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

MAR 6 1992

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: ID #000100-00607 and #000100-00628: Amended Registration of Metalaxyl in/on Ginseng (MRID #416889-00, #416889-01, CBTS #9054 and #9058).

FROM: W. T. Chin, Ph.D., Chemist W. T. Chin
Tolerance Petition Section III
Chemistry Branch, Tolerance Support
Health Effects Division (H7509C)

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

TO: Susan Lewis, PM #21
Registration Division (H7505C)

BACKGROUND

In connection with PP#1E3926, the Agency proposed establishing a tolerance for the combined residues of metalaxyl, [N-(2,6-dimethylphenyl)-N-(methoxyacetyl) alanine methyl ester] and its metabolites, in or on ginseng at 3.0 ppm (FR p.42577, 8/28/91). This proposed rule was subject to 30 days of public comment, which expired on 9/27/91.

The petitioner, IR-4, and Ciba-Geigy submitted an amended registration on 9/13/91 with Supplemental Labelings of Ridomil® 5G and Ridomil® 2E, the two formulations of metalaxyl, to clarify the Direction For Use of these products on ginseng.

Metalaxyl is a List A chemical. The Metalaxyl Registration Standard was issued in September, 1988; the Chemistry Chapter was issued on 6/22/87 and updated on 3/13/91.

DETAILED CONSIDERATIONS

Ciba-Geigy markets two formulations of metalaxyl: Ridomil® 5G (EPA Reg. #100-607, 5% ai and 95% inert) and Ridomil® 2E (EPA Reg. #100-628, 25.1% ai and 74.9% inert, 2 lb ai/gal). These two products were used for field trials in 1988-1989 on ginseng and the residue data generated were reported in MRID #614889-01 by which a 3.0 ppm tolerance for the combined residues of metalaxyl and its metabolites in/on ginseng has been proposed by the Agency (FR p.42577, 8/28/91).

However, the proposed rate shown under Direction For Use on page 6 of MRID #614889-00 was given in terms of lb ai (metalaxyl)/A/season without specifying the use of these two products, as cited below:

Direction For Use of Metalaxyl (p. 6, MRID #416889-00, 10/31/90)

"Metalaxyl applied to the soil before early spring growth followed by additional applications at monthly intervals will control phytophthora root rot in ginseng caused by phytophthora cactorum.

Apply metalaxyl at 0.75 lb ai/A uniformly to the soil surface in the spring before the plants begin growing. Make additional applications of metalaxyl at monthly intervals at 0.5 lb ai/A. Up to four supplemental applications may be made. The last application of metalaxyl may be made at 0.75 lb ai/A.

Notes: To avoid possible illegal residues, (1) Do not apply more than a total of 3 lbs ai of metalaxyl/A of ginseng/growing season and (2) Do not harvest ginseng within 9 days of a metalaxyl application."

Based on the proposed rate of metalaxyl shown above, the Direction For Use of these two products were clarified during the 1988-1989 field trials, as cited below:

Direction For Use of Ridomil® 5G and Ridomil® 2E (p. 8, MRID #416889-01, 9/12/90):

".... for a maximum of five applications of metalaxyl: The first treatment can be made using either Ridomil® 2E or Ridomil® 5G at 0.75 lb ai/A as a soil application prior to

early spring growth, followed by four additional supplemental applications using only Ridomil® 5G formulation at 0.50 lb ai/A at monthly intervals. The last application may be made at 0.75 lb ai/A. The directions do not allow the use of Ridomil® 2E formulation in any of the supplemental applications in order to minimize the possibility of resistance....."

In order to be consistent and to avoid possible misunderstandings, the petitioner currently submits an amended registration with revised Supplemental Labelings of Ridomil® 5G and Ridomil® 2E as follows:

The Revised Direction For Use of Ridomil® 5G (9/13/91)

"Ridomil® 5G applied to the soil before early spring growth followed by additional applications at monthly intervals will control phytophthora root rot in ginseng caused by phytophthora cactorum.

Apply Ridomil® 5G at 15 lbs/A uniformly to the soil surface in the spring before the plants begin growing. Make additional applications of Ridomil® 5G at monthly intervals at 10 lbs/A. Up to four supplemental applications may be made. The last application of Ridomil® 5G may be made at 15 lbs/A.

Notes: To avoid possible illegal residues, (1) Do not apply more than a total of 60 lbs of Ridomil® 5G/A of ginseng/growing season. (2) If Ridomil® 2E is applied to the soil before early spring growth, do not apply more than 45 lbs of Ridomil® 5G as supplemental applications. (3) Do not harvest ginseng within 9 days of a Ridomil® 5G application."

