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

AUG 12 1994

OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Concurrence with comment on draft of Federal Register Notice on the tolerance for metalaxyl leafy vegetables (excluding *Brassica* and spinach). CBTS# 14181

FROM: G.F. Kramer Ph.D., Chemist
Tolerance Petition Section III 
Chemistry Branch I, Tolerance Support
Health Effects Division (7509C)

THRU: R.A. Loranger Ph.D., Acting Branch Chief
Chemistry Branch I, Tolerance Support
Health Effects Division (7509C)

TO: Kathryn Scanlon, FHB/RD/PM-21 (7505C)

CBTS concurs with this draft of Federal Register Notice on the tolerance for metalaxyl with the following comment:

- 1) There are minor discrepancies between the tolerance expression as written and that listed in 40 CFR §180.408. The correct form is "metalaxyl [*N*-(2,6-dimethylphenyl)-*N*-methoxyacetyl alanine methyl ester] and its metabolites containing the 2,6-dimethylaniline moiety, and *N*-(2-hydroxymethyl-6-methyl)-*N*-(methoxyacetyl)-alanine methylester, each expressed as metalaxyl."
- 2) In order to conform with 40 CFR §180.34, the tolerance should be established on the "Leafy vegetables (except *Brassica*) group (except spinach)."

cc: PP 0F3893, S.F., Kramer, circ., R.F.
RDI: P.V. Errico (8/12/94)
G.F. Kramer:804V:CM#2:(703)305-5079:7509C



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

MAY 12 1992

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

Memorandum

Subject: ~~PP#F3873~~ Metalaxyl (**Ridomil 2E, 5G**) in/on Leafy Vegetables (Excluding Brassica, Excluding Spinach). Amendment of 3/17/92. CBTS# 9710. No MRID#. DP Barcode# D176810.

From: Robert Lascola, Chemist
Chemistry Branch I - Tolerance Support
Tolerance Petition Section III
Health Effects Division (H7509C)

Rob Lascola

Through: P. V. Errico, Section Head
Chemistry Branch I - Tolerance Support
Tolerance Petition Section III
Health Effects Division (H7509C)

P. V. Errico

To: Ben Chambliss/Susan Lewis (PM21)
Fungicide/Herbicide Branch
Registration Division (H7505C)

CIBA-GEIGY has submitted its response, including a revised Section B and a Confidential Statement of Formula for **Ridomil 70W**, to the deficiency (Conclusion 5a) outlined in our previous memo (R. Lascola, 12/18/91) concerning the proposed establishment of 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 methyl ester, each expressed as metalaxyl, in/on leafy vegetables (excluding Brassica and spinach) at 5 ppm.

The previously submitted Section B proposed a preplant soil application of 1-2 lbs ai/A of either **Ridomil 2E** or **5G**, followed by (if necessary) foliar application of **Ridomil MZ58**, a metalaxyl/mancozeb wettable powder mixture. Use of MZ58 was proposed in accordance with residue trials, submitted in support of the petition, which involved use of that formulation. However, CBTS did not approve the label, since there are no tolerances for mancozeb on non-Brassica leafy vegetables. In a communication with the petitioner (R. Lascola memo of 3/13/92), the Agency stated that it might be possible to translate data generated with **MZ58** to another wettable powder formulation with the same concentration of metalaxyl and similar inert ingredients. If these requirements were met, CBTS would anticipate that residues of metalaxyl

in crops treated with the new formulation would be the same as those found in **MZ58**-treated commodities.

The petitioner has submitted a revised Section B, which specifies the use of **Ridomil 70W**, a wettable powder metalaxyl/copper hydroxide mixture. The proposed preplant soil treatment with **Ridomil 2E** or **5G** remains unchanged. **70W** is to be applied foliarly at a rate of 1.05-1.4 lbs total ai/A (corresponding to 0.15-0.2 lb ai/A metalaxyl). This rate is identical to the rate proposed previously for the **MZ58** formulation. The inert ingredients for the **MZ58** and **70W** formulations are identical; therefore, similar metalaxyl residues are expected in the target commodities for application at the same rate of active ingredient. Also, copper is exempt from tolerances under 40 CFR §180.1021, and therefore no use is being proposed on the current label for any active ingredient lacking a tolerance for the leafy vegetables (except Brassica, except spinach) crop group.

The petitioner has therefore satisfied the remaining deficiency for this petition. **CBTS recommends in favor of the proposed crop group tolerance of 5 ppm for metalaxyl on leafy vegetables (except Brassica, except spinach).**

cc: R. Lascola, SF, RF, D. Edwards, PP#0F3893, Circulation (7), C. Furlow (PIB/FOD)
H7509C:CBTS:RLascola/rjl:CM#2:Rm803C:305-7478:5/6/92

RDI: P.V.Errico:5/7/92; R.Loranger:5/7/92.

