PP# 4105

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

MAR 21 1995

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM:

SUBJECT: *PP2F04105: Metalaxyl in or on Non-grass Animal Feeds (as Clover). Amendment Dated February 7, 1994.* **CBTS** #15086; **DP Barcode** #D211743; **No MRID #**

FROM: María Isabel Rodríguez, Chemist
Tolerance Petition Section III
Chemistry Branch I -- Tolerance Support
Health Effects Division (7509C)

María I. Rodríguez 3-20-1995

THROUGH: Edward Zager, Acting Chief
Chemistry Branch I -- Tolerance Support
Health Effects Division (7509C)

Edward Zager

TO: Jim Tompkins/Kathryn Scanlon
Product Management Team #21
Fungicide-Herbicide Branch
Registration Division (7505C)

and

Jane Smith, Acting Section Head
Registration Section
Risk Characterization and Analysis Branch
Health Effects Division (7509C)

The petitioner, Ciba Corporation, through a letter from Dr. Gregory R. Watson - Regulatory Manager, Ciba Corporation - dated February 7, 1994, is submitting revised Sections B and F for review as requested in CBTS Review #9625 (M.I. Rodríguez, 8-17-1993).

BACKGROUND:

In CBTS Review #9625, Ciba (then Ciba-Geigy) Corporation submitted an application requesting tolerances for the residues of the fungicide metalaxyl and its metabolites in/on the non-grass animal feeds group - forage - at 6.0 ppm - and hay - at

20.0 ppm. Alfalfa and clover are the representative commodities of the non-grass animal feeds (forage, fodder, straw and hay) group as defined under 40 CFR §180.34 (f)(9)(xviii)(A) and (B). Alfalfa already has a registered use and tolerances are established for forage (6 ppm) and hay (20 ppm). At that time, CBTS recommended against the proposed tolerances in/on the non-grass animal feeds group.

CONCLUSIONS/RECOMMENDATIONS:

Deficiencies associated with PP2F4105 have been resolved. TOXicological considerations permitting, CBTS recommends that the proposed tolerances in/on clover be established.

DISCUSSION:

In CBTS Review #9625 the petitioner was requested to submit the following information. The petitioner's comments to those questions/requests, as well as the CBTS's response to their comments, follow.

* Conclusions #6a and 6b:

6a. "Based on the systemic nature of metalaxyl and the greater than five-fold difference between the residues in alfalfa and clover hays (this submission), a crop group tolerance is not appropriate.

Alternatively, the petitioner could request individual tolerances for clover instead of a crop grouping expression. A tolerance of 1.0 ppm would be appropriate for clover, forage and a tolerance of 2.5 ppm would be appropriate for clover, hay with a PHI of 90 days."

6b. "Revised Sections B and F should be submitted for review. The revised Section B should limit use to clover (Alfalfa already has a registered use)."

- Petitioner's Response to Conclusions #6a and 6b:

The petitioner submitted a revised Section B, Supplemental Labeling, for Ridomil 2E Fungicide (EPA Reg. No. 100-607) for use on clover. A statement that reads: "Note: 1) To avoid possible illegal residues in clover, do not feed green forage or cut hay for 90 days following application." was added to the label.

The petitioner also submitted a revised Section F proposing tolerances for the residues of metalaxyl as indicated above in/on clover, forage at 1.0 ppm and clover, hay at 2.5 ppm.

The petitioner indicated that tolerances for alfalfa, forage (6.0 ppm) and alfalfa, hay (20.0 ppm) should remain as established.

- CBTS's Response:

The deficiencies indicated in Conclusions #6a and 6b are considered to be resolved.

* Other Considerations:

In CBTS Review #9625 we indicated that this is a 40 CFR §180.6(a)(2) situation with respect to secondary residues in meat and milk and that existing tolerances on meat, fat, and milk adequately cover residues expected the proposed use of metalaxyl on clover, hay and forage.

cc: MIRodríguez, PP#2F04105, Reading File, and Circulation.

RDI: RBPerfetti (3-17-95); RALoranger (3-20-95); EZager (3-20-95)
MIRodríguez: Draft (3-16-1995), Edited (3-20-1995).
Mail Code 7509C; Tel (703)-305-6710; CM #2, Rm 804-T.

PP#1015

CBTS # 15086
DP # D211743
Metalaxyl

Gregory R. Watson, Ph. D.
Ciba Plant Protection
Ciba-Geigy Corporation
PO Box 18300
Greensboro, NC 27419-8300
Telephone 910 632 2993
Telefax 910 292 6374

February 7, 1994

Document Processing Desk (PETN)
Office of Pesticide Programs - H7504C
U. S. Environmental Protection Agency
401 M. Street SW
Washington, D. C. 20460-0001

Attention: Mr. Sidney Jackson, Acting PM Team 21

Dear Mr. Jackson: PP 2F4105

SUBJECT: METALAXYL TECHNICAL (EPA REG. NO. 100-601) AND RIDOMIL® 2E (EPA REG. NO. 100-607); PP NO. 2F4105 NON-GRASS ANIMAL FEEDS CROP GROUPING: SUBMISSION OF REVISED SECTION B AND F, SUPPLEMENTAL LABELING

Please find enclosed revised supplemental labeling (5 copies), Section B and Section F (3 copies each) in association with PP No. 2F4105. We have revised this petition and labeling exactly as directed by Chemistry Branch I - Tolerance support in their August 17, 1993 review of this petition. The submission of these revised documents completes the data requirements in association with this petition and will allow Team 21 to proceed toward granting the requested metalaxyl tolerances in clover forage and hay. We respectfully submit that **review of the attached Section B and F is not required by CBTS** prior to granting of the requested tolerances as Ciba Plant Protection has altered the Section B and Section F **exactly as directed by CBTS.** Ciba Plant Protection believes that informal contact with the review team and management of CBTS is appropriate to arrange for a DRES run including the requested clover tolerances; completion of this DRES run will allow Team 21 to establish the clover tolerances requested in the revised Section F.

On February 17, 1992 Ciba Plant Protection submitted a petition requesting a Non-Grass Animal Feed Crop Grouping tolerance of 6.0 and 20.0 ppm in forage and hay, respectively. A Chemistry Branch I - Tolerance Support review of this PP No. 2F4105 dated August 17, 1993 stated that our request for a Non-Grass Animal Feeds Crop Grouping tolerance was not appropriate; the review gave the systemic nature of metalaxyl and the greater than 5-fold difference between the residues in alfalfa and clover hays (the representative crops for this crop grouping) as the rationale for denying this crop grouping request. This review continued to state that a tolerance of 1.0 and 2.5 ppm would be appropriate for clover forage and hay given the residue data provided in this petition: a PHI of 90 days for clover was also given as appropriate in the review. The review then stated that

a revised section B and F should be provided in this petition limiting the proposed use to clover with the stipulated 90 day PHI.

In summary, please find the following enclosed items:

❶ 5 copies of the supplemental label providing directions for use for Ridomil 2E (EPA Reg. No. 100-607) proposing use on clover including changes as directed by CBTS in their August 17, 1993 review of this petition. This label has been bolded to indicate changes in the enclosed labeling from that originally proposed in this petition.

❷ 3 copies of revised Sections B and F as directed by CBTS in their August 17, 1993 review of this petition. The enclosed Section B has been bolded to indicate changes in the enclosed labeling from that originally proposed in this petition.

❸ A copy of the initial filing of this petition in the Federal Register (item 17 in Initial Filings, Vol. 57, No. 112; dated June 10, 1992). **Please note that Federal Register filing of the amended tolerances requested in the enclosed Section F may be required before the requested tolerances can be established.**

❶ A copy of the supplemental labeling that was originally submitted in association with this petition; we hope that this will aid the review of the enclosed revised supplemental labeling.

Thank you for your consideration of these revised materials and our position that formal review of the revised Section B and Section F by CBTS is not required prior to establishment of the requested clover tolerances. We request that Team 21 file the amended tolerances in the Federal Register as soon as is possible to expedite the establishment of the metalaxyl tolerances in or on clover forage and hay. Please feel free to contact me at (910) 632-2993 if you have any questions concerning this petition or any other matter concerning metalaxyl that is pending at EPA.

Best Regards,

Gregory R. Watson, Ph.D.
Regulatory Manager

Enclosures

cc: Mr. Ben Chambliss, Team 21 (H7505C)

Revised

VOLUME 1 OF 1

TECHNICAL METALAXYL

EPA REG. NO. 100-601

PESTICIDE PETITION NO. 2F4105

PETITION FOR TOLERANCE IN NON-GRASS ANIMAL FEEDS CROP GROUPING:
ALTERED TO PETITION FOR TOLERANCE IN CLOVER

SECTIONS B AND F

DATE SUBMITTED: FEBRUARY 7, 1994

SUBMITTED BY
CIBA PLANT PROTECTION
CIBA-GEIGY CORPORATION
P. O. BOX 18300
GREENSBORO, NC 27419

SUPPLEMENTAL LABELING

RIDOMIL® 2E FUNGICIDE
EPA REG. NO. 100-607

FOR USE ON CLOVER

Active Ingredient:	
Metalaxyl: N-(2,6-dimethylphenyl)-N-(methoxyacetyl) alanine methyl ester	25.1%
Inert Ingredients:	74.9%
Total	100.0%

Ridomil 2E contains 2 lbs. active ingredient per gallon.

KEEP OUT OF REACH OF CHILDREN.

WARNING

AVISO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

All applicable directions, restrictions, and precautions on the EPA-registered Ridomil 2E label are to be followed.

This label must be in the possession of the user at the time of pesticide application.

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

FAILURE TO FOLLOW THE DIRECTIONS FOR USE AND PRECAUTIONS ON THIS LABEL MAY RESULT IN POOR DISEASE CONTROL, CROP INJURY AND/OR ILLEGAL RESIDUES.

General Information

Ridomil 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.

Clover

Ridomil 2E applied to the soil at planting will provide control of damping-off caused by Pythium spp. and root rots caused by Phytophthora spp.

Stand Establishment

Apply 1 to 2 pts./A as a broadcast surface spray at planting in a minimum of 20 gals. of water or following impregnation on fertilizer.

If seed was previously treated with metalaxyl as a seed dressing, an application of Ridomil 2E at 1 pt./A is recommended at planting. Use the higher rate (2 pts./A) in areas where disease pressure is expected to be heavy.

Note: **1) To avoid possible illegal residues in clover, do not feed green forage or cut hay for 90 days following application.**

Rotation (Plantback Restrictions)

Do not plant any crop which is not registered for use with metalaxyl in metalaxyl-treated soil for a period of 12 months, with the exception of wheat, barley and oats. See list below.

Rotation Crop	Planting Time from Ridomil 2E Application
Alfalfa (inc. birdsfoot trefoil)	- 0 - days
Almonds	- 0 - days
Apples	- 0 - days
Asparagus	- 0 - days
Avocados	- 0 - days
Blueberries	- 0 - days
Broccoli	- 0 - days
Cabbage	- 0 - days
Cauliflower	- 0 - days
Chinese Broccoli (gai lon, white flowering broccoli)	- 0 - days
Chinese Cabbage (tight-heading varieties only)	- 0 - days
Citrus	- 0 - days
Clover	**- 0 - days**
Cotton	- 0 - days
Cranberries	**- 0 - days**
Cucurbit Vegetables	- 0 - days
Deciduous Fruits and Nuts*	- 0 - days
Eggplant	- 0 - days
Ginseng	**- 0 - days**
Head Lettuce	- 0 - days
Hops	- 0 - days
Legume Vegetables	- 0 - days
Onions	- 0 - days
Papayas	- 0 - days
Peanuts	- 0 - days
Peppers	- 0 - days
Pineapples	- 0 - days
Potatoes	- 0 - days
Raspberries	- 0 - days
Root and Tuber Vegetables	- 0 - days
Soybeans	- 0 - days
Spinach	- 0 - days
Stone Fruits	- 0 - days
Strawberries	- 0 - days
Sugar Beets	- 0 - days
Tobacco	- 0 - days
Tomatoes	- 0 - days
Walnuts	- 0 - days
Wheat, Barley, Oats	14 days
Corn	12 months
Crops Not Intended for Food or Feed	- 0 - days
All Other Crops Intended for Food or Feed	12 months

* These crops and other perennial crops may be planted immediately following last application of Ridomil 2E provided they will not bear harvestable fruit within 12 months.

Ridomil® trademark of Ciba-Geigy Corporation
U.S. Patent No. 4,151,299

Ciba Plant Protection
Ciba-Geigy Corporation
Greensboro, NC 27419

CGA

February 7, 1994

SECTION F

TECHNICAL METALAXYL

PROPOSED TOLERANCES

We hereby request tolerances for the combined residues of the fungicide metalaxyl [N--(2,6-dimethylphenyl)-N-(methoxyacetyl)alanine methyl ester] and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methylphenyl)-N-(methoxyacetyl) alanine methyl ester, each expressed as metalaxyl equivalents, in or on the following:

Commodity	Proposed Tolerance
Clover, forage	1.0 ppm
Clover, hay	2.5 ppm

(Ciba Plant Protection requests that when the current 6.0 and 20.0 ppm alfalfa, forage and alfalfa, hay tolerances remain as established).

February 7, 1994

DP# 176861, D# 211743

Please read Instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 11-30-93

(A) EPA

United States Environmental Protection Agency
Office of Pesticide Programs (H7505C)
Washington, DC 20460

Application for Pesticide:

- [ ] Registration
- [x] Amendment
- [ ] Other

OPP Identifier Number: 157521

Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
100-607	Lewis	
4. Company/Product (Name)	PM#	[ ] None [ ] Restricted
Ridomil® 2E Fungicide	21	

5. Name and Address of Applicant *(Include ZIP Code)*

CIBA-GEIGY Corporation
Agricultural Division
P. O. Box 18300
Greensboro, NC 27419

[ ] *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No.__________

Product Name__________

Section II

- [ ] Amendment - Explain below
- [ ] Resubmission in response to Agency letter dated______
- [ ] Notification - Explain below.
- [ ] Final printed labels in response to Agency letter dated______
- [ ] "Me Too" Application.
- [ ] Other - explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Add Directions for Use for Non-Grass Animal Feeds Crop Grouping.

Section III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes* [ ] No	[ ] Yes [ ] No	[ ] Yes [ ] No	[ ] Metal [ ] Plastic [ ] Glass [ ] Paper [ ] Other (Specify)____
*** Certification must be submitted.**	If "Yes," Unit Package wgt. / No. per container	If "Yes," Package wgt. / No. per container	

3. Location of Net Contents Information	4. Size(s) of Retail Container	5. Location of Label Directions
[ ] Label [ ] Container		[ ] On Label [ ] On Labeling accompanying product

6. Manner In Which Label Is Affixed To Product: [ ] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other (______)

Section IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Karen S. Stumpf	Senior Regulatory Manager	919-632-2169

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature	3. Title
Karen S. Stumpf	Senior Regulatory Manager
4. Typed Name	5. Date
Karen S. Stumpf	2/17/92 Original Date

6. Date Application Received (Stamped)

CIBA-GEIGY

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

February 17, 1992 Original Letter

Document Processing Desk (PETN)
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: PP2F4102

SUBJECT: METALAXYL TECHNICAL - EPA REG. NO. 100-601
PETITION FOR TOLERANCES IN THE NONGRASS ANIMAL FEEDS CROP GROUPING
APPLICATION FOR AMENDED REGISTRATION
RIDOMIL® 2E FUNGICIDE - EPA REG. NO. 100-607

CIBA-GEIGY hereby requests that 40CFR180.408 be amended by establishing tolerances for the combined residues of metalaxyl and its metabolites in or on members of the Nongrass Animal Feeds Crop Grouping. Submitted simultaneously with this petition is an application for amended registration for Ridomil 2E Fungicide - EPA Reg. No. 100-607 - to allow soil application of 1-2 pts./A to all members of the aforementioned crop grouping for control of Pythium damping- off caused by Pythium spp. and root rots caused by Phytophthora spp.

