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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

05/26/98

MEMORANDUM

SUBJECT: Malathion: PC Code 057701, Case 0248. Magnitude of Residues of Malathion and Malaoxon in/on Stored Grains and Processed Commodities. (OPPTS 860.1520), MRID Nos. 43661401& 43666801, DP Barcode D216397.

FROM: Manying Xue, Chemist
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THROUGH: Francis B. Suhre, Branch Senior Scientist
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TO: Diana Locke, Risk Assessor
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Attached is a review of residue studies for malathion and malaoxon in/on corn grain, aspirated grain fractions and processed commodities from postharvest-treated corn grain (MRID 43666801); and wheat grain and aspirated grain fractions from postharvest-treated wheat grain (MRID 43661401). The review was prepared by Dynamac Corporation and has undergone secondary review in HED and all conclusions and recommendations reflect Agency policies. The submitted studies satisfy OPPTS 860.1500 (crop field trials) and 860.1520 (processed food/feed) for postharvest-treated corn grain, and 860.1500 for postharvest-treated wheat grain. Data remain outstanding for processed commodities of wheat grain (0PPTS 860.1520). The submitted studies show:

- Combined residues of malathion and malaoxon in/on postharvest-treated field corn grain and wheat grain did not exceed the established 8-ppm tolerance (presently expressed as malathion *per se*).

- Combined residues of malathion and malaoxon in corn grain concentrated in aspirated grain fractions (98x), meal (1.8x), flour (2.0x), dry-milled crude oil (4.5x), wet-milled crude oil (5.8x), dry-milled refined oil (1.3x), and wet-milled crude oil (3.5x).

(1)

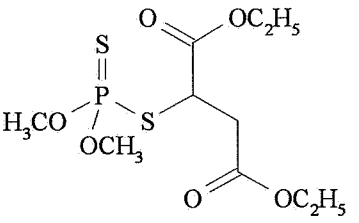
- Combined residues of malathion and malaoxon in wheat grain concentrated in aspirated grain fractions (38x).

Attachment: Dynamac review of Registrant's Response to Residue Chemistry DataRequirements.

cc: Xue, RF, Malathion List A File, SF, Lan

RDI: ResChemTeam: 05/12/98 :FBSuhre 05/26/98
7509C: CEBI: Mxue :CM-2: RM 718: 703 305-6198: 05/26/98

MALATHION



PC code 057701; Case 0248

(DP Barcode D216397)

REGISTRANT'S RESPONSE TO RESIDUE CHEMISTRY DATA REQUIREMENTS

BACKGROUND

In response to the Malathion Reregistration Standard Guidance Document, dated 2/88, Cheminova Agro A/S, through its authorized representatives Jellinek, Schwartz & Connolly, Inc. (JSC), submitted data depicting the magnitude of malathion and malaoxon residues in/on the following commodities: (I) grain, aspirated grain fractions and processed commodities collected from postharvest-treated field corn grain (1995; MRID 43666801, 2 volumes); and (ii) grain and aspirated grain fractions collected from postharvest-treated wheat grain (1995; MRID 43661401). Data from these submissions are evaluated herein for adequacy in fulfilling residue chemistry data requirements for the reregistration of malathion. The Conclusions and Recommendations stated below pertaining only to the above submissions.

In 1991, the Chemical Producers and Distributors Association, representing approximately 40 members of the Malathion Reregistration Coalition, met with the Agency to discuss, reregistration data requirements for postharvest use of malathion on stored grain. The basic producers American Cyanamid Co. and Cheminova Agro had stated that they were not going to support use of malathion on stored grains. The Agency concluded that residue data for stored wheat grain could be translated to barley, oats, and rye but that a separate study would be required for rice grain (P. Deschamp, 9/25/91). Subsequently, Cheminova informed the Agency that they would support the use of malathion on stored grain and submitted protocols for studies with stored corn and wheat grain. In a review of these protocols (DP Barcode D187727, 4/15/93, D. McNeilly), HED concluded that the study on corn grain could be translated to stored sorghum grain. HED also concluded that the proposed treatment schedule (treatment of the empty storage bin, treatment of the grain as it is entering the storage bin, and

treatment of the surface of the stored grain) was inadequate and recommended that additional samples be collected following multiple cycles of the proposed treatment schedule. The registrant's representative, JSC, in a conversation with J. Stokes of CBTS, proposed use of the following treatment schedule: treatment of the empty storage bin, treatment of the grain as it is entering the storage bin, and two treatments of the surface of the stored grain; samples would be collected after each of the surface treatments. This treatment schedule was approved by J. Stokes (letter from D. Allemang, JSC, to L. Rossi, SRRD, dated 1/14/94).

The qualitative nature of malathion residues in plants is adequately understood based on acceptable metabolism studies involving alfalfa, lettuce, cotton, and wheat. The residues of concern are malathion and malaoxon. The qualitative nature of the residue resulting from oral dosing of ruminants and poultry is adequately understood; neither malathion nor malaoxon was detected in any tissue. If the direct livestock treatment uses of malathion are removed from all product labels, the tolerances for residues of malathion in animal commodities can be revoked. However, if the direct livestock treatment uses of malathion are supported, then appropriate studies of dermal metabolism and magnitude of the residues in meat, milk, poultry, and egg are required.

