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

March 31, 1989

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Maneb (014505) Proposed label modification
Pennwalt letter of 3/31/88
[No MRID No., DEB No. 4819]

FROM: Susan V. Hummel, Chemist
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Susan V. Hummel

THRU: Francis B. Suhre, Acting Section Head
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Susan V. Hummel, for

TO: Susan Lewis, PM#21
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Registration Division (TS-767C)

Pennwalt Corporation has submitted a proposed label modification for sugar beets, in connection with the Maneb Special Review (Storage Stability) Data Call In Notice of 3/31/87. Pennwalt submitted residue data in response to that DCI using an application rate lower than their current application rate. Pennwalt now proposes to reduce the application rate on sugar beets to 1.6 lb ai/A.

The Special Review Storage Stability Data Call In Notice of 3/31/87 required residue data on all crops having maneb tolerances. A Registration Standard for Maneb was issued in 10/88, with residue chemistry data requirements the same as those in the Maneb Comprehensive Data Call In Notice of 4/1/87. The Residue Chemistry Chapter for the Maneb Registration Standard and several updates have been completed (8/25/86, 3/31/87, and 3/31/87). A Special Review was initiated for maneb and the other EBDC fungicides on 7/10/87. Residue data submitted in response to the Special Review Storage Stability DCI were reviewed in our memos of 6/30/88 (S. Hummel, DEB Nos. 3530, 3531, 3552, 3553, 3555). Additional residue data were reviewed in our memo of 12/13/88 (S. Hummel, DEB No. 4570). Chromatograms supporting the data reviewed in our memos of 6/10/88 and 12/13/88 were reviewed in our memo of 12/09/88 (S. Hummel, DEB No. 4005). Ground vs. aerial data were reviewed in our memo of 12/20/88 (S. Hummel, DEB NO. 3556) and found to be inadequate. Data on multiresidue

methodology for maneb and ETU were reviewed in our memo of 9/16/88 (L. Cheng). Data gaps remaining for the Storage Stability DCI were summarized in S. Hummel memo of 8/25/88. Since the primary reason for review of the maneb data was to assess dietary exposure for the EBDC Special Review, none of the data had been reviewed for compliance with the Maneb Registration Standard (or Comprehensive DCI).

Tolerances have been established for residues of the fungicide maneb (manganous ethylene bisdithiocarbamate) calculated as zineb (zinc ethylene bisdithiocarbamate), ranging from 0.1 part per million (ppm) in or on almonds and potatoes to 45 ppm on sugar beet tops (40 CFR 180.110). No tolerance has been established for sugar beet roots. The Maneb Registration Standard Residue Chemistry Chapter (8/25/86) required a tolerance proposal and appropriate supporting residue data for maneb in/on sugar beet roots.

Registered Use

According the Maneb Registration Standard Residue Chemistry Chapter, the maximum registered rate for maneb on sugar beets is 2.56 lb ai/A with a 14-day PHI. Apply at first sign of disease. Repeat at 7 to 10 day intervals. Both WP and Dust formulations were registered. However, Pennwalt indicated in their 90 day response to the Maneb Comprehensive Data Call In Notice that they would not support dust formulations. (See Pennwalt letter of 7/6/87 and W. Hazel review of 8/7/87.) We indicated that we had no objection to Pennwalt not supporting dust formulations, provided that all dust formulations for maneb were cancelled. We continue to recommend that all dust formulations of maneb be cancelled.

Proposed Use

Pennwalt proposes to amend their Maneb registrations to allow a maximum rate of 1.6 lb ai/A on sugar beets. No proposal for a maximum number of applications per season was included.

DEB Comment

The proposed application rate is the same as that used in the recently submitted residue data. We have no objection to Pennwalt reducing the maximum application rate on sugarbeets to 1.6 lb ai/A. However, the Maneb Comprehensive Data Call In Notice also required a maximum seasonal use rate or a maximum number of applications per season which is supported by residue data to be added to the label. (See Residue Data Deficiencies 10 and 15.)

Note to PM: Revised labels lowering the application rate for sugar beets are needed from all maneb registrants.

Alternatively, residue data reflecting the maximum rate and the minimum PHI could be submitted. For the purpose of the EBDC Special Review, the maximum application rate will be considered to remain at 2.56 lb ai/A until amendments are received from all maneb registrants, reducing the maximum application rate to 1.6 lb ai/A.

