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WASHINGTON, D.C. 20460

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Response to the Malathion Reregistration Standard:
Magnitude of the Residue Studies. (Case No. 0248,
Chemical I. D. No. 057701, MRID Nos. 43107601-03,
CBRS No. 13691, Barcode: D203171.

FROM: R. B. Perfetti, Ph.D., Chemist *R.B. Perfetti*
Reregistration Section 2
Chemistry Branch II: Reregistration Support
Health Effects Division (7509C)

THRU: W. J. Hazel, Ph.D., Section Head *W.J. Hazel*
Reregistration Section 2
Chemistry Branch II: Reregistration Support
Health Effects Division (7509C)

TO: Esther Saito, Chief
Reregistration Branch
Special Review & Reregistration Division (7508W)

Attached is a review of magnitude of the residue studies on apples and cantaloupes submitted by the Malathion Reregistration Coalition in response to the malathion Reregistration Standard. This review was completed by Dynamac Corporation under supervision of CBRS, HED. It has undergone secondary review in the branch and has been revised to reflect Agency policies.

Magnitude of the residue in apples:

- 1a. The field residue data reflecting use of the WP formulation (1993; MRID 43107601) indicate that the uncorrected combined residues of malathion and malaoxon in/on mature apples were 0.287-0.366 ppm from samples collected at one CA test site and harvested 3 days following the last of 11 foliar spray run-off applications of a 25% WP formulation at 0.6 lb ai/100 gal of water per application using ground equipment. The single application rate corresponds to 0.7-1.1 lb ai/A (<0.05-0.07x) based on spray volumes of 119-182 gallons of water per acre. These data are incomplete to satisfy reregistration requirements because only one field trial



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contains at least 50% recycled fiber

reflecting use of the WP formulation was conducted. Furthermore, the trial was conducted at a rate well below the registered 1x rate.

- 1b. The field residue data reflecting use of the EC formulation (1993; MRID 43107603) indicate that the uncorrected combined residues of malathion and malaoxon in/on mature apples were 11.048-17.030 ppm from samples collected at one CA test site and were 7.228-12.035 ppm from samples collected at one NY test site. These apple samples were harvested 3 days following the last of 10 (CA site) or 13 (NY site) foliar spray run-off applications of the 5 lb/gal EC formulation at 10.4 lb ai/100 gal of water per application using ground equipment. The single application rate corresponds to 11.3-15.4 lb ai/A (0.8-1.0x) in CA and 3.8-15.0 lb ai/A (0.25-1.0x) in NY based on spray volumes of 106-148 and 36-145 gallons per acre, respectively. These data are incomplete to satisfy reregistration requirements because only two field trials reflecting use of the EC formulation were conducted. Although incomplete, these limited data suggest that the established 8 ppm tolerance (expressed as malathion per se) for apples may be too low. The established tolerance will be reassessed when additional adequate apple field trial data are available.
- 1c. The following additional data are required to fully satisfy reregistration requirements for magnitude of the residue in apples:
 - Data depicting residues of malathion and its metabolite malaoxon in/on apples following applications of the WP and EC formulations according to the maximum registered use patterns. Separate sets of residue data are required for the WP and EC formulations since these malathion formulation classes are registered for mid- to late season foliar applications. According to the EPA Guidance on Number and Location of Domestic Crop Field Trials issued 6/2/94 (E. Saito and E. Zager), a total of 16 field trials for each formulation class should be distributed among Regions I (4 trials), II (2 trials), V (3 trials), IX (1 trial), X (1 trial), and XI (5 trials). Two independently composited samples from each trial are recommended. [Note: The required number of trials reflecting use of the EC formulation may be reduced to 14 since the Coalition has already provided acceptable data from two trials.] Samples should be analyzed within the storage interval (101-145 days) that fortified residues of malathion and malaoxon have been demonstrated to be stable in/on apples under frozen (-20 C) storage conditions or concurrent storage

stability data may be submitted with the crop field trials. Appropriate label revisions to incorporate maximum number of applications per season (or equivalent maximum seasonal rate) will be required when acceptable field residue data have been submitted and evaluated.

Magnitude of the residue in melons:

- 2a. The field residue data reflecting use of the EC formulation (1993; MRID 43107602) indicate that the uncorrected combined residues of malathion and malaoxon in/on mature cantaloupes were 2.140-2.248 ppm from samples collected at one CA test site and were 0.919-2.013 ppm from samples collected at one TX test site. These cantaloupe samples were harvested 1 day following the last of 10 (CA site) or 6 (TX site) foliar spray applications of the 5 lb/gal EC formulation at 1.88 lb ai/A/application (1x) using a backpack ground sprayer.
- 2b. These data are incomplete to satisfy reregistration requirements because only two field trials reflecting the application of the EC formulation were conducted. Furthermore, no data reflecting use of other formulations (D and WP) registered to Malathion Reregistration Coalition members were submitted. Before the adequacy of the established tolerance (8 ppm, expressed as malathion per se) for melons can be reassessed, acceptable residue data reflecting the use of all registered formulations are needed. The following additional data are required:
 - Data depicting residues of malathion and its metabolite malaoxon in/on cantaloupes following applications of the D, WP, and EC formulations according to the maximum registered use patterns. Separate sets of residue data are required for these formulations since they are all registered for mid- to late season foliar applications on melons. According to the EPA Guidance on Number and Location of Domestic Crop Field Trials issued 6/2/94 (E. Saito and E. Zager), a total of 8 field trials for each formulation class should be distributed among Regions II (1 trial), V (1 trial), VI (2 trials), and X (4 trials). Two independently composited samples from each trial are required. [Note: The required number of trials reflecting use of the EC formulation may be reduced to 6 since the Coalition has already provided acceptable data from two trials.] Samples should be analyzed within the storage interval (103 days) that fortified residues of malathion and malaoxon have been demonstrated to be stable in/on cantaloupes under frozen (-20 C) storage conditions. Appropriate

label revisions to incorporate maximum number of applications per season (or equivalent maximum seasonal rate) will be required when acceptable field residue data have been submitted and evaluated.

