R.F.
8-11-95

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

AUG 11 1995

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#2F04111 (CBTS #15214; Barcode #D212723). Iprodione on Cottonseed. Amendment dated 2/24/95 (MRID #'s 435607-00 and 435607-01).

FROM: Nancy Dodd, Chemist
Tolerance Petition Section II
Chemistry Branch I- Tolerance Support
Health Effects Division (7509C)

THROUGH: Michael Metzger, Chief
Chemistry Branch I- Tolerance Support
Health Effects Division (7509C)

TO: Jim Tompkins/Carl Grable, PM Team #21
Fungicide/Herbicide Branch
Registration Division (7505C)

Rhone-Poulenc has submitted an amendment dated 2/24/95 to PP#2F04111 which proposed the establishment of a permanent tolerance for residues of the fungicide iprodione [3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide], its isomer 3-(1-methylethyl)-N-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide, and its metabolite 3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidine-carboxamide in/on cottonseed at 0.10 ppm. The amendment consists of a letter dated 2/24/95, a revised label for Rovral® 4 dated 2/27/95, and residue data. This amendment was submitted in response to the review of PP#2F04111 dated 2/6/95 (G. Jeffrey Herndon).

CONCLUSIONS

1. A revised Section B/label must be submitted as requested. Using the product on cotton for continuous cotton culture would be acceptable for an EUP/temporary tolerance but not for a permanent tolerance. CBTS has determined that only crops with iprodione registrations can be rotated until the rotational crop data are reevaluated. Accordingly, the revised label must contain the following crop rotation restrictions:

CROP ROTATION RESTRICTIONS FOR BEANS, BROCCOLI, CARROTS, CHINESE MUSTARD, COTTON, DRY BULB ONIONS, GARLIC, LETTUCE, PEANUTS, AND POTATOES.

The following crops may be rotated after harvest: Beans, Broccoli, Carrots, Chinese Mustard, Cotton, Dry Bulb Onions, Garlic, Lettuce, Peanuts, and Potatoes.

2. Some outstanding issues can be resolved under a time-limited tolerance for cottonseed and a conditional registration for cotton. These issues are as follows:

a. Residue data for cotton gin byproducts, which are now considered a livestock feed item (in Table II, Subdivision O, June 1994), must be submitted.

b. A petition method validation by EPA's laboratory must be conducted for the common moiety method ["Method for the Analysis of Rovral-Related Residues: Common Moiety Method (Version 6.0 for Cottonseeds)", 7/20/94; MRID #433971-01], including an assessment of the petitioner's claimed limit of quantitation (LOQ) of 0.05 ppm.

c. An interference study must be conducted for the common moiety method, considering other pesticides containing the dichloroaniline moiety, such as vinclozolin, procymidone, propanil, methazole, and potentially oxadiazon and dichloronitroaniline.

d. Rotational crop data must be evaluated/reevaluated. (This is being done under the reregistration process.)

RECOMMENDATIONS

Provided the Section B/label is modified as described in Conclusion #1 above, CBTS recommends for the proposed use of iprodione (Rovral® 4 Flowable) on cotton under a time-limited tolerance for residues of iprodione [3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide], its isomer 3-(1-methylethyl)-N-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide, and its metabolite 3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide in/on cottonseed at 0.10 ppm and a conditional registration for cotton. Under the time-limited tolerance for cottonseed and the conditional registration for cotton, the following data must be provided:

a. Residue data for cotton gin byproducts, which are now considered a livestock feed item (in Table II, Subdivision O, June 1994), must be submitted.

b. A petition method validation by EPA's laboratory must be conducted for the common moiety method ["Method for the

Analysis of Rovral-Related Residues: Common Moiety Method (Version 6.0 for Cottonseeds)", 7/20/94; MRID # 433971-01], including an assessment of the petitioner's claimed limit of quantitation (LOQ) of 0.05 ppm.

c. An interference study must be submitted for the common moiety method, considering other pesticides containing the dichloroaniline moiety, such as vinclozolin, procymidone, propanil, methazole, and potentially oxadiazon and dichloronitroaniline.

d. Rotational crop data must be evaluated/reevaluated. (This is being done under the reregistration process.)

DETAILED CONSIDERATIONS

Deficiencies from the review of PP#2F04111 dated 2/6/95 (G.J. Herndon) are repeated below, followed by the petitioner's responses and CBTS's discussions/conclusions.

Deficiency #1a

The language on the proposed label concerning crop rotation should be changed to the following:

CROP ROTATION RESTRICTIONS FOR BEANS, BROCCOLI, CARROTS, CHINESE MUSTARD, COTTON, DRY BULB ONIONS, GARLIC, LETTUCE, PEANUTS, AND POTATOES.

The following crops may be rotated after harvest: Beans, Broccoli, Carrots, Chinese Mustard, Cotton, Dry Bulb Onions, Garlic, Lettuce, Peanuts, and Potatoes.