The Revised Direction For Use of Ridomil® 2E (9/13/91)

"Ridomil® 2E applied to the soil before early spring growth followed by additional applications of Ridomil® 5G (see Ridomil® 5G label) will control phytophthora root rot in ginseng caused by phytophthora cactorum.

Apply Ridomil® 2E at 3 pts/A as a drench in 100-400 gallons of water uniformly to the soil surface in the spring before the plants begin growing.

Note: Do not make any additional applications of Ridomil® 2E."

Comment/Conclusion

The last Note of the revised Direction For Use of Ridomil® 5G should be corrected to: (3) Do not harvest ginseng within 9 days after a Ridomil® 5G application.

The original Direction For Use previously submitted on p. 6 of MRID #416889-00 dated 10/31/90 is not changed, but is clarified by the supplemental labelings of Ridomil® 5G and Ridomil® 2E. Since field trials are reflective of the supplemental labelings of Ridomil® 5G and Ridomil® 2E and the residue data so generated are adequate to support the 3.0 ppm tolerance for the combined residues of metalaxyl and its metabolites in/on ginseng as proposed by the Agency, CBTS has no objections to this amended registration.

Recommendation

Pending correction of the Note (3) of the revised Direction For Use of Ridomil® 5G, CBTS has no objections to this amended registration.

cc: Circu, RF, PP#1E3926, W.T.Chin, Amended Reg. file.

RDI: P.V.Errico (3/4/92), R.Loranger(3/4/92)
H7509C: CBTS: CM#2, RM812, 305-5352, W.T.Chin,wc(3/5/92)

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

APR 8 1991

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: PP#1E3926 - Metalaxyl on Ginseng - Amendment of March 21, 1991 (DEB No. 7787)

FROM: Gary F. Otakie, Chemist
Tolerance Petition Section II
Chemistry Branch I - Tolerance Support
Hazard Evaluation Division (H7509C)

TO: Hoyt L. Jamerson, PM Team 43
Registration Division (H7505C)

and

Toxicology Branch II - Herbicide, Fungicide, and Antimicrobial Support
Hazard Evaluation Division (H7509C)

THRU: Elizabeth T. Haeberer, Section Head
Tolerance Petition Section II
Chemistry Branch I - Tolerance Support
Hazard Evaluation Division (H7509C)

Per a March 21, 1991 letter from George M. Markle, International Research Project No. 4, this amendment responds to the following deficiency noted in CBTS's review (see G. Otakie memo of February 22, 1991):

Deficiency

A revised Section B is needed. The Section B submitted is inconsistent with the proposed use directions on page 12 of the report, which recommends that the first application be made with either the 2E or 2G formulation while the remaining 4 supplemental applications be made with only the 2G formulation, to minimize the possibility of resistance. Also, if two formulations are proposed, the label must

include appropriate instructions to ensure that the combined application of the two formulations does not exceed the approved maximum application rate.

Petitioner's Response to Deficiency

The petitioner has submitted a revised Section B, which provides that the first application can be made with either the 2E or 5G formulation, and that only the 5G formulation be used for the up to four supplemental applications. Also, the following statement has been added to ensure that the combined application of the two formulations does not exceed the approved maximum application rate:

"1. Do not apply more than a total of three lbs a.i. of metalaxyl 2E or 5G/A of ginseng/growing season,"

CBTS's Comments/Conclusions

The revised Section B is acceptable.

Recommendation

TOX considerations permitting, CBTS recommends for the proposed 3.0 ppm metalaxyl tolerance on ginseng.

cc: RF, Circ, Otakie, PP#1E3926, PIB/FOD (Furlow), R. Schmitt, FDA, DRES/SACB (Kariya), E. Haeberer
Approved: E.T. Haeberer 3/28/91; R.A. Loranger 3/29/91

THE STATE UNIVERSITY OF NEW JERSEY
RUTGERS
INTERDISCIPLINARY RESEARCH, EDUCATION AND PUBLIC SERVICE
New Jersey Agricultural Experiment Station
P.O. Box 231 • New Brunswick • New Jersey 08903-0231
908/932-8075 • FAX: 908/932-8481

March 21, 1991

Hoyt C. Jamerson
Senior Use Officer
Emergency Response and Minor Use
Section
Registration Support Branch
Registration Division (H7505C)
OPP, EPA
Washington, DC 20460

Dear Hoyt:

RE: Metalaxyl/Ridomil
PP No.: 1E 3926

This refers to EPA's 28 FEB 91 letter, enclosing the above petition.

As requested, enclosed is a revised section B which clarifies the use of the 1E 3 5G formulations as reflected in the residue data report.

Section 18's have been requested for this use [illegible]. An expedited review would be helpful. We appreciate your continued cooperation.

