

US EPA ARCHIVE DOCUMENT



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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MAY 13 1988

MEMORANDUM

SUBJECT: PP#7F3470/FAP#7H5520. Metalaxyl in or on Blueberries, Walnuts, Almonds, Almond Hulls, Stone Fruits, Dried Apricots, and Prunes.

Review of Amendment of February 4, 1988.

RCB Nos.: 3788, 3789. MRID Nos.: 405031-00, -01.

FROM: Maxie Jo Nelson, Chemist
Tolerance Petition Section I
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C) *mjn*

THRU: Robert S. Quick, Section Head
Tolerance Petition Section I
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C) *RML*

TO: Lois A. Rossi, P. M. 21
Herbicide-Fungicide Branch
Registration Division (TS-767C)

and

Toxicology Branch
Hazard Evaluation Division (TS-769C)

SUMMARY OF DEFICIENCIES REMAINING TO BE RESOLVED FOR RCB

None, for this petition.

For approval of future metalaxyl tolerances (and to support the continued registration of metalaxyl-containing products), information on the testing of metabolite CGA-94689 for its recovery/behavior using the FDA Multiresidue Protocols of PAM I will need to be supplied.

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CONCLUSIONS

1. Data have now been submitted on the recovery/behavior of metalaxyl and two of its metabolites (CGA-62826 and CGA-37734) tested through FDA Multiresidue Protocols I thru IV of PAM I.
2. No deficiencies now remain to be resolved for RCB in re this petition submission.
3. For approval of future metalaxyl tolerances (and to support the continued registration of metalaxyl-containing products), FDA Multiresidue test information must also be supplied for the metabolite CGA-94689.

RECOMMENDATION

Toxicological considerations permitting, RCB now recommends in favor of the establishment of the proposed tolerances for the combined residue of the fungicide metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methylphenyl)-N-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on the following raw agricultural commodities:

<u>Commodity</u>	<u>Proposed Tolerance</u>
Blueberries	2.0 ppm
Stone Fruits Crop Group	1.0 ppm
Walnuts	0.5 ppm
Almonds	0.5 ppm
Almond Hulls	10.0 ppm

and processed food commodities:

<u>Commodity</u>	<u>Proposed Tolerance</u>
Apricots, Dried	4.0 ppm
Prunes	4.0 ppm

CGA-48988 = metalaxyl; N-(2,6-dimethylphenyl)-N-(methoxyacetyl) alanine methyl ester

CGA-37734 = N-(2,6-Dimethylphenyl)-2-hydroxy-acetamide

CGA-62826 = N-(2,6,dimethylphenyl)-N-(methoxyacetyl)-alanine

CGA-94689 = N-(2-hydroxymethyl-6-methylphenyl)-N-(methoxyacetyl)-alanine methyl ester

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NOTES TO PM:

1. You should advise the petitioner of Conclusion 3.
2. The chemical name for CGA-94689 which appears in 40 CFR 180.408, 21 CFR 193.277, and 21 CFR 561.273 is incorrect. It should read:

"N-(2-hydroxymethyl-6-methylphenyl)-N-(methoxyacetyl)-alanine methyl ester".

This should be corrected at the earliest opportunity.

DISCUSSION

By transmittal document dated 2/4/88 (received EPA, 2/8/88; received RCB, 5/10/88), the petitioner (Ciba-Geigy Corporation) submitted a study entitled, "Multiresidue Method Testing of Metalaxyl and Metabolites in Crops and Animal Tissues", Bill B. Williams and Charles H. Condra, Analytical Bio-Chemical Laboratories (performing laboratory), 12/14/87, Report No. 36320. The study was assigned MRID No. 405031-01.

The study involved the testing for recovery/behavior of metalaxyl and two of its metabolites (CGA-37734 and CGA-62826) using the FDA Multiresidue Protocols of PAM I (Pesticide Analytical Manual, Volume I).

The petitioner's summary of the results of the testing is appended to this review as an Attachment.

This information was submitted as a result of the RCB reviews (M. Nelson) of 3/6/87 and 8/26/87, this petition.

Additionally, the need for these data (with CGA-94689 specifically mentioned) was identified in the (6/12/87) Residue Chemistry Chapter of the Metalaxyl FRSTR (Final Registration Standard and Tolerance Reassessment).

We consider the submitted data to be of sufficient scope to allow us to recommend for the tolerances of this petition. However, FDA Multiresidue test information on the recovery/behavior of CGA-94689 using the PAM I protocols will be needed to support future metalaxyl tolerance requests (and to support the continued registration of metalaxyl-containing products).

No deficiencies remain to be resolved for RCB in re this petition.

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Attachment: Abstract from "Multiresidue Method Testing of Metalaxyl and Metabolites in Crops and Animal Tissues", 12/4/87, ABC Laboratory Project ID Final Report #36320. [MRID# 405031-01]

cc (with Attachment):

Reading File
Circulation
Reviewer (M. Nelson)
PP# 7F3470/FAP#5520
Metalaxyl Registration Standard
TAS (K. Arne)
ISB/PMSD (E. Eldredge)
FDA

TS-769C:RCB:Reviewer(MJN):CM#2:Rm804:557-7423:typist(mjn):5/13/88.

RDI:SectionHead:RSQuick:5/13/88:DeputyChief:RDSchmitt:5/13/88.

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AttachmentABSTRACT

Metalaxyl and two metabolites, CGA-62826 and CGA-37734, were analyzed by the Multiresidue Method Testing (MRMT) Procedure outlined by EPA Protocols I, II, III, and IV as referenced in the Pesticide Analytical Manual, Volume I (PAM I).

Under Protocol I, gas chromatographic (GC) behavior of metalaxyl, CGA-62826 and CGA-37734 was determined on 5% OV-101, 3% OV-17, 2% DEGS, and Ultrabond 20 SE packed columns using a nitrogen/phosphorus (N/P) detector. Metalaxyl and CGA-37734 chromatographed on all four columns. The 5% OV-101 column was the column of choice as determined by (1) adequate separation of the test compounds, (2) the best overall sensitivity and, (3) the best overall peak shape. After adjusting the gas chromatographic parameters to yield an RRc (Relative Retention Time, Corrected) of ethion to chlorpyrifos equal to 2.56 ± 0.03 (PAM I, Appendix II, Protocol I, Section I.C.1), RRc values relative to chlorpyrifos were determined for both test compounds: 0.40 or 0.52 for CGA-37734 (depending on column use history) and 0.83 for metalaxyl.

CGA-62826, which is a carboxylic acid, did not elute through any of the four columns. A small interfering peak at RRc 0.69 to chlorpyrifos eluting from the OV-101 column was not CGA-62826 as confirmed by GC/mass spectrometry; thus, this compound was deleted from the remainder of the testing program.

None of the test compounds eluted from standardized Florisil® cleanup columns (PAM I 211.14d and PAM I 252.12b). Consequently, no recovery work through the entire method (Protocol I) was performed.

Under Protocol II, only metalaxyl eluted from the charcoal cleanup column (PAM I 232.34). There was frequently an apparent matrix interference present at the expected retention time of CGA-37734. Therefore, only metalaxyl was tested and reported in the recovery trials on five fatty foods and one non-fatty food. In beef round, recovery of metalaxyl ranged from 100-130% at the 0.05-0.10 ppm fortification levels; in beef liver, the range of recovery was greater, 60-160% at the 0.05-0.80 ppm fortification levels. In dairy milk, recovery of metalaxyl ranged from 78-95% at the 0.02-0.04 ppm fortification levels. Recovery of metalaxyl from soybeans ranged from 76-105% at the 1.0-2.0 ppm fortification levels, but only 0-12% was recovered at the 0.05 ppm fortification level; thus, analysis of metalaxyl is not applicable at this low level. In eggs, recovery of metalaxyl ranged from 73-108% at the 0.05-0.10 ppm levels. Recovery of metalaxyl from cabbage (non-fatty food) ranged from 94-128% at the 0.05-4.0 ppm fortification levels.

Under Protocol III, only non-fatty foods were analyzed. In general, both CGA-37734 and metalaxyl could be quantitated. In tomatoes, recovery of CGA-37734 ranged from 73-166% and recovery of metalaxyl ranged from 106-144% at the 0.05-2.0 ppm fortification levels. In potatoes, recovery of CGA-37734 ranged from 97-128% and recovery of metalaxyl ranged from 84-104% at the 0.50-1.0 ppm fortification levels. Neither compound could be properly recovered at 0.05 ppm. In cabbage, recovery of CGA-37734 ranged from 52-87% and recovery of metalaxyl

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ranged from 88-116% at the 2.0-4.0 ppm fortification levels. Neither compound was quantitatively recovered at 0.05 ppm. In the case of CGA-37734, an apparent matrix interference was observed in one sample. In strawberries, recovery of CGA-37734 ranged from 67-150% and recovery of metalaxyl ranged from 94-102% at the 0.05-10.0 ppm fortification levels.

Under Protocol IV, the compounds were tested for natural fluorescence after chromatography on the specified HPLC system. None of the compounds tested were detectable upon HPLC chromatography by natural fluorescence at the specified wavelengths. Thus, testing with this protocol was terminated.

A summary of the results of multiresidue testing of metalaxyl and metabolites is also tabulated in the format recommended and published by FDA in PAM, Vol. I, "Methods Which Detect Multiple Residues," First Supplement - FY87 (PB87-911801) (See pages 36320-33 to 36320-67).

The raw data for this report is provided in a separate report entitled "Raw Data Report: Multiresidue Method Testing of Metalaxyl and Metabolites in Crops and Animal Tissues."

End
of
Document



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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MAY 18 1988

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#7F3470/7H5520. Tolerance Request For Residues of Metalaxyl in or on Blueberries, Walnuts, Almonds, Stone Fruits, Dried Apricots, and Prunes: TAS Dietary Exposure Assessment.

FROM: Susan L. Stanton *Susan L. Stanton 05/18/88*
Tolerance Assessment Program
HED/RCB (TS-769C)

THRU: Karl Arne, Ph.D. *W. Arne*
Branch Senior Scientist
HED/RCB (TS-769C)

TO: Lois Rossi, PM 21
Herbicide-Fungicide Branch
Registration Division (TS-767C)

Action Requested

Provide a dietary exposure analysis of proposed tolerances for residues of the fungicide metalaxyl in or on blueberries, walnuts, almonds, stone fruits, dried apricots, and prunes.

RCB has reviewed the petitions and, TOX considerations permitting, recommends that the proposed tolerances be established (memo Nelson to Rossi, 05/13/88).

Discussion

1. A routine chronic analysis was conducted using a Reference Dose (ADI) of 0.06 mg/kg body weight/day based on a NOEL of 6.25 mg/kg/day from a 6-month dog feeding study with a safety factor of 100. This value has been approved by the Tox Branch ADI Committee (05/23/86) and verified by the Agency reference dose committee (07/08/86).

2. The food uses evaluated were those established under 40 CFR 180.408, 21 CFR 193.277, the proposed uses from the current petitions (7F3470/7H5520), and other proposed uses on grapes

Metalaxyl Dietary Exposure Analysis Page 2

(6F3363/6H5493), strawberries (6F3337), and papayas (8E3605). Table 1 provides a complete listing of residue information.

3. The TAS routine chronic analysis calculates the Theoretical Maximum Residue Contribution (TMRC) for the U.S. population and each of 22 population subgroups (see Table 2) and compares this exposure estimate to the reference dose (ADI in this case).

The TMRC from all established and proposed food uses for the U.S. Population is calculated to be 0.012105 mg/kg body weight/day, which occupies approximately 20% of the ADI. The two most highly exposed population subgroups are children, 1-6 years (TMRC = 0.022249 mg/kg/day or 37% of the ADI) and non-nursing infants (TMRC = 0.020105 or 34% of the ADI). Table 3 provides a more detailed summary of the analysis for these 3 populations and includes estimates of exposure by tolerance type (published, new action, and other pending).

4. This analysis uses tolerance level residues with an assumption of 100% crop treated, a conservative approach that likely overestimates exposure significantly. However, since estimated exposure and risk using this approach are acceptable, no further data are required at this time.

cc: TAS File TOX (Rathman)
Reading File Metalaxyl SF
circ. PMSD
PP#7F3470/7H5520

Table 1

CHEMICAL INFORMATION FOR CASWELL NUMBER 375AA DATE: 05/17/88 PAGE: 1

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Metalaaxy1	6m feeding- dog	Increased alkaline phosphatase activity, inc. relative liver weights.	ADI SF --> 100	No data gaps, however MID was not reached in rat or mouse onco studies. Re-quirements to be re-evaluated after mutagenicity data are submitted.	TOX complete 5/23/86. EPA verified 7/8/86. WHO last reviewed 1982.
Caswell #375AA	NOEL= 6.2500 mg/kg		OPP RID= 0.060000		
CAS No. 57837-19-1	250.00 ppm		EPA RID= 0.060000		
A.I. CODE: 113501	LEL= 25.0000 mg/kg	No evidence of oncogenicity in rats or mice.			
CFR No. 180.408	1000.00 ppm				
	ONCO: CLASS E (TOX NOTE)				On IRIS.

FOOD CODE	FOOD NAME	PETITION NUMBER	NEW	TOLERANCE (PPM)	
				PENDING	PUBLISHED
01006AA	RASPBERRIES	3F2848			0.5000
01009AA	BLUEBERRIES	7F3470	2.0000		
01014AA	GRAPES-FRESH	6F3362		2.0000	
01014DA	GRAPES-RAISINS	6H5493		6.0000	H
01014JA	GRAPES-JUICE	6F3362		2.0000	
01016AA	STRAWBERRIES	6F3337		5.0000	
02001AA	CITRUS CITRUS	3F2786			1.0000
02002AA	GRAPEFRUIT-UNSPECIFIED	3F2786			1.0000
02002AB	GRAPEFRUIT-PULP	3F2786			1.0000
02002JA	GRAPEFRUIT-JUICE	3F2786			1.0000
02003AA	KUMQUATS	3F2786			1.0000
02004AA	LEMONS-UNSPECIFIED	3F2786			1.0000
02004AB	LEMONS-PULP	3F2786			1.0000
02004HA	LEMONS-PEEL	3F2786			1.0000
02004JA	LEMONS-JUICE	3F2786			1.0000
02005AA	LIMES-UNSPECIFIED	3F2786			1.0000
02005AB	LIMES-PULP	3F2786			1.0000
02005HA	LIMES-PEEL	3F2786			1.0000
02005JA	LIMES-JUICE	3F2786			1.0000
02006AA	ORANGES-UNSPECIFIED	3F2786			1.0000
02006AB	ORANGES-PULP	3F2786			1.0000
02006HA	ORANGES-PEEL	3F2786			1.0000
02006JA	ORANGES-JUICE	3F2786			1.0000
02007AA	TANGELOS	3F2786			1.0000
02008AA	TANGERINES	3F2786			1.0000
02008JA	TANGERINE-JUICE	3F2786			1.0000
03001AA	ALMONDS	7F3470	0.5000		
03009AA	WALNUTS	7F3470	0.5000		
04001AA	APPLES-FRESH	3F2847			0.2000
04001DA	APPLES-DRIED	3F2847			0.2000
04001JA	APPLES-JUICE	3F2847			0.2000
05001AA	APRICOTS-FRESH	7F3470	1.0000		
05001DA	APRICOTS-DRIED	7H5520	4.0000		
05002AA	CHERRIES-FRESH	7F3470	1.0000		
05002DA	CHERRIES-DRIED	7F3470	1.0000		
05002JA	CHERRIES-JUICE	7F3470	1.0000		
05003AA	NECTARINES	7F3470	1.0000		
05004AA	PEACHES-FRESH	7F3470	1.0000		
05004DA	PEACHES-DRIED	7F3470	1.0000		
05005AA	PLUMS(DAWSONS)-FRESH	7F3470	1.0000		

Table 1 (cont.)

CHEMICAL INFORMATION FOR CASWELL NUMBER 375AA DATE: 05/17/88 PAGE: 2

Metalaxy1	CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES		DATA GAPS/COMMENTS	STATUS	
				ADI	SF			
Caswell #375AA		6m feeding- dog	Increased alkaline phosphatase activity, inc. relative liver weights.	100	-->	No data gaps, however MTD was not reached in rat or mouse onco studies. Re-quirements to be re-evaluated after mutagenicity data are submitted.	TOX complete 5/23/86.	
CAS No. 57837-19-1		NOEL= 6.2500 mg/kg		OPP RfD= 0.060000			EPA verified 7/8/86.	
A.I. CODE: 113501		250.00 ppm		EPA RfD= 0.060000			WHO last reviewed 1982.	
CFR No. 180.408		LEL= 25.0000 mg/kg	No evidence of oncogenicity in rats or mice.					
		1000.00 ppm						
		ONCO: Class E (TOX NOTE)						On IRIS.

FOOD CODE	FOOD NAME	PETITION NUMBER	TOLERANCE (PPM)		PUBLISHED
			NEW	PENDING	
05005DA	PLUMS-PRUNES(DRIED)	7F5520	4.0000		H
05005JA	PLUMS, PRUNE-JUICE	7F3470	1.0000		
06001AA	AVOCADOS	1F2531		4.0000	
06010AA	PAPAYAS-UNSPECIFIED	8E3605	0.1000		
06010AB	PAPAYAS-PULP	8E3605	0.1000		
06010DA	PAPAYAS-DRIED	8E3605	0.1000		
06010JA	PAPAYAS-JUICE	8E3605	0.1000		
06013AA	PINEAPPLE-FRESH/PULP	2F2743		0.1000	
06013DA	PINEAPPLE-DRIED	2F2743		0.1000	
06013JA	PINEAPPLE-FRESH/JUICE	2F2743		0.1000	
08020AA	HOPS	7H5532		50.0000	H
10002AA	CANTALOUPE-UNSPECIFIED	3F2827		1.0000	
10002AB	CANTALOUPE-PULP	3F2827		1.0000	
10003AA	CASABAS	3F2827		1.0000	
10004AA	CRENSHAWMS	3F2827		1.0000	
10005AA	HONEYDEW MELONS	3F2827		1.0000	
10007AA	PERSION MELONS	3F2827		1.0000	
10008AA	WATERMELON	3F2827		1.0000	
10010AA	CUCUMBERS	3F2827		1.0000	
10011AA	PUMPKIN	3F2827		1.0000	
10013AA	SQUASH-SUMMER	3F2827		1.0000	
10014AA	SQUASH-WINTER	3F2827		1.0000	
10017AA	BITTER MELON	3F2827		1.0000	
10020AA	TOMELGOURD	3F2827		1.0000	
11001AA	EGGPLANT	6F3387		1.0000	
11003AA	PEPPERS(SWEET/GARDEN)	6F3387		1.0000	
11003AB	CHILI PEPPERS	6F3387		1.0000	
11003AD	PEPPERS-OTHER	6F3387		1.0000	
11004AA	PIMENTOS	6F3387		1.0000	
11005AA	TOMATOES-WHOLE	6F3387		1.0000	
11005JA	TOMATOES-JUICE	1H5314		3.0000	H
11005RA	TOMATOES-PUREE	1H5314		3.0000	H
11005TA	TOMATOES-PASTE	1H5314		3.0000	H
11005UA	TOMATOES-CATSUP	1H5314		3.0000	H
13001AA	BETS-TOPS(GREENS)	3F2827		0.1000	
13002AA	CELERY	3F2827		0.1000	
13003AA	CHICORY (FRENCH OR BELGIAN ENDIVE)	3F2827		0.1000	
13005AA	BROCCOLI	3F2955		2.0000	
13006AA	BRUSSEL SPROUTS	3F2827		0.1000	
13007AA	CABBAGE-GREEN AND RED	3F2955		2.0000	

Table 1 (cont'L)

CHEMICAL INFORMATION FOR CASWELL NUMBER 375AA DATE: 05/17/88 PAGE: 3

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES		DATA GAPS/COMMENTS	STATUS
			ADI	SF		
MetalaXyl	6m feeding- dog	Increased alkaline phos-	100	100	No data gaps, however MTD	TDX complete 5/23/86.
Caswell #375AA	NOEL= 6.2500 mg/kg	phatase activity, inc.	OPP RD= 0.060000		was not reached in rat or	EPA verified 7/8/86
CAS No. 57837-19-1	250.00 ppm	relative liver weights.	EPA RD= 0.060000		mouse onco studies. Re-	WHO last reviewed 1982.
A. I. CODE: 113501	LEL= 25.0000 mg/kg	No evidence of oncogeni-			quitevents to be re-eval-	
CFR No. 180.408	1000.00 ppm	city in rats or mice.			uated after mutagenicity	
	ONCO: Class E (TOX NOTE)				data are submitted.	On IRIS.

FOOD CODE	FOOD NAME	PETITION NUMBER	NEW	TOLERANCE (PPM)	
				PENDING	PUBLISHED
13008AA	CAULIFLOWER	3F2955			2.0000
13009AA	COLLARDS	3F2827			0.1000
13010AA	CABBAGE-CHINESE/CELERY (INC. BOK CHOY)	3F2955			2.0000
13011AA	KALE	3F2827			0.1000
13012AA	KOHLRABI	3F2827			0.1000
13013AA	LETTUCE-LEAFY VARIETIES	3F2827			0.1000
13014AA	DANDELION	3F2827			0.1000
13015AA	ENDIVE/CURLY AND ESCAROLE	3F2827			0.1000
13016AA	FENNEL	3F2827			0.1000
13017AA	CRESS (GARDEN/FIELD)	3F2827			0.1000
13020AA	LETTUCE-UNSPECIFIED	3F2827			0.1000
13021AA	MUSTARD GREENS	3F2827			0.1000
13022AA	PARSLEY	3F2827			0.1000
13023AA	RHUBARB	3F2827			0.1000
13024AA	SPINACH	2F2762			10.0000
13025AA	SWISS CHARD	3F2827			0.1000
13039AA	CRESS/UPLAND	3F2827			0.1000
13045AA	LETTUCE-HEAD VARIETIES	2F2762			5.0000
14001AA	BETS-ROOTS	3F2827			0.1000
14007AA	GARLIC	1F2500			3.0000
14010AA	LEEKs	1F2500			3.0000
14011AA	ONIONS-DRY-BULB (CIPOLLINI)	1F2500			3.0000
14011DA	ONIONS-DEHYDRATED OR DRIED	1F2500			3.0000
14013AA	POTATOES(WHITE)-WHOLE	1F2500			0.5000
14013AB	POTATOES(WHITE)-UNSPECIFIED	1F2500			0.5000
14013AC	POTATOES(WHITE)-PEELED	1F2500			0.5000
14013DA	POTATOES(WHITE)-DRY	1F2500			4.0000
14013HA	POTATOES(WHITE)-PEEL ONLY	1F2500			0.5000
14017AA	SHALLOTS	1F2500			3.0000
15001AA	BEANS-DRY-GREAT NORTHERN	3F2918			0.2000
15001AB	BEANS-DRY-KIDNEY	3F2918			0.2000
15001AC	BEANS-DRY-LIMA	3F2918			0.2000
15001AD	BEANS-DRY-NAVY (PEA)	3F2918			0.2000
15001AE	BEANS-DRY-OTHER	3F2918			0.2000
15001AF	BEANS-DRY-PINTO	3F2918			0.2000
15002AA	BEANS-SUCCULENT-LIMA	3F2918			0.2000
15003AA	BEANS-SUCCULENT-GREEN	3F2918			0.2000
15003AB	BEANS-SUCCULENT-OTHER	3F2918			0.2000
15003AC	BEANS-SUCCULENT-YELLOW/WAX	3F2918			0.2000
15004AA	CORN/POP	2F2695			0.1000

Table 1 (cont.)