Tolerances for residues in/on food/feed commodities are currently expressed in terms of malathion *per se* (*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 metabolite malaoxon are the compounds to be regulated in plant commodities. Codex MRLs exist for residues of malathion *per se* in/on various raw agricultural 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.

CONCLUSIONS

Magnitude of the Residue in Stored Grain

Field corn grain:

1a. The submitted data indicate that the combined residues of malathion and malaoxon in/on postharvest-treated field corn grain will not exceed the established 8-ppm tolerance (presently expressed as malathion *per se*). The combined residues of malathion and malaoxon were 6.62 and 6.96 ppm in/on two samples of stored field corn grain collected immediately after the last application in the following treatment schedule: (I) thorough spray application of the 5 lb/gal EC formulation to the inside surface of an empty storage bin at 20 lb ai/100 gal (1x the maximum registered rate for this application mode); (ii) application of the 6% D formulation to the surface of newly harvested corn grain during bin loading at 0.624 lb ai/1,000 bushels (1x); and (iii) two additional applications of the 6% D formulation to the grain surface immediately after

the bin was loaded and 60 days later at 0.312 lb ai/1,000 bushels/application (1x).

1b. The submitted aspirated grain fractions data for postharvest-treated corn are acceptable and indicate that the combined residues of malathion and malaoxon concentrated 98x.

1c. The submitted corn processing study is acceptable and may be used to fulfill reregistration requirements. The study indicates that the combined residues of malathion and malaoxon concentrated 1.8x in meal, 2.0x in flour, 4.5x in dry-milled crude oil, 5.8x in wet-milled crude oil, 1.3x in dry-milled refined oil, and 3.5x in wet-milled refined oil processed from field corn grain bearing detectable combined residues of malathion and malaoxon following a series of postharvest treatments according to the use pattern the registrant wishes to support. The combined residues did not concentrate in grits, starch and dry- and wet-milled bleached and deodorized oil.

Wheat grain:

2a. The submitted data indicate that the combined residues of malathion and malaoxon in/on postharvest-treated wheat grain will not exceed the established 8-ppm tolerance (presently expressed as malathion *per se*). The combined residues of malathion and malaoxon were 7.00 and 7.95 ppm in/on two samples of stored wheat grain collected immediately after last application in the following treatment schedule: (I) thorough spray application of the 5 lb/gal EC formulation to the inside surface of an empty storage bin at 20 lb ai/100 gal (1x the maximum registered rate for this application mode); (ii) application of the 6% D formulation to the surface of newly harvested wheat grain during bin loading at 0.624 lb ai/1,000 bushels (1x); and (iii) two additional applications of the 6% D formulation to the grain surface immediately after the bin was loaded and 60 days later at 0.312 lb ai/1,000 bushels/application (1x).

2b. The submitted aspirated grain fractions data for postharvest-treated wheat are acceptable and indicate that the combined residues of malathion and malaoxon concentrated 38x.

2c. The registrant must submit a study depicting the potential for concentration of residues of malathion and malaoxon in bran, flour, germ, middlings, and shorts processed from wheat grain treated postharvest with malathion. The data from this study will be translated to the processed commodities of stored barley, oat, and rye grain.

RECOMMENDATIONS:

1a. The submitted study indicates the need for tolerances for on processed commodities, corn meal and flour. According to the maximum concentration factors (1.8x and 2.0x) for corn grits and meal, and the average combined residues in corn grain (6.79 ppm), a tolerance of 14 ppm should be appropriate for corn meal and flour

1b. The submitted data from corn and wheat studies indicate the need for a tolerance on aspirated grain fractions. Based on the maximum concentration factor (98x) for aspirated corn grain fractions (≤2540μm) and the average combined residues in corn grain (6.79 ppm), a tolerance of 700 ppm should be appropriate for aspirated grain fractions.

1c. The product labels for the Cheminova 5 lb/gal EC (EPA Reg. No. 4787-20) and Platte 5 lb/gal EC (EPA Reg. No. 34704-108) and 6% D (EPA Reg. No. 34704-110) formulations must be amended to reflect the use patterns depicted in subject studies. The available data will support the following combined uses of D and EC formulations on stored grain: (I) surface spray treatment of the empty storage bin at 20 lb ai/100 gal; (ii) surface treatment of grain during bin loading at 0.624 lb ai/1,000 bushels; and (iii) two additional surface treatments immediately after the bin is loaded and 60 days thereafter at 0.312 lb ai/1,000 bushels/application.

