

US EPA ARCHIVE DOCUMENT

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SUBJECT: EPA Reg. No. 524-306. ROUNDUP. (Glyphosate) Nitrosemine Impurity N-nitrosoglyphosate. Monsanto Agricultural Products Co., St. Louis, Missouri  
FROM: Roland A. Gessert, D.V.M.; Toxicology Branch  
TO: Ms. Libby Zink, Special Registrations Section

In an effort to remove label requirements for protective clothing and respirators for applicators, Monsanto conducted extensive studies to demonstrate the possible exposure of an applicator to the trace impurity N-nitroso-N-phosphonomethylglycine (NPMG, or N-nitrosoglyphosate).

Actual field measurements were made showing the amount of glyphosate and N-nitrosoglyphosate that the applicator may be exposed to when loading and applying Roundup herbicide. Results reported included tank filling and spraying with boom, handgun, and backpack sprayers. The studies covered exposure by inhalation, dermal, and clothing routes, plus assays of the formulation used and spray solutions prepared. N-nitrosoglyphosate was not detected in any of the intercept samples.

In the boom spray application, the boom was set at 6 feet from the ground to give maximum operator exposure to drift. The tank was filled with 500 gallons of water and 9 gallons of Roundup formulation. This resulted in an application rate of 3.09 pounds of glyphosate acid per acre (1.03 gallons of Roundup per acre).

In the handgun application, the spray tank was filled with 5 gallons of Roundup per 500 gallons of water, 150 gallons of solution being sprayed per acre over a period of about 1 hour.

In the backpack handpump application, the sprayer was filled with 3 gallons of water and 147 ml of Roundup (a 1.3% v/v solution), 3 gallons of solution being applied in 45 minutes.

Air samples were collected using a Bendix High Volume Air Sampler model 500 fitted with a 4-inch diameter Reeve Angel glass fiber/organic binder filter pad. To represent the quantity of N-nitrosoglyphosate an operator may breathe during application of Roundup, the collector/pad was held next to the operator's face by use of a specially designed shoulder harness.

Estimates of the amount that may deposit on skin surfaces and the protection that clothing may afford during application of the herbicide were made by attaching 24 ply 4 x 4 inch surgical gauze pads at strategic locations on the applicator's body. A total of 11 pads were used for each test, located as follows: EXPOSED: Top of head, forehead, chest, shoulder, back, right bicep, left forearm, thigh.

UNDER CLOTHING: Right forearm, left bicep, ankle.

The Roundup used in the tests contained 0.14 ppm of N-nitrosoglyphosate; the theoretical content of the sprayed solution, therefore, would be approximately 0.0014 ppm. The average recovery for the assay method for laboratory fortified gauze was 72.3% for glyphosate and 82.5% for N-nitrosoglyphosate.

In none of the field studies was any N-nitrosoglyphosate detected.

Toxicology Branch will defer to Chemistry Branch for determination of the adequacy of the assay methods. However, it would be anticipated that operator exposure during the filling operation would be nil. Also, the "high" 0.14 ppm level in the Roundup formulation actually is very low mathematically. And even though the diluted level of 0.0014 ppm is chemically detectable, the toxicological significance of exposure to this level is open to question. But if actual exposure of the operator to the glyphosate solution is essentially nil, then actual exposure of the operator to the impurity N-nitrosoglyphosate would be essentially non-existent. N-nitrosoglyphosate does not constitute an oncogenic hazard in Roundup herbicide handling or use.

**RECOMMENDATION:** The requirement for protective clothing and respirator may be deleted from the labeling.



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J. E. W. 3/31/78