CHEMICAL INFORMATION FOR CASWELL NUMBER 375AA DATE: 05/17/88 PAGE: 4

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Metaxyl	6m feeding- dox	Increased alkaline phosphatase activity, inc. relative liver weights.	ADI SF --> 100	No data gaps, however MTD was not reached in rat or mouse onco studies. Requirements to be re-evaluated after mutagenicity data are submitted.	TOX complete 5/23/86. EPA verified 7/8/86. WHO last reviewed 1982.
Caswell #375AA	NOEL= 6.2500 mg/kg		OPP RED= 0.060000		
CAS No. 57837-19-1	250.00 ppm		EPA RED= 0.060000		
A.I. CODE: 113501	LEL= 25.0000 mg/kg	No evidence of oncogenicity in rats or mice.			
CFR No. 180.408	1000.00 ppm				
	ONCO: Class E (TOX NOTE)				On IRIS.

FOOD CODE	FOOD NAME	PETITION NUMBER	NEW	TOLERANCE (PPM)	PENDING	PUBLISHED
15005AA	CORN/SWEET	2F2695		0.1000		
15006AA	PEANUTS-WHOLE	3F2919		0.2000		
15007AA	PEAS(GARDEN)-MATURE SEEDS/DRY	3F2918		0.2000		
15009AA	PEAS(GARDEN)-GREEN IMMATURE	3F2918		0.2000		
15011AA	LENTILES-WHOLE	3F2918		0.2000		
15011AB	LENTILES-SPLIT	3F2918		0.2000		
15013AA	MUNG BEANS (SPROUTS)	3F2918		0.2000		
15018AA	SUNFLOWER-SEEDS	3F2827		0.1000		
15022AA	BEANS-DRY-BROADBEANS(MATURE SEED)	3F2918		0.2000		
15022AB	BEANS-SUCCULENT-BROADBEANS(IMMATURE SEED)	3F2918		0.2000		
15023AA	BEANS-DRY-PIGEON BEANS	3F2918		0.2000		
15027AA	BEANS-UNSPECIFIED	3F2918		0.2000		
15029AA	SOYBEANS-SPROUTED SEEDS	3F2818		1.0000		
15030AA	BEANS-DRY-HYACINTH(MATURE SEEDS)	3F2918		0.2000		
15030AB	BEANS-SUCCULENT-HYACINTH(YOUNG PODS)	3F2918		0.2000		
15031AA	BEANS-DRY-BLACKEYE PEAS(COMPEAS)	3F2918		0.2000		
15032AA	BEANS-DRY-CARBANZO(CHICK PEA)	3F2918		0.2000		
16002AA	ASPARAGUS	6F3330		7.0000		
16004AA	ONIONS-GREEN	1F2500		10.0000		
24001AA	BARLEY	2F2695		0.1000		
24002EA	CORN/GRAIN-ENDOSPERM	2F2695		0.1000		
24002HA	CORN/GRAIN-BRAN	2F2695		0.1000		
24002SA	CORN SUGAR	2F2695		0.1000		
24003AA	OATS	2F2695		0.1000		
24004AA	RICE-ROUGH	2F2695		0.1000		
24004AB	RICE-MILLED	2F2695		0.1000		
24005AA	RYE-ROUGH	2F2695		0.1000		
24005GA	RYE-GERM	2F2695		0.1000		
24005WA	RYE-FLOUR	2F2695		0.1000		
24006AA	SORGHUM (INCLUDING MILO)	2F2695		0.1000		
24007AA	WHEAT-ROUGH	2F2764		0.2000		
24007GA	WHEAT-GERM			1.0000	H	
24007HA	WHEAT-BRAN			1.0000	H	
24007WA	WHEAT-FLOUR			1.0000	H	
24012AA	MILLET			0.1000		
25002SA	BEEF SUGAR			0.1000		
26001AA	BUCKWHEAT			0.1000		
26011AA	GUAR BEANS			0.2000		
270020A	CORN/GRAIN-OIL			0.1000		
270030A	COTTONSEED-OIL			0.1000		

Table 1 (con't)

CHEMICAL INFORMATION FOR CASWELL NUMBER 375AA DATE: 05/17/88 PAGE: 6

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Metalaxyl	6m feeding-dog	Increased alkaline phosphatase activity, inc. relative liver weights.	ADI SF --> 1001 OPP RfD= 0.060000 EPA RfD= 0.060000	No data gaps, however MTD was not reached in rat or mouse onco studies. Re-quirements to be re-evaluated after mutagenicity data are submitted.	TOX complete 5/23/86. EPA verified 7/8/86. WHO last reviewed 1982.
Caswell #375AA	NOEL= 6.2500 mg/kg				
CAS No. 57837-19-1	250.00 ppm				
A.I. CODE: 113501	LEI= 25.0000 mg/kg				
CFR No. 180.408	1000.00 ppm	city in rats or mice.			
	ONCO: Class E (TOX NOTE)				

FOOD CODE	FOOD NAME	PETITION NUMBER	TOLERANCE (PPM)		PUBLISHED
			NEW	PENDING	
55008LA	TURKEY-GIBLETS (LIVER)	1F2500		0.4000	H
55008MA	TURKEY-FLESH(W/O SKIN & W/O BONES)	1F2500		0.0500	
55008MB	TURKEY-FLESH(+SKIN & W/O BONES)	1F2500		0.4000	H
55008MC	TURKEY-UNSPECIFIED	1F2500		0.0500	
55013BA	POULTRY/OTHER-BYPRODUCTS	1F2500		0.0500	
55013LA	POULTRY/OTHER-GIBLETS(LIVER)	1F2500		0.4000	H
55013MA	POULTRY/OTHER-FLESH (+SKIN & W/O BONES)	1F2500		0.4000	H
55014AA	EGGS-WHOLE	1F2500		0.0500	
55014AB	EGGS-WHITE ONLY	1F2500		0.0500	
55014AC	EGGS-YOLK ONLY	1F2500		0.0500	
55015BA	CHICKEN-BYPRODUCTS	1F2500		0.0500	
55015LA	CHICKEN-GIBLETS(LIVER)	1F2500		0.4000	H
55015MA	CHICKEN-FLESH(W/O SKIN & W/O BONES)	1F2500		0.0500	
55015MB	CHICKEN-FLESH(+SKIN & W/O BONES)	1F2500		0.4000	H
90997AA	INEST. RACS--TOLERANCE TOO SPECIFIC	1H5299		0.0500	
90999AA	FEED RACS--INEST. FROM USDA SURVEY	3H5376		0.4000	H
90999AB	FOOD RACS--INEST. FROM USDA SURVEY	3H5376		0.4000	H

Table 2

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

DATE: 05/17/88

PAGE: 1

CHEMICAL INFORMATION	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Metals Casswell #375AA CAS No. 57817-19-1 A.I. CODE: 113501 CFR No. 180.408	6m feeding - dog NOEL= 6.2500 mg/kg 250.00 ppm LEL= 25.0000 mg/kg 1000.00 ppm ONCO-CLASS E (TOX NOTE)	Increased alkaline phosphatase activity, inc. relative liver weights. No evidence of oncogenicity in rats or mice.	ADI SF --> 100 OPP RID= 0.060000 EPA RID= 0.060000	No data gaps, however MTD was not reached in rat or mouse onco studies. Requirements to be re-evaluated after mutagenicity data are submitted.	TOX complete 5/23/86. EPA verified 7/8/86. WHO last reviewed 1982.

TOTAL TMRC (MG/KG BODY WEIGHT/DAY)

POPULATION SUBGROUP	CURRENT TMRC*	NEW TMRC**	NEW TMRC AS PERCENT OF REF	DIFFERENCE AS PERCENT OF REF	EFFECT OF ANTICIPATED RESIDUES
U.S. POPULATION - 48 STATES	0.010966	0.012105	20.174428	1.898188	
U.S. POPULATION - SPRING SEASON	0.011110	0.012372	20.620160	2.103130	
U.S. POPULATION - SUMMER SEASON	0.011063	0.012368	20.613353	2.175778	
U.S. POPULATION - FALL SEASON	0.010782	0.011777	19.628195	1.658373	
U.S. POPULATION - WINTER SEASON	0.010878	0.011872	19.786067	1.655400	
NORTHEAST REGION	0.012308	0.013649	22.748507	2.235425	
NORTH CENTRAL REGION	0.010711	0.011841	19.734690	1.882427	
SOUTHERN REGION	0.009548	0.010320	17.199632	1.286710	
WESTERN REGION	0.011948	0.013464	22.440750	2.528065	
HISPANICS	0.012258	0.013205	22.008395	1.578692	
NON-HISPANIC WHITES	0.011047	0.012275	20.457737	2.045570	
NON-HISPANIC BLACKS	0.009555	0.010232	17.053410	1.129107	
NON-HISPANIC OTHERS	0.012863	0.013835	23.058675	1.619860	
NURSING INFANTS (< 1 YEAR OLD)	0.006080	0.007964	13.272952	3.140062	
NON-NURSING INFANTS (< 1 YEAR OLD)	0.015982	0.020105	33.507678	6.871025	
FEMALES (13+ YEARS, PREGNANT)	0.007835	0.008714	14.523613	1.465385	
FEMALES 13+ YEARS, NURSING CHILDREN (1-6 YEARS OLD)	0.009831	0.011067	18.444645	2.060333	
CHILDREN (7-12 YEARS OLD)	0.019496	0.022249	37.080908	4.587465	
MALES (13-19 YEARS OLD)	0.013821	0.015270	25.450593	2.415162	
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)	0.009905	0.010554	17.590788	1.082655	
MALES (20 YEARS AND OLDER)	0.008511	0.009198	15.330290	1.145647	
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)	0.010867	0.011700	19.500667	1.388315	
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)	0.008644	0.009587	15.978092	1.572252	

*Current TMRC does not include new or pending tolerances.
**New TMRC includes new, pending, and published tolerances.

Table 3

TOLERANCE ASSESSMENT SUMMARY FOR Metalaxyl
CASWELL #375AA

DATE: 05/17/88

ANALYSIS FOR POPULATION SUB-GROUP: U.S. POPULATION - 48 STATES

EXISTING TOLERANCES (PUBLISHED ONLY)		
RESULT IN A TMRC OF:	0.010966	MG/KG/DAY
THE EXISTING TMRC IS EQUIVALENT TO:	18.276240	% OF THE ADI.
PROPOSED NEW TOLERANCES (CURRENT PETITION ONLY)		
RESULT IN A TMRC OF:	0.000391	MG/KG/DAY
THESE NEW TOLERANCES WILL OCCUPY:	0.650930	% OF THE ADI.
IF THE NEW TOLERANCES (CURRENT PETITION ONLY) ARE APPROVED THE RESULTANT TMRC WILL BE:		
THE NEW TMRC WILL OCCUPY	0.011356	MG/KG/DAY
	18.927170	% OF THE ADI.
OTHER PENDING TOLERANCES EXCLUDING THE CURRENT NEW PETITION HAVE A TMRC OF:		
THIS TMRC WILL OCCUPY	0.000748	MG/KG/DAY
	1.247258	% OF THE ADI.
IF ALL PENDING TOLERANCES (INCLUDING THE CURRENT NEW PETITION) ARE GRANTED THE RESULTANT TMRC WILL BE:		
THE TOTAL TMRC WILL OCCUPY	0.012105	MG/KG/DAY
	20.174428	% OF THE ADI.

ANALYSIS FOR POPULATION SUB-GROUP: CHILDREN (1-6 YEARS OLD)

EXISTING TOLERANCES (PUBLISHED ONLY)		
RESULT IN A TMRC OF:	0.019496	MG/KG/DAY
THE EXISTING TMRC IS EQUIVALENT TO:	32.493443	% OF THE ADI.
PROPOSED NEW TOLERANCES (CURRENT PETITION ONLY)		
RESULT IN A TMRC OF:	0.000837	MG/KG/DAY
THESE NEW TOLERANCES WILL OCCUPY:	1.395113	% OF THE ADI.
IF THE NEW TOLERANCES (CURRENT PETITION ONLY) ARE APPROVED THE RESULTANT TMRC WILL BE:		
THE NEW TMRC WILL OCCUPY	0.020333	MG/KG/DAY
	33.888557	% OF THE ADI.
OTHER PENDING TOLERANCES EXCLUDING THE CURRENT NEW PETITION HAVE A TMRC OF:		
THIS TMRC WILL OCCUPY	0.001915	MG/KG/DAY
	3.192352	% OF THE ADI.
IF ALL PENDING TOLERANCES (INCLUDING THE CURRENT NEW PETITION) ARE GRANTED THE RESULTANT TMRC WILL BE:		
THE TOTAL TMRC WILL OCCUPY	0.022249	MG/KG/DAY
	37.080908	% OF THE ADI.

ANALYSIS FOR POPULATION SUB-GROUP: NON-NURSING INFANTS (< 1 YEAR OLD)

EXISTING TOLERANCES (PUBLISHED ONLY)		
RESULT IN A TMRC OF:	0.015982	MG/KG/DAY
THE EXISTING TMRC IS EQUIVALENT TO:	26.636653	% OF THE ADI.
PROPOSED NEW TOLERANCES (CURRENT PETITION ONLY)		
RESULT IN A TMRC OF:	0.003412	MG/KG/DAY
THESE NEW TOLERANCES WILL OCCUPY:	5.687192	% OF THE ADI.
IF THE NEW TOLERANCES (CURRENT PETITION ONLY) ARE APPROVED THE RESULTANT TMRC WILL BE:		
THE NEW TMRC WILL OCCUPY	0.019394	MG/KG/DAY
	32.323845	% OF THE ADI.
OTHER PENDING TOLERANCES EXCLUDING THE CURRENT NEW PETITION HAVE A TMRC OF:		
THIS TMRC WILL OCCUPY	0.000710	MG/KG/DAY
	1.183833	% OF THE ADI.
IF ALL PENDING TOLERANCES (INCLUDING THE CURRENT NEW PETITION) ARE GRANTED THE RESULTANT TMRC WILL BE:		
THE TOTAL TMRC WILL OCCUPY	0.020105	MG/KG/DAY
	33.507678	% OF THE ADI.

End
of
Document

~~R. GUTAK~~
M. NELSON

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

SEP 21 1989

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCESMEMORANDUM

SUBJECT: Dietary Exposure Analysis for the Proposed Use of Metalaxyl in or on Blueberries, Walnuts, Almonds, Almond Hulls, Stone Fruits, Dried Apricots, and Prunes, PP#7F3470 and FAP#7H5520.

FROM: Rita Briggs, Ph.D. RB 9/20/89
HED/SACB/TAS Staff (H7509C)

THRU: J. R. Tomerlin, Ph.D. JT 9/20/89
Acting TAS Program Manager (H7509C)

TO: Lois A. Rossi, P.M. 21
Herbicide-Fungicide Branch
Registration Division (TS-767C)

E 9/21/89

Action Requested

Provide an estimate of dietary exposure to metalaxyl from published tolerances, pending tolerance on hops, and the proposed tolerances on: blueberries, walnuts, almonds, almond hulls, stone fruits, and the processed food commodities - dried apricots and prunes.

Discussion

1. Toxicology Endpoint: The routine chronic TAS analysis used a reference dose (ADI) of 0.06 mg/kg body weight/day, based upon a NOEL of 6.25 mg/kg body weight/day and an uncertainty factor of 100 from a 6-month dog feeding study. This value has been approved by HED (05/23/86) and Agency (07/08/86) reference dose committees.
2. Residue Information: Food uses evaluated were published tolerances from 40 CFR 180.408, food additive tolerances from 185.4000, pending tolerance on hops, and the proposed use on blueberries, walnuts, almonds, almond hulls, stone fruits, dried apricots and prunes (M.J. Nelson memo 5/13/88). A summary of the residue data used in the analysis is attached as Table 1.
3. Chronic Exposure Analysis: The TAS chronic exposure analysis uses tolerance level residues and 100 per cent crop treated to estimate the Theoretical Maximum Residue Contribution (TMRC) for the overall U.S. population and 22 population subgroups (Table 2).

Metalaxyl Dietary Exposure Analysis, page 2

4. Comments: A TAS analysis based on PP#7F3470 and FAP#7H5520 showed that dietary exposure estimates for the U.S. population and all 22 subgroups ranged from 13 to 34% of the ADI (Table 2). Therefore, the dietary exposure from the proposed use of metalaxyl on the food commodities included in these petitions is acceptable.

Attachments

cc: TAS (Tomerlin, SACB), DEB, Caswell #375AA, Gardner (TOX).

Table 1

CHEMICAL INFORMATION FOR CASWELL NUMBER 375AA DATE: 09/15/89 PAGE: 1

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
MetaLaxyl	6mo feeding- dog	Increased alkaline phos-	ADI SF -->100	No data gaps, however MTD	HED complete 05/23/86.
Caswell #375AA	NOEL= 6.2500 mg/kg	phatase activity, incr	OPP RfD= 0.060000	was not reached in rat or	EPA verified 07/08/86.
CAS No. 57837-19-1	250.00 ppm	relative liver weights.	EPA RfD= 0.060000	mouse onco studies. Re-	WHO last reviewed 1982.
A.I. CODE: 113501	LEL= 25.0000 mg/kg	No evidence of oncogeni-		quiments to be re-eval-	
CFR No. 180.408	1000.00 ppm	city in rats or mice.		uated after mutagenicity	
	ONCO: Class E (HED NOTE)			data are submitted.	On IRIS.

FOOD CODE	FOOD NAME	PETITION NUMBER	NEW	TOLERANCE (PPM)	PUBLISHED
				PENDING	
01006AA	RASPBERRIES	3F2848			0.5000
01009AA	BLUERBERRIES	7F3470			
02001AA	CITRUS CITRUS	3F2786	1.0000		1.0000
02002AA	GRAPEFRUIT-UNSPECIFIED	3F2786			1.0000
02002AB	GRAPEFRUIT-PULP	3F2786			1.0000
02002JA	GRAPEFRUIT-JUICE	3F2786			1.0000
02003AA	KUMQUATS	3F2786			1.0000
02004AA	LEMONS-UNSPECIFIED	3F2786			1.0000
02004AB	LEMONS-PULP	3F2786			1.0000
02004HA	LEMONS-PEEL	3F2786			1.0000
02004JA	LEMONS-JUICE	3F2786			1.0000
02005AA	LIMES-UNSPECIFIED	3F2786			1.0000
02005AB	LIMES-PULP	3F2786			1.0000
02005HA	LIMES-PEEL	3F2786			1.0000
02005JA	LIMES-JUICE	3F2786			1.0000
02006AA	ORANGES-UNSPECIFIED	3F2786			1.0000
02006AB	ORANGES-PULP	3F2786			1.0000
02006HA	ORANGES-PEEL	3F2786			1.0000
02006JA	ORANGES-JUICE	3F2786			1.0000
02007AA	TANGELOS	3F2786			1.0000
02008AA	TANGERINES	3F2786			1.0000
02008JA	TANGERINE -JUICE	3F2786			1.0000
03001AA	ALMONDS	7F3740	0.5000		
03009AA	WALNUTS	7F3470	0.5000		
04001AA	APPLES-FRESH	3F2847			0.2000
04001DA	APPLES-DRIED	3F2847			0.2000
04001JA	APPLES-JUICE	3F2847			0.2000
05001AA	APRICOTS-FRESH	7F3470	1.0000		H
05001DA	APRICOTS-DRIED	7F3470	4.0000		
05002AA	CHERRIES-FRESH	7F3470	1.0000		
05002DA	CHERRIES-DRIED	7F3470	1.0000		
05002JA	CHERRIES-JUICE	7F3470	1.0000		
05003AA	NECTARINES	7F3470	1.0000		
05004AA	PEACHES-FRESH	7F3470	1.0000		
05004DA	PEACHES-DRIED	7F3470	1.0000		
05005AA	PLUMS(DAWSONS) -FRESH	7F3470	1.0000		H
05005DA	PLUMS-PRUNES(DRIED)	7F3470	1.0000		
05005JA	PLUMS, PRUNE -JUICE	7F3470	4.0000		H
06001AA	AVOCADOS	1F2531	4.0000		4.0000
06010AA	PAPAYAS-UNSPECIFIED	8E3605			0.1000

Table 1, continued

CHEMICAL INFORMATION FOR CASWELL NUMBER 375AA DATE: 09/15/89 PAGE: 2

FOOD CODE	FOOD NAME	STUDY TYPE	EFFECTS	REFERENCE DOSES		DATA GAPS/COMMENTS	STATUS
				ADI	SF -->100		
06010AB	PAPAYAS-PULP	6mo feeding- dog	Increased alkaline phos-			No data gaps, however MTD	HED complete 05/23/86.
06010DA	PAPAYAS-DRIED	NOEL= 6.2500 mg/kg	phataase activity, incr	OPP RfD= 0.060000		was not reached in rat or	EPA verified 07/08/86.
06010JA	PAPAYAS-JUICE	250.00 ppm	relative liver weights.	EPA RfD= 0.060000		mouse onco studies. Re-	WHO last reviewed 1982.
06013AA	PINEAPPLE-FRESH/PULP	LEL= 25.0000 mg/kg	No evidence of oncogeni-			quirements to be re-eval-	
06013DA	PINEAPPLE-DRIED	1000.00 ppm	city in rats or mice.			uated after mutagenicity	
06013JA	PINEAPPLE-FRESH/JUICE	ONCO: Class B (HED NOTE)				data are submitted.	On IRIS.
08020AA	HOPS			20.0000			
10002AA	CANTALOUPE-UNSPECIFIED						
10002AB	CANTALOUPE-PULP						
10003AA	CASABAS						
10004AA	CRENSHAWNS						
10005AA	HONEYDEW MELONS						
10007AA	PERSION MELONS						
10008AA	WATERMELON						
10010AA	CUCUMBERS						
10011AA	PUMPKIN						
10013AA	SQUASH-SUMMER						
10014AA	SQUASH-WINTER						
10017AA	BITTER MELON						
10020AA	TOWELGOURD						
11001AA	EGPLANT						
11003AA	PEPPERS(SWEET/GARDEN)						
11003AB	CHILI PEPPERS						
11003AD	PEPPERS-OTHER						
11004AA	PIMIENTOS						
11005AA	TOMATOES-WHOLE						
11005JA	TOMATOES-JUICE						
11005RA	TOMATOES-PUREE						
11005TA	TOMATOES-PASTE						
11005UA	TOMATOES-CATSUP						
13001AA	BETS-TOPS(GREENS)						
13002AA	CELERY						
13003AA	CHICORY (FRENCH OR BELGIAN ENDIVE)						
13005AA	BROCCOLI						
13006AA	BRUSSEL SPROUTS						
13007AA	CABBAGE-GREEN AND RED						
13008AA	CAULIFLOWER						
13009AA	COLLARDS						
13010AA	CABBAGE-CHINESE/CELERY (INC. BOK CHOY)						
13011AA	KALE						

Table 1, continued

PAGE: 3

DATE: 09/15/89

CHEMICAL INFORMATION FOR CASWELL NUMBER 375AA

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
MetaLaxyl	6mo feeding- dog	Increased alkaline phosphatase activity, incr relative liver weights.	ADI SF -->100	No data gaps, however MTD was not reached in rat or mouse onco studies. Requirements to be re-evaluated after mutagenicity data are submitted.	HED complete 05/23/86.
Caswell #375AA	NOEL= 6.2500 mg/kg		OPP RED= 0.060000		EPA verified 07/08/86.
CAS No. 57837-19-1	250.00 ppm		EPA RED= 0.060000		WHO last reviewed 1982.
A.I. CODE: 113501	LEL= 25.0000 mg/kg	No evidence of oncogenicity in rats or mice.			
CFR No. 180.408	1000.00 ppm				
	ONCO: Class E (HED NOTE)				On IRIS.

