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

JUN 2 2 1987

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Metalaxyl Registration Standard

FROM: Charles L. Trichilo, Chief
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

TO: Amy Rispin
Science Integration Staff
Hazard Evaluation Division (TS-769)

and

L. Rossi
Product Manager Team # 21
Registration Division (TS-767)

Attached are the Product and Residue Chemistry chapters for the metalaxyl Final Registration Standard and Tolerance Reassessment (FRSTR) prepared by Dynamac Corporation under supervision of Residue Chemistry Branch, HED. The initial Registration Standard for this chemical was prepared by D. Keehner and R. Allison of the former Special Pesticide Review Division. The Standard was published in December, 1981.

The due date for these chapters is June 26, 1987.

This standard includes data available and reviewed up to April 27, 1987.

The Agency has determined that product chemistry data for all technical and manufacturing-use products must be resubmitted for each pesticide because new requirements have been introduced and previously submitted data must be updated. Therefore, the Residue Chemistry Branch will no longer evaluate previously submitted product chemistry data to determine their adquacy in meeting the requirements of Subdivision D of the Pesticide Assessment Guidelines. The Product Chemistry chapter provides a summary, but not an evaluation, of the available

data for the technical grade of the active ingredient. These data are presented for informational purposes only. Attached to the Product Chemistry chapter are comprehensive generic and product specific data requirement tables for the technical grade of the active ingredient and manufacturing-use products, respectively, of metalaxyl.

These chapters have undergone secondary review in Residue Chemistry Branch and have been revised to reflect the Branch policies.

The Product Chemistry chapter contains Appendices A,B,C,D and E. These are to be protected. Only the copies of the standard in RCB and those sent to R. Mountfort, E. Eldredge and Toxicology Branch contain such information.

The Tolerance Assessment Summary (TAS) calculations were not available at the time of issuance of these chapters. When they are completed the information will be forwarded as an addendum to the Residue Chemistry chapter of the metalaxyl Registration Standard.

Finally, Registration Division please note, Residue Chemistry Branch has completed the data tables for the Residue Chemistry chapter and they are included in this package.

If you need additional input please advise.

cc: R. Gardner, TOX, HED (With CBI Attachments)
L. Rossi, FHB, RD (With CBI Attachments)
E. Eldredge, ISB, PMSD (With CBI Attachments)
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bcc: A. Barton/HED
MSS
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SIS
Subject File
Reading File
P. Lombardo/FDA
M. Cordle/FSIS, USDA

RDI: RBPerfetti:6/22/87:RSchmitt:6/22/87:x557-7484.

DYNAMAC
CORPORATION

Final Report

Metalaxyl (FRSTR)
Task 1: Product Chemistry Chapter

Contract No. 68-02-4226

June 12, 1987

Submitted to:
Environmental Protection Agency
Arlington, VA 22202

Submitted by:
Dynamac Corporation
The Dynamac Building
11140 Rockville Pike
Rockville, MD 20852

METALAXYL

PRODUCT CHEMISTRY

TASK 1

INTRODUCTION

FIFRA 3(c)(2)(A) required the Agency to establish guidelines for registering pesticides in the United States. The Agency requires registrants to provide quantitative data on all added ingredients, active and inert, which are equal to or greater than 0.1% of the product by weight.

To establish the composition of products proposed for registration, the Agency requires data and information not only on the manufacturing and formulation process, but also a discussion on the formation of manufacturing impurities and other product ingredients, intentional and unintentional. Furthermore, to assure that the composition of the product as marketed will not vary from the composition evaluated at the time of registration, applicants are required to submit a statement certifying upper and lower composition limits for the added ingredients, and upper limits for some unintentional ingredients. Subdivision D of the Pesticide Assessment guidelines (October 1982) suggests specific precision limits for ingredients based on the variability of the ingredients as a function of the manufacturing process.

In addition to the data on product composition, the Agency also requires data to establish the physical and chemical properties of both the pesticide active ingredient and its formulations. For example, data are needed concerning the identity and physical state of the active ingredient (e.g., melting and boiling points, ambient vapor pressure and solubility). Corresponding to each of the Topical Discussions listed below is the Guidelines Reference No. in "Data Requirements for Pesticide Registration" (40 CFR 158.120), which explains the minimum data the Agency will need to adequately assess the product chemistry of metalaxyl.

	Guidelines Reference No. of 40 CFR 158.120
Product Identity and Composition	61-(1-3)
Analysis and Certification of Product Ingredients	62-(1-3)
Physical and Chemical Characteristics	63-(2-21)

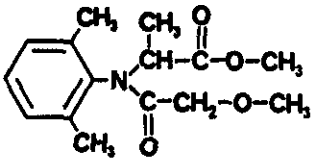
It should be noted that although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore, in this chapter, available product chemistry data will be summarized for the technical grade of the active ingredient only. These data will be evaluated with regard to their adequacy in meeting the requirements of 40 CFR Part 158.120 because this document is a Final Registration Standard and Tolerance Reassessment

(FRSTR). We note that the Confidential Appendixes for the Metalaxyl Registration Standard (Guidance Document) dated December 1981 were not available for this review.

PRODUCT IDENTITY AND COMPOSITION

61-1. Product Identity and Disclosure of Ingredients

Metalaxyl is the BSI-, E-ISO-, F-ISO-, and ANSI-approved common name for a fungicide registered in the U.S. as a technical product by Ciba-Geigy Corp. The structure is depicted below.



The chemical name (IUPAC) for metalaxyl is methyl N-(2-methoxylacetyl)-N-(2,6-xylyl)-DL-alaninate. Other names include: Methyl N-(2,6-dimethylphenyl)-N-(2-methoxyacetyl)-DL-alaninate (CA; 9CI); Ridomil; Apron; Fubol; and CGA-48988.

Other identifying characteristics and codes are:

Empirical Formula:	$C_{15}H_{21}NO_4$
Molecular Weight:	279.3
CAS Registry No.:	57837-19-1
Shaughnessy No.:	113501

[The above information was obtained from the Pesticide Manufacturing and Toxic Materials Control Encyclopedia, 1980, pp. 500-501, and The Pesticide Manual, 1983, p. 7990.]

It has been previously determined that the available data for the 90% technical (T) satisfy the requirements of the 1978 Proposed Guidelines, sec. 163.61-3 (refer to the Metalaxyl Registration Standard [Guidance Document] dated December 1981). Refer to Appendix A for an updated Confidential Statement of Formula for the 90% technical, EPA Reg. No. 100-601, which is the only registered metalaxyl manufacturing-use product.

61-2. Description of Beginning Materials and Manufacturing Process

The following manufacturing processes are published in Marshall Sittig's "Pesticide Manufacturing and Toxic Materials Control Encyclopedia," pp. 500-501.

> "(A) A mixture of 100 g of 2,6-dimethylaniline, 223 g of 2-bromopropionic acid methyl ester and 84 g of $NaHCO_3$ was stirred for 17 hours at 140°C, then cooled, diluted with 300 ml of water and extracted with diethyl ether. The extract was washed with a small amount of water, dried

over sodium sulfate, filtered, and the ether evaporated. After the excess 2-bromopropionic acid methyl ester had been distilled off, the crude product was distilled in a high vacuum.

"(B) A mixture of 11 g of the ester obtained according to (A), 6.5 g of methoxyacetyl chloride, 2 ml of dimethyl formamide, and 250 ml of absolute toluene was stirred at room temperature and refluxed for 1 hour. The solvent was evaporated off, and the crude product then distilled in vacuo.

The D-forms of both cis-trans-isomers were obtained by acylating the pure D-form of alpha-(2,6-dimethylanilino)-propionic acid methyl ester with methoxyacetic acid or with one of the reactive derivatives thereof."

It has been previously determined that the available data for the 90% T satisfy the requirements of the 1978 Proposed Guidelines, sec. 163.61-4 (refer to the Metalaxyl Registration Standard [Guidance Document] dated December 1981). However, an inconsistency in the Guidance Document was noted. Additional requirements were listed in a footnote to Table 2 which the registrant has not satisfied. Refer to Confidential Appendix B for a discussion of the manufacturing process used to produce Ciba-Geigy's 90% technical product. We could not verify that this process was reviewed in the Metalaxyl Registration Standard (Guidance Document) issued December 1981. The following are required:

- o Complete information must be provided regarding the nature of the process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, the chemical equations for each intended reaction, equipment used to produce each intermediate and the final product, reaction conditions, the duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each beginning material must be provided, along with information regarding the properties of each beginning material used to manufacture each product. In order to assess the potential for contamination with nitrosamines, a description of the manufacturing process conditions favoring formation of nitrosamines must be provided.

61-3. Discussion of the Formation of Impurities

It has been previously determined that the available data for the 90% T do not satisfy the requirements of the 1978 Proposed Guidelines, sec. 161.61-5 (refer to the Metalaxyl Registration Standard [Guidance Document] dated December 1981). Refer to Confidential Appendix C for a discussion of the formation of impurities in the 90% technical product. The following additional information is required:

- o A detailed discussion of all impurities that are or may be present at $\geq$0.1%, based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production must be submitted. This

discussion must also address the possible formation of nitrosamines from metalaxyl and its impurities.

ANALYSIS AND CERTIFICATION OF PRODUCT INGREDIENTS

62-1. Preliminary Analysis

It has been previously determined that the available data for the 90% T satisfy the requirements of the 1978 Proposed Guidelines, sec. 161.61-7 (refer to Table 2 of the Metalaxyl Registration Standard [Guidance Document] dated December 1981). However, we note an inconsistency in the Guidance Document. Data for preliminary analyses of metalaxyl technical were required under the "Product Analytical Methods and Data" section. Refer to Confidential Appendix D for a discussion of the preliminary analysis of Ciba-Geigy's 90% technical product. The following are required:

- o Five or more representative samples must be analyzed for the amount of active ingredient and each impurity for which a certified limit is required. Complete validation data (accuracy, precision) must be submitted for each analytical method used.

62-2. Certification of Ingredient Limits

It has been previously determined that the available data for the 90% T satisfy the requirements of the 1978 Proposed Guidelines, sec. 161.61-6 (refer to the Metalaxyl Registration Standard [Guidance Document] dated December 1981). No additional data have been submitted.

We note that current guidelines regarding Certification of Ingredient Limits have not been fulfilled. The following additional data are therefore required for the 90% T:

- o Upper and lower limits for metalaxyl must be provided, certified, and validated by sample analysis using analytical procedures for which accuracy and precision data have been provided.

- o Upper limits for each impurity present at ≥0.1% (w/w) and for each "toxicologically significant" impurity present at <0.1% (w/w) must be provided, certified, and validated by sample analysis using analytical procedures for which accuracy and precision data have been provided. [We defer to the Toxicology Branch regarding the toxicological significance of impurities present at <0.1% (w/w).]

- o All nitrosoamines must be identified and quantified in six samples of each product; two samples of each must be analyzed shortly after production, 3 months after production, and 6 months after production. A method sensitive to 1 ppm of N-nitroso contaminants must be used. An upper limit must be provided (and certified) for all nitrosoamines found.

- o Certifications should be submitted on EPA Form 8570 Rev. 2-85.

62-3. Analytical Methods to Verify Certified Limits

It has been previously determined that the available data for the 90% T satisfy the requirements of the 1978 Proposed Guidelines, sec. 163.61-7 (refer to the Metalaxyl Registration Standard [Guidance Document] dated December 1981). However, we note an inconsistency in this assessment. Additional requirements for methods for quantitative detection of any impurities in the technical were requested in a footnote to Table 2, and validation data (including preliminary analyses of five or more samples of technical metalaxyl) were requested in the "Product Analytical Methods and Data" section of the Guidance Document. Therefore, the following is required:

- o Analytical methods must be provided to determine the active ingredient and each toxicologically significant impurity (including nitrosamines) for which a certified limit is required. Each method must be accompanied by validation studies indicating its accuracy and precision. These methods must be suitable for enforcement of certified limits. [RCB defers to the Toxicology Branch regarding the toxicological significance of impurities and intentionally added inerts for which certified limits are required.]

[The following is presented for informational purposes only.]

Ciba-Geigy Corp. (1978; MRID 00104498) submitted an unvalidated GLC method using flame ionization detection (FID) for determination of metalaxyl and its impurities in the technical product. Samples are dissolved in acetone and analyzed for metalaxyl per se using a GLC column packed with 10% OV-101 on 80-100 mesh Gas Chrom Q and methyl stearate as an internal standard. Peak area corresponding to metalaxyl is adjusted for a response factor. No additional details were provided for this method. The registrant also submitted infrared, ultraviolet, mass spectrum, and nuclear magnetic resonance (NMR) scans for the metalaxyl technical. The only procedural details provided for these analyses were that solvents were $CDCl_3$ [sic] and methanolic HCl for the NMR and ultraviolet scans, respectively.

PHYSICAL AND CHEMICAL CHARACTERISTICS

It has been previously determined that the available data for the 90% T satisfy the requirements of the 1978 Proposed Guidelines. sec. 163.61-1 thru 11 (refer to the Metalaxyl Registration Standard [Guidance Document] dated December 1981), except for the octanol/water partion coefficient and pH. Summarized in Table 1 are additional physicochemical properties of technical metalaxyl.

Table 1. Physicochemical properties of the 90% metalaxyl technical.

Guidelines Reference No. of 40 CFR 158.120; Name of Property		Description	Bibliographic citation
63-11.	Octanol-water partition coefficient	1.65	EPA Memorandum[a]
63-12.	pH	2-4, 10% suspension; 3-5, 1% suspension	EPA Memorandum[a]

[a] EPA Memorandum from C.L. Trichilo to H.M. Jacoby dated Sept. 17, 1982 and located in the metalaxyl subject file.

These data are adequate to satisfy requirements for these physicochemical properties.

References (used):

00104498. Ciba-Geigy Corp. 1978. Chemistry of CGA-48988 technical. (Compilation; unpublished study received Sept. 5, 1978 under 100-601; CDL:235062-A.)

Environmental Protection Agency. 1981. Metalaxyl Guidance Document; December 1981.

Trichilo, C.L. 1982. Metalaxyl Registration Standard-Product Chemistry Chapter. (Located in the subject file for metalaxyl; No MRID assigned.)

TABLE A. GENERIC DATA REQUIREMENTS FOR 90% METALAXYL TECHNICAL[a] (Ciba-Geigy Corp.; EPA REG. NO. 100-601)

Data Requirement	Composition[b]	Does EPA Have Data to Satisfy This Requirement?[c]	Bibliographic Citation (MRID or as noted)	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[d]
158.120 Product Chemistry				
Product Identity and Composition				
61-1 - Product Identify and Disclosure of Ingredients	TGAI	Yes	e,f, Reg. jacket	No
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	Partially[g]	e, 00104498	Yes[h]
61-3 - Discussion of Formation of Impurities	TGAI	Partially[g]	e,i	Yes[j]
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis of Product Samples	TGAI	Partially[g]	e,i	Yes[k]
62-2 - Certification of Ingredient Limits	TGAI	Partially[l]	e	Yes[m]
62-3 - Analytical Methods to Verify Certified Limits	TGAI	Partially[g]	e, 00104498	Yes[n]
Physical and Chemical Characteristics				
63-2 - Color	TGAI	Yes	e	No
63-3 - Physical State	TGAI	Yes	e	No
63-4 - Odor	TGAI	Yes	e	No
63-5 - Melting Point	TGAI	Yes	e	No
63-6 - Boiling Point	TGAI	NR[o]	e	No
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	Yes	e	No

(continued, footnotes follow.)

TABLE A. (Continued).

Data Requirement	Composition[b]	Does EPA Have Data to Satisfy This Requirement?[c]	Bibliographic Citation (MRID or as noted)	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[d]
158.120 Product Chemistry (continued)				
63-8 - Solubility	TGAI or PAI	Yes	e	No
63-9 - Vapor Pressure	TGAI or PAI	Yes	e	No
63-10 - Dissociation Constant	TGAI or PAI	Yes	e	No
63-11 - Octanol/Water Partition Coefficient	TGAI	Yes	i	No
63-12 - pH	TGAI	Yes	i	No
63-13 - Stability	TGAI	Yes	e	No
Other Requirements:				
64-1 - Submittal of samples	N/A P	N/A	N/A	No

[a] The 90% technical is the only registered metalaxyl manufacturing-use product.
[b] Composition: TGAI = technical grade of the active ingredient; PAI = pure active ingredient.
[c] Data requirements based on Proposed Guidelines of 1978, unless otherwise indicated.
[d] Data must be submitted no later than 6-8 months from the date of this Standard.
[e] See Metalaxyl Guidance Document dated December 1981.
[f] Information obtained from desk references.
[g] We note ambiguity in the Metalaxyl Guidance Document concerning citations 61-2,3 and 62-1,3. Available data are not adequate as assessed by C.L. Trichilo in an EPA memorandum dated Sept. 17, 1982 and located in the subject file for metalaxyl.
[h] Complete information must be provided regarding the nature of the process (batch or continuous), the relative amounts of beginning material and the order in which they are added, the chemical equations for each intended reaction, equipment used to produce each intermediate and the final product, reaction conditions, the duration of each step fo the process, purification procedures, and quality control measures. In addition, the name and

address of the manufacturer, producer, or supplier of each beginning material must be provided, along with information regarding the properties of each beginning material used to manufacture each product. In order to assess the potential for contamination with nitrosamines, a description of manufacturing process conditions favoring formation of nitrosamines must be provided.

i Ciba-Geigy Corp. submission included with EPA memorandum from C.L. Trichilo to H.M. Jacoby dated Sept. 17, 1982 and located in the subject file for metalaxyl.

j A detailed discussion of all impurities that are or may be present at ≥0.1%, based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production must be submitted. This discussion must also address the possible formation of nitrosamines from metalaxyl and its impurities.

k Five or more representative samples must be analyzed for the amount of active ingredient and each impurity for which a certified limit is required. Complete validation data (accuracy, precision) must be submitted for each analytical method used.

l Available data do not meet the requirements of 40 CFR 158.120, Part 62-2.

m Upper and lower limits for metalaxyl must be provided, certified, and validated by sample analysis using analytical procedures for which accuracy and precision data have been provided. Upper limits for each impurity present at ≥0.1% (w/w), and for each "toxicologically significant" impurity present at <0.1% (w/w) must be provided, certified, and validated by sample analysis using analytical procedures for which accuracy and precision data have been provided. [We defer to the Toxicology Branch regarding the toxicological significance of impurities present at <0.1% (w/w).] All nitrosoamines must be identified and quantified in six samples of each product; two samples of each must be analyzed shortly after production, 3 months after production and 6 months after production. A method sensitive to 1 ppm of N-nitroso contaminants must be used. An upper limit must be provided (and certified) for all nitrosoamines found. Certifications should be submitted on EPA Form 8570 Rev. 2-85.

n Analytical methods must be provided to determine the active ingredient and each toxicologically significant impurity (including nitrosamines) for which a certified limit is required. Each method must be accompanied by validation studies indicating its accuracy and precision. These methods must be suitable for enforcement of certified limits. [RCB defers to the Toxicology Branch regarding the toxicologic significance of impurities and intentionally added inerts for which certified limits are required.]

o Not required; a solid at room temperature.

p N/A = Not applicable.

DYNAMAC
CORPORATION

Final Report

Metalaxyl (FRSTR)
Task 2: Residue Chemistry Chapter

Contract No. 68-02-4226

June 12, 1987

Submitted to:
Environmental Protection Agency
Arlington, VA 22202

Submitted by:
Dynamac Corporation
The Dynamac Building
11140 Rockville Pike
Rockville, MD 20852

METALAXYL

RESIDUE CHEMISTRY

Task 2

Table of Contents

METALAXYL

RESIDUE CHEMISTRY

Task-2

INTRODUCTION

Metalaxyl (N-[2,6-dimethylphenyl]-N-[methoxyacetyl]-alanine methyl ester) is a fungicide federally registered for use on apples, avocados, members of the Brassica Leafy Vegetables Group, citrus fruits, cotton, members of the Cucurbit Vegetables Group, hops, members of the Legume Vegetables Group (including field beans, French beans, kidney beans, lima beans, snap beans, wax beans, broad beans [Fava beans], chickpeas [garbanzo beans], lentils, garden peas, field peas, sugar peas, southern peas [black-eyed peas, crowder peas, cowpeas, and catjang], and soybeans), lettuce, onions, peanuts, pineapple, potatoes, raspberries, spinach, tobacco, and tomatoes. Metalaxyl is also federally registered for use as a seed treatment on alfalfa, barley, beets (garden and sugar), bentgrass, black-eyed peas, buckwheat, clover, corn, cotton, cowpeas, dill, fescue, forage grasses, kidney beans, lentils, lespedeza, lima beans, millet, milo, oats, okra, peanuts, peas, popcorn, rice, ryegrass, sorghum, soybeans, sunflowers, sweet corn, trefoil, velvet beans, vetch, and wheat. In addition, metalaxyl is registered for use: (i) on broccoli, cauliflower, and onions grown for seed; (ii) on non-bearing citrus, nut, pome fruit, and stone fruit trees; and (iii) on nursery stock/transplants of broccoli, cabbage, cauliflower, cucumbers, lettuce, melons, spinach, squash, strawberries, and tomatoes. Metalaxyl formulations registered for use on food/feed crops include: (i) the 1 and 5% granulars (Gs); (ii) the 2 lb/gal emulsifiable concentrate (EC); (iii) the 9, 10, 25, and 35% wettable powders (WPs); and (iv) the 2.65 lb/gal flowable concentrate (FlC). Metalaxyl formulations are applied: (i) to the soil for most crops; (ii) foliarly and to the soil for members of the Brassica Leafy Vegetables Group, members of the Cucurbit Vegetables Group, crops grown solely for seed, and nursery stock and transplants; (iii) foliarly to onions and potatoes; (iv) to the soil and as a trunk spray to citrus; and (v) as a seed-piece dip treatment to pineapple. According to the Preliminary Quantitative Usage Analysis of Metalaxyl (R.F. Torla, 11/86, BUD, OPP, EPA), 29-51% of the domestically available metalaxyl is used on non-agricultural sites, 24-49% on tobacco, 5-11% on soybean seeds, 12-15% on potatoes, 3% each on citrus, cucurbits, and onions, and 1% on cotton seed. Minor uses (<1% each) include: apples, asparagus, broccoli, cotton, lettuce, tomatoes, and seed treatments of alfalfa, beans, oats, peanuts, peas, rice, rye, and sorghum, and strawberry nursery stock. Tolerances have been proposed for the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on: (i) asparagus at 7 ppm (1986;PP#6F3330); (ii) wet and dry grape pomace at 3 and 6 ppm, respectively (1986;PP#6F3362/6H5493); (iii) grapes at 2 ppm (1986;PP#6F3362/6H5493); (iv) raisins and raisin waste at 6 and 9 ppm, respectively (1986;PP#6F3362/6H5493); (v) strawberries at 5 ppm (1986;PP#6F3337); (vi) walnuts and almonds at 0.5 ppm (1987;PP#7F3470/7H5520); (vii) members of the Stone Fruits Group at 1 ppm (1987;PP#7F3470/

(v) strawberries at 5 ppm (1986; PP#6F3337); (vi) walnuts and almonds at 0.5 ppm (1987; PP#7F3470/7H5520); (vii) members of the Stone Fruits Group at 1 ppm (1987; PP#7F3470/7H5520); (viii) blueberries at 2 ppm (1987; PP#7F3470/7H5520); (ix) and hulls at 5 ppm (1987;PP#7F3470/7H5520); and (x) dried apricots and prunes at 4 ppm (1987;PP#7F3470/7H5520). Tolerances for food/feed items are currently expressed in terms of the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed at metalaxyl(40 CFR 180.408, 21 CFR 193.277, and 21 CFR 561.273).

In the original Metalaxyl Pesticide Registration Standard (Guidance Document) issued December 1981, outstanding data gaps did not exist for several aspects of residue chemistry. However, since publication of this original Guidance Document, new Pesticide Assessment Guidelines (Subdivision O) for Residue Chemistry have been issued (October 1982). These guidelines reflect current Residue Chemistry Branch policy. As a result, many of the conclusions made in the original Standard concerning the adequacy and usefulness of residue chemistry data submitted in support of metalaxyl uses have been reversed or altered in this Final Registration Standard and Tolerance Reassessment (FRSTR).

NATURE OF THE RESIDUE IN PLANTS

Conclusions:

The metabolism of metalaxyl (N-(2,6-dimethylphenyl)-N-(methoxyacetyl)-alanine-methyl ester) in plants, including potatoes, grapes, and lettuce is adequately understood. ^{14}C-Residue analysis shows that tubers did not metabolize much of the metalaxyl that was translocated from the foliage. Potato foliage metabolism involved ring methyl oxidation and hydrolysis of the methyl ester bond. Potato tuber metabolism is similar to that for foliage with the addition of ring hydroxylation. Grapes did not appear to metabolize or conjugate metalaxyl to the same degree as grape foliage, and three different paths of metabolism were proposed (as discussed in text.) Lettuce metabolism includes oxidation of a ring methyl group, cleavage of the methylester and methylether bonds, and N-dealkylation. In addition, seed treatment studies, which involved cabbage, cucumber, barley, beet, tomato, pepper, squash, lettuce, sunflower, wheat, soybeans, navy beans, peas, and sweet corn did not reveal significant amounts of ^{14}C-activity in the mature plant tissue. Thus, no identification or quantification was even possible.

Table 1 on pages 4-6 depicts the molecular structure of metalaxyl and some of its possible metabolites in plant commodities. Of these metabolites, II, III, IV, VII, IX, and X have been found to be involved in glucose conjugation. The possible routes of metabolism involve oxidation, hydrolysis, hydroxylation, and dealkylation as already described.

References (used):

MRIDs: 00071603. 00071604. 00071605. 00071606. 00071607.
00071608. 00071609. 00071610. 00114379. 00128102.

References (not used):

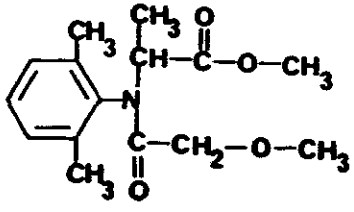
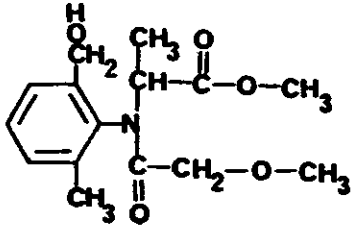
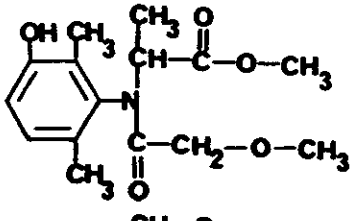
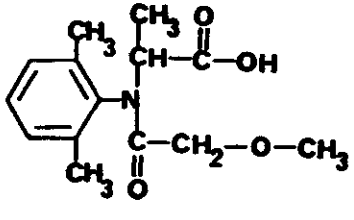
[These MRIDs contain information that was previously reviewed or determined to be inappropriate (refer to the Metalaxyl Guidance Document issued December 1981); also included are MRIDs not considered previously that duplicate cited information or are irrelevant.]

MRIDs 00071601. 00071602. 00071620. 00071624. 00100467. 00100477. 00100478.
00100480. 00100481. 00103042. 00103043. 00104380. 00104381. 00104382.
00104383. 00104384. 00104385. 00104485. 00104654. 00110507. 00133326.

Discussion of the data:

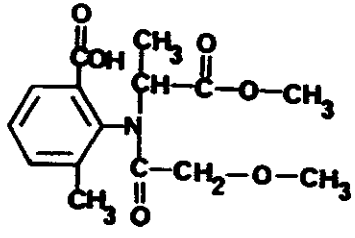
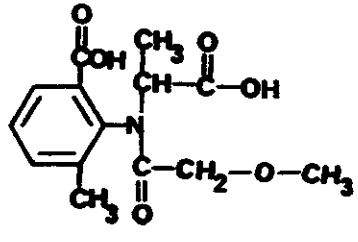
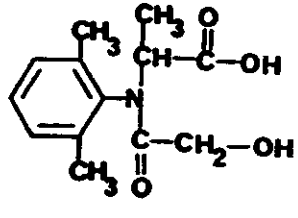
Ciba-Geigy Corp. (1980; MRID 00071604) submitted a [^{14}C]metalaxyl metabolism study that pertained to greenhouse-grown potatoes. Nine 6-week old white potato plants (var. Norchip) growing in individual 10-quart pails received six foliar applications at 2-week intervals of a 2 lb/gal EC formulation at 1.125 lb ai/A/application. Soil surfaces were covered to prevent direct contact of radiolabel with soil. The formulation contained 26.8% of [^{14}C]metalaxyl (uniformly ring-labeled, 24.6 uCi/mg specific activity) and each plant received 6 mg of radiolabel. Foliage samples were taken immediately after the first spray application, and foliage and immature tubers were sampled

Table 1. Metalaxyl and its metabolites in plants and animals.

Code	Structure	Chemical Name	Common Name/ Abbreviation	Found in:	Reference (MRID)
I		N-(2,6-dimethylphenyl)-N-(methoxyacetyl)-alanine methyl ester	Metalaxyl, CGA-48988	lettuce foliage grapes and grape leaves potato tubers and foliage potato foliage	00114379, 00071610. 00071607, 00071606. 00071603, 00071604. 00071609.
II		N-[2-(hydroxymethyl)-6-methylphenyl]-N-(methoxyacetyl)-alanine methyl ester	CGA-94689	lettuce foliage[a] grapes and grape leaves[a] potato tubers and foliage[a] potato foliage	00114379, 00071610, 00071680. 00071607, 00071606. 00071603, 00071604. 00071609.
III		N-(3-hydroxy-2,6-dimethylphenyl)-N-(methoxyacetyl)-alanine methyl ester	CGA-100255	lettuce foliage[a] grapes and grape leaves[a] potato tubers and foliage[a]	00114379, 00071610, 00071680. 00071607, 00071606. 00071603, 00071604.
IV		N-(2,6-dimethylphenyl)-N-(methoxyacetyl)-alanine	CGA-62826	lettuce foliage[a] grapes and grape leaves[a] potato tubers potato foliage	00114379, 00071610. 00071607, 00071606. 00071603, 00071604. 00071609, 00071604.

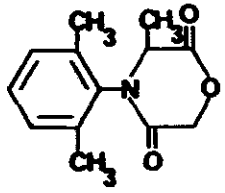
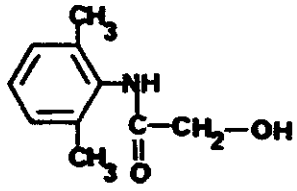
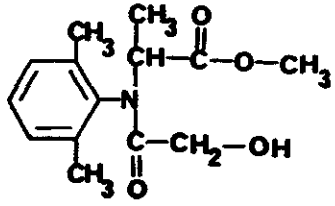
(Continued).

Table 1. (Continued).

Code	Structure	Chemical Name	Common Name/ Abbreviation	Found in:	Reference (MRID)
V		N-(2-carboxy-6-methylphenyl)-N-(methoxyacetyl)-alanine methyl ester	CGA-108905	lettuce foliage potato tubers and foliage potato foliage	00071610. 00071603, 00071604. 00071609.
VI		N-(2-carboxy-6-methylphenyl)-N-(methoxyacetyl)-alanine	CGA-108906	potato tubers potato foliage	00071603. 00071609.
VII		N-(2,6-dimethylphenyl)-N-(hydroxyacetyl)-alanine	CGA-107955	lettuce foliage[a] potato tubers and foliage[a] grapes and grape leaves[a]	00114379, 00071610. 00071603, 00071604. 00071607.

(Continued).

Table 1. (Continued).

Code	Structure	Chemical Name	Common Name/ Abbreviation	Found in:	Reference (MRID)
VIII		N-(2,6-dimethylphenyl)-2-methyl-3,5-dioxomorpholine	CGA-68125	potato tubers and foliage[b]	00071604.
IX		N-(2,6-dimethylphenyl)-2-hydroxyacetamide	CGA-37734	lettuce foliage[c]	00114379, 00071610.
X		N-(2,6-dimethylphenyl)-N-(hydroxyacetyl)-alanine methyl ester	CGA-67869	lettuce foliage[c]	00114379, 00071610.

[a] Found in the free form and as the glucose conjugate.
[b] Hydrolysis and storage can produce CGA-68125 from CGA-107955; this may be an artifact (MRID 00100477).
[c] Found as the glucose conjugate.

immediately after the third spray application. One week after the final treatment, all foliage and mature tubers were harvested. Foliage and tubers were extracted by a referenced (AG-214) but undescribed biphasic technique. Samples of tubers and foliage were combusted to determine total ^{14}C-activity. ^{14}C-Activity present in extracts from tubers and foliage was characterized by cochromatographic TLC analysis using silica gel plates, solvents of varying polarities, and reference standards. Radiolabel zones on the plates were located using a radiochromatogram spark chamber; ^{14}C-activity was quantified by scraping the radiolabel zone and liquid scintillation counting (LSC). Total ^{14}C-residues in foliage expressed as ppm metalaxyl equivalents, were 40.8 ppm, 45.8 ppm, and 25.9 ppm at the first treatment, third treatment, and final harvest date, respectively. Tuber content of ^{14}C-activity was 0.10 and 0.16 ppm of metalaxyl equivalents at the third treatment and final harvest, respectively. ^{14}C-Residue concentration in the tubers of treated plants indicates that ^{14}C-activity translocated from the foliage to the tubers. Control plants, kept in close proximity to the treated plants, had ^{14}C-activities of 0.05-1.10 ppm for foliage and 0.003-0.02 ppm for tuber; this demonstrates the volatile nature of [^{14}C]metalaxyl and its metabolites. The extraction technique accounted for 97.2% (19.0% organosoluble; 78.2% water-soluble) and 84.9% (56.2% organosoluble; 28.7% water-soluble) of the total ^{14}C-activity in foliage and tuber samples, respectively, at harvest (11 weeks posttreatment). Identified metabolites and their percentages of the total ^{14}C-residue are listed in Table 2.

Table 2. Distribution and characterization of ^{14}C-residues in foliage and tubers from potato plants following foliar applications of [^{14}C]metalaxyl.

Metabolites	Percentage of total ^{14}C-activity in: Foliage	Tuber
Metalaxyl (I)	7.7	30.4
CGA-94689 (II)	1.6	1.9
CGA-62826 (IV)	2.9	4.2
CGA-107955 (VII)	<0.2	<0.2
CGA-100255 (III)	1.5	4.2
CGA-68125 (VIII)	<0.2	<0.2
CGA-108905 (V)	<0.2	<0.2
CGA-94689 conjugate	21.8	-
CGA-100255 conjugate plus unknown	20.6	-
CGA-107955 conjugate	3.8	-
Unresolved ^{14}C-activity	45.2	39.2
Total	105.1	79.9

Approximately 20% of the total ^{14}C-activity is unaccounted for in tubers (Table 2). Results of the tuber analysis suggest that the tubers did not metabolize much of the metalaxyl that is translocated from the foliage. In addition, data were provided that indicates that [^{14}C]metalaxyl and/or its metabolites are concentrated in the fleshy part of the potato.

Ciba-Geigy Corp. (1979; MRID 00071609) submitted a study that characterized and quantified [^{14}C]metalaxyl-related residues in field-treated potato

leaves. Plants were grown, treated, sampled, and tissues were extracted in a manner as described previously by Gross (1977) in the metalaxyl Guidance Document dated December 1981 (MRID 00071605). Water-soluble ^{14}C-activity was further purified using an Amberlite XAD-4 resin. Cellulase was used to release potential conjugated forms of metalaxyl metabolites. Some of the metabolite fractions were analyzed by mass spectrometry (MS). The pattern of metabolites in potato leaves at harvest included CGA-94689 (5.7%), CGA-62826 (13.5%), CGA-108905 (two isomers for a total of 42.9%), CGA-108906 (4.5%), and metalaxyl (2.7%), for a total of 69.3% of the ^{14}C-activity in potato leaves. The pattern of these metabolites suggests that two independent degradation pathways occurred: one involves ring methyl oxidation and the other involves hydrolysis of the methyl ester bond.

Ciba-Geigy Corp. (1980; MRID 00071603) submitted a field-grown potato study that pertains to the uptake and metabolism of [^{14}C]metalaxyl. Six-week old white potato plants (var. Green Mountain) received six foliar applications at 2-week intervals of uniformly ring-labeled [^{14}C]metalaxyl at 0.38 lb ai/A/application (eight plants) or 1.14 ai/A/application (16 plants); applications were made using a boom sprayer. Tubers and foliage were sampled 24 hours after the first treatment and at tuber maturity, 1 week after the final application. Samples were prepared for analysis by a referenced (AG-214) but undescribed biphasic extraction. Subsamples of plant tissue were also subjected to combustion analysis to determine total ^{14}C-activity. Some potato tubers were extracted with methanol:water (80:20 v/v); the filtrate was partitioned with methylene dichloride (MDC). The resulting aqueous phase was acidified and partitioned again with MDC. The aqueous phase was then concentrated and redissolved in methanol. ^{14}C-Residues in extracts were characterized by two-dimensional TLC in conjuction with solvents of varying polarities; reference standards were cochromatographed on the plates. Radiolabel zones were located by autoradiography, and quantification was accomplished by LSC of scraped zones. Plants havested 1 week after the final application at 0.38 lb ai/A contained total ^{14}C-activity (expressed as ppm metalaxyl equivalents) of 1.9 ppm in or on foliage, and 0.14 ppm, 0.11 ppm, and 0.22 ppm in or on whole tubers, flesh, and peel, respectively. Plants harvested 1 week after the final application at 1.14 ai/A contained total ^{14}C-activity of 31.9 ppm in or on foliage, and 0.5 ppm, 1.4 ppm, and 1.9 ppm in or on whole tubers, flesh, and peel, respectively. Characterization and quantification of ^{14}C-residues, are listed in Table 3.

