UNITED STATES ENVIRONMENTAL

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DATE: August 5, 1978

SUBJECT: Review of Monsanto Chemical Co. Validation of Industrial Bio-Test Laboratories 21 day Subacute Dermal Toxicity Study with Roundup in Rabbits.

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TO: Mr. Robert Taylor, PM #25

Previous Toxicology review

Under a listing entitled "Summary Toxicological Evaluation", Petition file 5F-1536 No. 112893, brief mention is made of this study; numbers of animals, dose levels and final observations are listed. To facilitate a more through hazard assessment and to establish a classification for the data, the present memorandum includes a review of the data in summary form.

Registration No.

EPA Reg. 524-308
Acc. No. 234139

IBT NO. A1549
BTL 72-37

Formulation

Test material was "MON 2139", which is a water based formulation of "CP 70139" which is the isopnopylamine salt of roundup active ingredient; N-phosphonomethyl glycine

Conclusions

1. Validation report - The validation report on IBT A 1549 21 day subacute dermal study with Roundup in rabbits that was submitted by Monsanto to support Reg. No. 524-308 is accurate, and does reflect the data the validator reviewed.

2. This study is classified as CORE MINIMUM DATA, and will support Roundup registration.

Review of Data

Test outline 5 groups of 5 M & 5 F rabbits each were treated 5 days/ week/3weeks as follows:

Group	skin Condition	dose level mg/kg	number applications
untreated control	intact		
I	intact	37.9 (use dilution)	15
II	abraded	37.9 (use dilution)	15
III	intact	189.5	15
IV	abraded	189.5	15

Results : rabbit

Mortality - 3 rats died in group III, 2 died in group IV-both on the high dose (25% fatalities in the high dose).

Skin irritation-All concentrations tested were irritationg to rabbit skin; the higher dose level was slightly more irritating than the lower dose level.

lower dose- A gradual increase from slight erythema after two applications to red, well defined erythema, moderate edems and esclerosis by 15 app. (lower dose not low enough, should not induce any effects).

higher dose- pale erythema and slight edema after 2 applications, increasing to red erythema, severe edema witheschorosis by 15 applications.
Note: no Draize readings taken.

effect (s) on body weight
Significant losses in body weight occurred in higher bosed animals.

Hematologic studies, clinical blood chemistry and urine analysis
A significant leukocytosis and increase in neutxophils occurred, occomparied by decrease in percent of lymphocytes were noted in treatment groups I-IV at 21 days.

Gross and microscopic studies

No significant gross or microscopic changes were observed at necropsy, other than local skin treatment sites.

Organ weights and ratios

Statestically significant differences in organ weights and body wt/organ wt. ratios were all attributed to losses in rabbit body weight, or were considered random in nature.

Test Classification - CORE MINIMUM data

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