

US EPA ARCHIVE DOCUMENT

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OK OK

DATE: November 13, 1979

SUBJECT: EPA Reg. #524-308; Glyphosate; "Free-Standing" Summary of PP#9F2162; petition proposing the establishment of a tolerance for residues of glyphosate and its metabolite in the crop grouping stone fruit at 0.2 ppm. CASWELL#661A

FROM: William Dykstra
Toxicology Branch (TS-769)

WHD 11/13/79 WSL

TO: Richard Mountfort
Product Manager#25

Residue Chemistry Branch
(TS-769)

THRU: Dr. Adrian Gross, Chief
Toxicology Branch (TS-769)

William M. Butler for Dr. Adrian Gross

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

Recommendations

- 1) The requested tolerance can be toxicologically supported. The data considered in setting the tolerance 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
- 2) The data which are currently lacking and considered desirable:
 - (a) repeat of oncogenicity - 2 species
 - (b) teratology - rabbit at higher level and 2nd species for teratogenic evaluation
 - (c) repeat of mutagenicity data - multi-test evidence
- 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 Unpublished, TOX approved tolerances utilize the ADI to 10.80%. The current action utilizes 0.13% of the ADI. All tolerances on glyphosate utilize 10.93% 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. A 100 fold safety factor was used to calculate the ADI.

(2)

$$\text{ADI} = 5 \text{ mg/kg/day} \times \frac{1}{10} = 0.05 \text{ mg/kg/day}$$

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

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 any teratologic effects. Additionally, the oncogenic potential of glyphosate is not fully elucidated. The life-time mouse and rat studies, however, provide adequate 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 relatively low at present.

TOX/HED:th:RD Initial WOODROW:11-9-79