DETAILED CONSIDERATIONS

Residue Analytical Methods

Samples of field corn commodities from the submitted study (MRID 43666801) were analyzed for residues of malathion and malaoxon by ABC Laboratories, Inc. (Columbia, MO) using a GC/FPD (flame photometric detection). The method entitled "Analytical Method for the Gas Chromatographic Determination of Malathion and Malaoxon Residues in/on Corn Grain and Processed Commodities." Samples of wheat grain and aspirated grain fractions from the submitted study (MRID 43661401) were analyzed for residues of malathion and malaoxon using a method entitled "Analytical Method for the Gas Chromatographic Determination of Malathion and Malaoxon Residues in/on Wheat Grain and Aspirated Grain Fractions." The limit of quantitation (LOQ) was 0.01 ppm for each compound for all tested commodities except wheat aspirated grain fractions for which the LOQ was 0.05 ppm for each compound.

Table 1. Method validation and concurrent method recoveries of GLC/FPD methods using various matrices fortified with malathion and malaoxon.

Raw Agricultural Commodity	Fortification Level (ppm)		Percent Recovery	
	Malathion	Malaoxon	Malathion	Malaoxon
Corn, field, grain	0.01	0.01	110, 130	100, 100
	1.00	1.00	103, 104	101, 104
	10.0	10.0	100	95
	100	--	118	<0.01 ppm
Corn, aspirated grain fraction	0.01	0.01	140	140
	10.0	10.0	105	104
	1500	100	108	100
Corn, meal	0.10	0.10	121	99
	20	20	105, 110	106, 107
Corn, flour	1.00	1.00	111, 114	112, 113
Corn, bleached oil (dry-milling)	0.01	0.01	100, 100	100, 110
	0.30	0.30	93	96
	100	100	102	102
Corn, starch	0.01	0.01	110	100
	20	20	103	102
Corn, crude oil (wet milling)	1.00	1.00	145	104
Wheat, grain	0.01	0.01	90, 100, 110	80, 100, 130
	0.05	0.05	100, 104	112, 114
	0.10	0.10	89, 89	92, 94
	20	20	104, 106	113, 114
	100	100	89	95
	500	500	90	95
Wheat, aspirated grain fraction	0.05	0.05	104, 118	132, 134
	20	20	90, 95	90, 90
	500	--	107	<1.00 ppm

Storage Stability Data

The storage intervals were 44 days for corn meal, 44 days for flour, and bleached and deodorized oil (wet and dry milled; 35 and 37 days). The maximum storage intervals prior to residue analysis of commodities collected from various trials and processing studies are presented in Table 2.

The storage stability data are not needed for processed corn and wheat and the aspirated grain fractions, because a study of residues of malathion and malaoxon in/on various raw and processed commodities (W. Smith, DP Barcode D213229) indicated that residues of malathion and malaoxon are relatively stable under frozen storage condition for at least 12 months in /on

cottonseed and cottonseed meal, hulls, and bleached and deodorized oils; wheat straw, bran, flour, middlings, and shorts; leaf lettuce; tomatoes and tomato catsup, juice, and dried pomace. The only significant declines in combined residues were observed in wheat grain and forage and potato tubers. And the storage stability data of processed wheat commodities can be translated to processed corn commodities and the aspirated grain fractions.

Table 2. Storage intervals prior to residue analysis of commodities collected from various trials and processing studies.

Commodity	MRID	Storage Conditions	Storage Interval (days)
Corn, field, grain Corn, aspirated grain fractions Corn, processed commodities	43666801	-30 to -1 C [a]	RAC: 44, 104 RAC to be processed: 23-31 Processed commodities: 18-44 [b] Total: 44-104
Wheat, grain Wheat, aspirated grain fractions	43661401	-30 to -1 C [a]	RAC: 74, 189 RAC to be processed: 68 Aspirated grain fractions: 13 Total: 74-189

[a] Temperatures of >-1 C were observed for a brief period (<30 minute) during sample transfer in the processing facility.

[b] Field corn aspirated grain fractions, grits, and dry- and wet-milled crude and refined oil samples were stored 18-27 days prior to analysis; corn meal, flour, and dry- and wet-milled bleached and deodorized oil samples were stored 35-44 days prior to analysis.

Magnitude of the Residue in Stored Grain

Field Corn Grain, Aspirated Grain Fractions, and Processed Commodities

Established tolerance: A tolerance of 8 ppm has been established for residues of malathion *per se* in/on corn grain [40 CFR §180.111]. No tolerance has been established for aspirated grain fractions or for any processed corn commodity.

Use patterns registered to Cheminova: A REFS search, conducted 6/28/95, identified one malathion end-use product, the 5 lb/gal EC formulation (EPA Reg. No. 4787-20, accepted 2/2/89, transferred from EPA Reg. No. 241-47), registered to Cheminova for use on stored grains (barley, corn, oats, rice, rye, sorghum, and wheat). The 5 lb/gal EC formulation is registered for the following postharvest applications: (i) residual spray of walls, floors, and machineries in grain elevators, truck beds, and box cars prior to grain storage at 20 lb ai/100 gal; (ii) spray treatment of grains going into storage at 0.625 lb ai in 2-5 gal of water/1,000 bushels; and (iii) surface treatment(s) to stored grains at 0.3125 lb ai in 1-2 gal of water/1,000 bushels; a repeat application may be made for surface treatment. A maximum number of applications during storage has not been specified.

