

DATA EVALUATION RECORD

1. CHEMICAL: Metolachlor (108801)
2. FORMULATION: Technical
3. CITATION: Fritz, H. (1976) Reproduction Study CGA-24705 Tech:
Rat: II: (Test for Teratogenic or Embryotoxic Effects):
PH 2.632. Received January 19, 1977 under 7F1913. (Un-
published report prepared by CIBA-GEIGY Ltd., Basle,
Switzerland; CDL:95768-A).
4. TRADE SECRET CLAIM: Yes
5. REASON FOR REVIEW: Generic Standard for Metolachlor.
6. REVIEWED BY: William L. Burnam
Pharmacologist, Metabolic Effects Branch
Criteria and Evaluation Division
7. DATE OF REVIEW: January 23, 1978
8. TEST TYPE: Teratogenic Study
 - A. Material and Methods: Pregnant Sprague-Dawley rats (25 per dose) were intubated from day 6 to day 15 of gestation with either 0, 60, 180 or 360 mg/kg/day of metolachlor in 2% CMC. Dams were autopsied on day 21. The viscera and skeleton were examined according to standard procedures. Statistics were alluded to in the results but except for Table 4, the reviewer could not determine where statistics were used, what type were used and what was considered the level of significance. Maternal body weights were recorded daily. Fetuses were weighted at autopsy.
 - B. Reported Results: There were no compound related effects on mean number of implantations, embryonic resorption, fetal resorptions, fetal death or soft tissue or skeletal malformations.
 - C. Discussions: The decrease in food consumption for the high dosed dams may indicate that this was the beginning of toxic maternal doses. These doses were neither fetotoxic nor teratogenic to rats. The general protocol is in keeping with the spirit of the EPA Guidelines.
 - D. Conclusions: Doses of metolachlor up to 360 mg/kg/day during the critical of gestation had no adverse effects on the offspring. This study meets the requirements for a teratogenic study in one species of mammal.