FOOD CODE	FOOD NAME	PETITION NUMBER	NEW	TOLERANCE (PPM)	PUBLISHED
				PENDING	
13012AA	KOHLRABI	3F2827			0.1000
13013AA	LETTUCE-LEAFY VARIETIES	3F2827			0.1000
13014AA	DANDELION	3F2827			0.1000
13015AA	ENDIVE/CURLEY AND ESCAROLE	3F2827			0.1000
13017AA	CRESS (GARDEN/FIELD)	3F2827			0.1000
13020AA	LETTUCE-UNSPECIFIED	3F2827			0.1000
13021AA	MUSTARD GREENS	3F2827			0.1000
13022AA	PARSLEY	3F2827			0.1000
13023AA	RHUBARB	3F2827			0.1000
13024AA	SPINACH	2F2762			10.0000
13025AA	SWISS CHARD	3F2827			0.1000
13039AA	CRESS/UPLAND	3F2827			0.1000
13045AA	LETTUCE-HEAD VARIETIES	2F2762			5.0000
14001AA	BEETS-ROOTS	3F2827			0.1000
14007AA	GARLIC	1F2500			3.0000
14010AA	LEEKS	1F2500			10.0000
14011AA	ONIONS-DRY-BULB (CIPOLLINI)	1F2500			3.0000
14011DA	ONIONS-DEHYDRATED OR DRIED	1F2500			3.0000
14013AA	POTATOES(WHITE)-WHOLE	1F2500			0.5000
14013AB	POTATOES(WHITE)-UNSPECIFIED	1F2500			0.5000
14013AC	POTATOES(WHITE)-PEELED	1F2500			0.5000
14013DA	POTATOES(WHITE)-DRY	1F2500			4.0000
14013HA	POTATOES(WHITE)-PEEL ONLY	1F2500			0.5000
14017AA	SHALLOTS	1F2500			10.0000
15001AA	BEANS-DRY-GREAT NORTHERN	3F2918			0.2000
15001AB	BEANS-DRY-KIDNEY	3F2918			0.2000
15001AC	BEANS-DRY-LIMA	3F2918			0.2000
15001AD	BEANS-DRY-NAVY (PEA)	3F2918			0.2000
15001AE	BEANS-DRY-OTHER	3F2918			0.2000
15001AF	BEANS-DRY-PINTO	3F2918			0.2000
15002AA	BEANS-SUCCULENT-LIMA	3F2918			0.2000
15003AA	BEANS-SUCCULENT-GREEN	3F2918			0.2000
15003AB	BEANS-SUCCULENT-OTHER	3F2918			0.2000
15003AC	BEANS-SUCCULENT-YELLOW/WAX	3F2918			0.2000
15004AA	CORV/POP	2F2695			0.1000
15005AA	CORN/SWEET	2F2695			0.1000
15006AA	PEANUTS-WHOLE	3F2919			0.2000
15007AA	PEAS(GARDEN)-MATURE SEEDS/DRY	3F2918			0.2000
15009AA	PEAS(GARDEN)-GREEN IMMATURE	3F2918			0.2000
15011AA	LENTILES-WHOLE	3F2918			0.2000

Table 1, continued

CHEMICAL INFORMATION FOR CASWELL NUMBER 375AA DATE: 09/15/89 PAGE: 4

FOOD CODE	FOOD NAME	PETITION NUMBER	NEW	TOLERANCE (PPM)		PUBLISHED	STATUS
				PENDING	PUBLISHED		
15011AB	LENTILES-SPLIT	3F2918			0.2000		
15013AA	MUNG BEANS (SPROUTS)	3F2918			0.2000		HED complete 05/23/86.
15018AA	SUNFLOWER-SEEDS	3F2827			0.1000		EPA verified 07/08/86.
15022AA	BEANS-DRY-BROADBEANS(MATURE SEED)	3F2918			0.2000		WHO last reviewed 1982.
15022PB	BEANS-SUCCULENT-BROADBEANS(IMMATURE SEED)	3F2918			0.2000		
15023AA	BEANS-DRY-PIGEON BEANS	3F2918			0.2000		
15027AA	BEANS-UNSPECIFIED	3F2918			0.2000		
15029AA	SOYBEANS-SPROUTED SEEDS	3F2818			1.0000		
15030AA	BEANS-DRY-HYACINTH(MATURE SEEDS)	3F2918			0.2000		
15030AB	BEANS-SUCCULENT-HYACINTH(YOUNG PODS)	3F2918			0.2000		
15031AA	BEANS-DRY-BLACKEYE PEAS(COWPEAS)	3F2918			0.2000		
15032AA	BEANS-DRY-CARBANZO(CHICK PEA)	3F2918			0.2000		
16002AA	ASPARAGUS	6F3330			7.0000		
16004AA	ONIONS-GREEN	1F2500			10.0000		
24001AA	BARLEY	2F2695			0.1000		
24002EA	CORN/GRAIN-ENDOSPERM	2F2695			0.1000		
24002HA	CORN/GRAIN-BRAN	2F2695			0.1000		
24002SA	CORN SUGAR	2F2695			0.1000		
24003AA	OATS	2F2695			0.1000		
24004AA	RICE-ROUGH	2F2695			0.1000		
24004AB	RICE-MILLED	2F2695			0.1000		
24005AA	RYE-ROUGH	2F2695			0.1000		
24005GA	RYE-GERM	2F2695			0.1000		
24005WA	RYE-FLOUR	2F2695			0.1000		
24006AA	SORGHUM (INCLUDING MILO)	2F2695			0.1000		
24007AA	WHEAT-ROUGH	2F2764			0.2000		
24007GA	WHEAT-GERM				1.0000	H	
24007HA	WHEAT-BRAN				1.0000	H	
24007WA	WHEAT-FLOUR				1.0000	H	
24012AA	MILLET	2F2695			0.1000		
25002SA	BET SUGAR	6F3387			0.1000		
26001AA	BUCKWHEAT	2F2695			0.1000		
26011AA	GUAR BEANS				0.2000		
270020A	CORN/GRAIN-OIL	2F2695			0.1000		
270030A	COTTONSEED-OIL	1F2500			0.1000		
27003WA	COTTONSEED-MEAL	1F2500			0.1000		
270070A	PEANUTS-OIL	3F2918			0.2000		
270100A	SOYBEANS-OIL	3F2818			1.0000		
270110A	SUNFLOWER-OIL	3F2827			0.1000		
28023AA	SOYBEANS-UNSPECIFIED	3F2818			1.0000		On IRIS.

Table 1, continued

CHEMICAL INFORMATION FOR CASWELL NUMBER 375AA DATE: 09/15/89 PAGE: 5

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES		DATA GAPS/COMMENTS	STATUS
			ADI	SF		
MetaLaxyl	6mo feeding- dog	Increased alkaline phosphatase activity, incr relative liver weights.	--100		No data gaps, however MTD was not reached in rat or mouse onco studies. Re-quirements to be re-evaluated after mutagenicity data are submitted.	HED complete 05/23/86.
Caswell #375AA	NOEL= 6,2500 mg/kg		OPP	RD= 0.060000		EPA verified 07/08/86.
CAS No. 57837-19-1	LEL= 250.00 ppm		EPA	RD= 0.060000		WHO last reviewed 1982.
A.I. CODE: 113501	1000.00 ppm					
CFR No. 180.408	ONCO: Class E (HED NOTE)					

FOOD CODE	FOOD NAME	PETITION NUMBER	TOLERANCE (PPM)		PUBLISHED
			NEW	PENDING	
28023AB	SOYBEANS-MATURE/SEEDS DRY	3F2818		1.0000	
28023WA	SOYBEANS-FLOUR/FULL FAT	3F2818		1.0000	
28023WB	SOYBEANS-FLOUR/LOW FAT	3F2818		1.0000	
28023WC	SOYBEANS-FLOUR/DEFATED	3F2818		1.0000	
50000DB	MILK-NON-FAT SOLIDS	1F2500		0.0200	
50000FA	MILK-FAT SOLIDS	1F2500		0.0200	
50000SA	MILK SUGAR (LACTOSE)	1F2500		0.0500	
53001BA	BEEF-MEAT BYPRODUCTS	1F2500		0.0500	
53001BB	BEEF (ORGAN MEATS)-OTHER	1F2500		0.0500	
53001DA	BEEF-DRIED	1F2500		0.0500	
53001FA	BEEF (BONELESS)-FAT (BEEF TALLOW)	1F2500		0.4000	H
53001KA	BEEF (ORGAN MEATS)-KIDNEY	1F2500		0.4000	H
53001LA	BEEF (ORGAN MEATS)-LIVER	1F2500		0.4000	H
53001NA	BEEF (BONELESS)-LEAN (W/O REMOVEABLE FAT)	1F2500		0.0500	
53002BA	GOAT-MEAT BYPRODUCTS	1F2500		0.0500	
53002BB	GOAT (ORGAN MEATS)-OTHER	1F2500		0.0500	
53002FA	GOAT (BONELESS)-FAT	1F2500		0.4000	H
53002KA	GOAT (ORGAN MEATS)-KIDNEY	1F2500		0.4000	H
53002LA	GOAT (ORGAN MEATS)-LIVER	1F2500		0.4000	H
53002NA	GOAT (BONELESS)-LEAN (W/O REMOVEABLE FAT)	1F2500		0.0500	
53003AA	HORSE	1F2500		0.4000	H
53005BA	SHEEP-MEAT BYPRODUCTS	1F2500		0.0500	
53005BB	SHEEP (ORGAN MEATS)-OTHER	1F2500		0.0500	
53005FA	SHEEP (BONELESS)-FAT	1F2500		0.4000	H
53005KA	SHEEP (ORGAN MEATS)-KIDNEY	1F2500		0.4000	H
53005LA	SHEEP (ORGAN MEATS)-LIVER	1F2500		0.4000	H
53005MA	SHEEP (BONELESS)-LEAN (W/O REMOVEABLE FAT)	1F2500		0.0500	
53006BA	PORK-MEAT BYPRODUCTS	1F2500		0.0500	
53006BB	PORK (ORGAN MEATS)-OTHER	1F2500		0.0500	
53006FA	PORK (BONELESS)-FAT (INCLUDING LARD)	1F2500		0.4000	H
53006KA	PORK (ORGAN MEATS)-KIDNEY	1F2500		0.4000	H
53006LA	PORK (ORGAN MEATS)-LIVER	1F2500		0.4000	H
53006MA	PORK (BONELESS)-LEAN (W/O REMOVEABLE FAT)	1F2500		0.0500	
55008BA	TURKEY-BYPRODUCTS	1F2500		0.0500	
55008LA	TURKEY-GIBLETS (LIVER)	1F2500		0.4000	H
55008MA	TURKEY-FLESH(W/O SKIN & W/O BONES)	1F2500		0.0500	
55008MB	TURKEY-FLESH(+SKIN & W/O BONES)	1F2500		0.4000	H
55008MC	TURKEY-UNSPECIFIED	1F2500		0.0500	
55013BA	POULTRY/OTHER-BYPRODUCTS	1F2500		0.0500	
55013LA	POULTRY/OTHER-GIBLETS(LIVER)	1F2500		0.4000	H

Table 1, continued

CHEMICAL INFORMATION FOR CASWELL NUMBER 375AA DATE: 09/15/89 PAGE: 6

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES		DATA GAPS/COMMENTS	STATUS
			ADI	SF		
MetaLaxyl	6mo feeding- dog	Increased alkaline phos- phatase activity, incr relative liver weights.		-->100	No data gaps, however MTD was not reached in rat or mouse onco studies. Re- quirements to be re-eval- uated after mutagenicity data are submitted.	HED complete 05/23/86. EPA verified 07/08/86. WHO last reviewed 1982.
Caswell #375AA	NOEL= 6.2500 mg/kg		OPP RFD= 0.060000			
CAS No. 57837-19-1	250.00 ppm		EPA RFD= 0.060000			
A.I. CODE: 113501	LEL= 25.0000 mg/kg	No evidence of oncogeni- city in rats or mice.				
CFR No. 180.408	1000.00 ppm					
	ONCO: Class E (HED NOTE)					On IRIS.

FOOD CODE	FOOD NAME	PETITION NUMBER	NEW	TOLERANCE (PPM)	
				PENDING	PUBLISHED
55013MA	POULTRY/OTHER-FLESH (+SKIN & W/O BONES)	1F2500			0.4000 H
55014AA	EGGS-WHOLE	1F2500			0.0500
55014AB	EGGS-WHITE ONLY	1F2500			0.0500
55014AC	EGGS-YOLK ONLY	1F2500			0.0500
55015BA	CHICKEN-BYPRODUCTS	1F2500			0.0500
55015LA	CHICKEN-GIBLETS(LIVER)	1F2500			0.4000 H
55015MA	CHICKEN-FLESH(W/O SKIN & W/O BONES)	1F2500			0.0500
55015MB	CHICKEN-FLESH(+SKIN & W/O BONES)	1F2500			0.4000 H

Table 2

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS DATE: 09/15/89 PAGE: 1

CHEMICAL INFORMATION		STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Metals	6mo feeding - dog	Increased alkaline phosphatase activity, incr relative liver weights. No evidence of oncogenicity in rats or mice.	(ADI SF -->100 OPP RfD= 0.060000 EPA RfD= 0.060000)	No data gaps, however MTD was not reached in rat or mouse onco studies. Re-quirements to be re-evaluated after mutagenicity data are submitted.	HED complete 05/23/86. EPA verified 07/08/86. WHO last reviewed 1982.	
Caswell #3759A	NOEL= 6.2500 mg/kg					
CAS No. 57837-19-1	250.00 ppm					
A.I. CODE: 113501	LEL= 25.0000 mg/kg					
CFR No. 180.408	1000.00 ppm					
	ONCO: Class E (HED NOTE)				On IRIS.	
POPULATION SUBGROUP						
U.S. POPULATION - 48 STATES		TOTAL TMRC (MG/KG BODY WEIGHT/DAY)	NEW TMRC**	NEW TMRC AS PERCENT OF REF	DIFFERENCE AS PERCENT OF REF	EFFECT OF ANTICIPATED RESIDUES
		0.009847	0.010713	17.854560	1.443717	
	U.S. POPULATION - SPRING SEASON	0.009876	0.010778	17.963413	1.503668	
	U.S. POPULATION - SUMMER SEASON	0.009862	0.010970	18.284000	1.847583	
	U.S. POPULATION - FALL SEASON	0.009733	0.010481	17.468760	1.247743	
	U.S. POPULATION - WINTER SEASON	0.009878	0.010584	17.639488	1.176757	
NORTHEAST REGION						
		0.010734	0.011825	19.708002	1.817667	
NORTH CENTRAL REGION						
		0.009682	0.010513	17.521177	1.384563	
SOUTHERN REGION						
		0.008827	0.009430	15.716563	1.004162	
WESTERN REGION						
		0.010606	0.011679	19.465173	1.788830	
HISPANICS						
		0.011335	0.012216	20.359613	1.468672	
NON-HISPANIC WHITES						
		0.009814	0.010740	17.900325	1.543783	
NON-HISPANIC BLACKS						
		0.009040	0.009529	15.881050	0.813930	
NON-HISPANIC OTHERS						
		0.011941	0.012659	21.097627	1.196373	
NURSING INFANTS (< 1 YEAR OLD)						
		0.006080	0.007841	13.067942	2.935052	
NON-NURSING INFANTS (< 1 YEAR OLD)						
		0.015982	0.019630	32.716098	6.079445	
FEMALES (13+ YEARS, PREGNANT)						
		0.007701	0.008118	13.529440	0.694430	
FEMALES 13+ YEARS, NURSING						
		0.009223	0.009812	16.352883	0.981952	
CHILDREN (1-6 YEARS OLD)						
		0.019491	0.020344	33.907010	1.421840	
CHILDREN (7-12 YEARS OLD)						
		0.013822	0.014328	23.880127	0.843993	
MALES (13-19 YEARS OLD)						
		0.009350	0.009796	16.326707	0.743260	
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)						
		0.008331	0.008646	14.409397	0.524815	
MALES (20 YEARS AND OLDER)						
		0.007692	0.009242	15.403083	2.582488	
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)						
		0.008041	0.008624	14.374162	0.971707	

*Current TMRC does not include new or pending tolerances.
 **New TMRC includes new, pending, and published tolerances.

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of
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REGISTRATION DIVISION DATA REVIEW RECORD

Confidential Business Information - Does Not Contain National Security Information (E.O. 12065)

1. CHEMICAL NAME <i>Metalaxyl SH Code 113501-1</i>			
2. IDENTIFYING NUMBER	3. ACTION CODE	4. ACCESSION NUMBER	TO BE COMPLETED BY PM
<i>D7F 3470</i>	<i>230</i>	<i>365762 thru</i>	5. RECORD NUMBER
<i>B7H 5520</i>	<i>250</i>	<i>36575</i>	6. REFERENCE NUMBER
<i>B7C-607</i>	<i>335</i>		7. DATE RECEIVED (EPA) <i>11-24-86</i>
			8. STATUTORY DUE DATE
			9. PRODUCT MANAGER (PM) <i>Russell Mack</i>
			10. PM TEAM NUMBER <i>21</i>

14. CHECK IF APPLICABLE		TO BE COMPLETED BY PCB
<input type="checkbox"/> Public Health/Quarantine	<input type="checkbox"/> Minor Use	11. DATE SENT TO HED/TSS <i>11-28-86</i>
<input type="checkbox"/> Substitute Chemical	<input type="checkbox"/> Part of IPM	12. PRIORITY NUMBER <i>479</i>
<input type="checkbox"/> Seasonal Concern	<input type="checkbox"/> Review Requires Less Than 4 Hours	13. PROJECTED RETURN DATE <i>12-31-86</i>

15. INSTRUCTIONS TO REVIEWER	
A. HED <input checked="" type="checkbox"/> Total Assessment - 3(c)(5)	C. <input type="checkbox"/> BFSD
<input type="checkbox"/> Incremental Risk Assessment - 3(c)(7) and/or E.L. Johnson memo of May 12, 1977.	D. <input type="checkbox"/> TSS/RD
B. SPRD (Send Copy of Form to SPRD PM)	E. <input type="checkbox"/> Other
<input type="checkbox"/> Chemical Undergoing Active RPAR Review	
<input type="checkbox"/> Chemical Undergoing Active Registration Standards Review	

F. INSTRUCTIONS
<i>Please Review list</i>
<i>Track</i>
<i>Track</i>

16. RELATED ACTIONS

17. 3(c)(1)(D)	18. REVIEWS SENT TO
<input type="checkbox"/> Use Any or All Available Information <input type="checkbox"/> Use Only Attached Data	<input checked="" type="checkbox"/> TB <input checked="" type="checkbox"/> EEB <input type="checkbox"/> EF <input type="checkbox"/> PL
<input type="checkbox"/> Use Only the Attached Data for Formulation and Any or All Available Information on the Technical or Manufacturing Chemical.	<input checked="" type="checkbox"/> RCB <input checked="" type="checkbox"/> EFB <input type="checkbox"/> CH <input type="checkbox"/> BFSD

19. To	TYPE OF REVIEW	NUMBER OF ACTIONS							
		Registration	Petition	EUP	SLN	Sec. 18	Inert	MNR. USE	Other
HED	TOXICOLOGY								
	ECOLOGICAL EFFECTS								
	<input checked="" type="checkbox"/> RESIDUE CHEMISTRY	<i>1</i>	<i>2</i>						
	ENVIRONMENTAL DATA								
RD/TSS	CHEMISTRY								
	EFFICACY								
	PRECAUTIONARY LABELING								
BFSD	ECONOMIC ANALYSIS								

20. <input type="checkbox"/> Label Submitted with Application Attached	21. <input type="checkbox"/> Confidential Statement of Formula	22. <input type="checkbox"/> Representative Labels Showing Accepted Uses Attached	23. Date Returned to RD (to be completed by HED)	24. Include an Original and 4 (four) Copies of This Completed Form for Each Branch Checked for Review.
--	--	---	--	--

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TO: M. J. Nelson Date: 2/20/87

Petition No.: ^{7F3470}~~7H5520~~ Metal 2xyl is assigned to you for review.

(1) To help us decide as soon as possible on a method tryout, please indicate before 2/27/87 (date), if there are any major deficiencies in the data of this petition and whether or not a tryout is needed.

(2) To meet permanent petition or substantive amendment deadlines, complete and submit your review to your Section Head ~~within 45 days,~~ in this case by when complete (date).

