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

JUN 2 1 1991

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: PP#OF3893 (EPA Reg. Nos. 100-607, 100-608): Metalaxyl Technical: (Ridomil®2E). Tolerance In/On Leafy Vegetables (Excluding Brassica Vegetables, Excluding Spinach). Analysis of Residue Data and Analytical Method.
CBTS#: 7171. MRID#s: 415878-00, 415878-01
DP Barcode #: 156811

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THRU: Richard D. Schmitt, Ph. D., Chief
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TO: B.Chambliss/S. Lewis, PM-21
Herbicide-Fungicide Branch
Registration Division (H7505 C)

CIBA-GEIGY requests the amendment of **40 CFR 180.408** to establish a tolerance 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-methylphenyl)-N-(methoxyacetyl)-alanine methylester, each expressed as metalaxyl, in/on leafy vegetables (excluding brassica and spinach) at 5 ppm.

BACKGROUND

Tolerances for the combined residues of metalaxyl and its metabolites have been previously established in/on a number of raw agricultural commodities ranging from 0.1 to 20 ppm (**40 CFR 180.408(a)**). These include meat and meat byproducts (including poultry) ranging from 0.05 to 0.4 ppm, eggs (0.05 ppm) and milk (0.02 ppm), leafy vegetables (0.1 ppm), head lettuce (5 ppm), spinach (10 ppm), peanut hay and vines (20 ppm).

The Residue chemistry Chapter of the Registration Standard (6/22/87) recommended that the tolerance in/on leafy vegetables (0.1 ppm) be revoked since tolerances were established for the combined residues of metalaxyl and its metabolites in/on head lettuce (5 ppm) and spinach (10 ppm). These tolerances on spinach and lettuce were established based on the use of Ridomil 2E. An amended registration to allow use of Ridomil 5G on spinach for a 10 ppm tolerance was recommended by CBRS (memo K. Dockter, 2/19/91).

To reassess the tolerance on the leafy vegetables crop group, the registrants were required to propose use directions and appropriate supporting residue data for celery and leaf lettuce. These data were submitted in the subject petition which proposes a tolerance of 5 ppm metalaxyl and its metabolites in/on the crop group leafy vegetables (excluding Brassica and spinach). Representative crops in the leafy vegetables group (excluding Brassica vegetables) are celery, spinach, head and leaf lettuce (40CFR180.34).

Pending tolerances for residues of metalaxyl and its metabolites include grapes (PP#6F3362), strawberries (PP#6F3337), blueberries, stonefruits, walnuts and almonds (PP#7F3470), sugar beets (PP#8F3617), alfalfa and barley (PP#8F3695) and root and tuber vegetables (PP#9F3698).

A tolerance with regional registration for the combined residues of the fungicide and its metabolites is established in **40 CFR 180.408(c)** for papaya at 0.1 ppm.

Tolerances for indirect or inadvertent residues of metalaxyl and its metabolites have been established for wheat fodder, forage and straw (2 ppm), and wheat grain (0.2 ppm) in (**40 CFR 180.408(b)**). Indirect or inadvertent food and feed additive tolerances have been established for residues of metalaxyl and its metabolites on wheat milling fractions at 1 ppm in **40 CFR 185.4000(b)** and **40 CFR 186.4000(b)** respectively.

Feed additive tolerances have been established for residues of metalaxyl and its metabolites in/on several feed commodities at levels of 0.4 to 20 ppm in **40 CFR 186.4000(a)**.

Recently, TOX considerations permitting, CBTS recommended in favor of an indirect or inadvertent tolerance for the combined residues of metalaxyl and its metabolites in/on oat grain (0.2 ppm) and the food or feed items oat milling fractions at 1 ppm (memo S. Bacchus, 2/20/91, PP#OE3826/OH5591).

CBTS also recommended in favor of a proposed tolerance of 3 ppm for residues of metalaxyl and its metabolites in/on ginseng pending receipt of a revised Section B (memo G. Otakie, 2/22/91,

PP#1E3926). The formulations proposed for use on ginseng were preplant and soil applications of Ridomil 2E and Ridomil 5G.

Metalaxyl is included in the List A Chemicals in **51 FR#34**, **7740**, (2/22/89). A Registration Standard for metalaxyl was issued 6/22/87 and the Guidance Document is dated 9/88. The Product Chemistry and Residue Chemistry Reregistration Update was issued 3/13/91.