The proposed pathways for metabolism of metalaxyl in potato plants are as follows. There are two proposed pathways for foliage. In the first, metalaxyl is oxidized to CGA-94689, which is then either conjugated to glucose or is converted to the isomer form of CGS-108905 and CGS-108906 and then to conjugated glucose. In the second pathway, metalaxyl is hydrolyzed to CGA-62826 which is either glucose conjugated or metabolized to a glucose conjugate of CGA-108906 or CGA-107955. For tubers, the proposed metabolic pathway is the same as for foliage except for an additional reaction: hydroxylation of metalaxyl to CGA-100255, which is then conjugated to glucose. These data demonstrate that metalaxyl is translocated to tubers from the foliage, and that approximately 51-57% of the total ^{14}C-activity present in tubers was unchanged parent material (metalaxyl).

Table 3. Characterization and quantification of ^{14}C-residues in whole tubers and foliage from potatoes treated with [^{14}C]metalaxyl at 1.14 lb ai/A.

Metabolite	Percent of total ^{14}C-activity in: Foliage		Tuber	
	After first application	After last application	After last application	
Metalaxyl (I)	19.8[a]	2.2[a]	51.0[a]	57.0[b]
CGA-100255 (III)	-	-	-	4.0
CGA-94689 (II)	8.5	20.2	5.6	1.6
CGA-62826 (IV)	-	-	-	2.8
CGA-107955 (VII)	1.8	1.0	1.0	1.4
CGA-108905 (V)	<0.2	<0.2	<0.2	0.6
CGA-108906 (VI)	-	-	<0.2	0.6
CGA-94689 conjugate	18.7	30.4	5.6	2.5
CGA-100255 conjugate	8.9	2.7	1.4	0.4
CGA-107955 conjugate	0.8	0.9	1.0	0.6
Total	58.5	57.4	65.6	71.5

[a] Data from biphasic extraction.
[b] Data from methanol:water and MDC extractions.

Ciba-Geigy Corp. (1978; MRID 00071606) submitted a field-grown grape metabolism study that involved [^{14}C]metalaxyl. Two grapevines were sprayed seven times (until run-off) with a spray mixture of [^{14}C]metalaxyl (uniformly ring-labeled; specific activity of 20.0 uCi/mg) formulated as a 50% WP. At 52 days after the last application, plant material, including ripe grapes, leaves, and green and woody stems, was harvested. Plant material was extracted using various organic solvents, which included hexane, methanol, dichloromethane, and ethylacetate. Non-extractable residues were analyzed for total ^{14}C-activity by combustion analysis. Extractable residues were characterized and quantified by TLC, GLC, HPLC and GLC/MS. For TLC, five developing solvent systems of varying polarity were used. Silica gel plates were developed and cochromatographed with reference standards, which were localized by a UV light source. Radiolabeled zones on the plates were localized by a radioscanner. In addition, filtrates were subjected to further chromatographic separation using an Amberlite XAD-2 column and Sephadex gel filtration. Conjugate forms of ^{14}C-residues were subjected to cellulase enzymatic cleavage to facilitate the characterization of metabolites. The identity of ^{14}C-residues was confirmed by GLC/MS analysis. The results of the radiolabel analysis are presented in Table 4.

Grapes did not metabolize metalaxyl to the same degree as did leaves, which converted a majority of the metalaxyl to CGA-100255 and CGA-94689. In addition, grapes did not conjugate much of the metalaxyl-related metabolites as did leaves, which conjugated about 40% of the total ^{14}C-activity. The proposed metabolic pathway is that metalaxyl undergoes hydrolysis, oxidation, and hydroxylation to form CGA-62826, CGA-100255, and CGA-94689, which can then be conjugated with glucose.

Table 4. Radiolabeled metabolites found in grapes and grape leaves at harvest.

Metabolites	Percentage of total ^{14}C-activity in: Grapes		Grape leaves
	Juice	Presscake	
Metalaxyl (I)	7.8	56.3	22.4
CGA-100255 (III)	1.5	2.0	8.0
CGA-100255[a] (III)	0.2	0.6	5.0
CGA-94689 (II)	2.6	7.2	23.2
CGA-94689[a] (II)	2.4	6.2	32.2
CGA-62826 (IV)	0.9	0.6	1.0
CGA-62826[a] (IV)	0.1	0.2	2.0
Total[b]	15.5	73.1	93.8

[a] In glucose conjugate form.

In another study submitted by Ciba-Geigy Corp (1979; MRID 00071607), field-grown grapes received six foliar applications, sprayed until run-off, with [^{14}C]metalaxyl (uniformly ring-labeled; specific activity 3 uCi/mg) at 0.0025 lb ai/gal. Leaves and ripe grapes were harvested 68 days after the last application, and extracted and analyzed by TLC and GLC/MS. Free and conjugated forms of CGA-62826 (0.9%), CGA-107955 (0.9%), CGA-94689 (20.4%), and CGA-100255 (4.3%) were identified in grapes.

Ciba-Geigy Corp. (1982; MRID 00114379) submitted a study that examined the metabolism of uniformly ring-labeled [^{14}C]metalaxyl (specific activity 24.6 uCi/mg) in greenhouse-grown head lettuce. Lettuce plants received two or four foliar applications (10, 24, 38, and 52 days posttransplant) at 14-day intervals of a 2 lb/gal EC formulation at 0.2 lb ai/A/application. Fully mature plants were harvested on the day of and 7 days after the last of four applications; 50% mature plants were harvested 7 days after the second of two applications. Lettuce samples were extracted using a referenced (AG-214) but undescribed biphasic extraction procedure. Portions of the homogenized subsamples and nonextractable material were subjected to combustion analysis to determine total ^{14}C-activity. ^{14}C-Residues were characterized using TLC with two-dimensional developments. Solvents of differing polarity were used, and standards were cochromatographed to facilitate identification of unknowns. Radiolabeled zones on the plates were visualized by autoradiography, and the zones were scraped and ^{14}C-activity determined by LSC. In addition, conjugated metabolites were subjected to enzyme hydrolysis using cellulase and beta-glucosidase to facilitate metabolite identification by TLC.

Results of the radiolabel analysis showed that total extractable ^{14}C-activity was 100.1% (50% mature plants at 7 days posttreatment), 94.3% (100% mature plants at 0 days posttreatment), and 87.7% (100% mature plants at 7 days posttreatment). The distribution of identified extractable ^{14}C-residues is presented in Table 5. The portion of ^{14}C-activity present in mature plants as parent material decreased markedly from 64.1% at 0 days posttreatment to 14.4% at 7 days posttreatment. Concurrently, conjugate forms increased with the posttreatment interval.

Table 5. Distribution and characterization of ^{14}C-residues in greenhouse-grown head lettuce harvested 0 or 7 days following foliar applications of [^{14}C]metalaxyl.

	Percent of total plant ^{14}C-activity in:		
	50% mature (7 days)	100% mature (0 days)	100% mature (7 days)
Metabolites			
Metalaxyl (I)	29.5	64.1	14.4
CGA-100255 (III)	1.2	0.8	0.4
CGA-62826 (IV)	2.3	0.7	4.6
CGA-94689 conjugates	22.5	5.6	10.9
CGA-100255 conjugates	4.5	2.1	4.5
CGA-107955 conjugates	1.9	0.4	2.2
CGA-62826 + CGA-67869 conjugates	6.3	2.0	7.0
CGA-37734 conjugate	1.4	0.4	1.2
Total	69.6	76.1	45.2

Ciba-Geigy Corp. (1979; MRID 00071608) submitted a study pertaining to the metabolism of [^{14}C]metalaxyl in greenhouse-grown lettuce. Thirty-six 5-week old lettuce seedlings received two foliar applications (14-day interval) of a 25% WP formulation containing uniformly ring-labeled [^{14}C]metalaxyl (specific activity 5 uCi/mg), and were harvested 2 weeks after the last treatment.

Foliage parts were extracted with methanol:water (8:2); the methanol extract was dried and then sequentially extracted with hexane and DCM. The non-extractable residue from the methanol step was subjected to combustion analysis. Hexane, DCM, and water phase extracts were analyzed by TLC using solvents of varying polarities. In addition, the hexane-phase extract was analyzed using a GLC equipped with a RAM and a FID. Radiolabeled zones on TLC plates were localized by a plate scanner; ^{14}C-activity was scrapped of the total plant ^{14}C-activity, off the plates and analyzed by LSC. Results of the radioanalysis showed that, of the total plant ^{14}C-activity, metalaxyl accounted for 21.5% whereas CGA-100255 and CGA-94689 accounted for 1.6 and 5.1%, respectively. Water-soluble conjugates accounted for 30.1% of the total ^{14}C-activity. These data indicate that lettuce plants degrade metalaxyl by oxidation of the ring methyl group and hydroxylation of the ring.

Ciba-Geigy Corp. (1980; MRID 00071610) submitted a continuation of the [^{14}C]metalaxyl metabolism study in lettuce. The methods used for growing and treating the plants have been previously described (MRID 00071608). Extracts were analyzed by TLC using varying polar solvents and cochromatographic standards, and by GC, HPLC, and GLC/MS. In addition, cellulase was used for the enzymatic cleavage of glucose conjugates; GC samples were derivatized by acetylation and methylation reactions to faciliate MS-chromatographic identification. Results of the radiolabel analysis were as follows. Seventy-six percent of the total ^{14}C-activity in the foliage tissue was

extracted by methanol:water. The characterization and quantification of ^{14}C-activity in the methanol extracts are listed in Table 6.

Table 6. Characterization of ^{14}C-residues in the foliage of lettuce plants after treatment with [^{14}C]metalaxyl.

Metabolite	Percentage of total extractable ^{14}C-activity
Metalaxyl (I)	18.6
CGA-100255 (III)	6.2
CGA-67869 (X)	8.9
CGA-37734 (IX)	2.9
CGA-94689 (II; two isomer forms)	22.1
CGA-62826 (IV)	6.0
CGA-107955 (VII)	10.1
CGA-108905 (V)	1.2
Total	76.0

The metabolic pathways for the degradation of metalaxyl were as follows. The metalaxyl aromatic ring is hydroxylized to yield CGA-100255. The ring methyl group is oxidized to yield CGA-94689. The cleavage of the methylester and methylether bonds produces CGA-62826 and CGA-67869, and subsequently produces CGA-107955. The N-dealkylation of metalaxyl yields CGA-37734. All the metabolites formed were conjugated to glucose, with the exception of metalaxyl and CGA-108905.

Ciba-Geigy Corp. (1982; MRID 00128102) submitted a [^{14}C]metalaxyl seed treatment study (no. ABR-82078) that utilized ten different crops. Seeds were treated with [^{14}C]metalaxyl (uniformly ring-labeled with a specific activity of 0.55 mCi/mM) that was prepared as a 2 lb/gal EC formulation. Tomato, pepper, cucumber, squash, beet, lettuce, cabbage, and sunflower seeds were treated at 0.5 fl. oz ai/100 lb seed. Sorghum, pea, and sun flower seeds were treated at 1.0, 1.25, and 2.0 fl. oz ai/100 lb seed, respectively. Plant parts were analyzed for ^{14}C-activity in an unspecified manner. The results of the radioanalysis showed values of <0.1 ppm of metalaxyl equivalents.

No characterization of the ^{14}C-residues was done since the recovered ^{14}C-activities were at levels too low for quantification.

Ciba-Geigy Corp. (1982; MRID 00128102) submitted an additional seed treatment [^{14}C]metalaxyl study, (ABR-81061). Barley, winter wheat, soybeans, navybeans, peas, and sweet corn seeds were treated, and plants were grown in two locations (NY and MS). Rice and peanuts seeds were treated, and plants were grown in only one location (MS). Seeds were treated at 2 fl. oz/100 lbs of seed with [^{14}C]metalaxyl in a 2 lb/gal EC formulation (0.5 oz ai/100 lb of seed The [^{14}C]metalaxyl was uniformly ring-labeled and had a specific activity of 0.70 mCi/mM. Plants were sampled at various intervals during the course of the study and analyzed for total ^{14}C-activity according to unspecified standard methods. All tested samples had <0.1 ppm of [^{14}C]metalaxyl equivalents; no characterization of ^{14}C-residues was attempted.

NATURE OF THE RESIDUE IN ANIMALS

Conclusions:

The nature of the residue of metalaxyl (N-(2,6-dimethylphenyl)-N-(methoxyacetyl)-alanine methyl ester) in animals has previously been determined as being inadequately understood for the purposes of establishing permanent tolerances for metalaxyl residues in animal products (refer to the Metalaxyl Guidance Document dated December 1981). The sole ruminant metabolism study discussed in the original Guidance Document failed to characterize ^{14}C-residues in tissues. Additional studies have not been submitted subsequent to issuance of the original Guidance Document. The following data are therefore required:

- o Metabolism studies utilizing ruminants and poultry in which animals must be dosed for a minimum of 3 days with [^{14}C]metalaxyl at a level sufficient to make residue identification and quantification possible. Milk and eggs must be collected twice daily during the dosing period. Animals must be sacrificed within 24 hours of the final dose. The distribution and characterization of residues must be determined in milk, eggs, liver, kidney, and muscle and also skin and gizzard for hen. If the metabolism of metalaxyl in ruminants or poultry is found to differ from that in rats, or with each other, then swine metabolism data may be required. Data reflecting solvent extraction of residues are also required.

- o Representative samples from the above described tests must also be analyzed by current enforcement methods to ascertain the validity of these methods.

References (used):

N/A.

References (not used):

[These MRIDs contain studies previously reviewed and determined to contribute useful information (refer to the Metalaxyl Guidance Document).]

MRIDs: 00071611. 00071612.

[These MRIDs contain studies previously reviewed and determined as being inappropriate (refer to the Metalaxyl Guidance Document), duplicate previously cited information, or are irrelevant information.]

MRIDs: 00100480. 00100481. 00104655.

Discussion of the data:

N/A.

RESIDUE ANALYTICAL METHODS

Conclusions:

Adequate gas-liquid chromatographic (GLC) methods are available for the collection of data pertaining to residues of metalaxyl and its metabolites containing the 2,6-dimethyaniline moiety in or on plant and animal commodities. Method AG-325 is not considered adequate for data collection since it only measures metalaxyl per se and is not reported to measure metabolites containing the 2,6-dimethyaniline moiety or the metabolite CGA-94689 (all of which are part of the tolerance definition). However, methods AG-330, AG-348, AG-349, AG-350, and AG-395 are considered adequate for data collection and enforcement purposes. Methods AG-348 and AG-349 are methods I and II, respectively, in the Pesticide Analytical Manual (PAM), Vol. II (Pesticide Reg. Sec. 180.408). In additional, these methods, and AG-395, underwent successful method try outs (MTO_S). Methods AG-325, AG-330, and AG-348 were subjected to interference studies and the only interference found was the analysis of chlorpropham by the AG-330 method. Methods AG-325, AG-330, AG-348, and AG-395 were also subjected to [^{14}C]metalaxyl verification tests. Because of the increased sensitivity in the measurement of CGA-94689 and the reduction in the amount of time required for analysis, we recommend the use of AG-395.

The Residue Chemistry Data Requirements in the 40 CFR 158.125(b)(15) require that regulated pesticide residues be subjected to one or more of the FDA/USDA multiresidue procedures described in PAM Vol. I, Appendix II. Multiresidue Protocol III (PAM Vol. I, Method 232.4) completely recovers (>80%) metalaxyl per se. We note that additional metabolites of metalaxyl are known to occur in plants and animals and are part of the current tolerance definition; there are no multiresidue procedures published for these metabolites. The following is therefore required:

- o Metalaxyl metabolites containing the 2,6-dimethylaniline moiety and CGA-94689 in or on crop samples must be subjected to analysis by multiresidue protocols. Protocols for Methods I, II, III, and IV are available from the National Technical Information Service under order no. PB203734/AS.

Additional methods, validation data, and residue data (for representative commodities) may be required if the metabolism studies requested in the sections entitled "Nature of the Residue in Plants" and "Nature of the Residue in Animals" indicate that additional metabolites constitute residues of toxicological concern.

References (used):

MRIDs: 00071622. 00071623. 00071676. 00104656. 00148440. 00157480.

Arne, K.H. 1982. PP#2F2732. Results of the metalaxyl method trial. (No MRID assigned.)

Arne, K.H. 1984. PP#3F2918 and 3F2919. Results of a method trial. (No MRID assigned.)

Corley, C. 1982. PP#1F2500. Method try-out request for metalaxyl and metabolites. (No MRID assigned.)

References (not used):

[The following references duplicate previously cited information or are irrelevant.]

MRIDs: 00071618. 00071621. 00071677. 00074489. 00100481. 00104377. 00104378. 00109461. 00155845.

Discussion of the data:

Ciba-Geigy Corp. (1978; MRID 00148440) submitted a gas-liquid chromatography (GLC) analytical method, AG-325, for the determination of residues of metalaxyl per se in or on tobacco and potato. Crop samples are initially extracted with 80% methanol by blending. An aliquot of the extract is acidified with hydrochloric acid and partitioned with dichloromethane (DCM). The DCM solution is evaporated and the residue is passed through a Grade V alumina column with ethyl:hexane (1:1, v/v). The sample is analyzed using a GLC (10% DC 200 on Chrom Q (80/100 mesh)) equipped with an alkali flame ionization detector (AFID) in the nitrogen specific mode. Green and cured tobacco samples fortified with 5 and 1 ppm of metalaxyl, respectively, yielded respective recovery values of 88 and 92.5%. Additional analysis (report no. ABR-78039) showed that 10 cured tobacco samples fortified with 1-60 ppm of metalaxyl had recoveries of 71-95% and three green tobacco samples fortified with 1-5 ppm of metalaxyl had recoveries of 82-88%. A potato sample fortified with 0.05 ppm of metalaxyl had a recovery of 86.1%. Blank values were <0.1 ppm and <0.05 ppm metalaxyl equivalents for tobacco and potato samples, respectively. Chromatographs did not distinguish metalaxyl since the metalaxyl peak was a shoulder peak to what appeared to be a solvent peak. Cured and green tobacco treated with [^{14}C]metalaxyl were also analyzed using method no. AG-325 (report no. ABR-78039). The GLC method accounted for 87-97% of the ^{14}C-activity in three 12-week-old green tobacco samples and 104% of the ^{14}C-activity in a single 12-week-old cured tobacco sample. Actual [^{14}C]-metalaxyl recoveries ranged from 29 to 35% of the total ^{14}C-activity. An interference study (1978; MRID 00104656) was done for the AG-325 method; there was no interference of metalaxyl peaks (0.05 ppm metalaxyl) with 66 tested compounds. Method AG-325 is not adequate for data collection since it only measures metalaxyl per se and is not reported to determine metabolites containing the 2,6-dimethylaniline moiety or CGA-94689 (all of which are part of the current tolerance definition).

Ciba-Geigy Corp. (1978; MRID 00148440) submitted a GLC method, AG-330, for the determination of residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety in or on tobacco. This method is a modification of AG-325. Residues of metalaxyl in or on tobacco are extracted by blending samples with 80% methanol. An aliquot is refluxed with 85% phosphoric acid and cobalt chloride; the resulting solution is then treated with sodium hydroxide and refluxed. This results in the formation

of 2,6-dimethylaniline (DMA) which is then derivatized with trichloroacetyl chloride (TCA) to minimize problems associated with the volatility of DMA. The derivatized material (TCA-DMA) is cleaned up with alumina column chromatography, and detected and quantitied using a GLC (3% Dexsil on Gas Chrom Q (80/100 mesh) equipped with a AFID in the nitrogen specific mode. The stated detection limit for the determination of metalaxyl residues in or on tobacco samples is 1 ppm. Reported control values were <1 ppm apparent metalaxyl residues. Chromatographic data showed that a green tobacco sample fortified with 10 ppm of metalaxyl had a recovery of 69% and that a cured tobacco sample fortified with 50 ppm of metalaxyl had a recovery of 77%. Additional analysis (1979; MRID 00148440) showed that 11 cured tobacco samples fortified with 5-500 ppm of metalaxyl had recoveries of 65-87% and one green tobacco sample fortified with 1 ppm of metalaxyl had a recovery of 66%. A [^{14}C]metalaxyl verification study of the AG-330 method (1979; MRID 00148440) found that total [^{14}C]metalaxyl recovery was 50-58% from 12-week-old treated green and cured tobacco. Recovery of ^{14}C-residues containing the DMA moiety was 97-104%, while the recovery of [^{14}C]CGA-94689 was 46-49%. An interference study (1978; MRID 00157480) was done for the AG-330 method. Of 65 compounds tested, only CIPC (chlorpropham), interfered with the quantification of metalaxyl at a level of 0.05 ppm. The interference of CIPC was overcome if GC-mass spectral (GC/MS) analysis was used. This method is considered adequate for data collection pertaining to residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety in or on plant commodities; this method is also suitable for enforcement purposes.

Ciba-Geigy Corp. (MRID 1980; 00148440) submitted a GLC analytical method, AG-348, for the determination of the combined residues of metalaxyl and its metabolites which contain the 2,6-dimethylaniline moiety in crops. This method is a modification of analytical method AG-330 that was originally developed for tobacco. Crop samples with a high moisture content (e.g., potatoes, cauliflower) are extracted with 80% methanol while dry crop samples (e.g., cottonseed) require an additional hexane/acetonitrile partitioning step. The hexane layer is discarded since it contains oils and fats which could cause interferences. The remaining procedural steps, including phosphoric acid treatment, base treatment, steam distillation, derivatization, and analysis, are identical to AG-330 with the exception of the cottonseed extracts which are subjected to an additional silica gel column cleanup. Additional quantitative analysis was also done by GC/MS. Recovery values of metalaxyl from crop samples were as follows: 0.10 and 0.50 ppm fortified potato had 73 and 77%, respectively; 0.40 ppm fortified honeydew melon had 63%; and 0.20 ppm fortified cauliflower had 70%. The blanks had <0.05 ppm of apparent metalaxyl, and the peaks on the accompanying chromatographs were sharp and distinguishable. Additional information in the text stated that a total of 18 cucurbit samples (honeydew melon, cucumbers, watermelons, and cantaloupes) fortified with 0.05-0.4 ppm of metalaxyl had 53-95% recovery and 18 brassica crop samples (broccoli, cabbage, cauliflower) fortified with 0.05-0.5 ppm of metalaxyl had 42-79% recovery. A [^{14}C]metalaxyl verification study of the AG-348 method (1982; MRID 00148440) showed that the method accounted for 73% and 42-48% of the total ^{14}C-activity in mature lettuce harvested 0 and 7 days posttreatment, respectively. Recovery of [^{14}C]CGA-94689 was only 12-17%, which is unacceptably low since this metabolite is part of the tolerance definition. However, additional studies, described below,

showed higher recoveries of nonlabeled CGA-94689. An additional [^{14}C]metalaxyl verification study (1981; MRID 00071676) for the AG-348 method showed 43 and 64% recovery of total ^{14}C-activity from treated (17-week) potato tubers. An interference study (1981; MRID 00157480) was done for the AG-348 method and, of the 229 tested compounds, no interference was found for the GC peaks of residues of metalaxyl (TCA-DMA). It is stated that 16 additional compounds would not interfere due to their chemical or physical properties or their similarity to tested compounds. A successful method try out of AG-348 was reported in memoranda by C. Corley and K.H. Arne (1982; no MRIDs assigned); values reported were the same as those in the PAM, Vol. II, for Method I. Recoveries of metalaxyl were 70 and 72% from two cottonseed samples fortified with 0.10 ppm of metalaxyl. Recoveries of three 2,6-dimethylaniline moiety-based metabolites (CGA-67869, CGA-107955, CGA-62826) were 62 and 66% from two cottonseed samples fortified with a total of 0.10 ppm of the metabolites. Recoveries of the hydroxylated metabolite CGA-94689, which is not a 2,6-dimethylaniline moiety-based compound, were 45 and 50% from two cottonseed samples fortified with 0.1 ppm of CGA-94689. Additional recovery percentages cited with Method I in PAM, Vol. II were 60 to 83% from ten potato tuber samples fortified with 0.05-1.0 ppm of metalaxyl. The method AG-348 is considered adequate for data collection and enforcement of tolerances pertaining to residues of metalaxyl in or on plant commodities.

Ciba-Geigy Corp. (1980; MRID 00071622) submitted a GLC method, AG-349, for the determination of the residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety in animal tissues, milk, and eggs. This method is a modification of the analytical method AG-330 that was originally developed for tobacco. Modifications involved the extraction solvents and sample cleanup. Milk, eggs, muscle, liver, and kidney samples are extracted with acetonitrile and partitioned with hexane; fat samples are extracted with hexane and partitioned with acetonitrile. Liver and kidney samples extracts are cleaned up with ethyl ether/hexane solutions and a silica gel column. The other tissue extracts are subjected to an alumina column cleanup with hexane. The acidification, basification, steam distillation, derivatization, and GC analysis steps are the same as described for AG-330 and the TCA-DMA is quantified. Recoveries and fortification levels given parenthetically were: 83% (0.39 ppm) and 61% (0.2 ppm) from meat samples; 62% (0.05 ppm) and 59% (0.65 ppm) from fat samples; 63% (0.01 ppm) and 74% (0.02 ppm) from milk samples; and 85% (0.1 ppm) and 69% (0.02 ppm) from liver samples. Blank values of apparent metalaxyl ranged from <0.01 ppm for fat to <0.05 ppm for meat. The AG-349 method is Method II in PAM, Vol. II. Recoveries (cited with the method) from ten milk samples fortified with 0.01-0.10 ppm of metalaxyl were 52-76%; recoveries from five liver samples fortified with 0.1-0.4 ppm of metalaxyl were 54-116%. A successful method try out was conducted on method AG-349 (C. Corley, 1982 and K.H. Arne, 1982; no MRIDs assigned). Recoveries of metalaxyl were 68 and 70% from two beef liver samples fortified with 0.4 ppm of metalaxyl and 72 and 76% from two milk samples fortified with 0.02 ppm of metalaxyl. Recoveries of three 2,6-dimethylaniline moiety-based metabolites (CGA-67869, CGA-107955, CGA-62826) were 65 and 68% from two beef liver samples fortified with 0.15 ppm of each metabolite and 70 and 74% from two milk samples fortified with 0.02 ppm of each metabolite. Recoveries of the hydroxylated metabolite CGA-94689, which is not a

2,6-dimethylaniline moiety-based compound, were 45 and 48% from two beef liver samples fortified with 0.4 ppm of CGA-94689 and 48 and 50% from two milk samples fortified with 0.02 ppm of CGA-94689. This method is considered adequate for data collection and enforcement purposes.

Ciba-Geigy Corp. (1980; MRID 00071623) submitted a GLC analytical method, AG-350, for the determination of the combined residues of metalaxyl and its metabolites which contain the 2,6-dimethylaniline moiety in oil seed fractions. This method is a modification of method AG-330 and contains the hexane/acetonitrile extraction and partitioning steps as described in AG-348. A modification unique to method AG-350 is that soapstock samples are refluxed with phosphoric acid without prior extraction and partition. The acidic fraction is then partitioned with hexane. The resultant DMA is cleaned up by an acid-base partition and a Sep-Pak silica gel cartridge prior to derivatization with trichloroacetyl chloride. Percentage recoveries of metalaxyl residues were: 60% (0.05 ppm) and 55% (0.8 ppm) from two soybean hull samples; 38% (0.05 ppm) and 44% (0.8 ppm) from two soybean meal samples; 47% (0.05 ppm) and 65% (1.0 ppm) from two crude oil samples; and 60% (0.05 ppm) and 52% (0.1 ppm) from two soapstock samples (fortification levels listed parenthetically). Blanks showed <0.05 ppm of apparent metalaxyl. This method is deemed adequate for data collection and enforcement purposes.

Ciba-Geigy Corp. (1982; MRID 00148440) submitted a GLC total metalaxyl residue analytical method, AG-395. This method is a modification of AG-348 and determines residues of metalaxyl and its metabolites which contain the 2,6-dimethylaniline moiety in or on crop substrates. The modifications to method AG-348 are as follows. The methanol extract is evaporated to dryness; water is added to dissolve the residue; and the extract is refluxed for 15 minutes with methanesulfonic acid (instead of phosphoric acid) for 15 hours. The steam-distilled product is cleaned up with a silica Sep-Pak cartridge and analysis is done using a capillary gas chromatograph (fused silica capillary 0.25 um coating). Results of recovery analysis, that were accompanied with chromatographs, showed a 80% recovery from 0.1 ppm-fortified lettuce and a 95% recovery from 0.2 ppm-fortified spinach. The blank for lettuce was <0.05 ppm of apparent metalaxyl and the blank for spinach had a high value of 0.13 ppm of apparent metalaxyl. Additional recovery values were cited as 72-100.3% from 89 crop samples, which included avocadoes, beans, broccoli, cabbage, cantaloupe, cauliflower, cucumber, and squash that had been fortified with 0.05-5.0 ppm of metalaxyl. A [^{14}C]metalaxyl verification study of the AG-395 method (1983; MRID 00148440) found that the method accounted for 78 and 62% of the total ^{14}C-activity in or on mature lettuce at 0 and 7 days posttreatment, respectively. This method also accounted for 49% of the metabolite CGA-94689 in or on lettuce plants harvested 7 days posttreatment. A successful method try out for AG-395 was conducted (Arne, 1984; no MRID assigned). The report noted the possibility of methanesulfonic acid being contaminated with 2,6-dimethylaniline. The results of the method try out are presented in Table 7. This method is deemed to be adequate for data collection and enforcement purposes.

Table 7. Results of the method try out for AG-395.

Commodity	Fortified with:	Fortification level (ppm)	Percent recovery
Peanuts	Metalaxyl	0	nil[a]
		0.05	74, 77
		0.5	91, 63
	CGA-94689	0	nil
		0.05	62, 63
		0.5	65, 68
	Mixture[b]	0	nil
		0.05	81, 86
		0.5	88, 89
Peanut Hay	Metalaxyl	0	nil
		0.5	94, 102
		5.0	93, 88
	CGA-94689	0	nil
		0.5	65, 69
		5.0	52, 59
	Mixture[b]	0	nil
		0.5	94, 101
		5.0	75, 72

[a] Not explicitly defined.
[b] Mixture is defined as equal concentrations of CGA-62826, CGA-67869 and CGA-107955.

It is noted that the modifications of AG-395 improved the percentage recovery of CGA-94689 as compared to AG-348 with an increase of recovery from 45-50% for AG-348 to 52-69% for AG-395.

STORAGE STABILITY DATA

Conclusions:

The available data are sufficient to ascertain that residues of metalaxyl per se are stable in tobacco and potatoes for up to 12 months when stored in glass jars at 5 F (-15 C) and that the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety are stable in tobacco and potatoes for up to 18 months when stored in plastic bags at 5 F (-15 C). However, the following additional data are required:

- o The storage intervals and conditions of samples used to support all established tolerances for residues must be submitted. These data must be accompanied by data depicting the percent decline in residues at the times and under the conditions specified. (No additional stability studies are required for plant commodities stored at 5 F (-15 C) for up to 12 months.). On receipt of these data, the adequacy of the aforementioned tolerances will be reevaluated.

- o All residue data requested in this Standard must be accompanied by data regarding storage length and conditions of storage of samples analyzed. These data must be accompanied by data depicting the stability of residues under the conditions and for the time intervals specified, with the exception of plant commodities stored at 5 F (-15 C) for up to 12 months.

It should be noted that the nature of the residue in plants and animals has not been adequately described. If the requested metabolism data indicate the presence of additional residues of toxicological concern in plant or animal commodities, data depicting the stability of such residues in storage will be required.

References (used):

MRID: 00148440.

References (not used):

[The following MRID duplicates previously cited information.]

MRID: 00071678.

Discussion of the data:

Ciba-Geigy Corp. (1980; MRID 00148440) submitted data depicting the effect of frozen storage on metalaxyl residues in tobacco and potatoes. Tobacco and potato samples were fortified with metalaxyl at 5 and 0.2 ppm, respectively, using an acetone solution. The solvent was evaporated and the treated samples and unfortified controls were stored in glass jars at 5 F (-15 C). A control sample, a stored-fortified sample, and a freshly fortified sample were analyzed for residues of metalaxyl per se on the day of fortification (day 0), and after 1, 2, 4, 6, and 12 months of frozen storage (using method no. AG-325). Results are presented in Table 8.

In addition, field-treated tobacco and potato samples were analyzed for the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety on the day of harvest and after storage in plastic bags at 5 F (-15 C) for 18 months (using method no. AG-330). Results are presented in Table 9.

Table 8. Storage stability of metalaxyl per se in or on tobacco and potato samples analyzed by method no. AG-325.

Samples	Storage interval (months)	Fortification level (ppm)	Control value (ppm)	Percent recovery from: Freshly-fortified sample	Stored-fortified sample
Cured tobacco	0	5.0	<1.0	82	103
	1	5.0	<1.0	83	98
	2	5.0	<1.0	89	107
	4	5.0	<1.0	81	104
	6	5.0	<1.0	100	99
	12	5.0	<1.0	101	108
Potato	0	0.2	<0.05	80	71
	1	0.2	<0.05	108	102
	2	0.2	<0.05	116	115
	4	0.2	<0.05	104	103
	6	0.2	<0.05	98	114
	12	0.2	<0.05	100	95

Table 9. Combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety in field-treated tobacco and potato samples at harvest (first analysis) and after 18 months of storage at 5 F (second analysis). Samples were analyzed using method no. AG-330.

Sample	Application rate (lb ai/A)	Residue concentration (ppm) at: First analysis	Second analysis
Cured tobacco	3.0	83	85, 87, 87[a]
	6.0	128	152
Potatoes	0.5	0.15	0.16
	0.5	0.15	0.16
	1.0	0.16	0.17
	1.0	0.13	0.13

[a] Analyzed using triplicate subsamples.

MAGNITUDE OF THE RESIDUE IN PLANTS

It should be noted that the conclusions stated below are subject to change on receipt of the requested storage stability data. Also, it should be noted that the conclusions stated below address only the minimum residue chemistry data base acceptable for purposes of establishing group crop tolerances. The registrants should consider the complete data requirements stated in the 40 CFR 180.34 if they elect to propose crop group tolerances.

In the commodity sections which follow, "total metalaxyl residues" refers to the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl.

The 1986 Joint Meeting on Pesticide Residues proposed a change in the residue definition for Codex MRLs from metalaxyl per se to the sum of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, determined as 2,6-dimethylaniline, and calculated and expressed as metalaxyl. Note that all Codex MRLs for residues of metalaxyl are temporary, pending evaluation of data based on an improved analytical method.

Root and Tuber Vegetables Group

Conclusions for the Root and Tuber Vegetables Group:

The available data are insufficient to determine whether a crop group tolerance is appropriate. If the registrant seeks a crop group tolerance, then the following will be required:

- Use directions must be proposed and appropriate supporting residue data submitted for carrots and radishes.

Beets

Tolerance:

A tolerance of 0.1 ppm has been established for the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on beets (40 CFR 180.408[a]).

Use directions and limitations:

The 2.66 lb/gal FlC formulation is federally registered for use as a seed treatment to garden beet seed at 0.5 oz ai/100 lb of seed using conventional slurry or misting equipment.

Conclusions:

The available data are adequate to support the established tolerance of 0.1 ppm for total metalaxyl residues in or on beets. Additional data are not required.

There is no Canadian tolerance, Mexican tolerance, or Codex MRL for residues of metalaxyl in or on beets. Therefore, no compatibility questions exist with respect to the Codex MRL.

References (used):

MRID: 00128102.

Discussion of the data:

Ciba-Geigy Corp. (1982; MRID 00128102) submitted data (report no. ABR-82078) pertaining to ^{14}C-residues of metalaxyl in or on beet roots following seed treatment with uniformly ring-labeled [^{14}C]metalaxyl (as the 2 lb/gal EC formulation) at 0.5 oz ai/100 lb of seed (1x the maximum registered seed treatment rate) (Refer to the "Nature of the Residue in Plants" section for experimental details.) Seeds were planted in a NE field plot; beets were harvested 60 days after planting. Residues in or on a single beet sample were <0.031 ppm equivalents of metalaxyl (nondetectable). The available data depicting ^{14}C-residues of metalaxyl in beet roots and other crops (refer to the "Nature of the Residue in Plants" section for details) are adequate to support the established tolerance of 0.1 ppm for total metalaxyl residues in or on beets. Additional data are not required.

Potatoes

Tolerances:

Tolerances of 0.5, 4, and 4 ppm have been established for the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on potatoes (40 CFR 180.408[a]), processed potatoes (including potato chips) (21 CFR 193.277[a]), and dried, processed potato waste (21 CFR 561.273[a]), respectively.

Note to the PM: We recommend that the entries "potatoes, processed (including potato chips)" and "potato waste, dried, processed" be amended to reflect the appropriate commodity definitions "granules," "chips," "wet peel," and "dry peel."

Use direction and limitations:

The 9% WP formulation is registered for multiple foliar applications to potatoes at 0.18 lb ai/A; the first application may be made at flowering and may be repeated after 14 days. A third application may be made 14 days after the second application. The 9% WP formulation is also registered for multiple foliar applications to potatoes at 0.135-0.18 lb ai/A. Applications may begin when the plants are 6 inches high (and conditions are favorable for disease development) and may be repeated at 14-day intervals until the threat of disease is over. In addition, the 10% WP formulation is registered for multiple foliar applications to potatoes at 0.15-0.2 lb ai/A. Applications may begin when the plants are 6 inches high and may be repeated at 14-day intervals, thoughout the growing season. There is a 7-day PHI for all uses. There is no maximum seasonal application rate or a maximum number of applications per season.