☉:Disk8\3893AMDF.TXT

CIBA-GEIGY

Agricultural Division
CIBA-GEIGY Corporation
P.O. Box 18300
Greensboro, North Carolina 27419-8300
Telephone 919 632 6000

March 17, 1992

Document Processing Desk (AMEND)
Office of Pesticide Programs (H7504C)
U.S. Environmental Protection Agency
401 M. Street, S.W.
Washington, D.C. 20460

Attn: Ms. Susan Lewis, PM 21

Dear Ms. Lewis:

SUBJECT: PESTICIDE PETITION OF3893
METALAXYL/LEAFY VEGETABLES
YOUR LETTER OF FEBRUARY 21, 1992
DEB REVIEW OF DECEMBER 18, 1991
SUBMISSION OF REVISED SECTION B

In accordance with the subject review, enclosed are three copies of a revised Section B. This revision has been discussed at length with the Chemistry Branch reviewer, Robert Lascola. At his direction, the Section B has been rewritten using the EC formulation of metalaxyl for the soil application, followed by foliar applications of a metalaxyl and copper mixture.

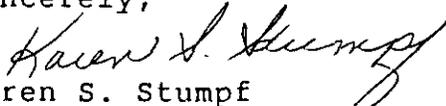
The problem with the previous Section B language stemmed from the fact that although the residue program included foliar applications of a metalaxyl/mancozeb combination, mancozeb at the present time cannot be registered on the Leafy Vegetables Crop Grouping because appropriate tolerances are lacking. The reviewer felt the Section B should reflect another metalaxyl combination which could be registered for these uses and where metalaxyl residues would be expected to be the same as for the metalaxyl/mancozeb combination. Thus the metalaxyl/copper mixture, which was recently registered on February 28, 1992 (100-720). Both Ridomil MZ58 Fungicide (100-629 and the formulation used in the residue trials) and Ridomil/Copper 70W contain ten percent metalaxyl. Rates for metalaxyl in the Section B are equivalent to the rates used in the foliar residue trials. Copper is exempt from tolerances and therefore could be registered on the subject crop grouping if desired. In fact Ridomil/Copper 70W is registered for use on spinach, a member of the Leafy Vegetables Crop Grouping.

CIBA-GEIGY trusts this second revision to the Section B will

resolve the Agency's concerns.

Also, at the reviewer's request, enclosed is a Confidential Statement of Formula for Ridomil/Copper 70W Fungicide.

Sincerely,


Karen S. Stumpf
Senior Regulatory Manager
Regulatory Affairs

Enclosures

Page _____ is not included in this copy.

Pages 7 through 10 are not included in this copy.

The material not included contains the following type of information:

- Identity of product inert ingredients.
- Identity of product impurities.
- Description of the product manufacturing process.
- Description of quality control procedures.
- Identity of the source of product ingredients.
- Sales or other commercial/financial information.
- A draft product label.
- The product confidential statement of formula.
- Information about a pending registration action.
- FIFRA registration data.
- The document is a duplicate of page(s) _____.
- The document is not responsive to the request.
- Internal deliberative information.
- Attorney-client privilege.
- Claimed Confidential by submitter upon submission to the Agency.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

METALAXYL TECHNICAL

PETITION FOR TOLERANCE IN THE LEAFY VEGETABLES
(EXCEPT BRASSICA, EXCEPT SPINACH) CROP GROUPING

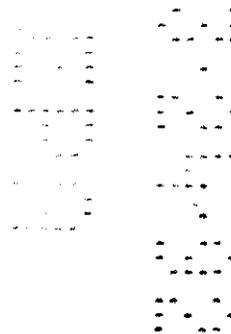
PESTICIDE PETITION NO. OF3893

CONTENTS: REVISED SECTION B

MARCH 17, 1992

CIBA-GEIGY CORPORATION
AGRICULTURAL DIVISION
P.O. BOX 18300
GREENSBORO, NC 27419

PAGE 1 OF 5



SECTION B

**AMOUNT, TIMING, AND FREQUENCY OF APPLICATION OF THE PESTICIDE
METALAXYL TO THE LEAFY VEGETABLES
(EXCLUDING BRASSICA VEGETABLES, EXCLUDING SPINACH)
CROP GROUPING**

General Information

Metalaxyl is a systemic fungicide for use on selected crops to control certain diseases caused by members of the Oomycete class of fungi. Other fungicides must be used to control diseases incited by other classes of fungi.

Leafy Vegetables

Includes celery, garden cress, upland cress, endive, fennel, lettuce (head and leaf), parsley, rhubarb, spinach and Swiss chard.

Metalaxyl 2E applied as a soil application will control damping-off caused by *Pythium* spp. in leafy vegetables and white rust (*Albugo occidentalis*) in spinach. Applications may be banded over the row, preplant incorporated, or injected with liquid fertilizer. For control of foliar Oomycetes, foliar applications of Metalaxyl/copper 70W should be made either alone or in combination with the soil application of Metalaxyl 2E.

Preplant Incorporated Application: Apply 1-2 lbs. ai of Metalaxyl 2E/treated acre as a broadcast soil application in a minimum of 20 gals. of water or liquid fertilizer to provide uniform coverage and incorporate in the top two inches of soil. For banded applications, a minimum of a seven inch band is recommended.

Surface Application: Apply 1-2 lbs. ai of Metalaxyl 2E/treated acre at planting in a minimum of 20 gals. of water or liquid fertilizer to provide uniform coverage. For banded applications, a minimum of a seven inch band is recommended. If natural rainfall is not expected before the seeds start germinating, Metalaxyl 2E should be incorporated mechanically before planting or be moved into the seed zone after planting with 1/2-1 inch of sprinkler irrigation.

