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Attn: Section 8(e) Coordinator
Office of Toxic Substances
USEPA
401 M Street, SW
Washington, DC 20460

8EHQ-80-373

TSCA 8(e) SUPPLEMENTAL NOTICE (DOCKET 8EHQ 1288-0373): N-ethyl perfluorooctanesulfonamidoethanol (CASRN 1691-99-2)

Dear 8(e) Docket Coordinator:

3M has received a revised draft statistical report from Covance Laboratories in connection with a two-year dietary study of N-ethyl perfluorooctanesulfonamidoethanol (N-EtFOSE) in rats. Based on review of a previous draft statistical report, 3M on December 4, 2000 submitted a notice to the 8(e) docket informing EPA of a statistically significant increase in hepatocellular adenomas in female rats. 3M is supplementing that notice with additional information regarding thyroid follicular-cell tumors in male rats. The final report for this study is in preparation.

In the study design, male and female rats were assigned to one of two control groups or one of five dosed groups that received the compound mixed into their feed. The dietary dose levels were 1, 3, 30, 100 and 300 parts per million (ppm), plus additional "recovery" groups at 100 ppm and 300 ppm. (The 300 ppm dose group was terminated early due to toxicity. The 1 ppm dose group and an additional concurrent control group were added several weeks later.)

The attached table presents the relevant findings with respect to thyroid lesions in the male rats. When the final report on this study becomes available, it will be submitted to the EPA. The findings of statistical significance presented in the attached table are not meant, in and of themselves, to imply biological significance. These data will be interpreted for biological significance in the final report.

Additional data regarding interim results and other toxicity testing for N-EtFOSE, including negative genotoxicity assays, can be found in EPA docket AR-226.

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Please contact me for further information.

Regards,

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

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EPA-OTS
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c: Dr. Charles Auer
Dr. Oscar Hernandez

Attachment

TABLE

RESULTS OF STATISTICAL ANALYSIS OF SELECTED THYROID LESIONS IN MALES FROM TWO-YEAR DIETARY STUDY WITH N-EtFOSE

Tumor	Historical Control [a]	Control A [b]	1 ppm	Control B [c]	3 ppm	30 ppm	100 ppm	100 ppm Rec
Thyroid Follicular-Cell Adenoma	17/391 (4.3 %) (0 % - 11.3 %)	1/60 (1.7 %)	2/60 (3.3 %)	0/55 (0 %) trend* [d]	3/50 (6.0 %)	1/50 (2.0 %)	6/60 (10.0 %)*	1/40 (2.5 %)
Thyroid Follicular-Cell Carcinoma	4/391 (1.0 %) (0 % - 3.2 %)	0/60 (0 %)	0/60 (0 %)	0/55 (0 %)	0/50 (0 %)	1/50 (2.0 %)	0/60 (0 %)	1/40 (2.5 %)
Thyroid Follicular-Cell Adenoma & Carcinoma	NA (0 % - 14.5 %)	1/60 (1.7 %)	2/60 (3.3 %)	0/55 (0 %) trend*	3/50 (6.0 %)	2/50 (4.0 %)	6/60 (10.0 %)*	2/40 (5.0 %)

* denotes statistical significance, $p<0.05$

a) Data from six prior two-year studies with Sprague-Dawley rats in the same laboratory.
b) Control for 1 ppm dose group.
c) Control for 3, 30, 100 ppm and 100 ppm recovery dose groups.
d) The significance indications in the control column are one-tailed for trend.