

SF ~~ANT~~

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

AUG 9, 1989

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCESMEMORANDUM

SUBJECT: PP's # 8F3695/8H5569: ~~Metalaxyl~~ Tolerances for Alfalfa and for Barley as Rotational Crop. Evaluation of Residue Data and Analytical Methodology. MRID No. 408329-01. DEB Nos. 4792, 4793, and 4794.

FROM: Joel Garbus, Ph.D., Chemist *Joel Garbus*
Tolerance Petition Section III
Dietary Exposure Branch
Health Effects Division (H7509C)

THRU: Richard D. Schmitt, Ph.D., Chief *Richard D. Schmitt*
Dietary Exposure Branch
Health Effects Division (H7509C)

TO: Lois Rossi, PM-21
Herbicide-Fungicide Branch
Registration Division (H7505C)

CIBA-GEIGY Corporation, Greensboro, NC, requests that permanent tolerances be established for the combined residues of metalaxyl [N-(2,6-dimethylphenyl)-N-(methoxyacetyl)-alanine methyl ester] and its metabolites containing the 2,6-dimethylaniline moiety and N-(2-hydroxymethyl-6-dimethylphenyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl equivalents, in or on alfalfa and in or on barley when planted as a rotational crop to alfalfa as follows:

Alfalfa, forage	10	ppm
Alfalfa, hay	20	ppm
Barley, grain	0.2	ppm
Barley, fodder, forage, straw	2.0	ppm

The petitioner also requests that a food additive tolerance be established for the combined indirect or inadvertent residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety and N-(2-hydroxymethyl-6-dimethylphenyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl equivalents, in or on Barley Milling Fractions at 1.0 ppm.

Tolerances are established [40 CFR 180.408(a)] for combined residues of the fungicide metalaxyl [N-(2,6-dimethylphenyl)-N-(methoxyacetyl)-alanine methyl ester] and its metabolites containing the 2,6-dimethylaniline moiety and N-(2-hydroxymethyl-6-dimethylphenyl)-N-(methoxyacetyl)-alanine methyl ester in or on numerous raw agricultural commodities ranging from 0.1 ppm to 20 ppm.

Indirect or inadvertent tolerances are established for indirect or inadvertent residues of metalaxyl when present in or on wheat fodder, forage, and straw at 2.0 ppm and in or on wheat grain at 0.2 ppm. [40 CFR 180.408(b)]

Food additive tolerances has been established for residues of metalaxyl and its metabolites in citrus oil, processed potatoes, processed tomatoes, and dried hops. (40 CFR 185.4000(a)).

Indirect or inadvertent food additive tolerances has been established for residues of metalaxyl and its metabolites in wheat milling fractions at 1.0 ppm (40 CFR 185.4000 (b)).

Feed additive tolerances have been established for residues of metalaxyl and its metabolites for several rac processing products at levels of 0.4 to 20 ppm. (40 CFR 186.4000(a)).

Indirect or inadvertent feed additive tolerances have been established for residues of metalaxyl and its metabolites in wheat milling fractions at 1.0 ppm (40 CFR 186.4000 (b)).

Conclusions

1. The residue of concern in or on alfalfa and barley will consist of metalaxyl, its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-dimethylphenyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl equivalents.

2. Adequate and validated enforcement analytical methodology is available for metalaxyl and its metabolites.

3. The petitioner should submit a revised Section B specifying which formulation is intended for this proposed use. The residue data will support a proposed use with Ridomil 2E.

4a. DEB concludes that the proposed tolerance of 10 ppm for alfalfa forage is too high and that 6 ppm would be more appropriate.

4b. The proposed tolerance for alfalfa hay of 20 ppm is supported by the residue data.

5a. Residue data used to establish the indirect or inadvertent residues of metalaxyl in/on wheat grain, fodder, forage, and straw can be translated to support the indirect or inadvertent residues of metalaxyl in/on barley from the proposed rotational crop use after alfalfa.

5b. The proposed tolerances for inadvertent residues of metalaxyl in/or barley grain, forage, fodder, and straw and for barley milling fractions in rotation after alfalfa should be submitted in a revised Section F using the language of 40 CFR 180.408(b), 40 CFR 185.4000 (b), and 40 CFR 186.4000 (b) respectively.

6. Currently established tolerances for animal tissues and milk are sufficient to accommodate any secondary residues in meat, milk, poultry and eggs from this use of metalaxyl on alfalfa and barley.

7. There are no Codex, Canadian, or Mexican limits for metalaxyl in/on alfalfa. There is a Codex limit of 0.05 ppm for parent only in or on cereal grains.

Note to PM

When 40 CFR 180.408(b), 40 CFR 185.4000 (b), and 40 CFR 186.4000 (b) are next updated, they should be revised by deleting the phrase " and other non-food crops" from the tolerance expression and replacing it with "and tobacco."