Foliar Application: Apply 1.05-1.4 lbs. ai of Metalaxyl/Copper 70W (0.15 lb. ai metalaxyl/0.90 lb. ai copper - 0.2 lb. ai metalaxyl/1.2 lbs. ai copper) per acre as a foliar spray in a minimum of 20 gals. of water. Begin applications when conditions are favorable for disease, but before infection, and continue at 14-day intervals until the threat of disease is over. Under heavy disease pressure, use the higher rate of Metalaxyl/copper.

Notes: To avoid possible illegal residues, (1) do not apply more than a total of 2.8 lbs. ai of metalaxyl/treated acre per crop, (2) do not make more than four foliar applications of Metalaxy/Copper 70W per crop, and (3) do not apply within five days of harvest.

White Rust Control (Spinach Only): In addition to the preplant incorporated or surface application described above; apply 0.125 lb. ai of Metalaxyl 2E/A of crop, shanked in 40-50 days after planting or after each cutting. A maximum of two applications can be made after each preplant or at-planting application. Use sufficient mechanical or by-pass agitation to keep the metalaxyl mixed with the water or fertilizer.

Notes: (1) The additional applications of metalaxyl noted above and made after each cutting by shanking the fungicide into the beds along with liquid fertilizer provide continuing control of white rust. However, white rust can only be controlled in a preventative disease control program that begins with an application of metalaxyl to the soil at planting. If metalaxyl is not used at planting, do not use metalaxyl at any other time throughout the season. Do not apply metalaxyl in foliar applications or in situations where white rust infections are already established. The use of metalaxyl in curative applications greatly increases the risk of the fungus developing resistance to metalaxyl. The development of resistance will destroy the effectiveness of metalaxyl in controlling white rust. (2) Do not harvest spinach within 21 days of a Metalaxyl 2E application. (3) Do not use Metalaxyl 2E for disease control in greenhouse crops.

Rotational Crops

Rotation Crop

Planting Time From Last
Metalaxyl Application

Leafy Vegetables

-0- days

July 25, 1990
Revised September 3, 1991
Revised March 17, 1992

SECTION BAMOUNT, TIMING, AND FREQUENCY OF APPLICATION OF THE PESTICIDE METALAXYL TO THE LEAFY VEGETABLES (EXCLUDING BRASSICA VEGETABLES, EXCLUDING SPINACH) CROP GROUPINGGeneral Information

Metalaxyl is a systemic fungicide which provides control of certain diseases caused by members of the Oomycete class of fungi on selected crops.

Leafy Vegetables (Excluding Spinach)

Includes celery, garden cress, upland cress, endive, fennel, lettuce (head and leaf), parsley, rhubarb and Swiss chard.

Metalaxyl 5G applied as a soil application will control damping-off in leafy vegetables caused by *Pythium* spp. Applications may be made banded over the row or preplant incorporated. For control of foliar Oomycetes, foliar applications of metalaxyl/copper should be made either alone or in combination with the soil application of Metalaxyl 5G.

Preplant Incorporated Application: Apply 1-2 lbs. ai of Metalaxyl 5G/treated acre as a broadcast soil application and incorporate in the top two inches of soil. For banded applications, a minimum of a seven inch band is recommended. When incorporated applications are made at the time of planting, position the drop tubes of the granules are mixed with the soil covering the seed at a rate of 0.5-1.0 oz. ai/1,000 linear feet of row. Avoid placing the granules directly in contact with the seed or injury may occur.

Surface Application: Apply 1-2 lbs. ai of metalaxyl 5G/treated acre uniformly to the soil surface at the time of planting. For banded applications, a minimum of a seven inch band is recommended. If natural rainfall is not expected before the seeds start germinating, Metalaxyl 5G should be incorporated mechanically before planting or be moved into the seed zone after planting with 1/2-1 inch sprinkler irrigation.

Foliar Application: Apply 1.05-1.4 lbs. ai of Metalaxyl/Copper 70W (0.15 lb. ai metalaxyl/0.90 lb. ai copper - 0.2 lb. ai metalaxyl/1.2 lbs. ai copper) per acre as a foliar spray in a minimum of 20 gals. of water. Begin applications when conditions are favorable for disease, but before infection, and continue at 14-day intervals until the threat of disease is over. Under heavy disease pressure, use the higher rate of Metalaxyl/Copper.

Notes: To avoid possible illegal residues, (1) do not apply more than a total of 2.8 lbs. ai of metalaxyl/treated acre per crop, (2) do not make more than four foliar applications of Metalaxyl/Copper per crop, and (3) do not apply within five days of harvest.

