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

July 13, 1998

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Malathion: PC Code 057701, Case 0248. Magnitude of Residue of Malathion and malaoxon in/on Winter Wheat Grain and its Processed Commodities. (OPPTS 860.1520), MRID No. 43510501, DPBarcode D211260.

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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 the magnitude of residues of malathion and malaoxon in/on winter grain and its processed commodities following pre-harvest treatment at an exaggerated rate (5x). Malathion has been used for pre- and post-harvest treatments on wheat grains. The submitted data included the magnitude of malathion and malaoxon residues in/on the following commodities: wheat grain, aspirated grain fractions, bran, middling, shorts and patent flour.

The review was prepared by Dynamac Corporation under contract to the HED. The adequacy in fulfilling residue chemistry data requirements (OPPTS 860.1520) was evaluated for malathion reregistration. This information has undergone secondary review in HED and has been revised to reflect Agency policy.

The data for aspirated grain fractions indicate that residues concentrate 36x in aspirated grain fractions ($\geq$2540 μm) and 56x in aspirated grain fractions($<$2540 μm). The concentration/reduction factors of malathion and malaoxon for processed commodities were $<$0.4x for bran and shorts, $<$0.2x for patent flour and 2.2x for middlings.

A tolerance of 8 ppm has been established for residues of malathion in/on wheat grain from both pre-harvest and post-harvest. No tolerances have been established for residues of

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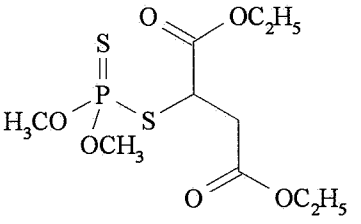
malathion in/on processed wheat commodities. The need for tolerances for the combined residues of malathion and malaoxon in processed wheat commodities will be determined on receipt of an adequate processing study based on post-harvest treatments. We have previously recommended for establishment of a tolerance of 700 ppm on aspirated grain fractions (M. Xue, D216397). The results of the present study do not change that recommendation.

Attachment: Dynamac review of Registrant's Response to Residue Chemistry Data Requirements (DP Barcode D211260).

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

RDI: ResChemTeam: 07/09/98 :FBSuhre 07/09/98
7509C: CEBI: Mxue :CM-2: RM 718: 703 305-6198: 07/13/98

MALATHION



PC No. 057701; Case 0248

(CBRS No. 15031; DP Barcode D211260)

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., submitted field residue data for wheat processed commodities (1995; MRID 43510501). Data from this submission is evaluated herein for adequacy in fulfilling residue chemistry data requirements for the reregistration of malathion. The Conclusions and Recommendations stated below pertain only to the above submission. 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 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 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 *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 AND RECOMMENDATIONS

1. The submitted residue data for wheat processed commodities from pre-harvest treatment (MRID 43510501) do not fulfill the requirements of OPPTS 860.1520, because residue data for wheat germ were not provided. However, this study was conducted before processing data were required for wheat germ. Also, an additional wheat processing study is being required on grain that has been treated post-harvest. For these reasons, we consider that this present study is adequate.

2. The residue data of wheat processed commodities were obtained from pre-harvest treatment at the application rate of 6.25 lb ai/A (5x) using 5 lb/gal EC formulation, following three foliar applications, with 6- to 8-day retreatment intervals, and a PHI of 7 days. The combined residues of malathion and malaoxon were 1.52 ppm for wheat grain, 55.26 ppm for aspirated grain fractions ($\geq$2540μm) and 85.7 ppm for aspirated grain fractions ($<$2540μm). The combined residues of malathion and malaoxon for processed wheat commodities were $<$0.62 ppm for bran, 3.33 ppm for middlings, $<$0.60 ppm for shorts and $<$0.36 ppm for patent flour.

3. The wheat grain dust data from the current submission indicate that residues concentrate 56x in aspirated grain fractions ($<$2540 μm). A tolerance (700 ppm) has been recommended for aspirated grain fractions from the magnitude of residue study of post-harvest treated stored grain and processed commodities (M. Xue, D216397). The results of the present study do not change that recommendation.

4. The concentration/reduction factors of malathion and malaoxon for processed commodities were <0.4x for bran and shorts, <0.2x for patent flour and 2.2x for middlings. The need for a tolerance for the combined residues of malathion and malaoxon in processed wheat commodities will be determined when adequate data on processed wheat commodities from post-harvest treated grain have been submitted to the Agency.

DETAILED CONSIDERATIONS

Residue Analytical Methods

Samples of wheat grain and wheat processed commodities from the submitted processing study were analyzed for residues of malathion and its malaoxon metabolite using a GLC method with flame photometric detection (EN-CAS Method No. 27/94). The limit of quantitation (LOQ) for each compound was 0.01 ppm, except for aspirated grain fractions where the LOQ was 0.05 ppm for each compound. This method uses a DB-5 column and flame photometric detection (FPD) in the phosphorous mode, and is essentially identical to the American Cyanamid Method M-1886 which has been recently proposed for enforcement purposes.

Method validation and concurrent method recoveries were conducted by EN-CAS Analytical Laboratories, Inc. (Winston-Salem, NC) to determine the suitability of the EN-CAS methods for residue data collection purposes. Untreated samples of wheat grain and wheat processed fractions from the respective processing study were fortified with malathion and malaoxon at various levels. No detectable residues of malathion or malaoxon were found (<0.01 ppm or <0.05 ppm) in/on all untreated samples of wheat grain and processed fractions, except that in one untreated sample, detectable malathion residues of patent flour were 0.01 ppm. Representative chromatograms, sample calculations, and standard curves were provided. The recovery data are presented in Table 1. The EN-CAS method is adequate for malathion and malaoxon data collection for wheat grain and wheat processed commodities.

