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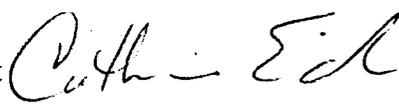
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

January 7, 2002

MEMORANDUM

SUBJECT: Chlorpropham (018301), Magnitude of the Residue on Potato Skin (Peel) after Post Harvest Fumigation, DP Barcode D276548, MRID No. 45426101.

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

Through: Catherine Eiden, Senior Scientist 
Reregistration Branch 3
Health Effects Division [7509C]

To: Gary Mullins, CRM
Special Review and Reregistration Division

PIN/NIP, Inc., has submitted data pertaining to the magnitude of chlorpropham residues in/on potato skin (peel) after post harvest fumigation (MRID 45426101). 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 (MRID 45426101) may be classified as supplemental. Upon review of this submission, HED makes the following conclusions:

1. The submitted residue data for potato peels are not adequate because the method used for analysis was not validated concurrently with the residue analyses.
2. Although inadequate, the data indicate that residues of chlorpropham in *peels* were below the reassessed tolerance for whole potatoes (30 ppm) following a single postharvest fog treatment of chlorpropham at a rate of 1.0 lb ai/60,000 lbs of potatoes (1.0x the maximum single application rate registered to Pin/Nip). A second potato storage facility was also treated once at a rate of 2.0 lb ai/60,000 lbs of potatoes (2.0x). The ranges of chlorpropham residues in/on 1.0x-treated potato skin, collected from the

top, middle, and bottom portions of the storage facility, respectively, were: (i) <0.056-4.556 ppm; (ii) <0.056-4.602 ppm; and (iii) <0.056-7.047 ppm. The ranges of chlorpropham residues in/on 2.0x-treated potato skin, collected from the top, middle, and bottom portions of the storage facility, respectively were: (i) <0.056-11.335 ppm; (ii) <0.056-9.651 ppm; and (iii) <0.056-9.213 ppm.

cc: Reg Std File, D.Drew, G. Mullins (SRRD)
RDI: C. Eiden (1/7/02)



Chemical Name Chlorpropham
PC Code: 018301
EPA Barcode: D276548

Crop Field Trials
GL: OPPTS 860.1500

MRID: 45426101
Case No.: 0271
Submission: S600803



EPA Reviewer: Danette Drew, Chemist, Date January 7, 2002

STUDY TYPE: Magnitude of Residue of Chlorpropham on Potato Skin After Post Harvest Fumigation; OPPTS 860.1500

TEST MATERIAL: Chlorpropham, isopropyl m-chlorocarbanilate

FORMULATION AND TYPE: Ready-to-Use (RTU)

SYNONYMS: Not available

CITATION: 45426101 Redfield, D.; Forsythe, J. (1998) Magnitude of Residue of Chlorpropham on Potato Skin After Post-Harvest Fumigation. Laboratory Project Number: 98-001. Unpublished study prepared by Balivi Research Laboratories. 35 p.

SPONSOR: PIN/NIP, Inc.

EXECUTIVE SUMMARY:

Pin/Nip, Inc. has submitted results of the subject study (MRID 45426101) which investigated the magnitude of chlorpropham residues in/on potato skin (or peel) after postharvest fumigation. It is noted that according to Table 1 of OPPTS 860.1000, the recognized raw agricultural commodity (RAC) of potato is tuber. In the study protocol of the submission, the registrant stated that previous studies show that about 99.4% of chlorpropham residues is on potato skins, and that the amount of chlorpropham in/on potato pulp is negligible.

Chlorpropham was applied as a single postharvest fog treatment to a commercial storage facility containing approximately 2,400,000 lbs of potatoes at a rate of 1.0 lb ai/60,000 lbs of potatoes (1.0x the maximum single application rate registered to Pin/Nip). A second potato storage facility, containing 1,800,000 lbs of potatoes was also treated once as above at a rate of 2.0 lb ai/60,000 lbs of potatoes (2.0x). Samples of treated and untreated potatoes from the top, middle, and bottom portions of storage facilities were collected at intervals of 0, 1, 15, 30, 60, and 90 days posttreatment. Samples were analyzed for residues of chlorpropham *per se* using HPLC/UV Method SOP No. 500 with a reported LOQ of 0.056 ppm. No concurrent method recovery data were provided. It is, however, noted that a similar HPLC/UV method (MRID 44397101) has been deemed adequate for data-collection purpose (D240103, 7/1/99, D. Drew). In addition, sample storage stability could not be verified since the registrant did not provide specific information pertaining to sample storage and conditions; the registrant, however, stated that samples were stored for less than 30 days prior to residue analysis.

The ranges of chlorpropham residues in/on 1.0x-treated potato skin, collected from the top, middle, and bottom portions of the storage facility, were: (i) <0.056-4.556 ppm; (ii) <0.056-4.602 ppm; and (iii) <0.056-7.047 ppm. The ranges of chlorpropham residues in/on 2.0x-treated potato skin, collected from

the top, middle, and bottom portions of the storage facility, respectively were: (i) <0.056-11.335 ppm; (ii) <0.056-9.651 ppm; and (iii) <0.056-9.213 ppm.

