ATTORNEY CLIENT PRIVILEGED INFORMATION

EVALUATION OF THE RISK TO SULFLURAMID WORKERS AS RELATED TO PFOS SERUM CONCENTRATIONS

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INTRODUCTION

Recently, workers from a facility that produces Sulfluramid baits were screened to determine serum levels of perfluorooctane sulfonate (PFOS). The purpose of the screening was to provide data for characterization of potential risks from occupational exposure in formulating Sulfluramid baits.

EVALUATION OF ANALYTICAL DATA

Analytical results from various worker populations can be summarized as follows:

EXPOSURE DURATION	NUMBER OF WORKERS	AVERAGE PFOS CONCENTRATION (PPB)	RANGE OF PFOS CONCENTRATIONS (PPB)
Non-exposed	8	120	51 - 261
3 months	4	118	58 - 208
6 months	12	164	39 - 431
9 months	2	112	96 - 128
1 year	4	258	165 - 440
2 years	2	94.5	94 - 95
3 years	1	186	- 186 -
5 years	2	193	160 - 225

This data set clearly shows that PFOS is present across the entire evaluated population regardless of whether exposure occurred or not. This is consistent with previously reported serum results from 3M which showed that PFOS has been found at tens of parts per billion levels in serum samples of nonoccupationally exposed 3M employees, in commercially available human serum and in pooled samples from multiple blood banks. The highest level of serum PFOS was seen in individuals exposure for one year. Close inspection of the exposure scenarios showed that 3 of the 4 workers were involved in the bait batching process while the fourth worker was involved with other functions in the bait shop. It is apparent that bait batching is the process

resulting in the greatest potential for exposure. Among the 12 individuals exposed for 6 months, 10 individuals worked in the bait shop while the remaining 2 were "bait batchers". The highest serum PFOS value for the 6 month exposure population was 431 ppb and was noted for one of the two "bait batchers". The average serum PFOS concentration for the 10 bait shop workers exposed for 6 months was 142 ppb and was consistent with results from the 3 month and 9 month exposure groups comprised of bait shop workers only. Taken collectively, the PFOS concentrations from the bait shop workers were generally comparable to the untreated population.

DISCUSSION AND CONCLUSION

The 3M Corporation has conducted screening of workers involved in the manufacture of PFOS and analogous chemical moieties to determine serum PFOS levels. In a 1997 study, 74 workers have an average PFOS serum concentration of 820 ppb (range of 50 to 6250 ppb). At a different manufacturing facility, average serum PFOS values were 1900 ppb (range of 0 to 9900 ppb) in 1995 and were 1500 ppb (range of 100 to 4800 ppb in 1997. A 1998 evaluation of 31 nonexposed employees showed PFOS serum levels of 47 ppb (range of 28 to 96 ppb).

Medical surveillance of workers in 3M fluorochemical production workers was routinely performed. An epidemiologic investigation of clinical chemistry, hematology and hormone levels in relation to serum PFOS levels was performed. This study concluded that significant hematological, clinical chemistry and hormonal abnormalities were not associated with serum PFOS levels up to 6 ppm (6000 ppb). Because of a limited number of employees with serum PFOS levels $\geq$ 6 ppm, no inferences regarding effect or lack of effect could be derived.

A 6-month oral dose monkey study has recently completed. In that study, the No Observed Adverse Effect Level (NOAEL) was 0.15 mg/kg/day. Serum PFOS levels at this dose level were determined to be approximately 75 ppm. In order to extrapolate these data to man, a 10X Uncertainty Factor is applied. The resultant 7.5 ppm PFOS serum level is consistent with the 6 ppm value assessed in the epidemiology study and adds further certainty to the use of the 6 ppm value for risk characterization.

A conservative characterization of risks associated with occupational exposure from Sulfluramid bait manufacture can be performed using the 3M epidemiologic data. As noted above, the highest serum PFOS level was 440 ppb for a "bait batcher"exposed for 1 year. This serum concentration represents 7.3% (440/6000) of the PFOS serum concentration deemed to cause no hematological, clinical chemistry or hormonal effects in PFOS exposed worker populations. This approach is appropriate since toxicology studies in animals demonstrate that clinical chemistry changes characterized by reduction in cholesterol and alterations of liver enzymes and the most sensitive toxicologic endpoints at low doses.

The serum PFOS levels seen in workers involved in the manufacture of Sulfluramid support the conclusion that no undue risks to workers should be expected.