DATA EVALUATION RECORD

1. CHEMICAL: Metolachlor (108801)

2. FORMULATION: Technical

3. CITATION: Fritz, H. (1976). Dominant Lethal on CGA-24705 Technical--Mouse (Unpublished report prepared by CIBA-GEIGY Limited, Basle, Switzerland).

4. TRADE SECRET CLAIM: Yes

5. REASON FOR REVIEW: Generic Standard for Metolachlor

6. REVIEWED BY: Christine F. Chaisson
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7. DATE OF REVIEW: January 26, 1978

8. TEST TYPE: Cytotoxic or mutagenic effects.

A. Materials and Methods: Male NMRI-derived albino mice were dosed once by intubation with 100 or 300 mg/kg of test substance carried in carboxymethylcellulose. Controls were dosed only with carrier. The males were mated for six weeks with two untreated females per week, which were checked daily for vaginal plugs. At day 14 of pregnancy, females were sacrificed, autopsied and embryos counted. Results were analized statistically with the Chi square or Fisher's exact test for comparison of numbers of mated and pregnant dams or embryonic deaths. The T-test or Mann-Whitney's U-test was used to compare totals of implantations.

B. Reported Results: After single doses of 100 or 300 mg/kg, no decreases in number of pregnancies per group of mated females was found. There were no effects in numbers of implantations per mating, or numbers of embryonic death.

C. Discussions: The protocol as described is valid, and the statistical evaluations are adequate for the considered parameters. Not discussed however was the apparent decrease in percentage of females mated per male (as noted by vaginal plug). This is not a genetic effect, but may have been due to toxic effects to the male. However no discussion of general health of the males after dosing was mentioned.

There were clearly no effects of the compound on embryonic death, pre- and post- implantation, nor on fertility rates in the mated females. No data was presented, however, on the condition of the resultant embryos. These observations would have been relevant to the question of genetic toxicity of the compound.

D. Conclusions: This study presents valid data to support the view that metolachlor does not induce genetic changes in mice after an acute oral exposure. No effects on the male germ cells (from A-spermatogonia to mature sperm) could be seen, as measured by fertility or zygote death. Malformation of embryo was not considered.

The tests would meet proposed requirements for one type of mutagenicity testing.