- 2c. According to the current crop groupings [40 CFR §180.34], melons are members of the cucurbit vegetables group; cantaloupes are the representative commodities of melons [40 CFR §180.1(h)]. The Agency has recently proposed the creation of the subgroups melons and squash/cucumber within the cucurbit vegetables group (58 FR 44990-45006, 8/25/93). For the establishment of a subgroup tolerance for melons, the representative commodities are cantaloupes and the required number of field trials remains 8.

If you need additional input please advise.

Attachment 1: Malathion Crop Field Trials Review.

cc (With Attachment 1): RBP, Malathion Reregistration Standard File and Malathion Subject File.

cc (Without Attachment): RF.

DYNAMAC
CORPORATION
Environmental Services

Final Report

MALATHION
Shaughnessy No. 057701
Case No. 0248
(CBRS No. 13691, DP Barcode
D203171)

TASK 4
Registrant's Response to Residue
Chemistry Data Requirements

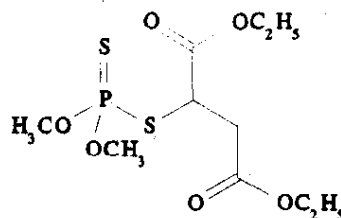
September 30, 1994

Contract No. 68-D2-0053

Submitted to:
U.S. Environmental Protection Agency
Arlington, VA 22202

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MALATHION



Shaughnessy No. 057701; Case 0248

(CBRS No. 13691; DP Barcode No. D203171)

Task 4

REGISTRANT'S RESPONSE TO RESIDUE CHEMISTRY DATA REQUIREMENTS

BACKGROUND

In response to the Malathion Reregistration Standard Guidance Document, dated 2/88, the Malathion Reregistration Coalition (MRC) submitted field residue data for apples (1993; MRIDs 43107601 and 43107603) and melons (1993; MRIDs 43107602). The members of the Malathion Reregistration Coalition are: Bonide Products; Chevron Chemical Company; Cornbelt Chemical Company; Dexol Industries; Dragon Corporation; Roussell Uclaf; Prentiss, Inc.; Purina Mills, Inc.; Rockland Corporation; Southern Agricultural Insecticides, Inc.; Sureco; Voluntary Purchasing Groups, Inc.; and Wilbur-Ellis Company. Data from these submissions are evaluated for adequacy in fulfilling residue chemistry data requirements for the reregistration of malathion. The Conclusions and Recommendations stated below pertain only to the above submissions. All other residue chemistry data requirements stated in the Malathion Reregistration Standard Guidance Document are not addressed herein.

The qualitative nature of malathion residues in plants is adequately understood based on acceptable metabolism studies involving alfalfa, lettuce, cotton, and wheat. The qualitative nature of the residue resulting from oral dosing of ruminants and poultry is adequately understood. However, if the direct livestock treatment uses of malathion are supported, then appropriate dermal metabolism and magnitude of the residue in meat, milk, poultry, and egg studies are required.

Tolerances for residues in/on food/feed commodities are currently expressed in terms of malathion (*O,O*-dimethyl dithiophosphate of diethyl mercaptosuccinate) [40 CFR §180.111, §185.3850, §185.7000, and §186.3850]. The HED Metabolism Committee has determined that the parent compound malathion and the malaaxon metabolite are the compounds to be regulated. Codex MRLs exist for residues of malathion *per se* in/on various plant and processed commodities. The Codex MRLs and the U.S. tolerances will be incompatible

when the U.S. tolerance expression for plant commodities is revised to include both residues of malathion and the metabolite malaoxon.

Adequate methods are available for the enforcement of tolerances as presently expressed. The Pesticide Analytical Manual (PAM) Vol. II lists a TLC method, a GLC method with KCl thermionic detection, and a spectrophotometric method as Methods I, II, and III, respectively, for the enforcement of malathion tolerances. The Residue Chemistry Science Chapter of the Malathion Reregistration Standard, dated 7/87, recommends use of the GLC method for tolerance enforcement. When the tolerance expression is revised to include both malathion and malaoxon, new enforcement methodology may be required.

CONCLUSIONS

Magnitude of the residue in apples:

- 1a. The field residue data reflecting use of the WP formulation (1993; MRID 43107601) indicate that the uncorrected combined residues of malathion and malaoxon in/on mature apples were 0.287-0.366 ppm from samples collected at one CA test site and harvested 3 days following the last of 11 foliar spray run-off applications of a 25% WP formulation at 0.6 lb ai/100 gal of water per application using ground equipment. The single application rate corresponds to 0.7-1.1 lb ai/A ($<0.05-0.07x$) based on spray volumes of 119-182 gallons of water per acre. These data are incomplete to satisfy reregistration requirements because only one field trial reflecting use of the WP formulation was conducted. Furthermore, the trial was conducted at a rate well below the registered 1x rate.
- 1b. The field residue data reflecting use of the EC formulation (1993; MRID 43107603) indicate that the uncorrected combined residues of malathion and malaoxon in/on mature apples were 11.048-17.030 ppm from samples collected at one CA test site and were 7.228-12.035 ppm from samples collected at one NY test site. These apple samples were harvested 3 days following the last of 10 (CA site) or 13 (NY site) foliar spray run-off applications of the 5 lb/gal EC formulation at 10.4 lb ai/100 gal of water per application using ground equipment. The single application rate corresponds to 11.3-15.4 lb ai/A ($0.8-1.0x$) in CA and 3.8-15.0 lb ai/A ($0.25-1.0x$) in NY based on spray volumes of 106-148 and 36-145 gallons per acre, respectively. These data are incomplete to satisfy reregistration requirements because only two field trials reflecting use of the EC formulation were conducted. Although incomplete, these limited data suggest that the established 8 ppm tolerance (expressed as malathion *per se*) for apples may be too low. The established tolerance will be reassessed when additional adequate apple field trial data are available.
- 1c. The following additional data are required to fully satisfy reregistration requirements for magnitude of the residue in apples:

