US EPA ARCHIVE DOCUMENT

SUBJECT: Roundup, file symbol 524-EUP-44, TB evaluation for human safety.

FROM: TB/RD, Mary L. Quaife, Ph.D. (now HED) MLQ 7/19/78

TO: Ms. Libby Zink, Special Registration Section

Monsanto Company, St. Louis, Mo., wishes an experimental permit to allow use of Roundup, EPA Reg. No. 524-308, in amount of 114 gallons (= 345 lbs active ingredient), for period of 6/1/78 to 6/1/80.

The product is to be used on asparagus for weed control, pre-emergence or post-harvest, or as directed spray at rates varying from 1 to 5 quarts (in 5 to 100 gallons of carrier/acre), on experimental plots in six different states.

A temporary tolerance for glyphosate and its metabolite, aminomethylphosphonic acid, on asparagus at 0.2 ppm (negligible) is asked for.

No new toxicity data accompany the application. Section G refers to studies previously done on technical compound, metabolite, formulations, and Roundup surfactants.

No confidential formulation is included. We require such - not reference to a previous PP.

We note, we have previously approved EUPs on Roundup (e.g., on 9/12/77, EUP-24, for one year due to unevaluated nitrosamine hazard to users of the formulation). We note that EPA is now on record that no such label statement, "Wear Protective Clothing and Respirator During Loading and Spraying Operations," need be included on experimental use permit labels for glyphosate products, based on data submitted by Monsanto on 2/16/78 regarding, "Exposure of Herbicide Applicator to N-Nitroso-glyphosate During Application of Roundup Herbicide," ltr. of 3/23/78, Mr. J. G. Touhey, SRS, to Dr. L. H. Hannah, Monsanto.

N.B. July 19, 1978.

An up-to-date 15/25/75 confidential formulation for 524-308 Roundup formulation is now at hand (courtesy of Mr. El Dorrenbacher, on R. Taylor PM team). Thus the above-stated requirement is fulfilled.

Available TOX data on Roundup (524-308) - cf.. e.g., 524-EUP, 5/2/77, reviewed by the undersigned, plus above information (2nd para, above), allow TB to conclude that the EUP (memo. title) is "safe" to humans. Available TOX data on glyphosate (cf., e.g., TB memo of 4/26/78, PP 8F2070) and on nitroso-glyphosate (cf., e.g., TB memo of 6/14/78, PP No. 5F1560) support safety to humans of the requested temporary tolerance (0.2 ppm on asparagus for glyphosate and its metabolite, aminomethylphosphonic acid).

CONCLUSION: TB finds requested 524-EUP-44 and temporary tolerance (0.2 ppm on asparagus) "safe" to humans.

EPA FORM 1320-6 (REV. 3-76)