Currently, Ridomil 2E is registered for use on alfalfa, one of the representative commodities of the Nongrass Animal Feeds group. Tolerances for residues of metalaxyl and its metabolites have previously been established in alfalfa forage at 6.0 ppm and alfalfa hay at 20.0 ppm. Data supporting these tolerances can be located under EPA MRID No. 40832901. The data enclosed in Volume 2 of 2 of this submission presents results of residue trials conducted in clover, the other representative commodity needed to support a crop grouping tolerance. Results of the clover trials coupled with the data previously supplied for alfalfa indicate that tolerances of 6.0 ppm in nongrass animal feeds forage and 20.0 ppm in nongrass animal feeds hay are appropriate for the crop grouping. For additional discussion on rates used in the clover trials and proposed Ridomil 2E label rates, please see the Introduction section of the Section G of the petition.

Tolerances for residues of metalaxyl and its metabolites have previously been established in a number of fruit and vegetable

crops, soybeans, cotton, hops, peanuts, walnuts and almonds. Tolerances have also been established for inadvertent residues of metalaxyl and its metabolites in wheat, barley and oat commodities as a result of rotation to these crops from a metalaxyl-treated target crop. Establishment of tolerances for metalaxyl in grapes (PP6F3362), ginseng (IR-4 PP1E3926), leafy vegetables (PP0F3893), cranberries (IR-4, PP1E4024), cole crops (PP2F4072), grasses (PP2F4063) and revised tolerances in cereal grains (PP1F3993) are pending.

As previously stated, tolerances have already been established for residues of metalaxyl and its metabolites in alfalfa. Because the Nongrass Animal Feeds Crop Grouping tolerances will cover residues in alfalfa, CIBA-GEIGY requests that the Agency withdraw the alfalfa tolerances upon establishment of the crop group tolerance.

Enclosed are three copies of a petition proposing establishment of the following tolerances for metalaxyl and its metabolites:

Raw Agricultural Commodity	Proposed Tolerance
Nongrass animal feeds forage	6.0 ppm
Nongrass animal feeds hay	20.0 ppm

xviii p. 297

Residue data supporting the proposed tolerances can be located in Volume 2 of 2 of the data accompanying this submission and also under EPA MRID No. 40832901 (alfalfa).

The safety of the proposed tolerance is demonstrated in previously submitted toxicology studies referenced in Section C of the petition. A no-observable effect level (NOEL) of 250 ppm (6.25 mg/kg/day) has been established from the results of a six month subchronic feeding study in beagle dogs with Metalaxyl Technical. Using a 100:1 safety factor and 250 ppm as the NOEL, the reference dose (Rfd) is calculated to be 0.0625 mg/kg bwt/day (rounded off to 0.06 mg/kg bwt/day). The theoretical maximum residue contribution from previously established tolerances is equal to 0.010533 mg/kg bwt/day and utilizes only 17.55 percent of the reference dose (FR, Vol. 58, No. 103, P. 24160). The substitution of a crop grouping tolerance for the alfalfa tolerances should not result in an increase in the TMRC and the percent of the Rfd utilized as these crops are not consumed directly by humans, but through animal products. Established tolerances for metalaxyl and its metabolites in animal products are adequate to cover the feeding of the nongrass commodities to beef and dairy cattle.

Enclosed are the following materials to further support this petition:

1. Three copies of the pesticide petition

2. A releaseable summary of the data submitted today in accordance with 40CFR152.50(c).

3. An application for amended registration for Ridomil 2E which includes the following:

   Five copies of proposed labeling

   A completed EPA Form 8570-1 - Application for Amended Registration

   A completed Certification with Respect to Citation of Data Form along with lists of data requirements according to 40CFR, Part 158 and citations of data previously submitted by CIBA-GEIGY for Metalaxyl Technical and Ridomil 2E which are applicable for evaluation of the proposed uses. CIBA-GEIGY is relying on the Selective Method for data support requirements.

An official check in the amount of $13,550 (Official check #2532533) has been forwarded simultaneously with a copy of this letter to the Headquarters Accounting Operations Branch in Pittsburgh in accordance with PR Notice 86-1 to cover petition fees.

Should you have any questions regarding the contents of the petition or the application for amended registration, please contact me at (919) 632-2169.

Thank you for handling this request.

Sincerely,

Karen S. Stumpf

Karen S. Stumpf
Senior Regulatory Manager
Regulatory Affairs

Enclosures

VOLUME 1 OF 2 OF SUBMISSION

TRANSMITTAL DOCUMENT

1) NAME AND ADDRESS OF SUBMITTER:

422268-00

AGRICULTURAL DIVISION
CIBA-GEIGY CORPORATION
POST OFFICE BOX 18300
GREENSBORO, NC 27419

2) REGULATORY ACTION:

METALAXYL TECHNICAL - EPA REG. NO. 100-601
PETITION FOR TOLERANCE IN THE NON-GRASS ANIMAL FEEDS CROP GROUPING

3) TRANSMITTAL DATE:

FEBRUARY 10, 1992

4) LIST OF SUBMITTED STUDIES:

MRID NUMBER	VOLUME NUMBER	STUDY TITLE	GUIDELINE REFERENCE
	1 OF 2	TRANSMITTAL DOCUMENT	N/A
42226801	2 OF 2	METALAXYL-MAGNITUDE OF RESIDUES IN CLOVER FORAGE AND HAY FOLLOWING APPLICATION OF RIDOMIL 2E - ABR-91030	171-4 (K)

5) COMPANY OFFICIAL: KAREN S. STUMPF Karen S. Stumpf
NAME SIGNATURE

6) COMPANY NAME: AGRICULTURAL DIVISION, CIBA-GEIGY CORPORATION

7) COMPANY CONTACT: KAREN S. STUMPF 919-632-2169
NAME PHONE

CAB # [illegible]
D# 211743

Original Sect A-G

Metalaxyl

VOLUME 1 OF 1

TECHNICAL METALAXYL

EPA REG. NO. 100-601

PETITION FOR TOLERANCE IN THE NON-GRASS ANIMAL FEEDS CROP GROUPING

CONTENTS: SECTIONS A-G

DATE SUBMITTED: FEBRUARY 17, 1992

AGRICULTURAL DIVISION
CIBA-GEIGY CORPORATION
POST OFFICE BOX 18300
GREENSBORO, NC 27419

[AGVALDM.VOLUME]V501MA1206KS

SECTION A

GENERAL CHEMISTRY

General chemistry data for Metalaxyl Technical (EPA Reg. No. 100-601), common name for the active ingredient in Ridomil® 2E Fungicide (EPA Reg. No. 100-607) and general chemistry data for Ridomil 2E are hereby referenced on the following pages.

February 17, 1992

DATA REQUIREMENT FOR THE SELECTIVE METHOD OF SUPPORT

1. PRODUCT NAME: Technical Metalaxyl	2. EPA REG. NO./FILE SYMBOL 100-601	3. FORMULATOR'S EXEMPTION SELECTED: YES ___ NO _X_	4. PAGE 1 OF 2
5. APPLICANT'S NAME AND ADDRESS: Agricultural Division CIBA-GEIGY Corporation Post Office Box 18300 Greensboro, NC 27419	6. APPLICATION FOR REGISTRATION DATE: / / (MO DAY YR)	7. NAME OF ACTIVE INGREDIENT(S): Metalaxyl	

8. DATA REQUIREMENTS		9. SOURCE OF DATA SATISFYING REQUIREMENT						10.
8a. REGULATION PART 158/ GUIDELINE NUMBER	8B. NAME OF TEST	9a. SUBMITTED BY APPLICANT	9b. DATE SUBMITTED	9c. SUBMITTED BY ANOTHER PERSON/FIRM (NAME)	9d. PERMISSION LETTER ENCLOSED	9e. PUBLIC LITERATURE	9f. N.A. OR WAIVER OR OTHER (EXPLAIN)	MRID NUMBER EPA ACCESSION NUMBER OR OTHER EPA IDENTIFYING NUMBER
§158.120	*PRODUCT CHEMISTRY*							
61-1	Identity of ingredients	Citing	6/30/78	No				234427 41912901
61-2	Statement of composition	Citing	4/3/89	No				41055201 41912901
61-3	Discussion of formation of ingredients	Citing	4/3/89	No				41055201 41912901
62-1	Preliminary analysis	Citing	4/3/89	No				41055202
62-2	Certification of limits	Citing	4/3/89	No				41055202 41912901
62-3	Analytical methods for enforcement limits	Citing	4/3/89	No				41055202
63-2	Color	Citing	6/30/78	No				234427
63-3	*Physical state*	Citing	6/30/78	No				234427
63-4	Odor	Citing	6/30/78	No				234427
63-5	Melting point	Citing	6/30/78	No				234427
63-6	Boiling point	Citing	6/30/78	No				234427
63-7	Density, bulk-density, or specific gravity	Citing	6/30/78	No				234427

[CENTERB-DOC.DATA-MATRIX]MATRIX-601-TECH

DATA REQUIREMENT FOR THE SELECTIVE METHOD OF SUPPORT

1. PRODUCT NAME: Technical Metalaxyl	2. EPA REG. NO./FILE SYMBOL 100-601	3. FORMULATOR'S EXEMPTION SELECTED: YES ___ NO _X_	4. PAGE 2 OF 2
5. APPLICANT'S NAME AND ADDRESS: Agricultural Division CIBA-GEIGY Corporation Post Office Box 18300 Greensboro, NC 27419	6. APPLICATION FOR REGISTRATION DATE: / / (MO DAY YR)	7. NAME OF ACTIVE INGREDIENT(S): Metalaxyl	

8. DATA REQUIREMENTS		9. SOURCE OF DATA SATISFYING REQUIREMENT						10.
8a. REGULATION PART 158/ GUIDELINE NUMBER	8B. NAME OF TEST	9a. SUBMITTED BY APPLICANT	9b. DATE SUBMITTED	9c. SUBMITTED BY ANOTHER PERSON/FIRM (NAME)	9d. PERMISSION LETTER ENCLOSED	9e. PUBLIC LITERATURE	9f. N.A. OR WAIVER OR OTHER (EXPLAIN)	MRID NUMBER EPA ACCESSION NUMBER OR OTHER EPA IDENTIFYING NUMBER
§158.120	PRODUCT CHEMISTRY (Continued)							
63-8	Solubility	Citing	6/30/78	No				2 3 4 4 2 7
63-9	Vapor pressure	Citing	6/30/78	No				2 3 4 4 2 7
63-10	Dissociation constant	Citing	6/30/78	No				2 3 4 4 2 7
63-11	Octanol/water partition coefficient	Citing	3/17/82	No				*
63-12	pH	Citing	3/17/82	No				*
63-13	Stability	Citing	6/30/78	No				2 3 4 4 2 7
63-14	Oxidizing/reducing reaction	Citing	3/17/82	No				*
63-15	Flammability	Citing	3/17/82	No				*
63-16	Explodability	Citing	3/17/82	No				*
63-17	Storage stability	Citing	3/17/82	No				*
63-18	Viscosity						N.A. (2)	
63-19	Miscibility						N.A. (3)	
63-20	Corrosion characteristics	Citing	3/17/82	No				*
63-21	Dielectric breakdown voltage						N.A. (4)	

*Letter to H. Jacoby dated 3/17/82.
(2) Product not a liquid.
(3) Product not an emulsifiable liquid.
(4) Not required on technical.

[CENTERB-DOC.DATA-MATRIX]MATRIX-601-TECH

DATA REQUIREMENT FOR THE OWNER SUBMISSION METHOD OF SUPPORT

1. PRODUCT NAME: Ridomil® 2E	2. EPA REG. NO./FILE SYMBOL: 100-607	3. FORMULATOR'S EXEMPTION SELECTED: YES ___ NO X	4. PAGE 1 OF 3
5. APPLICANT'S NAME AND ADDRESS: Agricultural Division CIBA-GEIGY Corporation P. O. Box 18300 Greensboro, NC 27419	6. APPLICATION FOR REGISTRATION DATE: / / MO DAY YR	7. NAME OF ACTIVE INGREDIENT(S): Metalaxyl	

8. DATA REQUIREMENTS		9. SOURCE OF DATA SATISFYING REQUIREMENT						10.
8a. REGULATION PART 158/ GUIDELINE NUMBER	8b. NAME OF TEST	9a. SUBMITTED BY APPLICANT	9b. DATE SUBMITTED	9c. SUBMITTED BY ANOTHER PERSON/FIRM (NAME)	9d. PERMISSION LETTER ENCLOSED	9e. PUBLIC LITERATURE	9f. N.A. OR WAIVER OR OTHER (EXPLAIN)	MRID NUMBER EPA ACCESSION NUMBER OR OTHE EPA IDENTIFYIN NUMBER
§158.20	PRODUCT CHEMISTRY							
61-1	Identity of ingredients	Citing	2/23/83	No				2 4 9 6 1 3
61-2	Statement of composition	Citing	2/23/83	No				2 4 9 6 1 3
61-3	Discussion of formation of ingredients	Citing	2/23/83	No				2 4 9 6 1 3
62-1	Preliminary analysis						N.A. (1)	
62-2	Certification of limits	Citing	2/23/83	No				2 4 9 6 1 3
62-3	Analytical methods for enforcement limits	Citing	6/30/78	No				2 3 4 4 2 7
63-2	Color	Citing	2/23/83	No				2 4 9 6 1 3
63-3	Physical state	Citing	2/23/83	No				2 4 9 6 1 3
63-4	Odor	Citing	2/23/83	No				2 4 9 6 1 3
63-5	Melting point		2/23/83	No			N.A. (2)	*
63-6	Boiling point	Citing	2/23/83	No				2 4 9 6 1 3
63-7	Density, bulk-density, or specific gravity	Citing	2/23/83	No				2 4 9 6 1 3

(1) Not produced by an integrated formulation system; technical is registered.
(2) Not required for end-use product.