- Data depicting residues of malathion and its metabolite malaoxon in/on apples following applications of the WP and EC formulations according to the maximum registered use patterns. Separate sets of residue data are required for the WP and EC formulations since these malathion formulation classes are registered for mid- to late season foliar applications. According to the EPA Guidance on Number and Location of Domestic Crop Field Trials issued 6/2/94 (E. Saito and E. Zager), a total of 16 field trials for each formulation class should be distributed among Regions I (4 trials), II (2 trials), V (3 trials), IX (1 trial), X (1 trial), and XI (5 trials). Two independently composited samples from each trial are required. [Note: The required number of trials reflecting use of the EC formulation may be reduced to 14 since the Coalition has already provided acceptable data from two trials.] Samples should be analyzed within the storage interval (101-145 days) that fortified residues of malathion and malaoxon have been demonstrated to be stable in/on apples under frozen (-20 C) storage conditions. Appropriate label revisions to incorporate maximum number of applications per season (or equivalent maximum seasonal rate) will be required when acceptable field residue data have been submitted and evaluated.

Magnitude of the residue in melons:

- 2a. The field residue data reflecting use of the EC formulation (1993; MRID 43107602) indicate that the uncorrected combined residues of malathion and malaoxon in/on mature cantaloupes were 2.140-2.248 ppm from samples collected at one CA test site and were 0.919-2.013 ppm from samples collected at one TX test site. These cantaloupe samples were harvested 1 day following the last of 10 (CA site) or 6 (TX site) foliar spray applications of the 5 lb/gal EC formulation at 1.88 lb ai/A/application (1x) using a backpack ground sprayer.
- 2b. These data are incomplete to satisfy reregistration requirements because only two field trials reflecting EC formulation were conducted. Furthermore, no data reflecting use of other formulations (D and WP) registered to the Malathion Reregistration Coalition were submitted. Before the adequacy of the established tolerance (8 ppm, expressed as malathion *per se*) for melons can be reassessed, acceptable residue data reflecting all registered formulations are needed. The following additional data are required:
 - Data depicting residues of malathion and its metabolite malaoxon in/on cantaloupes following applications of the D, WP, and EC formulations according to the maximum registered use patterns. Separate sets of residue data are required for these formulations since they are all registered for mid- to late season foliar applications on melons. According to the EPA Guidance on Number and Location of Domestic Crop Field Trials issued 6/2/94 (E. Saito and E. Zager), a total of 8 field trials for each formulation

class should be distributed among Regions II (1 trial), V (1 trial), VI (2 trials), and X (4 trials). Two independently composited samples from each trial are required. [Note: The required number of trials reflecting use of the EC formulation may be reduced to 6 since the Coalition has already provided acceptable data from two trials.] Samples should be analyzed within the storage interval (103 days) that fortified residues of malathion and malaoxon have been demonstrated to be stable in/on cantaloupes under frozen (-20 C) storage conditions. Appropriate label revisions to incorporate maximum number of applications per season (or equivalent maximum seasonal rate) will be required when acceptable field residue data have been submitted and evaluated.

- 2c. According to the current crop groupings [40 CFR §180.34], melons are members of the cucurbit vegetables group; cantaloupes are the representative commodities of melons [40 CFR §180.1(h)]. The Agency has recently proposed the creation of the subgroups melons and squash/cucumber within the cucurbit vegetables group (58 FR 44990-45006, 8/25/93). For the establishment of subgroup tolerance for melons, the representative commodities are cantaloupes and the required number of field trials remains 8.

RECOMMENDATIONS

The Coalition should be furnished a copy of this review. The Coalition should also refer to recent Agency guidance documents concerning submission of raw data (see Rejection Rate Analysis for Residue Chemistry, 2/93) and conducting field trials (see EPA Guidance on Number and Location of Domestic Crop Field Trials for Establishment of Pesticide Residue Tolerances, E. Saito and E. Zager, 6/94).

For future submissions of field residue studies on crops which the Malathion Reregistration Coalition is supporting, CBRS recommends that the Coalition conduct a comprehensive examination of all Coalition-registered formulations and use patterns to ensure that the field trials reflect the maximum application rate registered by any member of the Coalition.

DETAILED CONSIDERATIONS

Residue Analytical Methods

The raw agricultural commodities from the submitted field trials were analyzed for residues of malathion and its malaoxon metabolite using a GLC/flame photometric detection (FPD) method designated M-1923 and entitled " Malathion (CL 6,601): GC Method for the Determination of Malathion (CL 6,601) and Malaoxon (CL 28,967) Residues in Grasses (Including Tall Fescue, Bermuda, and Bluegrass) When Using Continuous Automated Sample

Injections." Briefly, residues of malathion and malaoxon are extracted from finely ground plant tissues with acetonitrile. The filtered extracts are subjected to cleanup procedures involving treatment with activated charcoal and passage of a methylene chloride-acetone solution through a silica-gel solid phase extraction cartridge. The malathion and malaoxon concentrations are determined by GLC using flame photometric detection in the phosphorus mode. The reported lower limit of quantitation is 0.01 ppm and the validated sensitivity of the method is 0.05 ppm for each compound.