Rotational Crops

Planting Time From Last
Metalaxyl Application

Rotation

-0- days

Leafy Vegetables

July 25, 1990
Revised September 3, 1991
Revised March 17, 1992

RECORD OF COMMUNICATION		<input checked="" type="checkbox"/> Phone Call <input type="checkbox"/> Discussion <input type="checkbox"/> Field Trip <input type="checkbox"/> Conference <input type="checkbox"/> Other
To: Karen Stumpf Product Manager Ciba-Geigy Corp. Greensboro, NC (919) 632-2169	From: Robert Lascola, Chemist 	Date: March 13, 1992 Time: 2 PM
Subject: Resolution of Section B deficiency for PP#0F3893, proposed tolerances for metalaxyl on non-Brassica leafy vegetables (excluding spinach).		
Summary: <p>Ms. Stumpf asked for advice on resolution of deficiencies noted in my memo of 12/18/91, in which I had noted that the proposed Section B was inadequate because it sanctioned the use of a metalaxyl/mancozeb WP mixture (Ridomil MZ58) in a foliar spray. There are no tolerances for mancozeb on non-Brassica leafy vegetables.</p> <p>After consultation with P. Errico and R. Loranger, it was decided that the best plan would be to substitute a comparable metalaxyl mixture for the MZ58. We do not feel that the residue data supports foliar application of an emulsifiable concentrate (such as Ridomil 2E, which is used as a soil treatment). We also could not recommend use of the soil treatment alone, since the residue data submitted with the petition involves soil and foliar application, and we could not separate the residues incurred by each treatment alone. In that case, we would stand a chance of overestimating the necessary tolerance.</p> <p>Upon presenting the suggestion to Ms. Stumpf, she replied that Ciba-Geigy has just obtained a registration for a metalaxyl/copper mixture (Ridomil/Copper 70W Fungicide, EPA Reg. No. 100-720) which is also a wettable powder and contains the same concentration of metalaxyl as the Ridomil MZ58. Therefore, the Agency should be able to translate metalaxyl residue data from the MZ58 to this new formulation. In addition, copper is exempt from the requirement for a tolerance, so there is no illegal use proposed in this case. She will submit a new Section B with the appropriate changes, as well as a CSF for the new product and Ridomil MZ58.</p>		
Conclusions, Action Taken, etc. We will review the revised Section B and CSFs upon receipt.		
cc: Record of Communication File, R. Lascola, PP#0F3893, Ben Chambliss/Susan Lewis (RD, PM21, H7505C), Metalaxyl SF, RF.		

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

DEC 18 1991

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Subject: PP#0F3893: Metalaxyl (**Ridomil 2E, 5G**) in/on Leafy Vegetables (Excluding Brassica, Excluding Spinach). Amendment of 9/9/91. CBTS# 8898. MRID# 420211-01. DP Barcode# D171050.

From: Robert Lascola, Chemist
Chemistry Branch I - Tolerance Support
Tolerance Petition Section III
Health Effects Division (H7509C)

Rob Lascola

Through: P. V. Errico, Section Head
Chemistry Branch I - Tolerance Support
Tolerance Petition Section III
Health Effects Division (H7509C)

P. V. Errico

To: Ben Chambliss/Susan Lewis, PM-21
Herbicide-Fungicide Branch
Registration Division (H7505C)

CIBA-GEIGY has submitted its response, including a revised Section B, to the deficiencies outlined in S. Bacchus' memo of 6/21/91 concerning the proposed establishment of 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 methyl ester, each expressed as metalaxyl, in/on leafy vegetables (excluding Brassica and spinach) at 5 ppm.

Tolerances for the combined residues of metalaxyl and its metabolites have previously been established under 40 CFR §180.408(a-c), §185.4000(a-b), and §186.4000(a-b). There are also several pending tolerances for metalaxyl. Metalaxyl is a List A chemical.

Conclusions

1. The petitioner has adequately delineated the dilution volumes for the various applications of **Ridomil 2E and 5G** (Deficiency 2b of S. Bacchus' 6/21/91 memo).
2. The petitioner has adequately described the details of the chromatographic procedures in modified analytical method AG-395. The petitioner has also adequately discussed the apparent residue levels in some control samples (Deficiency 3c of S. Bacchus' 6/21/91

memo).

3. The referenced storage stability study shows that metalaxyl residues in frozen lettuce are not stable over a 12-month storage interval. However, the data, if extrapolated to 15 months, show a limited decline (correction factor = 11.25%). Therefore, the storage stability data are adequate for this petition (Deficiency 4 of S. Bacchus' 6/21/91 memo).
4. Application of the correction factor arising from the storage stability study indicates that residue levels for head lettuce, leaf lettuce, and celery are still within the proposed 5 ppm crop group tolerance.
- 5a. CBTS concludes that the revised Section B, which no longer indicates foliar application of **Ridomil** alone, is consistent with the use patterns exhibited in the residue trials. However, CBTS finds that the label still contains deficiencies. Specifically, the label currently implies that application of mancozeb to leafy vegetables is legal, whereas there is only one leafy vegetable crop, celery, for which there is a tolerance (5 ppm). In addition, a Special Review has been initiated for mancozeb and revocation of all tolerances (including celery) has been proposed. Since there are no tolerances for mancozeb on all other non-Brassica leafy vegetables besides celery, the petitioner must submit a revised Section B which does not include foliar application of the mancozeb/metalaxyl mixture on those crops. Furthermore, if the Agency elects to revoke the mancozeb tolerance on celery, the petitioner will have to remove foliar application of the mancozeb/metalaxyl mixture on that commodity as well. (Deficiency 5b of S. Bacchus' 6/21/91 memo.)
- 5b. CBTS concludes that the late harvest and high temperatures for trial 02-FR-006-89 do not represent normal conditions for growing celery, that the celery grown under these conditions would be unusable, and that any field trial results obtained under those conditions would be invalid. Therefore, the residue values for use of 1x the label rate of **Ridomil 5G** on celery range from 0.19-2.1 ppm. CBTS further concludes that the residue data support the proposed crop group tolerance of 5 ppm for metalaxyl on leafy vegetables (except Brassica, except spinach). (Deficiency 5b of S. Bacchus' 6/21/91 memo.)

