

US EPA ARCHIVE DOCUMENT



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

December 17, 2001

MEMORANDUM

SUBJECT: Chlorpropham (018301), Magnitude of the Residue on Potato Peels and Pulp, DP Barcode D260114, MRID No. 44736001.

From: Danette Drew, Chemist
Reregistration Branch 3
Health Effects Division [7509C]

Through: Catherine Eiden, Senior Scientist
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To: Gary Mullins, CRM
Special Review and Reregistration Division

Balivi Research Laboratories, on behalf of PIN/NIP, Inc., has submitted data pertaining to the magnitude of chlorpropham residues in/on potato peels and pulp (1998; MRID 44736001). These data are evaluated in this document for adequacy in fulfilling residue chemistry data requirements. PIN/NIP, Inc. has previously submitted potato processing data (DP Barcode D185464, 4/16/93, J. Abbotts; and DP Barcode D193416, 8/11/93, J. Abbotts) which were deemed adequate to satisfy data requirements. The current submission (44736001) may be classified as supplemental. Upon review of this submission, HED makes the following conclusions:

1. The submitted residue data for potato peels and pulp are not adequate because the method used for analysis was not validated concurrently with the residue analyses. In addition, the registrant did not provide sufficient details of the chlorpropham applications, and values for chlorpropham residue in/on peel and pulp were reported in terms of the whole potato weight rather than in terms of the weight of each fraction.
2. Although inadequate, the data indicate that residues of chlorpropham were below the reassessed tolerance for whole potatoes (30 ppm) following two

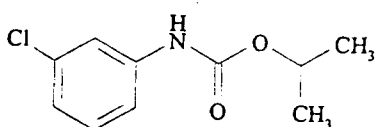
unspecified (treatment rate and formulation not provided) postharvest treatments of chlorpropham plus a third treatment using a 2 lb/gal EC formulation at 0.011 lb ai/1,000 lb of potatoes. Average residues were highest 24 hours after treatment (first sampling interval) and decreased at subsequent intervals. Residues in peel were 1.129-6.788 ppm and residues in pulp were <0.315-0.437 ppm, on a whole tuber basis.

3. The requirement for potato processing data has already been satisfied (DP Barcode D185464, 4/16/93, J. Abbotts; and DP Barcode D193416, 8/11/93, J. Abbotts). If the registrant wishes to use the currently submitted data in support of reregistration, then concurrent method validation data must be submitted. The registrant must also submit additional information regarding the analytical method (a more detailed description of the extraction process, and information regarding the HPLC system used for analysis). The two treatments of chlorpropham that were received by the potatoes prior to application of the EC formulation must be described in more detail (e.g., application rates, method of application). The residue levels in peel and pulp must be recalculated and reported in terms of peel and pulp weight.

This information was compiled by Dynamac Corporation under supervision of Reregistration Branch 3 (RRB3). This review has undergone secondary review by RRB3 and has been revised to reflect current HED and Office of Pesticide Programs (OPP) policies.

cc: Reg Std File, D.Drew, G. Mullins (SRRD)
RDI: C. Eiden (12/17/01)

CHLORPROPHAM



PC Code 018301; Case No. 0271

(DP Barcode D260114)

ADDENDUM TO THE RESIDUE CHEMISTRY CHAPTER OF THE REREGISTRATION ELIGIBILITY DECISION (RED) DOCUMENT

INTRODUCTION

Balivi Research Laboratories, on behalf of PIN/NIP, Inc., has submitted data pertaining to the magnitude of chlorpropham residues in/on potato peels and pulp (1998; MRID 44736001). These data are evaluated in this document for adequacy in fulfilling residue chemistry data requirements. PIN/NIP, Inc. has previously submitted potato processing data (DP Barcode D185464, 4/16/93, J. Abbotts; and DP Barcode D193416, 8/11/93, J. Abbotts) which were deemed adequate to satisfy data requirements.