Conclusions

1a. The nature of the residue in plants is adequately understood for the proposed tolerance of the combined residues of metalaxyl and its metabolites in/on the crop group, leafy vegetables (excluding Brassica). The regulated residues in plants are metalaxyl,[N-(2,6-dimethylphenyl)-N-(methoxyacetyl) alanine methyl ester], and its metabolites containing the 2,6 dimethylaniline moiety, and N-(2-hydroxymethyl-6-methylphenyl)-N-(methoxyacetyl)-alanine methylester, each expressed as metalaxyl.

1b. No feed items are involved in this petition. Therefore, the transfer of secondary residues to meat, milk, poultry and eggs is of no concern to this petition.

2a. The manufacture and the physical/chemical characteristics of metalaxyl have been submitted and reviewed both to establish existing tolerances (PP#1F2500/1H5299, P. Errico, 3/9/82) and for the Registration Standard (6/22/87). The Reregistration Standard Update (E. Zager, 3/13/91) has requested additional information about the manufacturing process. The manufacturing process is adequately understood for the proposed use on the leafy vegetables (except Brassica vegetables) group.

2b. A revised Section B stating the amount of solvent or water to be used for the proposed application rates is required.

3a. A multiresidue method is available for metalaxyl (PAM I). Adequate and validated methods are available for metalaxyl and its metabolites in PAM II as methods I and II, equivalent to CIBA-GEIGY methods AG 348 and 349, to enforce these proposed tolerances. CIBA-GEIGY method AG 395 was also validated in our laboratories and is adequate for data collection and enforcement purposes (Reregistration Update, 3/13/91).

3b. The unmodified validated AG 395 was used to analyze samples for the currently established tolerances in/on head lettuce (5 ppm) and spinach (10 ppm). For the unmodified AG 395, the derivatized DMA shows a retention time of 4.83 min. The data submitted using this method were considered adequate

for these current tolerances.

3c. Samples of leaf lettuce and celery were analyzed by a modified method AG 395 in which the derivatization step was eliminated. The underivatized DMA shows a retention time of approximately, 14.05 mins (leaf lettuce, celery). The hydrolysis step is essentially unchanged and recovery of the regulated metabolite has been previously demonstrated (RS, 6/22/87). This method may be adequate to support the petition. However, the petitioner should provide details of the columns, column conditions and instrumentation used. An explanation of the control values which exceed the limit of detection (>0.05-0.16 ppm) is also required.

4. The Registration Standard has requested storage stability data for lettuce (memo, R. Perfetti, 1/15/91). The registrant should provide CBTS with documentation of the studies in progress to satisfy the RS requirements. If these data indicate that the residues are stable for 3 to 15 month intervals, they can be used to support this tolerance request.

5a. Geographically representative data were reported for head and leaf lettuce and celery. The data submitted represent approximately 94% of the celery, and 97% of the lettuce production in the US.

5b. No residue data reflecting the foliar use of the Ridomil 2E formulation and the proposed soil and foliar treatment has been submitted. The petitioner should submit field residue data using the Ridomil 2E and 5G formulation at the maximum proposed soil and foliar use rates and the minimum PHI from the major growing areas in the US. If the petitioner wishes to pursue a crop group tolerance, and if one representative crop is excluded, residue data for another similar crop in the group should be substituted. Based on the variability of the residue data submitted thus far, a crop group tolerance may not be appropriate. The petitioners may need to propose appropriate tolerances on the individual crops used in the field trials. A final decision will be made when the residue data requested above have been submitted.

5c. In the interim, the Agency should, on its own initiative, change the established tolerance for "leafy vegetables (except brassica) group" at 0.1 ppm to "leafy vegetables (except brassica, lettuce, head, and spinach) group" at 0.1 ppm. Higher tolerances are established for head lettuce and spinach.

6. Codex tolerances are established for residues of metalaxyl per se in/on head lettuce at 2 ppm (see Attachment 1: International Residue Status sheet). No Canadian or Mexican

limits are established for metalaxyl per se nor for the combined residues of metalaxyl in/on the crop group leafy vegetables. The incompatibility problem which exists between the proposed US and Codex tolerances cannot be resolved at this time since the data establishing the US tolerances are reported as total residues of metalaxyl and its metabolites in metalaxyl equivalents. Codex tolerances do not include the metabolites of metalaxyl.