Recommendation

CBTS recommends **against** the proposed crop group tolerance of 5 ppm for metalaxyl on leafy vegetables (except Brassica, except spinach) for the reason delineated in Conclusion 5a.

Detailed Considerations

Each of the deficiencies outlined in our previous memo will be repeated, followed by the

petitioner's response and our comments.

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

Petitioner's Response. The petitioner has submitted a revised Section B for **Ridomil 2E** and **5G** which now calls for application of 1-2 lbs ai/A dissolved in a minimum of 20 gals of water or liquid fertilizer for preplant incorporated or surface applications. For foliar application, the recommended rate of 0.87-1.16 lbs ai/A mancozeb/metalaxyl should be dissolved in a minimum of 20 gals of water. Also, the **Ridomil 2E** labelling specifies application for control of white rust on spinach only. For this use, in addition to the preplant incorporated or surface application described above, 0.125 lb ai of metalaxyl/A of crop should be applied, shanked in 40-50 days after planting or after each cutting.

CBTS's Response. Although an application volume is not specifically indicated for the white rust control application, it is implied that the same dilution procedures would be used as for the preplant incorporated or surface applications. Therefore, CBTS considers that the dilution procedures have been adequately delineated and that this deficiency is resolved.

- **Deficiency 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 min (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.

Petitioner's Response. The petitioner has submitted the requested details concerning the instrumentation, columns, and column conditions for the GC-NPD and GC-MS methods used in the modified analytical method AG-395.

The petitioner suggests four potential reasons for the apparent residues in head lettuce, leaf lettuce, and celery control samples. 1) There are natural plant products which convert to 2,6-dimethylaniline or an isomer with similar chromatographic and mass spectral properties. 2) There was spray drift during the application (considered unlikely by the petitioner). 3) There was cross-contamination during field trials and/or sampling (also considered unlikely by the petitioner). 4) There was "volatility of the applied chemical which would be influenced by weather and/or soil conditions."

The petitioner further states, "In any event, the apparent residue levels in the controls (0.06-0.16 ppm) are generally much lower than those found in treated samples (average residues 0.84-1.5 ppm) and significantly lower than the established tolerance for head lettuce (5.0 ppm)."

CBTS's Response. CBTS concludes that the petitioner has adequately resolved this deficiency.

- **Deficiency 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.

Petitioner's Response. The petitioner notes that the Registration Standard asks that storage information be provided for lettuce residue data submitted under MRID# 0097511. "The missing data relate only to sample storage intervals for lettuce samples used to support current tolerances and, therefore, have no bearing on the newly proposed group tolerances." The petitioner cites MRID# 401066-01, which it claims shows that metalaxyl and five individually fortified metabolites are stable in lettuce for a minimum of 12 months at freezer storage temperature. This study was not reviewed in the 1988 FRSTR. Also cited are a study which shows that field-incurred residues of metalaxyl in potatoes and tobacco are stable for 18 months under freezer storage conditions (MRID# 00071678) and an in-progress study which shows that field-incurred residues of metalaxyl in spinach, peppers, potatoes, and cranberries are stable for at least one year. The latter study will be conducted for up to 38 months and will be completed in mid-1994. "Based on the data currently available, there is no reason to expect that residues of metalaxyl in lettuce, determined as DMA, would not be completely stable under freezer storage conditions for 3-15 months."

CBTS's Response. The referenced study, MRID# 401066-01, contains 12-month storage stability data for 5 commodities including lettuce and cabbage. Samples were injected with 1.0 ppm spikes of metalaxyl and 5 metabolites and were kept in storage at -15 °C. Samples were analyzed for "total" metalaxyl residues at 6-month intervals over a one-year period. Results for lettuce and cabbage are provided below.

Table 1. 12-Month Storage Stability of Metalaxyl in Lettuce and Cabbage.						
	Lettuce (ppm) ¹			Cabbage (ppm) ¹		
months	0	6	12	0	6	12
metalaxyl	1.0	1.1	0.98	1.0	0.93	1.1
CGA-62826	1.0	1.0	1.1	1.0	0.94	1.0
CGA-67869	1.0	1.2	1.2	1.0	0.94	0.96
CGA-107955	0.99	1.3	0.95	1.0	1.1	0.95
CGA-37734	0.99	1.0	1.2	1.0	0.97	0.96
CGA-94689	0.99	0.72	0.84	0.99	0.74	0.74

¹ - Values represent average of duplicate samples and are converted for procedural recoveries.

The petitioner claims that the apparent decline in residues observed for metabolite CGA-94689 does not mean that that metabolite is unstable in those commodities. They conclude that the decline is due to experimental deviation for three reasons: residues of CGA-94689 show no decline over a 12-month period in strawberries and apples, residues did not decline between the 6th month and 12th month measurements, and there was a "low accountability" of the metabolite by the method (average recovery was 30%).