(3) To meet temporary petition deadlines, complete and submit your review to your Section Head within 30 days, i.e., by _____ (date). He will submit it for final approval to meet the 45 day branch deadline for temporary tolerances.

Initial, date, and show this form to your Section Head.

R. S. Quick

No MTO needed.

(The method, AG-395,
underwent MTO in re
PP 3F2918, successfully.)

mjn
2/24/87

RM

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of
Document

REGISTRATION DIVISION DATA REVIEW RECORD

Confidential Business Information - Does Not Contain National Security Information (E.O. 12065)

1. CHEMICAL NAME
PHENACETYL

2. IDENTIFYING NUMBER <i>7F 3-70</i>	3. ACTION CODE <i>830</i>	4. ACCESSION NUMBER	TO BE COMPLETED BY PM
			5. RECORD NUMBER <i>201015</i>
			6. REFERENCE NUMBER
			7. DATE RECEIVED (EPA) <i>7-17-87</i>
			8. STATUTORY DUE DATE
			9. PRODUCT MANAGER (PM) <i>ROSSI</i>
			10. PM TEAM NUMBER <i>21</i>

14. CHECK IF APPLICABLE

Public Health/Quarantine Minor Use

Substitute Chemical Part of IPM

Seasonal Concern Review Requires Less Than 4 Hours

TO BE COMPLETED BY PCB

11. DATE SENT TO HED/TSS
8-25-87

12. PRIORITY NUMBER
49

13. PROJECTED RETURN DATE
12-11-87

15. INSTRUCTIONS TO REVIEWER

A. HED Total Assessment - 3(c)(5) C. BFSD

Incremental Risk Assessment - 3(c)(7) and/or E.L. Johnson memo of May 12, 1977. D. TSS/RD

Other

B. SPRD (Send Copy of Form to SPRD PM)

Chemical Undergoing Active RPAR Review

Chemical Undergoing Active Registration Standards Review

F. INSTRUCTIONS
Revised Sect. F and B
per RPS memo 3/4/87
...
...
...

16. RELATED ACTIONS

17. 3(c)(1)(D)

Use Any or All Available Information Use Only Attached Data

Use Only the Attached Data for Formulation and Any or All Available Information on the Technical or Manufacturing Chemical.

18. REVIEWS SENT TO

TB EEB EF PL

RCB EFB CH BFSD

19. To	TYPE OF REVIEW	NUMBER OF ACTIONS							
		Registration	Petition	EUP	SLN	Sec. 18	Inert	MNR. USE	Other
HED	TOXICOLOGY								
	ECOLOGICAL EFFECTS								
	<input checked="" type="checkbox"/> RESIDUE CHEMISTRY								
	ENVIRONMENTAL DATA								
RD/TSS	CHEMISTRY								
	EFFICACY								
	PRECAUTIONARY LABELING								
BFSD	ECONOMIC ANALYSIS								

20. Label Submitted with Application Attached

21. Confidential Statement of Formula

22. Representative Labels Showing Accepted Uses Attached

23. Date Returned to RD (to be completed by HED)

24. Include an Original and 4 (four) Copies of This Completed Form for Each Branch Checked for Review.

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

AUG 26 1987

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#7F3470/FAP#7H5520/EPA Reg. No. 100-607.

Metalaxyl in or on Blueberries, Walnuts, Almonds,
Almond Hulls, Stone Fruits, Dried Apricots and
Prunes.

Review of Amendment of July 15, 1987.

RCB#: 2604, 2699, 2700.

MRID#: None.

FROM: Maxie Jo Nelson, Chemist
Tolerance Petition Section I
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

mjn

THRU: Robert S. Quick, Section Head
Tolerance Petition Section I
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

mjn for

TO: Lois Rossi, PM 21
Fungicide-Herbicide Branch
Registration Division (TS-767C)

and

Toxicology Branch
Hazard Evaluation Division (TS-769C)

By letter dated July 15, 1987, Ciba-Geigy Corporation has submitted an amendment responding to the deficiencies raised in RCB's review (M. Nelson) of March 6, 1987.

The amendment consists of revised Sections B (labeling) and F (tolerance proposal) and a copy of the final report (dated June 29, 1987) from the recent (1986-87) Section 18 Specific Exemption use of Ridomil on blueberries in Arkansas.

- 2 -

CONCLUSIONS

1. The petitioner indicates all the necessary work to comply with the requirement for the testing of pesticide chemicals via FDA multiresidue protocols is underway, with an expected completion date of mid-October.

It is unclear if the petitioner is aware this testing requirement also applies to the metabolites. The PM should so inform the petitioner. Additionally, the petitioner should be advised that if metabolites are to be tested for recovery as a mixture, separate instrument responses must appear and be separately recognizable and quantifiable. In other words, an individual reference material must be available for each metabolite. All metabolites which constitute an appreciable portion of the regulable residue must be subjected to multiresidue testing.

This deficiency remains outstanding pending submission of all the necessary data.

2. The petitioner has submitted revised use directions for blueberries. The use directions now proposed for "established plantings" of blueberries permit a second application to be made when disease pressure warrants. We do not object to this since supporting residue data (decline studies) are available on blueberries reflecting a second application under "worst case" conditions (0-34 day PHIs). Residues were less than the proposed 2 ppm tolerance in all cases, even under 2X rate conditions (see 3/6/87 review, this petition).

The use directions for "new plantings" of blueberries are an additional use not proposed in the original submission. By examination of the available residue decline data on blueberries (see aforesaid 3/6/87 review) reflecting multiple 7.24 lbs ai/treated acre treatments, we can conclude that this additional use pattern is supportable.

Residues resulting from the proposed directions for use on blueberries should not result in residues in excess of the proposed tolerance level (2 ppm).

The requested information on the Section 18 program granted in 1986 on Arkansas blueberries was submitted as requested.

This deficiency is considered resolved.

3. The petitioner has submitted a revised Section F proposing a 10 ppm tolerance level for almond hulls, as we requested.

This deficiency is resolved.

- 3 -

RECOMMENDATION

RCB continues to recommend against the establishment of the proposed tolerances of this petition for the reason stated in Conclusion 1 above.

DISCUSSION

Our (M. Nelson) review of March 6, 1987, listed 3 deficiencies which precluded a favorable recommendation from RCB for the establishment of the proposed tolerances.

Multiresidue Testing

The first deficiency dealt with the need for the petitioner to comply with the residue chemistry data requirements in 40 CFR 158.125(b)(15) re the testing of pesticide chemicals via FDA multiresidue protocols.

The petitioner indicates the necessary work is in progress to comply with this requirement, with an expected completion date of mid-October, 1987.

Recently, RCB has received clarification from FDA (memo of 6/9/87) to the effect this information is also needed for the regulated metabolites.

It is unclear if the petitioner is aware this testing requirement applies to the metabolites. The PM should clarify this point to the petitioner. Additionally, the petitioner should be advised that "if metabolites are to be tested for recovery as a mixture, separate instrument responses must appear and be separately recognizable and quantifiable. In other words, an individual reference material must be available for each metabolite." All metabolites which constitute an appreciable portion of the regulable residue must be subjected to multiresidue testing.

This deficiency remains outstanding pending submission of all the necessary data.

Revised Labeling

The second deficiency pertained to blueberries and dealt with the need for the petitioner to either: (1) revise the proposed use directions to match the available field trial data (second application at, or shortly before, harvest); or, (2) conduct some additional field trials to reflect the use directions proposed (second application after harvest), in which case a more appropriate (lower) tolerance proposal for blueberries would be in order.

- 4 -

The petitioner has responded with a revised Section B (proposed directions for use) for blueberries, as follows:

"Established Plantings: Apply 0.25 lb ai/1,000 linear ft of row (3.625 lbs ai/A broadcast basis) in a 3' band over the row before the plants start growth in the spring. One additional application may be made to coincide with periods most favorable for root rot development.

"New Plantings: Apply 4-8 lbs ai [2-4 gallons of Ridomil® 2E]/A broadcast to the soil at or after the time of planting. Supplemental applications should be made at 2-3 month intervals or to coincide with periods most favorable for root rot development. For banded applications, an 18" band over the row is recommended.

"Note: On new plantings, do not apply more than 7.25 lbs ai/A during the 12 months before bearing harvestable fruit, or illegal residues may result."

The use directions now proposed for "established plantings" of blueberries permit a second application to be made when disease pressure warrants. We do not object to this since supporting residue data (decline studies) are available on blueberries reflecting a second application under "worst case" conditions (0-34 day PHIs). Residues were less than the proposed 2 ppm tolerance in all cases, even under 2X rate conditions (see 3/6/87 review, this petition).

The use directions for "new plantings" of blueberries are an additional use not proposed in the original submission. By examination of the available residue decline data on blueberries (see aforesaid 3/6/87 review) reflecting multiple 7.24 lbs ai/treated acre treatments, we can conclude that this additional use pattern is supported.

Residues resulting from the proposed directions for use on blueberries should not result in residues in excess of the proposed tolerance level (2 ppm).

This deficiency is considered resolved.

We also requested information on the Section 18 granted in 1986 for use on Arkansas blueberries, which the petitioner has now supplied. Little if any real residue would have been expected from the proposed use involved (soil application of 1 pt Ridomil® 2E/1000' row, up to 2 applications, 45-day PHI).

- 5 -

Revised Tolerance Proposal

The third deficiency dealt with the need for the petitioner to propose a higher (10 ppm) tolerance level for almond hulls.

The petitioner has submitted a revised Section F incorporating the requested change.

This deficiency is resolved.

cc: RF, Circ, Reviewer (M. Nelson), PP#7F3470/FAP#7H5520, PM#21,
TOX, PMSD/ISB (Eldridge).
TS-769C:RCB:Reviewer(MJN):CM#2:Rm804:557-7484:typist(mjn):8/21/87.
RDI:SectionHead:RSQuick:8/21/87:DeputyChief:RDSchmitt:8/25/87.

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

AUG 26 1987

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#7F3470/FAP#7H5520/EPA Reg. No. 100-607.

Metalaxyl in or on Blueberries, Walnuts, Almonds,
Almond Hulls, Stone Fruits, Dried Apricots and
Prunes.

Review of Amendment of July 15, 1987.

RCB#: 2604, 2699, 2700.

MRID#: None.

FROM: Maxie Jo Nelson, Chemist
Tolerance Petition Section I
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

mjn

THRU: Robert S. Quick, Section Head
Tolerance Petition Section I
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

mjn for

TO: Lois Rossi, PM 21
Fungicide-Herbicide Branch
Registration Division (TS-767C)

and

Toxicology Branch
Hazard Evaluation Division (TS-769C)

By letter dated July 15, 1987, Ciba-Geigy Corporation has submitted an amendment responding to the deficiencies raised in RCB's review (M. Nelson) of March 6, 1987.

The amendment consists of revised Sections B (labeling) and F (tolerance proposal) and a copy of the final report (dated June 29, 1987) from the recent (1986-87) Section 18 Specific Exemption use of Ridomil on blueberries in Arkansas.

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CONCLUSIONS

1. The petitioner indicates all the necessary work to comply with the requirement for the testing of pesticide chemicals via FDA multiresidue protocols is underway, with an expected completion date of mid-October.

It is unclear if the petitioner is aware this testing requirement also applies to the metabolites. The PM should so inform the petitioner. Additionally, the petitioner should be advised that if metabolites are to be tested for recovery as a mixture, separate instrument responses must appear and be separately recognizable and quantifiable. In other words, an individual reference material must be available for each metabolite. All metabolites which constitute an appreciable portion of the regulable residue must be subjected to multiresidue testing.

This deficiency remains outstanding pending submission of all the necessary data.

2. The petitioner has submitted revised use directions for blueberries. The use directions now proposed for "established plantings" of blueberries permit a second application to be made when disease pressure warrants. We do not object to this since supporting residue data (decline studies) are available on blueberries reflecting a second application under "worst case" conditions (0-34 day PHIs). Residues were less than the proposed 2 ppm tolerance in all cases, even under 2X rate conditions (see 3/6/87 review, this petition).

The use directions for "new plantings" of blueberries are an additional use not proposed in the original submission. By examination of the available residue decline data on blueberries (see aforesaid 3/6/87 review) reflecting multiple 7.24 lbs ai/treated acre treatments, we can conclude that this additional use pattern is supportable.

Residues resulting from the proposed directions for use on blueberries should not result in residues in excess of the proposed tolerance level (2 ppm).

The requested information on the Section 18 program granted in 1986 on Arkansas blueberries was submitted as requested.

This deficiency is considered resolved.

3. The petitioner has submitted a revised Section F proposing a 10 ppm tolerance level for almond hulls, as we requested.

This deficiency is resolved.

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RECOMMENDATION

RCB continues to recommend against the establishment of the proposed tolerances of this petition for the reason stated in Conclusion 1 above.

DISCUSSION

Our (M. Nelson) review of March 6, 1987, listed 3 deficiencies which precluded a favorable recommendation from RCB for the establishment of the proposed tolerances.

Multiresidue Testing

The first deficiency dealt with the need for the petitioner to comply with the residue chemistry data requirements in 40 CFR 158.125(b)(15) re the testing of pesticide chemicals via FDA multiresidue protocols.

The petitioner indicates the necessary work is in progress to comply with this requirement, with an expected completion date of mid-October, 1987.

Recently, RCB has received clarification from FDA (memo of 6/9/87) to the effect this information is also needed for the regulated metabolites.

It is unclear if the petitioner is aware this testing requirement applies to the metabolites. The PM should clarify this point to the petitioner. Additionally, the petitioner should be advised that "if metabolites are to be tested for recovery as a mixture, separate instrument responses must appear and be separately recognizable and quantifiable. In other words, an individual reference material must be available for each metabolite." All metabolites which constitute an appreciable portion of the regulable residue must be subjected to multiresidue testing.

This deficiency remains outstanding pending submission of all the necessary data.

Revised Labeling

The second deficiency pertained to blueberries and dealt with the need for the petitioner to either: (1) revise the proposed use directions to match the available field trial data (second application at, or shortly before, harvest); or, (2) conduct some additional field trials to reflect the use directions proposed (second application after harvest), in which case a more appropriate (lower) tolerance proposal for blueberries would be in order.

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The petitioner has responded with a revised Section B (proposed directions for use) for blueberries, as follows:

"Established Plantings: Apply 0.25 lb ai/1,000 linear ft of row (3.625 lbs ai/A broadcast basis) in a 3' band over the row before the plants start growth in the spring. One additional application may be made to coincide with periods most favorable for root rot development.

"New Plantings: Apply 4-8 lbs ai [2-4 gallons of Ridomil® 2E]/A broadcast to the soil at or after the time of planting. Supplemental applications should be made at 2-3 month intervals or to coincide with periods most favorable for root rot development. For banded applications, an 18" band over the row is recommended.

"Note: On new plantings, do not apply more than 7.25 lbs ai/A during the 12 months before bearing harvestable fruit, or illegal residues may result."

The use directions now proposed for "established plantings" of blueberries permit a second application to be made when disease pressure warrants. We do not object to this since supporting residue data (decline studies) are available on blueberries reflecting a second application under "worst case" conditions (0-34 day PHIs). Residues were less than the proposed 2 ppm tolerance in all cases, even under 2X rate conditions (see 3/6/87 review, this petition).

The use directions for "new plantings" of blueberries are an additional use not proposed in the original submission. By examination of the available residue decline data on blueberries (see aforesaid 3/6/87 review) reflecting multiple 7.24 lbs ai/treated acre treatments, we can conclude that this additional use pattern is supported.

Residues resulting from the proposed directions for use on blueberries should not result in residues in excess of the proposed tolerance level (2 ppm).

This deficiency is considered resolved.

We also requested information on the Section 18 granted in 1986 for use on Arkansas blueberries, which the petitioner has now supplied. Little if any real residue would have been expected from the proposed use involved (soil application of 1 pt Ridomil® 2E/1000' row, up to 2 applications, 45-day PHI).

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Revised Tolerance Proposal

The third deficiency dealt with the need for the petitioner to propose a higher (10 ppm) tolerance level for almond hulls.

The petitioner has submitted a revised Section F incorporating the requested change.

This deficiency is resolved.

cc: RF, Circ, Reviewer (M. Nelson), PP#7F3470/FAP#7H5520, PM#21,
TOX, PMSD/ISB (Eldridge).
TS-769C:RCB:Reviewer(MJN):CM#2:Rm804:557-7484:typist(mjn):8/21/87.
RDI:SectionHead:RSQuick:8/21/87:DeputyChief:RDSchmitt:8/25/87.

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of
Document



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

MAR 6 1987

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#7F3470/FAP#7H5520/EPA Reg. No. 100-607.

Metalaxyl in or on Blueberries, Walnuts, Almonds,
Almond Hulls, Stone Fruits, Dried Apricots, and
Prunes.

Evaluation of Analytical Method and Residue Data.

[Accession Nos.: 265762, 265763, 265764, 265765.]
[RCB Nos.: 1676, 1677, 1678.]

FROM: Maxie Jo Nelson, Ph.D., Chemist
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

THRU: Charles L. Trichilo, Ph.D., Chief
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

TO: Lois Rossi, PM Team Number 21
Fungicide-Herbicide Branch
Registration Division (TS-767C)

and

Toxicology Branch
Hazard Evaluation Division (TS-769C)

Ciba-Geigy Corporation proposes tolerances for combined residues of the fungicide, metalaxyl, trade-named Ridomil® [N-(2,6-dimethylphenyl)-N-(methoxyacetyl)alanine methyl ester], and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methylphenyl)-N-(methoxyacetyl)alanine methyl ester, each expressed as metalaxyl, in or on the following raw agricultural commodities:

<u>Commodity</u>	<u>Proposed Tolerance</u>
Blueberries	2.0 ppm
Stone Fruits Crop Group	1.0 ppm
Walnuts	0.5 ppm
Almonds	0.5 ppm
Almond Hulls	5.0 ppm

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and processed food commodities:

<u>Commodity</u>	<u>Proposed Tolerance</u>
Apricots, Dried	4.0 ppm
Prunes	4.0 ppm

Ciba-Geigy also requests that the registration of Ridomil® 2E Fungicide (EPA Reg. No. 100-607) be amended to permit use on these crops for control of Phytophthora root rot in blueberries and root, crown, and collar rot in stone fruits, walnuts, and almonds.

The raw agricultural commodities (rac's) comprising the "stone fruits" crop group are listed in 40 CFR 180.34(f)(9)(xii).

Tolerances are currently established to regulate metalaxyl residues in or on a variety of rac's, including commodities of animal origin, under 40 CFR 180.408 (a)(b); on processed food commodities under 21 CFR 193.277 (a)(b); and, on animal feed commodities under 21 CFR 561.273 (a)(b).

Ridomil® 2E has been used in Arkansas the past two years under a Section 18 emergency exemption for control of Phytophthora in blueberries. Use of Ridomil® 2E for non-bearing deciduous fruits and nuts was accepted by the Agency in June, 1983.

Petitions requesting tolerances for metalaxyl in strawberries (PP#6F3337); grapes and its processed products (PP#6F3362/FAP#6H5493); sugarbeets, fruiting vegetables, and dry tomato pomace (PP#6F3387/FAP#6H5499) are co-pending.

Metalaxyl was the subject of a Registration Standard issued in December, 1981. There are no outstanding data gaps which need to be addressed in this petition.

Conclusions

- 1a. The qualitative nature of the residue in plants is adequately understood. The residues of concern are parent metalaxyl; its metabolites which contain the 2,6-dimethylaniline (DMA) moiety; and, N-(2-hydroxymethyl-6-methylphenyl)-N-(methoxyacetyl) alanine, methyl ester.
- 1b. The qualitative nature of the residue in meat and milk is adequately understood. The metabolism is similar to that in plants. The same residues are of concern.
- 1c. No poultry metabolism studies are available. However, there are no poultry feed items associated with this petition.
- 2a. The petitioner will need to comply with the Residue Chemistry Data Requirements in 40 CFR 158.125(b)(15) re the testing of pesticide chemicals via FDA multiresidue protocols. (For additional information on this subject, refer to Attachments #2 and #3 of this review.)

- 2b. Method AG-395 has been submitted to FDA, but has not yet been published in the Pesticide Analytical Manual (PAM), Volume II. In the interim, the analytical method is available to anyone interested in pesticide enforcement when requested from:

By mail: William Grosse, Chief; Information Services Branch (TS-767C); Program Management and Support Division; Office of Pesticide Programs; Environmental Protection Agency; 401 M Street, SW; Washington, DC 20460.

Office location and telephone number: Rm 223, CM#2, 1921 Jefferson Davis Highway, Arlington, VA 22202.

- 3a. Field trial results support the establishment of a 2.0 ppm tolerance in blueberries treated twice at a 1X rate and harvested with a 0-day PHI. However, the proposed use directions specify the second application is to be made after harvest, not before. For such a use, a 2 ppm tolerance would be much higher than necessary.

The petitioner will need to either: (1) revise the proposed use directions (Section B) to match the available field trial data (second application at, or shortly before, harvest); OR, (2) conduct some additional field trials to reflect the presently proposed use directions (second application after harvest).

If the latter option is chosen, the petitioner will also need to propose a more appropriate (lower) tolerance level for blueberries (revised Section F) based on the resulting residue results.

Additionally, we will need to take into consideration in determining the appropriate tolerance level for blueberries, any/all data/information submitted to the Agency to support the Section 18 emergency exemption for use of Ridomil® 2E on Arkansas blueberries. We have been unable to locate that information in the Agency's files. We request the petitioner submit the details/data as part of this petition.

- 3b. Based on the reported residue findings, the proposed 0.5 ppm tolerance level for walnuts and almonds in conjunction with a PHI of 0-days for 3 broadcast applications at 8 lbs ai/A applied as Ridomil® 2E (the proposed use) is appropriate.
- 3c. The proposed tolerance of 5.0 ppm for almond hulls is too low, based on normalization of the 2X data. The petitioner should submit a revised Section F proposing a 10 ppm tolerance for almond hulls.
- 3d. The representative commodities of the stone fruits crop group are: sour or sweet cherry, peach, and plums or fresh prunes. The petitioner has provided residue data for all these rac's.

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Based on the reported residue findings, the proposed 1.0 ppm tolerance level for the stone fruits crop group in conjunction with a PHI of 0-days for 3 broadcast applications at 8 lbs ai/A applied as Ridomil® 2E (the proposed use) is appropriate.

- 3e. Based on the maximum concentration factor observed, 3.9X, and the proposed 1.0 ppm tolerance for stone fruit, a food additive tolerance of 4.0 ppm is being proposed for dried apricots and prunes (dried plums).