DATA REQUIREMENT FOR THE OWNER SUBMISSION METHOD OF SUPPORT

1. PRODUCT NAME: Ridomil® 2E	2. EPA REG. NO./FILE SYMBOL: 100-607	3. FORMULATOR'S EXEMPTION SELECTED: YES ___ NO X	4. PAGE 2 OF 3
5. APPLICANT'S NAME AND ADDRESS: Agricultural Division CIBA-GEIGY Corporation P. O. Box 18300 Greensboro, NC 27419	6. APPLICATION FOR REGISTRATION DATE: ___/___/___ MO DAY YR	7. NAME OF ACTIVE INGREDIENT(S): Metalaxyl	

8. DATA REQUIREMENTS		9. SOURCE OF DATA SATISFYING REQUIREMENT						10.
8a. REGULATION PART 158/ GUIDELINE NUMBER	8b. NAME OF TEST	9a. SUBMITTED BY APPLICANT	9b. DATE SUBMITTED	9c. SUBMITTED BY ANOTHER PERSON/FIRM (NAME)	9d. PERMISSION LETTER ENCLOSED	9e. PUBLIC LITERATURE	9f. N.A. OR WAIVER OR OTHER (EXPLAIN)	MRID NUMBER EPA ACCESSION NUMBER OR OTHER EPA IDENTIFYING NUMBER
§158.20	PRODUCT CHEMISTRY (Continued)							
63-8	Solubility						N.A. (2)	
63-9	Vapor pressure	Citing	2/23/83	No				249613
63-10	Dissociation constant						N.A. (2)	
63-11	Octanol/water partition coefficient						N.A. (2)	
63-12	pH	Citing	2/23/83	No				249613
63-13	Stability						N.A. (2)	
63-14	Oxidizing/reducing reaction	Citing	2/23/83	No				249613
63-15	Flammability	Citing	2/23/83	No				249613
63-16	Explodability	Citing	2/23/83	No				249613
63-17	Storage stability	Citing	2/23/83	No				249613
63-18	Viscosity	Citing	2/23/83	No				249613
63-19	Miscibility	Citing	2/23/83	No				249613

(2) Not required for end-use product.

DATA REQUIREMENT FOR THE OWNER SUBMISSION METHOD OF SUPPORT

1. PRODUCT NAME: Ridomil® 2E	2. EPA REG. NO./FILE SYMBOL: 100-607	3. FORMULATOR'S EXEMPTION SELECTED: YES ___ NO X	4. PAGE 3 OF 3
5. APPLICANT'S NAME AND ADDRESS: Agricultural Division CIBA-GEIGY Corporation P. O. Box 18300 Greensboro, NC 27419	6. APPLICATION FOR REGISTRATION DATE: / / MO DAY YR	7. NAME OF ACTIVE INGREDIENT(S): Metalaxyl	

8. DATA REQUIREMENTS		9. SOURCE OF DATA SATISFYING REQUIREMENT						10.
8a. REGULATION PART 158/ GUIDELINE NUMBER	8b. NAME OF TEST	9a. SUBMITTED BY APPLICANT	9b. DATE SUBMITTED	9c. SUBMITTED BY ANOTHER PERSON/FIRM (NAME)	9d. PERMISSION LETTER ENCLOSED	9e. PUBLIC LITERATURE	9f. N.A. OR WAIVER OR OTHER (EXPLAIN)	MRID NUMBER EPA ACCESSION NUMBER OR OTHER EPA IDENTIFYING NUMBER
§158.20	PRODUCT CHEMISTRY (Continued)							
63-20 63-21	Corrosion characteristics Dielectric breakdown voltage	Citing	2/23/83	No			N.A. (3)	249613

(3) Not registered for use around electrical equipment.

SECTION B

AMOUNT, TIMING, AND FREQUENCY OF APPLICATION OF THE PESTICIDE METALAXYL TO MEMBERS OF THE NON-GRASS ANIMAL FEEDS CROP GROUPING

General Information

Metalaxyl 2E 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.

Alfalfa and Other Non-Grass Animal Feeds*

*Including velvetbean, clover, kudzu, lespedeza, lupine, sainfoin, trefoil, crown vetch, milk vetch.

Metalaxyl 2E applied to the soil at planting will provide control of damping-off caused by Pythium spp. and root rots caused by Phytophthora spp.

Stand Establishment

Apply 0.25-0.5 lb. a.i./A as a broadcast surface spray at planting in a minimum of 20 gallons of water or following impregnation on fertilizer.

If seed was previously treated with metalaxyl as a seed dressing, an application of Metalaxyl 2E at 0.25 lb. a.i./A is recommended at planting. Use the higher rate (0.5 a.i./A) in areas where disease pressure is expected to be heavy.

Note: To avoid possible illegal residues, do not feed green forage or cut for hay for 60 days following application.

Rotational Crops	Planting Time From Last Ridomil® Application
Non-Grass Animal Feeds	-0- Days

February 17, 1992

Note: See explanation in Section G, Introduction, Paragraph 4, regarding rate of metalaxyl recommended in this Section B.

SECTION C

FULL REPORTS OF INVESTIGATIONS MADE WITH RESPECT TO THE SAFETY OF THE PESTICIDE CHEMICAL

The following pages reference toxicology data previously submitted by CIBA-GEIGY on:

Metalaxyl Technical
Ridomil 2E Fungicide

February 17, 1992

DATA REQUIREMENT FOR THE SELECTIVE METHOD OF SUPPORT

1. PRODUCT NAME: Technical Metalaxyl	2. EPA REG. NO./FILE SYMBOL 100-601	3. FORMULATOR'S EXEMPTION SELECTED: YES ___ NO _X_	4. PAGE 1 OF 2
5. APPLICANT'S NAME AND ADDRESS: Agricultural Division CIBA-GEIGY Corporation Post Office Box 18300 Greensboro, NC 27419	6. APPLICATION FOR REGISTRATION DATE: / / (MO DAY YR)	7. NAME OF ACTIVE INGREDIENT(S): Metalaxyl	

8. DATA REQUIREMENTS		9. SOURCE OF DATA SATISFYING REQUIREMENT						10.
8a. REGULATION PART 158/ GUIDELINE NUMBER	8B. NAME OF TEST	9a. SUBMITTED BY APPLICANT	9b. DATE SUBMITTED	9c. SUBMITTED BY ANOTHER PERSON/FIRM (NAME)	9d. PERMISSION LETTER ENCLOSED	9e. PUBLIC LITERATURE	9f. N.A. OR WAIVER OR OTHER (EXPLAIN)	MRID NUMBER EPA ACCESSION NUMBER OR OTHER EPA IDENTIFYING NUMBER
§158.135	TOXICOLOGY							
81-1	Oral LD-50 - rat	Citing	6/30/78	No				2 3 4 4 2 8
81-2	Acute dermal LD-50	Citing	6/30/78	No				2 3 4 4 2 8
81-3	Acute inhalation LC-50 - rat		*					
81-4	Primary eye irritation - rabbit	Citing	6/30/78	No				2 3 4 4 2 8
81-5	Primary dermal irritation	Citing	6/30/78	No				2 3 4 4 2 8
81-6	Dermal sensitization	Citing	6/30/78	No				2 3 4 4 2 8
81-7	Acute delayed neurotoxicity - hen						N.A. (1)	
82-1	90-day feeding - rodent, non-rodent	Citing	6/30/78	No				2 3 4 4 2 8
82-2	21-day dermal	Citing	1/21/81	No				2 4 4 1 8 2
82-3	90-day dermal						N.A. (2)	
82-4	90-day (21-day if used in tobacco) inhalation - rat	Citing	6/10/82	No				2 7 4 6 6 1
82-5	90-day neurotoxicity - hen, mammal						N.A. (3)	

(1) Not an organic phosphate compound.
(2) Product not purpose fully applied to skin; no comparable exposure.
(3) Acute tests do not show neuropathy or neurotoxicity.
*Waived by Agency in review dated 5/10/91.

[CENTERB-DOC.DATA-MATRIX]MATRIX-601-TECH

DATA REQUIREMENT FOR THE SELECTIVE METHOD OF SUPPORT

1. PRODUCT NAME: Technical Metalaxyl	2. EPA REG. NO./FILE SYMBOL 100/601	3. FORMULATOR'S EXEMPTION SELECTED: YES ___ NO _X_	4. PAGE 2 OF 2
5. APPLICANT'S NAME AND ADDRESS: Agricultural Division CIBA-GEIGY Corporation Post Office Box 18300 Greensboro, NC 27419	6. APPLICATION FOR REGISTRATION DATE: / / (MO DAY YR)	7. NAME OF ACTIVE INGREDIENT(S): Metalaxyl	

8. DATA REQUIREMENTS		9. SOURCE OF DATA SATISFYING REQUIREMENT						10.
8a. REGULATION PART 158/ GUIDELINE NUMBER	8B. NAME OF TEST	9a. SUBMITTED BY APPLICANT	9b. DATE SUBMITTED	9c. SUBMITTED BY ANOTHER PERSON/FIRM (NAME)	9d. PERMISSION LETTER ENCLOSED	9e. PUBLIC LITERATURE	9f. N.A. OR WAIVER OR OTHER (EXPLAIN)	MRID NUMBER EPA ACCESSION NUMBER OR OTHER EPA IDENTIFYING NUMBER
§158.135	TOXICOLOGY (Continued)							
83-1	Chronic feeding - rodent, non-rodent	Citing	Multiple	No				*
83-2	Oncogenicity study - rat and mouse	Citing	Multiple	No				*
83-3	Teratogenicity - two species	Citing	Multiple	No				*
83-4	Reproduction - two-generation	Citing	4/15/81	No				070015
84-2	Gene mutation	Citing	Multiple	No				*
84-2	Chromosomal aberration	Citing	Multiple	No				*
84-4	Other mechanisms of mutagenicity	Citing	6/10/82	No				274661
85-1	General metabolism	Citing	10/22/90	No				41664501- 41664502
86-1	Domestic animal safety						N.A. (4)	

(4) Not required for this product.
*See attached list.
[CENTERB-DOC.DATA-MATRIX]MATRIX-601-TECH

Multiple Toxicology Citations:

Type of Study	EPA Accession/MRID No.	Submitted
Rat chronic feeding/ oncogenicity study	070767	8/13/81
	070768	8/13/81
	070769	8/13/81
Mouse chronic feeding/ oncogenicity study	247660	6/10/82
Teratogenicity - Rat	234428	6/30/78
- Rabbit	070012	4/15/81
- Rabbit	255994, 255939	12/05/84
- Rat	256380	1/23/85
Mutagenicity	234428	6/30/78
	247661	6/10/82
	260496	11/27/85
	263117	5/30/86
General metabolism	070018	4/15/81
	070800	4/21/82
	670836	5/10/82
	41664501-41664502	10/22/90

DATA REQUIREMENT FOR THE OWNER SUBMISSION METHOD OF SUPPORT

1. PRODUCT NAME: Ridomil® 2E	2. EPA REG. NO./FILE SYMBOL: 100-607	3. FORMULATOR'S EXEMPTION SELECTED: YES ___ NO X	4. PAGE 1 OF 1
5. APPLICANT'S NAME AND ADDRESS: Agricultural Division CIBA-GEIGY Corporation P. O. Box 18300 Greensboro, NC 27419	6. APPLICATION FOR REGISTRATION DATE: / / MO DAY YR	7. NAME OF ACTIVE INGREDIENT(S): Metalaxyl	

8. DATA REQUIREMENTS		9. SOURCE OF DATA SATISFYING REQUIREMENT						10.
8a. REGULATION PART 158/ GUIDELINE NUMBER	8b. NAME OF TEST	9a. SUBMITTED BY APPLICANT	9b. DATE SUBMITTED	9c. SUBMITTED BY ANOTHER PERSON/FIRM (NAME)	9d. PERMISSION LETTER ENCLOSED	9e. PUBLIC LITERATURE	9f. N.A. OR WAIVER OR OTHER (EXPLAIN)	MRID NUMBER EPA ACCESSION NUMBER OR OTHER EPA IDENTIFYING NUMBER
§158.135	TOXICOLOGY							
81-1	Acute oral LD-50, rat	Citing	2/23/83	No				2 4 9 6 1 4
81-2	Acute dermal LD-50	Citing	2/23/83	No				2 4 9 6 1 4
81-3	Acute inhalation LC-50, rat	Citing	2/23/83	No				2 4 9 6 1 4
81-4	Primary eye irritation, rabbit	Citing	2/23/83	No				2 4 9 6 1 4
81-5	Primary dermal irritation	Citing	2/23/83	No				2 4 9 6 1 4
81-6	Dermal sensitization	Citing	2/23/83	No				2 4 9 6 1 4

SECTION D

RESIDUE DATA

Residue data which identify and support the request for tolerances for metalaxyl and its metabolites in the Non-Grass Animal Feeds Crop Grouping are located in Volume 2 of 2 of the data accompanying this petition and under EPA MRID #40832901.

February 17, 1992

SECTION E

PRACTICAL METHODS FOR REMOVING RESIDUES THAT EXCEED ANY PROPOSED TOLERANCES

The data presented in Section D of this pesticide petition indicate that the residue tolerances proposed in Section F will not be exceeded when metalaxyl is used in accordance with the amount, frequency, and time of application proposed in Section B. If the proposed Directions for Use are not followed and excessive metalaxyl residues result, there is no economic or practical method for removing these residues.

February 17, 1992

SECTION F

PROPOSED TOLERANCES

We hereby request tolerances for the combined residues of the fungicide metalaxyl [N-(2,6-dimethylphenyl)-N-(methoxyacetyl)alanine methyl ester] and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methylphenyl)-N-(methoxyacetyl)alanine methyl ester, each expressed as metalaxyl equivalents, in or on the following:

Non-Grass Animal Feeds Forage	6.0 ppm
Non-Grass Animal Feeds Hay	20.0 ppm

(CIBA-GEIGY hereby requests when the above tolerances are established, tolerances in alfalfa forage at 6.0 ppm and alfalfa hay at 20 ppm be withdrawn because the crop tolerances for non-grass animal feeds will cover residues in alfalfa.)

February 17, 1992

SECTION G

REASONABLE GROUNDS IN SUPPORT OF THIS PETITION

METALAXYL - NONGRASS ANIMAL FEEDS CROP GROUPING

INTRODUCTION

Metalaxyl, [N,(2,6-dimethylphenyl)-N-(methoxyacetyl)alanine-methyl ester, is the common name for the active ingredient contained in Ridomil® 2E Fungicide, EPA Reg. No. 100-607. Ridomil 2E is an emulsifiable concentrate containing two pounds active ingredient per gallon. An application to amend the registration of Ridomil 2E is submitted simultaneously with this petition to allow use on all members of the Nongrass Animal Feeds Crop Grouping as defined at 40CFR180.34(f)(9)(xviii)(A) and (B). Ridomil 2E is currently registered on alfalfa, one of the representative commodities of the Nongrass Animal Feeds Crop Grouping. Tolerances were established for metalaxyl and its metabolites in alfalfa forage at 6.0 ppm and alfalfa hay at 20.0 ppm in early 1991.

Metalaxyl is a systemic fungicide for use on many fruit and vegetable crops, as well as soybeans, peanuts, cotton, hops, tobacco, walnuts, and almonds. Petitions are pending for ginseng (IR-4, PP1E3926), leafy vegetables (PP0F3893), cranberries (IR-4, PP1E4024), grapes (PP6F3362), grasses (PP2F4063), cole crops (PP2F4072) and cereal grains (PP1F3993).

The purpose of this petition is to establish tolerances for metalaxyl in the Nongrass Animal Feeds Crop Grouping. Residue data has been generated for clover, the other representative commodity. The results of this work are presented in Volume 2 of 2 of the data accompanying this petition. These data coupled with the data supporting the alfalfa tolerances (located under EPA MRID No. 40832901) demonstrate that tolerances of 6.0 in Nongrass Animal Feeds forage and 20.0 ppm in Nongrass Animal Feeds Hay are appropriate. See further discussion under Field Studies in this Section G.