CBTS concludes that this study shows that metalaxyl residues in frozen lettuce are not stable over a 12-month storage interval. We do not agree with the petitioner's assessment that the decline in residues over a 12-month period for the metabolite CGA-94689 is due to experimental uncertainty. The stability of the chemical in fruits does not necessarily imply the same stability in leafy vegetables. Also, the metabolites CGA-107955 and CGA-37734 were observed to be stable in lettuce notwithstanding the "low accountability" of the method for their detection (47% and 61%, respectively).

However, the decline may be described as a limited decline, meaning that correction factors may be applied to the residue data. As is discussed in the 6/17/87 Registration Standard, in two lettuce metabolism studies CGA-94689 accounted for 24.1% (7-day PHI) and 29.1% (14-day PHI) of the total identified residue.¹ A decline of approximately 30% in CGA-94689 residues over 12 months (as seen in the cabbage study) would thus correspond to apparent residue levels 9% lower than existed at harvest. If we assume that the rate of decline is constant from 12 months to 15 months, we can estimate the correction factor to be $(9\% \times 1.25 =) 11.25\%$. The impact of this correction on the residue data submitted for this petition and the adequacy of the proposed tolerance will be discussed below. CBTS concludes that the storage stability data are adequate for this study.

Application of this correction factor to the observed residue values shows that for application of 1x the recommended rate, the maximum residue levels are 4.7 ppm (7 day PHI) or 4.4 ppm (14 day PHI) for head lettuce, 4.2 ppm (5 day PHI) for leaf lettuce, and 2.3 ppm (5 day PHI) for celery (also see the discussion of Deficiency 5b, below). These residues are within the proposed 5 ppm tolerance for the leafy vegetable (except Brassica and spinach) group.

- **Deficiency 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

¹ - Test 1: MRID# 114379. 87.7% of the activity was recovered; 45.2% was identified; 10.9% was CGA-94689. Test 2: MRID# 71608. 76.0% of the activity was identified; 22.1% was CGA-94689.

need to propose alternate 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.

Petitioner's Repsonse. The petitioner has responded to this deficiency in two parts. The first part addresses the lack of residue data reflecting the foliar use of **Ridomil 2E**. "As part of CIBA-GEIGY's resistance management program for metalaxyl, foliar applications are not labeled, except in a couple of special situations, for **Ridomil 2E Fungicide**. It is not CIBA-GEIGY's intention to label **Ridomil 2E** alone for foliar application to leafy vegetables. Such a practice would be contrary to our resistance policy. Therefore, additional residue data reflecting foliar applications of **Ridomil 2E** are not justified because **Ridomil 2E** will not be labeled for foliar applications. This plan is reflected in the labels that were submitted with this petition.

"The confusion stems from the inclusion in the Section B of a foliar application of **Ridomil 2E**, rather than **MZ58**. This circumstance stems from an assumption on our part that was incorrect. To alleviate this confusion, a revised Section B is enclosed which more correctly reflects the use pattern utilized in the residue trials." (Emphasis is the petitioner's.)

This revised Section B now calls for foliar application of 0.87-1.16 lbs ai/A of a mancozeb/metalaxyl mixture in a 4.8:1 ratio, whereas the previous label had called for foliar application of metalaxyl alone.

The second part interprets our statement "Based on the variability of the residue data submitted thus far, a crop group tolerance may not be appropriate" as stemming from the statement located in the body of the review, "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 for 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."

CIBA-GEIGY states, "The highest metalaxyl residue observed in celery was from a California trial, 02-FR-006-89, which encountered a series of adverse conditions, including extremely high temperatures that caused significant leaf burn. This circumstance was documented in the Field Procedures section of ABR-89113. For all practical purposes, this field test should be considered invalid owing to extreme weather conditions, which resulted in a celery crop that was undersized and of unmarketable quality. Therefore, excluding the maximum 1X residue (11 ppm) observed in one of four California celery tests, the maximum 1x celery residue was 2.1 ppm, which is within the proposed 5 ppm group tolerance."

CBTS's Response. CBTS concludes that the revised Section B, which no longer indicates foliar application of **Ridomil 2E** alone, is consistent with the use patterns exhibited in the residue trials. However, CBTS finds that the label still contains deficiencies. Specifically, the label currently implies that application of mancozeb to leafy vegetables is legal, whereas there is only one leafy vegetable crop, celery, for which there is a tolerance (5 ppm). In addition, a Special

Review was initiated for mancozeb and the other EBDC fungicides on 7/10/87. The PD 2/3 Preliminary Determination (54 FR 52158, published 12/20/89) proposed cancellation of use of mancozeb on celery and other crops. Cancellation of mancozeb tolerances on all crops was later proposed in 55 FR 20416 (5/16/90). The PD 4 Final Determination will be published 12/91. Since there are no tolerances for mancozeb on all other non-Brassica leafy vegetables besides celery, the petitioner must submit a revised Section B which does not include foliar application of the mancozeb/metalaxyl mixture on those crops. Furthermore, if the Agency finalizes the revocation of all mancozeb tolerances, the petitioner will have to remove foliar application of the mancozeb/metalaxyl mixture on celery as well.

