Metalaxyl S.F.

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

JUN 4 1996

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Mefenoxam: Replacement of Metalaxyl Technical with Mefenoxam Technical; Review of Bridging Data on Oranges, D225972. CBTS No. 17192. MRID 439619-01. ID #:000100-TOR PRAT CASE #: 039771.

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Linda L Kutney 6/3/96

THRU: Edward Zager, Acting Branch Chief
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TO: Barbara Madden, Chemical Manager
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Ciba-Geigy proposes that mefenoxam replace metalaxyl as the ai in registered end-use products. Residue data from field trials on oranges following side by side applications of metalaxyl and mefenoxam; method recovery validation and storage stability data are included in this submission.

The CBTS review of 4/24/96 ("Mefenoxam: Replacement of Metalaxyl Technical with Mefenoxam Technical; Review of Bridging Data," L. Kutney) recommended, pending receipt of a revised Section B and storage stability data, for mefenoxam registration on crops registered currently for metalaxyl (TOX considerations permitting). The recommendation is contingent on the following: mefenoxam use is half the rate used for metalaxyl, application methods are the same and a label restriction precludes the use of both pesticides on the same crop. Existing metalaxyl tolerances would be adequate to support the proposed uses of mefenoxam.

CONCLUSIONS

Data provided for oranges support the 4/26/96 recommendation for registration of the mefenoxam ai in place of metalaxyl ai.

DETAILED CONSIDERATIONS

Mefenoxam, the R-enantiomer of metalaxyl, is reportedly a more effective fungicide than metalaxyl technical (R and S enantiomers) or the S-enantiomer. Proposed mefenoxam use rates are half current metalaxyl rates. Metalaxyl tolerances exist for numerous plant and animal commodities [40 CFR 180.408a,c, 185.4000a and 186.4000a]. Metalaxyl is a list A chemical and product and residue chemistry chapters of the RED are completed (S. Hummel, 6/16/94).

NATURE OF THE METALAXYL/MEFENOXAM RESIDUE IN PLANTS

The nature of the metalaxyl residue in plants is adequately understood. Studies on potatoes, lettuce, grapes, and tobacco indicate that metalaxyl is taken up, translocated, and extensively metabolized by plants. Residues in plant commodities are defined by the current tolerance expression, including metalaxyl, metabolites that can be converted to 2,6-dimethyl aniline (2,6-DMA), and one metabolite containing the 2-hydroxymethyl-6-methyl aniline (HMMA) moiety, N-(2-hydroxymethyl-6-methylphenyl)-N-(methoxyacetyl) alanine methyl ester.

NATURE OF THE METALAXYL/MEFENOXAM RESIDUE IN ANIMALS

The nature of the residue in animals is adequately understood. Residues in livestock include metalaxyl, metabolites converted to 2,6-dimethyl aniline and those containing the 2-hydroxymethyl-6-methyl aniline (HMMA) (9/10/93 Metabolism Committee).

ANALYTICAL/ENFORCEMENT METHODS

Adequate enforcement methods are available to determine metalaxyl and its regulated metabolites in plants. These include methods I and II in PAM, Vol. II and Method AG-395. Metalaxyl, per se, is completely recovered (>80%) using FDA Multiresidue Protocol D (PAM, Vol. I Section 232.4) [*Source: PESTDATA, PAM, Vol I, Appendix, 8/93*].

Field trial data for mefenoxam on oranges were determined by Method AG-395, having a limit quantification of 0.05 ppm.

SUMMARY OF MEFENOXAM/METALAXYL RECOVERIES

Recoveries for oranges fortified at the 0.05 ppm to 2.0 ppm level, were acceptable, ranging from 66.0% to 98.6% for mefenoxam and from 64.6% to 88.8% for metalaxyl. Average recoveries were 77.9% for mefenoxam and 74.3% for metalaxyl.

RESIDUE DATA

Field trial residue data for mefenoxam on oranges were submitted as bridging data between metalaxyl and mefenoxam in support of replacing registered uses for the metalaxyl ai with mefenoxam ai. Currently established tolerances for metalaxyl in/on citrus are as follows: citrus fruit (1 ppm); citrus oil (7.0 ppm); citrus molasses (7.0 ppm) and pulp (7.0 ppm) [See 40 CFR 180.408(a); 185.4000(a); and 186.4000 (a), respectively].

