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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAY 29 1992

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

SUBJECT: Iprodione. Case # 2335. Response to Phase IV Review of 3/15/91. Method Validation Data for Feeding Studies. MRID # 421693-05 & -06. CBRS # 9664 & 9665. DP Barcode: D175846, D175865.

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TO: Kathy Davis, PM Team # 51
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Rhone-Poulenc Ag Company has submitted method validation data for the feeding studies summaries that were reviewed in our Phase IV memorandum (C. Olinger, 3/15/91). The 3/15/91 review concluded that the cow feeding study was not acceptable for Phase V review because of the lack of recovery data. It also concluded that the hen feeding study did not analyze poultry tissues and eggs for the regulated hydroxylated metabolite, and that the analytical method used had not been adequately validated. The 3/15/91 review also concluded that new cow and hen feeding studies must be conducted.

The full chemical name for iprodione is 3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide.

Cow Feeding Study (MRID # 421693-06)

In response to the FIFRA 88 Phase IV Data Call-In on iprodione, the registrant stated that a method validation study was conducted and completed in February 1982, and referenced such data in MRID [Accession] # 106082 as part of Appendix II. The work was performed by the Analytical Development Corporation, Monument, CO.

Recovery data were generated at 0.1 and 0.5 ppm of iprodione or its metabolite 3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidine-carboxamide (RP32490) in kidney, muscle, fat, and liver which ranged from 55% to 90%, and averaged 61% for RP32490 and 75% for iprodione. In milk, recoveries ranged from 79% to 90% when fortified at 0.01 or 0.20 ppm iprodione, and from 75% to 89% when fortified at 0.01 or 0.20 ppm RP32490. When bovine milk was fortified with RP36114, the regulated hydroxylated metabolite, at 0.01 or 0.10 ppm, recoveries ranged from 62% to 76%. Data comparing residue accountability between the analytical method and LSC determination using the radioactive goat tissues and milk (metabolism study) were also given.

Fortification data obtained concurrent with the dairy cow feeding study were also provided. Milk (control) was fortified with the parent compound, its metabolite RP32490, and hydroxylated metabolite RP36114 at 0.005, 0.01, 0.10, or 0.20 ppm (averages ≈ 89% for parent and RP32490 and 62% for RP36114).

Poultry Feeding Study (MRID # 421693-05)

The registrant submitted recovery data for iprodione and metabolite RP32490 fortified in eggs, liver, muscle, and fat. Our 3/15/91 memorandum specifically asked recovery data for the hydroxylated metabolite (i.e., RP36114). The registrant argued in the conclusion section (of its submission) that the poultry metabolism study showed no evidence of RP36114 in tissues and eggs, and therefore analysis for this metabolite in poultry tissues and eggs is not necessary.

According to our records, the Phase III submission (hen metabolism study summary, ADC Project # 675, dated May 7, 1990) identified RP36114 being present in eggs, liver, kidney, and fat in small amounts (up to 1.4% in eggs). In addition, the hydroxylated metabolite is regulated in the tolerance for iprodione residues in poultry meat, meat by-product, liver, fat, and eggs set at levels of 1.0-5.0 ppm. Thus, RP36114 must be analyzed in poultry tissues and eggs in a poultry feeding study.

CONCLUSIONS AND RECOMMENDATION

1. The registrant has submitted sufficient method validation data for the cow feeding study for our Phase V review. A determination on the adequacy of this study and thus whether a new cow feeding study is required will be made when the review is completed.

2. Analysis of the hydroxylated metabolite RP36114 in poultry tissues and eggs is required on the evidence of the poultry metabolism study results. The registrant has not submitted residue analysis of this chemical in poultry tissues and eggs, nor the

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recovery data for this metabolite. A new poultry feeding study to be conducted as specified in the DCI must be submitted.

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