

mc# 279187

8EHQ-0904-00394 AR226-1872



8EHQ-81-394

DuPont Haskell Laboratory
for Health and Environmental Sciences
Elkton Road, P.O. Box 50
Newark, DE 19714-0050

September 10, 2004

Via Federal Express

Document Processing Center (Mail Code 7407M)
Room 6428
Attention: 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
1201 Constitution Ave., NW
Washington, DC 20460

CONTAINS NO CBI

ORIGINAL

Dear 8(e) Coordinator:

8EHQ-0381-0394

- 1) Linear/Branched [78:22] (L/B)
- 2) Linear (L)
- 3) Branched [58:42 monomethyl/isopropyl](B)

04 SEP 17 11:10:03

This letter is to inform you of the results of a recently conducted oral repeated dose toxicity study in rats and mice with the above-referenced test materials.

Groups of 10 male rats and 10 male mice were dosed via gavage for 14 days at dose levels of 0, 0.3, 1, 3, 10, or 30 mg/kg of bodyweight for each of the three test materials. During the in-life portion of the study, body weights, food consumption, and clinical signs of toxicity were collected. In addition, at the end of the dosing period, lipid chemistry (total cholesterol, HDL, non-HDL, and triglycerides), liver and kidney weights were recorded, liver β -oxidation was measured, and the serum levels of PFOA were measured.

In general, the qualitative and quantitative biological responses of the 3 test materials (L/B, L, and B) were similar and confirm changes reported in other studies. Mortality occurred in 1/10 mice treated with 30 mg/kg of the linear (L) material. Lethargy was observed in only a few isolated cases in mice and was of short duration. Body weights and food consumption were decreased but less affected with the branched (B) form. Hemolysis (*ex vivo*) was seen in serum samples collected from rats, with the incidence higher in the two highest dosage groups. Liver weights were increased in mice at 0.3 mg/kg and above and in rats at 1 mg/kg and above with all forms. Liver β -oxidation was increased, while total cholesterol, HDL and non-HDL were all decreased in rats and mice with all forms. Triglycerides were decreased in the rats, but increased in the mice for all 3 test materials. No no-observed-effect-level (NOEL) was established in this study.

Under these experimental conditions, some of the findings described above appear to be reportable based upon guidance given in the EPA TSCA Section 8(e) Reporting guide (June 1991).

A copy of the final report/manuscript will be submitted to the Agency when available.

Sincerely,

A. Michael Kaplan

A. Michael Kaplan, Ph.D.
Director - Regulatory Affairs and Occupational Health

AMK/GLK:clp
(302) 366-5260

2004 OCT - 1 PM 2:58

RECEIVED
EPA/TOX
OPPT/DOE