Four field trials were conducted on oranges from 3/95 to 2/96 in Lake and Seminole Counties of Florida, and Fresno and Kern Counties of California. Three banded applications of Mefenoxam (Mefenoxam 45W, 44.7% ai) and metalaxyl (Ridomil 50W, 49.7% ai) were applied in side-by-side trials, using a soil surface spray, in a 12' band. Mefenoxam was applied at the 1X rate of 0.55 lbs. ai/foot linear row and Metalaxyl was applied at the 1X rate of 1.1 lbs. ai/foot linear row (this is twice the amount used for mefenoxam). PHI's of 0, 7, and 14 days were observed.

Samples were stored frozen (-20 C) for less than 1 month. Adequate storage stability data are available to conclude that residues are stable under these conditions.

Residue data values for mefenoxam and metalaxyl are given in the following table, along with the number of samples, minimum and maximum residues reported, and the mean. All maximum and mean residues of mefenoxam, at the 1X rate, were less than the corresponding metalaxyl residues. Untreated control oranges were all <0.05 ppm.

An adequate number of samples were analyzed. Residues from the proposed use of mefenoxam on oranges are not expected to exceed existing metalaxyl tolerances, and support earlier crop field trial data (4/24/96, L. Kutney).

MEFENOXAM & METALAXYL RESIDUES ON ORANGES FOLLOWING 1X APPLICATIONS
(Mefenoxam applied at 1X rate of 0.55 lbs. ai/foot linear row and Metalaxyl applied at 1X rate of 1.1 lbs. ai/foot linear row).

ORANGE CROP, DAYS PHI	MEFENOXAM (ppm DMA)				METALAXYL (ppm DMA)			
	NO.	MEAN	MIN	MAX	NO.	MEAN	MIN	MAX
0 DAY PHI	8	0.051	<0.05	0.06	8	0.068	<0.05	0.11
5 DAY PHI	2	0.05	<0.05	<0.05	2	0.05	<0.05	<0.05
7 DAY PHI	6	0.05	<0.05	<0.05	6	0.072	<0.05	0.09
14 DAY PHI	6	0.052	<0.05	0.06	6	0.078	<0.05	0.12
15 DAY PHI	2	0.05	<0.05	<0.05	2	0.05	<0.05	<0.05

INDIVIDUAL DATA REPORTED:		
0 DAY PHI	<0.05 <0.05 <0.05 <0.05 <0.05 <0.05 <0.05 0.06	<0.05 <0.05 <0.05 <0.05 <0.05 0.09 0.10 0.11
5 DAY PHI	<0.05 <0.05	<0.05 <0.05
7 DAY PHI	<0.05 <0.05 <0.05 <0.05 <0.05 <0.05	<0.05 <0.05 0.08 0.08 0.08 0.09
14 DAY PHI	<0.05 <0.05 <0.05 <0.05 <0.05 0.06	<0.05 <0.05 0.08 0.08 0.09 0.12
15 DAY PHI	<0.05 <0.05	<0.05 <0.05

NOTE: Residues are corrected for % Recovery

PROCESSING DATA

Dried citrus pulp is an animal feed item. There is no reasonable expectation that mefenoxam will concentrate differently than metalaxyl during processing, therefore residues from the proposed use of mefenoxam are not expected to exceed current tolerance levels for metalaxyl, in processed commodities.

SECONDARY RESIDUES IN MEAT AND MILK

Significant animal feed items would be involved following the proposed use of mefenoxam on oranges. However, secondary residues of mefenoxam in livestock, meat byproducts, fat, milkfat or whole milk are not expected to exceed current tolerances for metalaxyl.

OTHER CONSIDERATIONS

Harmonization between U.S., CODEX and Canadian tolerances for metalaxyl is not possible at this time since the CODEX and Canadian tolerance expressions include only the parent compound.

cc: RF, Mefenoxam SF, Metalaxyl SF, Metalaxyl Reg Std File, L. Kutney, E. Haeberer, Connie Welch, RD, Kathryn Scanlon, RD, Circu, Beth Doyle (DRES-SAB)
CM2:305-5351:RM816G:7509C:LLKutney:llk-5/31/96
RDI: E. Haeberer: 5/31/96, Perfetti: 6/3/96

138 METALAXYL 180.408

Strawberry, 0.2 mg/kg

The 1995 JMPR recommended withdrawal. Consideration should be postponed pending availability of the 1995 JMPR monograph.

Notes - The 1995 JMPR addressed CCPR concerns that 0.2 ppm would not accommodate U.S. or European GAP. It concluded that the data reflective of GAP submitted for 1995 JMPR review and previously summarized data were not adequate to support a limit, while being informed that U.S. GAP and data supporting the U.S. 10 ppm tolerance had not been submitted. **TAKE 1993-4 U.S. COMMENTS.**