The Product and Residue Chemistry Chapters for the Chlorpropham RED were issued 7/1/94 (D188707, D. Miller). According to the Residue Chemistry Chapter for the Chlorpropham RED, the only food/feed use of chlorpropham eligible for reregistration is postharvest application to stored potatoes. The reregistration of chlorpropham is being supported by the Chlorpropham Task Force II represented by Aceto Agricultural Chemicals Corporation and Decco/ Cerexagri (formerly Elf Atochem N.A., Inc.), the basic producers. PIN/NIP, Inc. is also separately pursuing the reregistration of its chlorpropham end-use product (EPA Reg. No. 65726-2).

The qualitative nature of the residue in plants (stored potatoes treated postharvest) and animals is adequately understood. The HED Metabolism Committee has determined that the residue to be included in the tolerance expression for stored potato is chlorpropham *per se* (isopropyl m-chlorocarbanilate), and that the residues to be regulated in the tolerance expression for ruminant and swine commodities are chlorpropham and 4-hydroxychlorpropham-O-sulfonic acid (4-HSA) (Memo of 4/16/93, J. Abbotts, No Barcode and Memo of 12/17/93, J. Abbotts, No Barcode).

Tolerances are currently established for residues of chlorpropham (CIPC; isopropyl m-chlorocarbanilate) and its metabolite, 1-hydroxy-2-propyl-3'-chlorocarbanilate, calculated as

chlorpropham, in/on potato (from postharvest use) at 50 ppm [40 CFR §180.181]. The available data indicate that the established tolerance for the RAC may be reduced, from 50 ppm to 30 ppm, provided use is limited to the following maximum application rates:

- aerosol fog at 0.022 lb ai/1,000 lbs potato in each of two applications 90 days apart followed by direct spray at 0.0104 lb ai/1,000 lbs potato; or
- aerosol fog at 0.033 lb ai/1,000 lbs potato and a second aerosol fog 140 days later at 0.017 lb ai/1,000 lbs potato.

No tolerances have been established for residues of chlorpropham in/on processed potato commodities. HED concluded that the proposed reassessed tolerance of 30 ppm for the residues of chlorpropham on the RAC is adequate to cover anticipated residues in processed potato waste; therefore, a separate tolerance is not required for processed potato commodities (D. Drew, D245701, 7/9/99).

Interim tolerances have been established for residues of chlorpropham in/on plant and animal commodities [40 CFR §180.319] at 0.05 ppm in milk, meat, fat and meat byproducts of cattle, hogs, horses, and sheep and 0.3 ppm in spinach. No Codex MRLs are established or proposed for residues of chlorpropham. Therefore, there are no issues regarding the compatibility of the U.S. tolerances with Codex MRLs.

The Pesticide Analytical Manual (PAM) Vol. II lists several methods for the enforcement of chlorpropham tolerances, as currently expressed, for plant commodities and milk. The PAM Vol. I method for chlorinated pesticides is listed as Method I, and an IR method is listed as Method II. The limit of detection for Method II is 1 ppm. Methods A, B, and D are spectrophotometric methods involving conversion of chlorpropham to 3-chloroaniline; PAM notes that IPC, monuron, diuron, linuron, and any other compound forming a volatile aniline on hydrolysis will also be determined in these procedures. Method C is a GC method with electron capture detection and involves conversion of chlorpropham to bromochloroaniline. Method E is a TLC method and Method F is similar to Method II.

The FDA PESTDATA database dated 8/93 (PAM Vol. I, Appendix II) indicates that chlorpropham is completely recovered (>80%) using FDA multiresidue method protocols D (Section 232.4) and E (Section 212.1/232.1, nonfatty matrices and Section 211.1/232.1, fatty matrices).