Although concurrent method recovery data and information pertaining to sample storage conditions and intervals were not provided, the current postharvest fumigation study is classified as supplemental and data from this submission may be used by HED for risk assessment.

The HED Metabolism Committee has determined that the residue to be included in the tolerance expression for potatoes is chlorpropham *per se*. The chlorpropham tolerance, presently listed in 40 CFR §180.181 for potatoes (from postharvest use), is expressed in terms of the combined residues of chlorpropham and the metabolite 1-hydroxy-2-propyl-3-chlorocarbanilate. The tolerance expression will be changed at issuance of the final Chlorpropham RED Document.

The reregistration requirements, for data depicting magnitude of the residue on stored potatoes and its processed commodities, are fulfilled based on adequate residue data submitted by Pin/Nip and the Chlorpropham Task Force (on behalf of Aceto Agricultural Chemicals Corporation and Decco/Cerexagri, Inc. [formerly Atochem North American, Inc]). The Residue Chemistry Chapter of the Chlorpropham RED dated 7/1/94 reported that adequate residue data are available to support postharvest uses on potatoes. 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).

COMPLIANCE: Signed and dated GLP, Quality Assurance and Data Confidentiality were provided.

I. MATERIALS AND METHODS

Samples of shredded potato skins were analyzed for residues of chlorpropham *per se* using HPLC/UV Method SOP No. 500. Analysis was performed by Balivi Research Laboratories (Meridian, ID). Briefly, whole potatoes were weighed and peeled with a vegetable peeler. The potato skins were weighed, shredded, and placed in a jar. Residues were extracted with reagent grade ethanol along with barban internal standard. Samples were agitated for one minute, heated in a water bath at 50 C for 15 minutes, and followed by agitation for one minute. Extracts were filtered through a glass fiber filter, and residues were quantitated by reverse phase HPLC. Detection was by UV at 254 nm. The reported method limit of quantitation (LOQ) was 0.056 ppm. No concurrent method recovery data were submitted.

Apparent residues of chlorpropham were nondetectable (<0.056 ppm) in/on 15, 18, and 17 samples of potato skins from the top, middle, and bottom sampling location for each sampling period, respectively. Two untreated samples of potato skins from the top sampling location bore detectable residues of chlorpropham at 0.622 and 0.274 ppm for the zero-hour and 24-hour sampling period, respectively. One untreated sample of potato skins from the bottom sampling location bore detectable residues of chlorpropham at 0.215 ppm for the zero-hour sampling period. Sample chromatograms of control and treated samples were provided; no interference was observed in the regions of chlorpropham in chromatograms for control samples of potato skin.

1. Test Compound

Chemical name:

IUPAC: Isopropyl 3-chlorocarbanilate

CAS name: Carbamic acid, (3-chlorophenyl)-, 1-methyl ester

CAS #: 101-21-3

Common name (ANSI, BSI or ISO): Chlorpropham

Developmental (Company) name: Not specified

2. Trial Numbers and Locations

Crop	US Growing Regions									Total Trials
Submitted										
Requested										

Comments: The table for trial numbers and location is not applicable for a postharvest fumigation study.

Chemical Name Chlorpropham
 PC Code: 018301
 EPA Barcode: D276548

Crop Field Trials
 GL: OPPTS 860.1500

MRID: 45426101
 Case No.: 0271
 Submission: S600803

3. Proposed Label Use Pattern

9.709 lb ai/gal (98.6% chlorpropham) ready-to-use (RTU) formulation (EPA Reg. No. 65726-3, dated 10/7/97)

Crop	Application					Comments/ Restrictions
	Method/Timing	Rate	Maximum Number	Total Seasonal Rate	PHI, days	
Potato	Aerosol application Postharvest Aerosol generator with forced air recirculation	1 lb ai/ 600 cwt [60000 lb] or 0.017 lb ai/1000 lb potato	2 (implied)	Not specified (NS)	NA ¹	Application rate depends on length and temperature of storage, with the highest application rate for 10 months of storage at 60 F. Applications may be split as long as total application rate does not exceed maximum for storage time. Forced air recirculation at lowest rate available for applicator must be used during application. The storage area must be kept closed during treatment or until fog settles. Application in field or to seed potato is prohibited.

¹ NA = not applicable for postharvest applications

4. Analytical Method Validation (Concurrent)

Crop matrix	Analyte	Spiking Level (mg/kg)	Recoveries obtained (%) ¹	Range (%)	Mean recovery (SD/RSD)

Comments: Concurrent method recoveries were not provided.

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5. Storage Stability Conditions

Commodity	Storage Temperature (°C)	Duration (days)
Potato tuber	refrigerated (temperature unspecified)	10

Comments: All samples of potato tubers were transported to the analytical laboratory within 3 days of collection with the exception of the 30-day samples which were received after 5 days due to the delivery schedule of the carrier. While at the analytical laboratory, samples of potato tubers were refrigerated (temperature unspecified) until processing. The registrant stated that all samples were processed and analyzed within 10 days of collection.

