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

September 30, 1997

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Malathion.Reregistration; Chem No. 057701; Case No. 0248; Magnitude of the Residue in Processed Commodities of Potatoes; GLN 860.1520; Cheminova Agro A/S; MRID 43524101. DP Barcode D2121115.

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TO: Larry Schnaubelt / Susan Jennings
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Special Review and Reregistration Division (7508W)

Attached please find a review of data depicting the magnitude of the residues of malathion and malaoxon on potatoes and processed commodities of potatoes following treatment at 5x the proposed maximum use rate. The submission was reviewed by Dynamac Corporation under the supervision of HED. This information has undergone secondary review in CEB-1 and is consistent with Agency policies.

The data are acceptable and confirm that no malathion tolerances are required for processed commodities of potatoes. The established tolerance of 8 ppm for residues in or on potatoes will be reassessed at the time of the Malathion RED.

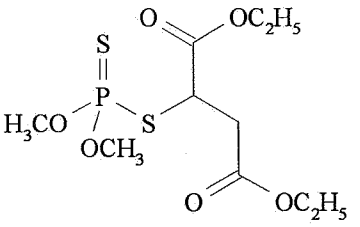
Attachment - Dynamac review of Registrant's Response to Residue Chemistry Data Requirements (CB 15123; D212115)

cc: W. Smith (CEB-I), SF, Reg Std File, RF

7509C:CEB-I:WOS:wos:Rm805A:CM2:305-5353:09/24/97
RDI: ResChemTeam (09/25/97) FSuhre (09/26/97).

(1)

MALATHION



Shaughnessy No. 057701; Case 0248

(CBRS No. 15123; DP Barcode D212115)

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 residue data for potato processed commodities (1995; MRID 43524101). Data from this submission are 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.

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.

CONCLUSIONS AND RECOMMENDATIONS

1. The submitted potato processing study (MRID 43524101) is adequate and fulfills the reregistration requirements for magnitude of the residue in potato processed commodities.

2. The combined residues of malathion and malaoxon were nondetectable (<0.02 ppm) in/on whole potatoes harvested 3 hours following the last of two foliar applications, with a 7-day retreatment interval, of the 5 lb/gal EC formulation at 7.7 lb ai/A/application (5x the

maximum seasonal rate the registrant wishes to support for potatoes), and were nondetectable in potato chips (<0.02 ppm), granules (<0.02 ppm), and wet peel (<0.10 ppm) processed from these potatoes. No food/feed additive tolerances for malathion residues of concern in the processed commodities of potatoes are required.

DETAILED CONSIDERATIONS

Residue Analytical Methods

Samples of potato and potato 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. 29/94). The limit of quantitation (LOQ) for each compound was 0.01 ppm, except for wet and dry peel for which 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.

Adequate method descriptions as well as acceptable radiovalidation data using samples from an alfalfa metabolism study have been submitted and evaluated (CBRS No. 12855, DP Barcode D196878, R. Perfetti, 2/28/94) for the American Cyanamid Method M-1886.

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 method for residue data collection purposes. Untreated samples of potatoes and potato processed fractions from the submitted processing study were fortified with malathion and malaoxon at various levels. Apparent residues of malathion and malaoxon each were nondetectable (<0.01 ppm or <0.05 ppm) in/on all untreated samples of potato and processed fractions. Representative chromatograms, sample calculations, and standard curves were provided. The recovery data are presented in Tables 1A and 1B. These data suggest that the EN-CAS method is adequate for malathion and malaoxon data collection for potatoes and potato processed commodities.

Table 1A. Method validation of EN-CAS Method No. ENC-29/94 using potatoes and processed potato commodities fortified with malathion and malaoxon.

Commodity	Fortification Level (ppm)	Analyte Fortified	Percent Recovery	
			Malathion	Malaoxon
Potato	0.01	Both analytes	83, 87, 92	80, 91, 92
	0.05	Both analytes	91, 92, 96	85, 88, 90
	0.50	Both analytes	79, 81, 93	84, 85, 89
	0.50	Malathion only	76	<0.01 ppm
	0.50	Malaoxon only	<0.01 ppm	82
Chips	0.01	Both analytes	70, 74	73, 100
	0.05	Both analytes	80, 90	99, 102
	0.50	Both analytes	91, 93	97, 101
	0.50	Malathion only	79	<0.01 ppm
	0.50	Malaoxon only	<0.01 ppm	91
Granules	0.01	Both analytes	109, 113	120, 123
	0.05	Both analytes	86, 92	97, 100
	0.50	Both analytes	92, 96	95, 97
	0.50	Malathion only	91	<0.01 ppm
	0.50	Malaoxon only	<0.01 ppm	97

Table 1B. Concurrent method recoveries of malathion and malaoxon from fortified potatoes and processed potato commodities analyzed using EN-CAS Method No. ENC-29/94.