Sincerely,

George M. Markle
Associate Director
IR-4 Project

cc: [illegible]
[illegible], CIBA-GEIGY

Post-it™ brand fax transmittal memo 7671

To Hoyt Jamerson	From George
Co. EPA	Co. IR-4
Dept.	Phone # 908-932-[illegible]
Fax # 703-557-3106	Fax # 908-932-8481

SECTION B

THE AMOUNT, FREQUENCY AND TIME OF APPLICATION OF METALAXYL IN GINSENG PRODUCTION

Formulations: (Registered labels are exhibited in Volume 2, pages 119 & 127)

1) Ridomil® 2E, EPA Reg. No. 100-607

EQUIVALENTS

Product		a.i./A
3 pints	=	0.75 lbs.

2) Ridomil 5G, EPA Reg. No. 100-628

Product		a.i./A
10 lbs.	=	0.5 lbs.
15 lbs.	=	0.75 lbs.

Revised 8 MAC 91

SECTION B

AMOUNT, TIMING AND FREQUENCY OF APPLICATION OF THE PESTICIDE METALAXYL TO GINSENG

General Information

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

Ginseng

Metalaxyl applied to the soil before early spring growth followed by additional applications at monthly intervals will control Phytophthora root rot in ginseng caused by **Phytophthora cactorum**.

Apply metalaxyl 2E or 5G at 0.75 lb. a.i./A uniformly to the soil surface in the spring before the plants begin growing. Make additional applications of metalaxyl 5G only at monthly intervals at 0.5 lb. a.i./A. Up to four supplemental applications may be made. The last application of metalaxyl 5G may be made at 0.75 lb. a.i./A.

Notes: To avoid possible illegal residues, (1) Do not apply more than a total of three lbs. a.i. of metalaxyl 2E or 5G/A of ginseng/growing season, and (2) Do not harvest ginseng within nine days of a metalaxyl application. (3) Do not use metalaxyl 2E for any of the supplemental applications.

Rotational Crops

Rotation Crop	Planting Time From Metalaxyl Application
Ginseng	0 days

October 29, 1990

Revised March 8, 1991

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

FEB 26 1991

Pesticide Petition 1E3926

Professor George M. Markle
IR-4 Project National Coordinator
New Jersey Agricultural Experiment Station
Box 231, Cook College, Rutgers University
New Brunswick, New Jersey 08903

Dear George:

This is in reference to the subject petition proposing establishment of a tolerance for residues of the fungicide metalaxyl in or on the raw agricultural commodity ginseng root (fresh) at 3.0 ppm.

We have completed an evaluation of the petition and find that we are unable to act favorably toward establishment of the proposed tolerance for the following reason:

The Section B which was submitted is inconsistent with the proposed use directions on page 12 of the report entitled Metalaxyl - Ginseng Residue Summary. These directions recommend that the first application be made with either the 2E or 5G formulation while the remaining four supplemental applications be made only with the 5G formulation, to minimize the possibility of resistance. Also, if two formulations are proposed, the label should include appropriate instructions to ensure that the combined application of the two formulations does not exceed the approved maximum application rate. Therefore, a revised Section B is requested.

Since the 2E formulation is recommended as an alternative to the 5G formulation for the single first application only, for simplicity, it is suggested that the proposed use be limited to the 5G formulation only.

An evaluation of the toxicological significance of the proposed use cannot be completed until the residue chemistry considerations discussed above are resolved.

Please respond within [illegible] days of the date of this letter, stating your intentions to comply with the information/data required as listed above. Include a projected time schedule for such compliance.

Sincerely,

Hoyt L. Jamerson
Minor Use Officer
Emergency Response and
Minor Use Section, RSB
Registration Division (H7505C)

CHEMISTRY BRANCH I - TOLERANCE SUPPORT, HED

DATA REVIEW QUICK FORM

Date: FEB 22 1991

MEMORANDUM

SUBJECT: Petition Review for Establishment of Tolerance(s). Evaluation of Analytical Method(s) and Residue Data.

FROM: GARY F. OTAKIE, Chemist
Tolerance Petition Section II
CHEMISTRY BRANCH I - TOLERANCE SUPPORT
Hazard Evaluation Division, H7509C

Gary F. Otakie

THRU: ELIZABETH T. HAEBERER, SECTION HEAD
Tolerance Petition Section II
CHEMISTRY BRANCH I - TOLERANCE SUPPORT
Hazard Evaluation Division, H7509C

