470A

CASWELL FILE

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, DC 20460

APR 30 1990

OFFICE OF
PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Iprodione- 6(a)(2): 2-generation reproduction study in rats

TO: Susan Lewis/Jim Stone PM 21
Registration Division (H7505C)

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Registrant Rhone-Poulenc Co.

Requested action

Review effects seen in ongoing reproduction study.

Report

The registrant submitted a letter (Nick Somma to Susan Lewis, RD, dated April 3, 1990) to the Agency which reported adverse effects in a 2-generation reproduction study in which rats received Iprodione at dietary levels of 0, 300, 1000 and 3000 ppm. All of the reported effects were observed in rats receiving the highest dosage. This information was submitted in order for the Agency to determine if Section 6(a)(2) of FIFRA is applicable to these data.

The following effects were reported:

-Body weight gain for F_0 parents (male and female) were 60-70% of controls prior to the first mating.

-Maternal weight gain during gestation days 14-20 was 75% of control after the first mating and 35% after the second.

-There was a greater number of stillborn pups (33 test vs 13 control) and a lower mean total number of pups (live + dead) per litter (10.48 test vs 14.27 control) following the second mating.
-A comparison of data for F_{1A} and F_{1B} pups through day 21 of lactation showed a significantly lower survival rate for pups from the 2nd mating (94 and 50%, respectively) and body weights were 60-65% of control.

Although the Agency has already accepted a 3-generation reproduction study (1976, MRID No. 00071927) in which rats received Iprodione at dietary levels of 0, 250, 500 and 2000 ppm, a study is in progress to satisfy the data requirements of the California Department of Food and Agriculture. Decreased fetal weight was seen at 2000 ppm in the previous study.

Conclusion

Although the reported effects are preliminary and TB II has not examined detailed data from the study, it appears that the observations in the offspring were most likely secondary effects from parental toxicity to a dosage (3000 ppm) which was too high. Therefore, Section 6(a)(2) of FIFRA is probably not applicable to these data. TB II will examine the final report for this study after it is submitted to the Agency, probably in late 1991.