Other registered use patterns: The submission contained specimen labels of Platte Chemical

Company 5 lb/gal EC (EPA Reg. No. 34704-108) and 6% D (EPA Reg. No. 34704-110) formulations. The 5 lb/gal EC formulation is registered for residual spray of walls, floors, and machineries in grain elevators, truck beds, and box cars prior to grain storage at 20 lb ai/100 gal. The 6% D formulation is registered for: (i) dust treatment of grains as grains are going into storage at 0.624 lb/1,000 bushels; and (ii) surface treatment(s) after grains are stored at 0.312 lb ai/1,000 bushels; a second surface treatment may be applied a month later, and subsequent treatments at 2-month intervals or as needed may be made. A maximum number of applications during storage has not been specified. The Platte 5 lb/gal EC and 6% D formulations were used as the test substances in the stored grain studies.

Discussion of the data: Cheminova submitted data (1995; MRID 43666801) from a study conducted in southeastern IA depicting the magnitude of the residue of malathion and its metabolite malaoxon in/on stored field corn grain and aspirated grain fractions and processed commodities collected from stored field corn grain.

Two grain bins, each with 5,000-bushel capacity (and each ~18 feet in diameter and 24 feet in height), were selected and designated as treated and untreated control bins. Using the Platte EC and D formulations, one of the bins was subjected to the following treatment schedule: (i) the 5 lb/gal EC formulation was thoroughly sprayed to the inside surface of an empty storage bin at 20 lb ai/100 gal (1x the maximum registered rate for this application mode); (ii) the 6% D formulation was applied to the surface of newly harvested corn grain during bin loading at 0.624 lb ai/1,000 bushels (1x); and (iii) two additional applications of the 6% D formulation were made to the surface of the grain immediately after the bin was loaded and 60 days later at 0.312 lb ai/1,000 bushels/application (1x). The number of treatments (4) as well as the sampling procedures are in compliance with the Agency-approved protocol.

Grain samples were collected from the treated and control bins immediately after the third and fourth treatments. A 5-lb grain sample was collected from each bin after the third treatment by using a 5-ft grain probe. To yield enough samples for the processing and aspirated grain fraction portions of the study, approximately 550 lbs of grain were collected from each bin after the fourth treatment; samples were collected from the top third of the grain using a shovel and then by auguring the grain from the bottom two-thirds of the bin. The collected grain samples (treated and untreated) were separately placed in labeled plastic-lined cloth bags and then boxed. Subsamples of the boxed grain samples collected following the fourth treatment were shipped via ACDS freezer truck to the Food Protein Research and Development Center of Texas A & M University where they were processed into aspirated grain fractions, dry-milled fractions, and wet-milled fractions.

Procedures for the preparation of aspirated grain fractions simulated commercial techniques. Briefly, corn grain was dried by forced air to 10-13% moisture, then circulated through a dust-generating apparatus consisting of a bucket elevator, two drag conveyors, and two holding bins for 120 minutes. During this interval, dust was collected at specific points by portable vacuum cleaners. The corn grains were then transferred to a holding bin, and all equipment and

surfaces were vacuumed. The light impurities from the vacuum cleaners were classified by screening through 2540-, 2030-, 1180-, 850-, and 425-μm mesh screens. Grain dust samples $\leq$2540 μm were composited. The registrant submitted material balance information and an adequate description of the preparation of aspirated corn grain fractions.

The dry-milling procedure began with the drying and cleaning of the field corn grain by aspiration and screening. The clean corn was moisture adjusted and milled to produce hull, grits, meal, flour, and germ. The germ was heat-conditioned and pressed in an expeller for the purpose of liberating the majority of the crude oil. The residual crude oil remaining in the solid material (presscake) exiting the expeller was later extracted with hexane. The solvent-extracted presscake was desolventized. The crude oil recovered from the expeller and solvent extraction was combined, sampled, and refined. The wet-milling procedure began with the drying and cleaning of the field corn grain by aspiration and screening. The cleaned corn was steeped in water and then milled to recover germ, hull, coarse gluten-starch, gluten, and starch. After drying, the germ was heat conditioned and the process continued as previously described for the dry-milling procedure for crude and refined oil.

Adequate raw data pertaining to application of the test substances and sample-handling procedures were provided. Residues in/on treated and untreated stored corn grain, aspirated corn grain fractions, dry-milled processed corn fractions, and wet-milled processed corn fractions were determined using an adequate GC/FPD method entitled "Analytical Method for the Gas Chromatographic Determination of Malathion and Malaoxon Residues in/on Corn Grain and Processed Commodities."

Stored corn grain: The results of the study pertaining to magnitude of the residue in stored corn grain are presented in Table 3. Apparent residues of malathion and its metabolite malaoxon were nondetectable (<0.01 ppm each) in/on two samples of untreated corn grain. The combined residue values for stored corn grain samples collected after the third treatment (75.5 and 80.5 ppm) were significantly higher than those samples collected after the fourth treatment (6.62 and 6.96 ppm). Although no explanation was provided, the sampling procedures may have contributed to these results. A smaller quantity (~5 lbs) of grain was collected after the third surface treatment and much of the samples were taken from the top of the grain bin. On the other hand, a larger quantity (~550 lbs) of grain was collected after the fourth treatment with samples taken from the top and bottom portions of the grain bin ensuring a greater possibility of grain mixing. In addition, grain samples collected after the third treatment reflected a storage interval of 0 days and therefore are not representative of real-life storage situations.

