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

MAR 28 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#8F3674. Propiconazole (Tilt®) in/on Corn and Pineapple. Submission Dated 10/25/93.

DP Barcode: D196789. CBTS # 12839.
MRID # 429830-01.

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THROUGH: Debra F. Edwards, Ph.D., Chief
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In this submission, Ciba-Geigy Corporation has submitted a revised Section F proposing time limited tolerances for corn grain and permanent tolerances on corn forage; corn fodder; corn, sweet (K+CWHR); pineapples and pineapple fodder. Tolerances previously proposed for livestock kidney and liver have been withdrawn from this petition. CBTS has recommended that these tolerances be established from our evaluation of PP#1F3974. Also submitted are storage stability data relating to the poultry metabolism study. A revised Section B contains changes unrelated to residue chemistry.

CBTS has already stated verbally to RD that a time-limited tolerance on corn grain associated with permanent tolerances on non-grain corn racs would not be acceptable.

Conclusions

1. Storage stability information has been submitted for the poultry metabolism study. This information, which includes HPLC chromatograms and dates of storage and analyses, leads us to conclude that storage stability of the propiconazole residue (including metabolites) in frozen poultry matrices is not a problem.

2. Our requirement for storage stability of propiconazole in corn processed products remains (Conclusion #4a of our 5/6/93 memo).

3. CBTS concludes that it is inappropriate to establish permanent tolerances on corn forage, fodder and sweet corn (K+CWHR) while concurrently establishing a tolerance with expiration date on grain. Once permanent tolerances have been established their removal would be practically difficult whether or not deficiencies relating to corn grain are ever resolved.

   A revised Section F should be submitted in which all tolerances should have an expiration date.

Recommendation

CBTS recommends against the proposed tolerances for reasons given in Conclusions 2 (stability in processed fractions) and 3 (revised Section F).

Detailed Considerations

Deficiencies as set forth in our 9/20/93 memo are listed along with Ciba-Geigy's response and CBTS' comments.

CBTS Deficiency #1 (Conclusion #1 from our 9/20/93 memo)

Ciba-Geigy has satisfactorily responded to our request for storage information for the goat metabolism study. Analogous information is required for the poultry study.

Ciba-Geigy Response

The following report has been submitted:

"Addendum I Metabolism of [Phenyl-^{14}C] Propiconazole in Chickens," A.M. Doweyko, 6/7/90. (MRID # 429830-01)

On completion of the in-life phase of the study, excreta and tissues were stored frozen immediately after sacrifice. Eggs were stored frozen after separation into whites and yolks. Samples were maintained at -20°C between bench work-ups and analysis. Intervals between earliest storage date and latest analysis date varied from 36 to 213 days. HPLC radio-chromatograms of acetone, methanol or acetonitrile extracts are given for excreta after 36 and 185 days in storage, egg whites after 44 and 191 days in storage, yolks after 45 and 191 days in storage and muscle after 64 and 196 days in storage. Analogous chromatograms from liver or kidney extracts have not been provided, which is unfortunate; if major changes were to occur they would probably occur first in these tissues. Although the

HPLC solvent systems varied, there are few qualitative differences in the number and relative intensities of the peaks.

Our updated "Guidance for Conducting Plant and Livestock Metabolism Studies," dated 7/16/92, states that storage stability data "should not normally be required for samples analyzed within 4-6 months of collection, provided evidence is given that attempts were made to limit degradation of residues by appropriate storage of matrices and extracts during the analytical portion of the study". It appears that most of the analyses were conducted within 6 months of storage. That combined with the HPLC information, although limited, leads us to conclude that storage stability in chicken matrices should not be a major problem. This deficiency is resolved.

CBTS Deficiency #2 (Conclusion #2 from our 9/20/93 memo)

Our requirement for storage stability of propiconazole in corn processed products remains (Conclusion #4a of our 5/6/93 memo).

Ciba-Geigy Response

The study will be conducted using fortified matrices. The final report should be submitted to EPA January-February, 1997. Interim reports of the study will be submitted.

CBTS Comment

This deficiency remains. We note that this timetable including interim reports has been submitted in conjunction with Ciba-Geigy's request to establish permanent tolerances on non-grain racs. This request is discussed in the next section of this memo.

Other Considerations

As noted above, the petitioner is requesting that permanent tolerances be established for corn forage, fodder and sweet corn (K+CWHR) and a tolerance with expiration date be established for corn grain. The expiration date would allow for completion of the stability study in processed corn fractions.

To our knowledge we have never established permanent tolerances on some corn racs in conjunction with time-limited tolerances on other corn racs. In our opinion establishing such tolerances would not set a good precedent. In this case, because residues in grain would usually be non-detectable there would be a temptation not to fulfill the data requirements for a permanent tolerance on corn grain. Seizure of grain samples would be unlikely, and once permanent tolerances have been established on some commodities it would be practically difficult to remove them. For this reason CBTS recommends against establishing

permanent tolerances on corn forage, fodder and sweet corn (K+CWHR).

cc: RF, Circu., Mike Flood, E. Haeberer, PP#8F3674.

7509C:CBTS:Reviewer(MTF):CM#2:Rm804P:703-305-7990:typist(mtf):3/24/94.
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