Elizabeth T. Haeberer

TO: HOYT L. JAMERSON PM 43
Registration Division, H7505C

and

Toxicology Branch - HFA SUPPORT
Hazard Evaluation Division, H7509C

1. Petition No(s): 1E3926
2. DEB No(s): 7340
3. MRID No(s): 416889-00 AND 416889-01
4. Pesticide(s): METALAXYL
5. Tolerance Proposal (RACs & Levels): GINSENG AT 3.0 PPM
6. Petitioner: IR-4 AND THE AGR. EXP. STATION OF NEW JERSEY ON BEHALF OF AGR. EXP. STATIONS IN NORTH CAROLINA AND WISCONSIN

7. Tolerance Expression: METALAXYL AND ITS METABOLITES PER 40 CFR 180.408 (a)

8. Established Pesticide Tolerances: 40 CFR 180.408 a AND b, VARIOUS RACS AND COMMODITIES OF ANIMAL ORIGIN FROM 0.1 PPM ON BEETS, BROCCOLI, GRAIN CROPS, PINEAPPLES, ETC. TO 20.0 PPM ON PEANUT HAY, 0.05 PPM EGGS, 0.02 PPM MILK, 0.05 AND 0.4 PPM IN MEAT AND FAT, RESPECTIVELY OF CATTLE, GOATS, HOGS, HORSES, SHEEP AND POULTRY

9. Established Food Additive Tolerances: 21 CFR 193.277 1.0 PPM IN WHEAT MILLING FRACTIONS TO 7.0 PPM IN CITRUS OIL

10. Established Feed Additive Tolerances: 21 CFR 561.273 0.4 PPM IN APPLE POMACE (WET) TO 16.0 PPM IN TOMATO POMACE (DRY)

11. Is Pesticide a Registration Standard Chemical? (Yes/No) _____

If yes, date Guidance Document issued: _____

12. Letter(s) of Authorization (if applicable): CIBA-GEIGY TO EPA DATED OCTOBER 25, 19?? FROM KAREN S. STUMPF

13. Formulation(s): RIDOMIL® 2E (EPA REG. NO. 100-607) WITH 2 LBS A.I./GAL OR 25.1% W/W A.I.; AND RIDOMIL® 5G (EPA REG. NO. 100-628), GRANULAR, 5% W/W A.I.

14. Inerts Status: UNDER RD

15. Manufacturing Process: CONFIDENTIAL APPENDIX B TO FRSTR AND IN PP# IF2500, 3/9/82, P.V. ERRICO; DEB DOES NOT FORSEE ANY RESIDUE PROBLEMS ON FRUITING VEGETABLES FROM IMPURITIES IN THE TECHNICAL AT THE LEVELS GIVEN (SEE 6F3387, 9/26/86 MEMO OF F.D. GRIFFITH).

16. Proposed Use(s): AS A SYSTEMIC FUNGICIDE TO CONTROL DISEASE CAUSED BY MEMBERS OF OOMYCETE CLASS OF FUNG
- APPLY METALAXYL AT 0.75 LB A.I./A TO SOIL SURFACE IN SPRING BEFORE PLANTS BEGIN GROWING.
- MAKE ADDITIONAL APPLICATIONS OF METALAXYL AT MONTHLY INTERVALS AT 0.5 LB A.I./A, UP TO TO FOUR SUPPLEMENTAL APPLICATIONS WITH LAST APPLICATION OF 0.75 LB A.I./A MAY BE MADE (i.e. TOTAL MAX. OF 5 APPLICATIONS AND 3 LBS AI/A); 9 DAY PHI

17. Plant Metabolism Data on: POTATOES, GRAPES AND LETTUCE

18. Plant Residues Comprised of: METALAXYL, AND FROM HYDROLYSIS OF METHYL ESTER BOND, RING METHYL OXIDATION AND HYDROXYLATION TO FORM CGA-62826, CGA-100255 AND CGA-94684 (SEE FRSTR PP 3-12).

19. Plant Metabolism Data Translatable Here: POTATOES, GRAPES AND LETTUCE

20. Nature of Plant Metabolism on the Subject RAC(s) of This Petition (is)/is not adequately defined.

The Residue of Concern is: METALAXYL AND METABOLITES CONTAINING 2,6-DIMETHYLANILINE MOIETY AND N-(2-HYDROXY METHLY-6-METHYL)-N-(METHOXYACETYL) ALANINE METHYL ESTER, EACH EXPRESSED AS METALAXYL EQUIVALENTS.

21. Animal Metabolism Data on: RATS, GOATS AND COWS. FRSTR REQUIRED NEW RUMINANT AND POULTRY METABOLISM STUDIES FOLLOWING DEB GUIDELINES; WHICH ARE CURRENTLY UNDER EPA REVIEW.

22. Animal Residues Comprised of: CURRENTLY SAME AS PLANTS. REQUIRED ANIMAL METABOLISM STUDIES IN ITEM 21 ABOVE, NOW BEING REVIEWED UNDER FRSTR.