Table 3. Residues of malathion and its metabolite malaoxon in/on field corn grain collected immediately after the following postharvest treatment regime: (i) surface spray treatment of an empty storage bin using the 5 lb/gal EC formulation at 20 lb ai/100 gal (1x); (ii) surface treatment of corn grain during bin loading using the 6% D formulation at 0.624 lb ai/1,000 bushels (1x); and (iii) two additional treatments of the grain surface using the 6% D formulation immediately after the bin was loaded and 60 days thereafter at 0.312 lb ai/1,000 bushels/application (1x).

Field Corn Matrix	Residues of Malathion and Malaoxon (ppm) [a]		
	Malathion	Malaoxon	Combined
Grains sampled after third treatment	75.5, 80.5 (78.0)	0.019, 0.017 (0.018)	75.5, 80.5 (78.0)
Grains sampled after fourth treatment	6.60, 6.93 (6.77)	0.022, 0.026 (0.024)	6.62, 6.96 (6.79)

[a] Average residue values are listed in parentheses.

The submitted data indicate that the combined residues of malathion and malaoxon in/on postharvest-treated field corn grain will not exceed the established 8-ppm tolerance (presently expressed as malathion *per se*). The combined residues of malathion and malaoxon were 6.62 and 6.96 ppm in/on two samples of stored field corn grain collected immediately after the last application in the following treatment schedule: (i) thorough spray application of the 5 lb/gal EC formulation to the inside surface of an empty storage bin at 20 lb ai/100 gal (1x the maximum registered rate for this application mode); (ii) application of the 6% D formulation to the surface of newly harvested corn grain during bin loading at 0.624 lb ai/1,000 bushels (1x); and (iii) two additional applications of the 6% D formulation to the grain surface immediately after the bin was loaded and 60 days later at 0.312 lb ai/1,000 bushels/application (1x).

Provided that label revisions are made for the Cheminova 5 lb/gal EC (EPA Reg. No. 4787-20) and Platte 5 lb/gal EC (EPA Reg. No. 34704-108) and 6% D (EPA Reg. No. 34704-110) formulations to reflect the use patterns depicted in the subject study, no additional data on magnitude of the residue in stored field corn grain will be required for reregistration purposes. The available data will support the following combined uses of D and EC formulations on stored field corn grain: (i) surface spray treatment of the empty storage bin at 20 lb ai/100 gal; (ii) surface treatment of corn grain during bin loading at 0.624 lb ai/1,000 bushels; and (iii) two additional surface treatments immediately after the bin is loaded and 60 days thereafter at 0.312 lb ai/1,000 bushels/application.

Aspirated grain fractions of corn: The results of the study pertaining to magnitude of the residue in aspirated corn grain fractions are presented in Table 4. Apparent residues of malathion and its metabolite malaoxon were 0.34 ppm and 0.019 ppm, respectively, in/on one sample of untreated aspirated corn grain fraction ($\leq$2540 μm); another sample of untreated aspirated corn grain fraction ($>$2540 μm) bore malathion and malaoxon residues of 0.12 ppm and $<$0.01 ppm (nondetectable), respectively.

Table 4. Residues of malathion and its metabolite malaoxon in/on aspirated grain fractions collected from corn grain treated postharvest according to the treatment schedule described in Table 3.

Field Corn Matrix	Residues of Malathion and Malaoxon (ppm) [a]			Concentration/Reduction Factors [b]		
	Malathion	Malaoxon	Combined	Malathion	Malaoxon	Combined
Grain (RAC)	6.60, 6.93 (6.77) [a]	0.022, 0.026 (0.024)	6.62, 6.96 (6.79)	--	--	--
Aspirated grain fractions (>2540 μm)	1051, 1167 (1109)	14.9, 17.0 (16.0)	1066, 1184 (1125)	164	667	166
Aspirated grain fractions (≤2540 μm)	651, 670 (661)	7.34, 7.51 (7.43)	659, 678 (668)	98	310	98

[a] Average residues are listed in parentheses.
[b] Calculated by dividing average residues in/on aspirated grain fractions by the average residues in/on corn grain.

The submitted aspirated grain fractions data for postharvest-treated corn indicate that the combined residues of malathion and malaoxon concentrated 98x in aspirated corn grain fractions collected from field corn grain samples bearing detectable residues of malathion and malaoxon following a series of postharvest treatments at the maximum use pattern the registrant wishes to support.

Aspirated grain fractions data (MRID 43666801) for preharvest-treated field corn grain have been submitted and are currently under review (DP Barcode D215103). These data indicate that the combined residues of malathion and malaoxon concentrated at least 40x in the aspirated grain fractions collected from field corn grain bearing nondetectable residues of malathion and malaoxon following three foliar preharvest treatments at 5x the maximum single application rate.