Conclusions:

It was previously determined that the available residue data were adequate to support a temporary tolerance of 0.05 ppm for residues in or on potatoes (refer to the Metalaxyl Guidance Document dated December 1981 for details). Additional residue data are not required since residue tests described in the original Guidance Document were conducted at 0.5 and 1.0 lb ai/A (2.5-5x the current maximum single application rate) and the current tolerance is set at 0.5 ppm (compared to a temporary tolerance of 0.05 ppm at the time of issuance of the original Guidance Document). Data were not submitted that depict metalaxyl residues of concern in chips, granules or flakes, and wet and dry potato peel processed from potatoes bearing measurable, weathered residues. However, since the present use results in significant residues on potatoes, the following is required:

- o Data depicting metalaxyl residues of concern in chips, granules or flakes, and wet and dry potato peel processed from potatoes bearing measurable, weathered residues. If residues concentrate in any of these processed commodities, appropriate food/feed additive tolerances must be proposed.

There is a Canadian tolerance of 0.1 ppm (negligible residue) for residues of metalaxyl in or on potatoes. There is no Mexican tolerance. There is a proposed Codex MRL of 0.05 ppm (step 6) for residues of metalaxyl *per se* in or on potatoes. Compatibility is not possible without a major revision of the U.S. residue definition, which is dependent on toxicological considerations.

References (used):

MRID: 00071616.

Discussion of the data:

[The following discussion excludes those residue studies which were apparently reviewed in the Metalaxyl Guidance Document dated December 1981 and those that utilized an unacceptable analytical method (no. AG-325).]

Ciba-Geigy Corp. (1981; MRID 00071616) submitted data from eight tests conducted in ME(2), MN(2), and NY(4) pertaining to the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on potatoes following 4-6 foliar applications (by aerial equipment in the MN tests and ground equipment in the remaining tests) of the 2 lb/gal EC formulation at 0.375-1.14 lb ai/A (1.9-5.7x the maximum permitted single lb ai/A application rate) with posttreatment intervals of 7-31 days. Combined metalaxyl residues were <0.05(nondetectable)-0.18 ppm in or on 14 potato samples. Seven control samples bore <0.05 ppm (nondetectable) of metalaxyl residue. Samples were analyzed using an adequate GLC method (no. AG-330); the limit of detection was 0.05 ppm. Recoveries were 53-80% from eight potato samples fortified with metalaxyl at 0.05-0.50 ppm. Samples were stored: (i) "fresh" (temperature unspecified) for 221 days; (ii) "frozen" (temperature unspecified) for 219 days; or (iii) under unspecified conditions for 203-229 days prior to analysis.

Ciba-Giegy Corp. (1981; MRID 00071616) also submitted data from four tests conducted in CA, MI, NY, and WI pertaining to the combined residues of metalaxyl in or on immature and mature potatoes following 5-6 "fungigation" applications (using ground equipment) of the 2 lb/gal EC formulation at 0.375 lb ai/A (1.9x the maximum permitted single lb ai/A application rate) with posttreatment intervals of 7-15 days. Combined metalaxyl residues were <0.05(nondetectable)-0.43 ppm and <0.05(nondetectable)-0.49 ppm in or on eight samples each of immature and mature potatoes, respectively. Four control samples of immature potatoes and five control samples of mature potatoes each bore <0.05 ppm (nondetectable). Samples were analyzed using an adequate GLC method (no. AG-348); the limit of detection was 0.05 ppm. Recoveries were 43-79% from six potato samples fortified with metalaxyl at 0.1-1.0 ppm. Samples were stored "frozen" (temperature unspecified) for 11-202 days prior to analysis.

Geographic representation was inadequate since the tests states of CA(6%), ME(6%), MI(4%), MN(4%), NY(3%), and WI(6%) collectively accounted for only 29% of the 1984 U.S. potato production (Agricultural Statistics, 1985, p. 164). However, it was determined in the Metalaxyl Guidance Document (dated December 1981) that the available residue data were adequate to support a temporary tolerance of 0.05 ppm for total metalaxyl residues in or on potatoes. Additional residue data are not required since residue tests described in the original Guidance Document were conducted at 0.5 and 1.0 lb ai/A (2.5-5x the current maximum single application rate) and the current tolerance is set at 0.5 ppm (compared to a temporary tolerance of 0.05 ppm at the time of issuance of the original Guidance Document). However, data were not submitted that depict total metalaxyl residues of concern in chips, granules or flakes, and wet and dry potato peel processed from potatoes bearing measurable, weathered residues. A processing study is therefore required.

Sugar beet roots

Tolerances:

Tolerances of 0.1 and 1 ppm have been established for the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on sugar beets (40 CFR 180.408[a]; FR Doc. 87-8274, 4/14/87) and sugar beet molasses (21 CFR 561.273[a]; FR Doc. 87-8275, 4/14/87), respectively.

Use directions and limitations:

The 2.65 lb/gal FlC formulation is federally registered for use as a seed treatment to sugar beet seed at 0.5 oz ai/100 lb of seed using conventional slurry or misting equipment.

Conclusions:

Data were not submitted to support the established tolerance of 0.1 ppm for total metalaxyl residues in or on sugar beet roots. However, since the registered seed treatment use on garden beet seed is identical to that on

sugar beet seed, the data for garden beets will be translated to support the established tolerance in or on sugar beet roots. In addition, data are not available to determine if metalaxyl residues concentrate in dehydrated pulp, molasses, and refined sugar processed from sugar beets bearng measurable, weathered residues. The following are therefore required:

- o Data depicting total metalaxyl residues of concern in molasses processed from sugar beets bearing measurable, weathered residues to support the established tolerance of 1.0 ppm in molasses. In addition, data must be submitted depicting metalaxyl residues of concern in dehydrated pulp and refined sugar processed from sugar beets bearing measurable, weathered residues. If residues are found to concentrate in either of these processed commodities, appropriate food/feed additive tolerances must be proposed.

There is no Mexican or Canadian tolerance for total residues of metalaxyl in or on sugar beets. There is a proposed Codex MRL of 0.05 ppm (step 6) for residues of metalaxyl *per se* in or on sugar beets. Compatibility is not possible without a major revision of the U.S. residue definition, which is dependent on toxicological considerations.

References (used):

N/A.

Discussion of the data:

N/A.

Leaves of Root and Tuber Vegetables Group

Conclusions for the Leaves of Root and Tuber Vegetables Group:

The available data are insufficient to determine whether a crop group tolerance is appropriate. If the registrant seeks a crop group tolerance, then the following will be required:

- o Use directions must be proposed and appropriate supporting residue data submitted for turnip tops.

Beet greens

Tolerance:

A tolerance of 0.1 ppm has been established for the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and *N*-(2-hydroxymethyl-6-methyl)-*N*-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on beet tops (40 CFR 180.408[a]).

Use directions and limitations:

The 2.65 lb/gal FlC formulation is federally registered for use as a seed treatment to garden beet seed at 0.5 oz ai/100 lb of seed using conventional slurry or misting equipment.

Conclusions:

The available data are adequate to support the established tolerance of 0.1 ppm for total metalaxyl residues in or on beet tops. Additional data are not required.

Note to the PM: We recommend that the entry "beet, tops" be amended to reflect the appropriate commodity definition "beet greens."

There is no Canadian tolerance, Mexican tolerance, or Codex MRL for residues of metalaxyl in or on beets. Therefore, no compatibility questions exist respect to the Codex MRL.

References (used):

MRID: 00128102.

Discussion of the data:

Ciba-Geigy Corp. (1982; MRID 00128102) submitted data (report no. ABR-82078) pertaining to ^{14}C-residues of metalaxyl in or on beet tops following seed treatment with uniformly ring-labeled [^{14}C]metalaxyl (as the 2 lb/gal EC formulation) at 0.5 oz ai/100 lb seed (1x the maximum registered seed treatment rate) (Refer to the "Nature of the Residue in Plants" section for experimental details.) Seeds were planted in a NE field plot; beets were harvested 60 days after planting and at maturity. Metalaxyl residues in or on two beet top samples were <0.33(nondetectable)-0.044 ppm equivalents of metalaxyl. The available data depicting ^{14}C-residues of metalaxyl in beet tops and other crops (refer to the "Nature of the Residue in Plants" section for details) are adequate to support the established tolerance of 0.1 ppm in or on beets. Additional data are not required.

Sugar beet tops

Tolerance:

A tolerance of 0.1 ppm has been established for the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on sugar beet tops (40 CFR 180.408[a]; FR Doc. 87-8274, 4/14/87).

Use directions and limitations:

The 2.65 lb/gal FlC formulation is federally registered for use as a seed treatment to sugar beet seed at 0.5 oz ai/100 lb of seed using conventional slurry or misting equipment.

Conclusions:

Data were not submitted to support the established tolerance of 0.1 ppm for total metalaxyl residues in or on sugar beet tops. However, since the registered seed treatment use on garden beet seed is identical to that on sugar beet seed, the data for garden beet greens will be translated to support the established tolerance in or on sugar beet tops. Additional data are not required.

There is no Mexican or Canadian tolerance for total residues of metalaxyl in or on sugar beets. There is a proposed Codex MRL of 0.05 ppm (step 6) for residues of metalaxyl per se in or on sugar beets. Compatibility is not possible without a major revision of the U.S. residue definition, which is dependent on toxicological considerations.

References (used):

N/A.

Discussion of the data:

N/A.

Bulb Vegetables Group

A crop group tolerance is inappropriate at the present time. If the registrant seeks a crop group tolerance, the following data will be required:

- o Use directions must be proposed and appropriate supporting residue data submitted for a commodity other than onions from the Bulb Vegetables Group.

Onions

Tolerances:

Tolerances of 3 and 10 ppm have been established for the combined residues of metalaxyl, its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on dry bulb and green onions, respectively (40 CFR 180.408[a]).

Use directions and limitations:

The 9% WP formulation is registered for multiple foliar applications to onions at 0.135-0.2 at 14-day intervals in sufficient water for thorough coverage. Respective preharvest intervals of 7 and 14 days are established for bulb and green onions. Four seasonal applications are permitted to green onions, and no maximum seasonal use rate or maximum number of applications per season is specified for dry bulb onions.

Conclusions:

The available data are adequate to support the established tolerances for the combined residues of metalaxyl and its metabolites (each expressed as metalaxyl) in or on dry bulb and green onions. However, no maximum seasonal use rate or maximum number of applications per season to dry bulb onions currently exists. Therefore, the following information is required:

- o The registrant must propose a label amendment that specifies a maximum seasonal use rate or maximum number of applications per season for dry bulb onions. Based on the available data, we recommend a maximum of four applications per season.

No Canadian or Mexican tolerance or Codex MRL is established for residues of metalaxyl in or on onions. Therefore, no compatibility questions exist with respect to the Codex MRL.

References (used):

MRIDs: 00071615. 00098428. 00130694. 00148103.

Discussion of the data:

Ciba-Geigy Corp. (1979-1983; MRIDs 00071615, 00098428, 00130694, 00148103) submitted data from 28 tests conducted in CA(7), FL(1), MI(3), NY(6), OR(4),

and TX(7) concerning the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on dry bulb onions. The following treatment regimes were represented: (i) four tests had five foliar applications utilizing ground and aerial equipment (2 tests each) of a 10% WP formulation (not registered for use on onions) at 0.2 lb ai/A application (1x the maximum registered single application rate); (ii) five tests had a preemergence broadcast soil application of the 2 lb/gal EC formulation (not registered for use on onions) at 2 lb ai/A (10x the maximum registered foliar application rate) followed by five foliar applications of a 10% WP formulation (not registered for use on onions) at 0.2 lb ai/A (1x the maximum registered single application rate) for a seasonal use rate of 3 lb ai/A; (iii) six tests had five foliar applications of a 25% WP formulation (not registered for use on onions) at 0.2 lb ai/A/application (1x the maximum registered single rate); (iv) two tests had five foliar applications of the 25% WP formulation (not registered for use on onions) at 0.2 lb ai/A/application (1x the maximum registered single application rate) followed by another foliar application of the same formulation at 0.4 lb ai/A (2x the maximum registered single application rate) for a seasonal use rate of 1.4 lb ai/A; and (v) five tests received five foliar applications of the 2 lb/gal EC formulation (not registered for use on onions) at 0.25 lb ai/A/application (1.25x the maximum registered single application rate), five tests received five foliar applications at 0.5 lb ai/A/application (2.5x the maximum registered single application rate), and one test received nine foliar applications at 0.25 lb ai/A/application (1.25x maximum registered single application rate). Posttreatment intervals were 7-34 days. Total metalaxyl residues in or on 43 dry bulb samples were <0.05(nondetectable)-2.20 ppm at 7-30 days posttreatment. Twenty control samples bore apparent total metalaxyl residues of <0.05(nondetectable)-0.12 ppm. Thirty-two additional dry bulb samples (rinsed with water prior to analysis) bore total metalaxyl residues of <0.05(nondetectable) -0.67 ppm at 7-34 days posttreatment. (Plants were treated with five to nine foliar applications at 1.25-2.5x the maximum registered single application rate.) Apparent total metalaxyl residues in or on 14 additional control samples (rinsed prior to analysis) were nondetectable (<0.05 ppm). In addition, total metalaxyl residues were determined in or on onion flake samples processed from bulb onions (rinsed prior to analysis) treated at 2.5x the maximum registered single application rate. Total metalaxyl residues in or on four samples of flakes were 0.06-0.25 ppm. Control values were not presented. Analysis of total metalaxyl residues, determined as DMA (2,6-dimethylaniline), was accomplished using adequate GLC analytical methods (nos. AG-348 and AG-395). The implied limit of detection of both methods was 0.05 ppm. Recovery of total metalaxyl was 52-71% from 13 bulb samples (rinsed) fortified with metalaxyl at 0.05-1 ppm. Recovery of total metalaxyl from 19 unrinsed bulb samples was 44-109% at fortification levels of 0.05-0.5 ppm. Recovery of total metalaxyl from one onion flake sample was 40% when fortified with metalaxyl at 0.5 ppm. Samples were stored frozen for ca. 3-14 months prior to analysis. Geographic representation was adequate since the test locations of CA(24%), FL(<1%), MI(7%), NY(11%), OR(9%), and TX(20%) accounted for ca. 71% of the 1982 dry bulb onion acreage (1982 Census of Agriculture, Vol.1, Part 51, pp. 346-347).

Ciba-Geigy Corp. (1979-1983; MRIDs 00071615, 00098428, and 00130694) submitted data from 19 tests conducted in CA(4), FL(2), MI(3), NY(4), OR(2), and TX(4) concerning the combined residues of metalaxyl, its

metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl -6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on green onions. The following treatment regimes were represented: (i) four tests had three foliar applications of a 25% WP formulation (not registered for use on onions) at 0.2 lb ai/A/application for a seasonal rate of 0.6 lb ai/A (0.75x the maximum permitted seasonal use rate); (ii) five tests had three foliar application of the 2 lb/gal EC formulation at 0.25 lb ai/A/application (0.94x the maximum permitted seasonal use rate) and five tests had three foliar applications at 0.5 lb ai/A/application (1.9x the maximum permitted seasonal use rate); and (iii) five tests had one preemergence broadcast soil application of the 2 lb/gal EC formulation at 2 lb/ai/A followed by three or four foliar application of the 10% WP formulation at 0.2 lb ai/A/application for maximum seasonal rates of 2.6 or 2.8 lb ai/A (3.25 or 3.5x the maximum permitted seasonal use rate). Posttreatment intervals were 7-14 days. Twenty-eight green onion (whole plant) samples bore total metalaxyl residues of 0.33-4.57 ppm, including one sample taken at the 14-day posttreatment interval which bore total metalaxyl residues of 1.1 ppm. Twelve control samples bore apparent total metalaxyl residues of <0.05(nondetectable)-0.14 ppm. Twenty-four additional green onion samples (rinsed, with roots removed) bore total metalaxyl residues of <0.05 (nondetectable)-9.1 ppm. Thirteen additional control samples (rinsed) bore total metalaxyl residues of <0.05(nondectectable)-0.14 ppm. Adequate GLC methods (nos. AG-348 and AG-395) were used to determine total metalaxyl residues. The limit of detection of both methods was 0.05 ppm. Recoveries of metalaxyl were 42-97% from 12 green onion samples (unrinsed) fortified at 0.2-2 ppm and 47-74% from 14 green onion samples (rinsed) at fortification levels of 0.05-2 ppm. Samples were stored frozen for ca. 2-13 months prior to analysis. Geographic representation was adequate since the test states of CA(36%), FL(1%), MI(2%), NY(4%), OR(1%), and TX(23%) accounted for ca. 67% of the 1982 U.S. green onion acreage (1982 Census of Agriculture, Vol. 1, Part 51, p. 347).

The submitted data, although obtained from unregistered uses and applied (in some instances) at highly exaggerated rates, indicates that tolerance exceeding residues in or on dry bulb and green onions are not likely to occur from the registered uses of metalaxyl. No additional data are required. However, the registrant must propose a maximum seasonal use rate or maximum number of applications per season for dry bulb onions. Based on the available data, we recommend a maximum of four applications per season.

Leafy Vegetables (Except Brassica vegetables) Group

Conclusions for the Leafy Vegetables (Except Brassica vegetables) Group:

The crop group tolerance of 0.1 ppm for combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on leafy vegetables (except Brassica vegetables) (40 CFR 180.408[a]) is inappropriate at the present time and should be revoked. Tolerances of 5 ppm and 10 ppm presently exist for residues of metalaxyl in or on the individual group members head lettuce and spinach, respectively. If the registrant wishes to establish a group tolerance, the following data will be required:

- o Use directions must be proposed, and appropriate supporting residue data submitted for the additional representative group members celery and leaf lettuce.

Lettuce

Tolerance:

A tolerance of 5 ppm has been established for the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on head lettuce (40 CFR 180.408[a]).

Use directions and limitations:

The 2 lb/gal EC formulation is registered for broadcast or band soil application at planting to head lettuce at 1-2 lb ai/A in 20-60 gal of water using ground equipment. Broadcast applications may be soil incorporated.

Conclusions:

The available data are adequate to support the established tolerance for the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, and are sufficient to determine that the label directions are adequate. Additional data are not required.

A proposed Codex MRL of 2 ppm (step 6) exists for residues of metalaxyl per se in or on lettuce. Compatibility with Codex is not possible without a major revision of the U.S. residue definition, which is dependent upon toxicological considerations. No Canadian or Mexican tolerances exist.

References (used):

MRIDs: 00071615. 00097511. 00114377. 00130695.

Discussion of the data:

Ciba-Geigy Corp. (1982-83; MRID 00130695) submitted data from six tests conducted in CA(2), FL(1), NE(1), NY(1) and TX(1) concerning the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on head lettuce harvested 7 or 14 days following the last of four foliar applications of the 10% WP formulation (not registered for this use) at 0.2 lb ai/A/application (0.1x the maximum registered single application rate); foliar applications were preceeded by a single preemergence broadcast soil application of the 2 lb/gal EC formulation at 2 lb ai/A (1x the maximum registered use rate). Total metalaxyl residues in or on 24 samples of head lettuce were 0.05-1.46 ppm. Apparent residues in or on 11 control samples were <0.05(nondetectable)-0.13 ppm. Total residues of metalaxyl and it metabolites were determined as DMA (2,6-dimethylaniline) using an adequate GLC analytical method (no. AG-395) with an implied limit of detection of 0.05 ppm. Recoveries were 75-117% from 12 samples fortified with metalaxyl at 0.05-2 ppm. Samples were stored frozen (temperature unspecified) for ca. 88-299 days prior to analysis.

Ciba-Geigy Corp. (1979-1982; MRIDs 00071615, 00097511, and 00114377) submitted data from 15 tests conducted in AZ(2), CA(8), FL(3), and NY(2) concerning the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on head lettuce harvested 0-15 days following the last of four foliar applications of the 2 lb/gal EC formulation (not registered for foliar application) at 0.25 or 0.50 lb ai/A/application (0.13 or 0.25x the maximum registered single application rate) or 7-14 days following the last of four or six foliar applications of the 25% WP formulation (not registered for use on head lettuce) at 0.2 lb ai/A/application (0.1x the maximum registered single application rate). Total metalaxyl residues in or on 42 samples of head lettuce were 0.06-4.1 ppm. Apparent residues in or on 17 control samples were nondetectable (<0.05 ppm). Total residues of metalaxyl and its metabolites were determined as DMA using adequate GLC analytical methods (modification of no. AG-330 and no. AG-348). The implied limit of detection of both methods was 0.05 ppm. Recoveries were 47-89% (modified no. AG-330) from 10 samples fortified with metalaxyl at 0.05-10 ppm and 42-66% (no. AG-348) from seven samples fortified with metalaxyl at 0.2-1.0 ppm. Samples were stored frozen ca. 41-515 days prior to analysis.

Ciba-Geigy Corp. (1981; MRID 00097511) submitted data from one test conducted in NY concerning the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on leaf lettuce (three varieties) harvested 7 or 10 days following the last of four foliar applications of the 25% WP formulation (not registered for use on lettuce) at 0.2 lb ai/A/application (0.1x the maximum registered single application rate). Total metalaxyl residues in or on six samples of

mature lettuce leaves (one sample/variety/posttreatment interval) were 0.44-1 ppm. Apparent residues in or on three control samples (one sample/variety) were nondetectable (<0.05 ppm each). Total metalaxyl residues were determined by an adequate GLC analytical method (no. AG-348) with an implied limit of detection of 0.05 ppm. Recovery was 46% from one sample fortified with metalaxyl at 1 ppm. Samples were stored frozen for ca. 126 days prior to analysis.

Geographic representation was adequate since the test locations of AZ(17%), CA(73%), FL(4%), NE(<1%), NY(1%) and TX(1%) accounted for ca. 96% of 1984 U.S. lettuce production (Agricultural Statistics, 1985, p. 159). Although the majority of the submitted data depicted "total" metalaxyl residues resulting from foliar applications (an unregistered use), we feel that these data indicate that the established tolerance of 5 ppm for the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, will not be exceeded following the registered soil application use of metalaxyl. Additional data are not required.

Spinach

Tolerance:

A tolerance of 10 ppm has been established for the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on spinach (40 CFR 180.408[a]).

Use directions and limitations:

The 2 lb/gal EC formulation is registered for broadcast or band soil application at planting to spinach at 1-2 lb ai/A in 20-50 gal of water using ground equipment. Broadcast applications may be soil incorporated.

Conclusions:

The available data are adequate to support the established tolerance for the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, and are sufficient to determine that the label directions are adequate. Additional data are not required.

A proposed Codex MRL of 1 ppm (step 6) exists for residues of metalaxyl per se in or on spinach. Compatibility with Codex is not possible without a major revision of the U.S. residue definition, which is dependent upon toxicological considerations. No Canadian or Mexican tolerances exist.

References (used):

MRIDs: 00071672. 00114378. 00130695.

Discussion of the data:

Ciba-Geigy Corp. (1982-83; MRID 00130695) submitted data from four tests conducted in CA(1), FL(1), NE(1), and NY(1) concerning the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on spinach harvested 7-14 days following the last of four foliar applications of the 10% WP formulation (not registered for this use) at 0.2 lb ai/A/application (0.1x the maximum registered single application rate); foliar applications were preceeded by a single preemergence broadcast soil application of the 2 lb/gal EC formulation at 2 lb ai/A (1x the maximum registered use rate). Sixteen samples of mature spinach bore total metalaxyl residues of 0.36-9.15 ppm. Apparent residues in or on 11 spinach control samples were <0.05(nondetectable)-0.89 ppm. Total residues of metalaxyl and its metabolites were determined as DMA (2,6-dimethylaniline) using an adequate GLC analytical method (no. AG-348) with a limit of detection of 0.05 ppm. Recoveries were 72-95% from six samples fortified with metalaxyl at 0.2-1 ppm. Samples were stored frozen (temperature unspecified) for ca. 134-310 days prior to analysis.

Ciba-Geigy Corp. (1980-82; MRIDs 00071672 and 00114378) submitted data from 12 tests conducted in CA(5), FL(1), MS(2), NY(3), and TX(1) concerning the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on spinach harvested 6-21 days following the last of three foliar applications (eight tests) of the 2 lb/gal EC formulation (not registered for foliar use) at 0.25 or 0.50 lb ai/A/application (0.13 or 0.25x the maximum registered single application rate) or 7-14 days following the last of four foliar applications (four tests) of the 25% WP formulation (not registered for use on spinach) at 0.2 lb ai/A/application (0.1x the maximum registered single application rate). Total metalaxyl residues in or on 39 spinach samples were 0.2-8 ppm. Two additional samples bore total metalaxyl residues of 20 and 14 ppm at 7 and 14 days posttreatment, respectively, following three foliar applications at 0.5 lb ai/A/application. Total metalaxyl residues were determined by an adequate GLC analytical method (no. AG-348). Recoveries were 46-86% from 13 spinach samples fortified at 0.05-4.00 ppm. Samples were stored frozen (at unspecified temperatures) for an unspecified period or 35-272 days prior to analysis.

Geographic representation was adequate since the test states of CA(24%), FL(1%), MS(<1%), NE(<1%), NY(5%), and TX(25%) accounted for ca. 55% of 1982 U.S. spinach acreage (1982 Census of Agriculture, Vol. 1, Part 51, p. 352) and are representative of the major U.S. spinach growing regions. Although tolerance-exceeding residues occured in or on two samples following multiple foliar application (an unregistered use), these data, in conjunction with data obtained from soil and multiple foliar applications, are adequate to support the established tolerance. Therefore, we conclude that the established tolerance of 10 ppm for the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, will not be exceeded following the registered soil application use of metalaxyl. Additional data are not required.

Brassica Leafy Vegetables Group

Conclusions for the Brassica Leafy Vegetables Group:

The crop group tolerance of 0.1 ppm for combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on Brassica Leafy Vegetables (except broccoli, cabbage, and cauliflower) (40 CFR 180.408[a]) is inappropriate at the present time and should be revoked. Tolerances of 2 ppm presently exist for residues of metalaxyl in or on the individual group members broccoli, cabbage, and cauliflower. If the registrant wishes to establish a group tolerance the following data will be required:

- Use directions must be proposed, and appropriate supporting residue data submitted for the additional representative group member mustard greens.

Broccoli

Tolerance:

A tolerance of 2 ppm has been established for the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on broccoli (40 CFR 180.408[a]).

Use directions and limitations:

The 9% WP formulation (formulated with chlorothalonil) is registered for multiple foliar applications to broccoli at 0.135-0.18 lb ai/A and, in the southeastern U.S. only, at 0.135 lb ai/A. Applications may begin when plants start emerging in direct-seeded crops, after transplants are set in the field, or when conditions are favorable for disease development, and may be repeated at 7- to 10-day intervals (southeastern U.S.) or at 14-day intervals. A 7-day PHI has been established. No maximum seasonal use rate or maximum number of applications per season has been established.

The 2 lb/gal EC formulation is registered for broadcast, banded or soil-incorporated application (in 20-50 gal of water) at 0.25-1 lb ai/A, 0.125-0.5 lb ai/13,000 ft of row, and 0.25-2 lb ai/A, respectively.

Conclusions:

The available data support the established tolerance of 2 ppm for total residues of metalaxyl in or on broccoli and are sufficient to determine that the label directions are adequate. Additional data are not required.

A proposed Codex MRL (step 6) of 0.5 ppm exists for residues of metalaxyl per se in or on broccoli. Compatibility with the Codex MRL is not possible without a major revision of the U.S. residue definition, which is dependent upon toxicological considerations. No Canadian or Mexican tolerances exist.

References (used):

MRIDs: 00071615. 00130773.

Discussion of the data:

Ciba-Geigy Corp. (1982-1983; MRID 00130773) submitted data from four tests conducted in CA(1), FL(1), NY(1), and TX(1) concerning the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on broccoli harvested 63-108 days following a single preemergence broadcast soil application of the 2 lb/gal EC formulation at 2 lb ai/A (1x the maximum permitted soil application rate). Total metalaxyl residues were <0.05(nondetectable)-1.57 ppm in or on eight samples of broccoli. Three control samples bore nondetectable (<0.05 ppm) residues of metalaxyl. Analyses of total metalaxyl residues, determined as DMA (2,6-dimethylaniline), were done using an adequate GLC analytical method (no. AG-395). The implied limit of detection of the method was 0.05 ppm. Recoveries were 84-125% from five broccoli samples fortified at 0.1-0.5 ppm. Samples were stored frozen for ca. 152-370 days prior to analysis.

Ciba-Geigy Corp. (1982-83; MRID 00130773) submitted data from six tests conducted in CA(2), FL(1), NE(1), NY(1), and TX(1) concerning the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on broccoli harvested 7 or 14 days following the last of four or five foliar applications of the 10% WP formulation (not registered for this use) at 0.2 lb ai/A/application (1.1x the maximum registered single foliar application rate); foliar applications were preceeded by a single preemergence broadcast soil application of the 2 lb/gal EC formulation at 2 lb ai/A (1x the maximum registered soil application rate). Total metalaxyl residues in or on 22 broccoli samples (including 12 samples harvested 7 days posttreatment) were 0.10-1.2 ppm. Eleven control samples bore apparent metalaxyl residues of <0.05 (nondetectable)-0.06 ppm. Total residues of metalaxyl and its metabolites were determined by an adequate GLC method (no. AG-395). Recoveries were 72-109% from 11 samples fortified with metalaxyl at 0.05-0.5 ppm. Samples were stored frozen (temperature unspecified) for ca. 48-370 days prior to analysis.

Ciba-Geigy Corp. (1979; MRID 00071615) submitted data from four tests conducted in CA(2) and FL(2) concerning the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on broccoli harvested 7 or 14 days following the last of five foliar applications of the 2 lb/gal EC formulation (not registered for foliar use) at 0.25 or 0.50 lb ai/A/application (1.4 or 2.7x the maximum registered single foliar application rate). Total metalaxyl residues in or on six broccoli samples (including three samples collected 7 days posttreatment) were 0.14-0.62 ppm; six additional samples (trimmed) bore total metalaxyl residues of 0.18-0.48 ppm (including three samples collected at 7 days posttreatment). Apparent residues in or on four control samples were nondetectable (<0.05 ppm). Total residues of

metalaxyl and its metabolites were determined as DMA by an adequate GLC analytical method (modification of no. AG-330) with an implied limit of detection of 0.05 ppm. Recoveries were 42-57% from four samples at fortification levels of 0.05-0.4 ppm. Samples were stored frozen (at unspecified temperatures) for ca. 315-455 days prior to analysis.

The test states of CA(92%), FL(<1%), NE(<1%), NY(<1%), and TX(6%) accounted for ca. 98% of 1984 U.S. broccoli production (Agricultural Statistics, 1985, p. 150); thus geographic representation was adequate. The available data support the established tolerance of 2 ppm for total metalaxyl residues in or on broccoli. No additional data are required.

Cabbage

Tolerance:

A tolerance of 2 ppm has been established for the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on cabbage (40 CFR 180.408[a]).

Use directions and limitations:

The 9% WP formulation (formulated with chlorothalonil) is registered for multiple foliar applications to cabbage at 0.135-0.18 lb ai/A and, in the southeastern U.S. only, at 0.135 lb ai/A. Applications may begin when plants start emerging in direct-seeded crops, after transplants are set in the field, or when conditions are favorable for disease development and may be repeated at 7- to 10-day intervals (southeastern U.S.) or at 14-day intervals. A 7-day PHI has been established. No maximum seasonal use rate or maximum number of applications per season has been established.

The 2 lb/gal EC formulation is registered for broadcast, banded, or soil-incorporated application (in 20-50 gal of water) at 0.25-1 lb ai/A, 0.125-0.5 lb ai/13,000 ft of row, and 0.25-2 lb ai/A, respectively.

Conclusions:

The available data support the established tolerance of 2 ppm for total metalaxyl residues in or on cabbage and are sufficient to determine that the label directions are adequate. Additional data are not required.

A proposed Codex MRL (step 6) of 0.5 ppm exists for residues of metalaxyl per se in or on cabbage. Compatibility with the Codex MRL is not possible without a major revision of the U.S. residue definition, which is dependent upon toxicological considerations. No Canadian or Mexican tolerances exist.

References (used):

MRIDs: 00071615, 00130773.

Discussion of the data:

Ciba-Geigy Corp. (1982-83; MRID 00130773) submitted data from four tests conducted in CA(1), FL(1), NY(1), and TX(1) concerning the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on cabbage harvested 73-108 days following a single preemergence broadcast soil application of the 2 lb/gal EC formulation at 2 lb ai/A (1x the maximum registered soil application rate). Total metalaxyl residues were <0.05(nondetectable)-0.15 ppm in or on eight treated cabbage samples with no apparent detectable residues (<0.05-0.05 ppm) in or on four control samples. Total residues of metalaxyl and its metabolites were determined as DMA (2,6-dimethylaniline) using an adequate GLC analytical method (no. AG-395) with an implied limit of detection of 0.05 ppm. Recoveries were 74-107% from four samples fortified with metalaxyl at 0.05-0.1 ppm. Samples were stored frozen for ca. 145-361 days prior to analysis.

Ciba-Geigy Corp. (1982-83; MRID 00130773) submitted data from six tests conducted in CA(2), FL(1), NE(1), NY(1), and TX(1) concerning the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on cabbage harvested 7 or 14 days following the last of four or five foliar applications of the 10% WP formulation (not registered for use on cabbage) at 0.2 lb ai/A/application (1.1x the maximum registered single foliar application rate); foliar applications were preceeded by a single preemergence broadcast soil application of the 2 lb/gal EC formulation at 2 lb ai/A (1x the maximum permitted soil application rate). Total metalaxyl residues in or on 23 cabbage samples (including 12 samples harvested 7 days posttreatment) were <0.05(nondetectable)-0.49 ppm; one additional sample (wrapper leaves removed) bore total metalaxyl residues of 0.09 ppm. Apparent residues in or on 13 control samples were nondetectable (<0.05 ppm). An adequate GLC analytical method (no. AG-395) was used for total metalaxyl residue determination. Recovery efficiencies were 70-128% from 11 samples fortified with 0.05-0.5 ppm of metalaxyl. Samples were stored frozen for ca. 48-242 days prior to analysis.

Ciba-Geigy Corp. (1979-80; MRID 00071615) submitted data from 10 tests conducted in CA(2), FL(2), NC(2), NY(2), and TX(2) concerning the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on cabbage harvested 6, 7, or 14 days following the last of five foliar applications of the 2 lb/gal EC formulation (not registered for foliar use) at 0.25 or 0.50 lb ai/A/application (1.4 or 2.8x the maximum registered single foliar application rate). Total metalaxyl residues in or on 27 cabbage samples (including 15 samples collected 6 or 7 days posttreatment) were 0.06-0.52 ppm. Apparent residues in or on 10 control samples were nondetectable (<0.05 ppm). Total residues of metalaxyl and its metabolites were determined as DMA using an adequate GLC analytical method (modification of no. AG-330). The implied limit of detection of the method was 0.05 ppm. Recovery efficiency from nine samples fortified with 0.05-0.5 ppm of metalaxyl was 50-68%. Samples were stored frozen for ca. 293-452 days prior to analysis.

Geographic representation was adequate since the test states of CA(8%), FL(16%), NC(5%), NE(<1%), NY(15%), and TX(16%) accounted for ca. 60% of 1982 U.S. head cabbage acreage (1982 Census of Agriculture, Vol. 1, Part 51, pp. 338-339). The available data are adequate to support the established tolerance of 2 ppm for total metalaxyl residues in or on cabbage. No additional data are required.

Cauliflower

Tolerance:

A tolerance of 2 ppm has been established for the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on cauliflower (40 CFR 180.408[a]).

Use directions and limitations:

The 9% WP formulation (formulated with chlorothalonil) is registered for multiple foliar applications to cauliflower at 0.135-0.18 lb ai/A and, in the southeastern U.S. only, at 0.135 lb ai/A. Applications may begin when plants start emerging in direct-seeded crops, after transplants are set in the field, or when conditions are favorable for disease development and may be repeated at 7- to 10-day intervals (southeastern U.S.) or at 14-day intervals. A 7-day PHI has been established. No maximum seasonal use rate or maximum number of applications per season has been established. The 2 lb/gal EC formulation is registered for broadcast, banded, or soil-incorporated application (in 20-50 gal of water) at 0.25-1 lb ai/A, 0.125-0.5 lb ai/13,000 ft of row, and 0.25-2 lb ai/A, respectively.

Conclusions:

The available data support the established tolerance of 2 ppm for total metalaxyl residues in or on cauliflower and are sufficient to determine that the label directions are adequate. Additional data are not required.

A proposed Codex MRL (Step 6) of 0.5 ppm exists for residues of metalaxyl per se in or on cauliflower. Compatibility with the Codex MRL is not possible without a major revision of the U.S. residue definition, which is dependent upon toxicological considerations. No Canadian or Mexican tolerances exist.

References (used):

MRIDs: 00071615. 00130773.

Discussion of the data:

Ciba-Geigy Corp. (1982-83; MRID 00130773) submitted data from four tests conducted in CA(1), FL(1), NY(1), and TX(1) concerning the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on cauliflower harvested 74-108 days following one preemergence broadcast soil application of the 2 lb/gal EC

formulation at 2 lb ai/A (1x the maximum registered soil application rate). Total metalaxyl residues in or on eight cauliflower samples were <0.05(nondetectable)-0.87 ppm. Apparent residues in or on four control samples were <0.05(nondetectable)-0.07 ppm. Total residues of metalaxyl and its metabolites were determined as DMA (2,6-dimethylaniline) using an adequate GLC analytical method (no. AG-395). Recoveries were 75-103% from four samples fortified with metalaxyl at 0.1-0.2 ppm. Samples were stored frozen for ca. 142-347 days prior to residue analysis.