It should be noted that Method M-1923 is essentially identical to the American Cyanamid Method M-1886 which has been recently proposed for enforcement purposes. Adequate method descriptions as well as acceptable radiovalidation data using samples from an alfalfa metabolism study have been submitted and evaluated (DP Barcode D196878, CBRS No. 12855, R. Perfetti, 2/28/94) for the American Cyanamid Method M-1886. Method M-1886 adequately recovered residues of malathion and malaoxon from samples of alfalfa hay treated with ^{14}C -malathion. The registrant has been required to conduct an independent laboratory validation, in accordance with PR Notice 88-5 dated 7/15/88, before the proposed method can be considered suitable for enforcement purposes.

Method validation and concurrent method recoveries were conducted by ABC Laboratories, Inc. (Columbia, MO) to determine the suitability of Method M-1923 for data collection. Untreated control samples of RACs from the respective field trials were fortified with malathion and malaoxon at various levels. Apparent residues of malathion and malaoxon were nondetectable (<0.01 ppm each) in/on all untreated control samples of RACs. Representative chromatograms, sample calculations, and standard curves were provided. The recovery data are presented in Tables 1A and 1B. These data suggest that Method M-1923 is adequate for data collection using the matrices tested.

Table 1A. Method validation of American Cyanamid Method M-1923 for determining malathion and its metabolite malaoxon from representative raw agricultural commodities fortified with each analyte.

Matrix (MRID)	Fortification Level (ppm)	Analyte Fortified	Percent Recovery *	
			Malathion	Malaoxon
Apples (43107601, 43107603)	0.005	Both analytes	94, 98	86, 98
	0.01	Both analytes	76, 85, 87	75, 87, 91
	1.0	Both analytes	90, 91, 93, 96	78, 84, 96, 97
	2.5	Both analytes	76, 80, 80, 92	72, 72, 76, 92
Cantaloupes (43107602)	0.005	Both analytes	80, 86, 96, 98	78, 84, 102, 106
	1.0	Both analytes	87, 88, 88, 100	84, 86, 88, 98
	2.5	Both analytes	88, 92, 92, 104	84, 84, 92, 100

* Each value represents an average of duplicate injections.

Table 1B. Concurrent method recoveries of malathion and its metabolite malaoxon from apples and cantaloupes fortified with each analyte and analyzed by American Cyanamid Method M-1923.

Matrix (MRID)	Fortification Level (ppm)		Percent Recovery ^a	
	Malathion	Malaoxon	Malathion	Malaoxon
Apples (43107601, 43107603)	0.01	0.01	100	96
	2.5	2.5	72	72
	3.18	--	85	--
	12.7	--	87	--
	--	0.01	--	110
	--	0.05	--	104
Cantaloupes (43107602)	0.01	0.01	110	100
	1.0	1.0	100	95
	2.5	2.5	96	92

^a Each value represents an average of duplicate injections.

Storage Stability Data

All samples from the submitted field trials were stored frozen (-20 °C) prior to residue analysis. Samples were stored for intervals of 43-144 days ($\approx$ 1.4-4.8 months) for apples and 51-99 days ($\approx$ 1.7-3.3 months) for cantaloupes.

Concurrent apple and cantaloupe storage stability studies were conducted to validate the results of the residue field trials. Immediately after harvest, untreated control apple and cantaloupe samples from each test location were ground and separately fortified in the field with malathion and malaoxon at 0.5 ppm. The fortified samples as well as the treated samples were shipped frozen from the field to the analytical laboratory and stored frozen under similar storage conditions and intervals. Samples were analyzed by American Cyanamid Method M-1923. The results of this study are presented in Table 2. These data indicate that fortified residues of malathion and malaoxon are stable under frozen storage conditions in/on apples for 145 days and cantaloupes for 103 days. These data support the storage conditions and intervals of samples used in the field trials.

Table 2. Recoveries of malathion and malaoxon in apples and cantaloupes following fortification with each analyte and storage at various intervals.

Matrix (MRID)	Test Location	Fortification Level (ppm)	Storage Interval (Days)	Percent Recovery	
				Malathion	Malaoxon
Apples (43107601, 43107603)	CA	0.5	101	74, 80, 82	--
	NY	0.5	53	86, 92, 158	--

Matrix (MRID)	Test Location	Fortification Level (ppm)	Storage Interval (Days)	Percent Recovery	
				Malathion	Malaoxon
	CA	0.5	145	--	94, 108
	NY	0.5	98	--	88, 100
	CA	0.5	68	82, 92	92, 96
Cantaloupes (43107602)	CA	0.5	61	74, 76, 90	78, 90, 94
	TX	0.5	103	74, 78, 80	82, 88, 90

Magnitude of the Residue in Plants

Apples

Established tolerance: A tolerance of 8 ppm has been established for residues of malathion *per se* in/on apples [40 CFR §180.111].

Use patterns registered to the Malathion Reregistration Coalition (MRC): A REFS search conducted 7/13/94 identified several malathion end-use products (EPs) and formulations presently registered to members of the MRC for multiple foliar and delayed dormant applications to apples. These various formulations may be tank-mixed or formulated (MAI) with other pesticides. Applications may be made, except during apple blossom period, at 10-14 day intervals as needed. A 3-day PHI is in effect. The registered application rates for each formulation are listed in Table 3.