23. Animal Metabolism Data Applicable Here: GINSENG NOT AN ANIMAL FEED ITEM.

24. Nature of Animal Metabolism Data is/(is not) adequately defined.
The Residue of Concern is: N/A - NO ANIMAL FEED ITEMS FROM THE PROPOSED USE ON GINSENG.

25. Analytical Method(s) (Give Reference and/or Brief Description)
CIBA-GEIGY METHOD AG-395 (SEE PP# 8F3617/8H554 NOVEMBER 28, 1988 MEMO OF F.D. GRIFFITH). METALAXYL AND METABOLITES CONTAINING THE 2,6-DIMETHYLANILINE MOIETY ('TOTAL' RESIDUES) ARE DETERMINED. SAMPLES EXTRACTED BY REFLUXING WITH 80% (V/V) METHANOL/WATER FOR TWO HOURS; SAMPLE EVAPORATED TO DRYNESS AND WATER ADDED, REFLUXED FOR 15 MINUTES AFTER ADDITION OF METHANESULFONIC ACID; EXTRACT BASIFIED AND 2,6-DIMETHYLANILINE FORMED IS STEAM DISTILLED AND CLEANED UP WITH SILICA SEPPAK; TRIFLUOROACETIC ACID IS ADDED TO ELUATE TO FORM SALT (DMA-TFA); CAPILLARY GAS CHROMATOGRAPHY USING NITROGEN/PHOSPHORUS DETECTOR IN NITROGEN MODE.

26. Has there been a Method Trial? (Yes) No) AG-395

If yes, provide details: FOR RESULTS OF MTO SEE PP# 3F2978, JULY 9, 1984 MEMO OF P. JUNG; METHOD SUBMITTED TO EDA AS ENFORCEMENT METHOD.

If no, is a Method Trial needed? _____

27. Residues Determined by Method(s): METALAXYL AND METABOLITES CONTAINING THE 2,6-DIMETHYLANILINE MOIETY

28. Method Validation (RACs/"spike chemical"/fortification level(s)/ recovery range/average recovery):

FRESH GINSENG FORTIFIED WITH METALAXYL FROM 0.05 TO 5.0 PPM WITH RECOVERIES FROM 71 TO 140%, N=14, MEAN 103.3%, SD = 23%; DRIED GINSENG WITH METALAXYL FROM 0.05 TO 5.0 PPM WITH RECOVERIES FROM 58 TO 109%; N=13, MEAN = 82.8%, SD = 14.6%

29. Method Validation (limit of detection and/or sensitivity in ppm):

Parent: LIMIT OF DETECTION = 0.05 PPM

Metabolite(s) (specify): PARENT AND METABOLITES DETERMINED AS ONE MOIETY.

30. Method Validation (state crops and control values reported):

FRESH AND DRY GINSENG CONTROLS RANGED FROM 0.06 TO 0.29 PPM (N=25)

31. Adequate Analytical Method(s) (are)/are not Available for Enforcement Purposes.

These Method(s) are located: PAM II METHOD I IS AG-348 (11/84), METHOD II IS AG-349; PAM I LUKE METHOD FOR METALAXYL, PER SE.

32. PAM I Multiresidue Methods Data are available for parent pesticide tested via Protocols (I II III IV) (circle, as applicable). Additional multiresidue test information for parent compound that is needed: NONE

33. PAM I Multiresidue Methods Data are available for metabolite(s) CGA-6286 AND CGA-37734 tested via Protocols (I II III IV) (circle, as applicable). Additional multiresidue test information for metabolite(s) that is needed: CGA-94684; N/A FOR MINOR USE PETITIONS

34. Residue Data (RAC(s) and Processed Commodities)

FIELD TRIALS WITH RESULTS FROM BOTH THE 2E (EC) AND 5G (GRANULAR) FORMULATIONS AT THE 1X RATE AND 5G AT 2X; IN WISCONSIN AND NORTH CAROLINA WITH RESIDUE RESULTS FOR BOTH FRESH AND DRY GINSENG ROOTS AT PHI'S FROM 7 TO 9 DAYS; RESULTS FROM 1X:

SUBSTRATE	FORMULATION	RANGE (PPM)	AVERAGE (PPM)
FRESH ROOTS	2E	0.30 - 1.2	0.61 +/- 0.31 (N=10)
	5G	0.18 - 2.5	0.95 +/- 0.78 (N=14)
DRY ROOTS	2E	0.31 - 1.8	1.0 +/- 0.59 (N=9)
	5G	0.10 - 2.1	0.88 +/- 0.63 (N=10)

RESULTS FROM 2X RATE

FRESH ROOTS	5G	0.68 - 6.7	
DRY ROOTS	5G	0.62 - 3.2	

35. Frozen Storage Stability Data (are)/are not Available.

If yes, give RACs/fortification levels/length of storage/recovery range/conditions of storage (°C): SEE FRSTR PP 20-2' DATA ON POTATOES AND TOBACCO; METALAXYL RESIDUES STABLE FOR 18 MONTHS UNDER FROZEN CONDITIONS. IN THIS STUDY RESIDUE SAMPLES WERE HELD IN FROZEN STORAGE FROM 5 TO 17 MONTHS AT -20.6 TO -17.8 °C.