Recommendations

CBTS recommends against this proposed tolerance for the combined residues of metalaxyl and its metabolites in/on the crop group leafy vegetables (except Brassica and spinach) on the basis of the deficiencies in Conclusions 2b, 3c, 4 and 5b.

Note to the PM:

The 40 CFR 180.408 notice should read "Tolerances are 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-methylphenyl)-N-(methoxyacetyl)-alanine methylester, each expressed as metalaxyl..... ". The underlined phenyl group is omitted in the 40CFR180.408 notice.

No Craven data were submitted in support of this petition.

DETAILED CONSIDERATIONS

Manufacture

The manufacture and the physical/chemical characteristics of metalaxyl have been submitted and reviewed both to establish existing tolerances (PP#1F2500/1H5299, P. Errico, 3/9/82) and for the Registration Standard (6/22/87). The Reregistration Standard Update (E. Zager, 3/13/91) has requested additional information about the manufacturing process. For the proposed use on leafy vegetables (except Brassica)group the manufacturing process is adequately understood.

Formulation

The formulation proposed for use on leafy vegetables in this petition is Ridomil® 2E Fungicide (EPA Reg. No. 100-607) or Ridomil 5G Fungicide (EPA Reg. No. 100-628). Ridomil® 2E Fungicide contains metalaxyl, (N-(2,6-dimethylphenyl)-N-(methoxyacetyl) alanine methylester, 25.1%) and inert ingredients (74.9%). Ridomil 5G is a granular formulation containing 5% metalaxyl ai and 95% inerts. Ridomil MZ58 contains 48% mancozeb and 10% metalaxyl ai, and 42% inerts.Clearance of the inerts is the purview of the Registration Division.

Proposed Use

The current petition proposes the use of metalaxyl in/on the crop group leafy vegetables (not including Brassica or spinach). For the control of Pythium spp. a preplant broadcast soil or surface banded application of Ridomil 2E or 5G (1-2 lb ai/A) is proposed. This can be followed by up to 4 foliar applications (0.2 lb ai/A each) of Ridomil 2E for control of diseases caused by Oomycetes. The total maximum proposed use rate is 2.8 lb ai/A per crop and the proposed PHI is 5 days.

Data submitted in support of this petition are based on field trial data using preplant metalaxyl (Ridomil 2E or 5G at 2 lb ai/A) followed by 4 foliar applications of Ridomil MZ58, at 0.2 lb or 0.4 lb ai metalaxyl/A. Even though Ridomil MZ58 is used in the field trials to support this petition, Section B of the petition specifies foliar applications of Ridomil 2E. Ridomil MZ58 contains 10% metalaxyl. The petitioner implied that the Agency agreed to use the data generated with Ridomil MZ58 to evaluate the residues which are likely to occur from use of Ridomil 2E for the pending tolerance request for the root and tuber vegetable group. We presume that they imply that is also valid for this proposed use (see Residue Data section for further comments).

A similar use pattern was used to establish tolerances for head lettuce at 5 ppm and spinach at 10 ppm (memo N. Dodd, PP#2F2762, 12/8/83). The registered use of metalaxyl on spinach was later amended to include a preplant application of Ridomil 5G at 2 lb ai/A followed by 2 side dressings of the same formulation shanked-in for a maximum of 2.5 lb ai metalaxyl/A. There is a 21 day PHI on the registered label for the use of Ridomil 2E on spinach which is not included on the current registered label for Ridomil 5G.

Since Ridomil MZ58 is not proposed for foliar use, the EBDC and ETU data submitted with this petition are not relevant to the proposed use of Ridomil 2E and will not be reviewed in this petition. These data were brought to Sue Hummel's attention for her review on mancozeb.

No directions were provided for the amount of water for the dilution of Ridomil 2E. A revised Section B should be submitted providing this information.

Nature of residue

Metabolism in plants

No new metabolism studies were reported in this study. Previously submitted radiolabelled studies indicate that metalaxyl is metabolized along the same pathway in a variety of

unrelated plants, such as lettuce, grapes, tobacco, and potatoes. The quantitative distribution of the metabolites may vary among different plant parts.