Ciba-Geigy Corp. (1982-83; MRID 00130773) submitted data from six tests conducted in CA(2), FL(1), NE(1), NY(1), and TX(1) concerning the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on cauliflower. Five tests received one preemergence broadcast soil application of the 2 lb/gal EC formulation at 2 lb ai/A (1x the maximum registered soil application rate) and four to six subsequent foliar applications of the 10% WP formulation (not registered for use on cauliflower) at 0.2 lb ai/A/application (1.1x the maximum registered single foliar rate). Samples in one test received one preemergence broadcast soil application of the 2 lb/gal EC formulation at 2 lb ai/A (1x the maximum registered soil application rate) and six subsequent foliar applications of the same formulation (not registered for foliar use) at 0.2 lb ai/A/application (1.1x the maximum registered single foliar application rate). Samples were harvested 7 or 14 days after the last foliar application. Twenty-four cauliflower samples (including 12 samples harvested at 7 days posttreatment) bore total metalaxyl residues of <0.05(nondetectable)-0.81 ppm. Eleven control samples bore nondetectable (<0.05 ppm) residues. Analysis for total residues of metalaxyl and its metabolites (determined as DMA) was performed by an adequate GLC analytical method (no. AG-395). Recovery efficiencies were 70-133% from 11 samples fortified at 0.1-0.5 ppm. Samples were stored frozen for ca. 52-229 days prior to analysis.

Ciba-Geigy Corp. (1979-80; MRID 00071615) submitted data from eight tests conducted in CA(2), FL(2), NY(2), and TX(2) concerning the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methyoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on cauliflower harvested 7 or 14 days following the last of five foliar applications of the 2 lb/gal EC formulation (not registered for foliar use) at 0.25 or 0.50 lb ai/A/application (1.4 or 2.8x the maximum registered foliar application rate). Total metalaxyl residues in or on 18 samples (from six tests) were <0.05 (nondetectable)-0.56 ppm. Six control samples (from these same tests) bore apparent nondetectable (<0.05 ppm) residues. Total residues were determined as DMA by an adequate GLC analytical method (no. AG-395). In addition, residues were determined in or on six additional samples (from two tests) by GLC (no. AG-395) and GC-MS (gas chromatography-mass spectroscopy). Total residues in or on three samples collected 7 days posttreatment and analyzed by GLC were <0.05(nondetectable)-0.37 ppm compared to 0.06-0.52 ppm in or on three samples collected 14 days posttreatment and analyzed using GC-MS. Two control samples analyzed by GLC bore nondetectable (<0.05 ppm) residues. No control values were presented for the GC-MS method. (The registrant stated that GC-MS determination of the samples collected 14 days post-treatment was necessary due to high levels of interference in those

samples.) Recoveries by GLC were 49-79% from eight samples fortified at 0.1-0.4 ppm. Samples were stored frozen 143-477 days prior to analysis.

Geographic representation was adequate since the test states of CA(71%), FL(<1%), NE(<1%), NY(7%), and TX(2%) collectively accounted for ca. 80% of the 1984 U.S. cauliflower production (Agricultural Statistics, 1985, p. 153). The available data support the established tolerance of 2 ppm for the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl in or on cauliflower. Additional data are not required.

Legume Vegetables Group

Tolerances:

Tolerances of 0.2 and 5 ppm have been established for the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on members of the Legume Vegetables Group in dry or succulent forms (40 CFR 180.480[a]) and in legume vegetable cannery waste (21 CFR 561.273[a]), respectively.

Use directions and limitations:

The 2 lb/gal EC formulation is registered for soil application to legume vegetables at 0.25 lb ai/13,000 linear ft of row (2 lb ai/A). Applications may be made at planting to the seed furrow or in a 7-inch band over the row.

Conclusions:

The available data are adequate to support the established tolerance of 0.2 ppm for total residues of metalaxyl in or on members of the Legume Vegetables Group. In addition, the available data submitted in support of the established tolerance of 8 ppm for total metalaxyl residues in or on the foliage of legume vegetables (forage) are sufficient to determine that the established tolerance of 5 ppm in cannery waste of legume vegetables will not be exceeded following the registered soil application use of metalaxyl. Additional data are not required.

Note to the PM: A tolerance of 1 ppm (5x the established tolerance for members of the Legume Vegetables Group) has been established for total residues of metalaxyl in or on soybeans. We therefore recommend that the commodity entry "Legume Vegetable Group (dry and succulent)" be changed to "Legume Vegetables Group (dry and succulent), except soybeans."

No Canadian or Mexican tolerances or Codex MRL exists for residues of metalaxyl in or on members of the Legume Vegetables Group. Therefore, no compatibility questions exist with respect to the Codex MRL.

References (used):

MRID: 00129003.

Discussion of the data:

Ciba-Geigy Corp. (1982-83; MRID 00129003) submitted data from six tests conducted in IA(1), MD(1), and NY(4) concerning the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on peas harvested 51-66 days following one preemergence broadcast soil application of the 2 lb/gal EC formulation at 0.25-4 lb ai/A (0.13-2x the maximum registered application rate). Ten samples of green peas bore <0.05(nondetectable)-0.11 ppm of total metalaxyl residues. Apparent residues in or on three control samples were <0.05 ppm (nondetectable). Total metalaxyl residues were determined as DMA

(2,6-dimethylaniline) using an adequate GLC method (no. AG-395) with a limit of detection of 0.05 ppm. Recoveries were 95-115% from three samples fortified with metalaxyl at 0.05-0.2 ppm. Samples were stored frozen for ca. 238-314 days prior to analysis.

Ciba-Geigy Corp. (1982-83; MRID 00129003) submitted data from 12 tests conducted in CA(2), MI(2), MN(4), NE(2), and WA(2) concerning the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on lima beans (succulent and dry), red kidney beans, navy beans, pinto beans, and snap beans harvested 78-131 days following one preemergence broadcast soil application of the 2 lb/gal EC formulation at 0.25-4 lb ai/A (0.13-2x the maximum registered application rate). Twenty-two treated bean samples (three snap bean, six pinto, two kidney, seven navy, and four lima [two succulent and two dry]) bore total metalaxyl residues of <0.05(nondetectable)-0.12 ppm. Apparent residues in or on a total of six control samples were <0.05 ppm (nondetectable). Total metalaxyl residues were determined using an adequate GLC method (no. AG-395). The limit of detection of the method was 0.05 ppm. Recoveries were 76% (fortification 0.05 ppm, snap beans), 88% (fortification 0.1 ppm, pinto beans), 95% (fortification 0.05 ppm, kidney beans), 77-98% (fortification 0.05-0.2 ppm, navy beans), and 112% (fortification 0.05 ppm, green lima beans). Recovery data were not presented from dry lima beans. Samples were stored frozen for ca. 187-296 days prior to analysis.

Geographic representation was adequate for dry beans since the test states of CA(15%), MI(20%), MN(3%), and NE(16%) along with the neighboring states of CO(11%) and ND(12%) produced ca. 77% of the 1984 U.S. commercial dry bean crop (Agricultural Statistics, 1985, p. 251). Although, the test states of IA(<1%), MD(<1%), NY(3%), and the neighboring states of DE(3%) and MN(21%), produced ca. 27% of the 1984 U.S. green pea crop (Agricultural Statistics, 1985, p. 162), and the test state of WA(<1%) and the neighboring state of OR(19%) accounted ca. 19% of 1984 U.S. snap bean production (Agricultural Statistics, 1985, p. 149), the submitted residue data from these test states are considered adequate for the geographic representation requirement for succulent legumes. The available data are adequate to support the established tolerances of 0.2 and 5 ppm for total residues of metalaxyl in or on members of the Legume Vegetables Group and in cannery waste from members of the Legume Vegetables Group (see "Foliage of the Legume Vegetables Group" section for a discussion of these data), respectively. Additional data are not required.

Soybeans

Tolerances:

A tolerance of 1 ppm has been established for residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on soybeans (40 CFR 180.480[a]). Feed additive tolerances of 2 ppm each have been established for the same residues in soybean hulls, meal, and soapstock (21 CFR 561.273[a]).

Use directions and limitations:

The 5% G and the 2 lb/gal EC formulations are registered for soil application to soybeans at 0.15-0.3 oz ai/1,000 linear ft of row. Applications may be made in a 7-inch band over the row at planting or directly in the seed furrow before the seed is covered. In addition, the 2 lb/gal EC formulation is also registered for broadcast or band soil application to soybeans at 0.6875-1.375 lb ai/treated A.

Conclusions:

The available data are adequate to support the established tolerance of 1 ppm for total metalaxyl residues in or on soybeans. In addition, the available data are adequate to support the established feed additive tolerances of 2 ppm each for total metalaxyl residues in soybean hulls, meal, and soapstock. Since forage, hay, and straw are raw agricultural commodities of soybeans, the following are required:

- The registrant must propose tolerances for total metalaxyl residues in or on soybean forage, hay, and straw. We recommend a tolerance of 8 ppm, toxicological considerations permitting, based on the available data.

A Codex MRL (step 3) of 0.1 ppm has been proposed for residues of metalaxyl per se in or on soybeans. Compatibility with the Codex MRL is not possible without a major revision of the U.S. residue definition, which is dependent upon toxicological considerations. No Canadian or Mexican tolerances exist.

References (used):

MRIDs: 00071672. 00104390. 00148440.

Discussion of the data:

Ciba-Geigy Corp. (1979-1980; MRID 00071672) submitted data from nine tests conducted in AL(1), KY(4), MS(2), and MD(2) concerning the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on soybeans harvested 117-172 days following one preemergence broadcast soil application or 147-177 days following one preplant broadcast soil-incorporated application of the 2 lb/gal EC formulation at 2 or 4 lb ai/A (1.45 or 2.90x the maximum registered broadcast soil application rate per treated A). Thirteen soybean samples (including two dry soybean samples) bore total metalaxyl residues of 0.08-0.52 ppm. Apparent residues in or on five soybean control samples were <0.05(nondetectable)-0.07 ppm. Total metalaxyl residues were determined as DMA (2,6-dimethylaniline) using adequate GLC methods (modification of no. AG-330 and no. AG-348). The limit of detection of both methods was 0.05 ppm. Recoveries were 42-69% (no. AG-348) from six samples and 46-61% (modified no. AG-330) from two samples fortified with 0.05-0.5 ppm of metalaxyl.

In addition, this Ciba-Geigy Corp. submission included data depicting total metalaxyl residues in processed products of soybeans (hulls, meal, soapstock, and crude and refined oil) harvested following preemergent broadcast treatments

with the 2 lb/gal EC formulation at 1.45 or 2.9x the maximum registered soil application rates. Soybeans from respective 1.45 and 2.9x treatments bore total metalaxyl residues of 0.23 and 0.30 ppm. Single hull samples treated at the 1.45x and 2.9x rates bore total metalaxyl residues of 0.34 ppm (concentration factor of 1.48x) and 0.35 ppm (concentration factor of 1.16x), respectively. One meal sample processed from soybeans treated at the 1.45x rate bore total metalaxyl residues of 0.36 ppm (concentration factor of 1.56x), and one meal sample at the 2.9x rate bore total metalaxyl residues of 0.39 ppm (concentration factor of 1.30x). One sample each of soapstock processed from soybeans treated at the 1.45x and 2.9x rates bore total metalaxyl residues of 0.30 ppm (concentration factor of 1.30x) and 0.56 ppm (concentration factor of 1.86x), respectively. Total metalaxyl residues in or on refined oil and crude oil samples processed from soybeans treated at either rate (one sample each) were <0.05 ppm (nondetectable). One control sample was analyzed for each commodity (hulls, meal, soapstock, refined oil, and crude oil); all bore <0.05 ppm (nondetectable) of combined metalaxyl residues. An adequate GLC analytical method (no. AG-350) was used for data collection. The limit of detection of the method was 0.05 ppm. Recoveries were 42 or 55% from two hull samples fortified at 0.05 or 0.8 ppm, respectively; 38 or 44% from two meal samples fortified at 0.05 or 0.8 ppm, respectively; 52 or 60% from two soapstock samples fortified at 0.05 or 0.8 ppm, respectively; 38% from one refined oil sample fortified at 0.05 ppm; and 47 or 65% from two crude oil samples fortified at 0.05 or 0.1 ppm of metalaxyl, respectively. Samples were stored frozen for ca. 365-393 days prior to analysis.

Ciba-Geigy Corp. (1982; MRID 00148440) submitted data from six tests conducted in IN(2), IA(2), and NE(2) concerning the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on soybeans harvested 120-144 days following one preemergence broadcast soil application of the 5% G (not registered for broadcast soil application) and the 2 lb/gal EC formulations at 2 lb ai/A (1.45x the maximum registered broadcast soil application rate per treated A). Eleven soybean samples bore total metalaxyl residues of 0.07-0.42 ppm. Apparent residues in or on three soybean control samples were <0.05 ppm (nondetectable). Samples were analyzed using an adequate GLC method (no. AG-348) with a limit of detection of 0.05 ppm. Recoveries were 74-127% from three samples fortified with metalaxyl at 0.1-0.5 ppm. Samples were stored frozen for ca. 27-60 days prior to analysis.

Ciba-Geigy Corp. (1982; MRID 00148440) submitted data from six tests conducted in MS(2), NE(2), and OH(2) concerning the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on soybeans harvested 134-142 days following one preplant in-furrow soil application of the 2 lb/gal EC or the 5% G formulation at 0.25 lb ai/13,000 linear ft of row (1x the maximum registered in-furrow soil application rate). Total metalaxyl residues in or on 12 samples of soybeans were <0.05(nondetectable)-0.11 ppm. Apparent residues in or on three control samples were each <0.05 ppm (nondetectable). Residues were determined as DMA (2,6-dimethylaniline) using an adequate GLC method (no. AG-348) with a limit of detection of 0.05 ppm. Recoveries were 48-91% from three samples fortified with metalaxyl at 0.2 ppm. Samples were stored frozen for ca. 42-62 days prior to analysis.

Ciba-Geigy Corp. (1978-1979; MRID 00104390) submitted data from four tests conducted in GA(2) and NC(2) concerning the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on soybeans (planted as a rotational crop) harvested 539-552 days following one preplant soil-incorporated broadcast application of the 50% WP formulation (not registered for use on soybeans) at 3 or 6 lbs ai/A to tobacco or an unspecified target crop. Two samples of soybeans and soybean grain (hull removed) bore total metalaxyl residues of 0.05-0.14 ppm and 0.35-0.49 ppm, respectively. Apparent residues in or on one soybean control sample and one grain control sample were <0.05 ppm (nondetectable) and 0.47 ppm, respectively. Samples of soybeans were analyzed using an adequate GLC method (modified no. AG-330), and samples of soybean grain (hulls removed) were analyzed by GC-MS due to interference in GLC analyses. The limit of detection of the GLC method was 0.05 ppm. Recovery of metalaxyl was 68 and 75% from one sample each of soybeans and soybean grain, respectively, fortified at 0.05-0.2 ppm. Samples were stored frozen for ca. 24-79 days prior to analysis.

Ciba-Geigy Corp. (1979-1980; MRID 00071672) submitted data from nine tests conducted in AL(1), KY(4), MS(2), and MD(2) concerning the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on soybean forage and fodder harvested following one preemergence broadcast soil or preplant broadcast soil-incorporated application of the 2 lb/gal EC formulation at 2 or 4 lb ai/A (1.45 or 2.90x the maximum registered broadcast soil application rate per treated A). Posttreatment intervals were 59-65 days for forage and 117-177 days for fodder. Total metalaxyl residues in or on 15 forage samples and 14 fodder samples were 0.89-6.1 and 0.66-6.3 ppm, respectively. Apparent residues in or on five samples each of forage and fodder were 0.08-0.26 and <0.05(nondetectable)-0.23 ppm, respectively. Total metalaxyl residues were determined as DMA (2,6-dimethylaniline) using adequate GLC methods (modification of no. AG-330 and no. AG-348). The limit of detection of both methods was 0.05 ppm. Recoveries were 45-92% from seven forage samples fortified at 0.1-5 ppm and 43-70% from seven fodder samples fortified at 0.5-2 ppm. Samples were stored frozen for 303-402 days prior to analysis.

Ciba-Geigy Corp. (1982; MRID 00148440) submitted data from six tests conducted in IN(2), IA(2), and NE(2) concerning the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on soybean forage and fodder harvested 59-144 days following one preemergence broadcast soil application of the 5% G (not registered broadcast soil application) and the 2 lb/gal EC formulations at 2 lb ai/A (1.45x the maximum registered broadcast soil application rate per treated A). Eleven samples each of forage and fodder bore total metalaxyl residues of 0.41-2.9 and 0.35-4 ppm, respectively. Apparent residues in or on three forage control samples were 0.11-0.22 ppm and <0.05(nondetectable)-0.35 ppm in or on three fodder control samples. Residues were determined using an adequate GLC method (no. AG-348) with a limit of detection of 0.05 ppm. Recoveries were 60-85% and 60-100% from three samples each of

forage and fodder, respectively, fortified at 0.2-2 ppm of metalaxyl. Samples were stored frozen for ca. 27-132 days prior to analysis.

Ciba-Geigy Corp. (1982; MRID 00148440) submitted data from six tests conducted in MS(2), NE(2), and OH(2) concerning the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on soybean forage and fodder harvested 61-142 days following one preplant in-furrow soil application of the 2 lb/gal EC or the 5% G formulation at 0.25 lb ai/13,000 linear ft of row (1x the maximum registered in-furrow soil application rate). Total metalaxyl residues in or on 12 forage samples were 0.22-1.5 ppm. Apparent residues in or on three control samples were 0.10-0.14 ppm. Twelve fodder samples bore 0.10-1.5 ppm of total metalaxyl residues. Apparent residues in or on five fodder control samples were <0.05(nondetectable)-0.40 ppm. Residues were determined as DMA (2,6-dimethylaniline) using an adequate GLC method (no. AG-348) with a limit of detection of 0.05 ppm. Recoveries were 55-95% (forage) and 60-107% (fodder) from five samples of each commodity that were fortified with 0.5-1 ppm of metalaxyl. Samples were stored frozen for ca. 42-143 days prior to analysis.

Ciba-Geigy Corp. (1978-1979; MRID 00104390) submitted data from six tests conducted in GA(2), NY(2), and NC(2) concerning the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on soybean forage and fodder (planted as a rotational crop) harvested 326-552 days following treatments with the 50% WP formulation (not registered) in one preplant soil-incorporated broadcast application at 3 or 6 lb ai/A to tobacco, or an unspecified target crop, or six foliar applications at 0.5-1 lb ai/A to the potato target crop. Total metalaxyl residues in or on six forage samples were 0.25-2.7 ppm. Total metalaxyl residues in or on two fodder samples analyzed by GLC or GC/MS methods, respectively, were 0.25-0.29 ppm or 0.4-1.3 ppm. Apparent residues in or on three forage samples were <0.05(nondetectable)-0.24 ppm. Apparent residues in or on one fodder control sample was 0.06 ppm by GLC. Apparent residues by GC/MC were 0.24 ppm and 0.8 ppm in or on one sample each of forage and fodder. Analyses were determined using an adequate GLC method (modified no. AG-330) and a confirmatory GC/MS method. The limit of detection of the GLC method was 0.05 ppm. Recoveries were 62-75% from two forage samples and 97% from one fodder sample fortified with 0.2-0.5 ppm of metalaxyl. Samples were stored frozen for 79-180 days prior to analysis.

Geographic representation was adequate since the test states of AL(2%), GA(2%), IN(8%), IA(14%), KY(2%), MS(4%), MO(6%), NE(3%), NY(<1%), NC(3%), and OH(7%), and the neighboring states of IL(16%) and MN(9%) accounted for ca. 76% of the 1984 U.S. soybean production (Agricultural Statistics, 1985, p. 126). The available data are adequate to support the established tolerance of 2 ppm for total residues of metalaxyl in or on soybeans. The registrant must propose tolerances for soybean forage, hay, and straw because these are raw agricultural commodities of soybeans. The data submitted concerning total metalaxyl residues in soybean forage and fodder are adequate to support tolerances of 8 ppm for total metalaxyl residues in or on soybean forage, soybean straw, and soybean hay.

We note that a crop group tolerance of 8 ppm has been established for the Foliage of the Legume Vegetables Group; however, since the registered uses of metalaxyl for soybeans are significantly different from those of other legume vegetables, the establishment of separate tolerances for soybean foliage is necessary. Additional residue data are not required.

Foliage of the Legume Vegetables Group

Tolerance:

A tolerance of 8 ppm has been established for the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on legume vegetable foliage (40 CFR 180.480[a]).

Use directions and limitations:

The 2 lb/gal EC formulation is registered for soil application to legume vegetables at 0.25 lb ai/13,000 linear ft of row (2 lb ai/A). Applications may be made at planting to the seed furrow or in a 7-inch band over the row.

Conclusions:

The available data are adequate to support the established tolerance of 8 ppm for total metalaxyl residues in or on members of the Foliage of the Legume Vegetables Group and are sufficient to determine that the label directions are adequate. Additional data are not required.

Note to the PM: Because the crop group definition for the Foliage of the Legume Vegetables Group and Legume Vegetables Group (except soybeans) must be analogous we recommend that the entry "Foliage of the Legume Vegetables Group" be amended to "Foliage of the Legume Vegetables Group (except soybeans)."

No Canadian or Mexican tolerance or Codex MRL exists for metalaxyl residues in or on foliage of legumes. Therefore, no questions of compatibility exist with respect to the Codex MRL.

References (used):

MRID: 00129003.

Discussion of the data:

[For the purposes of the following discussion the terms forage and fodder were defined by the registrant as hay and vine, respectively.]

Ciba-Geigy Corp. (1982-83; MRID 00129003) submitted data from 18 tests conducted in CA(3), IA(1), MI(2), MN(4), NE(2), NY(4), and WA(2) concerning the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on legume (peas and beans) forage harvested 18-66 days following one preemergence broadcast soil application of the 2 lb/gal EC formulation at 0.25-4 lb ai/A (0.12-2x the maximum registered use rate). Total metalaxyl residues in or on 29 forage samples were 0.33-5.7 ppm. One additional forage sample, from a 2x treatment rate, bore 9.22 ppm of total metalaxyl residues. Apparent residues in or on eight control samples were <0.05(nondetectable)-0.24 ppm. Two analyses of one additional forage control sample yielded apparent residues of 3.68 and 3.71 ppm. Total metalaxyl residues were determined using an

adequate GLC analytical method with a limit of detection of 0.05 ppm. Recoveries were 67-89% from eight samples fortified with metalaxyl at 0.5-2 ppm. Samples were stored frozen for ca. 187-314 days prior to analysis.

Ciba-Geigy Corp. (1982-83; MRID 00129003) submitted data from 18 tests conducted in CA(2), IA(1), MD(1), MI(2), MN(4), NE(2), NY(4), and WA(2) concerning the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on legume (peas and beans) fodder harvested 51-131 days following one preemergence broadcast soil application of the 2 lb/gal EC formulation at 0.25-4 lb ai/A (0.12-2x the maximum registered use rate). Total metalaxyl residues in or on 29 fodder samples were 0.18-6.88 ppm. Eight control samples bore apparent residues of <0.05 (nondetectable)-0.23 ppm; one additional control sample bore apparent residues of 1.28 ppm. Residues were determined using an adequate GLC method (no. AG-395). The limit of detection of the method was 0.05 ppm. Recoveries were 63-121% from nine samples fortified with 0.5-5 ppm metalaxyl. Samples were stored frozen for ca. 187-314 days prior to analysis.

Geographic representation was adequate for dry beans since the test states of CA(15%), MI(20%), MN(3%), and NE(16%), along with the neighboring states of CO(11%) and ND(12%), produced ca. 77% of the 1984 U.S. commercial dry bean crop (Agricultural Statistics, 1985, p. 251). Although the test states of IA(<1%), MD(<1%), and NY(3%), and the neighboring states of DE(3%) and MN(21%), accounted for only ca. 27% of the 1984 U.S. green pea crop (Agricultural Statistics, 1985, p. 162) and the test state of WA(<1%), and the neighboring state of OR(19%), accounted for ca. 19% of the 1984 U.S. snap bean production (Agricultural Statistics, 1985, p. 149), the submitted residue data from these states are considered adequate for the geographic representation requirement for succulent legumes. The available data are adequate to support the established tolerance of 8 ppm for total metalaxyl residues in or on the Foliage of the Legume Vegetables Group. (Refer to the "Soybeans" section for a discussion of residue data.) No additional data are required for this topic.

Fruiting Vegetables (except Cucurbits) Group

Tolerances:

Tolerances of 1 and 20 ppm have been established for the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on members of the Fruiting Vegetables (except Cucurbits) Group (40 CFR 180.408[a]; FR Doc. 87-8274, 4/14/87) and tomato pomace (dry and wet) (21 CFR 561.273[a]; FR Doc. 87-8275, 4/14/87), respectively. A feed additive tolerance of 3 ppm has been established for the same residues in processed tomatoes (21 CFR 193.277[a]).

Use directions and limitations:

The 2 lb/gal EC formulation is registered for use as a soil application to tomatoes at 1-2 lb ai/treated A immediately before or after planting (in 20-50 gal of water). The 9% WP formulation is registered for multiple foliar applications to tomatoes at 0.135-0.2 lb ai/A. Applications may begin when conditions are favorable for disease development and may be repeated at 14-day intervals until the threat of disease is over. In addition, the 2 lb/gal EC formulation is registered for use as a soil application under tomatoes at 1 lb ai/treated A; the application may be made 4 to 12 weeks before harvest and should be followed as soon as possible with an irrigation. Applications may not exceed 3 lb ai per season; no PHI is established.

The 2 lb/gal EC is proposed for use as a band-spray soil application over pepper and eggplant rows, at seeding, at 1 lb ai/A. It is proposed that two additional post-directed applications be made at 30-day intervals at 0.5 lb ai/A. No PHI is proposed on the label. [The proposed use directions were obtained from an EPA memorandum by Francis D. Griffith dated 9/26/86 and located in the correspondence file for PP#6F3387/6H5499.]

Conclusions:

The available data are adequate to support the crop group tolerance of 1.0 ppm for the combined residues of metalaxyl in or on members of the Fruiting Vegetables (except Cucurbits) Group. The available date also support the food additive tolerance of 3 ppm and the feed additive tolerance of 20 ppm for residues of metalaxyl in processed tomatoes and tomato pomace (dry and wet), respectively. Additional residue data are not required. However, no preharvest interval exists following registered uses of metalaxyl on members of the Fruiting Vegetables Group. The following is therefore required:

- The registrant must propose a preharvest interval following registered/proposed uses of metalaxyl on members of the Fruiting Vegetables (except Cucurbits) Group. Based on the available data, we recommend a 7-day preharvest interval.

There is no Canadian or Mexican tolerance for metalaxyl residues in or on members of the Fruiting Vegetables (except Cucurbits) Group. There is a Codex MRL (step 6) of 0.5 ppm for residues of metalaxyl per se in or on tomatoes. Compatibility is not possible without a major revision of the U.S. residue definition, which is dependent upon toxicological considerations.

References (used):

MRIDs: 00148103. 00148440. 00157480.

References (not used):

[The following MRIDs duplicate previously cited information or are irrelevant.]

MRIDs: 00085852. 00157478.

Discussion of the data:

Peppers: Ciba-Geigy Corp. (1983-1984; MRID 00157480) submitted data from nine tests conducted in CA(2), FL(2), MI(1), NJ(2), and TX(2) pertaining to residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on peppers. Plants were treated with one preplant-incorporated application of the 2 lb/gal EC formulation, at 1-2 lb ai/A, followed by two post-directed soil applications, of the 2 lb/gal EC formulation, at 0.5-1 lb ai/A, for a seasonal use rate of 2-4 lb ai/A (1-2x the maximum proposed seasonal use rate). Total metalaxyl residues following treatment at the 1x seasonal use rate were 0.13-0.52, 0.08-0.66, and 0.05-0.37 ppm in or on bell pepper samples (10 per posttreatment interval) 7, 14-15, and 21 days posttreatment, respectively. Total metalaxyl residues following treatment at the 2x seasonal use rate were 0.17-0.90, 0.19-0.98, and <0.05(nondetectable)-0.64 ppm in or on bell pepper samples (four per posttreatment interval) 7, 14-15, and 21 days posttreatment, respectively. Nine control bell pepper samples bore total metalaxyl residues of <0.05 (nondetectable)-0.12 ppm. Samples were analyzed using an adequate GLC method (no. AG-395); the limit of detection was 0.05 ppm. Recovery was 76-126% from nine bell pepper samples fortified with metalaxyl at 0.05-1.0 ppm. Samples were stored "frozen" (temperature unspecified) for 32-315 days prior to analysis.

Ciba-Geigy Corp. (1983-1984; MRID 00157480) also submitted data from four tests conducted in CA(1), LA(1), and TX(2) pertaining to residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on chili peppers (3 tests) and tabasco peppers (1 test). Plants were treated with one preplant-incorporated application of the 2 lb/gal EC formulation, at 1-2 lb ai/A, followed by two post-directed soil application of the 2 lb/gal EC formulation, at 0.5-1.0 lb ai/A, for a seasonal use rate of 2-4 lb ai/A (1-2x the maximum proposed seasonal use rate). Total metalaxyl residues following treatment at the 1x seasonal use rate were <0.05(nondetectable)-0.44, <0.05(nondetectable)-0.44, and <0.05(nondetectable)-0.16 ppm in or on six pepper samples each that were collected 7, 14, and 21 days posttreatment, respectively. Total metalaxyl residues following treatment at the 2x seasonal use rate were

0.17, 0.23, and 0.14 ppm in or on one sample each that was collected 7, 14, and 21 days posttreatment, respectively. Samples were analyzed using an adequate GLC method (no. AG-395); the limit of detection was 0.05 ppm. Recovery was 78-100% from five chili and tabasco pepper samples fortified with metalaxyl at 0.05-0.50 ppm. Samples were stored "frozen" (temperature unspecified) for 34-277 days prior to analysis.

In addition, Ciba-Geigy Corp. (1983; MRID 00157480) submitted data from two NC tests pertaining to residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on pimento peppers (one test) and bell peppers (one test). Plants were treated with one preplant-incorporated application of the 2 lb/gal EC formulation, at 1 lb ai/A, followed by one post-directed soil application, of the 2 lb/gal EC formulation, at 0.5 lb ai/A, for a seasonal use rate of 1.5 lb ai/A (0.75x the maximum proposed seasonal use rate). Total metalaxyl residues were 0.48-0.63, 0.34-0.51, and 0.21-0.30 ppm in or on two pepper samples each that were collected 7, 14, and 21 days posttreatment, respectively. Two control samples bore total metalaxyl residues of 0.09-0.23 ppm. Samples were analyzed using an adequate GLC method (no. AG-395) with a detection limit of 0.05 ppm. Recovery of metalaxyl from one sample each of pimento peppers and bell peppers was 74% (0.10 ppm) and 78% (0.20 ppm), respectively (fortification level in parentheses).

The test states of CA(18%), FL(23%), and MI(3%), NJ(7%), and TX(16%) collectively account for ca. 67% of U.S. sweet pepper acreage (1982 Census of Agriculture, Vol. 1, Part 51, p. 360); geographic representation was therefore adequate.

Tomatoes: Ciba-Geigy Corp. (1979-1980, 1983; MRIDs 00148103 and 00148440) submitted data from 12 tests conducted in CA(4), FL(2), MS(2), NY(2), and OH(2) pertaining to the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on tomatoes following 6-8 foliar applications (one CA test utilized aerial equipment; remaining tests utilized ground equipment) of the 2 lb/gal EC (in 11 tests) or the 10% WP (1 test) formulations at 0.38-0.75 lb ai/A (1.9-3.8x the maximum permitted single foliar application rate) with posttreatment intervals of 0-5 days. Combined metalaxyl residues were <0.05(nondetectable)-0.71 ppm in or on 35 tomato samples. Ten control samples bore apparent metalaxyl residues of <0.05 ppm (nondetectable). Samples were analyzed using adequate GLC methods (nos. AG-330 and AG-395); the limits of detection for both methods were 0.05 ppm. Recovery was 42-112% from 12 tomato samples fortified with metalaxyl at 0.1-1.0 ppm. Samples were stored "frozen" (temperature unspecified) or under unspecified conditions for 252-307 or 281-290 days, respectively, prior to analysis.

Ciba-Geigy Corp. (1979-1980; MRIDs 00148440 and 00157480) submitted data from six CA tests pertaining to the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on tomatoes following two soil-directed applications of the 2 lb/gal EC formulation. Plants were treated with a single preplant-incorporated application at 2-4 lb ai/A (2-4x the maximum registered soil application

rate at planting) followed by a single post-directed broadcast application at 1-2 lb ai/A (0.5-1x the maximum registered soil application rate at planting) for a seasonal use rate of 3-6 lb ai/A (1-2x the maximum registered seasonal use rate). Combined metalaxyl residues were <0.05(nondetectable)-0.36 ppm in or on 11 tomato samples harvested 14-42 days posttreatment. Four control samples bore combined metalaxyl residues of <0.05-<0.10 (nondetectable). Samples were analyzed using an adequate GLC method (no. AG-330); the limit of detection was either 0.10 ppm (two tests) or 0.05 ppm (four tests). Recovery was 48-65% from four tomato samples fortified with metalaxyl at 0.2-0.5 ppm. Samples were stored under unspecified conditions for 114-264 days prior to analysis.

Ciba-Geigy Corp. (1979-1980; MRIDs 00148103 and 00157480) submitted data from three tests conducted in CA(1), MS(1), and NY(1) pertaining to the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on tomatoes following six "fungigation" applications of the 2 lb/gal EC formulation at 0.375 lb ai/A (0.75x the maximum registered seasonal use rate) with posttreatment intervals of 0-5 days. Combined metalaxyl residues were <0.05(nondetectable)-0.22 ppm in or on eight tomato samples. Four control samples bore metalaxyl residues of <0.05(nondetectable)-0.06 ppm. Samples were analyzed using an adequate GLC analytical method (no. AG-348); the limit of detection was 0.05 ppm. Recovery was 50-58% from two tomato samples fortified with metalaxyl at 0.10-0.80 ppm. Samples were stored frozen (temperature unspecified) for 64-194 days prior to analysis.

Ciba-Geigy Corp. (1979; MRIDs 00148440 and 00157480) also submitted data from two CA studies pertaining to the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on tomatoes and processed products. Tomatoes received six foliar applications of the 2 lb/gal EC formulation (not registered for foliar application) at 0.38-0.75 lb ai/A (1.9-3.8x the maximum registered single foliar application rate) for a seasonal use rate of 2.28-4.50 lb ai/A (0.76-1.5x the maximum registered seasonal use rate); the posttreatment interval was 0 days. Combined metalaxyl residues were 0.14-0.62 and 0.30-0.71 ppm in or on four samples each of unwashed and washed tomatoes, respectively. A single sample of unwashed whole tomatoes in jars bore 0.70 ppm of metalaxyl. Total metalaxyl residues were 0.74 ppm in peeled fruit (1x, 1x), 0.95 ppm in peels (1x, 2x), 0.83 ppm in juice (1x, 1x), 2.7 ppm in wet pomace (seeds and peels) from juice (4x, 5x), 1.6 ppm in puree (2x, 3x), 1.9 ppm in wet pomace from puree (3x, 3x), 9.7 ppm in dry pomace from juice (14x, 17x), and 8.3 ppm in dry pomace from puree (12x, 14x) processed from tomatoes treated at 0.75 lb ai/A; the two concentration factors given in parentheses represent concentrations based on washed tomatoes (0.71 ppm) and unwashed tomatoes (0.58 ppm), respectively. Combined metalaxyl residues in one control sample of each commodity were: (i) <0.05 ppm (nondetectable) in or on unwashed tomatoes, washed tomatoes, unwashed whole tomatoes in jars, peeled tomatoes, tomato peels, tomato juice, and seeds and peel from juice or puree; (ii) 0.42 ppm in dried seeds and peel from tomato juice; and (iii) 0.18 ppm in dried seeds and peel from tomato puree. Samples were analyzed using an adequate GLC analytical method (no. AG-348); the limit of detection was 0.05 ppm. Recovery of metalaxyl

was: (i) 61-84% (0.05-0.8 ppm) from whole fruit; (ii) 58-64% (0.05-0.5 ppm) from peeled fruit; (iii) 58-79% (0.1-1 ppm) from peels; (iii) 62-66% (0.05-0.50 ppm) from juice; (iv) 42-80% (0.05-0.50 ppm) from seeds; and (v) 42-58% (0.05-1 ppm) from puree (fortification levels appear parenthetically). These data indicate that residues of metalaxyl may concentrate up to 17x in dry pomace, up to 3x in puree, and up to 5x in wet pomace processed from unwashed tomatoes bearing metalaxyl residues; and that residues are not expected to concentrate in juice.

Geographic representation was adequate since the test states of CA(27%), FL(50%), MS(<1%), NY(1%), and OH(1%) collectively accounted for ca. 79% of the 1984 U.S. tomatoes grown for fresh market (Agricultural Statistics, 1985, p. 172). The available data are adequate to support the crop group tolerance of 1 ppm for the combined residues of metalaxyl in or on members of the Fruiting Vegetables (except Cucurbits) Group. Additional residue data are not required. However, the registrant must propose a preharvest interval following registered proposed uses of metalaxyl on members of the Fruiting Vegetables (except Cucurbits) Group. Based on the available data, we recommend a 7-day preharvest interval.

Cucurbit Vegetables Group

Tolerance:

A tolerance of 1 ppm has been established for the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on members of the cucurbit vegetables group (40 CFR 180.408[a]).

Use directions and limitations:

The 2 lb/gal EC formulation is registered for broadcast and band applications (7-inch band recommended) to soil at planting of cucurbit vegetables (cucumbers, melons, and squash) or for preplant broadcast incorporated treatments at 1-2 lb ai/treated acre in 20-50 gallons of water. The 9% WP formulation (formulated with chlorothalonil) is registered for multiple foliar applications to cucurbit vegetables at 0.135-0.18 lb ai/A/application beginning when plants are at the first-true-leaf stage or when conditions are favorable for disease development. Applications may be continued at 14-day intervals until the threat of disease is over. The 10% WP formulation (formulated with mancozeb) is registered for multiple foliar applications to cucurbit vegetables at 0.15-0.20 lb ai/A/application, in sufficient water for thorough coverage, beginning when plants are at the two-leaf stage. Applications may be repeated at 14-day intervals until the threat of disease is over. No maximum seasonal rate or number of applications is specified for foliar applications. A 5-day PHI has been established.