Processed stored corn grain commodities: The results of the study portion pertaining to magnitude of the residue in processed stored corn grain commodities are presented in Table 5. Apparent residues of malathion and its metabolite malaoxon were nondetectable (<0.01 ppm each) in one sample of grits, three samples of dry-milled bleached oil, two samples of starch, and two samples of wet-milled bleached oil processed from untreated corn grain. Detectable apparent residues of malathion were observed in the following commodities processed from untreated grain: (i) three samples of meal (0.019-0.028 ppm); (ii) two samples of flour (0.054-0.055 ppm); (iii) one sample of dry-milled crude oil (0.37 ppm); (iv) one sample of dry-milled refined oil (0.14 ppm); and (v) one sample of wet-milled refined oil (0.31 ppm); apparent residues of malaoxon each were nondetectable (<0.01 ppm) in these fractions. In addition, two wet-milled crude oil samples processed from untreated corn grain bore detectable residues of malathion (0.38 and 0.36 ppm) and malaoxon (0.022 and 0.023 ppm). The registrant noted detectable residues of malathion in a reagent blank and determined that detectable residues in untreated samples may have resulted from laboratory contamination. However, after thoroughly cleaning all laboratory equipment, samples of untreated processed corn commodities that bore detectable residues were reanalyzed and results were found to be

the same, indicating that laboratory contamination was not the source of detectable residues in control samples.

Table 5. Residues of malathion and its metabolite malaoxon in/on corn fractions processed from corn grain treated postharvest according to the treatment schedule described in Table 3.

Field Corn Matrix	Residues of Malathion and Malaoxon (ppm) [a]			Concentration/Reduction Factors [b]		
	Malathion	Malaoxon	Combined	Malathion	Malaoxon	Combined
Grains (RAC)	6.60, 6.93 (6.77)	0.022, 0.026 (0.024)	6.62, 6.96 (6.79)	--	--	--
Grits	4.13, 5.17 (4.65)	0.040, 0.050 (0.045)	4.17, 5.22 (4.70)	0.7	1.9	0.7
Meal	11.5, 12.2, 12.3, 12.4 (12.1)	0.075, 0.087, 0.076, 0.080 (0.080)	11.6, 12.3, 12.4, 12.5 (12.2)	1.8	3.3	1.8
Flour	12.8, 13.7, 14.3, 14.4 (13.8)	0.099, 0.11, 0.12, 0.12 (0.112)	12.9, 13.8, 14.4, 14.5 (13.9)	2.0	4.7	2.0
Crude oil (dry milling)	30.3, 31.0 (30.7)	0.10, 0.10 (0.10)	30.4, 31.1 (30.8)	4.5	4.2	4.5
Refined oil (dry milling)	8.79, 9.47 (9.13)	<0.01, <0.01 (<0.01)	8.79, 9.47 (9.13)	1.3	<0.4	1.3
Bleached and deodorized oil (dry milling)	0.10, 0.10, 0.10, 0.11 (0.10)	<0.01, <0.01, <0.01, <0.01 (<0.01)	<0.11, <0.11, <0.11, <0.12 (<0.11)	0.01	<0.4	<0.02
Starch	0.014, 0.015 (0.015)	<0.01, <0.01 (<0.01)	<0.02, <0.03 (<0.02)	0.002	<0.4	<0.003
Crude oil (wet milling)	36.6, 42.6 (39.6)	0.094, 0.098 (0.096)	36.7, 42.7 (39.7)	5.8	4.0	5.8
Refined oil (wet milling)	23.1, 23.9 (23.5)	<0.01, <0.01 (<0.01)	23.1, 23.9 (23.5)	3.5	<0.4	3.5
Bleached and deodorized oil (wet milling)	0.15, 0.15, 0.15, 0.15 (0.15)	<0.01, <0.01, <0.01, <0.01 (<0.01)	<0.16, <0.16, <0.16, <0.16 (<0.16)	0.02	<0.4	<0.02

[a] Average residues are listed in parentheses. When calculating combined residues, nondetectable residues of malaoxon were not included in the total when residues of malathion were greater than 1.0 ppm.

[b] Calculated by dividing the average residues in the processed fraction by the average residues in/on corn grain.

The submitted corn processing study is acceptable and may be used to fulfill reregistration requirements. The study indicates that the combined residues of malathion and malaoxon concentrated 1.8x in meal, 2.0x in flour, 4.5x in dry-milled crude oil, 5.8x in wet-milled crude oil, 1.3x in dry-milled refined oil, and 3.5x in wet-milled refined oil processed from field corn grain bearing detectable combined residues of malathion and malaoxon following a series of postharvest treatments according to the use pattern the registrant wishes to support.

The combined residues did not concentrate in grits, starch and dry- and wet-milled bleached and deodorized oil.

Wheat Grain, Aspirated Grain Fractions, and Processed Commodities

Established tolerance: A tolerance of 8 ppm has been established for residues of malathion *per se* in/on wheat grain [40 CFR §180.111]. No tolerance for aspirated grain fractions or any processed wheat grain commodity has been established.