Nature of the Residue

The nature of the residue in plants and animals is not adequately understood. Additional Metabolism Data were required by the Maneb Comprehensive Data Call In Notice of 4/1/87. For the purpose of the ongoing Special Review of the EBDC's, the residues of concern are considered to be the parent compound, maneb (as determined by CS_2 evolution) and ETU. Metabolism of maneb will not be further discussed in this memo.

Analytical Methodology

Outstanding deficiencies from the Comprehensive DCI of 4/1/87 were not addressed in this submission and will not be discussed in this review. The data for multiresidue methodology was reviewed in L. Cheng memo of 9/16/88 and the deficiency resolved.

Storage Stability Data

Storage Stability data on potatoes (a root crop) were required by the Maneb Special Review Storage Stability Data Call In Notice of 3/31/87. The Storage Stability data received indicated that maneb residues in potatoes (translated to other root crops) would remain stable up to 6 months in frozen storage and that ETU residues in potatoes would remain stable up to 3 month in frozen storage.

Residue Data Requirements

Deficiency 10 - Sugar Beet Roots

Data depicting mancozeb, ETU, and other metabolites of concern in or on sugar beet roots harvested 14 days following multiple foliar applications, made 7 days apart, of a D and WP formulation (in separate tests) at 1.7 lb ai/A must be submitted. Separate tests must be performed using ground and aerial equipment for each formulation. The registrant must propose a maximum seasonal use rate or a maximum number of applications per season; required tests must reflect this proposed maximum rate. Tests must be performed in CA(23%), ID(15%), MN(20%), and ND(11%) which collectively produce ca. 69% of the total U.S. sugar beet crop (Agricultural Statistics, 1985, p. 164). Data depicting mancozeb, ETU, and other residues of concern in or

on sugar beet roots 14 days following the first of multiple foliar applications of the 4.8% D formulation at 1.92 lb ai/A must be provided.

Deficiency 11 - Sugar Beet Processed Products

Data depicting mancozeb, ETU, and other residues of concern in or on sugar beet pulp processed from sugar beet roots bearing measurable weathered residues must be submitted. Exaggerated rates may be needed to achieve these residues. If concentration is found to occur, a feed additive regulation would be required; final disposition of food/feed additive regulations would be dependent upon the Agency's position regarding Delaney Clause issues.

Deficiency 15 - Sugar Beet Tops

Data reflecting mancozeb, ETU, and other residues of concern in or on sugar beet tops harvested 14 days following the last of multiple foliar applications, 7 days apart, with the 80% WP (or a FlC) by aerial equipment, and with the 4.8% D formulation by both ground and aerial equipment (in separate tests) at 1.7 lb ai/A/application must be submitted. A maximum seasonal use rate or a maximum number of applications per season must be proposed; required tests must reflect the proposed maximum rate. Tests must be conducted in CA(23%), ID(15%), MN(20%) and ND(11%) which collectively produced ca. 69% of the 1984 U.S. sugar beet crop (Agricultural Statistics, 1985, p. 76). Data depicting mancozeb, ETU and other residues of concern in or on sugar beet tops 14 days following the last of multiple foliar applications of the 4.8% D formulation at 1.92 lb ai/A must be submitted. Tests must be conducted in CA.

Deficiency (listed in text, but not in DCI)

Since Sugar Beet Roots are a raw agricultural commodity, the registrant must propose a tolerance and provide appropriate supporting residue data.

Note to PM: The registrants should be informed of this deficiency in 3(c)(2)(B) format.

Residue Data Submitted

Residue data on sugar beets were submitted in response to the Maneb Special Review (Storage Stability) Data Call In Notice of 3/31/87. The registrant indicated their intent to reference these data as responses to the Maneb Comprehensive Data Call In Notice of 4/1/87. These data were reviewed in S, Hummel memo of 6/30/88 (DEB No. 3530, 3531, 3552, 3553, 3555) for compliance

with the 3/31/87 Special Review Storage Stability DCI. They were not reviewed for compliance with the 4/1/87 Comprehensive DCI. Chromatograms supporting these data were reviewed in S. Hummel memo of 12/9/88 (DEB No. 4005). In our review, we did not address geographic representation, agreement between label and data, and adequacy of tolerances. We reviewed the data for validity (QA/QC, storage stability, and correlation between chromatograms and data).