The Malathion Reregistration Coalition submitted data depicting the magnitude of the residue of malathion and its metabolite malaoxon in/on apples following multiple applications of the wettable powder (1993; MRID 43107601) and emulsifiable concentrate (1993; MRID 43107603) formulations. Details of these field trials are discussed below.

Field trial reflecting use of WP formulation (1993; MRID 43107601): In one test conducted in CA, mature Red Delicious apples were harvested 3 days following the last of 11 foliar spray run-off applications of the 25% WP formulation at an equivalent rate of 0.6 lb ai/100 gal of water per application using a backpack ground sprayer. Based on Coalition-calibrated spray volumes of 119-182 gallons per acre (GPA), the single application rate corresponds to 0.7-1.1 lb ai/A (<0.05-0.07x the maximum registered rate). The initial application was made when apple trees were at $\approx$ 0.5-inch green tip stage and repeated at 7-day intervals until the bloom period. As most malathion end-use products prohibit applications during tree bloom, no spray was scheduled during this period. Applications resumed during petal fall at 10- to 14-day intervals.

Field trials reflecting use of EC formulation (1993; MRID 43107603): In two tests conducted in CA(1) and NY(1), mature Red Delicious and Idared apples, respectively, were harvested 3

days following the last of 10 (CA site) or 13 (NY site) foliar spray run-off applications of the 57% or 5 lb/gal EC formulation at an equivalent rate of 10.4 lb ai/100 gal of water per application using a backpack ground sprayer. Based on spray volumes of 106-148 gallons per acre (GPA) in CA and 36-145 GPA in NY, the single application rate corresponds to 11.3-15.4 lb ai/A (0.8-1.0x) in CA and 3.8-15.0 lb ai/A (0.25-1.0x) in NY. In CA, the applications were made at 10- to 14-day intervals except for the ninth application, which was postponed to 23 days after the previous application due to the observance of phytotoxicity on the trees. In NY, the applications were made at 7-day intervals before bloom with no sprays during bloom, and at 10- to 14- day intervals after bloom.

Table 3. Malathion uses on apples registered to the Malathion Reregistration Coalition.

Registrant	EPA Reg. No. ^a	% ai	Equipment	Commercial Rates		Homeowner Rates	
				lb ai/100 gal	lb ai/A	lb ai/100 gal ^b	product/gal
Wettable Powder Formulation							
Bonide Products	4-355	6% WP	Ground	--	--	--	5 tbls
Dragon Corp.	16-152	5% WP	Ground	0.5	--	--	5 tbls
Wilbur-Ellis Co.	70-190	5% WP	Ground	0.5	--	--	5 tbls
	2935-84	25% WP	Ground	0.75-1.00	--	--	--
Rockland Corp.	572-62	6% WP	Ground	--	--	--	5 tbls
	572-186	4% WP	Ground	0.5	--	--	8 tbls
Prentiss, Inc.	655-549	25% WP	Ground	0.5-0.625	--	--	--
Sureco, Inc.	769-676	25% WP	Ground	0.5-0.75	--	--	--
	769-849	6% WP	Ground	--	--	--	5 tbls
	769-957	25% WP	Ground	0.5-0.75	--	--	--
Roussel Uclaf	10370-298	10% WP	Ground	1.0	--	--	5-6 tbls
Southern Agric.	829-75	25% WP	Ground	1.0	15	--	2 tbls
	829-236	6% WP	Ground	0.625	--	--	6 tbls
Emulsifiable Concentrate Formulation							
Bonide Products	4-99	50% EC	Ground	2 pts product	--	--	2 tsp
	4-157	1 lb/gal EC	Ground	1.0	--	1.0	2.5 tbls
Dragon Corp.	16-19	50% EC	Ground	--	--	--	1.5-2 tbls
Wilbur-Ellis Co.	70-124, 5887-10	50% EC	Ground	--	--	--	1-3 tsp
	2935-83	8 lb/gal EC	Ground	1-1.5	--	--	--
Dexol Industries	192-96	50% EC	Ground	--	--	--	1.5-2 tbls
Rockland Corp.	572-183	50% EC	Ground	33.3-66.7 fl. oz product	--	--	2 tsp
Prentiss, Inc.	655-598	50% EC	Ground	33.3-66.7 fl. oz product	--	--	2-4 tsp
	655-777	5 lb/gal EC	Ground, Air	0.625-1.25 [based on 400 gal water/A]	2.5-5	--	--
Sureco, Inc.	769-844	50% EC	Ground	2 pts product	--	--	1.5-2 tsp
	769-903	12.5% EC	Ground	--	--	--	2 tbls
	769-961	8 lb/gal EC	Ground	0.67-1.25	--	--	--
Roussel Uclaf	10370-33	5 lb/gal EC	Ground	1.25	--	1.30	2 tsp
	10370-147	50% EC	Ground	--	--	--	2 tsp
	10370-256	5 lb/gal EC	Ground	0.625-1.25 [based in 400 gal water/A]	2.5-5	--	--
	10370-273	57% EC	Ground	--	--	--	2 tsp
	10370-278	2 lb/gal EC	Ground	--	--	0.4-0.5	0.5-0.7 tbls

Table 3. (continued.)

