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has actually been processed
as

8EHQ-0501-0373

but is included here in

FYI-0101-1378

as well as it was received as
an attachment to this FYI.

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Document Processing Center (7407)
(Attn: Section 8(e) Coordinator)
Office of Toxic Substances
US EPA
401 M Street, SW
Washington, DC 20460

EPA-OTS



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TSCA 8(E) SUBSTANTIAL RISK SUPPLEMENTAL NOTICE ON: N-Ethyl perfluorooctylsulfonamido ethanol, see Docket 8EHQ 1288-0373

Dear 8(e) Coordinator:

3M has received a draft statistical report from Covance Laboratory on a 2-year rat feeding study of N-EtFOSE {N-Ethyl Perfluorooctanesulfonamido Ethanol (CAS 1691-99-2)}. The results of this study are corroborative of results submitted in 1988 to EPA in docket 8EHQ 1288-0373. This study was conducted using N-EtFOSE at a purity of approximately 98%, in contrast to the earlier study which was believed to be 84-88%.

Groups of male and female rats received the compound in their feed. There were seven groups of rats - two control groups, a low dose of 1 ppm in diet, a low intermediate dose of 3 ppm in diet, a high intermediate dose of 30 ppm in diet, a high dose of 100 ppm in diet and a high dose recovery group. The high dose recovery animals received the compound for the first year of the study at 100 ppm in diet and no compound during the second year of the study.

Statistical analyses of the tumor data from this study revealed that the high dose female group showed a statistically significant increase in benign liver tumors. The liver tumor data are presented below.

MALES

	Control 1	Control 2	1ppm	3ppm	30ppm	100ppm	100 ppm rec
Hepatocellular Adenoma	2/55	5/60	4/60	4/50	2/50	5/60	0/40
Carcinoma	0/55	0/60	0/60	0/50	0/50	0/60	0/40

Contain NO CBI

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FEMALES

	Control 1	Control 2	1ppm	3ppm	30ppm	100ppm	100 ppm rec
Hepatocellular Adenoma	0/55	2/60	1/60	1/50	3/50	6/60*	3/40*
Carcinoma	0/55	0/60	0/60	0/50	0/50	1/60	0/40

* significant $p < 0.05$, paired and trend, based on Control 1

Control 2 and the 1 ppm dose group were added after a 300 ppm dose group was discontinued. This was done two months into the study, when it became apparent that the 300 ppm dose group would not tolerate this level as a lifetime dose.

The liver is the target organ of toxicity for N-EtFOSE. Liver toxicity was present in the high dose (100 ppm) males and females. The liver toxicity was manifested histologically as hepatocellular vacuolation and hepatocellular centrilobular hypertrophy. These histologic liver changes were not manifested in the high dose (100 ppm) recovery animals indicating that the liver toxicity was a reversible effect.

The compound is not genotoxic, having been negative in multiple *in vitro* and *in vivo* genotoxicity assays.

The final report will be submitted to EPA upon receipt.

Please contact me, 651-733-5181, for further information.

Regards,



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