Conclusions:

The available data support the established crop group tolerance for total residues of metalaxyl and its metabolites in or on members of the cucurbit vegetables group and are sufficient to determine that the label directions are adequate. Additional data are not required.

No Canadian or Mexican tolerance has been established for total residues of metalaxyl in or on cucurbit vegetables. Codex MRLs of 0.2 ppm (step 6) are proposed for residues of metalaxyl *per se* in or on melons and squash. Codex MRLs of 0.5 ppm (step 6) are proposed for residues of metalaxyl *per se* in or on cucumbers and gherkins. Compatibility is not possible without a major revision of the U.S. residue definition, which is dependent upon toxicological considerations.

References (used):

MRIDs: 00071615. 00098428. 00130693. 00148103.

References (not used):

[The following reference contains data duplicated in the previously cited MRIDs.]

MRID: 00109461.

Discussion of the data:

Ciba-Geigy Corp. (1983; MRID 00148103, 1982; MRID 00130693, 1981; MRID 00098428, and 1979; MRID 00071615) submitted data from 53 tests conducted in CA(19), FL(11), MS(6), NE(4), NY(3), SC(2), TX(4), and VA(4) depicting total metalaxyl residues in or on fruit of the cucurbit vegetables group following multiple foliar or preemergent soil applications, or a combination of these two treatments (using ground equipment). The 2 lb/gal EC, 25% WP (not registered), or 10% WP formulation was applied at 0.2-0.5 lb ai/A/application (1-2.5x the maximum single foliar application rate) in four to eight foliar applications (0.8-4 lb ai/A/season). The 2 lb/gal EC formulation was applied in preemergent soil applications at 2 lb ai/A (1x the maximum preemergent rate). Residue data are presented in the following sections: cucumbers, melons (cantaloupes, honeydews, and watermelons), and squash. Samples were stored frozen for ca. 2-15 months after sampling and analyzed by adequate GLC methods (nos. AG-330, AG-348, or AG-395) with limits of detection of 0.05 ppm metalaxyl equivalents. Recoveries by these methods are listed separately in cucumber, melon, and squash sections.

Cucumbers: Ciba-Geigy Corp. (1979; MRID 00071615, 1981; MRID 00098428; and 1983; MRID 00148103) submitted data from 16 tests conducted in CA(2), FL(4), MS(2), NY(2), SC(2), TX(2), and VA(2) depicting total metalaxyl residues in or on cucumbers harvested 0, 2, 5, or 10 days following the last of four to eight foliar applications of the 2 lb/gal EC, 10% WP, or 25% WP (not registered) formulation at 0.2-0.5 lb ai/A/application (1-2.5x the maximum single application rate), totaling 0.8-4 lb ai/A/season. Residues were 0.06-0.51 ppm in or on 14 samples harvested 5 days following foliar treatment, including six samples bearing 0.06-0.25 ppm resulting from treatment at 1x the permitted rate and eight samples treated at 1.25-2.5x containing 0.12-0.51 ppm of total metalaxyl residues. Residues were 0.06-0.43 ppm in or on 15 cucumber samples at 0- to 2-days posttreatment and 0.08-0.15 ppm in or on six samples 10 days following the final foliar application. Apparent residues in or on 15 samples from control cucumbers were <0.05 ppm (nondetectable). Recoveries of metalaxyl were 95-110%, 66-93%, and 53-125% from two samples analyzed by method no. AG-495, six samples by method no. AG-348, and 12 samples by method no. AG-330, respectively. Samples were fortified with 0.05-1 ppm of metalaxyl.

Ciba-Geigy Corp. (1982; MRID 00130693) submitted data from four tests conducted in CA, FL, NE, and NY (one test in each state) depicting total metalaxyl residues in or on cucumbers harvested 0 or 5 days following the last of five foliar applications of the 10% WP formulation at 0.2 lb ai/A/application (1x the maximum single foliar application rate) and preemergent soil treatment using the 2 lb/gal EC formulation at 2 lb ai/A (1x). Total residues of metalaxyl were 0.13-0.30 and 0.16-0.51 ppm in or on four cucumber samples harvested from tests including preemergent plus foliar applications at posttreatment intervals of 5 and 0 days, respectively, following the last foliar application. Apparent residues in or on six samples from control cucumbers were <0.05 ppm (nondetectable). Recoveries were 68-88%(4) and 46-52%(2) from cucumber samples fortified with metalaxyl at 0.05-2 ppm and analyzed by method nos. AG-395 and AG-348, respectively (number of samples in parentheses).

Geographic representation of these tests was adequate since the test states of CA(8%), FL(4%), SC(6%), TX(7%), VA(<1%), and the neighboring states of NC(14%), OH(10%), and OR(4%) accounted for ca. 53% of 1984 cucumber production (Agricultural Statistics, 1985, p. 157).

Melons: Ciba-Geigy Corp. (1979; MRID 00071615 and 1981; MRID 00098428) submitted data from 20 tests conducted in CA(8), FL(4), MS(4), TX(2), and VA(2) depicting total metalaxyl residues in or on melons harvested 0, 2, 5, or 10 days following seven to eight foliar applications of the 2 lb/gal EC or 25% WP (not registered) formulation at 0.2-0.5 lb ai/A/application (1-2.5x the maximum single application rate), totaling 1.4-4 lb ai/A/season. Total metalaxyl residues were <0.05(nondetectable)-0.38 ppm in or on 20 samples harvested 5 days posttreatment, including eight cantaloupe samples bearing 0.07-0.38 ppm, four honeydew melon samples bearing <0.05-(nondetectable)-0.2 ppm, and eight watermelon samples containing <0.05 (nondetectable)-0.16 ppm. Melon samples harvested 0-2 or 10 days post-treatment contained <0.05(nondetectable)-0.5 ppm(20) and <0.05(non-detectable)-0.09 ppm(4), respectively, of total metalaxyl residues (number of samples reflected in each residue range in parentheses). Of the 20 melon samples collected at posttreatment intervals shorter than 5 days, residues were 0.07-0.38, 0.08-0.25, and <0.05(nondetectable)-0.05 ppm, respectively, in or on cantaloupe, honeydew, and watermelon samples. Apparent residues were <0.05 ppm (nondetectable) in or on 19 melon control samples. Recoveries of metalaxyl at fortifications of 0.05-0.5 ppm were 63-125% from 24 melon samples analyzed by method no. AG-330 and 48-71% from eight melon samples analyzed by method no. AG-348.

Ciba-Geigy Corp. (1982; MRID 00130693) submitted data from five tests conducted in CA(4) and FL(1) depicting total metalaxyl residues in or on melons (cantaloupe and honeydew) resulting from a preemergent soil application of the 2 lb/gal EC formulation at 2 lb ai/A (1x the preemergent application rate) alone, or in combination with five foliar applications of the 10% WP formulation at 0.2 lb ai/A/application (1x the single foliar application rate). Samples were harvested 80 or 85 days following preemergent soil applications and 0 or 5 days following the last of five foliar applications in tests with preemergent plus foliar treatments. Residues were 0.05-0.25 ppm in or on two samples (one each of cantaloupe and honeydew) collected 5 days following foliar treatments. Residues in or on a third melon sample from this test were reported as <0.50 ppm [sic]. Residues in or on three samples collected at the 0-day posttreatment interval were 0.07-0.43 ppm. Residues were 0.06-0.08 and <0.05(nondetectable)-0.07 ppm in or on two samples harvested at posttreatment intervals of 80 and 85 days, respectively, following preemergence treatment. Apparent residues in or on six control melon samples were <0.05 ppm (nondetectable). Recoveries of metalaxyl at 0.05-0.5 ppm fortification levels were 74-113%(2) and 67-81%(3) from samples analyzed by method nos. AG-395 and AG-348, respectively (number of samples in parentheses).

Geographic representation was adequate since test states of CA(52%), FL(<1%), TX(21%), and VA(<1%) accounted for ca. 73% of 1982 U.S. cantaloupe acreage; CA(60%) and MS(<1%) accounted for ca. 60% of 1982 U.S honeydew acreage; and CA(10%), FL(20%), MS(3%), and neighboring states of GA(9%), NC(4%), SC(5%), and TX(24%) accounted for ca. 75 % of 1982 U.S. watermelon

acreage (1982 Census of Agriculture, Vol. 1, Part 51, pp. 339, 345, and 357, respectively).

Squash: Ciba-Geigy Corp. (1981; MRID 00098428) submitted data from four tests conducted in CA(2) and NE(2) depicting total metalaxyl residues in or on summer squash following eight foliar applications of the 25% WP formulation (not registered) at 0.2 lb ai/A/application (1x the maximum single application rate). Samples were harvested 0, 5, and 10 days following the last treatment. Residues were <0.05(nondetectable)-0.15 ppm in or on four squash samples harvested at the 5-day posttreatment interval and <0.05(nondetectable)-0.22 ppm and <0.05(nondetectable)-0.19 ppm, respectively, in or on four squash samples each harvested at the 0- and 10-day posttreatment intervals. Apparent residues in or on four control samples of squash were <0.05 ppm (nondetectable). Samples were stored frozen and analyzed for total metalaxyl residues within ca. 3 months of sampling by an adequate GLC method (no. AG-348). Recoveries were 53-150% from 10 squash samples fortified at 0.05-0.5 ppm metalaxyl.

Ciba-Geigy Corp. (1982; MRID 00130693) submitted data from four tests conducted in CA(2), FL(1), and NE(1) depicting total metalaxyl residues in or on squash treated preemergence with the 2 lb/gal EC formulation or preemergence plus multiple foliar applications with the 2 lb/gal EC and 10% WP formulations, respectively. Preemergent applications were made at 2 lb ai/A (1x the maximum preemergent application rate). Five foliar applications were made at 0.21 lb ai/A/application (1x the single foliar application rate). Samples were collected 0 and 5 days following the last foliar application in combined treatments or 80 and 85 days following preemergent treatment alone. Total residues were 0.08-0.43 ppm in or on samples collected 5 days posttreatment and <0.05(nondetectable)-0.25 ppm in or on samples collected on the day of the final foliar application. Three samples were analyzed in duplicate. Residues were 0.21 ppm and 0.13-0.25 ppm in or on single samples (analyzed in duplicate) of squash at intervals of 80 and 85 days, respectively, following postemergent treatment alone. Apparent residues in or on five control samples were <0.05 ppm (nondetectable). Samples from CA and NE tests were frozen and analyzed within 178 days of sampling by an adequate GLC method (no. AG-348). Samples from the FL test were frozen and analyzed by an adequate GLC method (no. AG-395). Recoveries were 74-94%(3) by the former method and 83-104%(2) by the latter method from squash samples fortified at 0.05-0.4 ppm metalaxyl (number of samples in parentheses). The geographic representation of these tests was adequate since the test states of CA(15%), FL(21%), NE(<1%), and neighboring states of GA(7%), SC(2%), and TX(7%) accounted for ca. 52% of 1982 U.S. squash acreage (1982 Census of Agriculture, Vol. 1, Part 51, p. 353).

Geographic representation of tests conducted with members of the cucurbit vegetables group was adequate. The test states accounted for ca. 52-75% of U.S. commercial acreage of cucumbers, melons, and squash. Refer to individual commodity sections for full details and citations of production statistics. The available data support the established crop group tolerance of 1 ppm for total residues of metalaxyl in or on members of the cucurbit vegetables group. Additional data are not required.

Citrus Fruits Group

Tolerances:

A tolerance of 1 ppm has been established for the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on citrus fruits (40 CFR 180.408[a]). Food/feed additive tolerances of 7 ppm have been established for the same residues in or on citrus molasses and citrus pulp (21 CFR 561.273[a]) and citrus oil (21 CFR 193.277[a]).

Use directions and limitations:

The 2 lb/gal EC and the 5% G formulations are registered for soil banded application to citrus fruits under the tree canopy at 2-4 lb ai/treated A. In addition, the 2 lb/gal EC formulation is also registered for use as a trunk spray at 2 lb ai/15 gal in AZ, CA, and TX only. A maximum of three soil applications and three trunk applications (AZ, CA, and TX only) are permitted per year.

Conclusions:

The available data support the established tolerance for residues of metalaxyl in or on citrus fruits and are sufficient to determine the adequacy of the label directions. The available data also support the established food/feed additive tolerances of 7 ppm for residues in citrus molasses, citrus pulp, and citrus oil. No additional data are required for this topic.

There is no Canadian or Mexican tolerance for metalaxyl residues in or on citrus fruits. There is a proposed Codex MRL (step 6) of 5 ppm for residues of metalaxyl per se in or on citrus fruits. Compatibility is not possible without a major revision of the U.S. residue definition, which is dependent upon toxicological considerations.

References (used):

MRIDs: 00117969. 00133020. 00148440.

Discussion of the data:

Grapefruits: Ciba-Geigy Corp. (1981-82; MRIDs 00117969 and 00133020) submitted data from four tests conducted in CA(2) and TX(2) concerning the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on grapefruit harvested 0-64 days following three soil banded (post-dripline spray) applications of the 2 lb/gal EC or 5% G formulations at 8 or 16 lb ai/A/application (2-4x the maximum single application rate). Total metalaxyl residues in or on 31 grapefruit samples were <0.05(nondetectable)-0.94 ppm. Apparent residues in or on 11 grapefruit control samples were nondetectable (<0.05 ppm). Analyses were determined using adequate GLC analytical methods (nos. AG-348 and AG-395). The limit of detection of

both methods was 0.05 ppm. Recovery of metalaxyl was 60-116% from six samples fortified with 0.05-1 ppm of metalaxyl. Samples were stored frozen for ca. 185-270 days prior to analysis.

In addition, Ciba-Geigy Corp. (1981-82; MRIDs 00117969 and 00133020) submitted data from three tests conducted in CA(2) and TX(1) concerning the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on grapefruit harvested 1-60 days following the last of three trunk spray applications of the 2 lb/gal EC formulation at 9-18 g ai/tree/application (2 or 4 lb ai/A/application; 1 or 2x the maximum permitted single trunk application rate, assuming 2 lb ai/15 gal will treat a 1-acre grove). Twenty-five grapefruit samples bore total metalaxyl residues of <0.05(nondetectable)-0.11 ppm. Ten control samples bore nondetectable (<0.05 ppm) total metalaxyl residues. Samples were analyzed using an adequate GLC analytical method (no. AG-348) with a limit of detection of 0.05 ppm. Recovery of metalaxyl was 56-99% from 10 samples fortified at 0.05-0.20 ppm. Samples were stored frozen for ca. 239-365 days prior to analysis.

Although the test states of CA(14%) and TX(6%) do not represent the major U.S. grapefruit production state (FL; 76%), numerous tests conducted in FL reflicting metalaxyl residues in or on lemons and oranges preclude the necessity of additional FL tests reflecting residues in or on grapefruit; production figures obtained from Agricultural Statistics, 1985, p. 198, appear in parentheses.

Lemons: Ciba-Geigy Crop. (1981-82; MRIDs 00117969, 00133020, and 00148440 submitted data from five tests conducted in CA(4) and FL(1) concerning the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on lemons harvested 0-64 days following the last of 3-6 soil banded (post drip-line) applications of the 2 lb/gal EC formulation (three tests) or the 5% G formulation (two tests) at 8-16 lb ai/A/application (2-4x the maximum permitted single application rate or 2x the maximum permitted seasonal rate). In the FL test, total metalaxyl residues in or on five lemon samples harvested 0-15 days posttreatment were 0.13-0.24 ppm; one additional sample at 0 day bore 0.94 ppm total metalaxyl residues. Three control samples bore nondetectable (<0.05 ppm) residues. In one of the CA tests, total metalaxyl residues in or on 10 lemon samples were 0.36-0.72 ppm; five additional lemon samples treated at 16 lb ai/A (4x) bore total metalaxyl residues of 0.76-1.3 ppm. Five control samples bore total metalaxyl residues of <0.05(nondetectable)-0.09 ppm. In the remaining CA tests, in which three to six applications of the 5% G formulation were made at 8 lb ai/A/application, total metalaxyl residues in or on 15 samples harvested 1-60 days posttreatment were <0.05(nondetectable)-0.92 ppm. Total metalaxyl residues in or on three control samples were nondetectable (<0.05 ppm). Analyses of samples in all of the above described tests were done using adequate GLC analytical methods (nos. AG-348 and AG-395). The limit of detection of both methods was 0.05 ppm. Recoveries were 53-112% from 13 samples fortified with 0.05-0.5 ppm. Samples were stored frozen for ca. 177-272 days prior to analysis.

Geographic representation was adequate since the test states of CA(81%) and FL(<1%) account for ca. 81% of 1983/84 U.S. lemon production (Agricultural Statistics, 1985, p. 198).

Oranges: Ciba-Geigy Corp. (1981-82; MRIDs 00117969 and 00133020) submitted data from four tests conducted in FL concerning the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroyxmethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on oranges harvested 0-63 days following the last of two or three soil banded (post-dripline spray) applications of the 2 lb/gal EC or 5% G formulations at 8 or 16 lb ai/A (2-4x the maximum permitted single application). Total metalaxyl residues in or on 26 orange samples were <0.05(nondetectable)-0.79 ppm. Total metalaxyl residues in or on eight control samples were nondetectable (<0.05 ppm). Samples were analyzed using adequate GLC analytical methods (nos. AG-348 and AG-395). Recoveries were 59-86% from eight samples fortified with 0.05-0.50 ppm of metalaxyl. Samples were stored frozen for ca. 177-241 days prior to analysis.

Ciba-Geigy Crop. (1981; MRID 00117969) submitted data from one test conducted in FL concerning the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxy-methyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on oranges and processed products. Oranges received three soil banded (post-dripline spray) applications of the 2 lb/gal EC formulation at 8 or 16 lb ai/A/application (2-4x the maximum permitted single application rate). The posttreatment interval was 31 days. Two samples each of unwashed and washed oranges bore total metalaxyl residues of 0.14-0.28 and 0.13-0.16 ppm, respectively. Total metalaxyl residues were 0.06-0.11 ppm in pulp, 0.24-0.32 ppm in chopped peel (2x), 0.80-1.4 ppm in dried peel (7x), 0.25-0.46 ppm in peel frits (3x), <0.05(nondetectable)-0.06 ppm in juice, 0.52-1.3 ppm in molasses (6x), 0.20-0.40 ppm in press liquor (3x), and 0.94 ppm in crude oil (7x) processed from washed oranges bearing 0.13-0.16 ppm residues; concentration factors given in parentheses are the average of two values except for crude oil. Total metalaxyl residues in one control sample of each commodity were nondetectable (<0.05 ppm) in unwashed oranges, washed oranges, pulp, chopped peels, dried peels, peel frits, juice, molasses, press liquor, and crude oil. Samples were analyzed using an adequate GLC analytical method (no. AG-348) with a limit of detection of 0.05 ppm. Recoveries were 69% (0.2 ppm) from unwashed oranges, 92% (0.05 ppm) from washed oranges, 78% (0.5 ppm) from pulp, 78% (0.10 ppm) from chopped peels, 57% (0.5 ppm) from dried peels, 72% (0.10 ppm) from peel frits, 97% (0.05 ppm) from juice, 76% (0.2 ppm) from molasses, 77% (0.2 ppm) from press liquor, and 84% (0.5 ppm) from crude oil (fortification levels appear parenthetically). Samples were stored frozen for ca. 241 days prior to analysis. These data indicate that residues of metalaxyl may concentrate up to 7x in crude oil, 7x in dried peel, and 6x in molasses processed from washed oranges bearing metalaxyl residues, and that residues are not expected to concentrate in juice.

Ciba-Geigy crop. (1981-82; MRIDs 00117969 and 00133020) submitted data from three tests conducted in CA(2) and TX(1) concerning the combined residues of metalaxyl and its metabolites containing the 2,6-diemthylaniline

moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on oranges harvested 1-6 days following the last of three soil banded (post-dripline) applications of the 2 lb/gal EC or the 5% G formulations at 8 lb ai/A/application (2x the maximum permitted single application rate). Total metalaxyl residues in or on 26 orange samples were <0.05(nondetectable)-0.42 ppm. Total metalaxyl residues in or on 11 control samples were nondetectable (<0.05 ppm). Residue analysis was accomplished using adequate GLC analytical methods (nos. AG-348 and AG-395). The limit of detection of both methods was 0.05 ppm. Recovery of metalaxyl was 55-99% from 11 samples fortified with 0.05-1 ppm of metalaxyl. Samples were stored frozen for ca. 197-270 days prior to analysis.

Ciba-Geigy Corp. (1981-82; MRID 00117969) submitted data from three tests conducted in TX concerning the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxy-methyl6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on oranges harvested 1-60 days following the last of three trunk spray (post basal drench) applications of the 2 lb/gal EC formulation at 9 or 18 g ai/tree/application (2 or 4 lb ai/A/application; 1 or 2x the maximum permitted single trunk application rate). Total metalaxyl residues in or on 30 orange samples were <0.05(nondetectable)-0.51 ppm. Total metalaxyl residues in or on 10 control samples were nondetectable (<0.05 ppm). Analyses of samples were done using an adequate GLC analytical method (no. AG-348) with a limit of detection of 0.05 ppm. Recoveries were 57-86% from 11 samples fortified at 0.05-0.2 ppm. Samples were stored frozen for ca. 239-305 days prior to analysis.

Geographic representation was adequate since the test states of CA(29%), FL(68%), and TX(2%) produced ca. 99% of the 1983/84 U.S. orange crop (Agricultural Statistics, 1985, p. 198). The available data are sufficient to determine that total residues of metalaxyl in or on citrus will not exceed the established tolerance of 1 ppm.

Pome Fruits Group

Conclusions for the Pome Fruits Group:

The available data are insufficient to determine whether a crop group tolerance is appropriate. If the registrant seeks a crop group tolerance, the following data will be required:

- Use directions must be proposed, and appropriate supporting residue data submitted for the additional representative group member pears.

Apples

Tolerances:

Tolerances of 0.2, 0.4, and 2 ppm have been established for the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on apples (40 CFR 180.408[a]), wet apple pomace (21 CFR 561.273[a]), and dry apple pomace (21 CFR 561.273[a]), respectively.

Use directions and limitations:

The 2 lb/gal EC formulation is registered for use as a soil application at the trunk base at 0.5 lb ai/100 gal. One application may be made at planting or in the spring prior to tree growth; a second application may be made in the fall after harvest. There is no established PHI.

Conclusions:

The available data are adequate to support the established tolerance of 0.2 ppm for total metalaxyl residues in or on apples. The available data also support the 0.4 ppm and 2 ppm feed additive tolerances for residues in wet and dry apple pomace, respectively. No additional data are required for this topic.

No Canadian or Mexican tolerance exists. A proposed Codex MRL (step 6) of 0.05 ppm has been established for residues of metalaxyl per se in or on apples. Compatibility is not possible without a major revision of the U.S. residue definition, which is dependent upon toxicological considerations.

References (used):

MRIDs: 00126315. 00141519.

Discussion of the data:

Ciba-Geigy Corp. (1982-1983; MRIDs 00141519 and 00126315) submitted data from 10 tests conducted in CA(1), MD(1), NY(4), NC(1), and WA(3) concerning the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methyoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on apples

following application of the 2 lb/gal EC formulation. The following treatment regimens were represented: (i) a total of four tests received two (three tests) or four (one test) broadcast soil applications at 8 lb ai/A; (ii) two tests received one preemergence broadcast soil application at 8 or 16 lb ai/A; (iii) one test received one drench application at 8 lb ai/A; (iv) two tests received one post-dripline spray application at 8 or 16 lb ai/A and (v) two tests received one soil band application at 8 or 16 lb ai/A. Total metalaxyl residues in or on 57 apple samples were <0.05-0.16 ppm at 0-60 days posttreatment following 1-4 applications at 8 or 16 lb ai/A. In addition, two samples receiving one application at 16 lb ai/A bore 0.41 and 0.19 ppm of total metalaxyl residues at 34 and 50 days posttreatment, respectively. Eighteen control samples bore nondetectable (<0.05 ppm) residues. Samples were analyzed using adequate GLC methods (nos. AG-348 and AG-395). The limit of detection for both methods was 0.05 ppm. Recovery efficiencies were 43-111% from 15 samples fortified with 0.05-1 ppm of metalaxyl. Samples were stored frozen for ca. 36-412 days prior to analysis.

Ciba-Geigy Corp. (1982; MRID 00126315) submitted data from one test conducted in NY concerning the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on apples and processed products. Apples received one preemergence broadcast soil application of the 2 lb/gal EC formulation at 8 or 16 lb ai/A; the posttreatment interval was 34 days. Total metalaxyl residues were <0.05-0.09 and <0.05-0.13 ppm in or on two samples each of unwashed and washed apples, respectively. Total metalaxyl residues were 0.17 ppm in cores and peels (2x), 0.56 ppm in dried cores and peels (6x), 0.14 ppm in wet pomace (2x), and 0.47 ppm in dried pomace (5x) processed from unwashed apples bearing 0.09 ppm metalaxyl residues; concentration factors are given parenthetically. Residues did not concentrate in sauce or juice. Total metalaxyl residues in or on one control sample of each commodity were <0.05 ppm (nondetectable) in or on unwashed apples, washed apples, apple slices, cores and peel, dried cores and peels, apple sauce, dried pomace, and juice, and 0.06 ppm in or on wet pomace. Samples were analyzed using an adequate GLC method (no. AG-348); the limit of detection was 0.05 ppm. Recoveries of metalaxyl from one sample of each commodity were: 66% (0.2 ppm) from unwashed apples; 49% (0.1 ppm) from washed apples; 118% (0.1 ppm) from apple slices; 69% (0.05 ppm) from cores and peels; 47% (1 ppm) from dried cores and peels; 79% (0.2 ppm) from apple sauce; 66% (0.5 ppm) from wet pomace; 56% (1 ppm) from dried pomace; and 55% (0.2 ppm) from juice (fortification levels are shown parenthetically). Samples were stored frozen for ca. 68-96 days prior to analysis. These data indicate that residues of metalaxyl may concentrate up to 2x in wet pomace and 6x in dried cores and peels, and 5x in dried pomace processed from apples bearing metalaxyl residues.

Ciba-Geigy Corp. (1982; MRID 00126315) submitted data from three tests conducted in VA concerning the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on apples harvested 30-95 days following one crown drench application of the 2 lb/gal EC formulation at 0.005 lb ai/tree. Total metalaxyl residues in or on five treated apple samples and one untreated

control sample were nondetectable (<0.05 ppm). Samples were analyzed using an adequate GLC method (no. AG-348) with a limit of detection of 0.05 ppm. Recovery of metalaxyl was 80% from one apple sample fortified with 0.2 ppm of metalaxyl. Samples were stored frozen for ca. 97-133 days prior to analysis.

The test states of CA(6%), MD(<1%), NY(12%), NC(4%), PA(7%), WA(36%), and VA(6%) accounted for ca. 71% of 1984 U.S. apple production (Agricultural Statistics, 1985, p. 186), thus, geographic representation was adequate. The available data are adequate to support the established tolerance of 0.2 ppm for total residues of metalaxyl in or apples.

Small Fruits and Berries Group

Conclusions for the Small Fruits and Berries Group:

The available data are insufficient to determine whether a crop group tolerance is appropriate. If the registrant seeks a crop group tolerance, the following will be required:

- o Use directions must be proposed and appropriate supporting residue data submitted for blackberries (or other Rubus spp.), blueberries, cranberries, grapes, and strawberries.

Raspberries

Tolerance:

A tolerance of 0.5 ppm has been established for the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on raspberries (40 CFR 180.408[a]).

Use directions and limitations:

The 5% G and 2 lb/gal EC formulations are federally registered for soil applications to raspberries at 0.25 lb ai/1,000 feet of row (calculated to be 1.375 and 3.625 lb ai/A [on a broadcast basis] for the 2 lb/gal EC and 5% G formulations, respectively). Applications may be made (in a three-foot band over the row) in the fall after harvest and may be repeated in the spring. There is an established 45-day PHI.

Conclusions:

The available data are adequate to support the established tolerance of 0.5 ppm for the combined residues of metalaxyl in or on raspberries. Additional data are not required.

There is no Canadian tolerance, Mexican tolerance, or Codex MRL for residues of metalaxyl in or on raspberries. Therefore, no compatibility questions exist with respect to the Codex MRL.

References (used):

MRID: 00127769.

Discussion of the data:

Ciba-Geigy Corp. (1976-1977; MRID 00127769) submitted data from three tests conduct in OR(1) and WA(2) pertaining to the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on raspberries following two soil applications (in three-foot bands) of the 2 lb/gal EC formulation at 0.34-0.68 lb ai/A (0.25-0.50x the maximum registered single soil application rate for the 2

lb/gal EC formulation). Combined metalaxyl residues were <0.05(nondetectable)-0.20 ppm in or on six raspberry samples harvested 47 days posttreatment; two control samples bore <0.05 ppm (nondetectable) of combined metalaxyl residues. Samples were analyzed using an adequate GLC analytical method (no. AG-348); the limit of detection was 0.05 ppm. Recovery was 55-59% from two raspberry samples fortified with metalaxyl at 0.2-1.0 ppm. Samples were stored frozen (temperature unspecified) for 79 days prior to analysis.

Ciba-Geigy Corp. (1971, 1979; MRID 00127769) submitted data from seven tests conducted in CA(1), OR(2) and WA(4) pertaining to the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on raspberries following two soil applications (in three-foot bands) of the 2 lb/gal EC formulation at 1.36-3.63 lb ai/A (0.99-2.64x the maximum registered single soil application rate for an EC formulation) with posttreatment intervals of 45-60 days. Combined metalaxyl residues were <0.05(nondetectable)-0.12 ppm in or on 11 raspberry samples. In addition, Ciba-Geigy Corp. (1977, 1979-1980; MRID 00127769) submitted data from six tests conducted in CA(1), OR(2), and WA(3) pertaining to the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on raspberries following two soil applications (in three-foot bands) of the 5% G formulation at 1.36-3.63 lb ai/A (0.38-1x the maximum registered single soil application rate for the 5% G formulation). Combined metalaxyl residues were <0.05 (nondetectable)-0.16 ppm in or on nine raspberry samples harvested 45-62 days posttreatment. Five control samples from all tests bore combined metalaxyl residues of <0.05 ppm (nondetectable). Samples from all tests were analyzed using an adequate GLC analytical method (no. AG-348); the limit of detection was 0.05 ppm. Recovery was 58-82% from four raspberry samples fortified with metalaxyl at 0.2-0.5 ppm. Samples were stored frozen (temperature unspecified) for 79-149 days prior to analysis.

Geographic representation was adequate since the test states of CA(7%), OR(38%), and WA(44%) collectively accounted for 89% of the 1982 U.S. raspberry production (1982 Census of Agriculture, Vol. 1, Part 51, p. 372). The available data are adequate to support the established tolerance of 0.5 ppm for the combined residues of metalaxyl in or on raspberries. Additional data are not required.

Cereal Grains Group

Tolerance:

A tolerance of 0.1 ppm has been established for the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on grain crops (40 CFR 180.408[a]).

Use directions and limitations:

The 25% WP and 2.65 lb/gal FlC formulations are registered for seed treatment of barley, corn (field corn, sweet corn, and popcorn), oats, rice, rye, and wheat seed at 0.25-0.5 oz ai/100 lb of seed. The 2 lb/gal EC and 2.65 lb/gal FlC formulations are registered for seed treatment of sorghum seed at 0.25-0.5 and 1 oz ai/100 lb of seed, respectively. In addition, the 25% WP formulation is also registered for seed treatment of sorghum seed at 1 oz ai/100 lb of seed. The EC, WP, and FlC formulations may be applied with conventional slurry or mist seed-treating equipment. The use of treated seed for food, feed, or oil is prohibited. The use directions for the 25% WP formulation described above were obtained from the product label (EPA Reg. No. 100-639) dated April 8, 1987.

Conclusions:

The available data are insufficient to assess the adequacy of the established tolerance of 0.1 ppm for total metalaxyl residues in or on grain crops following seed treatment because data were not submitted for the representative group member field corn. In addition, data were not submitted depicting total residues in processed commodities of the representative group members of grain crops. The following data are required:

- Data depicting metalaxyl residues of concern in or on the grain of field corn harvested from seed treated with the 25% WP formulation at 0.5 oz ai/100 lb of seed.

- Data depicting metalaxyl residues of concern in milled products and grain dust from the milling process of: field corn (starch, crude and refined oils from wet milling and grits, meal, flour, crude and refined oils from dry milling); rice (hulls, bran, polished rice); and sorghum (flour, starch) grains bearing measurable, weathered residues. If residues concentrate during processing in any of these commodities, then appropriate food/feed additive tolerances must be proposed.

Note to the PM: Separate indirect or inadvertent tolerances of 0.2 and 1 ppm have been established for total metalaxyl residues in or on wheat grain and in wheat milling products, respectively, as a result of metalaxyl application to target crops subsequently rotated to wheat. Since wheat is a representative commodity of the Cereal Grains Group, we recommend that the entry "grain crops" be amended to reflect the appropriate commodity definition "Cereal Grains (except wheat) Group."

No Canadian or Mexican tolerance or Codex MRL is established for metalaxyl residues in or on cereal grains. Therefore, no compatibility questions exist with respect to the Codex MRL.

References (used):

MRID: 00128102.

References (not used):

[The following MRID contained information irrelevant to the residue chemistry of metalaxyl.]

MRID: 00024916.

Discussion of the data:

Ciba-Geigy Corp. (1982; MRID 00128102) submitted data (report no. ABR-82078) pertaining to ^{14}C-residues of metalaxyl in or on sorghum stalks and grain following sorghum seed treatment with uniformly ring-labeled [^{14}C]-metalaxyl (as the 2 lb/gal EC formulation) at 1 oz ai/100 lb of seed (2x the maximum seed treatment rate for the EC formulation). (Refer to the "Nature of the Residue in Plants" section for experimental details.) Seeds were planted in a NE field plot. Grain was harvested at an unspecified interval after planting. The registrant reported limits of "quantitation" were 0.028-0.075 ppm of metalaxyl equivalents. ^{14}C-Residues of metalaxyl in or on sorghum grain were <0.065 ppm (nondetectable).

This Ciba-Geigy Corp. submission also included data (report no. 81061) depicting ^{14}C-residues of metalaxyl in or on rice hulls and grain and sweet corn (cobs and kernels) following seed treatment with uniformly ring-labeled [^{14}C]metalaxyl (as the 2 lb/gal EC formulation, not registered for use on rice or corn) at ca. 0.5 fl. oz ai/100 lb seed (1x the maximum registered seed treatment rate for WP and FlC formulations). (Refer to the "Nature of the Residue in Plants" section for experimental details.) Corn and rice seed were planted in NY and MS field plots, respectively. Crops were grown to maturity (intervals after planting unspecified). The registrant reports limits of "quantitation" of 0.03-0.07 ppm for these data. ^{14}C-Residues of metalaxyl were <0.07 ppm (nondetectable) in or on sweet corn (cobs and kernels) and rice hulls and grain.

The available data are insufficient to assess the adequacy of the established tolerance for total metalaxyl residues in or on grain crops because data were not submitted depicting residues in or on the representative group member field corn. In addition, data were not submitted depicting residues in the milled products of grain crops obtained from grain bearing measurable, weathered residues and grain dust from these milled products. Additional data are required.

Forage, Fodder, and Straw of Cereal Grains Group

Tolerance:

A tolerance of 0.1 ppm has been established for the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on forage grasses (40 CFR 180.408[a].

Use directions and limitations:

The 25% WP and the 2.65 lb/gal FlC formulations are registered for use as a seed treatment to barley, corn (field corn, sweet corn, and popcorn), oats, rice, rye, and wheat seed at 0.25-0.5 oz ai/100 lb of seed. The 25% WP and 2.65 lb/gal FlC formulations are also registered for use as a seed treatment to sorghum seed at 1 oz ai/100 lb of seed. The 2 lb/gal EC formulation is registered for seed treatment of sorghum seed at 0.25-0.5 oz ai/100 lb of seed. The EC, WP, and FlC formulations may be applied with conventional slurry or mist seed-treating equipment. The use of treated seed for food, feed, or oil is prohibited. The use directions for the 25% WP formulation described above were obtained from the product label (EPA Reg. No. 100-639) dated April 8, 1987.

Conclusions:

The available data are insufficient to assess the adequacy of the established tolerance of 0.1 ppm for total metalaxyl residues in or on forage grasses because data were not submitted for forage and fodder of the representative group member field corn. The following data are required:

- o Data depicting metalaxyl residues of concern in or on field corn forage and fodder grown from seed treated with the 25% WP formulation at 0.5 oz ai/100 lb of seed.

Note to the PM: Separate indirect or inadvertent tolerances of 2 ppm (20x the established tolerance for forage grasses resulting from seed treatment) have been established for total metalaxyl residues in or on wheat fodder, forage, and straw as a result of metalaxyl application to target crops subsequently rotated to wheat. Since wheat forage, fodder, and straw are representative commodities of the Forage, Fodder, and Straw of the Cereal Grains Group, we recommend that the group definition "grasses forage" be redefined to reflect the appropriate commodity definition "Forage, Fodder, and Straw of Cereal Grains (except wheat) Group."

No Canadian or Mexican tolerance or Codex MRL is established for metalaxyl residues in or on cereal grains. Therefore, no compatibility questions exist with respect to the Codex MRL.

References (used):

MRID: 00128102.

References (not used):

[The following MRID contains information irrelevant to the residue chemistry of metalaxyl.]

MRID: 00024916.

Discussion of the data:

Ciba-Geigy Corp. (1982; MRID 00128102) submitted data (report no. ABR-82078) pertaining to ^{14}C-residues of metalaxyl in or on sorghum stalks following sorghum seed treatment with uniformly ring-labeled [^{14}C]metalaxyl (as the 2 lb/gal EC formulation) at 1 oz ai/100 lb of seed (1x the maximum seed treatment rate for the EC formulation). (Refer to the "Nature of the Residue in Plants" section for experimental details.) Seeds were planted in a NE field plot. Stalks were harvested at 60 days after planting or at maturity (interval unspecified). The registrant reported limits of "quantitation" of 0.028-0.075 ppm metalaxyl equivalents. ^{14}C-Residues of metalaxyl in or on sorghum stalks were <0.075 ppm (nondetectable).