We consider this 4.0 ppm proposed food additive tolerance level to be appropriate in conjunction with the proposed use.

Dried apricots and prunes are the only dried commodities in the stone fruits crop group which are regulable.

- 4a. The only animal feed item associated with this petition is almond hulls. Beef and dairy cattle may consume almond hulls at up to 25% of their diet.

The feeding of hulls from almonds treated with Ridomil® 2E in accordance with the proposed use will not result in residues in cattle tissues or milk that are higher than the tolerances which are already established on those animal commodities.

- 4b. Almond hulls are not fed either to poultry or swine.
5. An International Residue Limit (IRL) Status sheet is appended to this petition review as Attachment #1.

There are no established IRL's for the crops of this petition. The question of compatibility of tolerance levels thus does not arise.

We note that Codex currently regulates metalaxyl residues in terms of parent only. In a future meeting, Codex will reconsider its position in this regard.

Recommendations

RCB recommends against the establishment of the proposed tolerances of this petition at this time for the reasons stated in Conclusions 2a, 3a, and 3c, as follows:

- 2a. The petitioner will need to comply with the Residue Chemistry Data Requirements in 40 CFR 158.125(b)(15) re the testing of pesticide chemicals via FDA multiresidue protocols. (For additional information on this subject, refer to Attachments #2 and #3 of this review.)
- 3a. Field trial results support the establishment of a 2.0 ppm tolerance in blueberries treated twice at a 1X rate and harvested with a 0-day PHI. However, the proposed use directions specify the second application is to be made after harvest, not before. For such a use, a 2 ppm tolerance would be much higher than necessary.

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The petitioner will need to either: (1) revise the proposed use directions (Section B) to match the available field trial data (second application at, or shortly before, harvest); OR, (2) conduct some additional field trials to reflect the presently proposed use directions (second application after harvest).

If the latter option is chosen, the petitioner will also need to propose a more appropriate (lower) tolerance level for blueberries (revised Section F) based on the resulting residue results.

Additionally, we will need to take into consideration in determining the appropriate tolerance level for blueberries, any/all data/information submitted to the Agency to support the Section 18 emergency exemption for use of Ridomil® 2E on Arkansas blueberries. We have been unable to locate that information in the Agency's files. We request the petitioner submit the details/data as part of this petition.

- 3c. The proposed tolerance of 5.0 ppm for almond hulls is too low, based on normalization of the 2X data. The petitioner should submit a revised Section F proposing a 10 ppm tolerance for almond hulls.

If/when these tolerances are established, RCB has no objection to the amending of the Ridomil® 2E label to permit use on these crops.

NOTE TO PM: In the 1986 edition of 40 CFR, under §180.408, the following commodity listing has been inadvertently deleted: "Cattle, liver....0.4 ppm". This listing (which does appear in the 1985 edition) needs to be restored to the CFR as soon as possible.

We also note that the chemical name for one of the metalaxyl metabolites is incorrect. The error appears not only in 40 CFR 180.408, but in 21 CFR 193.277 and 21 CFR 561.273 as well.

The correct chemical name is: N-(2-hydroxymethyl-6-methylphenyl)-N-(methoxyacetyl)alanine methyl ester. This correction should be made in the appropriate CFR listings at the earliest opportunity.

Detailed Considerations

Manufacture and Formulation

The manufacturing process for technical metalaxyl has previously been submitted and discussed (ref. review of P. Errico, 3/9/82, PP#1F2500). Impurities are not expected to present a residue problem (ref. review of G. Makhijani, 3/29/79, PP#8G2121).

The formulation proposed for use on the rac's of this petition is Ridomil® 2E Fungicide (EPA Reg. No. 100-607), an emulsifiable concentrate that contains 25.1% ai (2 lbs ai/gallon).

The inert ingredients present in Ridomil® 2E are all exempt from the requirement of a tolerance under 40 CFR 180.1001(c)(d).

The Confidential Statement of Formula (CSF) for Ridomil® 2E, dated 9/18/79, is filed with PP#1F2500, and a revised CSF, dated 3/17/82, is on file in RD.

Proposed Uses

Blueberries. Ridomil® 2E is a soil-applied systemic fungicide for use in the control of Phytophthora root rot.

Apply 1 pint (0.25 lb ai)/1,000 linear feet of row to the soil surface in a three-foot band over the row [14.5 pints (3.625 lbs ai)/treated acre on a broadcast basis]. Make one application in the spring and another in the fall after harvest.

Stone Fruits, Almonds, and Walnuts. Apply Ridomil® 2E as a soil surface spray for control of crown, collar, and root rot caused by Phytophthora spp.

On new plantings, make the first application 2 weeks after planting. For established plantings, the first application should be made in the spring before the plants start growth. In both cases, make additional applications at 2-3 month intervals or to coincide with periods most favorable for development of the disease.

Apply 2-4 gals (4-8 lbs ai)/treated acre (6-12 fl. ozs./1,000 sq. ft.) in sufficient carrier to obtain thorough coverage of the soil under the canopy of the trees. Sufficient surface area should be treated in nurseries to cover the root zone of the plants. For banded applications, use proportionately less.

Precautions: (1) Do not dip the roots of trees in Ridomil® 2E solution, spray the roots, or concentrate the solution around tree trunks; and, (2) Do not apply to trees under stress.

Label Restrictions: (1) Do not graze livestock in treated areas; (2) Do not graze or feed cover crops grown in treated orchards; and, (3) Do not make more than three applications per year.

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Nature of the Residue

Plants. No new plant metabolism studies were submitted with this petition.

ϕ -¹⁴C-Metalaxyl metabolism studies in potatoes, grapes, and lettuce, have been submitted/discussed in previous petitions (ref. P. Errico review, 3/9/82, PP#1F2500; G. Makhijani review, 3/29/79, PP#8G2121; N. Dodd review, 12/8/83, PP#2F2762).

In plants, metalaxyl is metabolized through one or more of the following processes: oxidation of the ring methyl to benzyl alcohol/benzoic acid; hydroxylation of the phenyl ring; hydrolysis of the methyl ester; cleavage of the methyl ether; N-dealkylation and subsequent conjugation of some of the metabolites.

The qualitative nature of the residue in plants is adequately understood. The residues of concern are parent metalaxyl; its metabolites containing the 2,6-dimethylaniline (DMA) moiety; and, N-(2-hydroxymethyl-6-methylphenyl)-N-(methoxyacetyl) alanine, methyl ester.

Animals. No additional animal metabolism studies were submitted with this petition.

ϕ -¹⁴C-Metalaxyl metabolism studies in goats and rats have been submitted/discussed in earlier petitions (ref. P. Errico reviews, 3/9/82 and 7/16/82, PP#1F2500 and G. Makhijani review, 3/29/79, PP#8G2121).

The qualitative nature of the residue in meat/milk is adequately understood. The metabolism is similar to that in plants. The same residues are of concern.

No poultry metabolism studies are available. However, there are no poultry feed items associated with this petition.

Analytical Method

The petitioner should be advised of the need to comply with the Residue Chemistry Data Requirements in 40 CFR 158.125(b)(15) re testing of pesticide chemicals via FDA multiresidue protocols. (For additional information on this subject, refer to Attachments #2 and #3 of this review.)

The analytical method used to generate the residue data submitted to support this petition is coded AG-395, dated 12/7/82, titled "Improved Method for the Determination of Total Residues of Metalaxyl in Crop as 2,6-Dimethylaniline", and jointly authored by K. Balasubramanian and R. Perez.

This method has been previously submitted and extensively reviewed, most recently in re PP#6F3387/FAP#6H5499 (F. D. Griffith, Jr. memo of 9/26/86), which see.

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The data in this petition on the validation of AG-395 using ¹⁴C-metalaxyl-treated lettuce (Rpt. No. ABR-83033) have also been previously submitted and reviewed (see K. Arne memo, 12/13/83, PP#3F2918).

The recovery data which are contained in the individual field trial reports submitted for the crops of this petition are new data. Those validation results are summarized below:

<u>Commodity</u>	<u>Fortification Level (ppm)</u>	<u>Recovery (%)</u>	<u>Controls (ppm)</u>
Blueberries	0.05-1.0	66-112	<0.05
Stone Fruits			
Apricots	0.2-0.5	107-110	<0.05-0.15
" , dried	1.0	73	0.79
Cherries	0.1-0.5	85-107	<0.05
Peaches	0.05-0.5	86-94	<0.05
Prunes	0.05-0.5	82-93	<0.05-0.10
" , dried	0.2	95	<0.05
Walnuts	0.05-0.5	54-69	<0.05
Almonds, hulls	0.1-1.0	71-114	<0.05-0.24
" , shells	0.1-0.5	79-119	<0.05-0.22
" , nutmeats	0.05-0.5	72-107	<0.05-0.09

A successful method trial of AG-395 was conducted in re PP#3F2918 (ref. P. Jung memo, 7/9/84). The method determines the regulable residue, with a limit of detection of 0.05 ppm, expressed in metalaxyl equivalents.

Method AG-395 has been submitted to FDA, but has not yet been published in the Pesticide Analytical Manual (PAM), Volume II. In the interim, the analytical method is available to anyone interested in pesticide enforcement when requested from:

By mail: William Grosse, Chief; Information Services Branch (TS-767C); Program Management and Support Division; Office of Pesticide Programs; Environmental Protection Agency; 401 M Street, SW; Washington, DC 20460.

Office location and telephone number: Rm 223, CM#2, 1921 Jefferson Davis Highway, Arlington, VA 22202.

Residue Data

Storage Stability. Two freezer storage stability studies were submitted. The first (Rpt. No. ABR-80028) was conducted to demonstrate the validity of analytical results obtained by determination of residues of metalaxyl and its metabolites in tobacco and potato samples.

Those data have previously been submitted/reviewed (see memo of F. D. Griffith, Jr., 9/26/86, PP#6F3387/FAP#6H5499). The results demonstrated the stability of combined residues of metalaxyl and its metabolites which are converted to 2,6-dimethylaniline for at least 18 months under the freezer conditions employed (5°F).

The second (Rpt. No. ABR-86044) was conducted to determine the stability of metalaxyl (CGA-48988) and its metabolites (CGA-62826, CGA-67869, CGA-107955, CGA-37734, and CGA 94689) in fruit and vegetable crops.

Strawberries, apples, cabbage, lettuce, and potatoes were fortified at 1.0 ppm of each moiety and stored in a freezer at -15°C. Samples were analyzed using method AG-395 for "total" metalaxyl residues over a one-year period at six-month intervals. Results demonstrated the stability of metalaxyl and its metabolites for at least 12-months under freezer storage conditions.

Blueberries. The results of 7 field trials (NY, NJ, NC, AR, IN, and WA) conducted in 1983 and 1985 on blueberries were submitted.

Ridomil® 2E was applied twice in 50-230 gpa spray mix solution at 71- to 93-day intervals in a post drench band under the canopy at a broadcast equivalent rate of 3.62 lbs ai or 7.24 lbs ai/treated acre (1X and 2X proposed use rate, respectively) per application.

The first application was made in the early spring, and the second just before harvest. (Proposed use calls for the second treatment to be made in the late fall, after harvest.)

Samples were stored frozen for 10-12 months prior to analysis (in duplicate) via AG-395 for combined residues of metalaxyl and its metabolites.

The ranges of total residues which resulted in blueberries as a result of these treatments are summarized below:

Treatment Rate	Total Metalaxyl Residues (ppm)		
	PHI (days)		
	0-1	14-18	29-34
1X	<0.05-1.63	<0.05-1.62	<0.05-0.09
2X	<0.05-1.53	<0.05-0.46	<0.05-0.25

COMMENTS. These field trial results support the establishment of a 2.0 ppm tolerance in blueberries treated twice at a 1X rate and harvested with a 0-day PHI. However, the proposed use directions specify the second application is to be made after harvest, not before. For such a use, a 2 ppm tolerance would be much higher than necessary.

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The petitioner will need to either: (1) revise the proposed use directions (Section B) to match the available field trial data (second application at, or shortly before, harvest); OR, (2) conduct some additional field trials to reflect the presently proposed use directions (second application after harvest).

If the latter option is chosen, the petitioner will also need to propose a more appropriate (lower) tolerance level for blueberries (revised Section F) based on the resulting residue results.

Additionally, we will need to take into consideration in determining the appropriate tolerance level for blueberries, any/all data/information submitted to the Agency in the past to support the Section 18 emergency exemption for use of Ridomil® 2E on Arkansas blueberries. We have been unable to locate that information in the Agency's files. We request the petitioner submit the details/data as part of this petition.

Walnuts and Almonds. The results of 6 field tests, three each with walnuts and almonds, conducted in CA in 1983 were submitted.

Three treatments of Ridomil® 2E were made by broadcast application over an approximate 6-month period. Each treatment was at a rate of 8 or 16 lbs ai/A (1X and 2X proposed use rate, respectively).

The first application coincided with the first flush of tree growth in the spring. The additional applications were made at 2-3 month intervals. Samples were collected at approximately 0, 14, and 30 days following the last application.

Samples were stored frozen for ca 1-6 months prior to analysis (in duplicate) via AG-395 for combined residues of metalaxyl and its metabolites.

The ranges of total residues which resulted in walnuts and almonds (nutmeats, shells, and hulls) are summarized below:

Commodity	Treatment Rate	Total Metalaxyl Residues (ppm)		
		PHI (days)		
		0	14-16	28-30
Walnuts				
Nutmeats	1X	<0.05-0.08	<0.05-0.09	<0.05-0.08
	2X	<0.05-0.08	<0.05-0.13	<0.05-0.07
Almonds				
Nutmeats	1X	<0.05-0.19	<0.05-0.25	<0.05-0.20
	2X	<0.05-0.88	<0.05-0.80	<0.05-0.71
Shells	1X	0.07-0.63	0.10-2.37	0.10-4.00
	2X	0.15-6.78	0.11-6.42	0.18-6.79
Hulls	1X	0.93-2.14	0.76-4.00	1.33-3.39
	2X	1.56-20.4	1.32-14.6	1.71-13.0

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COMMENTS. Based on the reported residue findings, the proposed 0.5 ppm tolerance level for walnuts and almonds in conjunction with a PHI of 0-days for 3 broadcast applications at 8 lbs ai/A applied as Ridomil® 2E is appropriate.

However, the proposed tolerance of 5.0 ppm for almond hulls is too low, based on normalization of the 2X data. The petitioner should submit a revised Section F proposing a 10 ppm tolerance for almond hulls.

Stone Fruits. The results of 9 field tests conducted in 1983 on plums (CA), apricots (CA), peaches (CA, PA, and MS), and cherries (CA, NY, MI, OR) were submitted.

Treatments with Ridomil® 2E consisted of 3 broadcast applications at 8 or 16 lbs ai/A (1X and 2X the proposed use rate, respectively) in 22.7-150 gpa spray mix solution over a 4-6 month period.

The first application coincided with the first flush of tree growth in the spring. The additional applications were made at 1-3 month intervals thereafter. Samples of whole fruit were collected at approximately 0, 14, and 30 days following the last application.

Samples were stored frozen for <3 to >5 months prior to analysis (in duplicate) via AG-395 for combined residues of metalaxyl and its metabolites.

The ranges of total residues which resulted in the various sampled stone fruits are summarized below:

Commodity	Treatment Rate	Total Metalaxyl Residues (ppm)		
		PHI (days)		
		0	13-15	26-31
Apricots	1X	0.49,0.52	0.58,0.58	---
	2X	0.76,0.82	0.55,0.77	---
Cherries	1X	<0.05-0.35	<0.05-0.17	<0.05-0.12
	2X	0.26,0.26	<0.05-0.32	<0.05-0.25
Peaches	1X	<0.05-0.48	0.07-0.36	0.10-0.48
	2X	0.58,0.90	0.42,0.57	0.44,0.84
Plums	1X	0.17,0.19	0.26,0.27	0.23,0.24
	2X	0.33,0.34	0.35,0.41	0.42,0.47

COMMENTS. The representative commodities of the stone fruits crop group are: sour or sweet cherry, peach, and plums or fresh prunes. The petitioner has provided residue data for all these rac's.

Based on the reported residue findings, the proposed 1.0 ppm tolerance level for the stone fruits crop group in conjunction with a PHI of 0-days for 3 broadcast applications at 8 lbs ai/A applied as Ridomil® 2E is appropriate.

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Dried Apricots and Prunes. Residues were also determined for dried apricots and prunes.

Residues in the whole fruit used for preparing the dried fruit, residues in dried fruit, and the calculated concentration factors are presented in the table below for the recommended 1X rate (8.0 lbs ai/A) and the 2X rate (16.0 lbs ai/A).

<u>Commodity</u>	<u>Treatment Rate</u>	<u>Fresh Fruit Residues (ppm)</u>	<u>Dried Fruit Residue (ppm)</u>	<u>Conc. Factor</u>
Apricots	1X	0.49,0.52	1.98	3.92X
	2X	0.76,0.82	2.99	3.78X
Plums	1X	0.17,0.19	0.47	2.61X
	2X	0.33,0.34	0.63	1.88X

COMMENTS. Based on the maximum concentration factor observed, 3.9X, and the proposed 1.0 ppm tolerance for stone fruit, a food additive tolerance of 4.0 ppm is being proposed for dried apricots and prunes (dried plums).

We consider the 4.0 ppm proposed food additive tolerance level to be adequate and appropriate in conjunction with the proposed use.

Dried apricots and prunes are the only dried commodities in the stone fruits crop group which are regulable.

Residues in Meat, Milk, Poultry, and Eggs

The only animal feed item associated with this petition is almond hulls. Beef and dairy cattle may consume almond hulls at up to 25% of their diet. Almond hulls are not fed to poultry or swine.

A "worst case" theoretical diet (which RCB recognizes is artificial and not in accordance with standard feeding practice, but one which is designed to maximize metalaxyl residues fed livestock) for cattle (taking into consideration the 10 ppm tolerance level which RCB considers the appropriate level to be proposed for almond hulls; see discussion, Residue Data section) would consist of:

Peanut hay	(60% of diet x 20 ppm tolerance)	=	12.0 ppm
Tomato pomace, dry	(25% of diet x 16 ppm tolerance)	=	4.0 ppm
Almond hulls	(15% of diet x 10 ppm) =	1.5 ppm

Total: 17.5 ppm

Livestock feeding studies (cattle, goats) with metalaxyl have been previously submitted and reviewed (see P. Errico memos, 3/9/82 and 7/16/82 (p. 9), PP#1F2500/FAP#1H5299 and 9/24/82, PP#2F2695). No new feeding studies were submitted in re this present petition.

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Meat and milk tolerances have been established [40 CFR 180.408(a)] based on those studies. The highest feeding level was 75 ppm (dairy cattle).

COMMENTS. The feeding of hulls from almonds treated with Ridomil® 2E in accordance with the proposed use will not result in residues in cattle tissues or milk that are higher than the tolerances which are already established on those animal commodities.

Other Considerations

An International Residue Limit (IRL) Status sheet is appended to this petition review as Attachment #1.

There are no established IRL's for the crops of this petition. The question of compatibility of tolerance levels thus does not arise.

We note that Codex currently regulates metalaxyl residues in terms of parent only. In a future meeting, Codex will reconsider its position in this regard.

Attachments: three

Attachment #1: International Residue Limit Status Sheet

Attachment #2: FR notice/Vol. 51 No. 187/September 26, 1986/
pp. 34249-34250/Notice of Availability of Final
Guidance Document for Analytical Methods for
Multiresidue Protocols.

Attachment #3: "Multiresidue Method Testing", document prepared
by the Division of Chemical Technology, Food and
Drug Administration, September 1984.

cc:Reviewer (M. Nelson), RF, Circu., TOX, EAB, EEB, PM#21, FDA,
PP#7F3470/FAP#7H5520, ISB/PMSD (Eldridge).
TS-769C:RCB:Reviewer(MJN):CM#2:Rm804:557-7484:typist(mjn):3/5/87
RDI:Section Head:RSQuick:3/5/87:Deputy Chief:RDSchmitt:3/5/87

INTERNATIONAL RESIDUE LIMIT STATUS

[Handwritten signature]
2/24/87

CHEMICAL Metalaxyl

CODEX NO. 138

CODEX STATUS:

No Codex Proposal
Step 6 or above (on commodities listed)

Residue (if Step 8): _____
metalaxyl*

PROPOSED U.S. TOLERANCES:

Petition No. 7F3470/7H5520

RCB Reviewer Nelson

Residue: metalaxyl and metabolites
(ref. 40 CFR 180.408)

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

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

blueberries 2

Stone fruit crop group 1

walnuts 0.5

almonds 0.5

almond hulls 5

apricots, dried 4

prunes 4

CANADIAN LIMITS:

No Canadian limit (on above)

Residue: _____

MEXICAN LIMITS:

No Mexican limit

Residue: _____

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

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

NOTES: Codex proposed revision is sum of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety, determined as 2,6-di-methyl aniline and calculated and expressed as metalaxyl.
Page 1 of 1
Form revised 1986

National Technical Information Service (NTIS). The NTIS order number and price for the document are provided.

ADDRESS: Address orders to: National Technical Information Service, ATTN: Order Desk, 5285 Port Royal Road, Springfield, VA 22161, (703-487-4650).

Orders for the Pesticide Assessment Guidelines Addendum for Residue Analytical Methods Multiresidue Protocols may be placed by telephone to the NTIS order desk and charged against a deposit account or American Express, VISA, or MasterCard or sent by mail with check, money order, or account number.

FOR FURTHER INFORMATION CONTACT:

By mail:

Francis D. Griffith, Jr. Hazard Evaluation Division (TS-769C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW. Washington, DC 20460.

Office location and telephone number:
Rm. 804 Crystal Mall—Building #2,
1921 Jefferson Davis Highway,
Arlington, Virginia (703-557-7484).

SUPPLEMENTARY INFORMATION: The purpose of this Federal Register Notice is to inform pesticide registrants of the availability of pesticide multiresidue protocols for use in meeting the data requirements in 40 CFR 158.125(b)(15). These protocols are now available as an addendum to the Pesticide Assessment Guidelines Subdivision O-Residue Chemistry. Use of these testing schemes, Protocols I-IV, may indicate multiresidue methods are more suitable for the identification and determination of pesticide residues than those methods designated for the individual pesticides found in the Pesticide Analytical Manual Volume II (PAM-II).

The data developed under these Protocols will be published as entries in appropriate tables in the Pesticide Analytical Manual, Volume I. The data are for the use of any agency responsible for enforcing tolerances or monitoring residues and thus are not to be claimed as Confidential Business Information (CBI).