Detailed reviews of the metabolism of metalaxyl in plants have been used to support the currently established tolerances of metalaxyl (PP#1F2500, P. Errico, 3/9/82; PP#2F2762, K. Arne, 1/6/83) and for the Registration Standard (6/22/87).

Radiolabelled metabolism data were obtained from head lettuce grown in a greenhouse. These plants received 2 to 4 foliar applications 2 lb/gal EC formulation at 0.2 lb ai/A/application at 14 day intervals. Fully mature plants were harvested at 0 and 7 days after the last application while 50% mature plants were collected 7 days after the second of two applications.

In the 50% mature lettuce plants (7 day PHI) the regulated metabolite, CGA-94689 or N-(2-hydroxymethyl-6-methylphenyl)-N-(methoxyacetyl)-alanine methylester or conjugates, were found to be as nigh as 22.5%. It declined to approximately 10.9% in the fully mature greenhouse grown lettuce at the 7 day PHI. The parent metalaxyl in the mature lettuce had declined from 64.1% at the 0 day PHI to 14.4 % at the 7 day PHI. Thus at 10.9% the level of the metabolite, N-(2-hydroxymethyl-6-methylphenyl)-N-(methoxyacetyl)-alanine methylester (CGA 94689) can be approximately equal to that of the parent (14.4%) in mature lettuce (RS, 6/22/87).

Two isomer forms of this metabolite, comprising 22.1% of the total extractable ^{14}C-activity were also observed in 5 week old lettuce seedlings. These plants had received two foliar applications of a 25% WP formulation containing uniformly ring-labelled ^{14}C-metalaxyl and were harvested 2 weeks after the last treatment. Cellulase was used for the enzymatic cleavage of glucose conjugates.

From these radiolabelled studies in lettuce the metabolic pathways for the degradation of metalaxyl were proposed to be:
(i) oxidation of the ring methyl to the alcohol or carboxylic acid;
(ii) hydroxylation of the phenyl group;
(iii) cleavage of the methylester and methyl ether bonds,
(iv) n-dealkylation; and
(iv) subsequent conjugation of some of the various breakdown products. Potato foliage is the only plant material in which the metabolite contains the benzoic acid moiety (CGA-108905). This metabolite is not a regulated residue in plants.

The nature of the residues of metalaxyl and its metabolites in plants is adequately understood for the tolerances requested

in this petition. The residues of regulatory concern in plants are metalaxyl,[N-(2,6-dimethylphenyl)-N-(methoxyacetyl) alanine methyl ester], and its metabolites containing the 2,6 dimethylaniline moiety, and N-(2-hydroxymethyl-6-methylphenyl)-N-(methoxyacetyl)-alanine methylester , each expressed as metalaxyl.

Metabolism in animals

No feed items are involved in this petition. Therefore, the nature of the residues in animals is of no concern to this petition.

Currently, the residues of regulatory concern in animals, as in plants, are metalaxyl,[N-(2,6-dimethylphenyl)-N-(methoxyacetyl) alanine methyl ester], and its metabolites containing the 2,6 dimethylaniline moiety, and N-(2-hydroxy methyl-6-methyl)-N-(methoxyacetyl)-alanine methylester, each expressed as metalaxyl.

Analytical method

Adequate and validated enforcement methods are available for metalaxyl. A multiresidue method is available for metalaxyl in PAM I. With this method, the retention times of metalaxyl relative to chlorpyrifos are 0.81 min on OV-101, 0.9 min on OV-17 and 1.8 min on DEGS columns (PESTDATA, FDA, 11/90).

The parent and its metabolites can be enforced by methods I and II of PAM II. These methods are equivalent to CIBA-GEIGY methods AG 348 and 349. Another method by CIBA-GEIGY, AG 395, was validated in our laboratories. The PAM II methods and AG 395 include a derivatization step. For AG 395, the derivatized DMA shows a retention time of 4.83 min and the recovery of the metabolite, CGA-94689, from lettuce plants (7 day PHI) was 49%. This method was recommended for data collection and enforcement purposes (RS, 6/22/87).

Unmodified AG 395

The unmodified validated AG 395 was used to analyze the head lettuce and spinach samples for the currently established tolerances of metalaxyl and its metabolites in/on the racs. Data from these field trials conducted between 1982 and 1987 were resubmitted with the subject petition.