This Ciba-Geigy Corp. submission also included data (report no. 81061) depicting ^{14}C-residues of metalaxyl in or on rice stalks and sweet corn green forage following seed treatment with uniformly ring-labeled [^{14}C]-metalaxyl (as the 2 lb/gal EC formulation, not registered for use on rice or corn) at ca. 0.5 oz ai/100 lb seed (1x the maximum seed treatment rate for the WP and FlC formulations). (Refer to the "Nature of the Residue in Plants" section for experimental details.) Corn and rice seed were planted in NY and MS field plots, respectively. Crops were grown to maturity (intervals after planting unspecified). The registrant reported limits of "quantitation" of 0.03-0.07 ppm for these data. ^{14}C-Residues of metalaxyl were <0.07 ppm (nondetectable) in or on corn and rice forage/stalks.

The available data are insufficient to assess the adequacy of the established tolerance of 0.1 ppm for total metalaxyl residues in or on forage grasses because data were not submitted for forage and fodder of the representative group member field corn. Additional data are required.

Miscellaneous Commodities

Avocados

Tolerance:

A tolerance of 4 ppm has been established for the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on avocados (40 CFR 180.408[a]).

Use directions and limitations:

The 2 lb/gal EC formulation is registered for soil application (injected into or sprayed under irrigation water) to avocados at 0.5-1.0 oz ai/1,000 gal of irrigation water or 2.5% oz ai/20 ft diameter tree canopy; the 5% G formulation is registered for soil application (under sprinkler or drip irrigation water) at 0.037%-0.075 oz ai/sq yd or 2.5 oz ai/20 ft diameter tree canopy. Applications may be made at the beginning of the growing season or at transplanting with two additional applications at 3-month intervals. A 28-day PHI and a maximum seasonal use rate of 48 lb ai/A have been established.

Conclusions:

The available data are adequate to support the established tolerance for the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxy-acetyl)-alanine methyl ester, each expressed as metalaxyl, and are sufficient to determine that the label directions are adequate. Additional data are not required.

A proposed Codex MRL of 0.1 ppm (step 6) exists for residues of metalaxyl per se in or on avocados. Compatibility with Codex is not possible without a major revision of the U.S. residue definition, which is dependent upon toxicological considerations. No Canadian or Mexican tolerances exist.

References (used):

MRID: 00074488.

References (not used):

[The following MRID contains irrelevant information.]

MRID: 00074487.

Discussion of the data:

Data was submitted by Ciba-Geigy Corp. (1980; MRID 00074488) from 12 tests conducted in CA concerning the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl-N-(methyoxyacetyl)-alanine methyl ester, each

expressed as metalaxyl, in or on avocados harvested: 7-60 days following the last of three soil applications (drench or surface banded), to one hundred 20-ft diameter trees, of the 2 lb/gal EC or 15% G (not registered for this use) formulation at 16 or 32 lb ai/A (1x or 2x the maximum registered single application rate and 1 or 2x the maximum permitted seasonal use rate); or 28 or 56 days following the last of eight soil applications (through drip irrigation) of the 2 lb/gal EC formulation at 6 or 12 lb ai/A (0.375 or 0.75x the maximum registered single application rate and 1 or 2x the maximum permitted seasonal use rate). Total metalaxyl residues in or on 37 avocado samples were 0.80-3.2 (including 12 samples taken at 28 days posttreatment). Apparent residues in or on eight control samples were <0.05(nondetectable)-0.08 ppm. Total residues of metalaxyl and its metabolites were determined as DMA (2,6-dimethylaniline) by an adequate GLC analytical method (no. AG-348) with a limit of detection of 0.05 ppm. Recoveries were 46-81% from nine samples fortified with 0.05-2.0 ppm of metalaxyl. Samples were stored frozen (temperature unspecified) for ca. 101-134 days prior to analysis.

Geographic representation was adequate since the test state of CA accounted for 89% of the 1984 U.S. avocado production (Agricultural Statistics, 1985, p. 192). The submitted data indicate that tolerance-exceeding residues in or on avocados will not occur from the registered soil applications of metalaxyl. Additional data are not required.

Cottonseed

Tolerance:

A tolerance of 0.1 ppm has been established for the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on cottonseed (40 CFR 180.408[a]).

Use directions and limitations:

The 1-5% G and 2 lb/gal EC formulations are registered for soil application to cotton at 0.0625-0.125 lb ai/13,000 linear feet of row. Application may be made at-planting as an in-furrow seed treatment. Livestock may not graze in treated areas or be fed cotton foliage.

Conclusions:

The available data support the established tolerance for the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, and are sufficient to determine that the label directions are adequate. Additional data are not required. The data presented to determine the concentration of residues in processed commodities, however, were inadequate since the cottonseed used in processing did not bear measurable, weathered residues. The following data are required:

o Data depicting concentration of metalaxyl residues of concern during processing of cottonseed hulls, meal, crude oil, refined oil, and soapstock derived from cottonseed bearing measurable, weathered residues. (Exaggerated application rates may be necessary to obtain these levels on the cottonseed.) If concentration occurs during processing, the registrant must propose appropriate food/feed additive tolerances.

A proposed Codex MRL of 0.05 ppm (step 3) exists for residues of metalaxyl per se in or on cottonseed. Compatibility with Codex is not possible without a major revision of the U.S. residue definition, which is dependent upon toxicological considerations. No Canadian or Mexican tolerances exist.

References (used):

MRID: 00109402.

Discussion of the data:

Ciba-Geigy Corp. (1981; MRID 00109402) submitted data from six tests conducted in AL(1), CA(1), MS(3), and TX(1) concerning the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on cottonseed harvested 164-207 days following an at-planting, in-furrow, soil application of the 2 lb/gal EC or 5% G formulation at 0.125 or 0.25 lb ai/A (1-2x the maximum registered application rate). Data were also submitted regarding gin trash. Total metalaxyl residues in or on 19 cottonseed samples (delinted) were <0.05 ppm (nondetectable). Residues in or on six control samples were <0.05 ppm (nondetectable). Total residues of metalaxyl and its metabolites were determined as DMA (2,6-dimethylaniline) by an adequate GLC analytical method (no. AG-348) with a limit of detection of 0.05 ppm. Recoveries were 62-98% from 11 samples fortified with 0.05-1.0 ppm of metalaxyl. Samples were stored frozen (temperature unspecified) for ca. 35-283 days prior to analysis.

Ciba-Geigy Corp. (1981; MRID 00109402) submitted data from one test conducted in TX concerning the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxy-methyl6-methyl-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on cottonseed and processed products. Cottonseed was harvested 121 days following an at-planting, in-furrow, soil application of the 5% G formulation at 0.125 or 0.25 lb ai/A (1-2x the maximum registered application rate). Combined metalaxyl residues were <0.05 ppm (nondetectable) for two cottonseed samples and one control sample. Combined metalaxyl residues and estimated concentration factors in two samples (2x and 1x application rate, respectively) of each processed commodity were: 0.07 ppm (1x) in both samples of kernels; <0.05(nondetectable) and 0.06 ppm (1x, 1x) in meal; 0.05 and 0.08 ppm (1x, 2x) in hulls; 0.42 and 1.4 ppm (8x, 28x) in soapstock; 0.31 and 0.85 ppm (6x, >17x) in crude oil; 0.15 and 0.30 ppm (3x, 6x) in refined oil; and <0.05 ppm (nondetectable) (1x) in both samples of refined-bleached oil, refined-bleached hydrogenated

oil, and refined-bleached deodorized-hydrogenated oil. Combined metalaxyl residues in one control sample of each processed commodity were <0.05 ppm (nondetectable). Samples were analyzed using adequate GLC analytical methods (no. AG-348 for cottonseed and kernels; no. AG-350 for hulls, meal and soapstock); the limit of detection was 0.05 ppm for each method. Recoveries (with fortification levels in parentheses) from one or two samples of each processed commodity were: 68% (0.05 ppm) from cottonseed; 52-75% (0.05 ppm) from kernels; 61-72% (0.05 ppm) from meal; 61-73% (0.05 ppm) from hulls; 53-70% (0.1 ppm) from soapstock; 45-70% (0.05 ppm, 0.20 ppm) from crude oil; 50-85% (0.05 ppm) from refined oil; 63% (0.2 ppm) from refined-bleached oil; 37% (0.1 ppm) from refined-bleached hydrogenated oil; and 40% (0.05 ppm) from refined-bleached deodorized-hydrogenated oil. Samples were stored frozen (temperature unspecified) for ca. 255-305 days prior to analysis. These data indicate that metalaxyl residues markedly concentrate in hulls, soapstock, and oil (crude and refined) processed from cottonseed bearing nondetectable (<0.05 ppm), weathered residues. The estimated concentration factors show a potential need for food/feed additive tolerances for metalaxyl residues in hulls, soapstock, and oil, but are not useful for calculating the appropriate tolerance levels.

Ciba-Geigy Corp. (1981; MRID 00109402) also submitted data from one test conducted in MS concerning the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxy-methyl-6-methyl-N-(methyoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on cottonseed and processed products. Cottonseed was harvested 226 days following an at-planting, in-furrow, soil application of the 2 lb/gal EC formulation at 0.125 lb ai/A (1x the maximum registered application rate). Combined metalaxyl residues were <0.05 ppm (nondetectable) in an unspecified number of cottonseed samples. Treated cottonseed was also fortified at 4 ppm at 0 days postharvest. Combined metalaxyl residues in one sample of each commodity (except soapstock) processed from cottonseed fortified with metalaxyl were: 1.6 ppm in cottonseed (at time of fortification); 1.4 ppm in cottonseed (at fractionation); 0.15 ppm (0.09x) in kernels; 0.35 ppm (0.22x) in meal; 1.9 ppm (1x) in hulls; 2.8 and 3.9 ppm (2x) in two soapstock samples; 1.3 ppm (0.81x) in crude oil; 0.8 ppm (0.5x) in refined oil; and <0.05 ppm (nondetectable) (<0.03x) in refined-bleached oil, refined-bleached hydrogenated oil, and refined-bleached deodorized-hydrogenated oil (concentration factors in parentheses). Combined metalaxyl residues in one control sample of each commodity were <0.05 ppm (nondetectable) except for meal (0.08 ppm). Samples were analyzed using adequate GLC analytical methods (no. AG-348 for cottonseed and kernels; no. AG-350 for hulls, meal, and soapstock); the limit of detection was 0.05 ppm for each method. Recoveries (with fortification levels in parentheses) from one sample of each commodity (except soapstock) were: 63% (20 ppm) from cottonseed; 60% (1 ppm) from kernels; 67% (0.4 ppm) from meal; 50% (0.2 ppm) from hulls; 39% and 53% (2.5 and 0.5 ppm) from soapstock (two samples); 66% (2.0 ppm) from crude oil; 61% (1.0 ppm) from refined oil; 77% (0.1 ppm) from refined-bleached oil; and 42% (0.02 ppm) from refined-bleached deodorized-hydrogenated oil. Samples were stored frozen (temperature unspecified) for ca. 165-225 days prior to analysis.

Geographic representation was adequate since the tests states of AL(3%), CA(23%), MS(13%), and TX(29%) accounted for ca. 68% of the 1985 U.S. cotton production (Agricultural Statistics, 1986, p. 62). The available data are adequate to support the established tolerance of 0.1 ppm for the combined residues of metalaxyl in or on cottonseed. Additional residue data are not required. However, the available processing studies with cottonseed are inadequate because the processing fractions were derived from cottonseed that did not bear measurable, weathered residues (although certain processed fractions did contain detectable residues). Additional processing data are required.

Hops

Tolerances:

Tolerances of 0.6 and 2 ppm have been established for the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on green hops (40 CFR 180.408[a]) and dry hops (21 CFR 561.273[a]), respectively.

Use directions and limitations:

The 2 lb/gal EC formulation is registered for soil application to hops at 0.5 lb ai/A (in 20 gal of water). Applications may be made over the crowns after pruning, but before training. Applications after training should not be made. The feeding of hop refuse to livestock is prohibited. A maximum of one application is permitted per season.

Conclusions:

The available data are adequate to support the established tolerance of 0.6 ppm for total metalaxyl residues in or on green hops. However, the available data for dried hops do not support the established food additive tolerance of 2 ppm because these data indicate that metalaxyl residues may concentrate up to 7x in dried hops processed from green hops bearing measurable, weathered metalaxyl residues. Thus, the 2 ppm feed additive tolerance is insufficient; a more appropriate tolerance level is 4 ppm. Also, the registrant must propose a feed additive tolerance for spent hops. The following are required:

- The registrant must propose a tolerance for total metalaxyl residues in dried hops based on the concentration factor during drying of about 7x. The available data support a food additive tolerance of 4 ppm, toxicological considerations permitting. Based on the above recommendation the registrant must also propose a feed additive tolerance in spent hops at the same level as for dried hops.

No Canadian or Mexican tolerances exist. A proposed Codex MRL (step 6) of 10 ppm exists for residues of metalaxyl per se in or on dried hops. Compatibility with the Codex MRL is not possible without a major revision of the U.S residue definition, which is dependent upon toxicological considerations.

References (used):

MRID: 00079433.

References (not used):

[The following MRID contains irrelevant information.]

MRID: 00103135.

Discussion of the data:

Ciba-Geigy Corp. (1980; MRID 00079433) submitted data from two tests conducted in ID concerning the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on green hops and dried hops. Hops received one soil-drench application of the 2 lb/gal EC formulation at 0.5 or 1 lb ai/A (1 or 2x the maximum registered single application rate) followed by two foliar applications at 0.2 or 0.4 lb ai/A/application (0.4 or 0.8x the maximum registered single application rate), for a seasonal total of 0.9 or 1.8 lb ai/A (1.8 or 3.6x the maximum permitted seasonal rate). The posttreatment interval was 35 days. Total metalaxyl residues in or on two samples each of green hops collected after treatment at the 1.8 and 3.6x rates were 0.17-0.18 and 0.70-0.89 ppm, respectively. Two corresponding dry hop samples from the 1.8 and 3.6x rates bore total metalaxyl residues of 1.0-1.3 (5.6-7.64x) and 3.0-4.6 ppm (3.4-6.6x), respectively. Two green hop control samples and one dry hop control sample bore total metalaxyl residues of nondetectable (<0.05 ppm each) and 0.14 ppm, respectively. Samples were analyzed using an adequate GLC analytical method (no. AG-348) with a limit of detection of 0.05 ppm. Recovery of metalaxyl from two samples each of green hops and dry hops was 75-79% and 52-61%, respectively, when fortified with 0.05-1.0 ppm of metalaxyl. Samples were stored frozen for ca. 76-90 days prior to analysis.

Ciba-Geigy Corp. (1980; MRID 00079433) submitted data from two tests conducted in ID concerning the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on green hops and processed products. Hops received one soil-drench application of the 2 lb/gal EC formulation at 0.5 or 1 lb ai/A (1 or 2x the maximum registered single application rate); the posttreatment interval was 108 days. Two green hop samples treated at the 1x rate bore total metalaxyl residues of 0.14 and 0.18 ppm; one green hop sample treated at the 2x rate bore total metalaxyl residues of 0.2 ppm. One sample each of dried hops treated at the 1x or 2x rate bore total metalaxyl residues of 1.2 and 3.4 ppm, respectively. Using the maximum residue value in or on green hops at 1x (0.18 ppm) and 2x (0.20 ppm) resulting concentrations in dried hops were 6.7x and 17x, respectively. Total metalaxyl residues in or on two green hop control samples were 0.07-0.10 ppm. One dry hop control sample bore total metalaxyl residues of 0.07 ppm. Samples were analyzed by an adequate GLC method (no. AG-348) with a limit of detection of 0.05 ppm. In this same submission, a processing study was performed using a dried hop sample, from the above described

test, that was treated at the 1x rate and bore total metalaxyl residues of 1.2 ppm. One sample of each commodity bore total metalaxyl residues of <0.05 ppm (<0.04x) in spent hops, <0.05 ppm (<0.04x) in yeast, 0.07 ppm (0.06x) in filter cake, and 0.06 ppm (0.05x) in trub. One brewed beer sample (processed from an untreated hop sample bearing total metalaxyl residues of <0.05 ppm [nondetectable]) bore total metalaxyl residues of <0.01 ppm (nondetectable). Total metalaxyl residues in one control sample of each processed commodity were <0.05 ppm (nondetectable) in spent hops, yeast, filter cake, and trub, and <0.01 ppm (nondetectable) in beer. Recoveries were: 65-69% (0.05-1 ppm) from green cones; 59-67% (0.2-2 ppm) from dry cones; 58-59% (0.05-1 ppm) from spent hops, 71% (0.05 ppm) from yeast; 54-66% (0.05-1 ppm) from filter cake; 39-42% from trub; and 54% (0.02 ppm) from beer (fortification levels appear parenthetically). Samples were stored frozen for ca. 82-198 days prior to analysis.

Ciba-Geigy Corp. (1981; MRID 00079433) submitted data from six tests conducted in OR(2) and WA(4) concerning the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on dried hops. Hops received one soil-drench application of the 2 lb/gal EC formulation at 0.5 or 1 lb ai/A (1 or 2x the maximum registered single application rate) alone or followed with two foliar applications at 0.2 or 0.4 lb ai/A (0.4 or 0.8x the maximum registered single application rate). The posttreatment interval was 38-139 days. Total metalaxyl residues in or on 10 dry hop samples were 0.36-1.4 ppm. Three control samples bore total metalaxyl residues of 0.11-0.52 ppm. Samples were analyzed using an adequate GLC analytical method (no. AG-348). The limit of detection of the method was 0.05 ppm. Recovery of metalaxyl was 57-67% from four samples fortified with 0.1-2 ppm of metalaxyl. Samples were stored frozen for ca. 77-127 days prior to analysis.

Geographic representation was adequate since the test states of ID(10%), OR(12%), and WA(78%) produced virtually 100% of the 1984 U.S. commercial hop crop (Agricultural Statistics, 1985, p. 206). The available data are adequate to support the established tolerance of 0.5 ppm in or on green hops. However, the submitted residue data for dried hops indicate that residues concentrate ca. 7x when treated at the 1x rate. Therefore, we feel that the established 2 ppm feed additive tolerance for total metalaxyl residues in dried hops is insufficient and must be increased. A tolerance must also be proposed for total metalaxyl residues in spent hops. Based on the available data, we recommend feed additive tolerances of 4 ppm each for total metalaxyl residues in dried hops and spent hops, toxicological considerations permitting.

Peanuts

Tolerances:

Tolerances (levels presented parenthetically) have been established for the combined residues of metalaxyl and its metabolites containing the 2,6-dimethyaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on peanuts (0.2 ppm), peanut hulls (2 ppm), peanut hay (20 ppm), peanut vines (20 ppm) (40 CFR 180.408[a]), and peanut meal (1 ppm) and peanut soapstock (2 ppm) (21 CFR 561.273[a]).

Use directions and limitations:

The 5% G and 2 lb/gal EC formulations are registered for soil application to peanuts at 0.25 lb ai/A at-planting (in-furrow, 7-inch band) and 0.5-1.0 lb ai/A at early pegging or pod set with the EC formulation applied through irrigation water. The 1% G (formulated with pentachloronitrobenzene) is registered for soil application (at pegging) at 1 lb/13,000 linear ft of row. The above described uses for the 5% G and 2 lb/gal EC formulations were obtained from the product labels EPA Reg. Nos. 100-628 and 100-607 dated March 30 and April 8, 1987, respectively.

Conclusions:

The available data are insufficient to support the established tolerances for the combined residues of metalaxyl in or on nuts, hulls, hay, and vines because data were not provided reflecting the registered use of a G formation. The following additional data are required:

- Data depicting metalaxyl residues of concern in or on nuts, hulls, hay, and vines from soil applications of a G formulation at 0.25 lb ai/A (at-planting) and 1 lb ai/13,000 linear ft of row (at pegging). Tests must be conducted in AL(15%), GA(49%), NC(10%), OK(4%), and VA(6%), states which collectively produced ca. 84% of 1984 U.S. peanut product (Agricultural Statistics, 1985, p. 121).

No Canadian or Mexican tolerance or Codex MRL is established for residues of metalaxyl in or on peanuts. Therefore, no compatibility questions exist with respect to the Codex MRL.

References (used):

MRID: 00128738.

Discussion of the data:

Ciba-Geigy Corp. (1983; MRID 00128738) submitted data from seven tests conducted in GA(2), MS(2), NC(1), OK(1), and VA(1) concerning the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on peanuts. Peanuts were treated with an at-planting, broadcast soil application of the 2 lb/gal EC formulation at 2 or 4 lb ai/A, (2 or 4x the maximum registered single soil application

rate) followed by an application at pegging at 1 or 2 lb ai/A, for a seasonal use rate of 3 or 6 lb ai/A (2.4x or 4.8x the maximum seasonal use rate), and harvested 41-50 days posttreatment. Combined metalaxyl residues in or on a total of 29 samples of fodder, shells, and nuts were 0.23-17.5 ppm (10 samples), 0.11-0.99 ppm (10 samples), and <0.05(nondetectable)-0.11 ppm (nine samples), respectively at 2.4x. At the 4.8x rate, combined residues were 0.61-26.6 ppm (two samples), 0.59-1.7 ppm (three samples), and 0.1-0.2 ppm (two samples) in or on fodder, shells, and nuts, respectively. Apparent residues in or on 19 control samples were 0.06-2.15 ppm, <0.05 (non-detectable)-0.07 ppm, and <0.05 (nondetectable) from fodder, shells, and nuts, respectively. Samples were analyzed using an adequate GLC method (no. AG-395) with a limit of detection of 0.05 ppm. Recoveries from 19 samples (with fortification levels in parentheses) were 89-110% (1-5 ppm), 81-126% (0.1-0.5 ppm), and 90-143% (0.05-0.1 ppm) for fodder, shells, and nuts, respectively. Samples were stored frozen (temperature unspecified) for ca. 137-196 days prior to analysis.

Ciba-Geigy Corp. (1983; MRID 00128738) submitted data from two tests conducted in UK concerning the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on peanuts and processed products. Peanuts were harvested 42 days following soil applications of the 2 lb/gal EC at-planting (broadcast) and at pegging (overhead irrigation) at 2 or 4 lb ai/A and 1 or 2 lb ai/A, respectively (2.4x or 4.8x the maximum seasonal use rate). Combined metalaxyl residues in or on two samples each of nuts and fodder were 0.09-0.10 and 9.92-17.00 ppm, respectively at 1.2x. At 2.4x, one sample each of nuts and fodder bore total metalaxyl residues of 0.16 and 26.6 ppm, respectively. In addition, a processing study was done using two samples of nuts bearing combined residues of 0.08 and 0.16 ppm. Combined metalaxyl residues (maximum concentration factors are given in parentheses) in each processed commodity (two samples/commodity) were 0.15 and 0.49 ppm in meal (3x), 0.20 and 0.87 ppm in soapstock (5x), and <0.05 (nondetectable) in two fractions of crude and refined oil each. Combined metalaxyl residues were <0.05 ppm (non-detectable) in or on control samples (number/commodity in parentheses) of nuts (3), meal (1), crude oil fractions (2), refined oil (2), and soapstock (1). Combined metalaxyl residues in one control sample each of shells and fodder were 0.07 and 0.86 ppm, respectively. Samples were analyzed using adequate GLC analytical methods (no. AG-395 for kernels and meal, no. AG-350 for oils and soapstock); the limit of detection was 0.05 ppm for each method. Recoveries (with fortification levels in parentheses) were: 95-143% (0.05-0.10 ppm) from nuts; 116% (0.20 ppm) from meal; 64% (1 ppm) from soapstock; 79-97% (0.10-1 ppm) from crude oil fractions; and 82-90% (0.05-0.10 ppm) from refined oil fractions. Samples were stored frozen (temperatures unspecified) for about 137-196 days prior to analysis.

Geographic representation was adequate since the test states of GA(49%), MS(<1%), NC(10%), OK(4%), and VA(6%) accounted for ca. 69% of 1985 U.S. peanut production (Agricultural Statistics, 1985 p. 121). The available data are insufficient to support the established tolerances in or on the nuts (0.2 ppm), hulls (2 ppm), hay (20 ppm), and vines (20 ppm) for the combined residues of metalaxyl because data reflecting the use of a G formulation were not provided. Additional data are required.

Pineapples

Tolerances:

Tolerances of 0.1 ppm have been established for the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on pineapples, pineapple fodder, and pineapple forage (40 CFR 180.408[a]).

Use directions and limitations:

The 2 lb/gal EC formulation is registered for use as a "seedpiece dip" (crown dip) treatment to pineapples at 1 lb ai/100 gal. Applications may be made at 75-100 gal of dip solution/planted acre. If crop failure occurs within one year of planting treated crowns, the use of crop or crop residue for animal feed is prohibited.

Conclusions:

The available data support the established tolerances for total metalaxyl residues in or on pineapples and pineapple forage. However, data were not submitted which depict residues in pineapple juice and bran processed from fruit bearing measurable, weathered residues. Therefore, the following additional data are required:

- Data from a processing study depicting metalaxyl residues of concern in pineapple juice and pineapple bran (chopped, dehydrated pineapple tops and shells) processed from pineapple fruit bearing measurable, weathered residues. If residues concentrate in any of these processed commodities, then appropriate food/feed additive tolerances must be proposed.

Note to the PM: Since pineapple fodder is not considered to be a raw agricultural commodity of pineapples, we recommend that the established tolerance of 0.1 ppm for total metalaxyl residues in or on "pineapple fodder" be revoked.

No Canadian or Mexican tolerances exist. A proposed Codex MRL (step 3) of 0.05 ppm exists for residues of metalaxyl per se in or on pineapple flesh. Compatibility with Codex is not possible without a major revision of the U.S. residue definition, which is dependent upon toxicological considerations.

References (used):

MRID: 00109472.

Discussion of the data:

Ciba-Geigy Corp. (1979-81; MRID 00109472) submitted data from six tests conducted in HI concerning the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as

metalaxyl, in or on pineapple (peeled fruit) harvested 481-604 days following one preplant crown dip of the 2 lb/gal EC formulation at 1 or 2 lb ai/100 gal (1-2x the maximum registered application rate). Total metalaxyl residues in or on nine treated samples (peeled fruit) and four untreated control samples were nondetectable (<0.05 ppm). Samples were analyzed using an adequate GLC analytical method (no. AG-348) with a limit of detection of 0.05 ppm. Recoveries were 42-104% from six peeled fruit samples fortified with 0.05-0.1 ppm of metalaxyl. Samples were stored frozen for ca. 277-679 days prior to analysis.

Ciba-Geigy Corp. (1979-81; MRID 00109472) submitted data from six tests conducted in HI concerning the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on pineapple shells and fodder harvested 481-604 days following one preplant crown dip of the 2 lb/gal EC formulation at 1 or 2 lb ai/100 gal (1-2x the maximum registered application rate). Total metalaxyl residues in or on 10 samples each of pineapple shells and fodder were nondetectable (<0.05 ppm). Total metalaxyl residues in or on four control samples each of shells and fodder were <0.05 ppm (nondetectable). Samples were analyzed using an adequate GLC analytical method (no. AG-348) with a limit of detection of 0.05 ppm. Recoveries were 63-90% from shells (six samples) and 60-110% from fodder (eight samples) fortified with metalaxyl at 0.05-0.5 ppm. Samples were stored frozen for ca. 277-679 days prior to analysis.

Geographic representation was adequate since the test state of HI accounted for virtually 100% of the 1982 U.S. pineapple production (1982 Census of Agriculture, Vol. 1, Part 51, p. 383). These data indicate that registered use of metalaxyl on pineapples will not result in residues in or on pineapples and pineapple forage in excess of 0.1 ppm. However, data were not submitted depicting metalaxyl residues in processed commodities of pineapple. Additional data are required.

Sunflower seed and forage

Tolerances:

Tolerances of 0.1 ppm have been established for the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on sunflowers and sunflower forage (40 CFR 180.408[a]).

Use directions and limitations:

The 2 lb/gal EC and 2.6b lb/gal FlC formulations are federally registered for use as a seed treatment to sunflower seed at 0.2b-0.5 oz ai/100 lb of seed and 1 oz ai/100 lb of seed, respectively, using conventional slurry or misting equipment.

Conclusions:

The available data are adequate to support the established tolerances of 0.1 ppm each for total metalaxyl residues in or on sunflower seed and sunflower forage. However, data were not submitted depicting residues in processed commodities of sunflowers. The following are required:

- o Data depicting metalaxyl residues of concern in meal, hulls, crude oil and refined oil processed from sunflower seed bearing measurable, weathered residues. If residues concentrate in any of these commodities then appropriate food/feed additive tolerances must be proposed.

No Canadian or Mexican tolerances exist for residues of metalaxyl in or on sunflower seed. A proposed Codex MRL (step 6) of 0.05 ppm exists for residues of metalaxyl *per se* in or on sunflower seed. Compatibility with the Codex MRL is not possible without a major revision of the U.S. residue definition, which is dependent upon toxicological considerations.

References (used):

MRID: 00128102.

Discussion of the data:

Ciba-Geigy Corp. (1982; MRID 00128102) submitted data (report no. ABR-82078) pertaining to ^{14}C-residues of metalaxyl in or on sunflower seeds and stalks following seed treatment with uniformly ring-labeled [^{14}C]metalaxyl (as the 2 lb/gal EC formulation) at 0.5-2 oz ai/100 lb seed (0.5-2x the maximum registered seed treatment rate). (Refer to the "Nature of the Residue in Plants" section for experimental details.) Seeds were planted in a NE field plot; seeds and stalks were harvested 60 days after planting and at maturity. The registrant reported limits of "quantitation" were 0.028-0.075 ppm of metalaxyl equivalents. Maximum ^{14}C-residues of metalaxyl in or on two samples of mature sunflower seed and stalks were <0.053-<0.067 and <0.072-<0.074 ppm, respectively. The available data depicting ^{14}C-residues of metalaxyl in sunflower seeds and stalks are adequate to support

the established tolerances of 0.1 ppm in or on sunflower seeds and sunflower forage. However, data were not submitted depicting residues in sunflower processed commodities. Additional data are required.

Tobacco

Tolerance:

N/A (nonfood use).

Use directions and limitations:

The 2 lb/gal EC formulation is registered for preplant broadcast soil application to tobacco plant beds at 0.5 lb ai/A (in 50 gal of water). Applications may be made before, or at, the time of seeding to the surface of the plant bed and may be lightly incorporated or followed with one-half inch of sprinkler irrigation water. (In PA, 1 lb ai/A may be used.) The 2 lb/gal EC formulation is also registered for broadcast soil-incorporated application to field planted tobacco at 0.5-1 lb ai/A or 1-3 lb ai/A (in 15 gal of water). In addition, the 2 lb/gal EC formulation is registered for multiple foliar applications in the plant bed, and in the field, at 0.25 lb ai/A or 0.125 oz ai/150 sq yd of bed (EPA SLN Nos. FL-810017, GA-81004, KY-81003, MD-810014, NC-810011, PA-81008, SC-81001, TN-810016, and VA-81007). In FL, GA, KY, MD, NC, PA, TN, and VA, metalaxyl may be applied in 50 gal of water beginning either 70 days after transplanting or initial soil treatment and may be repeated at 7-day intervals until the bed is destroyed. In SC, the compound may be applied in 125-250 gal of water as a foliar spray beginning 70 days after transplanting, or initial soil treatment, and may be repeated 14 days later. A maximum of 3 lb ai/A per season is permitted including plant bed and field treatments.

Conclusions:

It has previously been determined that the available data are adequate to assess the exposure of humans to total metalaxyl residues in tobacco, and that the nature of the residue in tobacco is adequately understood (refer to the Metalaxyl Guidance Document issued December 1981). No additional data are required.

References (used):

MRID: 00148440.

References (not used):

[The following reference has been previously examined and judged inappropriate for use in the original Metalaxyl Guidance Document issued December 1981.]

MRID: 00140371.

Discussion of the data:

Ciba-Geigy Corp. (1981; MRID 00148440) submitted data from two tests conducted in FL concerning the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on flue-cured tobacco harvested 81-110 days following one preplant broadcast soil-incorporated application of the 2 lb/gal or the 5% G formulation at 3 lb ai/A (1x the maximum registered single application rate). Total metalaxyl residues in or on 12 samples of flue-cured tobacco leaves were <1.0(nondetectable)-2.8 ppm. Two control samples bore <1.0 ppm (nondetectable) of metalaxyl residues. Residues were determined using GC/MS analysis (gas chromatography/mass-spectroscopy) with a stated limit of detection of 1 ppm. Recovery of metalaxyl was 51-74% from two samples fortified with 1 ppm of metalaxyl. Samples were stored frozen for ca. 98 days prior to analysis.

Ciba-Geigy Corp. (1981; MRID 00148440) submitted data from two tests conducted in FL concerning the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on burley tobacco harvested 78-days following one preplant broadcast soil-incorporated application of the 5% G or 2 lb/gal EC formulations at 3 lb ai/A (1x the maximum registered single application rate). Four samples of burley tobacco leaves bore <1.0(nondetectable)-2.1 ppm of total metalaxyl residues. Apparent residues in or on one control sample were nondetectable (<1.0 ppm). Samples were analyzed using GC/MS analysis. The limit of detection of the method was stated to be 1 ppm. Recovery of metalaxyl was 53% from one sample fortified at 1 ppm. Samples were stored frozen for ca. 82 days prior to analysis.

It has been previously determined that the available data are adequate to assess the exposure of humans to total metalaxyl residues in or on tobacco and that the nature of the residues in tobacco is adequately understood (refer to the Metalaxyl Guidance Document issued December 1981). Additional data are not required.

Indirect or Inadvertent Tolerances

Tolerances:

Indirect or inadvertent tolerances have been established for total residues of metalaxyl at: 2 ppm in or on wheat forage, fodder, and straw (40 CFR 180.408[b]); 0.2 ppm in or on wheat grain (40 CFR 180.408[b]); and 1 ppm in wheat milling fractions (21 CFR 561.273[b] and 21 CFR 193.277[b]).

Note to the PM: The tolerance definitions in 40 CFR 180.408[a], 21 CFR 561.273[a], and 21 CFR 193.277[a] differ from the tolerance definitions in 40 CFR 180.408[b], 21 CFR 561.273[b], and 21 CFR 193.277[b], respectively. We strongly recommend that the tolerance definitions in 40 CFR 180.408[b], 21 CFR 561.273[b], and 21 CFR 193.277[b] be modified from "...residues of metalaxyl..." to "... combined residues of the fungicide metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl..." to make the tolerance definitions in 40 CFR 180.408[b], 21 CFR 561.273[b], and 21 CFR 193.277[b] identical to those in 40 CFR 180.408[a], 21 CFR 561.273[a], and 21 CFR 193.277[a], respectively.

Use directions and limitations:

Wheat may be grown as a rotational crop following application of the 5% G and 2 lb/gal EC formulations to the growing crops listed in the 40 CFR 180.408[a] and other nonfood crops. Wheat may be planted 14 days after the last application of the 5% G formulation and "during the fall following application" of the 2 lb/gal EC formulation. No specific time restrictions exist with respect to the last of application of the 2 lb/gal EC formulation to the primary crop and planting of the rotational wheat crop.

Conclusions:

The available data from processing studies using wheat grain bearing measurable, weathered residues adequately support the established tolerance for metalaxyl residues in the milled products of wheat following indirect or inadvertent exposure. In addition, the available data are sufficient to support the established tolerance for metalaxyl residues in or on the forage, fodder, straw, and grain of rotational wheat due to indirect or inadvertent exposure following application of the 2 lb/gal EC formulation. Data were not submitted depicting total metalaxyl residues in or on wheat fodder. However, this requirement will be waived since residue data for forage and straw were from tests conducted at exaggerated rates (preemergence treatment to wheat).
We note that the 2 lb/gal EC label does not specify an interval for planting of the rotational wheat crop after the last treatment to the target crop or prohibit rotation of wheat following application to target crops. The following is required:

- o The registrant must propose specific time restrictions with respect to the last application of the 2 lb/gal EC formulation to the primary crops and planting of the rotational wheat crop. Based on the available data, we recommend an interval of 14 days.

No Canadian or Mexican tolerance or Codex MRL is established for metalaxyl residues in or on forage, fodder, straw, grain, and milled products of wheat. Therefore, no compatibility questions exist with respect to the Codex MRL.

References (used):

MRIDs: 00071672. 00104387. 00114376.

Discussion of the data:

Ciba-Geigy Corp. (1977-1980; MRIDs 00071672, 00104387, 00114376) submitted data from 28 tests conducted in AL(2), CA(2), GA(4), IA(1), KY(4), MD(1), MI(1), MO(1), MS(2), NC(2), NY(6), PA(1), and WA(1) depicting total metalaxyl residues in or on wheat and rye forage, straw, and grain harvested following preemergence treatment and/or grown in rotation to the primary crops of potatoes, soybeans, and tobacco. Treatments included: (i) the 2 lb/gal EC formulation in preemergent or preplant incorporated (PPI) applications at 1 and 2 lb ai/A to winter wheat alone or following 2 and 4 lb ai/A (1.45-2.91x the maximum rate per treated acre for the 2 lb/gal EC) preemergent or PPI applications to the primary soybean crop; (ii) the 2 lb/gal EC or an unregistered (50W; undefined) formulation in six foliar applications at 0.5 or 1 lb ai/A/application (2.5-5x the maximum single foliar application rate for the 10% WP) to the primary potato crop; and (iii) an unregistered formulation (50W) in PPI treatments at 0.5, 3, or 6 lb ai/A (0.17-2x the maximum rate for the 2 lb/gal EC) to the soil in which the primary tobacco crop was planted. [None of these treatments are currently registered for these primary crops.] Respective posttreatment intervals for early (fall) forage, late (spring) forage, and straw/grain were: (i) 56-70, 124-175, and 209-259 days for preemergent treatments to wheat; (ii) 68-175, 242-420, and 294-422 days for the first wheat rotational crop; (iii) 448-603, 649-731, and 711-772 days for the second wheat rotational crop; and (iv) 48, 224, and 301 days for a rye rotational crop. (Residue data for rye may be translated to wheat.) Residue data are presented by treatment regime. Since treatments to the primary crops tobacco and potato are different, residue data for rotational plantings of wheat are reported separately.