The use pattern can be explained as follows. Data for alfalfa (EPA MRID No. 40832901) and clover (Volume 2 of 2 of the data accompanying this petition) were generated using 1.0 lb. ai/A of metalaxyl at planting (4 pts. of Ridomil 2E). When originally accepted for the use on alfalfa, the Ridomil 2E label recommended this rate. Because CIBA-GEIGY was interested in the entire group grouping, additional trials for clover were then placed at 1.0 lb. ai/A. After the alfalfa tolerances were established, CIBA-GEIGY, through continuing research efforts, determined only 0.25-0.5 lb. ai/A was needed to achieve the desired disease control. Therefore, the Ridomil 2E alfalfa label was amended to lower the rate from up to 4 pts. to

1-2 pts./A. Because this is now the recommended rate, the use rate for the Nongrass Animal Feeds group will be 1-2 pts./A. CIBA-GEIGY recognizes the residue data for clover were generated at the higher rate of 1.0 lb. ai/A (4 pts.) but because these commodities are fed to animals and existing milk and meat, tolerances are not affected by feeding of nongrass animal feeds, CIBA-GEIGY believes the data enclosed should be used to support the requested tolerances.

According to 40CFR180.34(f)(5), representative crops which exhibit more than a five-fold difference in residues may necessitate the setting of individual tolerances, rather than a crop grouping tolerance. In the case of alfalfa and clover, the clover maximum residues did exhibit more than a five-fold difference. Alfalfa maximum residues at a 60-day PHI were 5.1 ppm in alfalfa forage and 18 ppm in alfalfa hay. Clover maximum residues at a 60-day PHI were 0.99 ppm in clover forage and 2.3 ppm in clover hay (predicted residue). Note that with the exception of the residue trial on alfalfa in WA, residues in alfalfa forage and hay at a 60-day PHI were all within a five-fold difference when compared to the maximum clover residues. The residues seen in the WA alfalfa trial, however, were used to establish the tolerances. Because nongrass animal feeds are not used for direct human consumption, only through animal products, CIBA-GEIGY believes crop group tolerances should be established. Existing tolerances for metalaxyl in animal commodities are adequate to cover the feeding of nongrass animal feeds.

Metabolism in Plants, Animals and Soil

Previously, detailed accounts of ϕ-^{14}C-metalaxyl metabolism in lettuce, grapes, tobacco, potatoes, soil, and animals have been submitted (Pesticide Petition No. 1F2500) and are available under EPA Accession No. 070018. Additional data from a subsequent ^{14}C-metalaxyl metabolism study in lettuce have been submitted under EPA Accession No. 071108. Plants rapidly degrade metalaxyl to multiple metabolites via cleavage of the ester and ether bonds, oxidation of the phenyl and benzylic carbons, and N-dealkylation followed by conjugation.

The rat and goat rapidly metabolize and excrete metalaxyl via the same metabolic pathways as plants. Urinary metabolites are polar, primarily glucuronide and other conjugates. Metalaxyl and its metabolites are neither retained in animal tissues nor secreted in goat milk.

The major soil metabolite of metalaxyl is the acid, CGA-62826 [N-(2,6-dimethylphenyl)-N-(methoxyacetyl)alanine]. Residues are increasingly nonextractable with time. There is little leaching in silt loam or sandy loam soil.

Environmental Chemistry and Environmental Safety

Previously submitted environmental chemistry studies are submitted by reference in support of this petition (EPA Accession Nos. 234431 and 234438, EPA MRID No. 41156001).

Previously submitted environmental safety studies demonstrate that the use of metalaxyl, as proposed in Section B of this petition, would have no unreasonable adverse effects on fish and wildlife (EPA Accession Nos. 234439, 236854, and 244183, EPA MRID Nos. 41288101-41288104).

Toxicology

The safety of the proposed tolerances in Section F of this petition are demonstrated in previously submitted toxicology studies referenced in Section C of this petition.

A no-observable effect level (NOEL) of 250 ppm (6.25 mg/kg/day) has been established from the results of the six-month subchronic feeding study in beagle dogs with Technical Metalaxyl. Using a 100:1 safety factor and 250 ppm as the NOEL, the reference dose (Rfd) is calculated to be 0.063 mg/kg/bwt/day. The theoretical maximum residue contribution (TMRC) from previously established tolerances and food additive regulations is 0.010533 mg/kg/bwt/day or 17.55% of the Rfd (56 FR 24160). The substitution of a Crop Grouping tolerance for the alfalfa tolerances should not affect the percent of the Rfd utilized as these commodities are not consumed directly by humans, but rather fed to animals which are already covered by existing tolerances.

Field Studies

Twelve clover field trials, representing approximately 36% of United States clover production (Agricultural Statistics 1990, USDA), were conducted in California, Georgia, Illinois, Missouri, Nebraska, New York, North Dakota, Ohio, Oklahoma, Pennsylvania, South Dakota and Texas. The 1X treatment rate consisted of one at-planting broadcast application of Ridomil 2E at 1.0 lb. a.i./A. For residue comparison purposes, exaggerated 2X treatments were also applied.

Maximum 1X total residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline (DMA) moiety and N-[2-(hydroxymethyl)-6-methylphenyl-N-(methoxyacetyl)alanine methyl ester in clover forage (60-day PHI) and hay (90-day PHI) were 0.99 ppm and 1.6 ppm, respectively. For the 2X treatment rate, maximum total metalaxyl residues were 2.6 ppm and 3.0 ppm for forage (60-day PHI) and hay (90-day PHI), respectively.

Hay samples were not collected at the first cutting; however, metalaxyl residues in hay at a 60-day PHI can be predicted by calculating a forage-to-hay concentration factor from the second-cutting data, then multiplying the first-cutting forage residue by this factor. Using data from field test 04-FR-005-89, an example is presented below:

$$\frac{\text{0.87 ppm (hay, second cutting)}}{\text{0.37 ppm (forage, second cutting)}} = 2.351 \text{ (conc. factor)}$$

The range of calculated concentration factors is 1.167-4.500. The average concentration factor for all the forage-to-hay data is 2.287 (n = 22). [Note: concentration factors were not calculated if residues were below the 0.05 ppm screening level.]

Therefore, the maximum residue predicted in first-cutting hay (60-day PHI) using the average concentration factor would occur in field trial MW-FR-606-89 and is shown as follows:

2.287 x 0.99 ppm (forage, first cutting) = 2.3 ppm

Transfer of Residue to Animals

Beef and dairy cattle may consume alfalfa and clover. Poultry do not consume clover or alfalfa forage and hay; however, processed alfalfa meal may be included as a minor (i.e., 5%) constituent of poultry feed. This information was obtained from the published EPA document: Pesticide Assessment Guideline, Subdivision O, Residue Chemistry (Richard D. Schmitt, Ph.D., EPA 540/9-82-023, October, 1982 and revised on December 24, 1989).

A theoretical diet for cattle consuming maximum metalaxyl residues from alfalfa hay and peanut hay was calculated in ABR-89016 (MRID No. 41150101). Maximum 1X metalaxyl residues in clover forage (0.99 ppm) and hay (1.6 ppm) and the maximum predicted residue (2.3 ppm) in 60-day hay are less than the established tolerances for alfalfa forage (6 ppm) and hay (20 ppm), respectively. Based on the theoretical diet calculations and feeding studies discussed in ABR-89016 and the data presented in Volume 2 of 2, feeding of commodities from the Nongrass Animal Feed Group treated with metalaxyl at the maximum labeled (1X) rate of 1.0 lb. a.i./A will not cause the established residue tolerances of 0.5 ppm in round steak and tenderloin, 0.02 ppm in milk, and 0.4 ppm in liver and kidney to be exceeded.

Conclusions

Metalaxyl has been shown to be an effective fungicide to control diseases on a wide variety of vegetable crops, including nongrass animal feeds. Data presented support the establishment of tolerances at 6.0 ppm in nongrass animal feeds forage and 20.0 ppm in nongrass animal feeds hay to allow a soil application of Ridomil 2E at 1-2 pts./A to control diseases caused by Pythium and Phytophthora spp.

The residue data presented and referenced in Section D of this petition in combination with data previously generated on alfalfa will support tolerances for residues of metalaxyl and its metabolites as proposed in Section F.

Toxicology studies show that the use of metalaxyl, as proposed in Section B of this petition, should have no adverse effects on the user or on the public health.

[GANNONC.DRAFTS]H109CG0210KSS

End of Document

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

AUG 17 1993

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM:

SUBJECT: ID # PP2F4105: *Metalaxyl (Ridomil 2E) in or on Non-grass Animal Feeds (as Clover). Evaluation of Analytical and Residue Data.*
CBTS #9625
HED #2-1840
EPA Reg. #100607
DP Barcode #D175974
MRID #422268-01

FROM: María Isabel Rodríguez, Chemist
Tolerance Petition Section III
Chemistry Branch I - Tolerance Support
Health Effects Division (H7509C)

María Isabel Rodríguez
August 16, 1993.

THROUGH: Debra Edwards, Ph.D., Chief
Chemistry Branch I - Tolerance Support
Health Effects Division (H7509C)

Debra Edwards
8/16/93

TO: Susan Lewis/Benjamin Chambliss
Product Manager Team #21
Registration Division (H7505C)

Ciba-Geigy Corporation submitted an application requesting tolerances for the combined residues of the fungicide metalaxyl [*N*-(2,6-dimethylphenyl)-*N*-(methoxyacetyl)alanine methyl ester] and its metabolites containing the 2,6-dimethylaniline (known as DMA) moiety, and *N*-(2-hydroxymethyl-6-methylphenyl)-*N*-(methoxy-acetyl)alanine methyl ester, each expressed as metalaxyl equivalents, in or on all members of the non-grass animal feeds (forage and hay) crop grouping as defined under 40 CFR §180.34 (f) (9) (xviii) (A) and (B). The petitioner is proposing the following tolerances:

* Non-grass Animal Feeds - Forage - at 6.0 ppm

* Non-grass Animal Feeds - Hay - at 20.0 ppm

The non-grass animal feeds (forage, fodder, straw and hay) group is

defined under 40 CFR §180.34 (f)(9)(xviii)(A) and (B). The following commodities are included in this crop group: alfalfa; bean, velvet; clover; kudzu; lespedeza; lupine; sainfoin; trefoil; vetch; vetch, crown; and vetch, milk. Representative commodities are alfalfa and clover.

Previously, Ciba-Geigy submitted a petition (PP8F3695/8H5569, 8-3-1989, J. Garbus, MRID #408329-01) for the registration of Ridomil 2E on alfalfa. Tolerances were established for forage (6 ppm) and hay (20 ppm). The alfalfa label allows for one application of Ridomil 2E at 1.0 lb ai/A and a 60-day pre-harvest interval (PHI). Data for alfalfa and clover were generated using 1.0 lb ai/A of metalaxyl at planting (4 pts of Ridomil 2E). When originally accepted for use on alfalfa, the Ridomil 2E label recommended rates of up to 1.0 lb ai/A. Trials for clover were then placed at 1.0 lb ai/A. Then, the petitioner explains, it was determined that only 0.25-0.5 lb ai/A was needed to achieve the desired control. According to the petitioner, the Ridomil 2E in alfalfa was amended to lower the rate to 1-2 pts/A. No evidence of this change was found in our files. This same rate is being proposed for the non-grass animal feeds group. However, as will be seen below, the study (with clover) was carried out using 1.0 lb ai/Acre.

Ciba-Geigy Corporation is also requesting that when the above tolerances are established, tolerances in alfalfa forage at 6.0 ppm and alfalfa hay at 20 ppm be withdrawn because the crop tolerances for non-grass animal feeds will cover them.

According to 40 CFR §180.408 (a), tolerances are established for the combined residues of the fungicide metalaxyl [*N*-(2,6-dimethylphenyl)-*N*-(methoxyacetyl)alanine methyl ester] and its metabolites containing the 2,6-dimethylaniline moiety, and *N*-(2-hydroxy methyl-6-methyl)-*N*-(methoxyacetyl)-alanine methylester, each expressed as metalaxyl, in or on several raw agricultural commodities.

Tolerances are established for indirect or inadvertent residues of metalaxyl in or on the raw agricultural commodities when present therein as a result of the application of metalaxyl to the growing crops listed in 40 CFR §180.408 (a) and other non-food crops listed in 40 CFR §180.408 (b).

According to 40 CFR §180.408 (c), tolerances with regional registration are established for the combined residues of the fungicide and its metabolites, each expressed as metalaxyl, in or on the raw agricultural commodity papaya.

Food and feed additive tolerances are established at 40 CFR §185.4000 (a), (b), (c) and (d) and 40 CFR §186.4000 (a), (b), (c), and (d) for combined residues of metalaxyl and its metabolites in processed commodities in the range of 1-20 ppm.

Clover can be utilized for several agricultural functions: (1) as a pasture crop, either plain or mixed with some other grass or legume; (2) for hay, plain or mixed; (3) for soil-enrichment; (4) as a cover crop, particularly desirable in some orchards; (5) for silage; and (6) for green manuring. Clover is also an excellent honey crop. There are about 400 to 500

species of true clover plants, of which only about 10 to 15% are native to North America. The majority of important clover species in the United States are of food production significance.

BACKGROUND:

Metalaxyl is a systemic fungicide for use on selected crops like alfalfa and other non-grass animal feeds. Metalaxyl is the common name for the active ingredient contained in Ridomil 2E Fungicide. It is used to control certain diseases caused by members of the Oomycete class of fungi.

Metalaxyl is a List "A" chemical for which a Registration Standard Guidance Document was issued in December, 1981. The Residue Chemistry Chapter for the Final Registration Standard and Tolerance Reassessment (FRSTR) was completed in June, 1987. An update to the Residue Chemistry Chapter was completed in April, 1992.

CONCLUSIONS:

1. Product Chemistry data for metalaxyl were submitted and have been previously reviewed. These are adequate for the purposes of the proposed tolerance in/on non-grass animal feeds (forage and hay).

2. a. For the purposes of this petition, the nature of the residue in plants is considered to be understood. The residues of concern are metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and *N*-(2-hydroxymethyl-6-methyl)-*N*-(methoxyacetyl)-alanine methylester.

b. According to the FRSTR, the nature of the residue in animals is not understood. The residues currently regulated are the same as those in plants, metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and *N*-(2-hydroxymethyl-6-methyl)-*N*-(methoxyacetyl)-alanine methylester. For the purposes of the tolerance petition in/on non-grass animal feeds (forage and hay), CBTS recommends regulating these same residues while the requirement is satisfied for the FRSTR.

c. Animal feed items are derived from clover (forage and hay) and from the non-grass animal feeds crop group (forage and hay). This is a 40 CFR §180.6 (a) 2 situation with respect to secondary residues in meat and milk for this proposed use. The established tolerances on meat, fat, and milk adequately cover residues expected from the proposed use of metalaxyl.

3. The proposed use of metalaxyl in/on non-grass animal feeds crop group (forage and hay) was adequately described in the submitted petition.

4. Methods AG-348, AG-349, and AG-395 are adequate for residue data collection and enforcement of the proposed tolerances in/on non-grass animal feeds (forage and hay).

5. Adequate storage stability data for several raw agricultural commodities which have been previously submitted and reviewed can be translated to clover (forage and hay) and non-grass animal feeds (forage and

hay).

6. a. Based on the systemic nature of metalaxyl and the greater than five-fold difference between the residues in alfalfa and clover hays (this submission), a crop group tolerance is not appropriate.