Commodity	Fortification Level (ppm)		Percent Recovery	
	Malathion	Malaoxon	Malathion	Malaoxon
Potato	0.01	0.01	84	96
	5.0	0.25	86	89
Chips	0.01	0.01	71, 96	99, 110
	10	1.0	76, 91	98, 99
Granules	0.01	0.01	83	106
	10	1.0	93	104
Wet peel	0.05	0.05	93	102
	5.0	0.50	110	102
Dry peel	0.05	0.05	95	98
	10	1.0	64	93

Storage Stability Data

Potatoes were delivered to the processing facility (Wm. J. Englar and Associates, Inc., Moses Lake, WA) within 2 hours of collection and were stored at 2-8 C for 29 days prior to processing. Following processing, samples were stored frozen (-26 to -9 C) for up to 10 days prior to shipment by freezer truck (<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 total storage intervals between harvest and residue analysis were 187 days (~6 months) for potatoes and 423-448 days (~14-15 months) for potato processed commodities.

According to the Residue Chemistry Science Chapter of the Malathion Reregistration Standard Guidance Document, dated 7/31/87, residues of malathion *per se* are stable in/on frozen plant commodities for up to 6.2 months. In response to the Malathion Reregistration Standard Guidance Document Cheminova Agro A/S conducted a study investigating the storage stability of malathion and malaoxon residues in/on various raw agricultural and processed commodities. The results of the storage stability study (see reviews by D. Miller, D213229 and D219313, 11/7/95; K. Dockter, D217170, 9/2/97; and W. Smith, D223392, 9/23/97) indicated that residues of malathion and malaoxon are relatively stable under frozen storage conditions (-5 C) for at least 12 months in/on various raw agricultural and processed commodities. Residues on potatoes were stable for 6 months but a decline of ~30-35% was noted for residues at 12 months. These results have been taken into consideration in evaluating the present study and it is concluded that any decline that may have occured in storage of samples would not change the conclusions drawn concerning the need for tolerances on processed commodities. In the case of the raw agricultural commodity, samples were stored for only 6 months; therefore, it is assumed that no decline occurred.

Magnitude of the Residue in Processed Commodities

Potato Processed Commodities

Established tolerance: A tolerance of 8 ppm has been established for residues of malathion *per se* in/on potatoes [40 CFR §180.111]. No tolerances for malathion residues of concern have been established for any processed commodities of potatoes.

Use patterns registered to Cheminova: A REFS search, conducted 1/23/95, identified one Cheminova malathion end-use product, a 57% or 5 lb/gal EC formulation (EPA Reg. No. 4787-20, accepted 2/2/89, transferred from EPA Reg. No. 241-47) registered for use on potatoes. This formulation is registered for multiple foliar applications to potatoes at 0.94-1.56 lb ai/A/application in a minimum of 30 gal of water/A using ground equipment or in 5 gal of water/A using aerial equipment. A 0-day PHI is in effect. A maximum seasonal rate or maximum number of applications per growing season has not been established.

Other registered use patterns: The submission contained a specimen label for a 57% or 5 lb/gal EC formulation registered to Platte Chemical Company, Inc. (EPA Reg. No. 34704-108). The 5 lb/gal EC formulation is registered for multiple foliar applications to potatoes at 0.63-0.94 lb ai/A/application in a minimum of 10 gal of water/A using ground equipment or in 2 gal of water/A using aerial equipment. A 0-day PHI is established. This formulation was used as the test substance in the potato processing study.

Discussion of the data: Cheminova submitted data (1995; MRID 43524101) pertaining to the potential for concentration of residues of malathion and its malaoxon metabolite in the processed commodities of potatoes. In one test conducted in WA, mature potatoes were harvested within 3 hours of the last of two foliar applications to established potato plants, with a 7-day retreatment interval, of the Platte 5 lb/gal EC formulation at 7.7 lb ai/A/application (5x the maximum registered single application rate for the Cheminova EC formulation) in 29 gal/A using ATV sprayers. The registrant has stated previously (MRID 43360401; See review by D. Hrdy, D208047, 5/9/95) that they wish to support the following use pattern for potatoes: up to two foliar applications per growing season at 1.56 lb ai/A/application, with a 7-day retreatment interval and a 0-day PHI.

The harvested potato samples were boxed and shipped to the processing facility (Wm. J. Englar and Associates, Inc., Moses Lake, WA) within 2 hours of collection. Potato samples were stored at 2-8 C for 29 days prior to processing.