36. Regional Registration is/(is not) involved.

If yes, list States in which use is sought: _____

If yes, indicate/explain (see 51 FR 11341, 4/2/86 - Policy on Minor Uses) if a bona fide "Minor Use" is involved: _____

37. Geographic Representation (is)/is not adequate. If no, list RAC(s) and States from which additional data are needed: PER 2/21/: TELEPHONE CONVERSATION, DAVE BRASSARD OF BEAD INDICATED THAT BEAD HAD 5/6/86 MEMO ON FILE, FROM DR. JENIFER PARK, U. OF WISCONSIN, THAT 90% OF U.S GINSENG PRODUCTION WAS IN WISCONSIN.

38. Residues will not exceed proposed tolerance(s) on (commodities) GINSENG

but may exceed proposed tolerance(s) on (commodities) N/A

39. Livestock Feeding Studies on (species): DAIRY CATTLE, GOATS AND HENS

40. Animal Feeding Levels: RUMINANTS DOSED AT 1.5 TO 75 PPM METALAXYL HAD RESIDUES < 0.01 PPM IN MILK AND < 0.05 PPM IN FAT AND MEAT, 0.22 PPM (MAX) IN LIVER AND 0.83 PPM (MAX) IN KIDNEY; POULTRY DOSED AT 1.5 TO 5.0 PPM METALAXYL HAD RESIDUES < 0.05 PPM IN EGGS, FAT, LIVER, MEAT AND SKIN

41. Animal Residue Ingestion Levels from Proposed RAC Tolerance(s) N/A Levels (proposed tolerance level x percent in diet): _____ ppm in beef cattle; _____ ppm in dairy cattle/goats; _____ ppm in hogs; _____ ppm in horses; _____ ppm in sheep; _____ ppm in poultry.

42. Livestock Tolerances are Adequate in (species) N/A FOR THIS PETITION, NO ANIMAL FEED ITEMS INVOLVED, but not adequate in _____

43. Livestock Tolerances Need to be Established: Yes/No. If yes, species/levels: N/A FOR THIS PETITION

44. Other Comments: NONE

45. Other Considerations: NONE

46. Additional Information Needed: SEE ITEM 47.

47. Additional Data Needed: A REVISED SECTION B IS NEEDED. THE SECTION B SUBMITTED IS INCONSISTENT WITH THE PROPOSED USE DIRECTIONS ON PAGE 12 OF THE REPORT, WHICH RECOMMENDS THAT THE FIRST APPLICATION BE MADE WITH EITHER THE 2E OR 2G FORMULATION WHILE THE REMAINING 4 SUPPLEMENTAL APPLICATIONS BE MADE WITH ONLY THE 2G FORMULATION, TO MINIMIZE THE POSSIBILITY OF RESISTANCE. ALSO, IF TWO FORMULATIONS ARE PROPOSED THE LABEL MUST INCLUDE APPROPRIATE INSTRUCTIONS TO ENSURE THAT THE COMBINED APPLICATION OF THE TWO FORMULATIONS DOES NOT EXCEED THE APPROVED MAXIMUM APPLICATION RATE.

48. RECOMMENDATIONS: UPON RECEIPT OF A REVISED SECTION B, AS DESCRIBED ABOVE, CBTS CAN RECOMMEND IN FAVOR OF THE PROPOSED TOLERANCE OF 3.0 PPM FOR RESIDUES OF METALAXYL IN/ON GINSENG.

49. Other Comments Under Recommendations: SINCE THE 2E FORMULATION IS RECOMMENDED AS AN ALTERNATIVE TO THE 2G FORMULATION FOR A SINGLE FIRST APPLICATION ONLY, FOR SIMPLICITY THE PETITIONER SHOULD CONSIDER LIMITING THE PROPOSED USE TO THE 2G FORMULATION ONLY.

50. Compatibility with Codex Tolerances? (Explain) NO COMPATIBILITY PROBLEMS EXIST SINCE THERE ARE NO MEXICAN, CANADIAN OR CODEX TOLERANCES FOR METALAXYL ON GINSENG.