Recommendation

DEB recommends for the proposed use of metalaxyl on alfalfa (with barley as a rotational crop) provided the petitioner submit:

- a. a revised Section B specifying which formulation is intended for this proposed use and
- b. a revised Section F incorporating Conclusions 4a and 5b.

Manufacturing and Formulation

The manufacture and the physical/chemical characteristics of metalaxyl have been submitted and reviewed in establishing existing tolerances (See DEB review of PP1F2500, P. Errico, 3/9/1982.). These data are cited by reference in the current submission.

Metalaxyl is supplied in various formulations: as an emulsifiable liquid, (Ridomil 2E), in a granular form (Ridomil 5G), and as a component in mixtures (Ridomil MZ58, Ridomil PC 11G, and Ridomil/Bravo 81W). Ridomil 2E was employed in generating the residue data for the proposed usage.

Proposed Use

Metalaxyl, a systemic fungicide, is used to control damping-off and root rot caused by Pythium and Phytophthora spp. of the Oomycete class fungi. The proposed label does not specify the formulation. As metalaxyl is the active ingredient in different formulations the petitioner should submit a revised Section B specifying which formulation is intended for use on alfalfa (and barley as a rotational crop). Residue data for alfalfa was obtained with the use of Ridomil 2E.

For establishing stands of alfalfa, metalaxyl is to be applied at rates up to 1 lb ai/A at planting as a broadcast surface spray in 20 gals of water. Alternatively, it may be applied following impregnation on fertilizer.

If the alfalfa seed has been treated with metalaxyl, an application rate of 0.25 lb ai/A is recommended. In general, rates of 0.5 to 1.0 lb ai/A are recommended depending upon disease pressure.

The proposed label carries a restriction on the feeding of green alfalfa forage or the cutting of alfalfa for hay for 60 days following application.

Barley may be planted 14 days after the last application of metalaxyl.

Nature of the Residue:

Detailed discussions of the metabolism of metalaxyl by plants and animals have been submitted in support of currently established tolerances (See DEB reviews of 1F2500, P. Errico, 3/9/82 and of 2F2762, K. Arne, 1/6/83) and are cited by reference. The metabolism in plants and animals is similar. It is expected that metalaxyl applied to alfalfa or barley will be metabolized via the same pathways demonstrated for other crops with established tolerances. The residue of concern in or on alfalfa and barley will consist of metalaxyl, its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-dimethylphenyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl equivalents. The same metabolites are found in animal tissues.

Analytical Methods

CIBA-GEIGY analytical method AG-395 was used to determine total metalaxyl residues in alfalfa and barley samples. This method determines residues as 2,6-dimethyl aniline and reports residues as metalaxyl equivalents.

The method and its validation have been discussed and reviewed in previous DEB memoranda. (See DEB reviews of 1F2500, P. Errico, 3/9/82 and of 2F2762, K. Arne, 1/6/83.) The method is the enforcement method of PAM II.

DEB concludes that adequate and validated analytical methodology is available for metalaxyl and its metabolites.

Residue Data (Alfalfa)

Eight residue trials were conducted with alfalfa in seven states, CA, NE, WI, MN, WA, NY, and MI. Ridomil 2E, an emulsifiable formulation of metalaxyl, was applied at the proposed maximum rate of 1.0 lb ai/A to alfalfa at planting. Forage and hay samples were collected at PHI's ranging from 59 to 141 days. Samples were frozen and shipped to CIBA-GEIGY at Greensboro NC and stored frozen until analyzed. All samples were analyzed within 14 months. Storage stability of metalaxyl residues has been demonstrated for at least 18 months for lettuce, potatoes, grapes, and tobacco. (See DEB reviews of 1F2500, P. Errico, 3/9/82 and of 2F2762, K. Arne, 1/6/83.) It is assumed that equivalent stability would be shown in alfalfa.

Recoveries from fortified samples averaged $90.7 \pm 17\%$.

Residues in alfalfa forage resulting from a single application of metalaxyl at 1.0 lb ai/A at seeding were as follows:

<u>Location</u>	<u>PHI</u>	<u>Metalaxyl Equivalents (ppm)</u>	
Washington	59	5.0	5.1
	105	0.70	0.46
Michigan	59	0.76	0.50
	103	0.09	0.15
Minnesota	61	0.24	0.35
	103	0.67	0.61
Wisconsin	59	0.32	0.53
	106	0.40	0.29
Nebraska	62	0.65	1.2
	104	0.19	0.39
California	59	1.9	2.3
	102	0.74	0.50
	138	0.28	0.44
New York	62	0.18	0.40
	105	0.09	0.09
California	92	0.70	0.28
	141	0.15	0.11

Residues in alfalfa hay resulting from a single application of metalaxyl at 1.0 lb ai/A at seeding were as follows:

<u>Location</u>	<u>PHI</u>	<u>Metalaxyl Equivalents (ppm)</u>	
Washington	59	18	18
	105	3.0	2.8
Michigan	60	0.82	1.3
	103	0.27	0.30
Wisconsin	66	0.81	1.2
	121	0.50	0.48
Nebraska	67	1.0	2.2
	109	0.52	0.91
California	60	4.7	5.0
	104	1.4	1.1
	138	0.71	0.66
New York	62	1.2	1.3
	105	0.12	0.17
California	92	0.63	0.08
	141	1.5	1.8

A single sample of alfalfa meal prepared from forage cut at 59 days in Nebraska had 0.50 ppm of metalaxyl equivalents.

