



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

MAY 16 1995

MEMORANDUM

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT: PP#2F04063. Metalaxyl (113501) in/on Grass
Forage, Fodder, and Hay Crop Group (#17).
Letter of 6/13/94 Amending Petition.
DP 208076 CBTS 14525 MRID 432710-01

FROM: Maxie Jo Nelson, Ph.D., Chemist
CBTS/HED (7509C) *mjn*

THRU: Robert S. Quick, Section Head
CBTS/HED (7509C) *Robert S. Quick*

TO: (1) C. Welsh/K. Scanlon, PM Team 21
FHB/RD (7505C)

(2) Jane Smith, Acting Section Head
RCAB/HED (7509C)

By letter dated 6/13/94, the petitioner (Ciba-Geigy Corporation) has responded to the deficiencies raised in the CBTS review of 9/22/93 (M. Peters). Those deficiencies are paraphrased below, followed by the petitioner's response, and our comments/conclusions.

2. A 60-day feeding restriction for range grasses is not practical. The petitioner must either (a) propose a 0-day feeding/grazing restriction supported by the appropriate residue data and feeding studies, or (b) amend the label to impose a 60-day grazing/feeding restriction for grass forage and hay and add the statement, "Do not apply to range grasses".

Ciba-Geigy: The proposed supplemental labeling (Metalaxyl 2E Fungicide, EPA Reg. No. 100-607) has been revised per CBTS's option (b).

CBTS: This deficiency is resolved.

6. It appears that adequate methodologies are available for the purposes of data collection. However, this is contingent upon Ciba submitting actual ppm of the metalaxyl equivalents recovered from samples during the validation studies, sample calculations for determining % recoveries, and an explanation for the several control samples positive for metalaxyl.



Recycled/Recyclable
Printed with Soy/Canola Ink on paper that
contains at least 50% recycled fiber

Ciba-Geigy: The information requested is provided in accompanying Report ABR-94005 (assigned MRID# 432710-01).

CBTS: This deficiency is resolved.

7. Adequate storage stability studies are not available for grass forage and hay. Ciba must submit relevant storage stability studies to CBTS to support the proposed tolerances.

Ciba-Geigy: Additional data (Report ABR-93009, assigned MRID# 429194-01) on various crops have been submitted. These data have been reviewed by CBRS (2/27/94, S. Hummel). CBRS concluded that "these data will satisfy the storage stability data requirements for raw agricultural commodities frozen stored less than 24 months, except for oilseeds and grains". The freezer storage intervals for the grass forage and hay samples of this petition were in the range of 4-18 months.

CBTS: This deficiency is resolved.

8a. The residue data appear to support the proposed 10 ppm tolerance on grass forage. However, the petitioner must submit a revised Section F proposing a tolerance of 25 ppm on grass hay.

Ciba-Geigy: A revised Section F is submitted, as requested.

CBTS: This deficiency is resolved.

8b. The adequacy of the tolerances of 10 ppm on grass forage and 25 ppm on grass hay are contingent upon Ciba's satisfactorily addressing deficiencies 6 and 7.

Ciba-Geigy: Deficiencies 6 and 7 have now been addressed.

CBTS: Deficiencies 6 and 7 have been resolved; deficiency 8b is now moot.

9. Established meat, milk, poultry, and egg tolerances will not be exceeded as a result of the proposed use. However, CBTS cannot determine whether the original ruminant feeding studies calculated dietary burden on an as-fed or a dry matter basis.

Ciba-Geigy: The results from the ruminant feeding study were reported in ABR-82024 (EPA Acces. No. 100753). The 75 ppm dose rate was calculated on an as-fed basis.

CBTS: In its response, Ciba provides calculations of the dose rate (ppm) using an as-fed vs a dry matter basis. The dose rate on a dry weight basis gives a higher value (83 ppm dry wt. vs 75 ppm as-fed).

RECOMMENDATIONS

All outstanding deficiencies raised by CBTS in re this petition now having been resolved, and toxicological considerations permitting, CBTS recommends for the establishment of the proposed tolerances for combined residues of metalaxyl (as expressed in 40 CFR 180.408a) in or on grass, forage at 10 ppm and grass, hay at 25 ppm.

[Note to PM: If/when these proposed tolerances are established, concurrently delete the existing grasses tolerance of 0.1 ppm in §180.408a.]

cc: M. Nelson, RF, Circ, PP#2F4063, B. Doyle (DRES/SAB).

7509C:CBTS:MJN:mjn:CM#2:Rm804U:305-5785:MET4063.grs:5/9/95.
RDI:SecHd:RSQuick:5/9/95:BrSrSci:RALoranger:5/15/95:ActgBrChf:EZager:5/15/95.



13544

R133977

Chemical: Metalaxyl

PC Code:
113501

HED File Code: 11000 Chemistry Reviews

Memo Date: 5/16/1995

File ID: DPD208076

Accession #: 000-00-0112

HED Records Reference Center
11/30/2006