Alternatively, the petitioner could request individual tolerances for clover instead of a crop grouping expression. A tolerance of 1.0 ppm would be appropriate for clover, forage and a tolerance of 2.5 ppm would be appropriate for clover, hay with a PHI of 90 days.

b. Revised Sections B and F should be submitted for review. The revised Section B should limit use to clover (Alfalfa already has a registered use).

7. The petitioner has presented sufficient geographically representative residue data.

8. There is no Codex Proposal, nor Canadian or Mexican limits for residues of metalaxyl *per se* in non-grass animal feeds - forage and/or hay. Therefore, a compatibility issue is not relevant to the proposed tolerance. A copy of the International Residue Limit Status (IRLS) has been attached to this memorandum.

RECOMMENDATIONS:

The CBTS recommends against the proposed tolerance for the residues of the fungicide metalaxyl and its metabolites in or on the non-grass animal feeds group - forage - at 6.0 ppm - and hay - at 20.0 ppm. Alternatively, revised Sections B and F could be submitted for review. The petitioner could request individual tolerances instead of a crop grouping expression. A tolerance of 1.0 ppm would be appropriate for clover, forage and a tolerance of 2.5 ppm would be appropriate for clover, hay with a PHI of 90 days. (Refer to Conclusions #6a & #6b). The revised Section B should limit use to clover (Alfalfa already has a registered use).

If the petitioner wishes to propose a lower application rate, and presumably a lower tolerance, additional residue data should be submitted for review. These residue data should be generated using the maximum rate and minimum PHI. Revised Sections B and F should be submitted for review along with the field residue data.

DETAILED CONSIDERATIONS:

Product Chemistry:

No studies were submitted with this petition.

The manufacturing process of metalaxyl (technical product) as well as its physical/chemical characteristics have been adequately described

(PP1F2500/1H5299, 3-9-1982, P. Errico).

The chemical, with trade name Ridomil 2E (EPA Reg. No. 100-607), is an emulsifiable concentrate that contains 25.1% active ingredient and 74.9% inert ingredients (two pounds of active ingredient per gallon). Impurities are not likely to produce residue problems.

Metalaxyl is supplied in various formulations: as an emulsifiable liquid, Ridomil 2E, in a granular form, Ridomil 5G, and as a component in mixtures, Ridomil MZ58, Ridomil PC 11G, and Ridomil/Bravo 81W.

Proposed Use:

Metalaxyl applied to the soil at planting will provide control of damping-off and root rots.

Apply 0.25 to 0.5 lb ai/Acre (1 to 2 pts/Acre) as a broadcast surface spray at planting in a minimum of 20 gallons of water or following impregnation on fertilizer.

If seed was previously treated with metalaxyl as a seed dressing, an application of Ridomil 2E at 0.25 lb ai/Acre (1 pt/Acre) is recommended at planting. Use the higher rate [0.5 lb ai/Acre (2 pts/Acre)] in areas where disease pressure is expected to be heavy.

Do not feed green forage or cut for hay for 60 days following application.

Do not plant any crop which is not registered for use with metalaxyl in metalaxyl-treated soil for a period of 12 months, with the exception of wheat, barley and oats.

The use rate for the registered label for alfalfa is similar.

The proposed use of metalaxyl in/on non-grass animal feeds (forage, straw, and hay) was adequately described in the submitted petition.

Nature of the Residue in Plants:

No studies were submitted with this petition.

For this proposed use the residues of concern are those expressed in the current tolerances as the combined residues of metalaxyl [*N*-(2,6-dimethylphenyl)-*N*-(methoxy-acetyl)alanine methyl ester] ant its metabolites containing the 2,6-dimethyl-aniline moiety, and *N*-(2-hydroxymethyl-6-methyl)-*N*-(methoxyacetyl)-alanine methyl ester. Adequate enforcement exists as Methods I and II in the *Pesticide Analytical Manual, Volume II* (CBRS Review #9596, 6-22-1992, R.B. Perfetti).

Radiolabelled studies indicate that metalaxyl is metabolized along the same pathway in a variety of unrelated plants, such as lettuce, grapes, tobacco, and potatoes. Detailed data have been reviewed in previous

submissions (PP1F2500, 3-9-1982, P. Errico and PP2F2762, 1-6-1983, K. Arne).

In summary, metalaxyl is metabolized through one or more of the following processes: oxidation of the ring's methyl group to the alcohol and then the carboxylic acid, hydroxylation of the phenyl group, cleavage of the methyl ester and methyl ether, N-dealkylation, and/or subsequent conjugation of some breakdown products.

CBTS concludes that the nature of the residue in plants is adequately understood for this proposed use.

Nature of the Residue in Animals:

No studies were submitted with this petition. Radiolabelled metabolism studies in rats, goats, and cows have been previously submitted and reviewed.

In summary, degradation occurs via the same mechanisms as in plants.

Animal metabolism studies with rats have demonstrated that degradation occurs via one or more of the following processes: methyl ester hydrolysis, N-dealkylation, methyl ether cleavage, benzylic methyl oxidation, and/or subsequent formation of conjugates with glucuronic acid. The parent compound is rapidly excreted in both urine and feces (PP1F2500/H5299, 3-9-1982, P. Errico).

Radiolabelled studies with lactating goats have shown that small amounts (0.003-0.008 ppm) were recovered from milk, blood, and tissues. Less than 0.004 ppm had been recovered from the heart, skeletal muscle, and tenderloin. In fat <0.008-0.023 ppm was obtained while 0.19 ppm and 0.057 ppm were observed in the kidney and the liver, respectively (PP0E3826/H5591, DEB Review #'s 6232, 6233, 5-9-1990, S. Inasi, and PP6F3387/6H5499, 9-26-1986, F.D. Griffith).

According to the FRSTR, the nature of the residue in animals is not understood. The residues currently regulated are metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and *N*-(2-hydroxymethyl-6-methyl)-*N*-(methoxyacetyl)-alanine methylester. For the purposes of this tolerance petition in/on non-grass animal feeds (forage and hay), CBTS recommends regulating these same residues while the requirement is satisfied for the reregistration process.

Analytical Methodology for Plants:

Analytical Methods AG-348 and AG-349 correspond to Methods I and II of *PAM, Vol. II*. Method AG-395 is an improved modification of Method AG-348, exhibiting increased sensitivity for measurement of a metabolite and reduced time required for analysis. Method AG-395 has undergone successful Agency validation trial with plant samples. All these are adequate analytical methods for enforcement purposes. (DEB Review #8704, 10-23-1991, J. Abbotts).

Method AG-395 was discussed in detail in the 1987 FRSTR Residue Chemistry Chapter. In Method AG-395, residues are extracted in methanol:water

and refluxed with methanesulfonic acid and then basified, converting the residues of concern to DMA. After cleanup, the DMA residues are analyzed using GLC with a nitrogen/phosphorus detector in the nitrogen mode. The stated detection limit is 0.05 ppm. (PP1F3993, CBTS Review #9011, 6-19-1991, J. Morales).

In this method, crop samples (10 g) are extracted by refluxing with 80% (v/v) methanol/water for two hours. A 2 g aliquot of the extract is evaporated to dryness with a rotary evaporator. Depending on the substrate, 1.0 or 1.5 Ml of water is added to dissolve the residue. Ten milliliters of methanesulfonic acid is added and the sample is refluxed for approximately 15 minutes. The extract is basified after cooling and addition of water. DMA formed in the reaction is steam distilled. The steam-distilled product is cleaned-up prior to gas chromatographic analysis. After separation, DMA is detected with a nitrogen-phosphorus detector operating in the nitrogen-specific mode. Chromatographic conditions, as well as other modifications to the method were utilized. These were listed in the study and are as follows.

* Section 5.3: wet crop extraction section is omitted. The dry crop extraction section (5.4) is used for all samples.

* Section 5.5.4: water and 25% sodium hydroxide/water are doubled in volume to facilitate a more efficient steam distillation process.

* Section 5.6.1: glass wool plugs will not be installed in condensers.

* Section 5.7.5: DMA residues in dichloromethane are concentrated for GC detection. Sections 5.7.6 and 5.7.7 are omitted.

* Section 6.1.1: GC injection standards are prepared by serial dilution of a 1.0 $\mu g/\mu L$ stock solution of 2,6-dimethylaniline in dichloromethane.

* Section 6.2.2: The conversion factor to convert residues of DMA into metalaxyl equivalents in 2.308.

DMA results, expressed as (ng DMA found/mg crop injected) are converted to metalaxyl equivalents using the factor 2.308.

The average recovery and standard deviation for fortified substrate samples were 88.2 ± 13.4% (n = 38).

Analytical Methodology for Animals:

A suitable enforcement procedure exists for total metalaxyl residues in liver and milk. Metalaxyl and regulated metabolites were successfully recovered from beef liver in an Agency validation trial of Method II in *PAM, Vol. II*, Pesticide Reg. Sec. 180.408; it is coded AG-349. (CBRS Review #9596,

6-22-1992, R.B.-Perfetti). This method is a modification of Method AG-348. It uses acetonitrile as an extraction solvent for milk and tissues and hexane for eggs. The limits of detection are 0.01 ppm in milk, 0.1 ppm in liver and kidney, and 0.05 ppm in eggs. (PP6F3387/6H5499, RCB #768-769, 9-26-1986, F.D. Griffith).

Storage Stability Data:

Results of freezer storage stability experiments for several raw agricultural commodities have been previously reported and reviewed. Metalaxyl residues have shown to be stable for 18 months when stored in a freezer at -15 °C. In the submitted study, clover forage and hay samples were stored between 1 and 16 months prior to analysis. Therefore, translating the results from the 18-month storage stability studies, metalaxyl residue results for these samples were not affected by freezer storage. (CBRS Review #8166, 4-16-1992, J. Abbotts).

Residue Data:

A. Magnitude of the Residue in Plants:

> Eudy, L. W. January 10, 1992. Metalaxyl - Magnitude of Residues in Clover Forage and Hay Following Application of Ridomil 2E. Study performed and submitted by Ciba-Geigy Corporation, NC. Laboratory Project ID ABR-91030. EPA Guideline #171-4 (K). MRID #422268-01

The objective of this study was to provide additional residue data for metalaxyl in clover (forage and hay) following application of Ridomil 2E for use on the non-grass animal feed group (forage and hay).

Twelve clover field trials were conducted in California, Georgia, Illinois, Missouri, Nebraska, New York, North Dakota, Ohio, Oklahoma, Pennsylvania, South Dakota, and Texas.

Field trials were generated using 1 lb ai/A and 2 lb ai/A. This is 2X and 4X, respectively, the highest proposed use rate as described in Section B. The actual residue test results submitted by the registrant label those rates as 1X (1 lb ai/A) and 2X.

Clover was grown to maturity under normal agricultural practices. Clover forage and hay samples were collected at random. Samples were not cleaned or washed. Any surface soil that was removed was done by shaking the clover. After collection, samples were frozen and shipped with dry ice. Upon arrival, samples were stored in a freezer at approximately -20 °C. After preparation, the samples were placed in polyethylene bags or bottles, labeled, and returned to the freezer until residue analysis.

Analytical Method AG-395 was used to determine residues in clover forage and hay. Results are expressed as metalaxyl equivalents and the limit of determination is 0.05 ppm.

Residue results expressed as metalaxyl equivalents are reported in Table I (next pages).

Table I: Metalaxyl Residues Determined as DNA in Clover Forage and Hay Following Application of Ridomil 2E.

Field Test Location	Application Rate	PHI (*)	Substrate	Metalaxyl (**) Residue, ppm
IL	Control	--	Forage	<0.05
	2X	62	Forage	0.53
	2X	62	Forage	0.45
	Reagent Blank	--	------	<0.05
	Control	--	Forage	<0.05
	2X	79	Forage	0.37
	2X	79	Forage	0.51
	Reagent Blank	--	------	<0.05
	Control	--	Hay	0.06
	2X	79	Hay	0.87
	2X	79	Hay	0.73
	Reagent Blank	--	---	<0.05
NY	Control	--	Forage	<0.05
	2X	61	Forage	0.72
	2X	61	Forage	0.53
	4X	61	Forage	2.1
	Reagent Blank	--	------	<0.05
	Control	---	Forage	<0.05
	2X	288	Forage	0.06
	2X	288	Forage	<0.05
	4X	288	Forage	0.16
	Reagent Blank	---	------	<0.05
	Control	---	Hay	0.06
	2X	288	Hay	0.12
	2X	288	Hay	0.10
	4X	288	Hay	0.41
	Reagent Blank	---	---	<0.05
TX	Control	---	Forage	<0.05
	2X	179	Forage	0.56
	2X	179	Forage	0.57
	Reagent Blank	---	------	<0.05
	Control	---	Hay	<0.05
	2X	179	Hay	1.2
	2X	179	Hay	1.4
	Reagent Blank	---	---	<0.05
OK	Control	---	Forage	<0.05
	2X	210	Forage	0.07
	2X	210	Forage	0.12
	Reagent Blank	---	------	<0.05
	Control	---	Hay	<0.05
	2X	210	Hay	0.14
	2X	210	Hay	0.17
	Reagent Blank	---	---	<0.05
GA	Control	--	Forage	<0.05
	2X	60	Forage	0.53
	2X	60	Forage	0.63
	4X	60	Forage	1.5
	Reagent Blank	--	------	<0.05
	Control	---	Forage	<0.05
	2X	209	Forage	0.06
	2X	209	Forage	0.07
	4X	209	Forage	0.20
	Reagent Blank	---	------	<0.05

Field Test Location	Application Rate	PHI (*)	Substrate	Metalaxyl (**) Residue, ppm
	Control	---	Hay	<0.05
	2X	209	Hay	0.07
	2X	209	Hay	0.15
	4X	209	Hay	0.25
	Reagent Blank	---	---	<0.05
CA	Control	--	Forage	<0.05
	2X	59	Forage	0.29
	2X	59	Forage	0.23
	Reagent Blank	--	------	<0.05
	Control	---	Forage	<0.05
	2X	172	Forage	0.10
	2X	172	Forage	0.10
	Reagent Blank	---	------	<0.05
	Control	---	Hay	<0.05
	2X	172	Hay	0.37
	2X	171	Hay	0.34
	Reagent Blank	---	---	<0.05
MO	Control	--	Forage	<0.05
	2X	61	Forage	0.30
	2X	61	Forage	0.27
	Reagent Blank	--	------	<0.05
	Control	---	Forage	<0.05
	2X	279	Forage	0.06
	2X	279	Forage	0.08
	Reagent Blank	---	------	<0.05
	Control	---	Hay	0.07
	2X	279	Hay	0.14
	2X	279	Hay	0.16
	Reagent Blank	---	---	<0.05
ND	Control	--	Forage	<0.05
	2X	58	Forage	<0.05
	2X	58	Forage	0.20
	Reagent Blank	--	------	<0.05
	Control	--	Forage	<0.05
	2X	76	Forage	0.15
	2X	76	Forage	0.32
	Reagent Blank	--	------	<0.05
	Control	--	Hay	0.18
	2X	76	Hay	0.48
	2X	76	Hay	0.86
	Reagent Blank	--	---	<0.05
NE	Control	--	Forage	<0.05 (a)
	2X	60	Forage	0.99
	2X	60	Forage	0.79
	4X	60	Forage	2.6 (a)
	Reagent Blank	--	------	<0.05
	Control	--	Forage	<0.05
	2X	90	Forage	0.56
	2X	90	Forage	0.55
	4X	90	Forage	1.5
	Reagent Blank	--	------	<0.05

Field Test Location	Application Rate	PHI (*)	Substrate	Metalaxyl (**) Residue, ppm
	Control	--	Hay	0.17
	2X	90	Hay	1.6
	2X	90	Hay	1.4
	4X	90	Hay	3.0
	Reagent Blank	--	---	<0.05
SD	Control	--	Forage	0.06
	2X	60	Forage	0.14
	2X	60	Forage	0.14
	4X	60	Forage	0.21
	Reagent Blank	--	------	<0.05
	Control	--	Forage	0.05
	2X	91	Forage	0.15
	2X	91	Forage	0.16
	4X	91	Forage	0.25
	Reagent Blank	--	------	<0.05
	Control	--	Hay	0.08
	2X	91	Hay	0.24
	2X	91	Hay	0.24
	4X	91	Hay	0.42
	Reagent Blank	--	---	<0.05
OH	Control	--	Forage	<0.05
	2X	59	Forage	0.39
	2X	59	Forage	0.29
	Reagent Blank	--	------	<0.05
	Control	---	Forage	0.05
	2X	119	Forage	0.09
	2X	119	Forage	0.09
	Reagent Blank	---	------	<0.05
	Control	---	Hay	0.06
	2X	119	Hay	0.12
	2X	119	Hay	0.14
	Reagent Blank	---	---	<0.05
PA	Control	--	Forage	<0.05
	2X	60	Forage	0.35
	2X	60	Forage	0.53
	Reagent Blank	--	------	<0.05
	Control	---	Forage	<0.05
	2X	120	Forage	0.06
	2X	120	Forage	<0.05
	Reagent Blank	---	------	<0.05
	Control	---	Hay	0.07
	2X	120	Hay	0.27
	2X	120	Hay	0.24
	Reagent Blank	---	---	<0.05

* PHI is based on time between last application and sample collecting.

