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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA Registration #524-316. Alachlor

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THRU: Charles L. Trichilo, Ph.D., Chief
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TO: Robert Taylor, Product Manager #25
Herbicide-Fungicide Branch
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and

Toxicology Branch
Hazard Evaluation Division (TS-769)

Monsanto submits a $^{12}\text{C}/^{13}\text{C}/^{14}\text{C}$ -metabolism study of the herbicide alachlor [2-chloro-2',6'-diethyl-N-(methoxymethyl)acetanilide] on goats and chickens for risk assessment.

Tolerances are established for the herbicide alachlor [2-chloro-2',6'-diethyl-N-(methoxymethyl) acetanilide] and its metabolites (calculated as alachlor) in meat, fat and meat by-products of cattle, goats, hogs, horses, poultry and sheep and in milk and eggs at 0.02 ppm. The method sensitivity is 0.02 ppm.

Goat and chicken metabolism studies were conducted to determine radioactive residue levels which would result from feeding corn and soybean grain containing 0.2 ppm alachlor residues. Goats and chickens were fed a mixture of 5 major alachlor metabolites containing ^{14}C in the phenyl ring and ^{13}C at the 2-position of the acetamide moiety. Three goats were fed a level of 5.4 ppm alachlor equivalents for 5 days. Two goats were sacrificed at the end of the treatment period and one was sacrificed 5 days after the last dose. Milk was collected twice daily. Residues

in milk plateaued by the second day. Residues from feeding goats 5.4 ppm alachlor equivalents in the diet were 15 ppb in liver, 12 ppb in kidney, <3.7 ppb in muscle, <4.1 ppb in fat, and 5.4 ppb in milk. Residues were calculated for a feed level of 0.2 ppm alachlor equivalents assuming a linear relationship of feed and residue levels at low feed levels. Residues in goats resulting from a diet of 100% corn grain or soybean grain containing 0.2 ppm alachlor equivalents are calculated to be 0.55 ppb in liver, 0.44 ppb in kidney, 0.14 ppb in muscle, 0.15 ppb in fat, and 0.20 ppb in milk. Hens (an unspecified number) were fed a level of 9.7 ppm alachlor equivalents for an unspecified number of days. Residues in hens fed 9.7 ppm alachlor equivalents were 4.5 ppb in thigh muscle, 5.3 ppb in breast muscle, 16.8 ppb in kidney, 54.3 ppb in liver, <3.8 ppb in fat, and 30.4 ppb in eggs. Residues in hens resulting from a diet of 100% corn grain or soybean grain containing 0.2 ppm alachlor equivalents are calculated to be 0.09 ppb in thigh muscle, 0.11 ppb in breast muscle, 0.35 ppb in kidney, 1.1 ppb in liver, 0.08 ppb in fat, and 0.6 ppb in eggs.

RCB has determined the maximum expected dietary intake of alachlor residues (Alachlor Registration Standard, 3/12/83):

"The maximum expected dietary intake of alachlor residues by poultry and swine is 0.2 ppm based on the consumption of corn grain and soybean meal in any combination. The maximum intake by cattle (meat and dairy) is 3 ppm if the diet consisted solely of peanut forage and hay; a more reasonable diet would consist of 60% peanut hay and 40% corn grain which would result in a dietary intake of 1.9 ppm. For beef cattle the highest intake would consist of 25% peanut hay with 5% peanut hulls and 70% corn grain amounting to 1 ppm of alachlor residues."

RCB has summarized previously submitted feeding studies (Alachlor Registration Standard, 3/12/83):

"Monsanto Co. (9F0740) submitted data reflecting the feeding of the soybean metabolite(s) of alachlor (extracted from field-treated plants) to dairy cows, laying hens, and swine for 30 days at 0.2, 0.6, and 2 ppm. Only residues containing the 2,6-diethylaniline moiety were determined. The dairy cow study (IBT Project No. BTL-68-3) revealed that no residues were detected (<0.02 ppm) in fat, kidney, liver and muscle after 30 days or in milk over the entire test period. Residues were nondetectable (<0.02 ppm) in eggs over the 30-day test period and in fat, liver, and muscle of laying hens after 30 days of feeding. In the case of swine (IBT Project No. BTL-68-4), residues were nondetectable (<0.02 ppm) in fat, kidney, and liver after 30 days of feeding at all dosage levels and in muscle after dosing at <0.6 ppm; at 2 ppm (10X the expected dietary intake of swine), residues were <0.02-0.04 ppm after 30 days."

Conclusions

1. The reliability of the data is questionable since the data are based on a short feeding study (5 days for goats) and a small number of animals (2 for goats sacrificed immediately and an unspecified number of chickens).

2. Calculations of residues resulting from a 0.2 ppm feeding level are based on an assumption that a linear relationship for feeding levels vs. residue concentration exists at low feeding levels.

3. No analytical method exists to determine alachlor residue levels below 0.02 ppm.

4. A 0.2 ppm maximum expected dietary intake of alachlor is appropriate for poultry and swine but would be 2 ppm for dairy cattle and 1 ppm for beef cattle.

5. Residues of <0.02-0.04 ppm have been found in previously submitted studies in swine fed at a rate of 2 ppm alachlor residues although no residues were found in cows, hens, milk, or eggs at ≤ 2 ppm feeding levels,

Recommendations

We recommend that the established tolerances of 0.02 ppm in meat, milk, poultry and eggs be used to assess risk.

We would reexamine our recommendations if:

1. The petitioner submitted (as recommended in the Alachlor Registration Standard) animal metabolism studies which demonstrate that the residues of concern in animals do indeed contain the 2,6-diethyl-aniline moiety since only residues containing this moiety were determined in the previously submitted animal metabolism studies.

2. The petitioner submitted the results of the conventional feeding studies currently in progress.

3. The petitioner refined the analytical method to determine residues <0.02 ppm in meat, milk, poultry and eggs.

4. Appropriate feeding restrictions were imposed on such feed items as peanut hay to reduce livestock's dietary burden.

cc:R.F., Circu., Reviewer, Alachlor S.F., W. Boodee, M. Kovacs,
E. Zager

RDI:E.Zager:4/9/84:R.D.Schmitt:4/9/84

TS-769:RCB:N. Dodd:gmk:CM#2:RM800:Date:4/9/84