With regards to the residue value from trial 02-FR-006-89, the petitioner has included in the Field Procedures report the average temperatures for January - June of 1989. Temperatures in June averaged 77.0 °F, 2 degrees above normal. Harvest of the crop was in mid-July. CBTS obtained data² which showed that the average temperature in Fresno County, where the test was conducted, in July 1989 was 82.4 °F (average high 99.2 °F, maximum 107 °F). According to Considine³, "Celery plants will tolerate considerable heat after they are established in the field, but during the last month or so preceding harvest, temperatures should average no more than 60 to 70 °F." This is confirmed by a USDA Cooperative Extension specialist⁴ who stated (telecon, 12/6/91) that "a few days above 85 degrees will make the celery pithy or spongy and it will have no value". He further explained that it was unusual to grow celery in that region of California, because of the high temperatures, and if celery was grown there, it would normally be harvested by the beginning of June.

CBTS concludes that the late harvest and high temperatures for trial 02-FR-006-89 do not represent normal conditions for growing celery, that the celery grown under these conditions would be unusable, and that any field trial results obtained under those conditions would be invalid. Therefore, the residue values for use of 1x the label rate of **Ridomil 5G** on celery range from 0.19-2.1 ppm. CBTS further concludes that the residue data support the proposed crop group tolerance of 5 ppm for metalaxyl on leafy vegetables (except Brassica, except spinach).

cc: R. Lascola, PP#0F3893, RF, SF, RS (metalaxyl), C. Furlow (PIB/FOD), Circ, R.S. Quick.

RDI: P.V. Errico: 12/17/91; R. Loranger:12/17/91.

H7509C:CBTS/HED:CM#2, Rm803C: R. Lascola/rjl,305-7478:12/12/91

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² - From National Climatic Data Center, (704) 259-0682.

³ - Considine and Considine, Foods and Food Production Encyclopedia (1982).

⁴ - Dr. Vincent Rubatzky, UC-Davis: (916) 752-1247.

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of
Document



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

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JUN 21 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

FROM : Shanaz Bacchus, Chemist *Shanaz Bacchus*
Tolerance Support Section III
Chemistry Branch I
Health Effects Division (H7509 C)

THRU: Richard D. Schmitt, Ph. D., Chief *Richard D. Schmitt*
Tolerance Support - Chemistry Branch I
Health Effects Division (H7509 C)

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 high 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 ¹⁴C-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 ¹⁴C-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 crops. 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 $86.5 \pm 12.4\%$, 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:

	<u>Range (%)</u>	<u>Mean + SD (%)</u>
leaf lettuce ¹	59-104	89.92±13.52 ⁿ⁼¹⁴
celery	63-128	91.9±18.6 ⁿ⁼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(2²), 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 1).

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

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 reprepared 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.

Attachment 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.L. 5/24/91

Attachment: 1

Page 1 of 1

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL metolaxy/ (Ridomil 2E)
" " 59

CODEX NO. 138

CODEX STATUS:

No Codex Proposal
Step 6 or Above

PROPOSED U.S. TOLERANCES:

Petition No. DF 03893

DEB Reviewer Shanaz Baccus

Residue (if Step 8): _____

Metolaxy/ per se

Residue: Metolaxy/ and metabolites containing 2,6-dimethyl aniline moiety and N-(2-hydroxy methyl)-6-methyl-N-(methylacetyl)-alanine methyl ester expressed as metolaxy/

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

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

CANADIAN LIMITS:

No Canadian Limit (on above)

Residue: _____

MEXICAN LIMITS:

No Mexican Limit

Residue: _____

<u>Crop(s)</u>	<u>Limit (mg/kg)</u>
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<u>Crop(s)</u>	<u>Limit (mg/kg)</u>
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NOTES

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

TP53
1631

3037

Freedom of Information Section, Field Operations Division (H7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to: Rm. 246, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202.

Information submitted as a comment concerning this notice may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 246 at the address given above, from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Registration Division (H-7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, contact the PM named in each petition at the following office location/telephone number:

Product Manager	Office location/telephone number	Address
George LaRocca (PM 15).	Rm. 204, CM #2, 703-557-2400.	1921 Jefferson Davis Hwy., Arlington, Va.
Bill Miller (PM 16).	Rm. 211, CM #2, 703-557-2600.	Do.
Susan Lewis (PM 21).	Rm. 227, CM #2, 703-557-1900.	Do.
Rober Taylor (PM 25).	Rm. 245, CM #2, 703-557-1600.	Do.

[PF-541; FRL-3341-6]

Pesticide Tolerance Petitions; Initial Filings and Withdrawals

AGENCY: Environmental Protection Agency (EPA).
ACTION: Notice.

SUMMARY: This notice announces initial filings and withdrawals for pesticide petitions (PP) proposing the establishment of regulations for residues of certain pesticide chemicals in or on various agricultural commodities.

ADDRESSES: By mail, submit written comments to: Public Docket and

SUPPLEMENTARY INFORMATION: EPA has received pesticide petitions as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemicals in or on various agricultural commodities. EPA has also received as follows certain requests to withdraw without prejudice to future filings certain previously filed pesticide petitions.