** Determined as 2,6-dimethylaniline and converted to metalaxyl equivalents by the factor 2.308.

(a) Sample was apparently switched with the replicate.

Maximum 2X total residues in clover forage (60-day PHI) and hay (90-day PHI) were 0.99 ppm and 1.6 ppm, respectively. For the 4X treatment rate, maximum total metalaxyl residues, were 2.6 ppm and 3.0 ppm for forage (60-hay PHI) and hay (90-day PHI), respectively. Hay samples were not collected at the first cutting. However, metalaxyl residues in hay at a 60-day PHI were predicted by calculating a forage-to-hay concentration factor from the second cutting data, then multiplying the first-cutting forage residues by this factor. These data are summarized in Table II (next page).

The range of the calculated concentration factors is 1.2-4.5. The average concentration factor for all the forage-to-hay data is 2.3 (n=22).

Representative chromatograms and calibration curves were included in the study.

Based on the systemic nature of metalaxyl and the greater than five-fold difference between the tolerances in alfalfa and clover (this submission), the proposed tolerance is not appropriate. Alternatively, the petitioner could request individual tolerances for clover instead of a crop grouping expression. A tolerance of 1.0 ppm would be appropriate for clover, forage and a tolerance of 2.5 ppm would be appropriate for clover, hay with a PHI of 90 days. Revised Sections B and F should be submitted for review. The revised Section B should limit use to clover (Alfalfa already has a registered use).

B. Magnitude of the Residue in Animals (Meat, Milk, Poultry, and Eggs):

No feeding studies were submitted with this petition.

Livestock feeding studies have been previously submitted and adequately reviewed. Lactating dairy cows were fed metalaxyl at 0, 1.5, 7.5, and 15.0 ppm for up to 40 days. Milk samples were collected and analyzed 7, 14, 21, 28 and 40 days after feeding. No residues within the limit of detection (<0.01 ppm) were found in any of the milk samples reflecting the 7.5 and 15.0 ppm feeding levels.

Meat samples were collected and analyzed 14, 21, 28 and 40 days after treatment. Meat and fat samples showed no reported residues within the limit of detection (0.05 ppm). At the 1.5, 7.5, and 15.0 ppm feeding levels, residues ranged from 0.11 ppm to 0.22 ppm in liver, and 0.16 to 0.70 ppm in kidney. In other studies, lactating dairy cows were fed 75 ppm metalaxyl for 14 to 28 days. Liver and kidney samples were analyzed 14, 21, and 28 days after treatment. Residues ranged from <0.10 to 0.82 ppm in the liver, and from 0.11 to 5.5 ppm in the kidney. (DEB #7431, 6-27-1991, J. Abbotts)

Poultry feeding studies have been previously submitted and adequately reviewed. Hens were fed metalaxyl at 0.05 ppm, 1.5 ppm and 5.0 ppm for four weeks. Analysis of eggs, skin, fat, breast, and thigh muscle showed no metalaxyl residues within the limit of detection (0.01 ppm) and the feeding level (5.0 ppm). (PP6F3387/6H5499, 9-26-1986, F.D. Griffith).

Table II: Forage-to-hay Concentration Factors and Predicted Metalaxyl Residues in 60-day Hay Using Mean Concentration Factor of 2.3:

Field Test Location	Metalaxyl Residue (ppm) Second-cutting Forage	Metalaxyl Residue (ppm) Second-cutting Hay	Concentration Factor	Metalaxyl Residue (ppm) First-cutting Forage	Predicted Metalaxyl Residue (ppm) First-cutting Hay
IL	0.37 0.51	0.87 0.73	2.351 1.431	0.53 0.45	1.2 1.0
NY	0.06 <0.05	0.12 0.10	2.000 -----	0.72 0.53	1.7 1.2
TX	0.56 0.57	1.2 1.4	2.143 2.456	---- ----	----- -----
OK	0.07 0.12	0.14 0.17	2.000 1.417	---- ----	----- -----
GA	0.06 0.07	0.07 0.15	1.167 2.143	0.53 0.63	1.2 1.4
CA	0.10 0.10	0.37 0.34	3.700 3.400	0.29 0.23	1.7 0.5
MO	0.06 0.08	0.14 0.16	2.333 2.000	0.30 0.27	0.7 0.6
ND	0.15 0.32	0.48 0.86	3.200 2.688	<0.05 0.20	----- 0.5
NE	0.56 0.55	1.6 1.4	2.857 2.546	0.99 0.79	2.3 1.8
SD	0.15 0.16	0.24 0.24	1.600 1.500	0.14 0.14	0.3 0.3
OH	0.09 0.09	0.12 0.14	1.333 1.556	0.39 0.29	0.9 0.7
PA	0.06 <0.05	0.27 0.24	4.500 -----	0.35 0.53	0.8 1.2

A plausible livestock exposure analysis for dairy and beef animals, assuming the requested tolerances were performed and is as follows.

For clover hay and clover forage,

Beef

Feed	Tolerance, ppm	% in Diet	Exposure, ppm
Clover, hay	2.5	35	0.88
Tomato Pomace, Dry	20.0	30	6.00
Cottonseed	0.1	20	0.02
Soybean, meal	2.0	15	0.30
Total		100	7.20

Dairy

Feed	Tolerance, ppm	% in Diet	Exposure, ppm
Clover, hay	2.5	45	1.13
Tomato Pomace, Dry	20.0	20	4.00
Cottonseed	0.1	20	0.02
Soybean, meal	2.0	15	0.30
Total		100	5.45

Alfalfa is a poultry feed item and has been previously evaluated in poultry feed. There may be some minor feeding of lupine seed (10-15% in diet maximum), but clover and the other members of the non-grass animal feeds group are not poultry feed items.

This is a 40 CFR §180.6 (a) 2 situation with respect to secondary residues in meat and milk for this proposed use. The existing metalaxyl tolerances for poultry, fat, kidney, liver (0.4), meat, eggs, mbyp (excluding kidney and liver) (0.05 ppm), cattle, horse, goat, hog, and sheep, fat, kidney, liver (0.4 ppm), meat, mbyp (except kidney and liver) (0.05 ppm) adequately cover the uses in this petition.

If the animal metabolism study required in the FRSTR identifies additional metabolites requiring regulation, tolerances established for the use of metalaxyl in/on clover, forage and hay may need revision.

OTHER CONSIDERATIONS:

Codex Proposal:

There is no Codex Proposal, nor Canadian or Mexican limits for residues of metalaxyl *per se* in non-grass animal feeds - forage and/or hay. Therefore, a compatibility issue is not relevant to the proposed tolerance. A copy of the International Residue Limit Status (IRLS - Codex #138) has been attached to this memorandum.

Attachments: IRLS
cc: MIRodríguez, PP2F4105, Circulation, Metalaxyl, Subject File & Reading File.
RDI: D. Edwards (8-12-1993), P.V. Errico (8-11-1993), R.A. Loranger (8-12-1993)
M.I. Rodríguez: Draft (11-5-1992), Edited (8-16-1993): H7509C/CBTS/CM#2, Room 804-T/703-305-6710

Branch File: F:\USER\CB\METLAXYL.001

F. Kuos 10/21/92

Attachment: Page 1 of 1

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Metalaxyl

CODEX NO. 138

CODEX STATUS:

[✓] No Codex Proposal Step 6 or Above (on commodities specified)

Residue (if Step 8): metalaxyl per se

Crop(s)	Limit (mg/kg)

PROPOSED U.S. TOLERANCES:

Petition No. 2F4105

DEB Reviewer M.I. Rodriguez

Residue: Metalaxyl equivalents*

Crop(s)	Limit (mg/kg)
① Non-grass Animal Feeds Forage	6.0
② Non-grass Animal Feeds Hay	20.0

CANADIAN LIMITS:

[✓] No Canadian Limit (on commodities specified)

Residue: Metalaxyl per se

Crop(s)	Limit (mg/kg)

MEXICAN LIMITS:

[✓] No Mexican Limit

Residue:

Crop(s)	Limit (mg/kg)

NOTES

Form Revised 1989

*Metalaxyl ≡ N-(2,6-dimethylphenyl)-N-(methoxyacetyl)alanine methyl ester

Tolerance expressed as metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methylphenyl)-N-(methoxyacetyl)alanine methyl ester, each expressed as metalaxyl equivalents.

VOLUME 1 OF 1

TECHNICAL METALAXYL

EPA REG. NO. 100-601

PETITION FOR TOLERANCE IN THE NON-GRASS ANIMAL FEEDS CROP GROUPING

CONTENTS: SECTIONS A-G

DATE SUBMITTED: FEBRUARY 17, 1992

AGRICULTURAL DIVISION
CIBA-GEIGY CORPORATION
POST OFFICE BOX 18300
GREENSBORO, NC 27419

SECTION A

GENERAL CHEMISTRY

General chemistry data for Metalaxyl Technical (EPA Reg. No. 100-601), common name for the active ingredient in Ridomil® 2E Fungicide (EPA Reg. No. 100-607) and general chemistry data for Ridomil 2E are hereby referenced on the following pages.

February 17, 1992

DATA REQUIREMENT FOR THE SELECTIVE METHOD OF SUPPORT

1. PRODUCT NAME: Technical Metalaxyl	2. EPA REG. NO./FILE SYMBOL 100-601	3. FORMULATOR'S EXEMPTION SELECTED: YES ___ NO X	4. PAGE 1 OF 2
5. APPLICANT'S NAME AND ADDRESS: Agricultural Division CIBA-GEIGY Corporation Post Office Box 18300 Greensboro, NC 27419	6. APPLICATION FOR REGISTRATION DATE: / / MO DAY YR	7. NAME OF ACTIVE INGREDIENT(S): Metalaxyl	

8. DATA REQUIREMENTS		9. SOURCE OF DATA SATISFYING REQUIREMENT						10.
8a. REGULATION PART 158/ GUIDELINE NUMBER	8B. NAME OF TEST	9a. SUBMITTED BY APPLICANT	9b. DATE SUBMITTED	9c. SUBMITTED BY ANOTHER PERSON/FIRM (NAME)	9d. PERMISSION LETTER ENCLOSED	9e. PUBLIC LITERATURE	9f. N.A. OR WAIVER OR OTHER (EXPLAIN)	MRID NUMBER EPA ACCESSION NUMBER OR OTHER EPA IDENTIFYING NUMBER
§158.120	PRODUCT CHEMISTRY							
61-1	Identity of ingredients	Citing	6/30/78	No				234427 41912901
61-2	Statement of composition	Citing	4/3/89	No				41055201 41912901
61-3	Discussion of formation of ingredients	Citing	4/3/89	No				41055201 41912901
62-1	Preliminary analysis	Citing	4/3/89	No				41055202
62-2	Certification of limits	Citing	4/3/89	No				41055202 41912901
62-3	Analytical methods for enforcement limits	Citing	4/3/89	No				41055202
63-2	Color	Citing	6/30/78	No				234427
63-3	Physical state	Citing	6/30/78	No				234427
63-4	Odor	Citing	6/30/78	No				234427
63-5	Melting point	Citing	6/30/78	No				234427
63-6	Boiling point	Citing	6/30/78	No				234427
63-7	Density, bulk-density, or specific gravity	Citing	6/30/78	No				234427

DATA REQUIREMENT FOR THE SELECTIVE METHOD OF SUPPORT

1. PRODUCT NAME: Technical Metalaxyl	2. EPA REG. NO./FILE SYMBOL 100-601	3. FORMULATOR'S EXEMPTION SELECTED: YES ___ NO _X_	4. PAGE 2 OF 2
5. APPLICANT'S NAME AND ADDRESS: Agricultural Division CIBA-GEIGY Corporation Post Office Box 18300 Greensboro, NC 27419	6. APPLICATION FOR REGISTRATION DATE: / / (MO DAY YR)	7. NAME OF ACTIVE INGREDIENT(S): Metalaxyl	

8. DATA REQUIREMENTS		9. SOURCE OF DATA SATISFYING REQUIREMENT						10.
8a. REGULATION PART 158/ GUIDELINE NUMBER	8B. NAME OF TEST	9a. SUBMITTED BY APPLICANT	9b. DATE SUBMITTED	9c. SUBMITTED BY ANOTHER PERSON/FIRM (NAME)	9d. PERMISSION LETTER ENCLOSED	9e. PUBLIC LITERATURE	9f. N.A. OR WAIVER OR OTHER (EXPLAIN)	MRID NUMBER EPA ACCESSION NUMBER OR OTHER EPA IDENTIFYING NUMBER
§158.120	PRODUCT CHEMISTRY (Continued)							
63-8	Solubility	Citing	6/30/78	No				234427
63-9	Vapor pressure	Citing	6/30/78	No				234427
63-10	Dissociation constant	Citing	6/30/78	No				234427
63-11	Octanol/water partition coefficient	Citing	3/17/82	No				*
63-12	pH	Citing	3/17/82	No				*
63-13	Stability	Citing	6/30/78	No				234427
63-14	Oxidizing/reducing reaction	Citing	3/17/82	No				*
63-15	Flammability	Citing	3/17/82	No				*
63-16	Explodability	Citing	3/17/82	No				*
63-17	Storage stability	Citing	3/17/82	No				*
63-18	Viscosity						N.A. (2)	
63-19	Miscibility						N.A. (3)	
63-20	Corrosion characteristics	Citing	3/17/82	No				*
63-21	Dielectric breakdown voltage						N.A. (4)	

*Letter to H. Jacoby dated 3/17/82.
(2) Product not a liquid.
(3) Product not an emulsifiable liquid.
(4) Not required on technical.