ATTACHMENT(S): - (1) International Residue Limits Status Sheet

(2)

(7) (OTAKIE)

cc: RF, Circ, Reviewer, PP# 1E3926, PIB/FOD (FURLOW), R. SCHMITT FDA, DRES/SACB (KARIYA), E. Haeberer

Approved: ETHAEBERER E. T. Haeberer: RALORANGER R. Loranger 2/21/91.

INTERNATIONAL RESIDUE LIMIT STATUS

J. Knox 2/22/91

CHEMICAL METALAXYL (RIDOMIL)

CODEX NO. 198

CODEX STATUS:

☑ No Codex Proposal Step 6 or above (on Ginseng)

Residue(if Step 8): _____

~~Metalaxyl~~ per se

Crop(s)	Limit (mg/kg)

PROPOSED U.S. TOLERANCES:

Petition No. 1E3926

RCB Reviewer G. OTAKIE

PER 40 CFR 180.408

Residue: METALAXYL AND ITS METABOLITES CONTAINING THE 2,6-dimethylaniline MOIETY and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-Alanine methylester each expressed as metalaxyl

Crop(s)	Limit (mg/kg)
GINSENG	3.0 PPM

CANADIAN LIMITS:

☑ No Canadian limit (on Ginseng)

Residue: _____

Crop(s)	Limit (mg/kg)

MEXICAN LIMITS:

☑ No Mexican limit

Residue: _____

Crop(s)	Limit (mg/kg)

NOTES:

TP52 Otakie File Petition 15804

40 CFR Part 180

[PP 1E3926/R1133; FRL-3947-1]
RIN 2070-AB78

Pesticide Tolerances for Metalaxyl

AGENCY: Environmental Protection Agency (EPA).
ACTION: Final rule.

SUMMARY: This document establishes a tolerance for combined residues of the fungicide metalaxyl and its metabolites in or on the raw agricultural commodity ginseng. This regulation to establish a maximum permissible level for residues of the fungicide in or on the commodity

P12

was requested in a petition submitted by the Interregional Research Project No. 4 (IR-4).

EFFECTIVE DATE: This regulation becomes effective March 24, 1993.

ADDRESSES: Written objections, identified by the document control number, [PP 1E3926/R1133], may be submitted to: Hearing Clerk (A-110), Environmental Protection Agency, rm. M3708, 401 M St., SW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: By mail: Hoyt Jamerson, Emergency Response and Minor Use Section (H-7505W), Registration Division, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: No. 1, 6th Floor, CS #1, 2800 Jefferson Davis Hwy., Arlington, VA 22202, (703)-305-5310.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 28, 1991 (56 FR 42577), EPA issued a proposed rule that gave notice that the Interregional Research Project No. 4 (IR-4), New Jersey Agricultural Experiment Station, P.O. Box 231, Rutgers University, New Brunswick, NJ 08903, had submitted pesticide petition 1E3926 to EPA on behalf of the Agricultural Experiment Stations of North Carolina and Virginia.

The petition requested that the Administrator, pursuant to section 408(e) of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 346a(e)), propose the establishment of a tolerance for 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 methyl ester, in or on the raw agricultural commodity ginseng at 3.0 parts per million.

There were no requests for referral to an advisory committee received in response to the proposed rule.

However, one comment was received opposing the proposed establishment of the tolerance in or on ginseng. The commenter, generally, asserts that EPA has failed to conclude that the tolerance would be protective of the public health. EPA disagrees. The proposed rule states, and supports by analysis, that the tolerance would result in a negligible increase in dietary exposure to resiudes of metalaxyl. The tolerance process is highly protective in that it is based on the most sensitive animal test results available and a combination of highly conservative assumptions and risk assessment practices.

Specifically, the commenter asserts that EPA has not concluded that metalaxyl is useful for the purpose for which the tolerance is sought and that the tolerance is unnecessary since there is "no actual demonstrated need" for the proposed use of metalaxyl in order to produce an adequate or safe food supply and no emergency condition which is uncontrollable with fungicides for which tolerances already exist. The commenter implies that EPA should not allow the tolerance or use of metalaxyl on ginseng unless EPA can "conclusively and effectively" demonstrate that other fungicides, already registered and with tolerances for ginseng, are inadequate to provide for a safe and reliable supply of that food commodity.

EPA believes that the commenter has incorrectly interpreted the standard for approval of tolerances under FFDCA sec. 408. EPA construes the requirement in sec. 408 to consider the "necessity for the production of an adequate, wholesome and economical food supply" to prevent the Agency from denying a tolerance solely on the basis of a calculation of the risks posed by pesticide residues on agricultural products. Instead, the Agency must balance these risks against the benefits of the pesticide for food production. The commenter's reading of the FFDCA would negate this balancing by preventing issuance of a tolerance solely on the basis of failure of the pesticide to meet one possible aspect of the benefits consideration, i.e., essentiality. Although essential pesticides would clearly provide large benefits for food production, the statute in no way suggests that only essential pesticides provide benefits worthy of consideration in the risk/benefit weighing mandated by section 408.