As a result of recommended changes in the tolerance expression, the Chlorpropham Task Force II has proposed a GC/NPD method for tolerance enforcement in stored potato commodities. The method has undergone successful independent laboratory validation (ILV) as well as Agency tolerance method validation (DP Barcode D213081, 3/22/95, D. Miller). The GC method will be forwarded to FDA for inclusion in PAM Vol. II following incorporation of minor recommendations made by the Agency. For the determination of chlorpropham and its 4-HSA metabolite in meat and milk, separate enforcement methods have been submitted (DP Barcode

D218755, 9/27/95, D. Miller). A successful ILV is required before the Agency will initiate method validation

CONCLUSIONS AND RECOMMENDATIONS

1. The submitted residue data for potato peels and pulp are not adequate because the method used for analysis was not validated concurrently with the residue analyses. In addition, the registrant did not provide sufficient details of the chlorpropham applications, and values for chlorpropham residue in/on peel and pulp were reported in terms of the whole potato weight rather than in terms of the weight of each fraction.
2. Although inadequate, the data indicate that residues of chlorpropham were below the reassessed tolerance for whole potatoes (30 ppm) following two unspecified (treatment rate and formulation not provided) postharvest treatments of chlorpropham plus a third treatment using a 2 lb/gal EC formulation at 0.011 lb ai/1,000 lb of potatoes. Average residues were highest 24 hours after treatment (first sampling interval) and decreased at subsequent intervals. Residues in peel were 1.129-6.788 ppm and residues in pulp were <0.315-0.437 ppm, on a whole tuber basis.
3. The requirement for potato processing data has already been satisfied (DP Barcode D185464, 4/16/93, J. Abbotts; and DP Barcode D193416, 8/11/93, J. Abbotts). If the registrant wishes to use the currently submitted data in support of reregistration, then concurrent method validation data must be submitted. The registrant must also submit additional information regarding the analytical method (a more detailed description of the extraction process, and information regarding the HPLC system used for analysis). The two treatments of chlorpropham that were received by the potatoes prior to application of the EC formulation must be described in more detail (e.g., application rates, method of application). The residue levels in peel and pulp must be recalculated and reported in terms of peel and pulp weight.

DETAILED CONSIDERATIONS

Residue Analytical Methods

Samples of potato peels and pulp were analyzed for residues of chlorpropham by Balivi Research Laboratories (Meridian, ID) using an HPLC/UV method. This data-collection method has previously been reviewed by the Agency in conjunction with a potato processing study (DP Barcode D185464, 4/16/93, J. Abbotts; and DP Barcode D193416, 8/11/93, J. Abbotts); the method was deemed acceptable based on acceptable concurrent method recoveries of chlorpropham. For this method, samples were shredded and reagent alcohol and heat were used to extract residues of chlorpropham. After addition of an internal standard, the extract was isolated

by filtration and injected onto an HPLC. The registrant stated that an acetonitrile:water solvent system is used for HPLC analysis and that peaks are detected by UV at 254 nm; however, no further details of the HPLC conditions (such as column packing) were provided. No method validation or concurrent method recovery data were provided with the submission. The reported limits of quantitation were 0.056 ppm for peel and 0.315 ppm for pulp.

Conclusion: Samples of potato peels and pulp were analyzed for residues of chlorpropham using an HPLC/UV method. The registrant did not provide sufficient details of the analytical method. In addition, no method validation or concurrent method recovery data were provided to demonstrate that the analytical laboratory was able to adequately determine residues of chlorpropham in potato commodities. Unless the registrant can provide data demonstrating that the method was adequately validated at the time of analysis (by analysis of fortified samples), the method cannot be deemed adequate for analysis of the samples included in this submission.

Storage Stability Data

Samples of potatoes were kept refrigerated from sample collection until analysis. The registrant stated that all analyses were conducted within 10 days of sample collection, however, dates of sample collection or analysis were not included in the submission.

Conclusion: Because samples were analyzed within 10 days of sample collection, no storage stability data are required to support this study.

Magnitude of the Residue in Processed Food/Feed

Established tolerances: A tolerance has been established for residues of chlorpropham and its metabolite, 1-hydroxy-2-propyl-3'-chlorocarbanilate, calculated as chlorpropham, in/on potato (from postharvest use) at 50 ppm [40 CFR §180.181]. The 7/1/94 Residue Chemistry Chapter of the Chlorpropham RED concluded that based on adequate residue data reflecting postharvest treatment, the reassessed tolerance for residues of chlorpropham *per se* in/on potatoes is 30 ppm. No tolerances have been established for residues of chlorpropham in/on processed potato commodities.