Petitioner's Response to Deficiency #1a

A revised label for Rovral 4F (dated 2/27/95) has been submitted. The revised label contains the following crop rotation restrictions:

CROP ROTATION RESTRICTIONS FOR BEANS, BROCCOLI, CARROTS, CHINESE MUSTARD, DRY BULB ONIONS, GARLIC, LETTUCE, POTATOES, AND PEANUTS

The following crops may be rotated after harvest: Beans, Broccoli, Carrots, Chinese Mustard, Cotton, Dry Bulb Onions, Garlic, Lettuce, Peanuts, and Potatoes.

CROP ROTATION RESTRICTION FOR COTTON

This product may be used for continuous cotton culture only.

CBTS's Conclusion #1a

Deficiency #1a is not resolved. A revised Section B/label must be submitted as requested. Using the product on cotton for continuous cotton culture would be acceptable for an EUP/temporary tolerance but not for a permanent tolerance. CBTS has determined that only crops with iprodione registrations can be rotated until the rotational crop data are reevaluated. Accordingly, the revised label must contain the following crop rotation restrictions:

> **CROP ROTATION RESTRICTIONS FOR BEANS, BROCCOLI, CARROTS, CHINESE MUSTARD, COTTON, DRY BULB ONIONS, GARLIC, LETTUCE, PEANUTS, AND POTATOES.**
>
> The following crops may be rotated after harvest: Beans, Broccoli, Carrots, Chinese Mustard, Cotton, Dry Bulb Onions, Garlic, Lettuce, Peanuts, and Potatoes.

Deficiency #1b

The heading " The following crops may be rotated 1 month after the last iprodione application", and the crops listed under it should be deleted from the proposed label.

Petitioner's Response to Deficiency #1b

A revised Section B/label has been submitted dated 2/27/95.

CBTS's Conclusion #1b

Deficiency #1b is resolved by submission of the revised label dated 2/27/95.

Deficiency #2a

The petitioner should explain how they calculated the 3,5-DCPA/ECD interaction to be non-linear and why the high spikes (0.25 and 0.50 ppm) exhibited low apparent recoveries.

Petitioner's Response to Deficiency #2a (MRID # 435607-01)

(Note: Table 1 and Figure 1 are attached to this review as Attachment 1.)

> "The ECD response is reasonably linear over narrow, precisely defined concentrations, but not from zero to infinity and can be compound specific. If the 3,5-DCPA analyte data are plotted using both the linear and logarithmic models the curve differences are nearly imperceptible except at the very high and low ends of the curve (Figure 1). The logarithmic model for the standard

curve was selected by the analyst as the best mathematical description of instrument performance over the largest range of the 3,5-DCPA analyte concentrations (See attached copies of the final report pages 193-194)."

"Quantitative data (eg. sample weights, extraction volumes, final volumes, etc.) are located in Appendix C, Analytical Report (beginning on page 165 of the final report). These data indicate that the final volume (mL) for all sample extracts was not 5 mL. For the 0.25 ppm spikes the final volume was 10 mL (2X differential) which accounts for the ~50% recovery calculated by CBTS and the ~100% recovery calculated by the analyst. Similarly, the final volume for the 0.50 ppm spike was 20 mL (4X differential) which accounts for the ~23% recovery calculated by CBTS and the ~94% recovery calculated by the analyst (See attached copies of the final report pages 198-202). Although the analyst could have used a linear model with acceptable results, the logarithmic model does provide more accurate results at the high and low ends of the standard curve. Data presented in Table I and Figure 1 illustrate that the difference in percent recoveries using the linear vs. logarithmic models is very small (See attached copies of the final report pages 212-213)."

CBTS's Conclusion #2a

Deficiency #2a is resolved by submission of the requested information/explanation.

Deficiency #2b

The petitioner should provide copies of the pertinent extraction log pages (i.e. information on sample weights, extraction volumes, etc.) for the samples and spikes analyzed.

Petitioner's Response to Deficiency #2b (MRID # 435607-01)

"Quantitative data covering sample weights, extraction volumes, final volumes, etc. are located in Appendix C, Analytical Report, starting on page 165 of the final report. A copy of portions (beginning with page 184) of this information is attached for review and confirmation."

CBTS's Conclusion #2b

Deficiency #2b is resolved by submission of the requested information.

Attachment 1: Table 1 (% recoveries using linear/logarithmic standard curves) and Figure 1 (detector response vs. concentration using linear/logarithmic standard curves)

cc with Attachment 1: RF, Circu., N. Dodd (CBTS), E. Haeberer (CBTS), S. Knizner (CBRS), PP#2F4111, PM #21, List B File

RDI:E. Haeberer:6/27/95:R. Loranger:7/27/95
7509C:CBTS:CM#2:Rm804F:305-5681:N. Dodd:nd:8/10/95