Data submitters who use these multiresidue protocols should note the following:

1. Data should be gathered using the FDA multiresidue method Protocols I, II, III, and/or IV. The parent compound and all metabolites covered in the tolerance should be tested. These tests should be performed only by qualified laboratory personnel and followed as specified in the current edition of the Pesticide Analytical Manual Volume I.
2. Data should be obtained from

(OPP-36127 (FRL-3086-9))

Pesticide Assessment Guidelines Subdivision O-Addendum; Availability of Final Guidance Document for Analytical Methods for Multiresidue Protocols

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability.

SUMMARY: This addendum on Residue Analytical Methods is primarily for the regulated industry and provides four specific Food and Drug Administration (FDA) Pesticide multiresidue method protocols for testing each pesticide under the Residue Chemistry Data Requirements in 40 CFR 158.125(b)(15). This document is now available to the

34250

Federal Register / Vol. 51, No. 187 / Friday, September 26, 1986 / Notices

crops and/or animal products within the pesticide petition under review. If tolerances are being requested on many crops in a group of related crops, only one crop in the group need be tested. Fortified samples, in duplicate, are to be taken through each protocol and results reported as specified. Untreated control samples, in duplicate, are to be treated in the same manner.

These guidelines apply to new

pesticides and to all pesticides undergoing the re-registration process. For older pesticides, data on methodology specified in this Federal Register notice may have been published in the Pesticide Analytical Manual. If such data are currently available, they will be acceptable.

Document title, prices, and order number are as follows:

Document title	NTIS Order No	Price (hard copy)	Price (microfiche)
Pesticide Assessment Guidelines Subdivision O-Addendum Residue Chemistry Data Requirements For Analytical Methods in 40 CFR 158.125-Multiresidue Protocols	PB 86 200734/AS	\$9 96	\$5 95

For this document, your order should specify the title, the corresponding NTIS order number, and whether hard copy or microfiche is desired. The NTIS order number is the same for both microfiche and hard copy, but the price differs for each form. Send orders to the address provided above.

Dated: September 18, 1986.

John W. Meloe,

Director, Hazard Evaluation Division.

[FR Doc. 86-21821 Filed 9-25-86; 8:45 am]

BILLING CODE 6850-66-M

Multiresidue Method Testing

Analytical methods capable of determining many pesticide residues in a single analysis have long provided the basis for the U.S. Food and Drug Administration's programs to determine residue levels in the U.S. food supply. Through the years, as the several multiresidue methods have been added to FDA's programs, a concomitant effort has been made to test as many potential residues as possible through these methods. All the data collected from tests run according to specified protocols have been compiled and distributed.

Specific directions for each multiresidue method used by FDA are published in the agency's Pesticide Analytical Manual Vol. I (PAM I) as stated in 40 CFR 180.6(d) and 180.101(c). Compilation of data on the analytical behavior of pesticides and related chemicals are also published in PAM I. The data compiled in this way include: relative retention times of the compounds on a variety of gas-liquid chromatographic (GLC) columns; responses of various GLC detectors to the compounds; recovery of the compound through complete methods, and sometimes through important steps within the methods. The large amount of effort spent on the testing of multiresidue methods and compilation of results is justified by the advantages such compilations offer the analytical chemist. When analytical behavior data for numerous compounds through the method in use is known, the analyst is better equipped to recognize the residues that are present in a sample of unknown treatment history. In situations where the likelihood of some particular residue is known, the data lists for several methods can be consulted to help choose which method should be used.

Regulatory agencies which must assess the incidence of residue occurrence are also assisted by data compilations. The absence of many chemicals from the sample can be ascertained when it is known that the compounds could have been detected had they been present.

It has been found advisable to define protocols to follow in developing data on multiresidue method behavior. In order to compile data into usable formats, it is imperative that all contributing laboratories perform the tests in the same way. The goal in these method-testing exercises is not to find the optimum conditions for the one compound currently being tested, but to be able to describe how the compound will behave when determined by the precisely-defined method.

To this end, four protocols follow. Each references the PAM I method(s) involved, the types of compounds to which it applies, and the PAM I table(s) in which previously-collected data are published. The data development section of each

- 2 -

protocol provides the directions for setting instrument parameters and for testing the compounds through the parts of the method.

Follow the steps of these protocols, in the order written, to develop data which can be compiled with that from other laboratories. These data will be included in PAM I tables and distributed to the many laboratories around the world which use these methods.

Division of Chemical Technology
Food and Drug Administration
September 1984

Protocol I

Background

Methods: PAM I 211.1, 212.1, 252

Compound Type: Generally, non-polar compounds capable of detection by electron capture or phosphorus-selective GLC detectors. A wide variety of compounds are recovered through these methods; do not assume too readily that the compound is too polar to be recovered. [Note that the protocol is set up to test for recovery through the Florisil cleanup column first, so that time will not be wasted testing through the complete method compounds which are not eluted from Florisil.]

PAM I Tables: Appendix (all data)

Table 201-A (recoveries from Florisil and through complete methods)

Tables 331-A, 331-F, 331-G, 334-A (GLC data)

Data Development

I. Instrumentation

A. GC column

1. Required column: 5% OV-101 or equivalent
2. Additional columns of interest:
 - a. 3% OV-225
 - b. 2% DEGS (ANALABS)
 - c. 3% OV-17

B. GC detectors

1. Electron Capture (^{63}Ni constant current)
2. Hall 700 A (halogen)
3. Flame Photometric Detector (phosphorus)

C. GC parameters

1. Adjust column temperatures, 5% OV-101, so that relative retention to chlorpyrifos (RRc) of p,p'-DDT is 3.10 ± 0.03 (or RRc of ethion is 2.56 ± 0.03) (see PAM I 331A for RRc data).

For other columns of interest, see the following tables for operating conditions and RRcs:

- 2 -

- a. Table 331-F - OV-225 column
- b. Table 334-A - DEGS column
- c. Table 331-G - OV-17 column

2. Detector sensitivity: Select electrometer attenuation to produce 50% full scale deflection (FSD) for injection of 1.5 ng chlorpyrifos.

See the following PAM I sections for parameters for the various detectors:

- a. Section 311.4 - Electron capture
- b. Section 315 - Hall 700 A (halogen)
- c. Section 314 and Table 331-G - Flame photometric

II. GC analytical behavior of new compound

- A. Dissolve reference standard material in pesticide-grade solvent (iso-octane preferred) to prepare stock standard solution.
- B. Inject aliquots containing up to 1000 ng into GC system to determine the amount of standard required to cause 50% FSD at the prescribed parameters.
- C. Calculate RRC of new compound for all GC column/detector systems used.

III. Recovery of new compound through cleanup column

- A. Determine recovery through Florisil column, PAM I 211.14d and 252.12b. Use only Florisil which has been shown to permit elution of heptachlor epoxide in 6% EE/PE or eluate 1 and endrin in 15% EE/PE or eluate 2. Add 10-100 ug of analyte in 1-10 ml hexane solution to each Florisil column experiment in duplicate. If recoveries are less than 30%, report recoveries through Florisil and terminate work on this compound through this method.
- B. If new compound elutes in 6% EE/PE or eluate 1, rerun Florisil column experiment in the following manner.
 - (1) Elute Florisil column with 250 mL petroleum ether.
 - (2) Proceed with 6% EE/PE or eluate 1.

Report percent recovery and eluate(s) which contains analyte.

IV. Recovery of new compound through complete methods

- A. Select one representative fatty and one nonfatty food

sample. Analyze food first to assure that there are no residues in the sample which might interfere with the fortification test. Simultaneously, analyze a reagent blank for further information on the source of possible interferences.

Fortify 100 g samples in duplicate at approximately 0.05 ppm. Analyze duplicate fortified samples as described in PAM I 211.1 and 212.1 for fatty foods and nonfatty foods, respectively.

- B. Fortify 100 g samples in duplicate at the tolerance level or, if no tolerance exists, at approximately 0.5 ppm. Analyze duplicate fortified samples.
 - C. If the compound is recovered in experiments IV. A and B above, and if it was recovered in III. A using the Florisil elution system PAM I 252, then repeat IV A and B using the PAM I 252 elution system.
- V. Report all results in a format which parallels this protocol. Include results of checks made on instrument parameters, as described in I.C.

Division of Chemical Technology
Food and Drug Administration
September 1984

Protocol II

Background

Method: PAM I 232.3

Compound Type: Organophosphorus pesticides and their polar metabolites. Also certain organonitrogen compounds, if the GLC detector used responds to nitrogen.

PAM I Tables: Appendix (all data)

Table 201-H (recoveries through complete method)

Table 334-A (DEGS column RRs)

Tables 331-F, 331-G (GLC data)

Table 333-A (relative retention times on DC-200 column, equivalent to OV-101; detector response data for alkali flame (KCl thermionic) detector, rather than FPD.)

Data Development

I. Instrumentation

A. GC column

1. Required column: 4 ft x 2 mm (i.d.) 2% DEGS - (precoated packing, available from Analabs, Inc., Cat. No. GCM-035)
2. Additional columns of interest:
 - a. 3% OV-225
 - b. 3% OV-17
 - c. 5% OV-101

B. GC detectors

1. Flame photometric detector, phosphorus mode (FPD-P). This is the preferred detector for the determination of new compound data.
2. Alkali flame detector or N/P detector. (These detectors should be used only if FPD-P detector is not available.)

C. GC parameters

1. Operate DEGS column at 180°C; adjust temperature as needed to produce RRs for parathion and monocrotophos

- 2 -

as reported in PAM I Table 334-A.

For other columns of interest, see the following tables for operating conditions and RRCs:

- a. Table 331-F - OV-225 column
- b. Table 331-G - OV-17 column
- c. Table 331-A - OV-101 column

2. Detector sensitivity: Select electrometer attenuation so that injection of 1.5 ng chlorpyrifos produces 50% full scale deflection (FSD) on recorder or printer/plotter.

See the following PAM I sections for parameters for the various detectors:

- a. Table 331-G - FPD
- b. Section 313 - KClTD
- c. Section 316 - N/P

II. GC analytical behavior behavior of new compound

- A. Dissolve reference standard material in pesticide-grade acetone to prepare stock solutions and all subsequent dilutions. Also prepare acetone solutions of chlorpyrifos, parathion, and monocrotophos for accompanying work.
- B. Determine amount (ng) of new compound which produces 50% FSD.
- C. Calculate RRC of new compound for all GC columns/detector systems used.

III. Recovery of new compound through cleanup column

Determine recovery of compound, in duplicate, through PAM I 232.34 column chromatography. Add 5-50 ug of compound to cleanup column and elute as instructed. If recovery is less than 30%, do not proceed to test compound through entire method. Report recoveries through clean-up column alone.

IV. Recovery of new compound through complete method

- A. Select a representative nonfatty food sample. Analyze food by this method to assure that there are no residues in the sample which might interfere with the fortification test. Simultaneously, analyze a reagent blank for further information on the source of possible interferences.

Fortify 100 g samples, in duplicate at 0.05-0.10 ppm. Analyze the duplicate fortified samples as described in PAM I 232.3.

- 3 -

- B. Fortify 100 g samples in duplicate at the tolerance level or, if no tolerance exists, at 5 x level of A above. Analyze duplicate fortified samples.

- V. Report all results in a format which parallels this protocol. Include results of checks made on instrument parameters, as described in item I.C.

Division of Chemical Technology
Food and Drug Administration
September 1984

Protocol III

Background

Method: PAM I 232.4

Compound types: Applicable to all nonionic types of pesticides; detection of particular compounds is dependent on availability of the various element-selective detectors which can be used.

PAM I Tables: Appendix (GLC data)

Table 201-I (recoveries through the complete method)

Tables 331-A, 331-F, 331-G, 334-A (GLC data)

Data Development

I. Instrumentation

A. GC columns

1. Organochlorine compounds

a. Required column: 5% OV-101 or equivalent

b. Additional columns of interest:

(1) 3% OV-17

(2) 3% OV-225

2. Organophosphorus/organonitrogen compounds

a. Required column: 4' x 2 mm (i.d.) 2% DEGS (precoated packing, available from Analabs, Inc. Cat. No. GCM-035)

b. Additional columns of interest:

(1) 3% OV-225

(2) Ultrabond 20 SE (precoated packing available from Ultra Scientific Cat. No. RGC-023A)

(3) 3% OV-17

(4) 5% OV-101

B. GC detectors

1. Organochlorine compounds

- a. Preferred detector: Hall 700 A (halogen)
- b. Other detector: electron capture (^{63}Ni constant current). If an electron capture detector must be used, the analytical methodology must include Florisil clean-up (PAM I 212.2) prior to GC determination. (PAM I 311.4).

2. Organophosphorus compounds

- a. Preferred detector: flame photometric detector phosphorus mode (FPD-P).
- b. Other detectors: alkali flame detectors (KC1TD or N/P).

3. Organonitrogen compounds

- a. Alkali flame (KC1TD or N/P)
- b. Hall 700 A (nitrogen)

C. GC parameters

1. Column temperatures

- a. OV-101: operate at 200°C. Adjust temperature, if necessary, to give RRc for p,p'-DDT = 3.10 ± 0.03 . See PAM I 331-A for additional RRc.
- b. DEGS: operate at 180°C. Adjust temperature, if necessary, to give RRc for parathion and monocrotophos as noted in PAM I, Table 334-A.
- c. OV-17. See Table 331-G for conditions.
- d. OV-225. See Table 331-F for conditions. Note that this column cannot be used with electrolytic conductivity detectors or N-selective detectors.

2. Detector sensitivity: Select electrometer attenuation so that injection of 1.5 ng chlorpyrifos produces 50% full scale deflection (FSD) on recorder or printer/plotter.

See the following PAM I sections for parameters for the various detectors:

- a. Section 315 - Hall 700 A
- b. Tables 334-A, 331-G - FPD-P
- c. Section 311.4 - ^{63}Ni electron capture
- d. Section 313 - KC1TD
- e. Section 316 - N/P

II. GC analytical behavior of new compound

- 3 -

- A. Dissolve reference standard material in acetone or iso-octane, pesticide-grade, to prepare stock solutions. Make all dilutions of the stock solution with acetone.
- B. Determine amount (ng) of new compound which causes 50% FSD. Do not exceed 1000 ng injected.
- C. Calculate RRc of new compound for all GC column/detector systems used.

III. Recovery of new compound through complete method

- A. Select a representative nonfatty food sample. Analyze food by this method to assure that there are no residues in the sample which might interfere with the fortification test. Simultaneously, analyze a reagent blank for further information on the source of possible interferences.

Fortify duplicate (100 g) samples at 0.05-0.1 ppm. Analyze duplicate fortified samples as described in PAM I 232.4.

- B. Fortify duplicate (100 g) samples at tolerance level for compound or, if no tolerance exists, at 5x level of (A). Analyze duplicate fortified samples.

- IV. Report all results in a format which parallels this protocol. Include results of checks made on instrument parameters, as described in item I.C.

Division of Chemical Technology
Food and Drug Administration
September 1984

Protocol IV

Background

Method: PAM I 242.2 and JAOAC (1980) 63 1114-1124

Compound types: Applicable to a variety of compound types; detection is dependent on availability of the particular detection step required for specific compounds, i.e.,

N-methylcarbamates: HPLC and post-column fluorescence labeling, with fluorescence detection

Naturally fluorescent pesticides: HPLC and fluorescence detection

Volatile and thermally stable pesticides: PAM I GLC detection methods

PAM I Tables: Table 201-J (recoveries through several applications of complete method)

Tables 330 (GLC data: tables for each column/detector combination).

[Also see JAOAC (1980) 63 1114-1124 for retention times of compounds through HPLC column.]

Data Development

I. Instrumentation

A. HPLC

1. N-methylcarbamates: Set up HPLC with post-column fluorescence labeling and fluorescence detector, as described in JAOAC (1980) 63 1114-1124. Check for proper operation using carbofuran as described in the reference.
2. Fluorescent pesticides: Set up HPLC and fluorescence detector, as described in J. Chromatogr. (1983) 255 497-510 and JAOAC (1983) 66 234-240. Check for proper operation using carbofuran as described in the references.

- B. GLC. PAM Vol. I Chapter 3. If GLC is investigated, at a minimum, OV-101 and DEGS liquid phases should be examined at standard conditions and operating para-

- 2 -

meters. Use chlorpyrifos as the reference compound. Use appropriate selective GLC detectors at standard operating parameters. (See Protocols I, II, and III for details on GLC operations.)

II. Instrument analytical behavior of new compound.
(These directions refer to the two HPLC operations described above. See Protocols I, II, and III for details on collecting GLC data.)

- A. Dissolve reference standard material in methanol to prepare stock solutions. Dilute with methanol for HPLC working standards. [Note: For GLC working standards, dilute stock solutions with whatever solvent is appropriate for the GLC system.]
- B. Determine amount (ng) of compound which causes the detector to produce a 50% FSD recorder response. Note the peak shape of the compound to determine adequacy of chromatography.
- C. Determine linear response range of the detector to the compound.
- D. Determine stability of compound in methanol:

Short term stability study: Inject quantity of compound which produces 1/2 FSD response; repeat every 40 minutes for 8 hours.

Long term stability study: Inject quantity of compound which produces 1/2 FSD response; repeat once every day for eight days. Normalize response to carbofuran reference standard injected each day.

- E. Calculate the retention time of the compound relative to carbofuran on the HPLC system of JAOAC (1980) 63 1114-1124 or JAOAC (1983) 66 234-240, as appropriate.

III. Recovery of new compound through cleanup column:

Initially determine that charcoal-silanized Celite column has proper elution characteristics as per carbamate method (JAOAC (1980) 63, 1114-1124). Pass 25 ug of pesticide through newly prepared column as per carbamate method. After collection of eluant (20 mL methylene chloride + 125 mL toluene-acetonitrile) in round bottom flask, momentarily stop flow, remove bottom flask and replace with a second round bottom flask. Elute column with an additional 100 ml toluene-acetonitrile. Evaporate solvents in both round bottom flasks to dryness as per method. Dissolve residue in first flask to appropriate volume with appropriate solvent for determination. Dissolve residue in 2nd flask with 5 mL of solvent and determine percent of total added

- 3 -

pesticide carried over into second flask. Continue recovery studies with food products, IV, only if combined recoveries from charcoal column are greater than 50%. If 10% or more of pesticide elutes in 2nd flask, collect a separate additional 100 mL eluting solution in recovery studies with food products.

IV. Recovery of new compound through complete method

A. Select a representative food sample. (This method has been found applicable to both fatty and nonfatty food.) Analyze food by this method to assure that there are no interferences. Simultaneously, analyze a reagent blank for further information on the source of possible interferences.

Fortify 150 g of chopped food product, while it is in homogenizer, at appropriately 0.05 ppm. Analyze duplicate fortified samples.

B. Fortify 150 g samples at a level near the tolerance or at 5 X the level in A if there is no tolerance. Analyze duplicate fortified samples.

V. Report all results in a format which parallels this protocol. Include the results obtained with reference compounds to establish appropriate instrument parameters, as described in items I. A. and B.

Division of Chemical Technology
Food and Drug Administration
September 1984

End
of
Document

REGISTRATION DIVISION DATA REVIEW RECORD

Confidential Business Information - Does Not Contain National Security Information (E.O. 12065)

1. CHEMICAL NAME *METALAXYL*

2. IDENTIFYING NUMBER <i>100-601</i>	3. ACTION CODE <i>401</i>	4. ACCESSION NUMBER	TO BE COMPLETED BY PM
			5. RECORD NUMBER <i>200093</i>
			6. REFERENCE NUMBER <i>14</i>
			7. DATE RECEIVED (EPA) <i>7/17/87</i>
	<i>2604</i>		8. STATUTORY DUE DATE
			9. PRODUCT MANAGER (PM) <i>ROSS E</i>
			10. PM TEAM NUMBER <i>21</i>

14. CHECK IF APPLICABLE

Public Health/Quarantine Minor Use

Substitute Chemical Part of IPM

Seasonal Concern Review Requires Less Than 4 Hours

7/29/87

TO BE COMPLETED BY PCB

11. DATE SENT TO HED/TSS
[Redacted]

12. PRIORITY NUMBER
20

13. PROJECTED RETURN DATE
11-16-87

15. INSTRUCTIONS TO REVIEWER

A. HED Total Assessment - 3(c)(5) C. BFSD

Incremental Risk Assessment - 3(c)(7) and/or E.L. Johnson memo of May 12, 1977. D. TSS/RD

Other

B. SPRD (Send Copy of Form to SPRD PM)

Chemical Undergoing Active RPAR Review

Chemical Undergoing Active Registration Standards Review

F. INSTRUCTIONS

16. RELATED ACTIONS

17. 3(c)(1)(D)

Use Any or All Available Information Use Only Attached Data

Use Only the Attached Data for Formulation and Any or All Available Information on the Technical or Manufacturing Chemical.

18. REVIEWS SENT TO

TB EEB EF PL

RCB EFB CH BFSD

19. To	TYPE OF REVIEW	NUMBER OF ACTIONS							
		Registration	Petition	EUP	SLN	Sec. 18	Inert	MNR. USE	Other
HED	TOXICOLOGY								
	ECOLOGICAL EFFECTS								
	RESIDUE CHEMISTRY								
	ENVIRONMENTAL DATA								
RD/TSS	CHEMISTRY								
	EFFICACY								
	PRECAUTIONARY LABELING								
BFSD	ECONOMIC ANALYSIS								

20. Label Submitted with Application Attached

21. Confidential Statement of Formula

22. Representative Labels Showing Accepted Uses Attached

23. Date Returned to RD (to be completed by HED)

24. Include an Original and 4 (four) Copies of This Completed Form for Each Branch Checked for Review.

End
of
Document



U.S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAM (TS-767)
WASHINGTON, D.C. 20460

APPLICATION FOR PESTICIDE:

REGISTRATION
 AMENDMENT

Please read instructions
on reverse before com-
pleting.

