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Office of Pollution Prevention and Toxics
US EPA
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001

CERTIFIED MAIL

TSCA 8(E) SUPPLEMENTAL INFORMATION: potassium perfluorooctanesulfonate (CASRN 2795-39-3) Docket Ref: -0374

Contains NO CBI

Dear Sir:

3M is submitting the final report from Covance Laboratories on the 2–year rat feeding study for potassium perfluorooctanesulfonate (CASRN 2795-39-3), originally notified to EPA in a letter dated May 24, 2001. In addition, the report on chemical analysis for perfluorooctanesulfonate in biological samples associated with the study is included with this submission.

In the study included with submission, Sprague Dawley rats were given potassium perfluorooctanesulfonate (PFOS, 86.7 %) in the diet at 0, 0.5, 2, 5, & 20 ppm for up to 104 weeks. One group received 20 ppm in the diet for 52 weeks and was allowed to progress to termination without further treatment. Interim sacrifices occurred at weeks 4, 14 and 53 for histopathology, cell proliferation and perfluorooctanesulfonate determination. The prior TSCA 8e submission discussed preliminary observations regarding tumor incidence. Through term, survival was significantly increased for males and body weights were significantly decreased for females at 5 and 20 ppm. Absolute and relative liver weights in males and relative liver weights in females were increased at 20 ppm. Liver toxicity was present at minimal doses of 2 ppm in males and 5 ppm in females. Hepatotoxicity was not present in 20 ppm recovery animals. For males in the 20 ppm dose group, hepatocellular adenoma was increased. Hepatocellular adenoma was not observed in the 20 ppm recovery group males. Thyroid follicular cell adenoma was increased for the 20 ppm recovery group males, yet there were no other indications of thyroid abnormality. For females in the 20 ppm dose group, hepatocellular adenoma was increased. It should be noted that the prior notification had indicated an increase in pancreatic islet cell carcinoma in males at the 20 ppm dose level. This finding did not remain after a pathology peer review was conducted.

In addition, 3M is submitting a copy of the final report for the 26-week capsule toxicity study report on cynomolgus monkey on potassium perfluorooctanesulfonate. A draft report was submitted to EPA as an 8(e) August 21, 2000. A report on chemical analysis for perfluorooctanesulfonate in biological samples associated with the study is also included with this submission.

Groups of male and female cynomolgus monkeys were given oral capsules containing doses equivalent to 0, 0.03, 0.15, or 0.75 mg/kg/day potassium perfluorooctanesulfonate as the potassium for 182 days. Recovery animals from the control 0.15 and 0.75 mg/kg/day treatment groups were monitored for one year after treatment. Significant adverse effects at the 0.75 mg/kg/day dosage included compound-related mortality in two of six male monkeys, decreased body weights, increased liver weights, lowered serum total cholesterol, lowered estradiol levels, hepatocellular hypertrophy and lipid vacuolation. No peroxisomal or cell proliferation was detected. Complete reversal of clinical and hepatic effects occurred within 211 days post-treatment and was accompanied by significant decreases in serum and liver PFOS. Liver-to-serum PFOS ratios were comparable in all dose groups, with a range of 1:1 to 2:1. Serum concentrations in the 0.15 mg/kg/day dose group at the end of dosing (where no adverse effects were present) were 82.6 ± 25.2 ppm for males and 66.8 ± 10.8 ppm for females.

For further information on this study contact Dr. John Butenhoff, 651-733-1962.

Sincerely,

Larry R. Johnson

Larry R. Johnson
Director, Corporate Toxicology

Enclosures

Reports Submitted with letter of February 8, 2002:

- Final Report, 104-Week Dietary Chronic Toxicity and Carcinogenicity Study with Perfluorooctane Sulfonic Acid Potassium Salt (PFOS; T-6295) in Rats (Covance Study No. 6329-183), 3M Reference No. T-6295, January 2, 2002.

- Analytical Laboratory Report, Determination of the Presence and Concentration of Perfluorooctanesulfonate (PFOS) in Liver and Serum Specimens of Crl:CD(SD) IGS BR Rats Exposed to Perfluorooctane Sulfonic Acid Potassium Salt (PFOS T-6295), 3M Environmental Laboratory Report No. TOX-002, Laboratory Request No. U2121, 3M Ref. No. T-6295.4, February 21, 2001.

- Final Report, 26-Week Capsule Toxicity Study with Perfluorooctane Sulfonic Acid Potassium Salt (PFOS: T-6295) in Cynomolgus Monkeys (Covance Study No. 6329-223), 3M Reference No. T-6295.7, January 11, 2002.

- Analytical Laboratory Report, September 19, 2000, "26-Week Capsule Toxicity Study with Perfluorooctane Sulfonic Acid Potassium Salt (T-6295) in Cynomolgus Monkeys, Determination of the Presence and Concentration of Perfluorooctanesulfonate (PFOS) in Liver and Serum Samples," to accompany Covance Laboratories Inc., Study No. 6329-223, 3M Medical Department Study No. T-6295.7, Report No. FACT TOX-030