[CENTERB-DOC.DATA-MATRIX]MATRIX-601-TECH

DATA REQUIREMENT FOR THE OWNER SUBMISSION METHOD OF SUPPORT

1. PRODUCT NAME: Ridomil® 2E	2. EPA REG. NO./FILE SYMBOL: 100-607	3. FORMULATOR'S EXEMPTION SELECTED: YES ___ NO X	4. PAGE 1 OF 3
5. APPLICANT'S NAME AND ADDRESS: Agricultural Division CIBA-GEIGY Corporation P. O. Box 18300 Greensboro, NC 27419	6. APPLICATION FOR REGISTRATION DATE: ___/___/___ MO DAY YR	7. NAME OF ACTIVE INGREDIENT(S): Metalaxyl	

8. DATA REQUIREMENTS		9. SOURCE OF DATA SATISFYING REQUIREMENT						10.
8a. REGULATION PART 158/ GUIDELINE NUMBER	8b. NAME OF TEST	9a. SUBMITTED BY APPLICANT	9b. DATE SUBMITTED	9c. SUBMITTED BY ANOTHER PERSON/FIRM (NAME)	9d. PERMISSION LETTER ENCLOSED	9e. PUBLIC LITERATURE	9f. N.A. OR WAIVER OR OTHER (EXPLAIN)	MRID NUMBER OR EPA ACCESSION NUMBER OR OTHER EPA IDENTIFYING NUMBER
§158.20	PRODUCT CHEMISTRY							
61-1	Identity of ingredients	Citing	2/23/83	No				249613
61-2	Statement of composition	Citing	2/23/83	No				249613
61-3	Discussion of formation of ingredients	Citing	2/23/83	No				249613
62-1	Preliminary analysis						N.A. (1)	
62-2	Certification of limits	Citing	2/23/83	No				249613
62-3	Analytical methods for enforcement limits	Citing	6/30/78	No				234427
63-2	Color	Citing	2/23/83	No				249613
63-3	Physical state	Citing	2/23/83	No				249613
63-4	Odor	Citing	2/23/83	No				249613
63-5	Melting point		2/23/83	No			N.A. (2)	*
63-6	Boiling point	Citing	2/23/83	No				249613
63-7	Density, bulk-density, or specific gravity	Citing	2/23/83	No				249613

(1) Not produced by an integrated formulation system; technical is registered.
(2) Not required for end-use product.

DATA REQUIREMENT FOR THE OWNER SUBMISSION METHOD OF SUPPORT

1. PRODUCT NAME: Ridomil® 2E	2. EPA REG. NO./FILE SYMBOL: 100-607	3. FORMULATOR'S EXEMPTION SELECTED: YES ___ NO X	4. PAGE 2 OF 3
5. APPLICANT'S NAME AND ADDRESS: Agricultural Division CIBA-GEIGY Corporation P. O. Box 18300 Greensboro, NC 27419	6. APPLICATION FOR REGISTRATION DATE: / / MO DAY YR	7. NAME OF ACTIVE INGREDIENT(S): Metalaxyl	

8. DATA REQUIREMENTS		9. SOURCE OF DATA SATISFYING REQUIREMENT						10.
8a. REGULATION PART 158/ GUIDELINE NUMBER	8b. NAME OF TEST	9a. SUBMITTED BY APPLICANT	9b. DATE SUBMITTED	9c. SUBMITTED BY ANOTHER PERSON/FIRM (NAME)	9d. PERMISSION LETTER ENCLOSED	9e. PUBLIC LITERATURE	9f. N.A. OR WAIVER OR OTHER (EXPLAIN)	MRID NUMB. EPA ACCESSION NUMBER OR OTHER EPA IDENTIFYING NUMBER
§158.20	PRODUCT CHEMISTRY (Continued)							
63-8	Solubility						N.A. (2)	
63-9	Vapor pressure	Citing	2/23/83	No				249613
63-10	Dissociation constant						N.A. (2)	
63-11	Octanol/water partition coefficient						N.A. (2)	
63-12	pH	Citing	2/23/83	No				249613
63-13	Stability						N.A. (2)	
63-14	Oxidizing/reducing reaction	Citing	2/23/83	No				249613
63-15	Flammability	Citing	2/23/83	No				249613
63-16	Explodability	Citing	2/23/83	No				249613
63-17	Storage stability	Citing	2/23/83	No				249613
63-18	Viscosity	Citing	2/23/83	No				24961*
63-19	Miscibility	Citing	2/23/83	No				24961

(2) Not required for end-use product.

DATA REQUIREMENT FOR THE OWNER SUBMISSION METHOD OF SUPPORT

1. PRODUCT NAME: Ridomil® 2E	2. EPA REG. NO./FILE SYMBOL: 100-607	3. FORMULATOR'S EXEMPTION SELECTED: YES ___ NO X	4. PAGE 3 OF 3
5. APPLICANT'S NAME AND ADDRESS: Agricultural Division CIBA-GEIGY Corporation P. O. Box 18300 Greensboro, NC 27419	6. APPLICATION FOR REGISTRATION DATE: / / MO DAY YR	7. NAME OF ACTIVE INGREDIENT(S): Metalaxyl	

8. DATA REQUIREMENTS		9. SOURCE OF DATA SATISFYING REQUIREMENT						10.
8a. REGULATION PART 158/ GUIDELINE NUMBER	8b. NAME OF TEST	9a. SUBMITTED BY APPLICANT	9b. DATE SUBMITTED	9c. SUBMITTED BY ANOTHER PERSON/FIRM (NAME)	9d. PERMISSION LETTER ENCLOSED	9e. PUBLIC LITERATURE	9f. N.A. OR WAIVER OR OTHER (EXPLAIN)	MRID NUMBER OR EPA ACCESSION NUMBER OR OTHER EPA IDENTIFYING NUMBER
§158.20	PRODUCT CHEMISTRY (Continued)							
63-20 63-21	Corrosion characteristics Dielectric breakdown voltage	Citing	2/23/83	No			N.A. (3)	2 4 9 6 1 3

(3) Not registered for use around electrical equipment.

SECTION B

AMOUNT, TIMING, AND FREQUENCY OF APPLICATION OF THE PESTICIDE METALAXYL TO MEMBERS OF THE NON-GRASS ANIMAL FEEDS CROP GROUPING

General Information

Metalaxyl 2E 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.

Alfalfa and Other Non-Grass Animal Feeds*

*Including velvetbean, clover, kudzu, lespedeza, lupine, sainfoin, trefoil, crown vetch, milk vetch.

Metalaxyl 2E applied to the soil at planting will provide control of damping-off caused by Pythium spp. and root rots caused by Phytophthora spp.

Stand Establishment

Apply 0.25-0.5 lb. a.i./A as a broadcast surface spray at planting in a minimum of 20 gallons of water or following impregnation on fertilizer.

If seed was previously treated with metalaxyl as a seed dressing, an application of Metalaxyl 2E at 0.25 lb. a.i./A is recommended at planting. Use the higher rate (0.5 a.i./A) in areas where disease pressure is expected to be heavy.

Note: To avoid possible illegal residues, do not feed green forage or cut for hay for 60 days following application.

Rotational Crops	Planting Time From Last Ridomil® Application
Non-Grass Animal Feeds	-0- Days

February 17, 1992

Note: See explanation in Section G, Introduction, Paragraph 4, regarding rate of metalaxyl recommended in this Section B.

SECTION C

FULL REPORTS OF INVESTIGATIONS MADE WITH RESPECT TO THE SAFETY OF THE PESTICIDE CHEMICAL

The following pages reference toxicology data previously submitted by CIBA-GEIGY on:

Metalaxyl Technical
Ridomil 2E Fungicide

February 17, 1992

DATA REQUIREMENT FOR THE SELECTIVE METHOD OF SUPPORT

1. PRODUCT NAME: Technical Metalaxyl	2. EPA REG. NO./FILE SYMBOL 100-601	3. FORMULATOR'S EXEMPTION SELECTED: YES ___ NO _X_	4. PAGE 1 OF 2
5. APPLICANT'S NAME AND ADDRESS: Agricultural Division CIBA-GEIGY Corporation Post Office Box 18300 Greensboro, NC 27419	6. APPLICATION FOR REGISTRATION DATE: / / MO DAY YR	7. NAME OF ACTIVE INGREDIENT(S): Metalaxyl	

8. DATA REQUIREMENTS		9. SOURCE OF DATA SATISFYING REQUIREMENT						10.
8a. REGULATION PART 158/ GUIDELINE NUMBER	8B. NAME OF TEST	9a. SUBMITTED BY APPLICANT	9b. DATE SUBMITTED	9c. SUBMITTED BY ANOTHER PERSON/FIRM (NAME)	9d. PERMISSION LETTER ENCLOSED	9e. PUBLIC LITERATURE	9f. N.A. OR WAIVER OR OTHER (EXPLAIN)	MRID NUMBER EPA ACCESSION NUMBER OR OTHER EPA IDENTIFYING NUMBER
§158.135	TOXICOLOGY							
81-1	Oral LD-50 - rat	Citing	6/30/78	No				2 3 4 4 2 8
81-2	Acute dermal LD-50	Citing	6/30/78	No				2 3 4 4 2 8
81-3	Acute inhalation LC-50 - rat		*					
81-4	Primary eye irritation - rabbit	Citing	6/30/78	No				2 3 4 4 2 8
81-5	Primary dermal irritation	Citing	6/30/78	No				2 3 4 4 2 8
81-6	Dermal sensitization	Citing	6/30/78	No				2 3 4 4 2 8
81-7	Acute delayed neurotoxicity - hen						N.A. (1)	
82-1	90-day feeding - rodent, non-rodent	Citing	6/30/78	No				2 3 4 4 2 8
82-2	21-day dermal	Citing	1/21/81	No				2 4 4 1
82-3	90-day dermal						N.A. (2)	
82-4	90-day (21-day if used in tobacco) inhalation - rat	Citing	6/10/82	No				2 7 4 6 6 1
82-5	90-day neurotoxicity - hen, mammal						N.A. (3)	

(1) Not an organic phosphate compound.
(2) Product not purpose fully applied to skin; no comparable exposure.
(3) Acute tests do not show neuropathy or neurotoxicity.
*Waived by Agency in review dated 5/10/91.

{CENTERB-DOC.DATA-MATRIX}MATRIX-601-TECH

DATA REQUIREMENT FOR THE SELECTIVE METHOD OF SUPPORT

1. PRODUCT NAME: Technical Metalaxyl	2. EPA REG. NO./FILE SYMBOL 100/601	3. FORMULATOR'S EXEMPTION SELECTED: YES ___ NO X	4. PAGE 2 OF 2
5. APPLICANT'S NAME AND ADDRESS: Agricultural Division CIBA-GEIGY Corporation Post Office Box 18300 Greensboro, NC 27419	6. APPLICATION FOR REGISTRATION DATE: / / (MO DAY YR)	7. NAME OF ACTIVE INGREDIENT(S): Metalaxyl	

8. DATA REQUIREMENTS		9. SOURCE OF DATA SATISFYING REQUIREMENT						10.
8a. REGULATION PART 158/ GUIDELINE NUMBER	8B. NAME OF TEST	9a. SUBMITTED BY APPLICANT	9b. DATE SUBMITTED	9c. SUBMITTED BY ANOTHER PERSON/FIRM (NAME)	9d. PERMISSION LETTER ENCLOSED	9e. PUBLIC LITERATURE	9f. N.A. OR WAIVER OR OTHER (EXPLAIN)	MRID NUMBER EPA ACCESSION NUMBER OR OTHER EPA IDENTIFYING NUMBER
§158.135	TOXICOLOGY (Continued)							
83-1	Chronic feeding - rodent, non-rodent	Citing	Multiple	No				*
83-2	Oncogenicity study - rat and mouse	Citing	Multiple	No				*
83-3	Teratogenicity - two species	Citing	Multiple	No				*
83-4	Reproduction - two-generation	Citing	4/15/81	No				0 7 0 0 1 5
84-2	Gene mutation	Citing	Multiple	No				*
84-2	Chromosomal aberration	Citing	Multiple	No				*
84-4	Other mechanisms of mutagenicity	Citing	6/10/82	No				2 7 4 6 6 1
85-1	General metabolism	Citing	10/22/90	No				4 1 6 6 4 5 0 1- 4 1 6 6 4 5 0 ^
86-1	Domestic animal safety						N.A. (4)	

(4) Not required for this product.
*See attached list.
[CENTERB-DOC.DATA-MATRIX]MATRIX-601-TECH

Multiple Toxicology Citations:

Type of Study	EPA Accession/MRID No.	Submitted
Rat chronic feeding/ oncogenicity study	070767	8/13/81
	070768	8/13/81
	070769	8/13/81
Mouse chronic feeding/ oncogenicity study	247660	6/10/82
Teratogenicity - Rat	234428	6/30/78
- Rabbit	070012	4/15/81
- Rabbit	255994, 255939	12/05/84
- Rat	256380	1/23/85
Mutagenicity	234428	6/30/78
	247661	6/10/82
	260496	11/27/85
	263117	5/30/86
General metabolism	070018	4/15/81
	070800	4/21/82
	670836	5/10/82
	41664501-41664502	10/22/90

DATA REQUIREMENT FOR THE OWNER SUBMISSION METHOD OF SUPPORT

1. PRODUCT NAME: Ridomil® 2E	2. EPA REG. NO./FILE SYMBOL: 100-607	3. FORMULATOR'S EXEMPTION SELECTED: YES ___ NO X	4. PAGE 1 OF 1
5. APPLICANT'S NAME AND ADDRESS: Agricultural Division CIBA-GEIGY Corporation P. O. Box 18300 Greensboro, NC 27419	6. APPLICATION FOR REGISTRATION DATE: / / MO DAY YR	7. NAME OF ACTIVE INGREDIENT(S): Metalaxyl	

8. DATA REQUIREMENTS		9. SOURCE OF DATA SATISFYING REQUIREMENT						10.
8a. REGULATION PART 158/ GUIDELINE NUMBER	8b. NAME OF TEST	9a. SUBMITTED BY APPLICANT	9b. DATE SUBMITTED	9c. SUBMITTED BY ANOTHER PERSON/FIRM (NAME)	9d. PERMISSION LETTER ENCLOSED	9e. PUBLIC LITERATURE	9f. N.A. OR WAIVER OR OTHER (EXPLAIN)	MRID NO. OR EPA ACCESSION NUMBER OR OTHER EPA IDENTIFYING NUMBER
§158.135	TOXICOLOGY							
81-1	Acute oral LD-50, rat	Citing	2/23/83	No				249614
81-2	Acute dermal LD-50	Citing	2/23/83	No				249614
81-3	Acute inhalation LC-50, rat	Citing	2/23/83	No				249614
81-4	Primary eye irritation, rabbit	Citing	2/23/83	No				249614
81-5	Primary dermal irritation	Citing	2/23/83	No				249614
81-6	Dermal sensitization	Citing	2/23/83	No				249614

SECTION D

RESIDUE DATA

Residue data which identify and support the request for tolerances for metalaxyl and its metabolites in the Non-Grass Animal Feeds Crop Grouping are located in Volume 2 of 2 of the data accompanying this petition and under EPA MRID #40832901.