Registrant	EPA Reg. No. ^a	% ai	Equipment	Commercial Rates		Homeowner Rates	
				lb ai/100 gal	lb ai/A	lb ai/100 gal ^b	product/gal
Roussel Uclaf (continued)	10370-279	4.4 lb/gal EC	Ground	--	--	2.1-3.0	1.25-1.75 tbls
	10370-291	50% EC	Ground	--	--	--	2-3 tsp
Voluntary Purchasing Groups	7401-10	55% EC	Ground	2-3 pts product	--	--	--
	7401-172	12% EC	Ground	--	--	--	3 tbls
	7401-257	50% EC	Ground	--	--	--	2 tsp
Cornbelt Chemical	10107-10	5 lb/gal EC	Ground	1.25	--	--	--
Flowable Concentrate Formulation							
Bonide Products	4-59	3% FIC	Ground	--	--	--	10 tbls
	4-122	6% FIC	Ground	--	--	--	1.5-2.5 tbls
Wilbur-Ellis Co.	5887-77	6% FIC	Ground	--	--	--	1.5-2.5 tbls

^a The product jackets of the following EPs were not available for review: EPA Reg. Nos. 572-145, 769-901, 7401-328, and 7401-438.

^b Calculated by the study reviewer.

The submitted raw data pertaining to field trial information, application of the test substances, and sample-handling procedures were rather meager but reasonably sufficient to draw regulatory conclusions. For future submissions, the Coalition should refer to recent Agency guidance document concerning submission of raw data (see Rejection Rate Analysis for Residue Chemistry, 2/93).

At each test site, the treated and untreated plots consisted of 4 and 2 uniform apple trees, respectively. Approximately 10 lbs of apples per tree were hand-harvested from each test site. The collected samples were immediately frozen (-15 C) until shipment via freezer truck to the analytical laboratory, ABC Laboratories (Columbia, MO). At ABC, the samples were stored frozen (-20 C) until processing. The unwashed apples were ground, homogenized, stored in plastic bags, and returned to the freezer to allow the dry ice to sublime before subsampling. Subsamples were transferred from plastic bags to polyethylene bottles and returned to the freezer until extraction. The interval between harvest and residue analysis is estimated to be 43-144 days ($\approx$ 1.4-4.8 months). Residues in/on treated and untreated apples were determined using American Cyanamid Method M-1923 which is a GLC method using a DB-5 capillary column and flame photometric detection in the phosphorus mode. The results of the apple field trials are presented in Table 4. Apparent residues of malathion and malaoxon were nondetectable (<0.01 ppm each) in/on 4 untreated control samples.

Table 4. Residues of malathion and its metabolite malaoxon found in/on apples harvested 3 days following the last of multiple foliar applications of the 25% WP and 5 lb/gal EC formulations.

Formulation	Application Parameters	Trial Site	Uncorrected Residues (ppm) *		
			Malathion	Malaoxon	Combined
25% WP	11 foliar spray run-off applications at 0.6 lb ai/100 gal of water per application using a backpack sprayer. The single application rate corresponds to 0.7-1.1 lb ai/A (<0.05-0.07x) based on spray volumes of 119-182 gallons per acre.	CA	0.27, 0.30, 0.35, 0.30	0.017, 0.018, 0.016, 0.018	0.287, 0.318, 0.366, 0.318
5 lb/gal EC	10 (CA site) or 13 (NY site) foliar spray run-off applications at 10.4 lb ai/100 gal of water per application using a backpack sprayer. The single application rate corresponds to 11.3-15.4 lb ai/A (0.8-1.0x) in CA and 3.8-15.0 lb ai/A (0.25-1.0x) in NY based on spray volumes of 106-148 and 36-145 gallons per acre (GPA), respectively.	CA	17, 15, 11, 15	0.030, 0.056, 0.048, 0.028	17.030, 15.056, 11.048, 15.028
		NY	7.2, 12, 8.0, 10	0.028, 0.035, 0.031, 0.025	7.228, 12.035, 8.031, 10.025

* Each value represents an average of duplicate injections.

Geographic representation of field trials is inadequate since the test states of CA(8%) and NY(11%) accounted for only 19% of the 1991 U.S. apple production (1992 *USDA Agricultural Statistics*; p. 178). It should be noted that the Malathion Reregistration Standard Guidance Document required data reflecting each registered malathion formulation from field trials conducted in CA, NY, NC or VA, and WA.

The field residue data reflecting use of the WP formulation (1993; MRID 43107601) indicate that the uncorrected combined residues of malathion and malaoxon in/on mature apples were 0.287-0.366 ppm from samples collected at one CA test site and harvested 3 days following the last of 11 foliar spray run-off applications of a 25% WP formulation at 0.6 lb ai/100 gal of water per application using ground equipment. The single application rate corresponds to 0.7-1.1 lb ai/A (<0.05-0.07x) based on spray volumes of 119-182 gallons of water per acre. These data are incomplete to satisfy reregistration requirements because only one field trial reflecting use of the WP formulation was conducted. Furthermore, the trial was conducted at a rate well below the registered 1x rate.

The field residue data reflecting use of the EC formulation (1993; MRID 43107603) indicate that the uncorrected combined residues of malathion and malaoxon in/on mature apples were 11.048-17.030 ppm from samples collected at one CA test site and were 7.228-12.035 ppm

from samples collected at one NY test site. These apple samples were harvested 3 days following the last of 10 (CA site) or 13 (NY site) foliar spray run-off applications of the 5 lb/gal EC formulation at 10.4 lb ai/100 gal of water per application using ground equipment. The single application rate corresponds to 11.3-15.4 lb ai/A (0.8-1.0x) in CA and 3.8-15.0 lb ai/A (0.25-1.0x) in NY based on spray volumes of 106-148 and 36-145 gallons per acre, respectively. These data are incomplete to satisfy reregistration requirements because only two field trials reflecting use of the EC formulation were conducted. Although incomplete, these limited data suggest that the established 8 ppm tolerance (expressed as malathion *per se*) for apples may be too low. The established tolerance will be reassessed when additional adequate apple field trial data are available.

