

FYI-0700-1378

937 PP

AR 226 - 0614

RECEIVED
OPTIC

2000 JUL 28 11:09

3M

July 24, 2000

Contains NO CBI

MR 3800 9

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

CERTIFIED MAIL

TSCA 8(E) SUBSTANTIAL RISK NOTICE ON: N-Methyl
Perfluorooctanesulfonamido Ethanol

Dear Sir:

3M is reporting information that shows N-Methyl Perfluorooctanesulfonamido toxicity is consistent with that of related perfluorooctanyl sulfonates previously submitted to EPA [see 8(e) dockets #373 and 374]. Enclosed is the final report from Covance Laboratory on a 13-Week Dietary Study of N-Methyl Perfluorooctanesulfonamido Ethanol (N-MeFOSE) in Rats. As expected, higher dose levels (30 and 100ppm N-MeFOSE in food) produced liver effects. The liver changes included increased liver weights, hepatocyte hypertrophy, and hepatocellular vacuolation. Lower cholesterol and triglycerides levels were also found in the high dose (100ppm) and mid dose (30ppm) animals. Neither liver effects nor cholesterol/triglyceride changes were found in the low dose (3ppm) animals.

Significantly reduced body weights were present in the high dose animals beginning at week 4 and continuing until the end of the study. Significantly reduced body weights occurred in the mid dose animals beginning at week 7 and continued until the end of the study. Weekly body weights of the low dose animals during the second half of the study were somewhat less than controls. None of the low dose weekly body weights were significantly different from controls. However, the overall body weight gain during the study (weeks 1 through 14) of the low dose animals was significantly less than the controls.

2000 AUG -3 PM 2:37

RECEIVED
OPTIC

FYI-00-001378



85000000031

000001

Document Processing Center (7407)
Page Two
July 24, 2000

The Covance report concludes that the 3ppm dose was the no-observable – adverse-effect level (NOAEL) as the minor body weight effect found at 3ppm was not correlated with any clinical chemistry or anatomic pathological changes; it was not considered to be biologically adverse. .

The study report is attached.

Please contact Dr. William Weppner, 651-733-6374, for further information.

Sincerely,


Charles Reich
Vice President,
Specialty Materials Markets

Enclosures:

1. 4-Week Range-Finding Dietary Toxicity Study with N-Methyl Perfluorooctanesulfonamido Ethanol (N-MeFOSE) in Rats (T-6314)
2. 13-Week Dietary Study with N-Methyl Perfluorooctanesulfonamido Ethanol (N-MeFOSE) in Rats (T-6314)

000002