Potatoes were processed according to commercial procedures. Briefly, potatoes were washed with water. A subsample of washed potatoes was peeled, hand trimmed to remove damaged areas, sliced, fried in oil at 160-177 C, drained, and salted for **potato chips**. The remaining washed potatoes were steam peeled, mechanically scrubbed to remove the peel, and hand trimmed to remove damaged areas. The peel was hydraulically pressed and combined with the cut trim waste as the **wet peel** fraction. A wet peel subsample was air-dried and milled for the **dry peel** fraction. A subsample of peeled potatoes was sliced, spray-washed with water to remove starch, pre-cooked at 68-74 C, and cooled to <32 C. The cooled sample was mashed, mixed with food additives, and frozen until further processing. Once thawed, a subsample of the mash was dried in a fluid-bed drier to 10% moisture, more mash was added and the drying procedure repeated until ~8 kg of mash sample was dried. The dried mash was combined with 20% solids mash, dried again at 80-94 C, sifted through mesh screens, and cooled to 8-10% moisture for the **potato granule** fraction. The registrant submitted adequate descriptions and material balance sheets for the processing procedures.

The processed potato fractions were stored frozen (-26 to -9 C) at the processing facility for up to 10 days prior to shipment by freezer truck (<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 187 days (~6 months) for potatoes and 423-448 days (~14-15 months) for potato processed commodities. Residues in/on treated and untreated potato and potato processed commodities were determined

using EN-CAS Method No. 29/94. The results of the potato processing study are presented in Table 2. Apparent residues of malathion and malaoxon were nondetectable (<0.01 ppm each) in/on one sample each of untreated potatoes, and potato chips and granules processed from untreated potatoes. Apparent residues of malathion and malaoxon were nondetectable (<0.05 ppm each) in/on one sample each of wet and dry peel processed from untreated potatoes.

Table 2. Residues of malathion and malaoxon in potato commodities processed from potatoes treated with two foliar applications, with a 7-day retreatment interval, of the 5 lb/gal EC formulation at 7.80 lb ai/A/application (5x).

Potato Commodity	Residues (ppm) [a]			Concentration/Reduction Factors [b]		
	Malathion	Malaoxon	Combined	Malathion	Malaoxon	Combined
Whole potato	<0.01, <0.01 [<0.01]	<0.01, <0.01 [<0.01]	<0.02, <0.02 [<0.02]	--	--	--
Chips	(<0.01, <0.01, <0.01) (<0.01, <0.01, 0.01) [<0.01]	(<0.01, <0.01, <0.01) (<0.01, <0.01, <0.01) [<0.01]	(<0.02, <0.02, <0.02) (<0.02, <0.02, <0.02) [<0.02]	--	--	--
Granules	<0.01, <0.01 [<0.01]	<0.01, <0.01 [<0.01]	<0.02, <0.02 [<0.02]	--	--	--
Wet Peel	<0.05, <0.05 [<0.05]	<0.05, <0.05 [<0.05]	(<0.10, <0.10) [<0.10]	--	--	--
Dry Peel	0.05, 0.06 [0.06]	<0.05, <0.05 [<0.05]	<0.10, <0.11 [<0.11)	>6	--	6

[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 potatoes.

The submitted potato processing study (MRID 43524101) is adequate to satisfy reregistration requirements for magnitude of the residue in potato processed commodities. The combined residues of malathion and malaoxon were nondetectable (<0.02 ppm) in/on whole potatoes harvested 3 hours following the last of two foliar applications, with a 7-day retreatment interval, of the 5 lb/gal EC formulation at 7.7 lb ai/A/application (5x the maximum seasonal rate the registrant wishes to support for potatoes), and were nondetectable in potato chips (<0.02 ppm), granules (<0.02 ppm), and wet peel (<0.10 ppm) processed from these potatoes. No food/feed additive tolerances for malathion residues of concern in the processed commodities of potatoes are required.

Detectable residues of malathion were observed in potato dry peel at 0.06 ppm; however, the Agency does not require feed additive tolerances for pesticide residues in potato dry peel.

EPA MEMORANDA CITED IN THIS REVIEW

CBRS No.:	12855
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

MASTER RECORD IDENTIFICATION NUMBERS

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

43524101 Bookbinder, M. (1995) Magnitude of the Residue of Malathion and Its Metabolite Malaoxon in/on Potato Processed Commodities: Lab Project Number: 92-0075: AA920138. Unpublished study prepared by American Agricultural Services,Inc. and EN-CAS Analytical Labs. 373 p.