The following additional data are required to fully satisfy reregistration requirements for magnitude of the residue in apples:

- Data depicting residues of malathion and its metabolite malaaxon in/on apples following applications of the WP and EC formulations according to the maximum registered use patterns. Separate sets of residue data are required for the WP and EC formulations since these malathion formulation classes are registered for mid- to late season foliar applications. According to the EPA Guidance on Number and Location of Domestic Crop Field Trials issued 6/2/94 (E. Saito and E. Zager), a total of 16 field trials for each formulation class should be distributed among Regions I (4 trials), II (2 trials), V (3 trials), IX (1 trial), X (1 trial), and XI (5 trials). Two independently composited samples from each trial are required. [Note: The required number of trials reflecting use of the EC formulation may be reduced to 14 since the Coalition has already provided acceptable data from two trials.] Samples should be analyzed within the storage interval (101-145 days) that fortified residues of malathion and malaaxon have been demonstrated to be stable in/on apples under frozen (-20 C) storage conditions. Appropriate label revisions to incorporate maximum number of applications per season (or equivalent maximum seasonal rate) will be required when acceptable field residue data have been submitted and evaluated.

Melons

Established tolerance: A tolerance of 8 ppm has been established for residues of malathion *per se* in/on melons [40 CFR §180.111].

Use patterns registered to the Malathion Reregistration Coalition (MRC): A REFS search was conducted on 7/13/94 to determine the malathion end-use products (EPs) and formulations registered to the Malathion Reregistration Coalition. Several malathion formulations are presently registered for multiple foliar and delayed dormant applications to melons (cantaloupes, casabas, crenshaws, honeydews, honey balls, muskmelons, Persian, watermelons, and any hybrids of these). These formulations may be tank-mixed or formulated (MAI) with other pesticides. Applications are made at 7-day intervals or as

needed. A 1-day PHI is in effect. The registered application rates for each formulation are listed in Table 5.

The Malathion Reregistration Coalition submitted data (1993; MRID 43107602) depicting the magnitude of the residue of malathion and its metabolite malaoxon in/on melons. In two tests conducted in CA(1) and TX(1), mature cantaloupes were harvested 1 day following the last of 10 (CA site) or 6 (TX site) foliar spray applications of the 5 lb/gal EC formulation at 1.88 lb ai/A/application (1x the maximum registered rate for this formulation class) using a backpack ground sprayer and 20-30 gal/A of spray volumes. The initial application of the test formulation was made when cantaloupe plants were in the 4- to 6-true leaf stage (CA site) or 8- to 10-true leaf stage (TX site). The subsequent applications were made at 7-day intervals, except during bloom.

The submitted raw data pertaining to field trial information, application of the test substances, and sample-handling procedures were rather meager but reasonably sufficient to draw regulatory conclusions. For future submissions, the Coalition should refer to recent Agency guidance document concerning submission of raw data (see Rejection Rate Analysis for Residue Chemistry, 2/93).

Table 5. Malathion uses on melons registered to the Malathion Reregistration Coalition.

Registrant	EPA Reg. No. ^a	% ai	Equipment	Commercial Rates		Homeowner Rates	
				lb ai/100 gal	lb ai/A	lb ai/100 gal ^b	product/gal
Dust Formulation							
Roussel Uclaf	10370-128	5% D	Ground	--	1.5-1.8	--	--
Voluntary Purchasing Groups	7401-267	5% D	Ground	--	1.1-2.2	--	--
Wilbur-Ellis Co.	2935-87	4% D	Ground, Air	--	1.6-2.0	--	--
Wettable Powder Formulation							
Southern Agric.	829-75	25% WP	Ground	1.75	--	--	3.5 tbls
Emulsifiable Concentrate Formulation							
Bonide Products	4-99	50% EC	Ground	6-12 pts product	--	--	3 tsp
	4-126	9.4% EC	Ground	--	--	--	1.7 oz
Wilbur-Ellis Co.	70-124, 5887-10	50% EC	Ground	--	--	--	1.5-3 tsp
	2935-83	8 lb/gal EC	Ground, Air	--	1.5-1.75	--	--
Prentiss, Inc.	655-777	5 lb/gal EC	Ground, Air	--	0.94-1.88	--	--
Sureco, Inc.	769-903	12.5% EC	Ground	--	--	--	2 tbls
	769-961	8 lb/gal EC	Ground	--	1-1.25	--	--
Roussel Uclaf	10370-147	50% EC	Ground	--	--	--	2 tsp
	10370-256	5 lb/gal EC	Ground	--	0.94-1.88	--	--
	10370-273	57% EC	Ground	--	--	--	1 tsp
	10370-278	2 lb/gal EC	Ground	--	--	1.8-2.0	2.25-2.5 tbls
	10370-279	4.4 lb/gal EC	Ground	--	--	1.0-1.2	0.6-0.7 tbls
	10370-291	50% EC	Ground	--	--	--	1 tbls
Voluntary Purchasing Groups	7401-115	8 lb/gal EC	Ground	--	1.25	--	--
	7401-257	50% EC	Ground	--	--	--	2 tsp
Cornbelt Chemical	10107-10	5 lb/gal EC	Ground	0.94	--	--	--

^a The product jackets of the following EPs were not available for review: EPA Reg. Nos. 769-901 and 7401-328.

^b Calculated by the study reviewer.

