September 16, 1977

Hazard Assessment of Roundup
Ref. Nitrosamine Generators (7/29/77)

Chief
Toxicology Branch (WH-567)

Special Registration Officef
Registration Division (WH-567)

THRU: Associate Director for Scientific Review
Registration Division (WH-567)

The Toxicology Branch has no objection to granting a temporary tolerances of 0.2 ppm and 0.5 ppm for Roundup and its metabolite in fresh and dry alfalfa and liver and kidney of domestic animals. The studies on which these tolerances are based are: 2 year rat and dog feeding studies (NOEL = 100 and 300 ppm); 18 month mouse study; rat reproduction study; rabbit teratology study, and a dominant lethal mutagenicity study. These studies support the proposed tolerances.

Chemistry Branch (6/30/77) stated no tolerances were needed for eggs, milk or other meat tissue. No residues of the nitrosamines in the formulation were found in 49 field crops receiving preplant or multiple post plant treatments. By means of a ^{14}C- glyphosate study, a hypothetical maximum value for ^{14}C-NNG residue in various crops might range from 1 to 7 ppb. It is the opinion of the TOX Branch that no adverse effects should result from ingestion of crops even if the maximum hypothetical nitroso residues are present.

Like the Chemistry Branch, we can make no estimate of the hazard to the applicator from the 0.2 - 0.4 ppm N-nitrosoglyphosate (NNG) present in the formulated Roundup. It is our opinion that applicator exposures to this quantity of NNG is remote and that no unreasonable risk is present under normal conditions of use. However to be conservative, the EUP label should advise the applicators to use protective clothing and respirator during the loading and spraying operations.

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