Residue data were submitted for maneb and ETU residues on sugar beets from four locations in CA, ID, MN, and ND (MRID No. 405873-05). These were the same locations specified in the Maneb Comprehensive Data Call In Notice of 4/1/87. Manex 4F, a flowable formulation of Maneb, was applied at the rate of 1.6 lb ai/A, by ground equipment. Seven applications were made. Samples were harvested 14 days after the last application. The samples were stored 126 days before analysis. This storage time is longer than the three months ETU residues remain stable in root crops in frozen storage. The following residues were reported.

Maneb Residue Data from 1987 Growing Season

Commodity	Rate (lb ai/A)	#Applications	PHI (days)	Max. Storage (days)	Residue (ppm) Maneb Ave.	Maneb Max.	ETU Ave.	ETU Max.
Sugar Beets	1.6	7	14	126	0.35	1.8	<0.01	<0.01
Sugar Beet Tops	1.6	7	14	126	42.01	179	0.07	0.50

DEB Comments

A tolerance will be needed for sugar beets, since none has been established to date.

Residue data are still needed for aerial applications, and for dust formulations. We note that Pennwalt does not intend to support dust formulations, per their 90 day response to the 4/1/87 Comprehensive DCI; however, dust formulations are still registered. Alternatively, all dust formulations of maneb products may be cancelled and aerial applications may be removed from all maneb labels.

These data will be reviewed for Registration Standard purposes after the required metabolism data are received. The registrants should note that additional residue data may be required if additional metabolites of toxicological concern are identified in the metabolism studies.

Processing Data

Processing data were submitted for sugar beets. White sugar, molasses, and sugar beet pulp were analyzed. Residues of maneb were found to be reduced in white sugar (0.38x) and molasses (0.38x) and were found to concentrate in sugar beet pulp (1.31x). A feed additive tolerance for residues of maneb in sugar beet pulp will be needed.

CONCLUSIONS

1. We have no objection to the proposed reduction in the application rate on sugar beets. The proposed application rate is the same as that used in the recently submitted residue data. However, a maximum seasonal use rate and a number of applications are also needed on the label.

2. Pennwalt and all other registrants of maneb products registered for use on sugar beets should be informed that revised labels are needed with a maximum application rate of 1.6 lb ai/A and with a maximum seasonal use rate or maximum number of applications which are supported by residue data. (The residue data submitted would support a maximum of 7 applications per season.) Alternatively, residue data could be submitted to support the current maximum use pattern.

3. All maneb registrants should be informed that residue data are still needed for aerial applications and for dust formulations. Alternatively, all dust formulations of maneb products may be cancelled and aerial applications may be removed from all maneb labels.

4. These data will be reviewed for Registration Standard purposes after the required metabolism data are received. The registrants should note that additional residue data may be required if additional metabolites of toxicological concern are identified in the metabolism studies.

5. A tolerance will be needed for residues of maneb in sugar beets. A feed additive tolerance for residues of maneb in sugar beet pulp will be needed.

6. Other data gaps for the 4/1/87 Comprehensive DCI were not addressed in this submission nor discussed in this review. The registrants should be advised to resolve the remaining data gaps.

RECOMMENDATIONS

We recommend that the registrant be advised of our conclusions, and that all maneb registrants be required to do the following:

1. Submit revised labels reducing the maximum application rate for maneb on sugar beets to 1.6 lb ai/A and add a maximum seasonal use rate and maximum number of applications, which are supported by residue data.

2. Submit residue data for aerial applications, and for dust formulations. Alternatively, all dust formulations of maneb products may be cancelled and aerial applications may be removed from all maneb labels.

3. Submit petitions for tolerances for residues of maneb on sugar beets and sugar beet pulp.

cc: R.F., circu, S. Hummel, R. Schmitt, Maneb S.F., Maneb S.R.F. (Hummel), Maneb R.S.F. (Edwards), V. Bael (SRB/RD), PMSD/ISB
RDI:FBS:03/28/89:EZ:03/30/89
TS-769:DEB:RM810:CM#2:SVH:svh:03/31/89
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