SECTION I

1. COMPANY/PRODUCT NO. 100-607	2. DATE 7-15-87	3. PRODUCT MANAGER Rossi (21)	4. PROPOSED CLASSIFICATION <input checked="" type="checkbox"/> GENERAL <input type="checkbox"/> RESTRICTED
-----------------------------------	--------------------	----------------------------------	--

5. NAME AND ADDRESS OF APPLICANT (Include ZIP Code)

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

CHECK IF THIS IS A NEW ADDRESS

6. PRODUCT NAME

Ridomil® 2E Fungicide

SECTION II

1. SUBJECT OF AMENDMENT

- RESUBMISSION IN RESPONSE TO RCB review DATED 3/6/87
- FINAL PRINTED LABEL IN RESPONSE TO AGENCY LETTER DATED _____
- OTHER (explain below)

SECTION III

1. WILL THIS PRODUCT BE PACKAGED IN: CHILD-RESISTANT PACKAGING <input type="checkbox"/> YES <input type="checkbox"/> NO UNIT PACKAGING <input type="checkbox"/> YES <input type="checkbox"/> NO If YES; unit pkg. wt. _____ No. per container _____ WATER - SOLUBLE PACKAGING <input type="checkbox"/> YES <input type="checkbox"/> NO If YES, pkg. wt. _____ No. per container _____		2. TYPE OF CONTAINER <input type="checkbox"/> METAL <input type="checkbox"/> PLASTIC <input type="checkbox"/> GLASS <input type="checkbox"/> PAPER <input type="checkbox"/> OTHER (Specify) _____
3. LOCATION OF NET CONTENTS <input type="checkbox"/> LABEL <input type="checkbox"/> CONTAINER	4. SIZE(S) OF RETAIL CONTAINER	
5. LOCATION OF LABEL DIRECTIONS <input type="checkbox"/> ON LABEL <input type="checkbox"/> ON MATERIAL ACCOMPANYING PRODUCT	6. MANNER IN WHICH LABEL IS AFFIXED TO PRODUCT <input type="checkbox"/> LITHOGRAPH <input type="checkbox"/> OTHER (Specify) <input type="checkbox"/> PAPER GLUED <input type="checkbox"/> STENCILED	

SECTION IV

1. CONTACT POINT (Complete items directly below for identification of individual to be contacted, if necessary, to process this application). NAME Karen S. Stumpf			6. DATE APPLICATION RECEIVED (Stamped)
TITLE Sr. Reg. Specialist		TELEPHONE NO. (Include Area Code) (919) 292-7100	
2. SIGNATURE <i>Karen S. Stumpf</i>	3. TITLE Sr. Reg. Specialist		
4. TYPED NAME Karen S. Stumpf	5. DATE SIGNED 7-15-87		

End
of
Document

557-1900 / 1/10/1987

REGISTRATION DIVISION DATA REVIEW RECORD

Confidential Business Information - Does Not Contain National Security Information (E.O. 12065)

1. CHEMICAL NAME

METALAXYL

2. IDENTIFYING NUMBER

100-601

3. ACTION CODE

401

4. ACCESSION NUMBER

TO BE COMPLETED BY PM

5. RECORD NUMBER

200043

6. REFERENCE NUMBER

14

7. DATE RECEIVED (EPA)

7/17/87

8. STATUTORY DUE DATE

1/18

RCB # 2604

9. PRODUCT MANAGER (PM)

Rossi

10. PM TEAM NUMBER

21

14. CHECK IF APPLICABLE

Public Health/Quarantine

Minor Use

Substitute Chemical

Part of IPM

Seasonal Concern

Review Requires Less Than 4 Hours

11/17/87

TO BE COMPLETED BY PCB

11. DATE SENT TO HED/TSS

12. PRIORITY NUMBER

50

13. PROJECTED RETURN DATE

11-16-87

15. INSTRUCTIONS TO REVIEWER

A. HED Total Assessment - 3(c)(5)

C. BFSD

Incremental Risk Assessment - 3(c)(7) and/or E.L. Johnson memo of May 12, 1977.

D. TSS/RD

B. SPRD (Send Copy of Form to SPRD PM)

Chemical Undergoing Active RPAR Review

E. Other

Chemical Undergoing Active Registration Standards Review

F. INSTRUCTIONS

Wesley

16. RELATED ACTIONS

Lois Rossi will do today 8/17/87.

17. 3(c)(1)(D)

Use Any or All Available Information Use Only Attached Data
 Use Only the Attached Data for Formulation and Any or All Available Information on the Technical or Manufacturing Chemical.

18. REVIEWS SENT TO

TB EEB EF PL
 RCB EFB CH BFSD

Quick - Rossi 8/17/87

19. To	TYPE OF REVIEW	NUMBER OF ACTIONS							
		Registration	Petition	EUP	SLN	Sec. 18	Inert	MNR. USE	Other
HED	TOXICOLOGY								
	ECOLOGICAL EFFECTS								
	RESIDUE CHEMISTRY								
	ENVIRONMENTAL DATA								
RD/TSS	CHEMISTRY								
	EFFICACY								
	PRECAUTIONARY LABELING								
BFSD	ECONOMIC ANALYSIS								

20. Label Submitted with Application Attached

21. Confidential Statement of Formula

22. Representative Labels Showing Accepted Uses Attached

23. Date Returned to RD (to be completed by HED)

24. Include an Original and 4 (four) Copies of This Completed Form for Each Branch Checked for Review.

End
of
Document

Shaughnessy No.: 113501

Date Out of EAB: JUL 30 1987

Nelson

To: Lois Rossi
Product Manager # 21
Registration Division (TS-767)

From: Therese M. Dougherty, Chief
Environmental Chemistry Review Section 1
Exposure Assessment Branch
Hazard Evaluation Division (TS-769-C)

TD

Attached, please find the EAB review of...

Reg./File # : 7F 3470, 7H 5520, and 100-607

Chemical Name: Metalaxyl

Type Product : Fungicide

Product Name : Ridomil 2E

Company Name : CIBA-GEIGY

Purpose : Request amendment of label to add blueberries, stone fruits, walnuts, and almonds (I.D. #100-607).

Action Code: 230, 250, 335

EAB #(s): 70114-116

Date Received: 11/28/86

TAIS Code: 303

Date Completed: JUL 30 1987

Total Reviewing Time: 0.5 day

Monitoring study requested: _____

Monitoring study voluntarily: _____

Deferrals to: _____ Ecological Effects Branch
_____ Residue Chemistry Branch
_____ Toxicology Branch

2.

Photodegradation (water)- Study unacceptable. Data required.

Photodegradation (soil)- Data requirement satisfied.

Aerobic soil metabolism- Data requirement satisfied.

Leaching- Data indicate metalaxyl and its major degradate (CGA-62826) leach and have the potential to reach ground water. Data requirement partially satisfied. A New ground water monitoring study may be needed.

Soil field dissipation- Study unacceptable. Data required.

Fish accumulation- Data requirement satisfied.

Therefore, aqueous photodegradation and field dissipation data are needed to add blueberries, stone fruits, walnuts, and almonds to the Ridomil 2E label. However, before any new crops (orchard or field) can be added to the label, a new ground water monitoring study that meets our current guidelines may be required. This will depend upon a thorough re-evaluation of some previous monitoring studies.

9. BACKGROUND:

A. Introduction

A brief summary of the data requirements for a field/orchard crop use of metalaxyl is as follows:

- Hydrolysis- metalaxyl is resistant to hydrolysis, having a half-life of greater than 4 weeks at pH 5, 7, and 9 at 20-30°C. One degradation product was found: N-2,6-dimethylphenyl-N-(2-methoxyacetyl) alanine. The requirement is satisfied.
- Photodegradation (aqueous)- The light source did not simulate sunlight. Study must be repeated.
- Photodegradation- Metalaxyl did not photodegrade on soil. Requirement is satisfied.
- Aerobic/anaerobic soil metabolism- under aerobic conditions, metalaxyl had a half-life of about 40 days. The major degradate was CGA-62826 [N-(2,6-dimethylphenyl)-N-(2-methoxyacetyl)alanine] Under anaerobic conditions the half-life of parent was about 66 days. Both requirements are satisfied.
- Leaching/adsorption- metalaxyl and its degradates readily leach in sandy soils and those low in organic matter. It is considered to be a strong leacher. Requirement is satisfied.
- Soil field dissipation- the half-life is about two weeks and the major degradate is CGA-62826, which degrades to nonextractable material and CO₂. CGA-62826 declined to 0.5% of applied at end of one year. Application rate was 3.65 lb.ai/A using the 50 WP formulation. Due to lack of field leaching data, more dissipation data is required.

3.

- Fish accumulation- parent or residues did not accumulate beyond 10X in whole fish. Depuration (14 days) removed 80% of the parent/residues. Data requirement is satisfied.
- Rotational crop- Field rotational crop data indicate that residues of concern are present in crops planted 12 months after treatment. Present FAB policy requires tolerances on crops that contain residues at or longer than a 12 month treatment-to-planing interval.

Potential for Groundwater Contamination: Metalaxyl and its soil degradates readily leach in loamy and silty soils that are low in organic matter. Sandy soils present a very real possibility of ground water contamination due to leaching. To what extent residues will reach ground water depends on speed of leaching, amount of rainfall, presence of microbes, and depth of water table. A ground water monitoring study that meets our current guidelines is needed.

B. Directions for Use

See attached label. The application rate proposed for blueberries is 14.5 pints (3.62 lbs ai)/treated acre, whereas the label rate for raspberries is 5.5 pints (1.38 lbs ai)/acre. The maximum rate proposed for stone fruits, walnuts, and almonds is 4 gal (8 lbs ai)/acre and the rate for citrus fruits is 2 gal (4 lbs ai)/acre. Current application rates range from 0.135-8.0 lb ai/acre.

10. DISCUSSION OF INDIVIDUAL STUDY:

Not applicable. No new study submitted.

11. COMPLETION OF ONE-LINER:

Being completed.

12. CONFIDENTIAL APPENDIX:

Submission does not contain CBI.

REGISTRATION DIVISION DATA REVIEW RECORD

Confidential Business Information - Does Not Contain National Security Information (E.O. 12065)

19605 HED

12-1-86

1. CHEMICAL NAME <i>Metalaunt</i>				Sh. No. <i>113501-1</i>			
2. IDENTIFYING NUMBER		3. ACTION CODE		4. ACCESSION NUMBER		TO BE COMPLETED BY PM	
<i>DIF 2470</i>		<i>330</i>		<i>265762 thru</i>		6. RECORD NUMBER <i>60600</i>	
<i>207 5000</i>		<i>250</i>		<i>265765</i>		6. REFERENCE NUMBER	
<i>3 111-417</i>		<i>335</i>				7. DATE RECEIVED (EPA) <i>11-24-86</i>	
						8. STATUTORY DUE DATE	
						9. PRODUCT MANAGER (PM) <i>R. M. ...</i>	
						10. PM TEAM NUMBER <i>21</i>	

14. CHECK IF APPLICABLE

<input type="checkbox"/> Public Health/Quarantine	<input type="checkbox"/> Minor Use	① 184599 11-28-86 ② 184601 ③ 186038	TO BE COMPLETED BY PCB
<input type="checkbox"/> Substitute Chemical	<input type="checkbox"/> Part of IPM		11. DATE SENT TO HED/TSS <i>11-28-86</i>
<input type="checkbox"/> Seasonal Concern	<input type="checkbox"/> Review Requires Less Than 4 Hours		12. PRIORITY NUMBER <i>49</i>
			13. PROJECTED RETURN DATE <i>12-31-86</i>

15. INSTRUCTIONS TO REVIEWER

A. HED	<input type="checkbox"/> Total Assessment - 3(c)(5)	C. <input type="checkbox"/> BFS
	<input type="checkbox"/> Incremental Risk Assessment - 3(c)(7) and/or E.L. Johnson memo of May 12, 1977.	D. <input type="checkbox"/> TSS/RD
B. SPRD (Send Copy of Form to SPRD PM)	<input type="checkbox"/> Chemical Undergoing Active RPAR Review	E. <input type="checkbox"/> Other
	<input type="checkbox"/> Chemical Undergoing Active Registration Standards Review	

F. INSTRUCTIONS
*Please process via Fast Track
Please
Comment on label,
A letter and data reference
attached also*

16. RELATED ACTIONS

17. 3(c)(1)(D)

<input type="checkbox"/> Use Any or All Available Information	<input type="checkbox"/> Use Only Attached Data	18. REVIEWS SENT TO			
<input type="checkbox"/> Use Only the Attached Data for Formulation and Any or All	<input type="checkbox"/> Available Information on the Technical or Manufacturing Chemical.	<input checked="" type="checkbox"/> TB	<input checked="" type="checkbox"/> EEB	<input type="checkbox"/> EF	<input type="checkbox"/> PL
		<input checked="" type="checkbox"/> RCB	<input checked="" type="checkbox"/> EFB	<input type="checkbox"/> CH	<input type="checkbox"/> BFS

19. To	TYPE OF REVIEW	NUMBER OF ACTIONS							
		Registration	Petition	EUP	SLN	Sec. 18	Inert	MNR. USE	Other
HED	TOXICOLOGY								
	ECOLOGICAL EFFECTS								
	RESIDUE CHEMISTRY								
	<input checked="" type="checkbox"/> ENVIRONMENTAL DATA <i>EAB</i>	<i>1</i>	<i>2</i>						
RD/TSS	CHEMISTRY								
	EFFICACY								
	PRECAUTIONARY LABELING								
BFS	ECONOMIC ANALYSIS								

20. <input type="checkbox"/> Label Submitted with Application Attached	21. <input type="checkbox"/> Confidential Statement of Formula	22. <input type="checkbox"/> Representative Labels Showing Accepted Uses Attached	23. Date Returned to RD (to be completed by HED)	24. Include an Original and 4 (four) Copies of This Completed Form for Each Branch Checked for Review.
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RIDOMIL® 2E SUPER LABEL

(Front Cover)

One Gallon and One Quart Labelmaster Booklet

Ridomil® 2E

Fungicide

For the control of certain diseases in various crops caused by the Oomycete class of fungi.

One Gallon
U. S. Standard Measure

One Quart
U. S. Standard Measure

Active Ingredient:

Metalaxyl: N-(2,6-dimethylphenyl)-N-(methoxyacetyl) alanine methyl ester	25.1%
<u>Inert Ingredients:</u>	<u>74.9%</u>
Total:	100.0%

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

EPA Reg. No. 100-607
EPA Est. 100-AL-1

Keep Out of Reach of Children.

WARNING

AVISO

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

See additional precautionary statements inside booklet.

See directions for use inside booklet.

© 1986 CIBA-GEIGY Corporation
Agricultural Division
CIBA-GEIGY Corporation
P. O. Box 18300
Greensboro, NC 27419

CIBA-GEIGY

RDML2E/MSTF7

-2-

DIRECTIONS FOR USE AND CONDITIONS OF SALE AND WARRANTY

IMPORTANT: Read the entire Directions for Use and the Conditions of Sale and Warranty before using this product.

Conditions of Sale and Warranty

The Directions for Use of this product reflect the opinion of experts based on field use and tests. The directions are believed to be reliable and should be followed carefully. However, it is impossible to eliminate all risks inherently associated with use of this product. Crop injury, ineffectiveness, or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application all of which are beyond the control of CIBA-GEIGY or the Seller. All such risks shall be assumed by the Buyer.

CIBA-GEIGY warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes referred to in the Directions for Use subject to the inherent risks referred to above. CIBA-GEIGY makes no other express or implied warranty of Fitness or Merchantability or any other express or implied warranty. In no case shall CIBA-GEIGY or the Seller be liable for consequential, special, or indirect damages resulting from the use or handling of this product. CIBA-GEIGY and the Seller offer this product, and the Buyer and user accept it, subject to the foregoing Conditions of Sale and Warranty, which may be varied only by agreement in writing signed by a duly authorized representative of CIBA-GEIGY.

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DIRECTIONS FOR USE

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

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

Do not apply this product in such a manner as to directly, or through drift, expose workers or other persons, except those knowingly involved in the application. The area being treated must be vacated by unprotected persons.

Reentry Statements

Do not enter treated areas without protective clothing until sprays have dried.

Because certain states may require more restrictive reentry intervals for various crops treated with this product, consult your State Department of Agriculture for further information.

Written or oral warnings must be given to workers who are expected to be in the treated area or in an area about to be treated with this product. Oral warnings must be given which inform workers of areas or fields that may not be entered without specific protective clothing until sprays have dried and appropriate actions to take in case of accidental exposure, as described under Precautionary Statements at the back of this label. When oral warnings are given, warnings shall be given in a language customarily understood by workers. Oral warnings must be given if there is reason to believe that written warnings cannot be understood by workers. Written warnings must include the following information: "WARNING. Area treated with Ridomil 2E on (date of application). Do not enter without appropriate protective clothing until sprays have dried. Flush eyes or skin with plenty of water. Call a physician if irritation persists. Remove contaminated clothing and wash before reuse."

-4-

General Information

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

THIS PRODUCT IS NOT TO BE USED IN FOLIAR APPLICATIONS OR IN SOLUTIONS USED TO DIP PLANTS.

Note: Ridomil is a systemic fungicide having a specific mode of action and could be subject to development of resistant strains of fungi. Development of resistance cannot be predicted. Therefore, CIBA-GEIGY cannot assume liability for crop damage resulting from resistant strains of fungi. If treatment is not effective following the use of Ridomil as recommended, a resistant strain of fungi may be present. If the treatment is ineffective due to the presence of a Ridomil resistant strain of fungi, neither Ridomil nor any other fungicide with similar action will effectively control that disease. Consideration should then be given to the prompt use of other types of suitable fungicides. Consult with your State Agricultural Experiment Station or Extension Service Specialist for guidance on your particular crop and disease control situation.

Do not make foliar applications to field grown tobacco, or other crops since this practice may encourage more rapid development of resistance.

To avoid spray drift, do not apply under windy conditions. Avoid spray overlap, as crop injury may result.

Mixing Instructions

Add one-fourth to one-half of the required amount of water to the spray tank, add the proper amount of Ridomil 2E, then add the rest of the water. When tank mixing other products with Ridomil 2E, follow the proper sequence of adding products to the spray tank. Wettable powders or water dispersible granules should be added to the water in the tank first, followed by flowable products, with emulsifiable concentrates, such as Ridomil 2E, added last. Provide sufficient agitation during mixing and application to maintain a uniform emulsion.

Ridomil 2E is usually compatible with Balan[®], Bravo[®], Dasanit[®] + Di-Syston[®], Dithane[®] M-22, Dithane M-45, Dasanit + Nemacur[®], Dasanit, D.z.n[®], Difolatan[®], Enide[®], Furadan[®], Manzate[®], Manzate 200, Mocap[®], Mocap Plus 1-2EC, Paarlant[®], and Tillam[®].

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To assure the compatibility of Ridomil 2E with these and other products, pour the products into a small container of water in the correct proportions. After thorough mixing, let stand for five minutes. If the combination remains mixed, or can be re-mixed readily, the mixture is compatible.

Calculate the amount of Ridomil 2E needed for band treatment by the formula:

$$\frac{\text{band spacing in inches}}{\text{row spacing in inches}} \times \text{broadcast rate per acre} = \text{amount needed per acre of field}$$

Apples

Use of Ridomil 2E will aid in the control of crown rot caused by Phytophthora cactorum when used in conjunction with good cultural practices and rootstocks that are most tolerant to the disease. Applications should be made before symptoms appear especially in areas of the orchard favorable for disease development. Ridomil 2E will not revitalize trees showing moderate to severe crown rot symptoms.

Mix 1 qt. of Ridomil 2E with 100 gal. of water. Apply the amount of diluted mixture indicated in the table below around the trunk of each tree. Make one application at the time of planting or in the spring before growth starts. Make another application in the fall after harvest.

<u>Trunk Diameter</u>	<u>Qts. of Diluted Mixture/Tree</u>
<1 inch	1 qt.
1-3 inches	2 qts.
3-5 inches	3 qts.
>5 inches	4 qts.

Note: Do not dip roots of trees in solutions containing Ridomil.

Avocados

Root Rot - Phytophthora cinnamomi - Begin applications at the start of the growing season or at transplanting. Two additional applications should be made at three month intervals. Applications are not needed during the winter months of November through February. Ridomil 2E may be applied as a soil surface spray under sprinkler irrigation systems, as a directed spray under drip emitters or injected into the irrigation water.

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Sprinkler Irrigation: Apply as a soil surface spray under the canopy of the tree in sufficient water to obtain uniform coverage. See the table for the amount of Ridomil 2E to use based on the diameter of the tree canopy. Start applications at the beginning of the growing season or at transplanting and continue at three-month intervals.

Drip Irrigation: Apply the recommended amount of Ridomil 2E (see table) to the soil directly under the drip emitter at each tree. If there is more than one emitter per tree, distribute the total amount of Ridomil 2E needed among the emitters.

Injection into Irrigation Water (Sprinkler or Drip Irrigation only): Inject Ridomil 2E into the irrigation water at a rate of 2-4 fl. oz./1,000 gals. (3 3/4 - 7 1/2 ppm active ingredient) at each irrigation. If Ridomil is not applied at each irrigation, use the table below to determine how much Ridomil 2E should be injected into the irrigation water. If Ridomil is to be used more frequently than every three months, adjust the rates so that no more than the specified amount is applied during each three-month period.

Precautions: 1) Apply only through irrigation systems containing anti-siphon and check valves to prevent contamination of well during shutdown and overflow of solution tank. 2) Inject ahead of any right angle turn in the main line to insure adequate mixing. 3) Chemical injection pumps and water pumps must have interlocking controls to insure simultaneous shutoff. 4) Application when drift may occur, such as from windy conditions, or when system joints and connections are leaking, or when nozzles are not providing uniform distribution, may cause crop injury.

<u>Diameter of Tree Canopy (Ft.)</u>	<u>Amount of Ridomil 2E Per Ten Trees/3 Months</u>
2	1/2 - 1 fl. oz.
5	3 - 6 fl. oz.
10	13 - 26 fl. oz.
15	29 - 58 fl. oz.
20	51 - 103 fl. oz.

Notes: 1) For best results, use Ridomil 2E as soon as soil tests indicate the presence of Phytophthora. 2) For new plantings, the use of Phytophthora resistant root stocks with Ridomil is recommended. Mature trees in moderate to advanced stages of decline cannot be cured with Ridomil. 3) Do not apply more than 24 gals./A of Ridomil 2E/year or make an application within 28 days of harvest, or illegal residues may result.

Blueberries

Ridomil 2E is a soil-applied systemic fungicide for use in the control of *Phytophthora* root rot.

Apply 1 pt./1,000 linear ft. of row to the soil surface in a three-foot band over the row (14.5 pts./treated acre on broadcast basis). Make one application in the spring and another in the fall after harvest.

Citrus

Use Ridomil 2E on citrus for control of citrus foot rot, root rot, and trunk canker caused by *Phytophthora* spp. Apply to the soil as a drench or as a spray in a banded application.

Citrus in Nurseries

Make the first application of Ridomil 2E at the time of planting. Make repeat applications at three-month intervals during the period when trees are actively growing.

Soil Drench: Apply 4-6 fl. oz./100 gals. of water as a drench over the row at the rate of 100-250 gals./1,000 feet of row. The width of the drench treatment should be wide enough to cover the root systems of the plants.

