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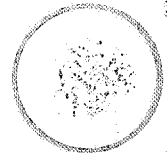
Glyphosate / Tox

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

MAR 19 1985

Caswell file

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RELEASABLE

MEMORANDUM

SUBJECT: PP# 5^F3157/5H5446; EPA Reg. #: 524-308; **Glyphosate** FACE OF. PESTICIDES AND TOXIC SUBSTANCES
in/on peanuts
Caswell #: 661A

TO: Robert Taylor
Product Manager (25)
Registration Division (TS-769)

and

Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

THRU: Robert P. Zendzian, Ph.D. *3/18/85*
Acting Head, Review Section IV
Toxicology Branch
Hazard Evaluation Division (TS-769)

FROM: William Dykstra, Ph.D. *William Dykstra 3/18/85*
Toxicology Branch
Hazard Evaluation Division (TS-769)

Refer W/S 3/19/85

Action Requested:

Evaluate petition request for the use of glyphosate in/on peanuts.

Recommendations:

1. Glyphosate is considered an oncogen in male mice. Renal tubule adenomas which are both dose-related and compound-related have been identified. A consensus review of the study is attached.

In light of these findings, 409 (H, food additive) tolerances can not be toxicology supported due to the Delaney rule.

Other relevant toxicity data with glyphosate are presented below:

- o Teratology - rat - negative at 3500 mg/kg/day; fetotoxic NOEL was 1000 mg/kg/day;
- o Teratology - rabbit - negative at 350 mg/kg/day; fetotoxic NOEL was 175 mg/kg/day.

- o Mutagenicity - negative in the following studies:
 - a. Rec-assay in two strains of B. subtilis up to 2000 ug/test.
 - b. Reverse Mutation in 5 histidine - requiring strains of S. typhimurium and 1 tryptophan-requiring strain of E. coli, with and without metabolic activation.
 - c. Ames test in four strains of Salmonella, with and without metabolic activation.
 - d. Dominant lethal study in the mouse at 2000 mg/kg.
- o Three-generation reproduction - rat - NOEL of 10 mg/kg/day based on pathological findings of renal focal tubular dilation in high dose male F_{3b} weanlings.
- o Chronic/oncogenic - rat - NOEL was 31 mg/kg/day; oncogenic potential was negative.

Review:

1. Proposed Tolerances

Tolerances are established for combined residues of glyphosate and its metabolite aminomethylphosphonic acid on peanuts.

40 CFR 180.364

Peanuts.	0.1
Peanut, Forage.	0.5
Peanut, Hay.	0.5
Peanut, Hulls.	0.5

I. When used as directed on the requested wiper applicator label, the peanut tolerances will need to be the following:

Peanuts.	2.0
Peanut, Forage	0.5*
Peanut, Hay.	0.5*
Peanut, Hulls.	2.5

*Forage and hay treated from only wiper applications, cannot be fed.

II. 21 CFR 561.253

Peanut, meal 3.0

When used as directed on the requested wiper applicator label, a food additive tolerance will be needed for peanut meal.

2. No new toxicity data were submitted.
3. Inerts are cleared under 180.1001 for Roundup.