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

TSCA 8(e) SUBSTANTIAL RISK NOTICE: potassium perfluorooctanesulfonate (CASRN 2795-39-3)

Dear 8(e) Coordinator:

3M has received a draft statistical report from Covance Laboratories in connection with a two-year dietary study of potassium perfluorooctanesulfonate (PFOS) in rats. The final report for this study is in preparation; however, the data from the statistical report are believed to represent information which meet the reporting threshold for section 8(e) of TSCA.

In the study design, male and female rats were assigned to a control group or one of five dosed groups that received PFOS mixed into their feed. The dietary dose levels were 0.5, 2, 5, and 20 parts per million (ppm) plus an additional "recovery" group at 20 ppm for which dosing ended at one year and the rats were allowed to recover through the end of the study.

The attached table summarizes the relevant findings. 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.

A considerable body of toxicity information on PFOS can be found in EPA docket AR-226. PFOS has been subjected to numerous assays for genotoxicity. The results of those assays show a lack of genotoxicity.

Please contact me for further information.

Regards,

JRZobel MD

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

c: Dr. Charles Auer
Dr. Oscar Hernandez

Attachment

TABLE: RESULTS OF STATISTICAL ANALYSIS OF SELECTED NEOPLASTIC LESIONS FROM TWO-YEAR DIETARY STUDY OF PFOS IN RATS.

FEMALES

Tumor	Historical Control [a]	Control	0.5 ppm	2 ppm	5 ppm	20 ppm	20 ppm Rec
Hepatocellular Adenoma	4/394 (1.0 %) (0 % – 4.3 %)	0/60 (0 %) trend*[b]	1/50 (2.0 %)	1/49 (2.0 %)	1/50 (2.0 %)	5/60 (8.3 %)*	2/40 (5.0 %)
Hepatocellular Carcinoma	0/394 (0 %)	0/60 (0 %)	0/50 (0 %)	0/49 (0 %)	0/50 (0 %)	1/60 (1.7 %)	0/40 (0 %)
Hepatocellular Adenoma & Carcinoma	NA (0 % - 4.3 %)	0/60 (0 %) trend**	1/50 (2.0 %)	1/49 (2.0 %)	1/50 (2.0 %)	6/60 (10.0 %)*	2/40 (5.0 %)

MALES

Tumor	Historical Control	Control	0.5 ppm	2 ppm	5 ppm	20 ppm	20 ppm Rec
Hepatocellular Adenoma	6/393 (1.5 %) (0 % - 3.3 %)	0/60 (0 %) trend*	3/50 (6.0 %)	3/50 (6.0 %)	1/50 (2.0 %)	7/60 (11.7 %)*	0/40 (0%)*[c]
Pancreatic Islet Cell Carcinoma	5/390 (1.3 %) (0 % - 4.8 %)	0/60 (0 %) trend*	2/49 (4.1 %) p = 0.1793	1/50 (2.0 %) NA	4/50 (8.0 %) p = 0.2148	5/50 (10.0 %) p = 0.0463*	3/40 (7.5 %)
Thyroid Follicular-Cell Adenoma	17/391 (4.3 %) (0 % - 11.3 %)	3/60 (0 %)	5/49 (10.2 %)	4/50 (8.0 %)	4/49 (8.2 %)	4/59 (6.8 %)	9/39 (23.1 %)*[d]
Thyroid Follicular-Cell Carcinoma	4/391 (1.0 %) (0 % - 3.2 %)	3/60 (5.0 %)	1/49 (2.0 %)	1/50 (2.0 %)	2/49 (4.1 %)	1/59 (1.7 %)	1/39 (2.6 %)
Thyroid Follicular-Cell Adenoma & Carcinoma	NA (0 % - 14.5 %)	6/60 (10.0 %)	6/49 (12.3 %)	5/50 (10.0 %)	5/49 (10.2 %)	5/59 (8.5 %)	10/39 (25.6 %)*[c]

* denotes statistical significance at $p < 0.05$
** denotes statistical significance at $p < 0.01$

a) Data from six prior two-year studies with Sprague – Dawley rats in the same laboratory.
b) The significance indications in the control column are one-tailed for trend.
c) For high-dose recovery values, the significance is for one-tailed, pair-wise comparison to the high-dose group.
d) For high-dose recovery values, the significance is for one-tailed, pair-wise comparison to the control and high-dose group.