Circle No. 64 OK

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DATE: December 7, 1977

SUBJECT: Glyphosate, request to establish tolerances for combined residues of it and its metabolite, aminomethylphosphonic acid, on cottonseed and soybean grain each at 6 ppm; on soybean forage and hay each at 15 ppm; on liver and kidney of cattle, goats, hogs, horses, poultry, and sheep at 0.1 ppm; and on soybean hulls (food additive) at 20 ppm.

FROM: TB/RD

TO: PM Mr. Taylor

PP No. 7F1971

Monsanto Agricultural Prods. Co.
St. Louis, Missouri

Petitioner requests tolerances listed in memo title (above).

No new TOX data are included, except for a 21-day dermal study on formulation, MON 0139.* Note: Most supporting data are from IBT.

TB recommends against granting tolerances requested in this PP. In a word, toxicity data on N-nitrosoglyphosate submitted to date are not judged adequate to support them. (Please see TB memo of 11/10/77, PP No. 7F1904 (copy attached), for further details.)

* "21-day dermal toxicity study with MON-0139 and MON-0011 in albino rabbits," BTL 73-20 and 73-21, 3/23/73, IBT No. 601-02468, by W.J. Hamilton, C. Mastri, and M. L. Keplinger.

A 21-day dermal study was done on MON-0139 (isopropylamine salt of glyphosate, 4 lb/gal.), Lot No. XHC-129, and MON-0011 (adjuvant for MON-0468), Lot No. XHB-77. Groups of 5M and 5F rabbits each received 15 applications of 2 ml/kg body weight of tap water or of each test compound in 0.8% or 4% (v/v) concentration in water on intact skin under occlusive plastic wrap, 6 hrs/day, 5 times/wk, for 3 wks. Concurrently, the experiment was duplicated, except that application sites were abraded. Both "use" and 5x use levels are apparent descriptions of the two concentrations tested. Rabbits used total 100.

Results. There were no effects of either test material (compared to control results) on body weight; mortality; behavior; hematologic, urinalysis, or blood chemistry values; selected organ weights and ratios; or gross or microscopic findings, except on skin. However, MON-0011 caused superficial eschar and edema at exposure site, especially in 5x rabbits (in addition to pustules, desquamation, erythema, and slight fissures with surface bleeding noted in animals from all groups). Microscopically, rabbits from all groups showed acanthosis, hyperkeratosis, dermal inflammatory infiltrates, and eschar.

Study is classified as "supplementary" because (1) only two dose-levels of test substances were included and (2) local skin effects are not graded as described by Draize; although they are graded for severity (mic

M.L.Q., 12/7/77
Mary L. Quaife, Ph.D., TB/RD
December 7, 1977

12/8/77

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