Discussion of data: PIN/NIP, Inc, has submitted a study (1998; MRID 44736001) depicting residues of chlorpropham in potato peel and pulp following treatment of stored potatoes with chlorpropham (EC formulation). The study was conducted by Balivi Research Laboratories. The registrant stated that current storage practices for potatoes involve placing the potatoes in storage after harvest where they are held for up to 10 months prior to distribution. Potatoes are treated with chlorpropham soon after being placed in storage to inhibit sprouting during storage. When sold to a distributor, the potatoes are then treated again, by the distributor, with an emulsifiable concentrate (EC) formulation of chlorpropham before packaging in bags for supermarket delivery.

The submitted study was conducted to determine chlorpropham levels in potatoes following treatment with an EC formulation of chlorpropham. We note that PIN/NIP, Inc. does not currently have a registered EC formulation of chlorpropham.

Potatoes, which were previously treated twice with chlorpropham by aerosol fogger (treatment rates not provided; treatments were made approximately 3 and 5 months earlier), were removed from storage, rinsed with water to remove adhering soil, and allowed to dry. The potatoes were then loaded onto a potato piler and a 2 lb/gal EC formulation (EPA Reg. No. not provided) was applied at a rate of 0.011 lb ai/1,000 lb of potatoes. This application rate is 1x the maximum application rate for this type of formulation as listed in the Residue Chemistry Chapter of the Chlorpropham RED. The potatoes were collected in mesh sacks (three sacks) and transferred to storage. Samples of potatoes (three potatoes from each sack) were collected at 0 hours (immediately prior to application of the EC formulation), 24 hours, 5 days, 15 days, 29 days, 46 days, and 60 days following treatment. An additional mesh sack contained potatoes that were not treated with the EC formulation and served as controls.

Potato samples were refrigerated (temperature unspecified) after collection. The potatoes were then separated into peel and pulp and each fraction was analyzed using an HPLC/UV method (see "Residue Analytical Methods"). Residues in peel and pulp were reported in terms of ppm equivalents based on the weight of the whole potato. The results of the potato processing study are presented in Table 1. Actual ppm values for peel and pulp could not be calculated as sample weights for each fraction were not reported. However, based on the data provided in the sample calculations (p. 15 of MRID 44736001), peel accounted for ~12% of the weight of the whole potato. Accordingly, actual residue values for peel are approximately one order of magnitude higher than the values present in Table 1.

The registrant reported mean residue values for whole potato, that were simply obtained by adding the mean residue values for potato peel and pulp.

Study summary: The submitted residue data for potato peel and pulp are not adequate because the method used for analysis was not validated concurrently with the residue analyses. In addition, the registrant did not provide sufficient details of chlorpropham applications, and values for chlorpropham residue in/on peel and pulp were reported in terms of the whole potato weight rather than in terms of the weight of each fraction.

Although inadequate, the data indicate that residues of chlorpropham in/on whole tubers were below the reassessed tolerance for potatoes (30 ppm) following two unspecified postharvest treatments of chlorpropham plus a third treatment using a 2 lb/gal EC formulation at 0.011 lb ai/1,000 lb of potatoes. Average residues were highest 24 hours after treatment (first sampling interval) and decreased at subsequent intervals. On a whole tuber basis, residues in/on peel were 1.129-6.788 ppm and residues in pulp were <0.315-0.437 ppm.

The requirement for potato processing data has already been satisfied (DP Barcode D185464, 4/16/93, J. Abbotts; and DP Barcode D193416, 8/11/93, J. Abbotts). If the registrant wishes to use the currently submitted data in support of reregistration, then concurrent method validation data must be submitted. The registrant must also submit additional information regarding the analytical method (a more detailed description of the extraction process, and information regarding the HPLC system used for analysis). The two treatments of chlorpropham that were received by the potatoes prior to application of the EC formulation must be described in more detail (e.g., application rates, method of application). The residue levels in peel and pulp must be recalculated and reported in terms of peel and pulp weight.