Preemergence treatments to wheat: Residues of total metalaxyl were 0.24-1.6 ppm in or on early forage, <0.05(nondetectable)-1.0 ppm in or on late forage, 0.05-1.2 ppm in or on straw, and <0.05(nondetectable)-0.18 ppm in or on grain following preemergence treatments to wheat at 1 lb ai/A.

Discussion of the data:

Following preemergence treatments at 2 lb ai/A, total metalaxyl residues were 1.5-2.8 ppm in on early forage, 0.07-0.98 ppm in or on late forage, registrant reported interference for three grain samples and one forage sample analyzed by method no. AG-348. Data for two of these samples were reported inconsistently in different tables of reports AG-A 5915 and 6209 (MRID 00071672) as interference or 0.05-0.07 ppm residues. We note that residues in or on wheat products harvested from plots in which both primary and rotational crops were treated were lower than residues in or on samples from preemergent treatment to the rotational crop only. Confirmatory data were generated by gas chromatography-mass spectrometry (GC/MS) for four wheat grain samples from preemergence treatments at 1 lb ai/A of the 2 lb/gal EC. Residues of total metalaxyl in or on grain were 0.05-0.16 ppm by GC/MS as compared to 0.06-0.18 ppm by method no. AG-348. Three control grain samples bore residues of <0.05(nondetectable)-0.07 ppm by GC/MS and <0.05(nondetectable)-0.14 ppm by method no. AG-348.

Multiple foliar treatments to the primary crop potato: Residues in or on wheat products from respective 1st and 2nd rotational crops following six foliar treatments at 0.5 lb ai/A to the primary crop potato were 0.9-1 ppm and 0.09 ppm in or on early forage, <0.05(nondetectable)-0.55 ppm and 0.11 ppm in or on late forage, 0.06-0.56 ppm and 0.28 ppm in or on straw, and <0.05(nondetectable)-0.19 ppm and <0.05 ppm (nondetectable) in or on grain. After six foliar treatments at 1 lb ai/A to the primary crop potato, respective residues from 1st and 2nd rotational wheat crops were 1.5 ppm and 0.09 ppm in or on early forage, 0.61 ppm and 0.58 ppm in or on late forage, 1.1 ppm and 1.4 ppm in or on straw, and 0.44 ppm and 0.15 ppm in or on grain. Residues were 0.28 ppm in or on early forage, 0.19 ppm in or on late forage, 0.18 ppm in or on straw, and 0.06 ppm in or on grain of the rotational crop rye grown following the primary potato crop treated in six foliar applications at 0.5 lb ai/A.

Preemergent treatments to the primary crop tobacco: Residues in or on wheat products from respective 1st and 2nd rotational crops following preemergent/PPI treatment at 3 lb ai/A to the primary crop tobacco were <0.05 ppm (nondetectable) and <0.05(nondetectable)-0.06 ppm in or on early forage, <0.05(nondetectable)-0.18 ppm and 0.07-0.51 ppm in or on late forage, <0.05(nondetectable)-0.52 and 0.05-0.08 ppm in or on straw, and <0.05(nondetectable)-0.11 and ≤0.05 ppm in or on grain. After preemergent treatment at 6 lb ai/A to the primary crop tobacco, residues in or on wheat products from the respective 1st and 2nd rotational crops were 0.35 ppm and 0.13 ppm in or on early forage, 0.12-0.16 ppm and 0.06 ppm in or on late forage, <0.05(nondetectable)-1.0 ppm and 0.11 ppm in or on straw, and <0.05(nondetectable)-0.11 ppm and <0.05 ppm (nondetectable) in or on grain.

Summary of residue data: Samples were stored frozen for 1-33 months before analysis by adequate GLC methods (nos. AG-330 or AG-348) or by a confirmatory GC/MS method (described in CAL report of Jan. 30, 19??) with response monitoring at m/e 148 and m/e 267. Control samples bore total metalaxyl residues of: (i) <0.05 ppm (nondetectable) in or on one to three samples each of forage, straw, and grain analyzed by method no. AG-330;

(nondetectable)-0.32 ppm in or on 19 samples of straw, and <0.05 (nondetectable)-0.18 ppm in or on 20 samples of grain analyzed by method no. AG-348; and (iii) <0.05(nondetectable)-0.07 ppm in or on three grain samples by GC/MS. We note that residues approaching the 0.2 ppm tolerance level were detected in or on five control grain samples (0.09-0.18 ppm). Recoveries were 61-78%, 69%, and 95% from one to three samples each of forage, straw, and grain, respectively, at fortification levels of 0.05-0.8 ppm, by method no. AG-330 and 33-85%, 47-87%, and 39-94% from 21-28 samples each of forage, straw, and grain, respectively, at fortification levels of 0.05-2 ppm, by method no. AG-348. No data depicting storage stability of total metalaxyl residues in or on wheat products were submitted.

The test states of AL(<1%), CA(2%), GA(1%), IA(<1%), KY(<1%), MD(<1%), MI(2%), MO(3%), MS(<1%), NC(1%), NY(<1%), PA(<1%), and WA(6%) collectively accounted for 15% of 1984 U.S. production; geographical representation is adequate (ca. 65% total 1984 production) if the neighboring states of AR(2%), ID(3%), IL(3%), KS(17%), MN(5%), NE(3%), OH(2%), OK(7%), OR(3%), and SD(5%) are representative of the tests (Agricultural Statistics, 1985, p. 5).

Ciba-Geigy Corp. (1980-1982; MRID 00114376) submitted data depicting total metalaxyl residues in milled products of wheat grain from three tests that included preemergence treatments of wheat with the 2 lb/gal EC formulation at 1-2 lb ai/A alone and in combination with a PPI treatment at 4 lb ai/A to a primary soybean crop. No details of the milling process were provided. Residues in or on grain harvested 246-252 days following the last treatment, preemergent treatment to wheat, were <0.05(nondetectable)-0.09 ppm. Residues of total metalaxyl in processed products of grain were 0.05-0.09 ppm in bran, 0.10-0.21 ppm in shorts, 0.12-0.25 ppm in red dog (middlings?), and <0.05(nondetectable)-0.14 ppm in flour. Concentration factors for each test were 1-1.8x for bran, 2.0-4.2x for shorts, 1.3-5x for red dog, and <1.0-2.8x for flour. Residues in control samples were <0.05(nondetectable), 0.10, 0.23, and 0.07 ppm in one sample each of bran, shorts, red dog, and flour, respectively, using method no. AG-348. We believe that residues are unlikely to exceed the tolerance for total metalaxyl residues in milled products of wheat following indirect or inadvertent exposure.

The available data are sufficient to support the established tolerances for total metalaxyl residues in or on wheat products as a result of indirect or inadvertent exposure following application of the 2 lb/gal EC formulation. No data were submitted depicting total metalaxyl residues in fodder of wheat due to indirect or inadvertent exposure. However, this requirement will be waived since residue data for forage and straw were from tests conducted at exaggerated rates. The label must specify an interval between the last application of the 2 lb/gal EC formulation to target crops and planting of the rotational wheat crop.

Seed Treatments

Use directions and limitations:

The 25% WP and 2.65 lb/gal FlC formulations are registered for use on the seeds of alfalfa, beans, black-eyed peas, buckwheat, clover, cowpeas, dill, kidney beans, lentils, lespedeza, lima beans, millet, milo, okra, peas, sorghum, soybeans, sunflowers, trefoil, velvet beans, and vetch at 0.5 oz ai/100 lb of seed and 0.25-0.50 oz ai/100 lb of seed, respectively. The 25% WP and 2.65 lb/gal FlC formulations are both registered for use at 0.25-0.50 oz ai/100 lb of seed on the seeds of barley, corn, cotton, forage grasses, oats, popcorn, rice, rye, sweet corn, and wheat. In addition, the 2.65 lb/gal FlC formulation is registered for use on pea seed at 1.12 oz ai/100 lb of seed and garden beet and sugar beet seed at 0.5 oz ai/100 lb of seed. The 2.65 lb/gal FlC formulation is also registered for seed treatment of peanuts at 0.25-0.50 oz ai/100 lb of seed and 0.5 lb ai/100 lb of seed. The 2.65 lb/gal FlC formulation is registered for use on sorghum and sunflower seed at 1 oz ai/100 lb of seed.

Conclusions:

The available radiotracer and non-radiotracer studies are adequate to indicate that uptake of metalaxyl residues from treated seed into the aerial portions of the growing crops (with the exception of beets) will not occur following registered seed treatment uses of metalaxyl. Additional data are not required.

Proposed Codex MRLs exist for residues of metalaxyl *per se* in or on: cereal grains, peas, sugar beets, and sunflower seed at 0.05 ppm (step 6); cottonseed at 0.05 ppm (step 3); and soybeans at 0.1 ppm (step 3). Compatibility is not possible without a major revision of the U.S. residue definition, which is dependent upon toxicological considerations. No Canadian or Mexican tolerances exist.

References (used):

MRIDs: 00071615. 00128102.

Discussion of the data:

Ciba-Geigy Corp. (1982; MRID 00128102) submitted data (report nos. ABR-81061 and ABR-82078) pertaining to ^{14}C-residues of metalaxyl in or on various crops following seed treatment with uniformly ring-labeled [^{14}C]metalaxyl (as the 2 lb/gal EC formulation). (Refer to the "Nature of the Residue in Plants" section for experimental details.) Seeds were planted in MS, NE, or NY field plots; residue data are summarized in Table 11.

Table 11. ^{14}C-Activity (ppm metalaxyl equivalents) in various commodities grown from seed treated with [^{14}C]metalaxyl.

Commodity	Application rate (oz ai/100 lb of seed)	f(x)[a]	^{14}C-Activity[b] (ppm metalaxyl equivalents)
Tomatoes[c]	0.5	N/A[d]	<0.074
Peppers[c]	0.5	N/A	<0.076
Cucumbers[c]	0.5	N/A	<0.063
Squash[c]	0.5	N/A	<0.031
Beet roots[c]	0.5	1	<0.031
Beet tops[c]	0.5	1	
60-day			0.044
Mature			<0.030
Lettuce[c]	0.5	N/A	
45-day			<0.043
Mature			<0.034
Cabbage[c]	0.5	N/A	
45-day			<0.036
Mature			<0.035
Peas[c]	1.25	1.12	
Stalks			<0.032
Pods			<0.035
Peas			<0.030
Sorghum[c]	1.0	1.0	
60-day stalks			<0.030
Mature stalks			<0.075
Grain			<0.065
Sunflowers[c]	0.5-2.0	0.05-2.0	
60-day stalks			<0.028, <0.029
Mature stalks			<0.072, <0.074
Seed			<0.053, <0.067
Rice[e]	0.5	N/A	
Stalks			0.057, 0.064
Hulls			<0.043, <0.044
Brown rice			<0.036, <0.036
Peanuts[e]	0.5	0.06	
18-week vines			0.066, 0.068
Mature vines			0.031, 0.035
Shells			<0.032, 0.035
Nuts			<0.034, <0.034
Soybeans[f]	0.5	1	
9-week forage			<0.033, <0.035
Mature stalks			0.062, 0.068
Pods			<0.031, <0.032
Beans			<0.035, 0.036

(Continued).

Table 11. (Continued).

Navy beans[f]	0.5	1	
10-week forage			<0.030, <0.032
Mature vines			0.050, 0.057
Pods			<0.034, <0.035
Beans			<0.031, <0.031
Peas[f]	0.5	0.45	
Vines			<0.069, <0.071
Pods			<0.035, <0.036
Peas			<0.030, <0.031
Sweet corn[f]	0.5	1	
Green forage			<0.031, <0.031
Cobs			<0.030, <0.031
Kernels			<0.032, <0.033

[a] Proportion of the maximum registered use rate.
[b] It is stated that "<" values are at a level too low for reliable quantitation.
[c] Grown in a NE field plot.
[d] N/A = Not applicable since there are no registered seed treatment uses on this crop.
[e] Grown in a MS field plot.
[f] Grown in a NY field plot.

Ciba-Geigy Corp. (1979; MRID 00071615) submitted data from six tests conducted in AL(2), AR(1), CA(1), and MS(2) pertaining to the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expresssed as metalaxyl, in or on cottonseed grown from seed that was treated with the 2 lb/gal EC formulation at 0.31-0.62 g ai/kg of seed (0.49-0.99 oz ai/100 lb of seed; 0.98-1.98x the maximum registered seed treatment rate for cotton). Plants were harvested 167-216 days after planting. Combined metalaxyl residues in or on 20 cottonseed samples (including six control samples) were <0.05 pm (nondetectable). Samples were analyzed using an adequate GLC analytical method (no. AG-348) with a stated limit of detection of 0.05 ppm. Recovery was 58-102% from seven cottonseed samples fortified with metalaxyl at 0.05-0.50 ppm. Samples were stored for 259-317 days prior to analysis.

The available radiotracer and non-radiotracer studies are adequate to indicate that uptake of metalaxyl residues from treated seed into the aerial portions of the growing crops (with the exception of beets) will not occur following registered seed treatment uses of metalaxyl. Additional data are not required.

Crops Grown Solely for Seed

Broccoli and cauliflower

Tolerances:

Tolerances of 2 ppm have been established for the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on broccoli and cauliflower following registered agricultural crop treatments (40 CFR 180.408[a]). No tolerances exist for these same residues in or on broccoli and cauliflower grown solely for seed.

Use directions and limitations:

The 35% WP formulation is registered for multiple foliar applications at 0.125-0.25 lb ai/A/application (0.7-1.4x the maximum single foliar application rate for agricultural crop treatment) to broccoli and cauliflower grown solely for seed in AZ as permitted by EPA SLN No. AZ-830001. Applications may be made in 25-100 gal/A using ground equipment and 5-10 gal/A using aerial equipment. Human and animal consumption of foliage and plant parts is prohibited. A 7-day PHI is in effect. No maximum seasonal use rate or maximum number of applications per season is specified.

Conclusions:

No data were submitted depicting total metalaxyl residues in or on broccoli and cauliflower treated with the 35% WP formulation and grown for seed. No tests using ground and/or aerial equipment were conducted in AZ to support the use permitted under EPA SLN No. AZ-830001. However, total residues were not tolerance exceeding in samples from tests conducted with the 2 lb/gal EC formulation at the 1.4 and 2.7x rates for foliar application to the agricultural crops of broccoli and cauliflower (refer to the "Brassica Leafy Vegetables Group" section for experimental details). We believe that residues are unlikely to exceed the established tolerances for total metalaxyl residues in or on broccoli and cauliflower crops grown from treated seed crops. Therefore, no data are required.

No Canadian or Mexican tolerances exist for residues of metalaxyl in or on broccoli or cauliflower. Codex MRLs of 0.5 ppm (step 6) each exist for residues of metalaxyl per se in or on broccoli and cauliflower. Compatibility with the Codex MRL is not possible without a major revision of the U.S. residue definition, which is dependent upon toxicological considerations.

References (used):

N/A.

Discussion of the data:

N/A.

Onions

Tolerances:

Tolerances of 3 and 10 ppm have been established for the combined residues of metalaxyl, its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on dry bulb and green onions, respectively (40 CFR 180.408[a]). No tolerances have been established for these same residues in or on dry bulb and green onions grown solely for seed.

Use directions and limitations:

The 2 lb/gal EC formulation is registered for at-planting broadcast or banded applications at 0.5-1 lb ai/A (not a registered use for agricultural onion crops). Broadcast applications may be incorporated in the top 2-4 inches of soil, and band applications may be made in 7-inch bands at proportionately lower rates (rate/treated A was unspecified).

Conclusions:

No data were submitted depicting total metalaxyl residues in or on dry bulb and green onions grown from treated seed. Total residues in or on dry bulb and green onions were not tolerance exceeding in samples from tests utilizing preemergence broadcast applications of the 2 lb/gal EC formulation at twice the rate for seed crop onions plus multiple foliar applications of the 10% WP formulation, for seasonal treatments of 2.6-3 lb ai/A/season (refer to the "Bulb Vegetables Group" section for experimental details). Therefore, we believe that residues are unlikely to exceed the established tolerances for total metalaxyl residues in or on dry bulb and green onion crops grown from treated seed crops. Therefore, no data are required.

No Canadian or Mexican tolerance or Codex MRL is established for residues of metalaxyl in or on onions. Therefore, no compatibility questions exist with respect to the Codex MRL.

References (used):

N/A.

Discussion of the data:

N/A.

Non-bearing Orchard Crops

Citrus fruits

Tolerance:

A tolerance of 1 ppm has been established for the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl in or on citrus fruit (40 CFR 180.408[a]) following treatment of bearing trees. Tolerances of 7 ppm each are established for the same residues in molasses, dried pulp, and oil of citrus fruits from bearing trees. No tolerances exist for these residues in citrus products following treatment of non-bearing trees.

Use directions and limitations:

The 2 lb/gal EC formulation is registered for use on nonbearing citrus or citrus nursery stock (trees that will not bear harvestable fruit for 12 months) as: (i) a soil drench at 1.5-3.75 oz ai/1,000 feet of row; (ii) a soil surface spray at 2 lb ai/A; (iii) a water ring drench at 0.05-0.15 oz ai/reset or new planting; and (iv) a soil-surface spray (beneath the tree canopy) at 2-4 lb ai/A. The 5% G formulation is also registered for use to the soil of seedbeds, liners, or bedded stock at 4 lb ai/treated acre at planting; applications may be at 3- and 6-month intervals after planting. These uses are identical to uses on bearing citrus trees.

Conclusions:

No data were submitted depicting residues in or on citrus products following use to non-bearing citrus trees or citrus nursery stock. However, no additional data are required for non-bearing uses since data for uses to bearing citrus trees will satisfy this requirement (refer to "Citrus Fruits Group" section for details).

No Canadian or Mexican tolerance is established for metalaxyl residues in or on citrus fruits. A Codex MRL (step 6) of 5 ppm has been established for residues of metalaxyl per se in or citrus fruits. Compatibility is not possible without a major revision of the U.S. residue definition, which is dependent upon toxicological considerations.

References (used):

N/A.

Discussion of the data:

N/A.

Pome Fruits

Tolerances:

Tolerances of 0.2, 0.4, and 2.0 ppm have been established for the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl in or on apples (40 CFR 180.408[a]), wet apple pomace (21 CFR 561.273[a]), and dry apple pomace (21 CFR 561.273[a]), respectively, following registered treatment of bearing trees. No tolerances exist for these residues combined in pome fruits following treatment of non-bearing/nursery stock trees within 12 months of treatment.

Use directions and limitations:

The 2 lb/gal EC and 5% G formulations are registered for multiple applications at 4-8 lb ai/A or 1.5-3 oz ai/1,000 sq ft to the soil under the canopy of non-bearing (trees that will not bear harvestable fruit for 12 months) pome fruit trees. Applications may be repeated at 3-month intervals as necessary throughout the growing season. Fruits may not be harvested for 12 months following the final treatment.

The 2 lb/gal EC formulation is also registered for use as a soil drench treatment at 1 quart of a 0.5 lb ai/100 gal solution/tree (0.12 lb ai/tree). Applications may be made in early spring and fall to the soil at the base of the trunks of non-bearing apple or apple nursery stock trees which will not bear harvestable fruit within 12 months of application. This treatment appears to the identical to the soil drench treatment registered for bearing apple trees.

Conclusions:

This is considered to be a non-food use. No additional data is needed.

No Canadian or Mexican tolerance is in effect for metalaxyl residues in or on pome fruits. A Codex MRL (step 6) of 0.05 ppm has been established for residues of metalaxyl per se in or on apples. Compatibility is not possible without a major revision of the U.S. residue definition, which is dependent upon toxicological considerations.

References (used):

N/A.

Discussion of the data:

N/A.

Stone fruits

Tolerance:

No tolerance has been established for the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on stone fruits following treatment of non-bearing/nursery stock trees within 12 months of treatment.

Use directions and limitations:

The 2 lb/gal EC and 5% G formulations are registered for multiple applications at 4-8 lb ai/A or 1.5-3 oz ai/1,000 sq ft to the soil under the canopy of non-bearing (trees that will not bear harvestable fruit for 12 months) stone fruit trees. Applications may be repeated at 3-month intervals as necessary throughout the growing season. Fruits may not be harvested for 12 months following the final treatment.

Conclusions:

This is considered to be a non-food use. No additional data is required.

No Canadian or Mexican tolerance or Codex MRL is in effect for metalaxyl residues in or on stone fruits. Therefore, no compatibility questions exist with respect to the Codex MRL.

References (used):

N/A.

Discussion of the data:

N/A.

Tree nuts

Tolerance:

No tolerance has been established for combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on tree nuts following treatment of non-bearing/nursery stock trees within 12 months of treatment.

Use directions and limitations:

The 2 lb/gal EC and 5% G formulations are registered for multiple applications at 4-8 lb ai/A or 1.5-3 oz ai/1,000 sq ft to the soil under the canopy of non-bearing nut trees (trees that will not bear harvestable fruit for 12 months) . Applications may be repeated at 3-month intervals as necessary throughout the growing season. Nuts may not be harvested for 12 months following the final treatment.

Conclusions:

This is considered to be a non- food use. No additional data is required.

No Canadian or Mexican tolerance or Codex MRL is in effect for metalaxyl residues in or on tree nuts. Therefore, no compatibility questions exist with respect to the Codex MRL.

References (used):

N/A.

Discussion of the data:

N/A.

Transplant Uses

Tolerance:

No tolerances exist for the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on broccoli, cabbage, cauliflower, cucumbers, lettuce, melons, spinach, squash, strawberries, and tomatoes following application to nursery stock or transplants.

Use directions and limitations:

The 2 lb/gal EC formulation is registered for use as a soil application to nursery stock or transplants of broccoli, cabbage, cauliflower, cucumbers, lettuce, melons, spinach, squash, and tomatoes at 0.5-1.0 lb ai/50 gal. The application may be made before or at the time of seeding at 2 gal/150 sq yd and may be lightly incorporated or followed with one-half inch of sprinkler irrigation water.

In addition, the 5% G formulation is registered for use as a soil application to nursery stock or transplants of cucumbers, melons, squash, and tomatoes at 0.5-1.0 lb ai/A (or 0.25-0.5 oz ai/150 sq yd). The application may be made before, or at, the time of seeding and may be lightly incorporated or followed with one-half inch of sprinkler irrigation water.

The 2 lb/gal EC formulation is also registered for foliar applications to strawberries (in CA only) at 1.0 lb ai/A (in 100-200 gal of water) one month after planting (EPA SLN No. CA-820024). A second application may be made 30 days later. There is no established PHI; there is a maximum seasonal use rate of 2.0 lb ai/A.

Conclusions:

Data were not submitted depicting combined metalaxyl residues in or on broccoli, cabbage, cauliflower, cucumbers, lettuce, melons, spinach, squash, and tomatoes following application to nursery stock or transplants. However, additional residue data are not required since registered post-transplant uses to these commodities are likely to result in higher residues compared to application to nursery stock or transplants. Data in support of the registered post-transplant uses will be adequate to support uses to nursery stock or transplants of these commodities.

A tolerance and use directions have been proposed for use of metalaxyl on strawberries (1986; PP#6F3337). It appears that the proposed use will probably result in higher residues in or on strawberries compared to the registered use to nursery stock or tranplants. Therefore, data submitted in support of the proposed use will be adequate to support uses to nursery stock or transplants of strawberries.

There are no Canadian or Mexican tolerances for residues of metalaxyl in or on broccoli, cabbage, cauliflower, cucumbers, lettuce, melons, spinach, squash, strawberries, and tomatoes. Codex MRLs (step 6) have been proposed for residues of metalaxyl per se in or on: broccoli cabbage, cauliflower, cucumbers, and tomatoes at 0.5 ppm; lettuce at 2 ppm; melons and squash, at 0.2 ppm; and spinach at 1 ppm. A Codex MRL (step 3) has been proposed for residues of metalaxyl per se in or on strawberries at 0.2 ppm. Compatibility is not possible without a major revision of the U.S residue definition, which is dependent upon toxicological considerations.

References (used):

N/A.

Discussion of data:

N/A.

MAGNITUDE OF THE RESIDUE IN MEAT, MILK, POULTRY, AND EGGS

Fat, meat, and meat by-products (except kidney and liver) of cattle, goats, hogs, horses, and sheep

Tolerances:

Tolerances of 0.05 ppm have been established for the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl in the meat and meat by-products (except kidney and liver) of cattle, goats, hogs, horses, and sheep. Tolerances of 0.4 ppm have been established for the same residues in the fat of cattle, goats, hogs, horses, and sheep (40 CFR 180.408[a]).

Conclusions:

It was previously determined (refer to the original Metalaxyl Guidance Document issued December 1981) that large animal feeding studies and tolerance proposals would be required for residues of metalaxyl in animal commodities if tolerances for residues in or on feed items were proposed. Such tolerances now exist and the dietary intake of residues of metalaxyl by beef cattle would be 16.1 ppm if: (i) the diet consisted of 25% peanut hay, 20% peanut vine, 25% dry tomato pomace, 15% dry citrus pulp, and 15% citrus molasses; (ii) residues in or on peanut hay and vines were each 20 ppm; and (iii) residues in citrus molasses, dry citrus pulp, and dry tomato pomace were 7, 7, and 20 ppm, respectively. The dietary intake of residues of metalaxyl by swine would be 2.91 ppm if: (i) the diet consisted of 10% peanut meal, 5% peanut soapstock, 50% processed potato waste, 1% dry citrus pulp, 20% soybean meal, 5% each of soybean hulls and soapstock, and 4% wheat milled by-products; (ii) residues in peanut meal and soapstock were 1 and 2 ppm, respectively; (iii) residues in processed potato waste, wheat milled by-products, and dry citrus pulp were 4, 1, and 7 ppm, respectively; and (iv) residues in or on soybean meal, hulls and soapstock were each 2 ppm. There are no established or proposed direct animal uses for the fungicide metalaxyl. The adequacy of the available data will not be assessed at the present time. A decision regarding the necessity for additional data is reserved for the following reason:

- Presently, the nature of the residue in animals is not adequately understood. On receipt of the data requested in the section entitled "Nature of the Residue in Animals," the appropriate nature of tolerances for residues in animal products will be determined and, with consideration for any newly found metabolites of toxicological concern, the adequacy of the available data regarding the magnitude of the residue in fat, meat, and meat by-products (except kidney and liver) of cattle, goats, hogs, horses, and sheep will be determined.

There are no Canadian or Mexican tolerances and no Codex MRL has been established for metalaxyl residues in fat, meat, and meat by-products (except kidney and liver) of cattle, goats, hogs, horses, and sheep. Therefore, no compatibility questions exist with respect to the Codex MRL.

References (used):

MRID: 00071674. 00114376.

Discussion of the data:

Ciba-Geigy Corp. (1980; MRID 00071674) submitted a study pertaining to the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester (each expressed as metalaxyl), in the fat and meat of lactating dairy cattle. This study was not reviewed in the original Metalaxyl Guidance Document issued December 1981. Twelve lactating cows were treated in the following manner. Three cows were orally dosed (in the feed) with 1.5 ppm of metalaxyl for 14, 21, or 28 consecutive days; four cows were orally dosed with 7.5 ppm of metalaxyl for 14, 21, 28, or 40 consecutive days; and three cows were orally dose with 15.0 ppm of metalaxyl for 14, 21, or 28 consecutive days. Cows were slaughtered and tissues were removed immediately after the dosing treatment ended. Two additional cows served as controls. Combined metalaxyl residues in nine samples each of meat and fat from all treated cows and two samples each from control cows were <0.05 ppm (nondetectable) in tenderloin, round muscle (eight samples only), perirenal fat, and omental fat. One additional round muscle sample collected from a cow dosed with 15 ppm of metalaxyl for 14 consecutive days contained combined metalaxyl residues of 0.05 ppm. An adequate GLC analytical method (no. AG-349) was used for analysis; the limit of detection was 0.05 ppm. Recovery from four meat samples (two tenderloin, two round muscle) spiked with 0.05 or 0.10 ppm of metalaxyl was 80-100% and 64-77%, respectively. Recovery from four fat samples (two perirenal, two omental) spiked with 0.05 or 0.10 ppm of metalaxyl was 50-87% and 67-70%, respectively. Meat and fat tissues were stored frozen (temperature unspecified) for 302-341 days prior to analysis.

Ciba-Geigy Corp. (1982; MRID 00114376) submitted a study pertaining to the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in the fat and meat of lactating dairy cattle. This study was not reviewed in the original Metalaxyl Guidance Document issued December 1981. Three lactating cows were orally dosed with a feed amendment (at 75 ppm in the diet) of metalaxyl for 14, 21, or 28 consecutive days and were sacrified within 24 hours of the final dose. An additional two cows served as controls and were sacrified at 14 and 28 days. Combined metalaxyl residues in five samples each (including two control samples) of omental and perirenal fat were <0.05 ppm (nondetectable). Combined metalaxyl residues in three tenderloin samples from dosed cows and two samples from control cows were <0.05(nondetectable)-0.09 ppm and <0.05 ppm (nondetectable), respectively. Combined metalaxyl residues in six round muscle samples from dosed cows and four samples from control cows were 0.06-0.14 ppm and 0.05-0.08 ppm, respectively. Samples were analyzed using an adequate GLC method (no. AG-349); the limit of detection was 0.05 ppm. Recovery was 53%, 63%, 90%, and 78% from one sample each of round muscle, tenderloin, perirenal fat, and omental fat, respectively, fortified with metalaxyl at 0.05-0.50 ppm. Samples were stored frozen (temperature unspecified) for 0.5-2 months prior to analysis.

Kidney and liver of cattle, goats, hogs, horses, and sheep

Tolerances:

Tolerances of 0.4 ppm have been established for the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in the kidney and liver of cattle, goats hogs, horses, and sheep (40 CFR 180.408[a]).

Conclusions:

It was previously determined (refer to the original Metalaxyl Guidance Document issued December 1981) that large animal feeding studies and tolerance proposals would be required for residues of metalaxyl in animal commodities if tolerances for residues in or on feed items were proposed. Such tolerances now exist and the dietary intake of metalaxyl residues for beef cattle and swine has been previously described in the "Fat, meat, and meat by-products (except kidney and liver) of cattle, goats, hogs, horses, and sheep" section. There are no established or proposed direct animal uses for the fungicide metalaxyl. The adequacy of the available data will not be assessed at the present time. A decision regarding the necessity for additional data is reserved for the following reason:

- Presently, the nature of the residue in animals is not adequately understood. On receipt of the data requested in the section entitled "Nature of the Residue in Animals," the appropriate nature of tolerances for residues in animal products will be determined and, with consideration for any newly found metabolites of toxicological concern, the adequacy of the available data regarding the magnitude of the residue in kidney and liver of cattle, goats, hogs, horses, and sheep will be determined.

There are no Canadian or Mexican tolerances, nor is there a Codex MRL for metalaxyl residues in kidney and liver of cattle, goats, hogs, horses, and sheep. Therefore, no compatibility questions exist with respect to the Codex MRL.

References (used):

MRIDs: 00071674. 00100753.

Discussion of the data:

Ciba-Geigy Corp. (1982; MRID 00100753) submitted a study pertaining to the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxy-acetyl)-alanine methyl ester, each expressed as metalaxyl, in the liver and kidney of dairy cattle and goats. This study was not reviewed in the original Metalaxyl Guidance Document issued December 1981. Three dairy cows were orally dosed with a feed amendment (at 75 ppm in the diet) of metalaxyl for 14, 21, or 28 consecutive days (refer to the "Fat, meat,

and meat by-products [except kidney and liver] of cattle, goats, hogs, horses, and sheep" section [MRID 00114376] for additional details). An additional two cows served as controls and were sacrificed at 14 and 28 days. Three goats were orally dosed (by gelatin capsules) at a level of 15 ppm of metalaxyl in the diet for three consecutive days. After administration of the last dose, goats were sacrificed at 4, 10, and 24 hours. Kidney and liver samples were taken from the slaughtered cows and goats. Results of the cow and goat tissue analysis were as follows. Control samples from cow kidney and liver (four samples each) bore <0.10 ppm (nondetectable) of apparent metalaxyl. Cow kidney samples contained 5.3-5.5 ppm, 0.11-0.13 ppm, and 0.11 ppm of combined metalaxyl at dosing days 14, 21, and 28, respectively (two samples/dosing day). Cow liver samples contained 0.82-1.1, 0.14, and <0.10(nondetectable)-0.12 ppm of combined metalaxyl at dosing days 14, 21, and 28, respectively (two samples/dosing day). Three goat kidney samples contained 0.57 ppm (4 hrs), 0.10 ppm (10 hrs), and <0.10 ppm (nondetectable) (24 hrs) of combined metalaxyl; liver samples had 0.13 ppm (4 hrs) and <0.10 ppm (nondetectable) (10 hrs and 24 hrs) with the time between dosing and sacrifice listed parenthetically (one sample/posttreatment interval). Samples of kidney and liver from cows and goats were analyzed by an adequate GLC method (no. AG-349; the limit of detection was 0.05 ppm). Recovery from samples fortified with metalaxyl was: (i) 77-81% and 58-74% from cow liver samples fortified with 0.10 and 1.0 ppm of metalaxyl, respectively (two samples/fortification level); (ii) 92-94% and 63-71% from cow kidney samples fortified with 0.1 and 1.0 ppm of metalaxyl, respectively (two samples/fortification level); (iii) 33% and 58% from goat liver samples fortified with metalaxyl at 0.1 and 1.0 ppm, respectively (one sample/ fortification level); and (iv) 72% and 64% from goat kidney fortified with metalaxyl of 0.1 and 1.0 ppm, respectively (one sample/ fortification level). The cow and goat samples were stored at 0 F (-17.8 C) for 8-22 days and 8-9 days, respectively prior to extraction.

Ciba-Geigy Corp. (1980; MRID 00071674) submitted a study pertaining to the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester (each expressed as metalaxyl), in the liver and kidney of lactating dairy cattle. This study was not reviewed in the original Metalaxyl Guidance Document issued December 1981. Twelve lactating cows were treated as described in the "Fat, meat, and meat by-products (except kidney and liver) of cattle, goats, hogs, horses and sheep" section (MRID 00071674). The results of the residues in liver and kidney are listed in Table 10 on page 107. An adequate GLC method was used (no. AG-349); the limit of detection was 0.05 ppm. Recoveries were 54-103% (average of 68%) from nine liver samples fortified with 0.10-0.20 ppm of metalaxyl; recoveries of metalaxyl from four kidney samples were 44-61% (average of 56%) following fortification with 0.10-0.50 ppm of metalaxyl. Samples were stored frozen for 28-66 days prior to extraction and analysis.

Table 10. Metalaxyl residues in liver and kidney of lactating dairy cattle.

Tissue	Dose level (ppm)	Total metalaxyl residues (ppm) on dose day: 14	21	28	40
Liver	0	<0.10[a]	--[b]	<0.10,<0.10	--
	1.5	0.11	<0.10,<0.10	<0.10,<0.10	--
	7.5	0.21	<0.10, 0.11	0.14,<0.10	0.22
	15.0	0.20	0.17, 0.13	0.17, 0.13	--
Kidney	0	<0.10	--	<0.10	--
	1.5	0.58,0.70,0.63	0.21	0.16	--
	7.5	0.35	0.32	0.32	0.47,0.57
	15.0	0.63,0.83	0.26	0.37	--

[a] Nondetectable.
[b] A dash signifies that there was no treatment for that day.

Milk

Tolerance:

A tolerance of 0.02 ppm has been established for the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in milk (40 CFR 180.408[a]).

Conclusions:

It was previously determined (refer to the original Metalaxyl Guidance Document issued December 1981) that large animal feeding studies and tolerance proposals would be required for residues of metalaxyl in animal commodities if tolerances for residues in or on feed items were proposed. Such tolerances now exist and the dietary intake of residues of metalaxyl by dairy cattle would be 18.1 ppm if: (i) the diet consisted of 60% peanut hay, 25% dry tomato pomace, 10% citrus molasses, and 5% dry citrus pulp; (ii) residues in or on peanut hay and dry tomato pomace each amounted to 20 ppm; and (iii) residues in citrus molasses and dry citrus pulp each amounted to 7 ppm. There are no established or proposed direct animal uses for the fungicide metalaxyl. The adequacy of the available data will not be assessed at the present time. A decision regarding the necessity for additional data is reserved for the following reason:

- Presently, the nature of the residue in animals is not adequately understood. Upon receipt of the data requested in the section entitled "Nature of the Residue in Animals," the appropriate nature of tolerances for residues in animal products will be determined and, with consideration for any newly found metabolites of toxicological concern, the adequacy of the available data regarding the magnitude of the residue in milk will be determined.

There are no Canadian or Mexican tolerances, nor is there a Codex MRL for metalaxyl residues in milk. Therefore, no compatibility questions exist with respect to the Codex MRL.

References (used):

MRID: 00071674. 00114376.

