

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DATE: July 17, 1979

SUBJECT: "Free Standing" summary of PP#8E2122, PP#9H5196; Request for tolerance for glyphosate in or on sugarcane at 2.0 ppm and food additive tolerance request for glyphosate in or on molasses at 20.0 ppm and raw sugar at 2.0 ppm. EPA Reg.#524-Q, MON-8000, Acc.#097402, CASWELL#661A

FROM: William Dykstra, Ph.D
Toxicology Branch

TO: Robert Taylor & RCB, TS-769
Product Manager#25

WMD 7/17/79

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

Recommendations

1. 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/day (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 described:
 - (a) oncogenicity - 2 species
 - (b) teratology - rabbit at higher level and 2nd species for teratologic evaluation.
 - (c) mutagenicity data - multi-test evidence
3. The petitioner has been notified of toxicity deficiencies regarding glyphosate.
4. Tolerances for glyphosate have been established under CFR 40 180.364.
5. The published tolerances utilize 6.93% of the ADI. An unpublished, TOX approved tolerance utilizes the ADI to 7.05%. The current action utilizes the ADI to 10.78%. Therefore the current action utilizes 3.73% of the ADI. Other pending tolerances utilize the ADI to 14.38%.

(2)

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.

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

$$\text{ADI} = 5 \text{ mg/kg/day} \times \frac{1}{100} = .05 \text{ mg/kg/day}$$

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 main 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 diet is relative low at present. The current action utilizes 3.73% of the ADI and a total of 10.78% of the ADI is utilized by all pre-tolerances on glyphosate.

This chemical is to be for import crops only and not for application to sugar cane in the Continental U.S.A.

TOX/HED:th:RD Initial WDYKSTRA:7-17-79

ik
W.D. Yunker