenue NW
Washington DC 20460-0001

RE: TSCA 8(E) SUPPLEMENTAL SUBMISSION:
Docket No. 8EHQ-1180-373

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OPPT-810
2004 JUL 21 11 8:49

Dear Sirs:

3M has received preliminary results for a 90-day inhalation study in rats conducted with perfluorooctanesulfonyl fluoride (POSF, CAS# 307-35-7) indicating that the test substance metabolizes to perfluorooctane sulfonate (PFOS, CAS# 2795-39-3).

The study was conducted by Huntingdon Life Sciences, Ltd. Sprague Dawley rats, five females and five males per group, were exposed to POSF vapor at 0, 30, 100, and 300 ppm by nose for six hours per day, five days per week, for thirteen continuous weeks. Animals were evaluated after a four-week recovery period following the thirteen-week exposure.

Analysis of sera samples, livers, and urine from these rats identified PFOS, the hydrolysis product of POSF, as well as perfluorooctanoate (PFOA), a manufacturing residual of POSF. POSF itself was not identified in the sera, liver, and urine. In males, PFOS and PFOA concentrations increased in proportion to POSF exposure concentration level in all biological matrices. In females, PFOS concentrations increased in proportion to POSF exposure concentration level in all matrices. PFOA was detected in proportion to POSF exposure concentration in the urine of females; however, because PFOA is rapidly eliminated in female rats compared to male rats, PFOA was only detectable above the limit of detection (serum) or background (liver) in serum and liver samples from females in the highest exposure concentration group.

As consistent with previously submitted studies, 3M believes that the POSF test substance metabolizes to PFOS. 3M does not believe that the POSF test substance metabolizes to PFOA. Rather, the PFOA concentrations in male rat sera were in the range expected based on the level of PFOA contamination of the test substance and



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the relationship of exposure concentration of PFOA to steady-state serum PFOA concentrations (Hinderliter et al., 2004)¹.

Additional findings of this study include body weight effects, liver hypertrophy, respiratory irritation, and some clinical chemistry effects similar to those observed after PFOS and/or PFOA treatment, as reported previously to EPA. A no-effect level was not observed; liver cell histopathologic effects were observed at 30 ppm.

POSF was used as an intermediate gas in an isolated industrial process to produce PFOS and related products. 3M no longer manufactures POSF.

A final report will be forwarded to EPA when received.

Please contact John Butenhoff (651-733-1962) if you have any questions or if we can provide additional information.

Sincerely,

A handwritten signature in black ink, appearing to read "L. Zobel", is written over the printed name.

Larry R. Zobel, MD MPH
Staff Vice President and Medical Director

¹ Hinderliter, P. M., DeLorme, M. P., and Jepson, G. W. (2004). Perfluorooctanoic acid: relationship between repeated inhalation exposures and plasma PFOA concentration in the rat. *Toxicological Sciences*, 78 (Supplement Number 1-S), abstract no. 1918.