Table 1. Concurrent method recoveries of malathion and malaoxon from fortified wheat grain and processed wheat commodities analyzed using EN-CAS Method No. ENC-27/94.

Commodity	Fortification Level (ppm)		Percent Recovery	
	Malathion	Malaoxon	Malathion	Malaoxon
Wheat grain	0.01	0.01	81	123
	2.0	0.10	96	106
Grain dust (>2540 μm)	0.05	0.05	96	120
	200	5.0	101	76
Grain dust (≤2540 μm)	0.05	0.05	103	123
	200	5.0	97	102
Bran	0.01	0.01	107	123
	0.50	0.05	93	115
Middlings	0.01	0.01	108	122
	5.0	0.05	96	111
Shorts	0.01	0.01	88	105
	5.0	0.05	100	106
Patent flour	0.01	0.01	106	124
	5.0	0.05	89	110

Storage Stability Data

Wheat grain samples were stored frozen (<0 C) for 3 days following harvest, and shipped by freezer truck (<-7 C) to the Engineering Biosciences Research Center (Texas A&M University, Bryan, TX) for processing. The grain samples were stored frozen (-23 to -5 C) before processing. The processed fractions were shipped frozen (<-7 C) to the analytical laboratory (EN-CAS Laboratory, Winston-Salem, NC). At the analytical laboratory, samples were stored frozen (-27 to -12 C) prior to analysis. The intervals between harvest and residue analysis were 475-477 days (~16 months) for wheat grain and 308-338 days (~10-11 months) for wheat processed commodities.

There are 12 month storage stability study available for wheat, bran, flour, middlings and shorts (W. Smith, 09/23/97, D223392). There are no 16 month data depicting the frozen storage stability of malathion and its metabolite malaoxon in/on wheat grain. However, tolerance decisions on wheat grain will be made from other post-harvest treatment studies. If any instability occurred in storage of grain samples in the present study, the result would be an

over estimate of concentration factors. Therefore, no further storage stability data will be required in support of the present study.

Magnitude of the Residue in Processed Commodities

Wheat 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 tolerances have been established for residues of malathion in any wheat processed commodities.

Use patterns on wheat: Malathion is registered for both pre- and post-harvest uses on wheat. The present submission is based on pre-harvest application of 5 lb/gal EC formulation registered to Platte Chemical Company (EPA Reg. No. 34704 -108). Three applications were made to the crop at rate of 6.25 lb/A (5x), with 6- to 8- day retreatment intervals and a PHI of 7 days.

Discussion of the data: Cheminova submitted data (1995; MRID 43510501) pertaining to the potential for concentration of residues of malathion and its malaoxon metabolite in the processed commodities of wheat.

Wheat grain was processed according to simulated commercial procedures. Briefly, after collecting grain subsamples, the remaining grain was dried to ≤12% moisture and cleaned by aspiration and screening through 13/64- and 6/64-inch screens. The light impurities were collected by aspiration and sieved into six grain dust fractions based on particle size; the six fractions were then combined into two fractions, <2540 μm and >2540 μm. Cleaned grain was moisture adjusted, broken into small pieces in fine roller mills, and sieved to separate the bran and middlings. Then the middlings were reduced to flour in a smooth roller mill and sieved into shorts (>240 μm), low grade flour (≥132 μm), and patent flour (<132 μm). The registrant submitted adequate descriptions and material balance sheets for the processing procedures.

Table 2. Residues of malathion and malaoxon in wheat commodities processed from wheat grain treated with three foliar applications, with 6- to 8-day retreatment intervals, of the 5 lb/gal EC formulation at 6.25 lb ai/A/application (5x).

Wheat Grain Commodity	Residues (ppm) [a]			Concentration/Reduction Factors [b]		
	Malathion	Malaoxon	Combined	Malathion	Malaoxon	Combined

Wheat grain	(1.3, 1.3), (1.6, 1.8) [1.5]	(0.01, 0.02), (0.01, 0.02) [0.02]	(1.31, 1.32), (1.61, 1.82) [1.52]	--	--	--
Grain dust (≥2540 μm)	(53, 56) [54.5]	(0.71, 0.80) [0.76]	(53.71, 56.80) [55.26]	36	38	36
Grain dust (<2540 μm)	(83, 86) [84.5]	(1.2, 1.2) [1.2)]	(84.2, 87.2) [85.7]	56	60	56
Bran	(0.52, 0.69) [0.61]	(<0.01, <0.01) [<0.01]	(<0.53, <0.70) [<0.62]	0.4	<0.5	<0.4
Middlings	(3.3, 3.3) [3.3]	(0.03, 0.03) [0.03]	(3.33, 3.33) [3.33]	2.2	1.5	2.2
Shorts	(0.58, 0.60) [0.59]	(<0.01, <0.01) [<0.01]	(<0.59, <0.61) [<0.60]	0.4	<0.5	<0.4
Patent Flour	(0.34, 0.35) [0.35]	(<0.01, <0.01) [<0.01]	(<0.35, <0.36) [<0.36]	0.2	<0.5	<0.2

[a] Residue values in parentheses represent multiple analyses of a single sample; average residue values are listed in brackets.

[b] Calculated by dividing average residues found in the processed fraction by the average residues found in wheat grain.

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MASTER RECORD IDENTIFICATION NUMBERS

The citation for the MRID document referred to in this review is presented below.

43510501 Bookbinder, M. (1995) Magnitude of the Residue of Malathion and Its Metabolite Malaoxon in/on Winter Wheat Processed Commodities: Lab Project Number: 92-0080: AA920136: EL6110. Unpublished study prepared by American Agricultural Services,Inc.; EN-CAS Analytical Labs; and Texas A&M University. 425 p.