Discussion of the data:

Ciba-Geigy Corp. (1980; MRID 00071674) submitted a study pertaining to the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester (each expressed as metalaxyl), in the milk of lactating dairy cattle. This study was not reviewed in the original Metalaxyl Guidance Document issued December 1981. Twelve lactating cows were treated as described in the "Fat, meat, and meat by-products (except kidney and liver) of cattle, goats, hogs, horses, and sheep" section (MRID 00071674). Cows were milked twice daily until the time of sacrifice; milk samples collected at 7, 14, 21, 28, and 40 days were analyzed for combined metalaxyl residues. The results of residues in milk were <0.01 ppm (nondetectable) metalaxyl in all 22 milk samples from cows dosed at 7.5 and 15 ppm and four milk samples from control cows. An adequate GC method was used for analysis (no. AG-349); the limit of detection was 0.01 ppm. The percentage recoveries of milk samples spiked with 0.01, 0.02, and 0.105 of ppm metalaxyl were 52-71% (four samples), 56-76% (four samples), and 60-65% (two samples), respectively (number of samples listed parenthetically). Milk samples were stored frozen (temperature unspecified) for 98-142 days prior to extraction.

Ciba-Geigy Corp. (1982; MRID 00114376) submitted a study pertaining to the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in the milk of lactating dairy cattle. This study was not reviewed in the original Metalaxyl Guidance Document issued December 1981. Five lactating cows were treated as described in the "Fat, meat, and meat by-products (except kidney and liver) of cattle, goats, hogs, horses, and sheep" section (MRID 00114376). Cows were milked twice daily until sacrifice; residue data were reported for samples taken from cows on dosing days 1(3), 14(3), 20(2), and 27(2) (number of samples in parenthesis). Combined metalaxyl residues in all samples were 0.02 ppm. Three milk samples from control cows each contained combined metalaxyl residues of <0.01 ppm (nondetectable). Samples were analyzed using an adequate GLC method (no. AG-349); the limit of detection was 0.01 ppm. Samples were stored for an unreported period under unspecified conditions prior to analysis.

Poultry and eggs

Tolerances:

Tolerances of 0.4 ppm have been established for the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester,

each expressed as metalaxyl, in fat, kidney, and liver, and 0.05 ppm in meat and meat by-products (except kidney and liver). A tolerance of 0.05 ppm has been established for the same residues in eggs (40 CFR 180.408[a]).

Conclusions:

It was previously determined (refer to the original Metalaxyl Guidance Document issued December 1981) that large animal feeding studies and tolerance proposals would be required for residues of metalaxyl in animal commodities if tolerances for residues in or on feed items were proposed. Such tolerances now exist and the dietary intake of residues of metalaxyl by laying hens would be 1.73 ppm if: (i) the diet consisted of 20% cull potatoes, 50% soybean seed, 20% soybean meal, and 10% processed potato waste; (ii) residues in or on soybean seed, soybean meal and processed potato waste amounted to 1, 2, and 4 ppm respectively; and (iii) cull potatoes contain 23% dry matter ([0.5 ppm/0.23] x 0.20 = 0.43 ppm). The dietary intake of turkeys and broilers would be 0.94 ppm if: (i) the diet consisted of 30% soybean meal, 15% soybean seed, 5% soybean soapstock, 7% cull potatoes, and 43% wheat grain; (ii) residues in or on soybean meal, grain, and soapstock amounted to 1, 2, and 2 ppm, respectively; (iii) residues in or on wheat grain amounted to 0.2 ppm; and (iv) cull potatoes contain 23% dry matter ([0.5 ppm/0.23] x 0.07 = 0.15 ppm). There are no established or proposed direct animal uses for the fungicide metalaxyl. The adequacy of the available data will not be assessed at the present time. A decision regarding the necessity for additional data is reserved for the following reason:

- Presently, the nature of the residue in animals is not adequately understood. On receipt of the data requested in the section entitled "Nature of the Residue in Animals," the appropriate nature of tolerances for residues in animal products will be determined and, with consideration for any newly found metabolites of toxicological concern, the adequacy of the available data regarding the magnitude of the residue in poultry and eggs will be determined.

There are no Canadian or Mexican tolerances and no Codex MRL has been established for metalaxyl residues in poultry and eggs. Therefore, no compatibility questions exist with respect to the Codex MRL.

References (used):

MRID: 00071673.

Discussion of the data:

Ciba-Geigy Corp. (1980; MRID 00071673) submitted a study pertaining to the combined residues of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methyl)-N-(methoxyacetyl)-alanine methyl ester (each expressed as metalaxyl), in poultry and eggs. This study was not reviewed in the original Metalaxyl Guidance Document issued December 1981. Sixty egg-laying hens were treated in the following manner. Four groups of 15 birds were given the following treatments: non-treated (controls), 0.5 ppm of metalaxyl 1.5 ppm of metalaxyl, and 5.0 ppm of metalaxyl; treated birds received metalaxyl mixed into the feed rations.

Calculation Of Proposed Tolerances For Secondary Residues Of Asana® Insecticide

Poultry

The diet for a laying hen which would contain the maximum theoretical fenvalerate residue would be:

Feed Item	% In Diet	Tolerance (ppm)	Diet (ppm)
Sorghum Grain	60	5.0	3.00
Sugarcane Molasses	4	2.0	0.08
Sunflower Meal	15	1.0	0.15
Tomato Pomace, Wet	2	1.0	0.02
Pea Seed	19	0.25	0.05
	100		3.30

The diet for a turkey or broiler which would contain the maximum theoretical fenvalerate residue would be:

Feed Item	% In Diet	Tolerance (ppm)	Diet (ppm)
Apple Pomace, Dry	5	20	1.0
Sorghum Grain	60	5	3.0
Sugarcane Molasses	3	2	0.06
Sunflower Meal	15	1	0.15
Tomato Pomace, Wet	3	1	0.03
Pea Seed, Dry	10	0.25	0.03
Bean Seed, Dry	4	0.25	0.01
	100		4.28

Using the linear relationships between ppm fenvalerate fed (x) and ppm equivalent detected (y) as shown in Du Pont Report No. AMR-1461-89, the poultry nature and magnitude of the residue summary, the following equations predict secondary fenvalerate residues in poultry and products.

Eggs were collected at 0, 1, 3, 5, 7, 10, 14, 17, 21, 24, 25, 27, and 28 days, washed, and pooled by treatment. On the 7th, 14th, 21st, and 28th day of the test, three birds were sacrificed from each of the treatments. Fat, liver, skin, and lean meat were collected and pooled by treatment. The results of the residue analysis were as follows. Eight samples each of eggs, skin, fat, and breast and thigh muscle from hens dosed at 1.5 and 5.0 ppm and two samples each from control hens contained <0.05 ppm (nondetectable) of metalaxyl; eight liver samples from hens dosed at the 1.5 and 5.0 ppm dose levels and two liver samples from control hens had <0.1 ppm (nondetectable) of metalaxyl (one sample/dose level/sampling day). An adequate GC method (no. AG-349) was used for analysis; the limit of detection was 0.05 ppm in all tissues except liver which had a detection limit 0.1 ppm. Recovery from fortified eggs and tissues (two samples each) were: 40% (0.05 ppm) and 70% (0.50 ppm) from eggs, 87% (0.05 ppm) and 78% (0.50 ppm) from skin, 73% (0.40 and 0.50 ppm) from fat, 79% (0.10 ppm) and 64% (0.80 ppm) from liver, and 67% (0.05 ppm) and 74% (0.50 ppm) from breast and thigh muscle (metalaxyl fortification levels listed parenthetically). Eggs were separated into yolks and whites and were stored at 0 F (-17.8 C). Tissues were also stored at 0 F (-17.8 C); samples were stored for 35-54 days prior to solvent extraction.

REGULATORY INCIDENTS

No information has been received to date pertaining to regulatory incidents involving metalaxyl although the Registration Division (OPP, EPA) has requested such information (request dated 8/29/86). Also, no information has been received pertaining to metalaxyl residues in or on food commodities tested through FDA's residue monitoring program.

TOLERANCE REASSESSMENT SUMMARY

It should be noted that data gaps exist for animal metabolism and storage stability. Thus, on receipt of the data requested in these sections, the conclusions stated below regarding the adequacy of the established tolerances are subject to change. Furthermore, since the data required for individual commodities are dependent on the metabolism data, we recommend that metabolism data be obtained and submitted prior to any required residue data. [Tolerances for residues in animal commodities will not be assessed until the requested animal metabolism studies are completed and reviewed.]

Sufficient data are available to ascertain the adequacy of the established tolerances for residues of metalaxyl in or on: apples, avocados, beets, beet tops, broccoli, cabbage, cauliflower, citrus fruits, cottonseed, cucurbit vegetables, foliage of legume vegetables, fruiting vegetables, legume vegetables, lettuce, onions, pineapples, pineapple forage, potatoes, raspberries, soybeans, spinach, sugar beets, sugar beet tops, sunflower seed and wheat.

Insufficient data are available to ascertain the adequacy of the established tolerances for residues of metalaxyl in or on: field corn (grain, forage, and fodder), and peanuts (nuts, hulls, hay, and vines).

The registrant must: (i) propose a label amendment that specifies a maximum seasonal use rate or maximum number of applications per season for dry bulb onions; (ii) propose tolerances for total metalaxyl residues in or on soybean forage, hay, and straw; (iii) propose a preharvest interval following registered/proposed uses of metalaxyl on members of the Fruiting Vegetables Group; (iv) propose tolerances for total metalaxyl residues in dried hops and spent hops; and (v) propose a specific time restriction with respect to the last application of the 2 lb/gal EC formulation to primary crops and planting of rotational wheat.

Processing studies are required for field corn, cotton, pineapples, potatoes, rice, sorghum, sugar beets and sunflower.

In addition to the conclusions stated above regarding established tolerances, we recommend that: (i) the commodity entry "Legume Vegetable Group (dry and succulent)" be changed to "Legume Vegetables Group (dry and succulent), except soybeans"; (ii) the commodity entry "Foliage of the Legume Vegetables Group" be changed to "Foliage of the Legume Vegetables Group (except soybeans)"; (iii) the commodity entry "grain crops" be changed to "Cereal Grains (except wheat) Group"; (iv) the commodity entry "pineapple fodder" be revoked; (v) the commodity entries "potatoes, processed (including potato chips)" and "potato waste, dried, processed" be changed to the appropriate commodity definitions "granules," "chips," "wet peel," and "dry peel"; and (vi) the commodity entry "beet, tops" be changed to "beet greens".

The TAS figures are not currently available. These will be presented in an addendum to the Residue Chemistry Chapter.

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00156010. Balu, K. 1985. Ridomil groundwater monitoring study results during 1983-1984: Report no: EIR-85023. Unpublished compilation prepared by Ciba-Geigy Corp. 132 p.

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GENERIC DATA REQUIREMENTS FOR METALAXYL.

Data Requirement	Test Substance[1]	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Time Frame for Submission[2]
158.125 Residue Chemistry					
171-2. Chemical identity[3]					
171-3. Directions for use		(see Index)		Yes[4]	6 months
171-4. Nature of the residue (Metabolism)					
- Plants	PAIRA	Yes	00071603, 00071604, 00071605, 00071606, 00071607, 00071608, 00071609, 00071610, 00114379, 00128102.	No	
- Livestock	PAIRA	No		Yes[5]	18 months
171-4. Residue analytical method					
- Plant and animal residues	TGAI and Metabolites	Partially	00071622, 00071623, 00071676, 00104656, 00148440, 00157740, Arne (1982), Arne (1984), Corley (1982).	Yes[6]	15 months

(Continued).

GENERIC DATA REQUIREMENTS FOR METALAXYL. (Continued).

Data Requirement	Test Substance[1/]	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Time Frame for Submission[2/]
171-4. Storage stability data	PAI or TEP, and metabolites	Partially	00148440.	Yes[7/,8/]	18 months
171-4. Magnitude of the Residue					
- Crop field trials					
- Root and Tuber Vegetables Group					
o Beets		Yes	00128102.	No	
o Potatoes	TEP	Partially	00071616.	Yes[9/]	24 months
o Sugar beet roots	TEP	No	--	Yes[10/]	24 months
- Leaves of Root and Tuber Vegetables Group					
o Beet greens		Yes	00128102.	No	
o Sugar beet tops		No	--	No	
- Bulb Vegetables Group					
o Onions		Yes	00071615, 00098428, 00130694, 00148103.	No	
- Leafy Vegetables Group					
o Lettuce		Yes	00071615, 00097511, 00114377, 00130695.	No	

(Continued).

GENERIC DATA REQUIREMENTS FOR METALAXYL. (Continued).

Data Requirement	Test Substance[1/]	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Time Frame for Submission[2/]
o Spinach		Yes	00071672, 00114378, 00130695.	No	
- Brassica Leafy Vegetables Group					
o Broccoli		Yes	00071615, 00130773.	No	
o Cabbage		Yes	00071615, 00130773.	No	
o Cauliflower		Yes	00071615, 00130773.	No	
- Legume Vegetables Group		Yes	00129003.	No	
o Soybeans	TEP	Partially	00071672, 00104390, 00148440.	Yes[11/]	
- Foliage of the Legume Vegetables Group		Yes	00129003.	No	
- Fruiting Vegetables Group		Yes	00148103, 00148440, 00157480.	No	

(Continued).

GENERIC DATA REQUIREMENTS FOR METALAXYL. (Continued).

Data Requirement	Test Substance[1]	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Time Frame for Submission[2]
- Cucurbit Vegetables Group		Yes	00071615, 00098428, 00130693, 00148103.	No	
- Citrus Fruits Group		Yes	00117969, 00133020, 00148440.	No	
- Pome Fruits Group o Apples		Yes	00126315, 00141519.	No	
- Small Fruits and Berries Group o Raspberries		Yes	00127769.	No	
- Cereal Grains Group	TEP	Partially	00128102, 00071672, 00104387, 00114376.	Yes[12],[13]	18 months[12] 24 months[13]
- Forage, Fodder, and Straw of Cereal Grains Group	TEP	Partially	00128102.	Yes[14],[15],	18 months[14] 6 months[15]

(Continued).

GENERIC DATA REQUIREMENTS FOR METALAXYL. (Continued).

Data Requirement	Test Substance[1]	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Time Frame for Submission[2]
- Miscellaneous Commodities					
o Avocados		Yes	00074488.	No	
o Cottonseed	TEP	Partially	00109402.	Yes[16]	24 months
o Hops	TEP	Partially	00079433.	Yes[17]	24 months
o Peanuts	TEP	Partially	00128738.	Yes[18]	24 months
o Pineapples	TEP	Partially	00109472.	Yes[19]	24 months
o Sunflower seed	TEP	Partially	00128102.	Yes[20]	24 months
o Tobacco		Yes	00148440.	No	
- Non-bearing Orchard Crops					
o Pome fruits	TEP	Yes	--	No	
o Stone fruits	TEP	Yes	--		
o Tree nuts	TEP	Yes	--		
- Meat/milk/poultry/ eggs		Yes	00071674, 00114376, 00100753, 00071673.	Reserved[21]	

1/ Test Substance: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabeled; TEP = Typical end-use product; EP = End-use product.

2/ Data must be submitted within the indicated time frame, based on the date of this Guidance Document.

3/ Refer to Product Chemistry Data Requirement tables.

4/ The registrant must propose (i) a label amendment that specifies a maximum seasonal use rate or maximum number of applications per season for dry bulb onions; based on the available data, we recommend a maximum of four applications per season (ii) a preharvest interval following registered/propose uses of metalaxyl on members of the Fruiting Vegetables (except Cucurbits) Group; based on the available data, we recommend a 7-day preharvest interval. Also, refer to footnote 16 for additional required label amendments for wheat as a rotational crop.

5/ Metabolism studies utilizing ruminants and poultry in which animals must be dosed for a minimum of 3 days with [^{14}C]metalaxyl at a level sufficient to make residue identification and quantification possible. Milk a egg must be collected twice daily during the dosing period. Animals must be sacrificed within 24 hours of the final dose. The distribution and characterization of residues must be determined in milk, eggs, liver, kidney, and muscle and also skin and gizzard for hen. If the metabolism of metalaxyl in ruminants or poultry is found to differ from that in rats, or with each other, then swine metabolism data may be required. Data reflecting solvent extraction of residues are also required. Representative samples from the above described tests must also be analyzed by current enforcement methods to ascertain the validity of these methods.

6/ Metalaxyl metabolites containing the 2,6-dimethylaniline moiety and CGA-94689 in or on crop samples must be subjected to analysis by multiresidue protocols. Protocols for Methods I, II, III, and IV are available from the National Technical Information Service under order no. PB203734/AS.

7/ The storage intervals and conditions of samples used to support all established tolerances for residues must be submitted. These data must be accompanied by data depicting the percent decline in residues at the times and under the conditions specified. (No additional stability studies are required for plant commodities stored at 5 F (-15 C) for up to 12 months.) On receipt of these data, the adequacy of the aforementioned tolerances will be reevaluated.

8/ All residue data requested in this Standard must be accompanied by data regarding storage length and conditions of storage of samples analyzed. These data must be accompanied by data depicting the stability of residues under the conditions and for the time intervals specified, with the exception of plant commodities stored at 5 F (-15 C) for up to 12 months.

9/ Data depicting metalaxyl residues of concern in chips, granules or flakes, and wet and dry potato peel proce from potatoes bearing measurable, weathered residues. If residues concentrate in any of these processed commodities, appropriate food/feed additive tolerances must be proposed.

10/ Data depicting total metalaxyl residues of concern in molasses processed from sugar beets bearing measurable, weathered residues to support the established tolerance of 1.0 ppm in molasses. In addition, data must be submitted depicting metalaxyl residues of concern in dehydrated pulp and refined sugar processed from sugar beets bearing measurable, weathered residues. If residues are found to concentrate in either of these processed commodities, appropriate food/feed additive tolerances must be proposed.

11/ The registrant must propose tolerances for total metalaxyl residues in or on soybean forage, hay, and straw. We recommend a tolerance of 8 ppm, toxicological considerations permitting, based on the available data.

12/ Data depicting metalaxyl residues of concern in or on the grain of field corn harvested from seed treated with the 25% WP formulation at 0.5 oz ai/100 lb of seed.

13/ Data depicting metalaxyl residues of concern in milled products and grain dust from the milling process of: field corn (starch, crude and refined oils from wet milling and grits, meal, flour, crude and refined oils from dry milling); rice (hulls, bran, polished rice); and sorghum (flour, starch) grains bearing measurable, weathered residues. If residues concentrate during processing in any of these commodities, then appropriate food/feed additive tolerances must be proposed.

14/ Data depicting metalaxyl residues of concern in or on field corn forage and fodder grown from seed treated with the 25% WP formulation at 0.5 oz ai/100 lb of seed.

15/ The registrant must propose specific time restrictions with respect to the last application of the 2 lb/gal EC formulation to the primary crops and planting of the rotational wheat crop. Based on the available data, we recommend an interval of 14 days.

16/ Data depicting concentration of metalaxyl residues of concern during processing of cottonseed hulls, meal, crude oil, refined oil, and soapstock derived from cottonseed bearing measurable, weathered residues. (Exaggerated application rates may be necessary to obtain these levels on the cottonseed.) If concentration occurs during processing, the registrant must propose appropriate food/feed additive tolerances.

17/ The registrant must propose a tolerance for total metalaxyl residues in dried hops based on the concentration factor during drying of about 7x. The available data support a food additive tolerance of 4 ppm, toxicological considerations permitting. Based on the above recommendation the registrant must also propose a feed additive tolerance in spent hops at the same level as for dried hops.

18/ Data depicting metalaxyl residues of concern in or on nuts, hulls, hay, and vines from soil applications of a G formulation at 0.25 lb ai/A (at-planting) and 1.0 lb ai/13,000 linear ft of row (at pegging). Tests must be conducted in AL(15%), GA(49%), NC(10%), OK(4%), and VA(6%), states which collectively producted ca. 84% of 1984 U.S. peanut product (Agricultural Statistics, 1985, p. 121).

19/ Data from a processing study depicting metalaxyl residues of concern in pineapple juice and pineapple bran (chopped, dehydrated pineapple tops and shells) processed from pineapple fruit bearing measurable, weathered residues. If residues concentrate in any of these processed commodities, then appropriate food/feed additive tolerances must be proposed.

20/ Data depicting metalaxyl residues of concern in meal, hulls, crude oil and refined oil processed from sunflower seed bearing measurable, weathered residues. If residues concentrate in any of these commodities then appropriate food/feed additive tolerances must be proposed.

21/ Presently, the nature of the residue in animals is not adequately understood. On receipt of the data requested in the section entitled "Nature of the Residue in Animals", the appropriate nature of tolerances for residues in animal products will be determined and, with consideration for any newly found metabolites of toxicological concern, the adequacy of the available data regarding the magnitude of the residue in animal commodities (milk, poultry, eggs, fat, meat, liver, and kidney) will be determined.

original

DYNAMAC
CORPORATION

Final Report

Metalaxyl (FRSTR)
Task 1: Product Chemistry Chapter

Contract No. 68-02-4226

June 12, 1987

Submitted to:
Environmental Protection Agency
Arlington, VA 22202

Submitted by:
Dynamac Corporation
The Dynamac Building
11140 Rockville Pike
Rockville, MD 20852

METALAXYL

PRODUCT CHEMISTRY

TASK 1

INTRODUCTION

FIFRA 3(c)(2)(A) required the Agency to establish guidelines for registering pesticides in the United States. The Agency requires registrants to provide quantitative data on all added ingredients, active and inert, which are equal to or greater than 0.1% of the product by weight.

To establish the composition of products proposed for registration, the Agency requires data and information not only on the manufacturing and formulation process, but also a discussion on the formation of manufacturing impurities and other product ingredients, intentional and unintentional. Furthermore, to assure that the composition of the product as marketed will not vary from the composition evaluated at the time of registration, applicants are required to submit a statement certifying upper and lower composition limits for the added ingredients, and upper limits for some unintentional ingredients. Subdivision D of the Pesticide Assessment guidelines (October 1982) suggests specific precision limits for ingredients based on the variability of the ingredients as a function of the manufacturing process.

In addition to the data on product composition, the Agency also requires data to establish the physical and chemical properties of both the pesticide active ingredient and its formulations. For example, data are needed concerning the identity and physical state of the active ingredient (e.g., melting and boiling points, ambient vapor pressure and solubility). Corresponding to each of the Topical Discussions listed below is the Guidelines Reference No. in "Data Requirements for Pesticide Registration" (40 CFR 158.120), which explains the minimum data the Agency will need to adequately assess the product chemistry of metalaxyl.

	Guidelines Reference No. of 40 CFR 158.120
Product Identity and Composition	61-(1-3)
Analysis and Certification of Product Ingredients	62-(1-3)
Physical and Chemical Characteristics	63-(2-21)

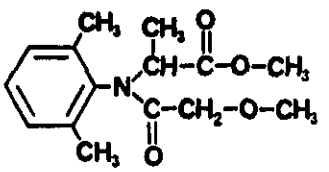
It should be noted that although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore, in this chapter, available product chemistry data will be summarized for the technical grade of the active ingredient only. These data will be evaluated with regard to their adequacy in meeting the requirements of 40 CFR Part 158.120 because this document is a Final Registration Standard and Tolerance Reassessment

(FRSTR). We note that the Confidential Appendixes for the Metalaxyl Registration Standard (Guidance Document) dated December 1981 were not available for this review.

PRODUCT IDENTITY AND COMPOSITION

61-1. Product Identity and Disclosure of Ingredients

Metalaxyl is the BSI-, E-ISO-, F-ISO-, and ANSI-approved common name for a fungicide registered in the U.S. as a technical product by Ciba-Geigy Corp. The structure is depicted below.



The chemical name (IUPAC) for metalaxyl is methyl N-(2-methoxylacetyl)-N-(2,6-xylyl)-DL-alaninate. Other names include: Methyl N-(2,6-dimethylphenyl)-N-(2-methoxyacetyl)-DL-alaninate (CA; 9CI); Ridomil; Apron; Fubol; and CGA-48988.

Other identifying characteristics and codes are:

Empirical Formula:	$C_{15}H_{21}NO_4$
Molecular Weight:	279.3
CAS Registry No.:	57837-19-1
Shaughnessy No.:	113501

[The above information was obtained from the Pesticide Manufacturing and Toxic Materials Control Encyclopedia, 1980, pp. 500-501, and The Pesticide Manual, 1983, p. 799D.]

It has been previously determined that the available data for the 90% technical (T) satisfy the requirements of the 1978 Proposed Guidelines, sec. 163.61-3 (refer to the Metalaxyl Registration Standard [Guidance Document] dated December 1981). Refer to Appendix A for an updated Confidential Statement of Formula for the 90% technical, EPA Reg. No. 100-601, which is the only registered metalaxyl manufacturing-use product.

61-2. Description of Beginning Materials and Manufacturing Process

The following manufacturing processes are published in Marshall Sittig's "Pesticide Manufacturing and Toxic Materials Control Encyclopedia," pp. 500-501.

> "(A) A mixture of 100 g of 2,6-dimethylaniline, 223 g of 2-bromopropionic acid methyl ester and 84 g of $NaHCO_3$ was stirred for 17 hours at 140°C, then cooled, diluted with 300 ml of water and extracted with diethyl ether. The extract was washed with a small amount of water, dried

over sodium sulfate, filtered, and the ether evaporated. After the excess 2-bromopropionic acid methyl ester had been distilled off, the crude product was distilled in a high vacuum.

"(B) A mixture of 11 g of the ester obtained according to (A), 6.5 g of methoxyacetyl chloride, 2 ml of dimethyl formamide, and 250 ml of absolute toluene was stirred at room temperature and refluxed for 1 hour. The solvent was evaporated off, and the crude product then distilled in vacuo.

The D-forms of both cis-trans-isomers were obtained by acylating the pure D-form of alpha-(2,6-dimethylanilino)-propionic acid methyl ester with methoxyacetic acid or with one of the reactive derivatives thereof."

It has been previously determined that the available data for the 90% T satisfy the requirements of the 1978 Proposed Guidelines, sec. 163.61-4 (refer to the Metalaxyl Registration Standard [Guidance Document] dated December 1981). However, an inconsistency in the Guidance Document was noted. Additional requirements were listed in a footnote to Table 2 which the registrant has not satisfied. Refer to Confidential Appendix B for a discussion of the manufacturing process used to produce Ciba-Geigy's 90% technical product. We could not verify that this process was reviewed in the Metalaxyl Registration Standard (Guidance Document) issued December 1981. The following are required:

- o Complete information must be provided regarding the nature of the process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, the chemical equations for each intended reaction, equipment used to produce each intermediate and the final product, reaction conditions, the duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each beginning material must be provided, along with information regarding the properties of each beginning material used to manufacture each product. In order to assess the potential for contamination with nitrosamines, a description of the manufacturing process conditions favoring formation of nitrosamines must be provided.

61-3. Discussion of the Formation of Impurities

It has been previously determined that the available data for the 90% T do not satisfy the requirements of the 1978 Proposed Guidelines, sec. 161.61-5 (refer to the Metalaxyl Registration Standard [Guidance Document] dated December 1981). Refer to Confidential Appendix C for a discussion of the formation of impurities in the 90% technical product. The following additional information is required:

- o A detailed discussion of all impurities that are or may be present at $\geq$0.1%, based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production must be submitted. This

discussion must also address the possible formation of nitrosamines from metalaxyl and its impurities.

ANALYSIS AND CERTIFICATION OF PRODUCT INGREDIENTS

62-1. Preliminary Analysis

It has been previously determined that the available data for the 90% T satisfy the requirements of the 1978 Proposed Guidelines, sec. 161.61-7 (refer to Table 2 of the Metalaxyl Registration Standard [Guidance Document] dated December 1981). However, we note an inconsistency in the Guidance Document. Data for preliminary analyses of metalaxyl technical were required under the "Product Analytical Methods and Data" section. Refer to Confidential Appendix D for a discussion of the preliminary analysis of Ciba-Geigy's 90% technical product. The following are required:

- o Five or more representative samples must be analyzed for the amount of active ingredient and each impurity for which a certified limit is required. Complete validation data (accuracy, precision) must be submitted for each analytical method used.

62-2. Certification of Ingredient Limits

It has been previously determined that the available data for the 90% T satisfy the requirements of the 1978 Proposed Guidelines, sec. 161.61-6 (refer to the Metalaxyl Registration Standard [Guidance Document] dated December 1981). No additional data have been submitted.

We note that current guidelines regarding Certification of Ingredient Limits have not been fulfilled. The following additional data are therefore required for the 90% T:

- o Upper and lower limits for metalaxyl must be provided, certified, and validated by sample analysis using analytical procedures for which accuracy and precision data have been provided.

- o Upper limits for each impurity present at $\geq$0.1% (w/w) and for each "toxicologically significant" impurity present at <0.1% (w/w) must be provided, certified, and validated by sample analysis using analytical procedures for which accuracy and precision data have been provided. [We defer to the Toxicology Branch regarding the toxicological significance of impurities present at <0.1% (w/w).]

- o All nitrosoamines must be identified and quantified in six samples of each product; two samples of each must be analyzed shortly after production, 3 months after production, and 6 months after production. A method sensitive to 1 ppm of N-nitroso contaminants must be used. An upper limit must be provided (and certified) for all nitrosoamines found.

- o Certifications should be submitted on EPA Form 8570 Rev. 2-85.

62-3. Analytical Methods to Verify Certified Limits

It has been previously determined that the available data for the 90% T satisfy the requirements of the 1978 Proposed Guidelines, sec. 163.61-7 (refer to the Metalaxyl Registration Standard [Guidance Document] dated December 1981). However, we note an inconsistency in this assessment. Additional requirements for methods for quantitative detection of any impurities in the technical were requested in a footnote to Table 2, and validation data (including preliminary analyses of five or more samples of technical metalaxyl) were requested in the "Product Analytical Methods and Data" section of the Guidance Document. Therefore, the following is required:

- o Analytical methods must be provided to determine the active ingredient and each toxicologically significant impurity (including nitrosamines) for which a certified limit is required. Each method must be accompanied by validation studies indicating its accuracy and precision. These methods must be suitable for enforcement of certified limits. [RCB defers to the Toxicology Branch regarding the toxicological significance of impurities and intentionally added inerts for which certified limits are required.]

[The following is presented for informational purposes only.]

Ciba-Geigy Corp. (1978; MRID 00104498) submitted an unvalidated GLC method using flame ionization detection (FID) for determination of metalaxyl and its impurities in the technical product. Samples are dissolved in acetone and analyzed for metalaxyl per se using a GLC column packed with 10% OV-101 on 80-100 mesh Gas Chrom Q and methyl stearate as an internal standard. Peak area corresponding to metalaxyl is adjusted for a response factor. No additional details were provided for this method. The registrant also submitted infrared, ultraviolet, mass spectrum, and nuclear magnetic resonance (NMR) scans for the metalaxyl technical. The only procedural details provided for these analyses were that solvents were $CDCl_3$ [sic] and methanolic HCl for the NMR and ultraviolet scans, respectively.

PHYSICAL AND CHEMICAL CHARACTERISTICS

It has been previously determined that the available data for the 90% T satisfy the requirements of the 1978 Proposed Guidelines. sec. 163.61-1 thru 11 (refer to the Metalaxyl Registration Standard [Guidance Document] dated December 1981), except for the octanol/water partion coefficient and pH. Summarized in Table 1 are additional physicochemical properties of technical metalaxyl.

Table 1. Physicochemical properties of the 90% metalaxyl technical.

Guidelines Reference No. of 40 CFR 158.120; Name of Property		Description	Bibliographic citation
63-11.	Octanol-water partition coefficient	1.65	EPA Memorandum[a]
63-12.	pH	2-4, 10% suspension; 3-5, 1% suspension	EPA Memorandum[a]

[a] EPA Memorandum from C.L. Trichilo to H.M. Jacoby dated Sept. 17, 1982 and located in the metalaxyl subject file.

These data are adequate to satisfy requirements for these physicochemical properties.

References (used):

00104498. Ciba-Geigy Corp. 1978. Chemistry of CGA-48988 technical. (Compilation; unpublished study received Sept. 5, 1978 under 100-601; CDL:235062-A.)

Environmental Protection Agency. 1981. Metalaxyl Guidance Document; December 1981.

Trichilo, C.L. 1982. Metalaxyl Registration Standard-Product Chemistry Chapter. (Located in the subject file for metalaxyl; No MRID assigned.)

TABLE A. GENERIC DATA REQUIREMENTS FOR 90% METALAXYL TECHNICAL[a] (Ciba-Geigy Corp.; EPA REG. NO. 100-601)

Data Requirement	Composition[b]	Does EPA Have Data to Satisfy This Requirement?[c]	Bibliographic Citation (MRID or as noted)	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[d]
158.120 Product Chemistry				
Product Identity and Composition				
61-1 - Product Identify and Disclosure of Ingredients	TGAI	Yes	e,f, Reg. jacket	No
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	Partially[g]	e, 00104498	Yes[h]
61-3 - Discussion of Formation of Impurities	TGAI	Partially[g]	e,i	Yes[j]
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis of Product Samples	TGAI	Partially[g]	e,i	Yes[k]
62-2 - Certification of Ingredient Limits	TGAI	Partially[l]	e	Yes[m]
62-3 - Analytical Methods to Verify Certified Limits	TGAI	Partially[g]	e, 00104498	Yes[n]
Physical and Chemical Characteristics				
63-2 - Color	TGAI	Yes	e	No
63-3 - Physical State	TGAI	Yes	e	No
63-4 - Odor	TGAI	Yes	e	No
63-5 - Melting Point	TGAI	Yes	e	No
63-6 - Boiling Point	TGAI	NR[o]	e	No
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	Yes	e	No

(continued, footnotes follow.)

TABLE A. (Continued).

Data Requirement	Composition[b]	Does EPA Have Data to Satisfy This Requirement?[c]	Bibliographic Citation (MRID or as noted)	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[d]
158.120 Product Chemistry (continued)				
63-8 - Solubility	TGAI or PAI	Yes	e	No
63-9 - Vapor Pressure	TGAI or PAI	Yes	e	No
63-10 - Dissociation Constant	TGAI or PAI	Yes	e	No
63-11 - Octanol/Water Partition Coefficient	TGAI	Yes	i	No
63-12 - pH	TGAI	Yes	i	No
63-13 - Stability	TGAI	Yes	e	No
Other Requirements:				
64-1 - Submittal of samples	N/A P	N/A	N/A	No

[a] The 90% technical is the only registered metalaxyl manufacturing-use product.
[b] Composition: TGAI = technical grade of the active ingredient; PAI = pure active ingredient.
[c] Data requirements based on Proposed Guidelines of 1978, unless otherwise indicated.
[d] Data must be submitted no later than 6-8 months from the date of this Standard.
[e] See Metalaxyl Guidance Document dated December 1981.
[f] Information obtained from desk references.
[g] We note ambiguity in the Metalaxyl Guidance Document concerning citations 61-2,3 and 62-1,3. Available data are not adequate as assessed by C.L. Trichilo in an EPA memorandum dated Sept. 17, 1982 and located in the subject file for metalaxyl.
[h] Complete information must be provided regarding the nature of the process (batch or continuous), the relative amounts of beginning material and the order in which they are added, the chemical equations for each intended reaction, equipment used to produce each intermediate and the final product, reaction conditions, the duration of each step fo the process, purification procedures, and quality control measures. In addition, the name and

address of the manufacturer, producer, or supplier of each beginning material must be provided, along with information regarding the properties of each beginning material used to manufacture each product. In order to assess the potential for contamination with nitrosamines, a description of manufacturing process conditions favoring formation of nitrosamines must be provided.

i Ciba-Geigy Corp. submission included with EPA memorandum from C.L. Trichilo to H.M. Jacoby dated Sept. 17, 1982 and located in the subject file for metalaxyl.

j A detailed discussion of all impurities that are or may be present at ≥0.1%, based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production must be submitted. This discussion must also address the possible formation of nitrosamines from metalaxyl and its impurities.

k Five or more representative samples must be analyzed for the amount of active ingredient and each impurity for which a certified limit is required. Complete validation data (accuracy, precision) must be submitted for each analytical method used.

l Available data do not meet the requirements of 40 CFR 158.120, Part 62-2.

m Upper and lower limits for metalaxyl must be provided, certified, and validated by sample analysis using analytical procedures for which accuracy and precision data have been provided. Upper limits for each impurity present at ≥0.1% (w/w), and for each "toxicologically significant" impurity present at <0.1% (w/w) must be provided, certified, and validated by sample analysis using analytical procedures for which accuracy and precision data have been provided. [We defer to the Toxicology Branch regarding the toxicological significance of impurities present at <0.1% (w/w).] All nitrosoamines must be identified and quantified in six samples of each product; two samples of each must be analyzed shortly after production, 3 months after production and 6 months after production. A method sensitive to 1 ppm of N-nitroso contaminants must be used. An upper limit must be provided (and certified) for all nitrosoamines found. Certifications should be submitted on EPA Form 8570 Rev. 2-85.

n Analytical methods must be provided to determine the active ingredient and each toxicologically significant impurity (including nitrosamines) for which a certified limit is required. Each method must be accompanied by validation studies indicating its accuracy and precision. These methods must be suitable for enforcement of certified limits. [RCB defers to the Toxicology Branch regarding the toxicologic significance of impurities and intentionally added inerts for which certified limits are required.]

o Not required; a solid at room temperature.

p N/A = Not applicable.

METALAXYL

PRODUCT CHEMISTRY

TASK - 1

(FINAL REPORT)

CONFIDENTIAL APPENDIXES

Appendix A: 1 page
Appendix B: 1 page
Appendix C: 1 page
Appendix D: 1 page
Appendix E: 1 page

Confidential appendixes to RCB's scientific review of the Registration Standard for the pesticide metalaxyl [Confidential FIFRA Trade Secret/ CBI.]

Page _____ is not included in this copy.

Pages __160__ through __164__ are not included in this copy.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

_____ Identity of product impurities.

__X__ Description of the product manufacturing process.

__X__ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

_____ The product confidential statement of formula.

_____ Information about a pending registration action.

_____ FIFRA registration data.

_____ The document is a duplicate of page(s) _____.

_____ The document is not responsive to the request.

_____ Internal deliberative information.

_____ Attorney-client privilege.

_____ Claimed Confidential by submitter upon submission to the Agency.

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