This construction of FFDCA sec. 408 is supported by sec. 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). EPA must consider the provisions of the FFDCA and the FIFRA together and construed in a manner that is harmonious, if possible, given EPA's overlapping responsibilities under the two statutes—to regulate the use of pesticides under FIFRA and to regulate pesticide residues in food under FFDCA. FIFRA sec. 3(c)(5) provides in part the following:

> The Administrator shall not make any lack of essentiality a criterion for denying registration of any pesticide. Where two pesticides meet the requirements of this paragraph, one should not be registered in preference to the other. * * *

If EPA were to deny a pesticide tolerance under FFDCA solely because there are other adequate pesticides for the affected crop, EPA's registration decisions under FIFRA would be negated by the tolerance determination. Thus, the FIFRA language on essentiality would become a nullity.

The commenter is also concerned that the tolrance would allow the unnecessary introduction of metalaxyl residues into the environment and ground and surface waters of the U.S.

The Agency points out that the Federal Food, Drug, and Cosmetic Act (FFDCA) is not the mechanism through which EPA considers pesticide effects on public health that occur through other than dietary routes. FFDCA section 408 only refers to tolerances on raw agricultural commodities. Other pesticidal effects are appropriately considered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) when a pesticide is registered. Under sec. 3(c)(5) of FIFRA, the Agency registers a pesticide, generally, if it will not cause "unreasonable adverse effects on the environment." FIFRA sec. 2(j) defines "environment" to include "water, air, land, and all plants and man and other animals living therein, and the interrelationships which exist among these."

The commenter is further concerned, in the case of metalaxyl on ginseng, that EPA's conclusion concerning utilization of RfD for the overall population and resulting negligible nature of the dietary population exposure "fails to take into account of the unusual consumptive patterns connected with the use of ginseng in certain portions of the population."

Before making tolerance decisions on a pesticide, EPA uses a Dietary Risk Evaluation System (DRES) to calculate the theoretical maximum residue contribution and risk estimates for the general population and a number of subgroups. If the DRES analysis indicates that exposure, and thus estimated risk, to a subgroup is so high that adverse effects are likely to occur, the Agency will not approve a tolerance even if the estimated risks to the average population are acceptable. None of the population subgroups examined in EPA's DRES analysis had consumption patterns that raised risk concerns from metalaxyl on ginseng assumed that metalaxyl would be present on all ginseng consumed at the tolerance level. This is a very conservative assumption. Metalaxyl is unlikely to be used on all ginseng, and studies have shown that the level of residues on foods, when they reach the consumer, is typically well below the established tolerance level. Accordingly, EPA believes that the tolerance is protective of public health.

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It also appears that the commenter is asserting that a certification of usefulness under section 408(l) is required before EPA may issue a tolerance regulation for metalaxyl on ginseng. This is incorrect. The metalaxyl tolerance is issued in response to a petition pursuant to section 408(e) of the FFDCA on behalf of the Agricultural Experiment Stations of North Caroline and Virginia. Tolerances issued in response to section 408(e) petitions, from persons other than registrants of the pesticides, do not require certifications of usefulness. Moreover, EPA believes the tolerance is protective of public health in view of the negligible increase in dietary exposure even assuming metalaxyl is present on all ginseng consumed.

The data submitted in the petition and other relevant material have been evaluated and discussed in the proposed rule. Based on the data and information considered, the Agency concludes that the tolerance will protect the public health. Therefore, the tolerance is established as set forth below.

Any person adversely affected by this regulation may, within 30 days after publication of this document in the Federal Register, file written objections with the Hearing Clerk, at the address given above. 40 CFR 178.20. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections. 40 CFR 178.25. Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested and the requestor's contentions on each such issue. 40 CFR 178.27. A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested. 40 CFR 178.32.

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the Federal Register of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 15, 1993.

Douglas D. Campt,

Director, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. Section 180.408(a) is amended in the table therein by adding and alphabetically inserting the raw agricultural commodity ginseng, to read as follows:

§ 180.408 Metalaxyl; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Ginseng	3.0
* * * * *	

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[FR Doc. 93-6730 Filed 3-23-93; 8:45 am]

BILLING CODE 6560-50-F

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Chemical:	**Metalaxyl**
PC Code:	**113501**
HED File Code	**11500 Petition Files Chemistry**
Memo Date:	**09/03/2003**
File ID:	**00000000**
Accession Number:	**412-04-0145**

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