

US EPA ARCHIVE DOCUMENT

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

4-11-80 OK

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA Reg.#524-308 (Roundup); "Free-Standing" Summary of PP#OF2329;
glyphosate in or on peanuts. CASWELL#661A

FROM : William Dykstra
Toxicology Branch, HED (TS-769) WTD 4/11/80

TO : Robert Taylor & Residue Chemistry Branch
Product Manager#25 (TS-769)
Registration Division (TS-767)

Petitioner: Monsanto Agricultural Products Co.
800 N. Lindbergh Blvd.
St. Louis, Mo. 63166

Recommendations: The requested tolerances can be toxicologically supported. The data considered in setting the tolerances are summarized below:

- °Oral LD₅₀ Rabbit: 3.8 gm/kg
- °90-Day Rat Feeding Study: NOEL = 2000 ppm
- °90-Day Dog Feeding Study: NOEL = 2000 ppm
- °Teratology (2 studies) Rabbit: negative at 30 mg/kg (highest dose)
- °3-Generation Rat Reproduction: NOEL = 100 ppm
- °2-Year Dog Feeding: NOEL = 300 ppm
- °2-Year Rat Feeding: NOEL = 100 ppm
- °Neurotoxicity (hen): negative at 7.5 gm/kg
- °Host-Mediated Assay: negative
- °Ames Assay: negative
- °Reverse-Mutation Assay: negative
- °Rec-Assay: negative

- 2) The data which are currently lacking and considered desirable:
- (a) repeat of oncogenicity - 2 species
 - (b) teratology - rabbit at higher dose level and 2nd species for teratogenic evaluation.

(2)

- 3) The petitioner has been notified of toxicity deficiencies regarding glyphosate.
- 4) Tolerances for glyphosate have been established under 40 CFR 180.364.
- 5) The published tolerances utilize 6.93% of the ADI. Unpublished, TOX approved tolerances utilize the ADI to 19.01%. The current action utilize 0.02% of the ADI. All tolerances on glyphosate utilize 19.03% of the ADI.
- 6) The ADI is based on the NOEL of 100 ppm (5 mg/kg/day) in a 2-year rat feeding study. This is the most sensitive species for which chronic data are available. A 100 fold safety factor was used to calculate the ADI.

$$\text{ADI} = \text{NOEL} \times \frac{1}{100}$$

The MPI for a 60 kg person is 3 mg/day

- 7) No regulatory actions are pending against the pesticide and no RPAR criteria have been exceeded.
- 8) One of the deficiencies in the glyphosate data base is the lack of an adequate teratology study. It is however concluded that the studies at hand together with the reproduction study show that glyphosate has low potential for showing and teratogenic effects.

Additionally, the oncogen potential of glyphosate is not fully elucidated. The life-time mouse and rat studies, however, provides assurance that glyphosate has a relatively low oncogenic potential. A further assurance of low risk associated with glyphosate is found in the fact that on a theoretical basis the exposure via the diet is about one-fifth of the ADI at present.

TOX/HED:th:CFRICK:4-10-80

B. Frick

4/15/80
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