The recovery of metalaxyl residues from head lettuce fortified at the 0.05-20 ppm levels was in the range 58-118%. The mean for 27 field samples was 79 ± 15.5 percent. For 22 samples of spinach fortified at the 0.2-20 ppm levels with metalaxyl, recoveries ranged from 56-110 percent (mean 86.5 ± 12.4%, MRID#416362-01).

Modified AG 395

For the subject petition, a modified version of method AG-395 was used to analyse residues of metalaxyl and its metabolites containing the 2,6-dimethyl aniline (DMA) moiety. The method was modified by omission of the derivatization step. Leaf lettuce and celery samples from field trials conducted in 1988 and 1989 were analyzed by this method.

Briefly, crop samples (10 g) are refluxed with 80% v/v methanol/water for two hours. A 2 gram aliquot of the extract is evaporated to dryness with a rotary evaporator. The residue is dissolved in 1 or 1.5 ml water. The sample is refluxed for 12-15 minutes in 10 ml of methanesulfonic acid which rapidly converts residues to 2,6-dimethylaniline (DMA). The pH of the extract is made basic after cooling and addition of water.

Cleanup of the steam-distilled product is by a Sep-Pak silica cartridge. Analysis is by gas chromatography. After separation on a 30 meter DB-WAX fused silica capillary column, DMA is detected using a Nitrogen-Phosphorus detector operating in the nitrogen specific mode.

Derivatization by trifluoroacetic acid to obtain DMA-TFA was omitted from this method. DMA standard solutions supplied by CIBA-GEIGY were used for quantitation. The limit of detection is 0.05 ppm. The combined residues of metalaxyl and its metabolites are expressed as metalaxyl equivalents.

In the unmodified AG395, the derivatized DMA shows a retention time of 4.83 ppm (head lettuce). When the method is modified, the underivatized DMA shows a retention time of approximately, 14.05 mins (leaf lettuce, celery).

Recovery Data using modified AG395

The petitioners claim average metalaxyl recoveries as follows:

	Range (%)	Mean + SD (%)
leaf lettuce[1]	59-104	$89.92 \pm 13.52^{a=14}$
celery	63-128	$91.9 \pm 18.6^{a=20}$

[1] Samples from 1 field trial were omitted from this calculation of the mean. The cooperator did not maintain necessary and proper records in the residue trial notebook.

The recovery of the regulated metabolite, N-(2-hydroxymethyl-6-methylphenyl)-N-(methoxyacetyl)-alanine methylester (CGA 94689) is not reported. However, the hydrolysis step is essentially unchanged and recovery of the regulated metabolite has been previously demonstrated. Recovery of the metabolite at 49% was considered to be superior to its recovery when other methods were used (RS, 6/22/87). This modified AG395 may be adequate to support the petition providing that the petitioner submits details of the columns, column conditions and instruments used to provide the data.

Storage Stability

No storage stability data were submitted with this petition. Storage stability studies submitted for the Registration Standard ascertain that the residues of metalaxyl per se are stable at -15°C in potatoes and tobacco for up to 18 months when stored in plastic bags and for 12 months when stored in glass jars (FRSTR, 6/22/87).

Samples from field trials were stored frozen for the following intervals prior to analysis:

head lettuce	3-15 months
leaf lettuce	7-13 months
celery	3-12 months
spinach	2-8 months

The Registration Standard has requested storage stability data for lettuce (memo, R. Perfetti, 1/15/91; Metalaxyl Product Chemistry and Residue Chemistry Reregistration Standard Updates, E. Zager, 3/13/91). For this petition request, the registrant should provide storage stability studies to support the submitted field data. These studies should show that the residues are stable for up to 15 months under the storage conditions of the analyzed samples in this tolerance request.

Residue Data

The residue data available for the entire leafy vegetables (except Brassica vegetables) group will be discussed. This approach was taken since the maximum combined residues of metalaxyl observed in celery in a worst scenario is 11 ppm which is close to the 10 ppm tolerance previously established in/on spinach.

Head Lettuce

Field trials were conducted in AZ(2[2]), CA(4) FL (2), MI(1), NE(1), NY(2), TX(3). These states represent 97% of the 1987 US production of lettuce. Geographical representation of lettuce production by state was: AZ(21.9%), CA(68%), FL(3.5%), MI(3.7%), NY(11.7%) (**Agricultural Statistics 1988, USDA**). The fields were treated with preemergent soil applications of either Ridomil 2E or 5G at 2 lb ai/A (1X) or 4 lb ai/A (2X). The soil applications were followed by four foliar applications of Ridomil MZ58 at the 1X (0.2 lb ai/A) or the 2X (0.4lb ai/A) dose rate. At the 1X and 2X dose rates the maximum doses of metalaxyl ai were 2.8lb/A and 5.6 lb/A. The proposed PHI is 5 days.