Initial Filings

1. PP 0F3872. Du Pont, Agricultural Products, P.O. Box 80038, Walker's Mill, Barley Mill Plaza, Wilmington, DE 19880-0038, proposes to amend 40 CFR part 180 by establishing a regulation for

a tolerance to permit residues of the herbicide thifensulfuron in or on field corn grain at 0.05 part per million (ppm) and field corn forage and fodder at 0.1 ppm. (PM 25)

2. *PP 0F3876*. Rhom and Haas Co., Independence Mall West, Philadelphia, PA 19105, proposes to amend 40 CFR 180.443 by establishing a regulation to permit combined residues of myclobutanil, [alpha-butyl-alpha-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanetrile], and both the free and bound forms of its metabolite, [alpha-(3-hydroxybutyl)-alpha-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanetrile], in or on almond hulls at 2.0 ppm and almond nuts at 0.1 ppm. (PM 21)

3. *PP 0F3878*. Rhone-Poulenc Ag Co., P.O. Box 12014, TW Alexander Drive, Research Triangle Park, NC 27709, proposes to amend 40 CFR 180.415 by establishing a regulation to permit residues of the fungicide aluminum tris (O-ethylphosphonate) in or on strawberries at 20 ppm. Analytical method used is flame photometric gas chromatography. (PM 21)

4. *PP 0F3880*. Merck Sharpe & Dohme, Merck & Co., Inc., Hillsboro Rd., Three Bridges, NJ 08807, proposes to amend 40 CFR 180.449 by establishing a regulation to permit residues of abamectin in or on strawberries at 0.02 ppm. Analytical method used is high-performance liquid chromatography. (PM 15)

5. *PP 0F3890*. ICI Americas, Inc., Concord Pike and New Murphy Rd., Wilmington, DE 19887, proposes to amend 40 CFR part 180 by establishing a regulation to permit combined residues of n-phosphonomethyl glycine (carboxymethylamine methyl phosphonate) and its metabolite AMPA resulting from application of the trimethylsulfonium salt in or on citrus fruits at 0.5 ppm. (PM 25)

6. *PP 0F3888*. Ciba-Geigy Corp., Agricultural Products, P.O. Box 18300, Greensboro, NC 27419-8300, proposes to amend 40 CFR 180.406 by establishing a regulation to permit combined residues of metalaxyl, N-(2,6-dimethylphenyl)-N-(methoxyacetyl) aniline methyl ester, and its metabolites in or on leafy vegetables (excluding Brassica vegetables) and spinach at 5.0 ppm. (PM 21)

7. *PP 0F3894*. Mobay Corp., Agricultural Chemicals Corp., P.O. Box 4913, Kansas City, MO 64120, proposes to amend 40 CFR 180.349 by establishing a regulation to permit combined residues of nemacur, ethyl 3-methyl-4-(methylthio)phenyl(1-methylthio)phosphoramidate, and its cholinesterase-inhibiting metabolites, in or on broccoli and cauliflower at 0.1 ppm. (PM 16)

Withdrawn Petitions

1. *PP 4F3121*. American Cyanamid, P.O. Box 400, Princeton, NJ 08540, has withdrawn without prejudice *PP 4F3121*, which proposed to establish a tolerance in 40 CFR 180.361 for the herbicide [N-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzeneamine] and its metabolites 4-[(1-ethylpropyl)-2-methyl-3,5-dinitrobenzyl alcohol in or on grapes at 0.1 ppm. (PM 25)

Original notice of this petition appeared in the Federal Register of October 17, 1984. (49 FR 40659).

2. *PP 6F3355*. Merck and Co., Inc., P.O. Box 2000 WBW-360, Rahway, NJ 07065, has withdrawn without prejudice *PP 6F3355*, which proposed to establish a tolerance in 40 CFR 180.242 for the fungicide thiabendazole (2-(4-thiazolyl)benzimidazole) in or on peanuts at 0.1 ppm and peanut hulls at 2.0 ppm.

Original notice of this petition appeared in the Federal Register of March 19, 1986 (51 FR 9514).

Authority: 7 U.S.C. 136a.

Dated: December 6, 1990.

Stephanie R. Irene,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 91-682 Filed 1-15-91; 8:45 am]

BILLING CODE 6560-60-F

1. PP#0E3893
2. Petitioner:
Ciba-Geigy
3. Pesticide:
Metalaxyl
4. Related Petition
5. Rec'd RD
6. Rec'd Chem. Br. 07/25/90
7. Tolerances Requested:
5.0 ppm - leafy vegetables
(excluding brassica
vegetables, excluding
spinach) crop grouping
8. Amendments and
Related Correspondence:
9. Filing Date: 10/25/90
10. F.R. Notice of Filing
11. Method Tryout:
12. Results of Tryout:
13. Anal. Standards Rec'd Chem. Br.:
14. Certif. of Usefulness (date
of letter to Company):
15. Deadlines: 45 days _____
90 days _____
16. Dute Date:
17. TOX Br. Recommendation
18. Petition Assigned to:
19. Chem. Br. Recommendation
20. Tolerances Established (F.R.)

END OF DOCUMENT



13544

R062930

Chemical:	Metalaxyl
PC Code:	113501
HED File Code	11500 Petition Files Chemistry
Memo Date:	08/06/2003
File ID:	DPD176810; DPD171050; DPD156811
Accession Number:	412-04-0144

HED Records Reference Center
06/29/2004