



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

SEP 3 1986

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA Reg. No. 100-639. Apron® 25W (metalaxyl) label amendment with cover letter dated 3/14/86 to increase use rate on corn seed for export only. No Accession No. RCB #1147.

FROM: Kenneth W. Dockter, Chemist *Kenneth W. Dockter*
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

THRU: A.R. Rathman, Section Head *ARR*
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

TO: Henry J. Jacoby/Rebecca S. Cool, PM#21
Registration Division (TS-767)

CIBA-GEIGY Corporation is submitting, "Final Printed Labeling for Export Uses" of Apron 25W Fungicide, EPA Reg. No. 100-639 to permit an increased use rate on corn seed for export, and to allow a, most notably, new use on sweet corn seed for domestic sale/use. This latter addition is just one of the several "administrative" changes included in the domestic section of the label provided. In the accompanying letter dated March 14, 1986, Karen Stumpf reasons that their request is supported by: 1) RCB's favorable review dated January 13, 1986 on this fungicide; and 2) the residue data submitted under PP#3F2827.

Metalaxyl [N-(2,6-dimethylphenyl)-N-(methoxyacetyl)alanine methyl ester] is formulated as Apron® 25W and contains 25% active. The inert ingredients are cleared under 40 CFR §180.1001.

The Metalaxyl (Ridomil) Registration Standard was issued August 13, 1981.

Currently, tolerances for the combined residues of the parent and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxy methyl-6-methyl)-N-(methoxyacetyl)-alanine methylester, each expressed as metalaxyl in or on grain crops are established under 40 CFR §180.408 at 0.1 ppm.

According to the latest label revision, dated 12/27/83, and accepted by RCB, uses of up to 0.5 oz ai/100 lbs seed for grain crops are allowed. Up to 1.0 oz is permitted for sorghum. (See P. Errico memo of 1/27/84; PP#3F2827.)

The currently submitted, "Final Printed Labeling for Export Uses" states:

"For control of Pythium damping-off and systemic downy mildew of corn: Apply Apron 25W as a seed treatment at the rate of 4-14 ounces per 100 lbs. of seed."

Other, "administrative", changes included in this labeling pertain to seed treatments for domestic sale or use. Notably, under Grain Crops, a new paragraph has been added which reads:

"For control of systemic downy mildew of sweet corn: Apply Apron 25W as a seed treatment at the rate of 4 ounces per 100 lbs. of seed."

The Company contends that, "residue data submitted under PP#3F2827 (EPA Accession No. 071388)" for sorghum seed treated with 1.0 oz ai supports this new use. The other changes are:

"Under Forage Legumes, 'suppression of early season downy mildew' has been added to the directions for use; under Seed and Pod Vegetables, chick peas (garbanzo beans) has been added as this is one of the varieties included in this crop grouping ..."

No other relevant data were provided in this package. Our response to the above claims and the RD instruction of, "review rate increase for sweet corn", resulting from the proposed amendment (to increase the use rate on corn seed for export, and to add the use on sweet corn seed for domestic sale or use) shall be addressed below in the light of current RCB policies pertaining to crops grown for seed for domestic vs. export sale or use, and the relevant data available in RCB's files.

In the aforementioned RCB "favorable review", R. Loranger stated that the proposed increased uses (to 3.5 oz) will require supporting residue data for at least two of the three (corn, millet, and sorghum) grains proposed. That conclusion remains valid, and is applicable to the current request. Therefore, we still require that supporting residue data for the currently proposed use of treating corn seed for export only.

The residue data referenced as Acc. No. 071388 by the Company in the current request, are from radioactive field studies on sorghum seed treated with metalaxyl at 1.0 oz ai/cwt. Residues of 0.030, 0.075, and 0.065 ppm parent equivalent were detected as radioactive uptake in 60-day stalks, mature stalks, and grain, respectively. Moreover, the Company claimed that the level of radioactivity was too low for reliable quantitation.

In RCB's review of that petition (PP#3F2827), P. Errico concluded that the resulting residues would not likely exceed the established tolerance in grain crops of 0.1 ppm. As above, this conclusion also remains valid. Additionally, since sorghum is a representative grain crop, we can conclude that a similar treatment to sweet corn seed for domestic use is not likely to result in residues exceeding the established tolerance.

Conclusions and Recommendations

RCB concludes that:

1. For the purpose of treating corn seed for export only, we consider the available data insufficient. Metalaxyl residues in corn may exceed the 0.1 ppm tolerance established for grain crops.
2. For the purpose of treating sweet corn seed for domestic use, we consider the available data adequate to show metalaxyl residues in sweet corn will not exceed the 0.1 ppm tolerance.

Therefore, RCB recommends against this label amendment at this time for the reason noted in Conclusion 1.

cc: Amended Use file (metalaxyl), Circu, R.F., S.F., Dockter,
Seed Crops file, PMSD/ISB
RDI: ARRathman:8/28/86:RDSchmitt:8/28/86
TS-769:RCB:CM#2:RM 804:77886:K.W. Dockter:edited by:Kd:9/2/86