UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

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MEMORANDUM

SUBJECT: TERATOLOGY STUDY IN RATS WITH ALACHLOR. Conducted by International Research & Development Corporation for Monsanto Agricultural Products Company

FROM: Roland Gessert, D.V.M.
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THRU: Chris Chaisson, Acting Chief
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Alachlor (Lot#MHK-6) was administered in a corn oil vehicle by gavage to four groups of 25 mated female Charles River COBS CD rats at dosages of 0, 50, 150, and 400 mg/kg/day on days 6 through 19 of gestation. Vitamin A was used as a positive control. Cesarean sections were performed on gestation day 20. The number and location of viable and non-viable fetuses, early and late resorptions, total implantations and corpora lutea were recorded upon uterine examination. Each fetus was weighed and examined for external, soft tissue, and skeletal abnormalities.

RESULTS

High-dose group dams exhibited soft stools, red matter around the nose and mouth, hair loss, and anogenital staining. Four high-dose group dams died during the last five days of gestation. The cause of death was not apparent at necropsy. These toxic signs indicate that the dams would not tolerate a higher dose.

Mean body weight gains were moderately reduced in the high-dose group throughout the treatment period.

uterine examinations indicated that for each group of 25 females, 0, 5, 2, and 2 in each of the control, low-, mid-, and high-dose groups respectively, were non-gravid. The four high-dose dams which died were gravid. No non-viable fetuses were present in any of the treated groups. There were no statistically significant differences in mean numbers of viable fetuses, resorptions, post-implantation losses, total implantations, corpora lutea, sex distribution, or mean fetal body weights in any of the alachlor-treated groups when compared to the control group.

In the 400 mg/kg/day dosage group however, a slight increase in the mean numbers of early and late resorptions resulted in a slight increase in mean post-implantation loss and a slight decrease in the mean number of viable fetuses.

A low incidence of skeletal malformations was observed in the low-dose and control groups which were obviously not dose-related. Developmental and genetic anomalies were comparable in control and treated groups.

CONCLUSIONS:

Treatment with technical alachlor produced signs of maternal and fetal toxicity in the 400 mg/kg/day dosage group, as evidenced by maternal deaths, a slight decrease in mean fetal body weight and a slight increase in mean post-implantation loss.

Technical alachlor did not produce a teratogenic response when administered orally to pregnant rats at a dosage level of 400 mg/kg/day or less.

NOEL for teratogenicity is 400 mg/kg/day.

NOEL for maternal and fetal toxicity is 150 mg/kg/day.

Study is CORE Guidelines.

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