February 17, 1992

SECTION E

PRACTICAL METHODS FOR REMOVING RESIDUES THAT EXCEED ANY PROPOSED TOLERANCES

The data presented in Section D of this pesticide petition indicate that the residue tolerances proposed in Section F will not be exceeded when metalaxyl is used in accordance with the amount, frequency, and time of application proposed in Section B. If the proposed Directions for Use are not followed and excessive metalaxyl residues result, there is no economic or practical method for removing these residues.

February 17, 1992

SECTION F

PROPOSED TOLERANCES

We hereby request tolerances for the combined residues of the fungicide metalaxyl [N-(2,6-dimethylphenyl)-N-(methoxyacetyl)alanine methyl ester] and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methylphenyl)-N-(methoxyacetyl)alanine methyl ester, each expressed as metalaxyl equivalents, in or on the following:

Non-Grass Animal Feeds Forage	6.0 ppm
Non-Grass Animal Feeds Hay	20.0 ppm

(CIBA-GEIGY hereby requests when the above tolerances are established, tolerances in alfalfa forage at 6.0 ppm and alfalfa hay at 20 ppm be withdrawn because the crop tolerances for non-grass animal feeds will cover residues in alfalfa.)

February 17, 1992

SECTION G

REASONABLE GROUNDS IN SUPPORT OF THIS PETITION

METALAXYL - NONGRASS ANIMAL FEEDS CROP GROUPING

INTRODUCTION

Metalaxyl, [N,(2,6-dimethylphenyl)-N-(methoxyacetyl)alanine-methyl ester, is the common name for the active ingredient contained in Ridomil® 2E Fungicide, EPA Reg. No. 100-607. Ridomil 2E is an emulsifiable concentrate containing two pounds active ingredient per gallon. An application to amend the registration of Ridomil 2E is submitted simultaneously with this petition to allow use on all members of the Nongrass Animal Feeds Crop Grouping as defined at 40CFR180.34(f)(9)(xviii)(A) and (B). Ridomil 2E is currently registered on alfalfa, one of the representative commodities of the Nongrass Animal Feeds Crop Grouping. Tolerances were established for metalaxyl and its metabolites in alfalfa forage at 6.0 ppm and alfalfa hay at 20.0 ppm in early 1991.

Metalaxyl is a systemic fungicide for use on many fruit and vegetable crops, as well as soybeans, peanuts, cotton, hops, tobacco, walnuts, and almonds. Petitions are pending for ginseng (IR-4, PP1E3926), leafy vegetables (PPOF3893), cranberries (IR-4, PP1E4024), grapes (PP6F3362), grasses (PP2F4063), cole crops (PP2F4072) and cereal grains (PP1F3993).

The purpose of this petition is to establish tolerances for metalaxyl in the Nongrass Animal Feeds Crop Grouping. Residue data has been generated for clover, the other representative commodity. The results of this work are presented in Volume 2 of 2 of the data accompanying this petition. These data coupled with the data supporting the alfalfa tolerances (located under EPA MRID No. 40832901) demonstrate that tolerances of 6.0 in Nongrass Animal Feeds forage and 20.0 ppm in Nongrass Animal Feeds Hay are appropriate. See further discussion under Field Studies in this Section G.

The use pattern can be explained as follows. Data for alfalfa (EPA MRID No. 40832901) and clover (Volume 2 of 2 of the data accompanying this petition) were generated using 1.0 lb. ai/A of metalaxyl at planting (4 pts. of Ridomil 2E). When originally accepted for the use on alfalfa, the Ridomil 2E label recommended this rate. Because CIBA-GEIGY was interested in the entire group grouping, additional trials for clover were then. placed at 1.0 lb. ai/A. After the alfalfa tolerances were established, CIBA-GEIGY, through continuing research efforts, determined only 0.25-0.5 lb. ai/A was needed to achieve the desired disease control. Therefore, the Ridomil 2E alfalfa label was amended to lower the rate from up to 4 pts. to

1-2 pts./A. Because this is now the recommended rate, the use rate for the Nongrass Animal Feeds group will be 1-2 pts./A. CIBA-GEIGY recognizes the residue data for clover were generated at the higher rate of 1.0 lb. ai/A (4 pts.) but because these commodities are fed to animals and existing milk and meat, tolerances are not affected by feeding of nongrass animal feeds, CIBA-GEIGY believes the data enclosed should be used to support the requested tolerances.

According to 40CFR180.34(f)(5), representative crops which exhibit more than a five-fold difference in residues may necessitate the setting of individual tolerances, rather than a crop grouping tolerance. In the case of alfalfa and clover, the clover maximum residues did exhibit more than a five-fold difference. Alfalfa maximum residues at a 60-day PHI were 5.1 ppm in alfalfa forage and 18 ppm in alfalfa hay. Clover maximum residues at a 60-day PHI were 0.99 ppm in clover forage and 2.3 ppm in clover hay (predicted residue). Note that with the exception of the residue trial on alfalfa in WA, residues in alfalfa forage and hay at a 60-day PHI were all within a five-fold difference when compared to the maximum clover residues. The residues seen in the WA alfalfa trial, however, were used to establish the tolerances. Because nongrass animal feeds are not used for direct human consumption, only through animal products, CIBA-GEIGY believes crop group tolerances should be established. Existing tolerances for metalaxyl in animal commodities are adequate to cover the feeding of nongrass animal feeds.

Metabolism in Plants, Animals and Soil

Previously, detailed accounts of ϕ-^{14}C-metalaxyl metabolism in lettuce, grapes, tobacco, potatoes, soil, and animals have been submitted (Pesticide Petition No. 1F2500) and are available under EPA Accession No. 070018. Additional data from a subsequent ^{14}C-metalaxyl metabolism study in lettuce have been submitted under EPA Accession No. 071108. Plants rapidly degrade metalaxyl to multiple metabolites via cleavage of the ester and ether bonds, oxidation of the phenyl and benzylic carbons, and N-dealkylation followed by conjugation.

The rat and goat rapidly metabolize and excrete metalaxyl via the same metabolic pathways as plants. Urinary metabolites are polar, primarily glucuronide and other conjugates. Metalaxyl and its metabolites are neither retained in animal tissues nor secreted in goat milk.

The major soil metabolite of metalaxyl is the acid, CGA-62826 [N-(2,6-dimethylphenyl)-N-(methoxyacetyl)alanine]. Residues are increasingly nonextractable with time. There is little leaching in silt loam or sandy loam soil.

Environmental Chemistry and Environmental Safety

Previously submitted environmental chemistry studies are submitted by reference in support of this petition (EPA Accession Nos. 234431 and 234438, EPA MRID No. 41156001).

Previously submitted environmental safety studies demonstrate that the use of metalaxyl, as proposed in Section B of this petition, would have no unreasonable adverse effects on fish and wildlife (EPA Accession Nos. 234439, 236854, and 244183, EPA MRID Nos. 41288101-41288104).

Toxicology

The safety of the proposed tolerances in Section F of this petition are demonstrated in previously submitted toxicology studies referenced in Section C of this petition.

A no-observable effect level (NOEL) of 250 ppm (6.25 mg/kg/day) has been established from the results of the six-month subchronic feeding study in beagle dogs with Technical Metalaxyl. Using a 100:1 safety factor and 250 ppm as the NOEL, the reference dose (Rfd) is calculated to be 0.063 mg/kg/bwt/day. The theoretical maximum residue contribution (TMRC) from previously established tolerances and food additive regulations is 0.010533 mg/kg/bwt/day or 17.55% of the Rfd (56 FR 24160). The substitution of a Crop Grouping tolerance for the alfalfa tolerances should not affect the percent of the Rfd utilized as these commodities are not consumed directly by humans, but rather fed to animals which are already covered by existing tolerances.

Field Studies

Twelve clover field trials, representing approximately 36% of United States clover production (Agricultural Statistics 1990, USDA), were conducted in California, Georgia, Illinois, Missouri, Nebraska, New York, North Dakota, Ohio, Oklahoma, Pennsylvania, South Dakota and Texas. The 1X treatment rate consisted of one at-planting broadcast application of Ridomil 2E at 1.0 lb. a.i./A. For residue comparison purposes, exaggerated 2X treatments were also applied.

Maximum 1X total residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline (DMA) moiety and N-[2-(hydroxymethyl)-6-methylphenyl-N-(methoxyacetyl)alanine methyl ester in clover forage (60-day PHI) and hay (90-day PHI) were 0.99 ppm and 1.6 ppm, respectively. For the 2X treatment rate, maximum total metalaxyl residues were 2.6 ppm and 3.0 ppm for forage (60-day PHI) and hay (90-day PHI), respectively.

Hay samples were not collected at the first cutting; however, metalaxyl residues in hay at a 60-day PHI can be predicted by calculating a forage-to-hay concentration factor from the second-cutting data, then multiplying the first-cutting forage residue by this factor. Using data from field test 04-FR-005-89, an example is presented below:

$$\frac{\text{0.87 ppm (hay, second cutting)}}{\text{0.37 ppm (forage, second cutting)}} = 2.351 \text{ (conc. factor)}$$

The range of calculated concentration factors is 1.167-4.500. The average concentration factor for all the forage-to-hay data is 2.287 (n = 22). [Note: concentration factors were not calculated if residues were below the 0.05 ppm screening level.]

Therefore, the maximum residue predicted in first-cutting hay (60-day PHI) using the average concentration factor would occur in field trial MW-FR-606-89 and is shown as follows:

2.287 x 0.99 ppm (forage, first cutting) = 2.3 ppm

Transfer of Residue to Animals

Beef and dairy cattle may consume alfalfa and clover. Poultry do not consume clover or alfalfa forage and hay; however, processed alfalfa meal may be included as a minor (i.e., 5%) constituent of poultry feed. This information was obtained from the published EPA document: Pesticide Assessment Guideline, Subdivision O, Residue Chemistry (Richard D. Schmitt, Ph.D., EPA 540/9-82-023, October, 1982 and revised on December 24, 1989).

A theoretical diet for cattle consuming maximum metalaxyl residues from alfalfa hay and peanut hay was calculated in ABR-89016 (MRID No. 41150101). Maximum 1X metalaxyl residues in clover forage (0.99 ppm) and hay (1.6 ppm) and the maximum predicted residue (2.3 ppm) in 60-day hay are less than the established tolerances for alfalfa forage (6 ppm) and hay (20 ppm), respectively. Based on the theoretical diet calculations and feeding studies discussed in ABR-89016 and the data presented in Volume 2 of 2, feeding of commodities from the Nongrass Animal Feed Group treated with metalaxyl at the maximum labeled (1X) rate of 1.0 lb. a.i./A will not cause the established residue tolerances of 0.5 ppm in round steak and tenderloin, 0.02 ppm in milk, and 0.4 ppm in liver and kidney to be exceeded.

Conclusions

Metalaxyl has been shown to be an effective fungicide to control diseases on a wide variety of vegetable crops, including nongrass animal feeds. Data presented support the establishment of tolerances at 6.0 ppm in nongrass animal feeds forage and 20.0 ppm in nongrass animal feeds hay to allow a soil application of Ridomil 2E at 1-2 pts./A to control diseases caused by Pythium and Phytophthora spp.

The residue data presented and referenced in Section D of this petition in combination with data previously generated on alfalfa will support tolerances for residues of metalaxyl and its metabolites as proposed in Section F.

Toxicology studies show that the use of metalaxyl, as proposed in Section B of this petition, should have no adverse effects on the user or on the public health.

[GANNONC.DRAFTS]H109CG0210KSS

SUPPLEMENTAL LABELING

RIDOMIL® 2E FUNGICIDE
EPA REG. NO. 100-607

NON-GRASS ANIMAL FEEDS

Active Ingredient:	
Metalaxyl: N-(2,6-dimethylphenyl)-N-(methoxyacetyl) alanine methyl ester	25.1%
Inert Ingredients:	74.9%
Total	100.0%

KEEP OUT OF REACH OF CHILDREN

WARNING/AVISO

PRECAUCIÓN AL USUARIO: Si usted no lee inglés, no use este producto hasta que la etiqueta haya sido explicado ampliamente.

All applicable directions, restrictions, and precautions on the EPA-registered Ridomil 2E label are to be followed.

This label must be in the possession of the user at the time of pesticide application.

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

FAILURE TO FOLLOW THE DIRECTIONS FOR USE AND PRECAUTIONS ON THIS LABEL MAY RESULT IN POOR DISEASE CONTROL, CROP INJURY AND/OR ILLEGAL RESIDUES.

General Information

Ridomil 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.

Alfalfa and Other Non-Grass Animal Feeds*

*Including velvetbean, clover, kudzu, lespedeza, lupine, sainfoin, trefoil, crown vetch, milk vetch.

Ridomil 2E applied to the soil at planting will provide control of damping-off caused by Pythium spp. and root rots caused by Phytophthora spp.

Stand Establishment

Apply 1 to 2 pts./acre as a broadcast surface spray at planting in a minimum of 20 gallons of water or following impregnation on fertilizer.

If seed was previously treated with metalaxyl as a seed dressing, an application of Ridomil 2E at 1 pt./acre is recommended at planting. Use the higher rate (2 pts./acre) in areas where disease pressure is expected to be heavy.

Note: To avoid possible illegal residues, do not feed green forage or cut hay for 60 days following application.

Rotation (Plantback) Restrictions

Do not plant any crop which is not registered for use with metalaxyl in metalaxyl-treated soil for a period of 12 months, with the exception of wheat, barley and oats. See list below.

Rotation Crop	Planting Time From Ridomil 2E Application
Alfalfa	-0- days
Almonds	-0- days
Apples	-0- days
Asparagus	-0- days
Avocados	-0- days
Blueberries	-0- days
Broccoli	-0- days
Cabbage	-0- days
Cauliflower	-0- days
Chinese Broccoli (gai lon, white flowering broccoli)	-0- days
Chinese Cabbage (tight-heading varieties only)	-0- days
Citrus	-0- days
Cucurbit Vegetables	-0- days
Deciduous Fruits and Nuts*	-0- days
Eggplant	-0- days
Hops	-0- days
Leafy Vegetables	-0- days
Legume Vegetables	-0- days
Non-Grass Animal Feeds**	-0- days
Onions	-0- days
Papayas	-0- days
Peanuts	-0- days
Peppers	-0- days
Pineapples	-0- days
Potatoes	-0- days
Raspberries	-0- days
Root and Tuber Vegetables	-0- days
Soybeans	-0- days
Spinach	-0- days
Stone Fruits	-0- days
Strawberries	-0- days
Tobacco	-0- days
Tomatoes	-0- days
Walnuts	-0- days
Wheat/Barley/Oats	14 days
Corn	12 months
Crops Not Intended for Food or Feed	-0- days
All Other Crops Intended for Food or Feed	12 months

*These crops and other perennial crops may be planted immediately following last application of Ridomil 2E provided they will not bear harvestable fruit within 12 months.

**Including velvetbean, clover, kudzu, lespedeza, lupine, sainfoin, trefoil, crown vetch, milk vetch.

Ridomil® trademark of CIBA-GEIGY Corporation for metalaxyl.
U.S. Patent No. 4,151,299

Agricultrual Division
Greensboro, North Carolina

February 10, 1992

[GANNONC.LABELR] - RDML2E-SL-NG - 2/10/92

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