Soil Surface Spray: Apply 2 gals./A of soil treated in a broadcast or banded surface spray to seedbeds, liners, or bedded stock in sufficient water to obtain uniform coverage. If applications are banded, the treated area should be wide enough to cover the root systems of the plants. Follow with a 1/2 inch irrigation.

Citrus Resets or New Plantings

Make the first application of Ridomil 2E to citrus resets or new plantings at the time of transplanting. Make up to three repeat applications, at three-month intervals to coincide with root growth flushes during the growing season.

Water Ring Drench: Mix 4-6 fl. oz./100 gals. of water. Apply 5 gals. of the mix around the base of each tree within the watering ring.

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Soil Surface Spray: Apply 1-2 gals./A (3-6 fl. oz./1,000 sq. ft.) in sufficient water to obtain uniform coverage of the soil surface. Apply spray to the soil surface beneath the tree canopy.

Citrus in Groves

Soil Application (Control of Phytophthora Foot and Root Rot): Apply 1-2 gals/A of soil treated (3-6 fl. oz./1,000 sq. ft.) in a banded surface spray under the canopy of the trees. Two additional applications may be made per year. Use the table as a guide for treating individual trees.

<u>Diameter of Tree Canopy (Ft.)</u>	<u>Fl. Oz. Ridomil 2E per Ten Trees</u>
5	1/2 - 1
10	2 1/2 - 5
15	5 - 10
20	10 - 20

Trunk Spray (Gummosis caused by Phytophthora spp.): Add one gallon of Ridomil 2E to 15 gallons of water and spray the surface of the trunks using enough spray to thoroughly wet the lesions. Up to three applications per year may be made.

Note: Trunk sprays for use only in Texas, California, and Arizona.

Cole Crops (Broccoli, Cabbage, Cauliflower)

Ridomil 2E applied as a soil application at seeding will control damping-off caused by Pythium spp. and basal stem rot caused by Phytophthora spp. Applications may be banded over the rows, broadcast or incorporated.

Broadcast and Banded Applications: Apply 4 pts./treated acre at planting in 20-50 gals. of water. For banded applications, 2 pts./13,000 linear ft. of row in a 7-inch band is recommended. For Pythium control, use 1/2-1 pt./13,000 linear ft. of row.

Incorporated application. Apply 4-8 pts./A as a broadcast soil application in 20-50 gals. of water and incorporate in the top 2 inches of soil. If plantings are made on beds, broadcast the Ridomil and incorporate before forming beds. For control of Pythium damping-off only use 1-2 pts./A.

Conifers in Nurseries

Ridomil 2E provides control of Phytophthora root rot of conifers.

Seedbeds and Plug-Plantings

Apply 2 1/2 pts./A as a broadcast spray over the beds in at least 50 gals. of water at the time of seeding or transplanting. Additional applications should be made at approximately six-month intervals.

2-0 Transplants*

Apply 5 pts./A as a broadcast spray over the beds in at least 50 gals. of water at the time of transplanting. Additional applications should be made at approximately six-month intervals.

*Newly transplanted two-year old seedlings.

CottonSeed Rots and Seedling Diseases of Cotton (Pythium spp.)

Apply 1/4-1/2 pt./13,000 linear feet of row as an in-furrow spray in 5-15 gals. of water at planting. Mount the spray nozzle so the spray is directed into the furrow over the seed just before the seeds are covered.

For broader spectrum disease control, Ridomil 2E can be applied with 2-4 qts. Terraclor® 2E/13,000 linear feet of row as an in-furrow spray.

Note: When Ridomil 2E is applied with Terraclor 2E, observe all precautions and restrictions that appear on the Terraclor 2E label.

Cucumbers, Melons, and Squash

Ridomil 2E applied at seeding will provide control of damping-off and cottony leak caused by Pythium spp. Applications may be made in a band over the row at the time of seeding or broadcast and lightly incorporated. If planting on beds, Ridomil 2E may be broadcast and incorporated before bedding.

Broadcast and Banded Application: Apply 4-8 pts./treated acre at planting in 20-50 gals. of water. For banded applications, a 7-inch band is recommended. To calculate the amount of Ridomil 2E needed per acre for banded applications, use the formula in the General Information section of this label.

Incorporated application: Apply 4-8 pts./A as a broadcast soil application in 20-50 gals. water and incorporate into the top 2 inches of soil. If plantings are made on beds, Ridomil 2E may be broadcast before bedding provided it is not incorporated more than 4 inches deep.

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Deciduous Fruits and Nuts in Nurseries
and Field Plantings (Nonbearing)

Phytophthora Root Rot

Make the first application of Ridomil 2E at the time of planting. Additional applications should be made at three-month intervals throughout the growing season. For established plantings, the first application should be made before the plants start growth in the spring.

Apply 2-4 gals./treated acre (6-12 fl. oz./1,000 sq. ft.) in sufficient water to obtain thorough coverage of the soil under the canopy of the trees. Sufficient surface area should be treated in nurseries to cover the root zone of the plants. Use the high rate in areas known to be infested with Phytophthora.

Notes: 1) Do not apply to plantings that will bear harvestable fruit within 12 months of application, or illegal residues may result. 2) When applying Ridomil 2E in apples, see Apples section of this label for specific recommendations.

Hops

Downy Mildew (Pseudoperonospora humuli): Apply 1 qt./A in a minimum of 20 gals. of water to the soil surface over the crowns after pruning, but before training. Early application before shoots are six inches long is preferable.

Notes: 1) Do not apply after training or make more than one application per year and 2) Do not feed hop refuse to livestock, or illegal residues may result.

Leafy Vegetables (Head Lettuce, Spinach)

Ridomil 2E applied as a soil application at seeding will control damping-off caused by Pythium spp. Applications may be banded over the rows, broadcast or incorporated.

Broadcast and Banded Applications: Apply 4-8 pts./treated acre at planting in 20-50 gals. of water. For banded applications, a 7-inch band is recommended. To calculate the amount of Ridomil 2E needed per acre, use the formula in the General Information section of this label.

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Incorporated application: Apply 4-8 pts./A as a broadcast soil application in 20-50 gals. of water and incorporate in the top 2 inches of soil. If plantings are made on beds, broadcast the Ridomil and incorporate before forming beds.

Legume Vegetables (Succulent or Dried)

Includes field beans, French beans, kidney beans, lima beans, mung beans, navy beans, pinto beans, runner beans, snap beans, wax beans, broad beans (fava beans), chickpeas (garbanzo beans), lentils, garden peas, field peas, sugar peas, southern peas (blackeyed peas, crowder peas, cowpeas, catjang), and edible soybeans.

Pythium Damping-Off and Root Rot: Ridomil 2E applied at seeding will control damping-off and root rot caused by Pythium spp. Applications can be made in the seed furrow or banded at planting.

Application: Apply 1 pt./13,000 linear feet of row in-furrow or in a 7-inch band at the time of planting.

Onions - Dry Bulb, Green, and Onions Grown for Seed

Ridomil 2E applied at seeding will control damping-off caused by Pythium spp. Applications may be made in a band over the rows, broadcast or incorporated.

Broadcast or Banded application: Apply 4-8 pts./A as a broadcast application at planting in 20-50 gals. of water. For banded applications, a 7-inch band is recommended. To calculate the amount of Ridomil 2E needed per acre for banded applications, use the formula in the General Information section of this label.

Incorporated application: Apply 4-8 pts./A as a broadcast soil application in 20-50 gals. of water and incorporate in the top 2 inches of soil. If plantings are made on beds, Ridomil 2E may be broadcast before planting provided it is not incorporated more than 4 inches deep.

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Stone Fruits*, Walnuts and Almonds

*Including apricots, cherries (sweet, sour), nectarines, peaches, plums (Chickasaw, Damson, Japanese), prunes.

Use of Ridomil 2E will aid in the control of crown, collar and root rot caused by Phytophthora spp. when used in conjunction with good cultural practices and rootstocks that are most tolerant to the disease. Ridomil 2E applications should be made before symptoms appear, especially in areas favorable for disease development. Ridomil 2E will not revitalize trees showing moderate to severe disease symptoms.

On new plantings, make the first application of Ridomil 2E two weeks after planting. Additional applications should be made at 2-3 month intervals or during periods most favorable for root, crown or collar rot development.

For established plantings, the application should be made in the spring before the plants start growth. Additional applications should be made at 2-3 month intervals or to coincide with periods most favorable for root, crown or collar rot development.

Apply 2-4 gals./treated acre (6-12 fl. oz./1,000 sq. ft.) in sufficient carrier to obtain thorough coverage of the soil under the canopy of the trees. Sufficient surface area should be treated in nurseries to cover the root zone of the plants. For banded applications, use the formula in the General Information section of this label to calculate the amount of Ridomil 2E needed per acre.

Soil surface sprays of Ridomil 2E will not be effective until the fungicide is moved into the root zone by rainfall or irrigation. Use the high rate in areas known to be infested with Phytophthora.

Precautions: (1) Do not dip the roots of trees in Ridomil 2E solutions, spray the roots or concentrate it around the tree trunks or injury may occur. (2) Do not apply to trees under stress.

Notes: (1) Do not graze livestock in treated areas, (2) Do not graze or feed cover crops grown in treated orchards, and (3) Do not make more than three applications per year, or illegal residues may result.

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Peanuts

Ridomil 2E is a soil-applied systemic fungicide for use in control of seedling and pod diseases of peanuts incited by Pythium spp.

Seedling Diseases: Apply 1 pt./A in-furrow in a 7-inch band at the time of planting.

Pod Rot: Apply 2 qts./A at early pod set through the irrigation water. Apply early in set to insure adequate flushing into soil.

Note: Where Rhizoctonia and Fusarium are a problem, fungicides that control these pathogens should be used with Ridomil.

Pineapples

Ridomil 2E, applied as a "seed piece" dip, provides effective control of heart rot disease of pineapple caused by Phytophthora spp.

Apply as a preplant crown dip at the rate of 2 qts./100 gals. of water. Use 75 to 100 gals. of dip solution per planted acre, depending on crown size, plant density and dipping techniques.

Note: If there is a crop failure within one year of planting treated crowns, do not harvest plant material for animal feed.

Raspberries

Phytophthora Root Rot (Phytophthora spp.): Apply 1 pt./1,000 ft. of row to the soil surface in a three foot band over the row (5.5 pts./A on broadcast basis). One application may be made in the fall after harvest, and a second application in the spring.

Note: Do not apply less than 45 days prior to harvest, or illegal residues may result.

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Soybeans

Ridomil 2E is a soil-applied systemic fungicide for use in the control of Phytophthora root and stem rot and Pythium damping-off. Ridomil 2E may be applied broadcast, banded or in the seed furrow before the seeds are covered. The seed furrow applications will provide more consistent results if rain is not expected before the seeds germinate.

For best results against Phytophthora root and stem rot, use Ridomil 2E with soybean varieties that have some tolerance to the races of Phytophthora present in the field. The high rate of Ridomil 2E should be used in areas with a history of heavy Phytophthora damage. Under heavy late season Phytophthora pressure, Ridomil 2E may not provide complete control.

Broadcast and Banded Applications: Apply 2 3/4-5 1/2 pts./treated acre at planting. For banded applications, a 7-inch band is recommended. Use the formula in the General Information section of this label to calculate the amount of Ridomil 2E needed per acre.

In-furrow Applications: Apply 3/5 - 1 1/5 fl. oz./1,000 linear feet of row in the seed furrow at planting. Use the table below to determine the amount of Ridomil 2E needed per acre based on row spacing.

Suggested Rates Per Acre According to Row Spacing

Row Spacing	Linear Feet of Soybean Row Per Acre	Amount of Ridomil 2E Needed Per Acre
38 in.	13,756	8 1/3-16 2/3 fl. oz.
36 in.	14,520	8 2/3-17 1/2 fl. oz.
30 in.	17,424	10 1/2-21 fl. oz.
24 in.	21,780	13-26 fl. oz.
20 in.	26,136	16-32 fl. oz.

Note: Ridomil 2E is specific for Pythium and Phytophthora and will not control other diseases that may attack soybeans.

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Tobacco

Ridomil 2E is a soil-applied systemic fungicide for use in the field before transplanting for control of black shank (Phytophthora parasitica, var. Nicotianae and blue mold (Peronospora tabacina) on all types of tobacco. Ridomil 2E may also be applied in tobacco plant beds for control of blue mold and damping-off caused by Pythium spp. Ridomil 2E will not control Anthracnose; continue using a preventive foliar fungicide control program.

For best results against black shank, use Ridomil 2E on tobacco varieties with some resistance to black shank. In fields where there is a history of severe black shank, use the highest rate and plant a variety that is resistant to the race of Phytophthora present. (Note: Burley L8 hybrids are only resistant to Phytophthora Race 0.) Ridomil 2E is not recommended for use in high black shank areas on very susceptible flue-cured varieties such as Hicks, Virginia Gold, and White Gold.

Notes: (1) The preferred method of blue mold control is to use Ridomil 2E in the plant bed and follow with an application in the field prior to transplanting. (2) Failure to adequately control nematodes in fields treated with Ridomil 2E may result in poor control of black shank.

Tobacco Plant Bed

For control of blue mold and damping-off caused by Pythium spp., apply Ridomil 2E only as a preplant broadcast soil application at the rate of 1 qt./A in 50 gals. of water (1 fl. oz. or 2 tablespoons/150 sq. yds. of bed in 2 gals. of water). Apply

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before or at the time of seeding to the surface of the plant bed and lightly incorporate or follow with one-half inch sprinkler irrigation water. In Pennsylvania, use 2 qts./A (2 fl. oz. or 4 tablespoons/150 sq. yds. of bed in 2 gals. of water).

Note: These treatments are only adequate to control blue mold in the plant bed and will not control blue mold in the field following transplanting. Follow the directions below for field planted tobacco.

Field Planted Tobacco

Blue Mold: Use Ridomil 2E as a broadcast soil application and incorporate in the top 2-4 inches of soil and form beds. For flue-cured tobacco, use 1-2 qts./A, depending on disease pressure and length of control desired. Under low disease pressure or for early season control, use 1 qt./A; for burley and other tobacco types, use 2 qts./A of Ridomil 2E.

Black Shank: Apply a broadcast application of Ridomil 2E using the appropriate rate in the table below. Apply with a conventional ground sprayer in a minimum of 15 gals. of water per acre. Incorporate Ridomil 2E in the top 2-4 inches of soil and form beds.

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Type of Tobacco*	Disease Level in Field	Rate of Ridomil 2E Per Acre
Flue-Cured	Low to Moderate (Less than 6% Disease)	2 qts.
	High (More than 6% Disease)	4 qts.**
Burley and Other***	Low to Moderate (Less than 6% Disease)	4 qts.
	High (More than 6% Disease)	6 qts.

*See General Information for recommendations on the use of resistant varieties.

**Florida and Georgia - Use 6 qts./A of Ridomil 2E in fields with very high black shank levels (greater than 60% disease).

***Pennsylvania - Do not use Ridomil 2E for black shank control.

For prolonged control of blue mold or black shank in field planted tobacco, make a supplemental application of 1 qt./A as a broadcast soil application at the last cultivation. Do not make this layby application if more than 2 qts./A of Ridomil 2E were applied at transplanting.

Note: Do not use Ridomil 2E in transplant water or in foliar application on field-grown tobacco, or crop injury may occur.

Tomatoes

Soil applications of Ridomil 2E at seeding will provide control of damping-off caused by Pythium spp. and soil applications applied 4-12 weeks before harvest under the vines will reduce fruit and root rot caused by Pythium spp. and Phytophthora spp.

Seedling Damping-Off (Pythium spp.): Apply 4-8 pts./A as a broadcast surface spray immediately before or after planting in 20-50 gals. of water. Lightly incorporate with mechanical equipment if application is made prior to planting or with sprinkler irrigation if applied after planting. For banded applications, use the formula shown in the General Information section to calculate the amount of Ridomil 2E needed per acre.

Fruit and Root Rot (Pythium spp. and Phytophthora spp.): Apply 4 pts./A as a soil surface application under the vines 4-12 weeks before harvest in sufficient water to obtain thorough coverage. Follow as soon as possible with an irrigation. For banded applications, use the formula shown in the General Information section to determine the amount of Ridomil 2E needed per acre.

Note: Do not apply more than 12 pts./A/season, or illegal residues may result.

Vegetable Bedding PlantsPythium Damping-Off of Broccoli, Cabbage, Cauliflower, Cucumbers, Lettuce, Melons, Spinach and Squash

Apply 2-4 pts./A as a preplant broadcast spray in 50 gals. of water (1-2 fl. oz. or 2-4 tablespoons/150 sq. yds. of bed in 2 gals. water) before or at the time of seeding to the surface of the beds and lightly incorporate or follow with one-half inch sprinkler irrigation water.

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Rotational Crops

If replanting is necessary following a soil application, tobacco or cotton may be replanted immediately. Tomatoes, broccoli, cabbage, cauliflower, cucumbers, melons, squash, onions, lettuce, or spinach may be replanted immediately provided that no more than 4 qts. per acre of Ridomil were applied to the soil. Do not make a second application of Ridomil. Wheat, or any crop on this label may be planted during the fall following application of Ridomil. Other small grain cover crops may also be planted during the fall following application provided they are plowed down and not used for food or feed. Corn, soybeans, root crops, or any crop on this label may be planted the year following treatment. Other crops may be planted 18 months following application.

Storage and Disposal

Store at temperatures above 40°F. Crystals may form at lower storage temperatures. If this occurs, place the product in a warm room (68°F or above) and roll or shake the container at frequent intervals until all crystals are dissolved.

Pesticide Disposal

Do not contaminate water, food or feed by storage or disposal. Open dumping is prohibited. Wastes resulting from the use of this product are acutely toxic. Improper disposal of unused pesticide, spray mixture, or rinsate is a violation of federal law. Pesticide, spray mixture, or rinsate that cannot be used according to label instructions must be disposed of according to federal, state or local procedures. For guidance in proper disposal methods, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office.

Container Disposal

Do not reuse empty container. Triple rinse (or equivalent) and offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or by open burning, if allowed by state and local authorities. If burned, keep out of smoke.

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Precautionary StatementsHazards to Humans and Domestic Animals

WARNING

Causes eye injury. Do not get in eyes. Avoid contact with skin or clothing. Harmful if swallowed, inhaled or absorbed through the skin. Avoid breathing vapors or spray mist.

Practical Treatment: In case of contact with eyes, immediately flush with plenty of water. Get medical attention. In case of contact with skin, wash thoroughly with soap and water. Get medical attention if irritation occurs. If swallowed, immediately contact a physician, hospital or local Poison Control Center. Do not induce vomiting. If inhaled, move to fresh air. If not breathing, give artificial respiration (preferably mouth to mouth) and get medical attention. Notes to Physician: If Ridomil 2E is ingested, lavage stomach. A slurry of activated charcoal in water can be left in the stomach. Give a saline laxative and supportive therapy.

Environmental Hazards

Do not apply directly to water. Apply only as specified on this label. Do not apply when weather conditions favor drift from treated areas. Do not contaminate water by cleaning of equipment or disposal of wastes.

Physical or Chemical Hazards

Do not use or store near heat or open flame.

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

D.z.n® trademark of CIBA-GEIGY for diazinon

Balan® trademark of Elanco Products for benefin

Bravo® trademark of SDS Biotech for chlorothalonil

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Dasanit® trademark of the Parent Company of Farbenfabriken Bayer GmbH, Leverkusen, for fensulfothion

Difolatan® trademark of Chevron Chemical Company for captafol

Di-Syston® trademark of the Parent Company of Farbenfabriken Bayer GmbH, Leverkusen, for disulfoton

Dithane® trademark of Rohm and Haas Company for maneb/mancozeb

Enide® trademark of Tuco Division of the Upjohn Company for diphenamid

Furadan® trademark of FMC Corporation of carbofuran

Manzate® trademark of E. I. DuPont de Nemours & Company for maneb/mancozeb

Mocap® trademark of Rhone Poulenc, Inc. for ethoprop

Nemacur® trademark of the Parent Company of Farbenfabriken Bayer GmbH, Leverkusen, for fenamiphos

Paarlan® trademark of Elanco Products for isopropalin

Terraclor® trademark of UniRoyal, Inc. for PCNB

Tillam® trademark of Stauffer Chemical Co. for pebulate

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Agricultural Division
CIBA-GEIGY Corporation
Greensboro, North Carolina 27419

RDML2E/MSTF7

October 15, 1986

(Back Cover)

Ridomil® 2E

Fungicide

For the control of certain diseases in various crops caused by the Oomycete class of fungi.

One Gallon
U. S. Standard Measure

One Quart
U.S. Standard Measure

Active Ingredient:

Metalaxyl: <u>N</u> -(2,6-dimethylphenyl)- <u>N</u> - (methoxyacetyl) alanine methyl ester	25.1%
<u>Inert Ingredients:</u>	<u>74.9%</u>
<u>Total:</u>	<u>100.0%</u>

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

See directions for use in attached booklet.

EPA Reg. No. 100-607

EPA Est. 100-AL-1

Keep Out of Reach of Children.

WARNING

AVISO

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

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Precautionary StatementsHazards to Humans and Domestic Animals

Causes eye injury. Do not get in eyes. Avoid contact with skin or clothing. Harmful if swallowed, inhaled or absorbed through the skin. Avoid breathing vapors or spray mist.

Practical Treatment: In case of contact with eyes, immediately flush with plenty of water. Get medical attention. In case of contact with skin, wash thoroughly with soap and water. Get medical attention if irritation occurs. If swallowed, immediately contact a physician, hospital or local poison control center. Do not induce vomiting. If inhaled, move to fresh air. If not breathing, give artificial respiration (preferably mouth to mouth) and get medical attention. Notes to Physician: If Ridomil 2E is ingested, lavage stomach. A slurry of activated charcoal in water can be left in the stomach. Give a saline laxative and supportive therapy.

Environmental Hazards

Do not apply directly to water. Apply only as specified on this label. Do not apply when weather conditions favor drift from treated areas. Do not contaminate water by cleaning of equipment or disposal of wastes.

Physical or Chemical Hazards

Do not use or store near heat or open flame.

Store at temperatures above 40°F.

Storage and DisposalContainer Disposal

Do not reuse empty container. Triple rinse (or equivalent), and offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by open burning, if allowed by state and local authorities. If burned, keep out of smoke.

See label booklet for proper disposal of pesticide wastes.



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R105095

Chemical:	Metalaxyl
PC Code:	113501
HED File Code	11500 Petition Files Chemistry
Memo Date:	02/03/2005
File ID:	00000000
Accession Number:	412-05-0092

HED Records Reference Center
02/14/2005