Values for control (untreated) alfalfa ranged from <0.05 to 0.13 ppm for forage and from <0.05 to 0.43 ppm for hay. When 2X the proposed label rate was applied the maximum residue levels found were 4.4 ppm for forage and 7.4 ppm for hay.

After the application of the proposed label rate of metalaxyl to alfalfa, the maximum residue value that was detected in alfalfa forage was 5.1 ppm; the maximum detected in alfalfa hay was 18 ppm.

DEB concludes that the proposed tolerance of 10 ppm for alfalfa forage is too high and that 6 ppm would be more appropriate.

DEB concludes that the proposed tolerance of 20 ppm for alfalfa hay is appropriate.

Residue data (Barley)

No residue data have been supplied for barley planted as a rotational crop to alfalfa. Instead the petitioner relies upon data submitted for the establishment of tolerances for wheat and wheat products when wheat is planted as a rotational crop to metalaxyl treated racs. The company states that it was informed

by the Agency (no source given) that the data for wheat would be considered as transferable to barley. Consequently, it has requested the same inadvertent tolerances for the rotational crop barley as that established for wheat. This includes a food additive tolerance for barley milling fractions.

The current tolerances for wheat as a rotational crop were derived from studies in which a maximum of 6 lbs ai/A were applied to the target crop (PP#22547). The proposed usage on alfalfa calls for a maximum of 1 lb ai/A. Considering the similarity between wheat and barley as cereal grains and comparing the usage rates with which the indirect tolerances on wheat were established (up to 6 lbs ai) with the rates of the proposed usage (1 lb ai), we conclude that the requested tolerances for barley as a rotational crop and for barley milling fractions will not be exceeded from the proposed use on alfalfa.

Meat, Milk, Poultry, and Eggs

The petitioner has calculated the dietary burden of metalaxyl and its metabolites that would be presented to livestock consuming diets containing treated alfalfa. For this purpose, the petitioner has constructed theoretically possible diets for cattle and poultry that would be comprised of components bearing the greatest levels of residue at tolerance values. For cattle the diet would be:

Alfalfa hay at 20.0 ppm as 80% of diet equals 16.0 ppm
Citrus pulp at 7.0 ppm as 20% of diet equals 1.4 ppm

for a total of 17.4 ppm

The results of feeding studies with cattle at high levels (15 and 75 ppm) were submitted in conjunction with PP#1F2500. Based upon the results of these feeding studies, we can calculate the levels of residue of metalaxyl expected in tissues of cattle and in milk. In all instances, calculated tissue levels (0.039 and 0.021 ppm in muscle, 0.005 ppm in milk) fall below currently established tolerances for meat (0.05 ppm) and milk (0.02 ppm).

The diet with maximum metalaxyl residues for poultry including alfalfa would be:

Alfalfa meal	at 10.0 ppm	as 5% of diet	equals 0.5 ppm
Soybean meal	at 2.0 ppm	as 20% of diet	equals 0.4 ppm
Peas	at 1.0 ppm	as 40% of diet	equals 0.4 ppm
Peanut meal	at 1.0 ppm	as 10% of diet	equals 0.1 ppm
Peanut			
Soapstock	at 2.0 ppm	as 5% of diet	equals 0.1 ppm
Cull			
Potatoes	at 0.5 ppm	as 20% of diet	equals 0.1 ppm

for a total of 1.6 ppm.

The results of feeding studies with poultry at high levels (1.5 and 5 ppm) were submitted in conjunction with PP#1F2500. No residues, (i.e., <0.05 ppm in all tissues and eggs except liver at <0.01) were found in any poultry tissues or in eggs at these levels. Based upon the results of these feeding studies, we conclude that the use of metalaxyl on alfalfa would fall under 180.6 (a) 2 for poultry tissues and eggs.

DEB concludes that establishing tolerances for the use of metalaxyl on alfalfa will not necessitate the revision of existing tolerances on animal commodities. The currently established tolerances for animal tissues are sufficient to accommodate the use of metalaxyl on alfalfa and the use of barley as a rotational crop to metalaxyl treated alfalfa..

International Residue Limit Status

There are no Codex, Canadian, or Mexican limits for metalaxyl in/on alfalfa. There is a Codex limit of 0.05 ppm for parent only in or on cereal grains.

cc: PP's # 8F3695/8H5569, ~~S. File~~ RF., Circ., Reviewer, PMSD/ISB
RDI: PE:8/1/89:RDS:8/3/89
H7509C:DEB:JG:jg:CM:2:Rm:803:557-1405:8/3/89.