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

JUN 16 1987

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#'s 4F3074. Propiconazole (Tilt®, Banner®, or CGA-64250®) on Crops and Livestock Commodities. Use of 0.025 ppm Level for Grains. Letter of May 27, 1987. MIRD No. RCB No.

FROM: Sami Malak, Ph.D., Chemist *Sami Malak*
Tolerance Petition Section III
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

TO: Lois Rossi, PM #21
Fungicide-Herbicide Branch
Registration Division (TS-767)

and

Toxicology Branch
Hazard Evaluation Division (TS-769)

THRU: Philip V. Errico, Section Head *Philip V. Errico*
Tolerance Petition Section III
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

Note: This is an expedited review at the request of the Registration Division's Director, Mr. E. F. Tinsworth (Letter of 5/28/87).

Ciba-Geigy submitted residue data and sample chromatograms for propiconazole on small grains requesting the use of 0.025 ppm (one half of the detection limit of 0.05 ppm-see MTO report, subject petition, S. Malak, 5/28/87) for purpose of calculating the dietary exposure level in grains. This value is proposed by Ciba-Geigy for the purpose of calculating the dietary exposure for use in the propiconazole risk assessment. The residue data associated with the submitted chromatograms have been previously submitted and reviewed in connection with subject petition (A. Smith, 4/9/85). No residues were detected in the grains of barley, rice, rye, and wheat (<0.05 ppm). We will review this amendment with respect to whether the analytical method will detect propiconazole down to 0.025 ppm.

Petitioner's Presentation

To substantiate the use of 0.025 ppm for cereal grain dietary exposure, Ciba-Geigy reported on 30 extrapolated residue values for wheat, barley, and rice. Extrapolation was stated to have been accomplished by correcting for control values (subtracting background levels from actual residue levels). When the petitioner corrected for the background values in the untreated controls, 26 of 30 samples had corrected levels <0.025 ppm. The remaining 4 samples had corrected levels of 0.026, 0.028, 0.029, and 0.045 ppm. How this extrapolation was accomplished by the petitioner is unclear.

RCB's Comments and Conclusions

Upon examination of the submitted data including the chromatograms, it is obvious that the limit of detection is 0.05 ppm. This level was also reported by the EPA's Analytical Chemistry Laboratory in Beltsville (see also MTO report, subject petition, S. Malak, 5/28/87). Furthermore, the data presented have not been validated for recovery or substantiated with standard injections at the low quantitation level of 0.025 ppm. Therefore, we are unable to accept the petitioner's reported extrapolated background levels below 0.05 ppm such as 0.004 and 0.01 ppm, since the extrapolation and correction for background calculated by the petitioner is unclear.

Based on the above comments, we conclude that the analytical methodology (Method AG-454A for crops) will not support the 0.025 ppm level for grains.

Recommendations

We continue to recommend for 0.05 ppm limit of detection for method AG-454A for crops.

cc: Circu, RF. SF (propiconazole, Banner®, Tilt®, or CGA-64250®), S. Malak, K. Arne, PP#4F3007, PP#4F3074, PP#4E3026, TOX, EAB, PM #21, Robert Thompson (RTP), FDA, and PMSD/ISB.

RDI:P. V. Errico:6/12/87;R. D. Schmitt:6/16/87
TS-769C:RCB:CM#2:RM814A:S.Malak:X557-4379:6/3/87.