Ridomil 2E

At the 7 and 14 day PHIs, the ranges of the combined residues of metalaxyl and its metabolites in twelve 1X treated, untrimmed, head lettuce samples were 0.06-4.25 ppm and 0.05-3.99 ppm respectively. In sixteen 2X treated samples, the range was 0.05-3.3 ppm at the 7 day PHI.

No sample of head lettuce treated with Ridomil 2E was collected at the 5 day PHI. However, the ranges of residues obtained from the soil treatment of leaf lettuce with Ridomil 2E (0.2-3.8 ppm) or 5G (0.63-3.6 ppm) are quite similar (see Table 2).

Ridomil 5G

At the 4-5 day PHI, the metalaxyl residues observed in head lettuce from the field trials in which 1X Ridomil 5G (soil) and foliar Ridomil MZ58 was used ranged from <0.05-3.3 ppm (n=16 samples). At the 2X dose rate, 4-5 day PHI, the levels of the residues ranged from 0.12-4.9 ppm (6 samples).

Leaf Lettuce

Residues of metalaxyl in/on leaf lettuce were obtained from field trials in AZ(1), CA(3), FL(2), MI(1), NY(1). These areas are geographically representative of lettuce production (see **Head Lettuce**). The residues from the trials of lettuce treated with the maximum proposed 1X dose of Ridomil 2E (PHI 5 days) ranged from 0.2-3.8 ppm (12 samples). At the same PHI and the 1X dose rate of preemergent Ridomil 5G and foliar Ridomil MZ58, an approximately similar range of residues, 0.63-3.6 ppm, was

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[2] Numbers in parentheses indicate the number of field trials in that state.

observed. Residues ranged from 0.58 to 8.4 ppm at the 2X dose and the 5 day PHI.

Table 1: Field Residue data - combined residues of metalaxyl in/on leafy vegetables crop group

		Ridomil 2E (soil)+ foliar Ridomil MZ58		Ridomil 5G (soil) + foliar Ridomil MZ58	
		Range (ppm)		Range (ppm)	
	PHI (days)	1X	2X	1X	2X
Head lettuce	4-5	---	---	<0.05-3.3 n=16	0.12-4.9 n=6
	7	0.06-4.25 n=12	0.05-3.3 n=16	0.08-0.1 n=1	0.21 n=1
	14	0.05-3.99 n=12	---	---	---
Leaf Lettuce	5	0.2-3.8 n=12	0.58-8.4 n=5	0.63-3.6 n=8	2.7-4.1 n=2
Celery	5	0.29-2.1 n=13	1.1-2.5 n=3	0.19-11* n=10	1.3-11 n=2

* Includes 2 samples from CA greater than 5 ppm. These samples were reprepped and reanalyzed 2 times after the initial analysis. Mean values of the three analyses for these 2 samples were 5.1 and 10.1 ppm.

Celery

Field trials were conducted in CA(4), FL(2), MI(1), MN(1). which represent 94% of the 1987 celery production in the US (**Agricultural Statistics**, 1988, USDA). Residues of metalaxyl and metabolites (measured as DMA equivalents) in/on untrimmed celery treated with the 1X dose of Ridomil 2E (5 day PHI) ranged from 0.29-2.1 ppm (13 samples).

There is great variability in the magnitude of residues observed in celery when Ridomil 5G is used as the preemergent soil treatment. At the 1X dose of preemergent Ridomil 5G plus foliar Ridomil MZ58 treatment, the range of residues observed was 0.19-11 ppm (5 day PHI, 10 samples). Residues greater than the requested tolerance of 5 ppm were observed in 2 (i.e. 20%) of these samples. In another field trial in CA in which preemergent Ridomil 5G and foliar Ridomil MZ58 were used, the residues in celery ranged from 1.6-2.1 ppm (2 samples).