Table 1. Residues of chlorpropham in potato peel and pulp following treatment with a 2 lb/gal EC formulation at 0.011 lb ai/1,000 lb potatoes.

Commodity	Treatment	Number of Samples	Chlorpropham Residues, ppm (mean) ^a						
			Interval After Treatment ^b						
			0 hour ^c	24 hour	5 Day	15 Day	29 Day	46 Day	60 Day
Peel	EC-Treated	9	1.246-2.306 (1.642)	4.096-5.649 (4.900)	3.437-6.788 (4.664)	3.110-4.548 (3.683)	1.420-4.069 (2.889)	1.374-3.685 (2.750)	1.129-2.627 (1.952)
	Non-EC-Treated	3	1.819-2.412 (2.120)	1.297-1.986 (1.646)	1.479-2.663 (2.113)	1.531-2.264 (1.830)	1.857-2.655 (2.221)	2.676-2.973 (2.843)	2.358-3.288 (2.680)
Pulp	EC-Treated	9	<0.315-0.437 (<0.362)	<0.315 (<0.315)	<0.315 (<0.315)	<0.315 (<0.315)	<0.315 (<0.315)	<0.315 (<0.315)	<0.315 (<0.315)
	Non-EC-Treated	3	<0.315 (<0.315)	<0.315-0.421 (<0.350)	<0.315 (<0.315)	<0.315 (<0.315)	<0.315 (<0.315)	<0.315 (<0.315)	<0.315 (<0.315)

^a Residue values reported for peel and pulp are expressed in terms of ppm equivalents based on the weight of the whole potato.
^b Interval after treatment with the EC formulation. Potatoes had previously been treated with chlorpropham approximately 3 and 5 months prior to EC treatment.

^c These samples were collected immediately before treatment with the 2 lb/gal EC formulation.

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AGENCY MEMORANDA CITED IN THIS REVIEW

CBRS No.: None
DP Barcode: None
Subject: Chlorpropham: Results of the HED Metabolism Committee Meeting Held on 3/22/93: Chlorpropham Metabolism in Potatoes.
From: J. Abbotts
To: F. Suhre
Dated: 4/16/93
MRID(s): None

CBRS No.: 11008
DP Barcode: D185464
Subject: Chlorpropham. Registrant Pin Nip, Inc. Response to the Reregistration Standard: Magnitude of the Residue in Postharvest Potatoes and Potato Processed Commodities.
From: J. Abbotts
To: V. Eagle
Dated: 4/16/93
MRID(s): 42566801

CBRS No.: 12273
DP Barcode: D193416
Subject: Chlorpropham, Reregistration. Registrant Pin Nip, Inc. Submission of Supplemental Data: Magnitude of the Residue in Postharvest potatoes and Potato Processed Commodities.
From: J. Abbotts
To: V. Eagle
Dated: 8/11/93
MRID(s): None

CBRS No.: None
DP Barcode: None
Subject: Chlorpropham.: Conclusions of the HED Metabolism Committee.
From: J. Abbotts
To: F. Suhre
Dated: 12/17/93
MRID(s): None

CBRS No.: 15122
DP Barcode: D213081
Subject: Chlorpropham. (018301) Results of Tolerance Method Validation (TMV) on Potatoes and Processed Potato Commodities. Case No. 0271.
From: D. Miller
To: V. Eagle
Dated: 3/22/95
MRID(s): None

CBRS No: 16107
DP Barcode: D218755
Subject: Chlorpropham. (018301) Enforcement Analytical Method for Meat and Milk Commodities. GLN 171-4(d).
From: D. Miller
To: M. Exton
Dated: 9/27/95
MRID(s): 43677001 and 43760301

MASTER RECORD IDENTIFICATION NUMBERS

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

44736001 Redfield, D; Forsythe, J. (1998) Magnitude of Residue of Chlorpropham on Potato Skin and Potato Pulp Following treatment with Chlorpropham in the Emulsifiable Concentrate Form. Study Number 98-003. Unpublished study prepared by Balivi Research Laboratories and submitted by PIN/NIP, Inc. 41 p.