Registered use patterns: The Cheminova-registered uses of malathion on stored wheat grain are identical to those for stored corn grain. In addition, the submission contained specimen labels for Platte Chemical Company 5 lb/gal EC (EPA Reg. No. 34704-108) and 6% D (EPA Reg. No. 34704-110) formulations. Refer to the "Field Corn Grain, Aspirated Grain Fractions, and Processed Commodities" section for descriptions of use patterns.

Discussion of the data: Cheminova submitted data (1995; MRID 43661401) from a study conducted in IL depicting the magnitude of the residue of malathion and its metabolite malaoxon in/on stored wheat grain and aspirated grain fractions. The wheat grain samples used in the study were not treated with malathion or any organophosphates during the field-growing season and represented a mixture of wheat varieties grown according to the typical agricultural practices of the area.

The identical procedures described under the "Field Corn Grain, Aspirated Grain Fractions, and Processed Commodities" section were followed for treatment of stored wheat grain. The sampling procedures as well as the procedures for collection of aspirated grain fractions were similar to those previously described.

Residues in/on treated and untreated stored wheat grain and aspirated grain fractions were determined using an adequate GC/FPD method entitled "Analytical Method for the Gas Chromatographic Determination of Malathion and Malaoxon Residues in/on Wheat Grain and Aspirated Grain Fractions."

Stored wheat grain: The results of the study pertaining to magnitude of the residue in stored wheat grain are presented in Table 6. Apparent residues of malathion and its metabolite malaoxon were nondetectable (<0.01 ppm each) in/on three samples of untreated wheat grain. The combined residue values for stored wheat grain samples collected after the third treatment (47.3 and 49.6 ppm) were significantly higher than those samples collected after the fourth treatment (7.00 and 7.95 ppm). As discussed in the "Field Corn Grain, Aspirated Grain Fractions, and Processed Commodities" section, samples collected after the fourth treatment are considered to be representative of real-life storage situations.

Table 6. Residues of malathion and its metabolite malaoxon in/on wheat grain collected immediately after the following postharvest treatment regime: (i) surface spray treatment of an empty storage bin using the 5

lb/gal EC formulation at 20 lb ai/100 gal (1x); (ii) surface treatment of wheat grain during bin loading using the 6% D formulation at 0.624 lb ai/1,000 bushels (1x); and (iii) two additional treatments of the grain surface using the 6% D formulation immediately after the bin was loaded and 60 days thereafter at 0.312 lb ai/1,000 bushels/application (1x).

Wheat Matrix	Residues of Malathion and Malaoxon (ppm) [a]		
	Malathion	Malaoxon	Combined
Grains sampled after third treatment	47.3, 49.6 (48.5)	<0.01, <0.01 (<0.01)	47.3, 49.6 (48.5)
Grains sampled after fourth treatment	7.00, 7.95 (7.48)	<0.01, <0.01 (<0.01)	7.00, 7.95 (7.48)

[a] Average residue values are listed in parentheses.

The submitted data indicate that the combined residues of malathion and malaoxon in/on postharvest-treated wheat grain will not exceed the established 8-ppm tolerance (presently expressed as malathion *per se*). The combined residues of malathion and malaoxon were 7.00 and 7.95 ppm in/on two samples of stored wheat grain collected immediately after last application in the following treatment schedule: (i) thorough spray application of the 5 lb/gal EC formulation to the inside surface of an empty storage bin at 20 lb ai/100 gal (1x the maximum registered rate for this application mode); (ii) application of the 6% D formulation to the surface of newly harvested wheat grain during bin loading at 0.624 lb ai/1,000 bushels (1x); and (iii) two additional applications of the 6% D formulation to the grain surface immediately after the bin was loaded and 60 days later at 0.312 lb ai/1,000 bushels/application (1x).

Provided that label revisions are made for the Cheminova 5 lb/gal EC (EPA Reg. No. 4787-20) and Platte 5 lb/gal EC (EPA Reg. No. 34704-108) and 6% D (EPA Reg. No. 34704-110) formulations to reflect the use patterns depicted in the subject study, no additional data on magnitude of the residues in stored wheat grain will be required for reregistration purposes. The available data will support the following combined uses of D and EC formulations on stored wheat grain: (i) surface spray treatment of the empty storage bin at 20 lb ai/100 gal; (ii) surface treatment of wheat grain during bin loading at 0.624 lb ai/1,000 bushels; and (iii) two additional surface treatments immediately after the bin is loaded and 60 days thereafter at 0.312 lb ai/1,000 bushels/application.

Aspirated grain fractions of wheat: The results of the study pertaining to magnitude of the residue in aspirated wheat grain fractions are presented in Table 7. Apparent residues of malathion and its metabolite malaoxon were below the limit of quantitation (<0.05 ppm each) in/on two samples of untreated aspirated wheat grain fractions (≤2540 μm); another sample of untreated aspirated wheat grain fraction (>2540 μm) bore malathion and malaoxon residues of 0.07 ppm and <0.05 ppm (nondetectable), respectively.

Table 7. Residues of malathion and its metabolite malaoxon in/on aspirated grain fractions collected from wheat grain treated postharvest according to the treatment schedule described in Table 6.