It would appear that the maximum residues observed in celery, therefore, may even exceed the 10 ppm tolerance established for spinach. The maximum residue (11 ppm) observed in celery cannot be considered an outlier since it is within 3 standard deviations of the mean (3.86 ± 4.17). Therefore, for this proposed use, the requested tolerance for the leafy vegetables crop group cannot be recommended.

Spinach

The above discussion for celery indicates that the proposed tolerance of 5 ppm combined residues of metalaxyl in/on the crop group leafy vegetables may be exceeded by the proposed use. The field trial data from spinach for the establishment of the 10 ppm tolerance in/on the rac (PP#2F2762) has been adequately reviewed elsewhere.

The registered use of metalaxyl on spinach was later amended to include a preplant soil application of Ridomil 5G at 2 lb ai/A followed by 2 side dressings of the same formulation shanked-in for a maximum of 2.5 lb ai metalaxyl/A. Spinach is registered for use on the Ridomil 2E label only.

Comments

The field residue data do not support the proposed tolerance of 5 ppm in/on the crop group leafy vegetables (except Brassica vegetables and spinach). The proposed use includes the foliar treatment of these crops with the Ridomil 2E formulation. No field residue data reflecting this formulation and the proposed soil and foliar treatment have been submitted. The petitioner references the acceptance of residue data for the foliar treatment of the root and tuber vegetables group using Ridomil MZ58 formulation (PP#8F3698). Because most of the edible portion of the crop is below the ground and not directly exposed by the foliar application, we were willing to accept the data for this one time only. However, for this use pattern for the leafy vegetables group we will need field residue data using the Ridomil 2E and 5G formulations at the maximum proposed soil and foliar use rates and minimum PHI from the major growing areas in the US. If one representative crop is excluded residue data for another similar crop in the group should be substituted.

Based on the variability of the residue data submitted thus far a crop group tolerance may not be appropriate. The petitioners may need to propose appropriate tolerances on the individual crops used in the field trials. A final decision will be made when the residue data requested above have been submitted.

Meat, milk, poultry, eggs

Head or leaf lettuce, celery, and other, members of the leafy vegetables (except Brassica vegetables) group are not considered feed items under Table II, Subdivision O Guidelines. Therefore, the secondary residues of metalaxyl in meat, milk, poultry and eggs are of no concern to this petition.

Other considerations

Codex tolerances are established for residues of metalaxyl per se in/on head lettuce at 2 ppm (see Attachment 1: International Residue Status sheet). No Canadian or Mexican limits are established for metalaxyl per se nor for the combined residues of metalaxyl in/on the crop group leafy vegetables. The incompatibility problem which exists between the proposed US and Codex tolerances cannot be resolved at this time since the data establishing the US tolerances are reported as total residues of metalaxyl and its metabolites in metalaxyl equivalents. Codex tolerances do not include the metabolites.

Attachmemt 1 - International Codex sheet

cc: S. Bacchus , PP#OF3893, SF, C. Furlow ISB/PMSD), RF, RS (metalaxyl), and Circ.

RDI: P.V. Errico:6/6/91: R. Loranger:6/7/91.
H7509C:CBTS/HED:CM#2:RM803-A:SBacchusX557-1439:s.b.:6/11/91

J K. 3/24/91

Attachment: 1

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INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL metalaxyl (Ridomil 2E " 5G)

CODEX NO. 138

CODEX STATUS:

[ ] No Codex Proposal Step 6 or Above

Residue (if Step 8): _____

Metalaxyl per se

Crop(s)	Limit (mg/kg)
Head lettuce	2*

PROPOSED U.S. TOLERANCES:

Petition No. PP 3F3893

DEB Reviewer Shanaz Bacchus

Residue: Metalaxyl and metabolites containing 2,6-dimethyl aniline moiety and N-(2-hydroxy methyl-6-methyl-N-(methoxyacetyl)-alanine methyl ester expressed as metalaxyl

Crop(s)	Limit (mg/kg)
Leafy vegetables crop group (excluding Brassica and Spinach)	5 ppm

CANADIAN LIMITS:

☑ No Canadian Limit (on shore)

Residue: _____

Crop(s)	Limit (mg/kg)

MEXICAN LIMITS:

☑ No Mexican Limit

Residue: _____

Crop(s)	Limit (mg/kg)

NOTES

* Only Codex MRL fitting leafy vegetables (except Brassica and Spinach) criteria

Form Revised 1989