DATE: August 5, 1978

SUBJECT: Review of Monsanto Chemical Co. validation of Industrial Bio-Test Laboratories tehatogenic study with Roundup in rabbits. IBT No. J-568; BTL 71-36 submitted in support of EPA Reg. No. 524-308 Acc. No. 234135

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The only reference to a previous review (by toxicology) of a teratogenic evaluation of Roundup tested in rabbits is a two sentence statement listed in Petition File 5F-1536 No.112893. The present memorandum will compare a review of the available data with the Monsanto validation report.

Conclusions

IBT No. J-568, BTL 71-36

1. Validation report - The validation report on IBT No. J-568 teratology study in rabbits performed by Industrial Bio-Test Labs. and submitted by Monsanto to support EPA Reg. No. 524-308 (Roungup), is accurate, and does refelct the supporting data the validator reviewed.

2. Aequacy of IBT J-568 teratology study
This study is designated Supplementary Data

Note: 10 and 30 mg/kg dosage levels only were employed in this test. No material toxic effects and no fetal toxic on teratogenic effects were determined.

Since the rat oral LD 50 for glyphosate (N-phospchonomythyl glycene) is 4320 mg/kg (3930-4750), it is possible that use of higher dosage levels could have produced teratogenic effects. (Much higher dosage levels should have been employed, as well as low. no effect doses).

Review of data

Pregnant doe rabbits were treated orally with either 10.0 or 30.0 mg/kg l.ut. of Roundup active ingredient (N-phosphonomethyl-glycine) from gestation day 6 through day 18, and were sacrificed on gestation day 29.

experimental outline

Group	Test material mg/kg/day	No. females insemenated	No pregnant animals
Control	NONE	15	12
+Control	Thalidomide	15	11
Roundup (active	10.0	17	16
"	30.0	17	14

Results

1). Positive control results indicated susceptibity of rabbit strain to + teratogens.

2). No effect in fetal on maternal body wt. gain could be attributed to the Roundup active test material. No. maternal deaths on unusual maternal reactions.

3). Treatment with Roundup active ingredient did not affect the incidence of resorptions.

4). Pre-natal treatment with the test material did not affect the 24 hour survival of young.

5). Examination for internal and skeletal development of young disclosed no affects which could be related to the administration if Roundup active ingredient.

6). Apparently, treatment of pregnant albino rabbits at dosage levels of 10 on 30 mg/kg body wt. during the period of onganogenesis with Roundup active ingredient did not produce teratogenic effects.

Study Classification—SUPPLEMENTAL DATA

Note: No attempt was made to determine or use a dose level high enough to induce any maternal toxicity; the possibility exists that doses >30mg/kg of Roundup active could produce teratogenic effects.

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