Wheat Matrix	Residues of Malathion and Malaoxon (ppm) [a]			Concentration/Reduction Factors [b]		
	Malathion	Malaoxon	Combined	Malathion	Malaoxon	Combined
Grain (RAC)	7.00, 7.95 (7.48) [a]	<0.01, <0.01 (<0.01)	7.00, 7.95 (7.48)	--	--	--
Aspirated grain fractions (>2540 μm)	10.0, 10.5 (10.3)	<0.05, <0.05 (<0.05)	10.0, 10.5 (10.3)	1.4	--	1.4
Aspirated grain fractions (≤2540 μm)	281, 283 (282)	0.50, 0.56 (0.53)	282, 284 (283)	37.7	53	37.8

[a] Average residues are listed in parentheses.
[b] Calculated by dividing average residues in/on aspirated grain fractions by the average residues in/on wheat grain.

The submitted aspirated grain fractions data for postharvest-treated wheat indicate that the combined residues of malathion and malaoxon concentrated 38x in aspirated grain fractions collected from wheat grain samples bearing detectable residues of malathion and malaoxon following a series of postharvest treatments at the maximum use pattern the registrant wishes to support.

Processed wheat fractions: The Malathion Reregistration Standard Guidance Document required the registrant to propose appropriate tolerances for malathion residues in bran, flour, middlings, and shorts based on a stored wheat grain processing data (MRID 00058826) for which **maximum** concentration factors of 57x, 8x, 10x, and 46x, respectively, were observed. HED now concludes that these data are inadequate because it seems unlikely that residues of malathion would concentrate in <u>every</u> processed fraction and because the potential for concentration of malaoxon residues was not investigated. The registrant must submit a study depicting the potential for concentration of residues of malathion and malaoxon in bran, flour, germ, middlings, and shorts processed from wheat grain treated postharvest with malathion according to the same treatment schedule that was used in the submitted field corn and wheat grain studies. The data from this study will be translated to the processed commodities of stored barley, oat, and rye grain.

<u>EPA MEMORANDA CITED IN THIS REVIEW</u>

DP Barcode: None
Subject: September 6, 1991 Conference with Malathion Reregistration Coalition Representatives to Discuss Reregistration Data Requirements for Malathion.
From: P. Deschamp
To: Chemistry Branch Files

Dated:	9/25/91
MRID(s):	None assigned.
DP Barcode:	D187727
Subject:	Malathion: Protocol for Stored Grain and Grain Dust Residue Studies and Corn Processing Study.
From:	D. McNeilly
To:	P. Perreault
Dated:	4/15/93
MRID(s):	None assigned.
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(s):	42894601
DP Barcode:	D208047, D210189, D210843, and D210294
Subject:	Response to the Malathion Reregistration Standard: Magnitude of the Residue Studies. Case No. 0248, Chemical I. D. No. 057701.
From:	D. Hrdy
To:	L. Schnaubelt/S. Jennings
Dated:	4/27/95
MRID(s):	43360401, 43372701, 43376801, 43372901, 43370601, 43360001, 43368301, 43362501, 43367201, 43361101, 43468201, 43479601, and 43499901.
DP Barcode:	D208772, D208242, D208233, D209529, and D210188
Subject:	Malathion: Registrant's Response to the Residue Chemistry Data Requirements: Magnitude of the Residue in Avocados, Beans, Blueberries, Grapes, Grasses, Onions, Rice, Wheat, and Orange Processed Commodities.
From:	[Currently under review]
To:	[Currently under review]
Dated:	[Currently under review]
MRID(s):	43350401, 43350402, 43362601, 43372601, 43383301, 43383401, 43383501, 43414901, 43417601, 43451701, and 43468101
DP Barcode:	D211260
Subject:	[Magnitude of the Residue in Wheat Processed Commodities.]
From:	[Currently under review]
To:	[Currently under review]

Dated:	[Currently under review]
MRID(s):	43510501
DP Barcode:	D213105 and D213929
Subject:	[Magnitude of the Residue in/on Alfalfa Forage and Hay, Clover Forage and Hay, Cottonseed, Field Corn Processed Commodities, Cottonseed Processed Commodities, Grape Processed Commodities, and Rice Processed Commodities.]
From:	[Currently under review]
To:	[Currently under review]
Dated:	[Currently under review]
MRID(s):	43546101, 43545201, 43596601, 43577401, 43585301, 43548401, and 43562301.

MASTER RECORD IDENTIFICATION NUMBERS

The citations for the MRID documents referred to in this review are presented below.

43661401 Rice, F.; Williams, B. (1995) Magnitude of the Malathion and Malaoxon Residues in or on Stored Wheat Grain and Aspirated Grain Fractions: Lab Project Numbers: 41701: FS-41701.SG: ABC 41701. Unpublished study prepared by ABC Labs., Inc. 521 p.

43666801 Rice, F. (1995) Magnitude of the Malathion and Malaoxon Residues in or on Stored Corn Grain and Processed Commodities: Final Report: Lab Project Number: 41702: FS-41702. Unpublished study prepared by ABC Labs Inc. 752 p.