Summary N-EtFOSE Rat Teratology

Study Numbers: 3M T-6316.7, Argus 418-011

Compound & Lot: N-EtFOSE (N-Ethyl-Perfluoroocyanesulfonamido Ethanol) – Lot FM3923 (30035, 30037, 30039) 98.2% pure (SMD Analytical Request 52489) Analytical Documentation filed along with final report. Note – same lot as used in two-year rat carcinogenicity study (T-6316, Covance 6329-212).

Study Title: Oral (Gavage) Developmental Toxicity Study of N-EtFOSE in Rats

Report Date: 17 December 1998

Study Monitor Summary: (written by Marvin T. Case) Pregnant rat females, 25 per group, were given daily oral (intubation) of N-EtFOSE at dose levels of 0, 1, 5, 10, and 20 mg/kg/day on days 6 through 17 of gestation. The rat fetuses which had been exposed in utero during organogensis were collected at day 20 of gestation. Approximately one-half of the fetuses were examined for soft tissue (visceral) changes and other half were examined for skeletal changes.

There were no compound related clinical signs of toxicity in the dosed rat dams. A body weight effect, reduced body weight gains, occurred in the pregnant females in highest two dose levels – 10 & 20 mg/kg. This body weight effect correlated with reduced food consumption in the same two groups. The maternal toxicity at 10 & 20 mg/kg was reflected in the pups as reduced pup weights. There was no effect on other litter parameters (corpora lutea, implantations, litter size, number of live fetus, early or late resorptions, pup sex ratio) at any dose level. Increased delayed ossification sites were found in 10 & 20 mg/kg fetuses - another reflection of maternal toxicity at these dose levels.

No compound-related soft tissue or skeletal malformations were found at any dose level. Thus, the compound was not found to be teratogenic in the rat.

The maternal toxic NOEL was 5 mg/kg.

The fetal toxic NOEL was also 5 mg/kg.

Teratogenic NOEL in the rat was > 20 mg/kg.

NOTE: Dose preparation samples were collected twice during the study and these samples were sent to 3M Evironmental Analytical laboratory in Bldg 2. Likewise, samples were collected from extra females assigned as toxicokinetic satellite animals (3/group except control and high dose 5/group). These animals were killed on gestation day 18 (day after last dose) and the following samples were collected: serum and liver from pregnant dams, fetuses and placentas (pooled by litter) from uterus. These samples were frozen and sent to 3M Evironmental Analytical laboratory in Bldg 2. At time of this summary, January 1999, analysis of these samples had not been done; therefore, these analytical results were not included in the final report nor in this summary.