Approximately 10 lbs of cantaloupes per replicate were manually harvested from each test site. The collected samples were placed into ice chests with dry ice and immediately transported to the respective field cooperator's facilities where samples were stored frozen before shipment via freezer truck to the analytical laboratory, ABC Laboratories (Columbia, MO). At ABC, the samples were stored frozen (-20 C) until processing. For processing, the unwashed and frozen melons were ground, homogenized, stored in plastic bags, and returned to the freezer to allow the dry ice to sublime before subsampling. Subsamples were

transferred from plastic bags to polyethylene bottles and returned to the freezer until extraction. The interval between harvest and residue analysis is estimated to be 51-99 days (≈ 1.7 -3.3 months). Residues in/on treated and untreated cantaloupes were determined using American Cyanamid Method M-1923 which is a GLC method using a DB-5 capillary column and flame photometric detection in the phosphorus mode. The results of the melon field trials are presented in Table 6. Apparent residues of malathion and malaoxon were nondetectable (< 0.01 ppm each) in/on 2 untreated control samples.

Table 6. Residues of malathion and its metabolite malaoxon found in/on cantaloupes harvested 1 day following the last of multiple foliar applications of the 5 lb/gal EC formulation.

Formulation	Application Parameters	Trial Site	Uncorrected Residues (ppm) *		
			Malathion	Malaoxon	Combined
5 lb/gal EC	10 (CA site) or 6 (TX site) foliar spray applications at 1.88 lb ai/A/application (1x) using a backpack ground sprayer and 20-30 gal/A of spray volumes.	CA	2.1, 2.2, 2.1	0.049, 0.048, 0.040	2.149, 2.248, 2.140
		TX	2.0, 0.91, 1.6	0.013, 0.0090, 0.013	2.013, 0.919, 1.613

* Each value represents an average of duplicate injections.

The field residue data reflecting use of the EC formulation (1993; MRID 43107602) indicate that the uncorrected combined residues of malathion and malaoxon in/on mature cantaloupes were 2.140-2.248 ppm from samples collected at one CA test site and were 0.919-2.013 ppm from samples collected at one TX test site. These cantaloupe samples were harvested 1 day following the last of 10 (CA site) or 6 (TX site) foliar spray applications of the 5 lb/gal EC formulation at 1.88 lb ai/A/application (1x) using a backpack ground sprayer.

These data are incomplete to satisfy reregistration requirements because only two field trials reflecting EC formulation were conducted. Furthermore, no data reflecting use of other formulations (D and WP) registered to the Malathion Reregistration Coalition were submitted. Before the adequacy of the established tolerance (8 ppm, expressed as malathion *per se*) for melons can be reassessed, acceptable residue data reflecting all registered formulations are needed. The following additional data are required:

- Data depicting residues of malathion and its metabolite malaoxon in/on cantaloupes following applications of the D, WP, and EC formulations according to the maximum registered use patterns. Separate sets of residue data are required for these formulations since they are all registered for mid- to late season foliar applications on melons. According to the EPA Guidance on Number and Location of Domestic Crop Field Trials issued 6/2/94 (E. Saito and E. Zager), a total of 8 field trials for each formulation class should be distributed among Regions II (1 trial), V (1 trial), VI (2 trials), and X (4 trials). Two independently composited samples from each trial are

required. [Note: The required number of trials reflecting use of the EC formulation may be reduced to 6 since the Coalition has already provided acceptable data from two trials.] Samples should be analyzed within the storage interval (103 days) that fortified residues of malathion and malaoxon have been demonstrated to be stable in/on cantaloupes under frozen (-20 C) storage conditions. Appropriate label revisions to incorporate maximum number of applications per season (or equivalent maximum seasonal rate) will be required when acceptable field residue data have been submitted and evaluated.

According to the current crop groupings [40 CFR §180.34], melons are members of the cucurbit vegetables group; cantaloupes are the representative commodities of melons [40 CFR §180.1(h)]. The Agency has recently proposed the creation of the subgroups melons and squash/cucumber within the cucurbit vegetables group (58 FR 44990-45006, 8/25/93). For the establishment of subgroup tolerance for melons, the representative commodities are cantaloupes and the required number of field trials remains 8.

EPA MEMORANDA CITED IN THIS REVIEW

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 DP Barcode: D196878
 Subject: Response to the Malathion Reregistration Standard: Radiovalidation of method in plants.
 From: R. Perfetti
 To: L. Rossi
 Dated: 2/28/94
 MRID: 42894601

MASTER RECORD IDENTIFICATION NUMBERS

Citations for the MRID document referred to in this review are presented below.

43107601 Schwab, D. and Lochhaas, C. (1993) Magnitude of malathion 25WP residue in apples. ABC Laboratory Project Final Report #40195. Unpublished study conducted by ABC Laboratories, Inc., Columbia, MO and submitted by W. Stickle of the Malathion Reregistration Coalition, Alexandria, VA. 84 p.

43107602 Schwab, D. and Lochhaas, C. (1993) Magnitude of malathion 5-E residue in melons. ABC Laboratory Project Final Report #40191. Unpublished study conducted by ABC Laboratories, Inc., Columbia, MO and submitted by W. Stickle of the Malathion Reregistration Coalition, Alexandria, VA. 101 p.

43107603 Schwab, D. and Lochhaas, C. (1993) Magnitude of malathion 5-E residue in apples. ABC Laboratory Project Final Report #40190. Unpublished study conducted by ABC Laboratories, Inc., Columbia, MO and submitted by W. Stickle of the Malathion Reregistration Coalition, Alexandria, VA. 106 p.