MICHIGAN DEPARTMENT OF NATURAL RESOURCES

INTEROFFICE COMMUNICATION

January 3, 1989

TO: File 63148-57-2

FROM: Catherine Simon

SUBJECT: Dow Corning Fluid 1107

Two partial lifetime feeding studies on DC 1107 were submitted by Dow Corning. In one study, groups of three male and three female young adult albino rabbits were administered 0.05% or 1.0% DC 1107 in the diet for eight months, after which time they were sacrificed. Controls consisted of six male and six female rabbits administered the basal diet only. The only effect observed that appeared to be treatment related was an increased liver weight in both the male and female high dose groups. The average liver weight for the control, low, and high dose groups was 66.6, 56.3, and 72.5 grams for the male rabbits, and 58.3, 54.5, and 79.9 grams for the female rabbits, respectively. Histopathological examination showed no hyperplasia in the liver of treated rabbits. A major deficiency of this study is the small size of the dose groups, which precludes statistical analysis of the results.

In the second study, groups of five male and five female albino rats of the FDRL strain were administered 0.05% or 1% DC 1107 in the diet for one year, after which time they were sacrificed. Controls consisted of ten male and ten female rats administered the basal diet only. Effects observed included a decreased body weight in the high dose female rats, increased thyroid weight in all treated groups, and an increased incidence of thyroid hyperplasia in all treated groups. Thyroid hyperplasia, graded as less than 1+, occurred with the following frequency in the control, low, and high dose groups: 2/10, 3/5, and 3/5 respectively, for the male rats, and 1/10, 3/5, and 5/5, respectively for the female rats. A major deficiency of this study was the small number of animals in the treated groups.

Although neither study was considered ideal for deriving an acceptable ambient concentration (AAC) to evaluate the emissions of DC 1107, the study in rats was chosen over the study in rabbits due to the greater number of test animals per dose group, and the longer duration of the study. The low dose level (0.05%) in this study might be considered a lowest observable adverse effect level (LOAEL), however, the significance of thyroid hyperplasia is difficult to interpret due to the limitations of this study, and lack of a similar finding in the rabbit study. The dietary level of 0.05% is equivalent to 25 mg/kg/day, assuming a factor of 0.05 for the fraction of body weight that is consumed per day as food (EPA, 1980). The AAC for DC 1107 to be used for evaluating emissions of this compound is 30 ug/m^3 on an annual average basis, and is derived as follows:

$$AAC = \frac{25\ mg/kg/day \times 0.35\ kg}{1000 \times 0.29\ m^3/day} = 30\ ug/m^3$$

Where:

0.35 kg = body weight for the rat.
0.29 m^3/day = daily inhalation rate for the rat.
1000 = Uncertainty factor for less than lifetime animal study, with some deficiencies.

The uncertainty factor of 1000 also incorporates a margin of safety for potential use of a LOAEL, since the quality of this study and additional data is somewhat better than what normally warrants an uncertainty factor of 1000.

REFERENCES

U.S. Environmental Protection Agency (EPA). 1980. Appendix C - Guidelines and methodology used in the preparation of health assessment chapters of the consent degree water criteria documents. 45 Federal Register 79347. November 28, 1980.