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6. Application and RAC Information

EUP - Chlorpropham/TYPE (RTU)/ - POTATO										
LOCATION (state)/YEAR	EPA REGION	CROP/VARIETY	GROWTH STAGE/ APPLICATION and RATE	METHOD OF APPLICATION	TANK MIXES/ ADJUVANTS	GROWTH STAGE/ HARVEST	HARVESTED PORTION	CROP GROUP	HARVEST PROCEDURES	
									Method/equipment (mechanical/hand from the plant/ ground/ flotation)	# & wt of samples/ replicate; replicate s/treatment
eastern ID/ commercial storage area/ 1998	Not applicable (NA)	Storage area contained approx. 1,800,000 lbs of potatoes/ Russet Burbank	Postharvest/ fog application at 2 lb ai/60,000 lb of potato	thermol aerosol fogger	None specified	Postharvest	Tuber	1	Potatoes were collected from three collection sites: top, middle, and bottom of the potato pile. Sample sets for each site were collected at zero hours, 24 hours, 15 days, 30 days, 60 days, and 90 days post fumigation.	Three potato samples were collected per collection site per collection time. A total of 27 potato samples were collected per sampling period.
eastern ID/ commercial storage area/1998	NA	Storage area contained approx. 2,400,000 lbs of potatoes/ Russet Burbank	Postharvest/ fog application at 1 lb ai/60,000 lb of potato	thermol aerosol fogger	None specified	Postharvest	Tuber	1	Potatoes were collected from three collection sites: top, middle, and bottom of the potato pile. Sample sets for each site were collected at zero hours, 24 hours, 15 days, 30 days, 60 days, and 90 days post fumigation.	Three potato samples were collected per collection site per collection time. A total of 27 potato samples were collected per sampling period.

Crop group 1 - Root and Tuber Vegetables.

Comments: No additional comments.

7. Site Specific Information

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POTATO LOCATION (state)/ YEAR	FARMING PRACTICES			SOIL CHARACTERISTICS				
	CULTIVATION/ IRRIGATION	FERTILIZER	MAINTENANCE CHEMICALS/RATE/TIMING	TYPE	% Organic Matter (OM)	pH	Cation Exchange Capacity (CEC)	WEATHER DATA (T°C, rainfall)

Comments: The table for site specific information is not applicable for a postharvest fumigation study.

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II. RESULTS

TABLE 1. Residue Data Summary from Postharvest Fumigation Study*

Location (state)/ Year	Crop Variety	Commodity/ Portion analyzed	Formulation	Application				Residues ² (mg/kg)		
				Appl. Rate (lbs ai/60,000 lb of potato)	No.	Interval Between Appls.	Total Rate (lbs ai/60,000 lb of potato)		% of Max Rate	Sampling time (days) ¹
eastern ID/ commercial storage area/1998	Russet Burbank	potato peel	RTU	2.0	1	NA	2.0	200%	0	<0.056, <0.056, <0.056
									1	6.160, 7.895, 8.047
									15	7.495, 8.758, 9.922
									30	7.195, 7.470, 7.749
									60	5.437, 8.029, 10.395
									90	8.979, 10.654, 11.335
									0	<0.056, 0.179, 0.577
									1	2.059, 3.317, 3.476
									15	3.465, 3.547, 4.556
									30	2.892, 3.306, 4.072
60	2.814, 3.227, 3.722									
90	1.708, 2.259, 4.142									
				1.0	1	NA	1.0	100%	0	

Top Sampling Location

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Location (state)/ Year	Crop Variety	Commodity/ Portion analyzed	Formulation	Application				Residues ² (mg/kg)		
				App. Rate (lbs ai/60,000 lb of potato)	No.	Interval Between Appls.	Total Rate (lbs ai/60,000 lb of potato)		% of Max Rate	Sampling time (days) ¹
Middle Sampling Location										
eastern ID/ commercial storage area/1998	Russet Burbank	potato peel	RTU	2.0	1	NA	2.0	200%	0	<0.056, <0.056, <0.056
				1.0	1	NA	1.0	100%	1	3.696, 5.634, 8.870
									15	5.049, 6.192, 6.325
									30	8.180, 8.216, 8.672
									60	6.332, 7.472, 9.651
									90	7.015, 7.096, 7.374
									0	<0.056, <0.056, 0.240
									1	2.391, 2.718, 2.851
									15	2.616, 3.191, 3.425
									30	2.334, 2.955, 3.056
					60	2.811, 3.087, 4.602				
					90	2.764, 3.624, 4.124				

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Location (state)/ Year	Crop Variety	Commodity/ Portion analyzed	Formulation	Application				Residues ² (mg/kg)		
				Appl. Rate (lbs ai/60,000 lb of potato)	No.	Interval Between Applis.	Total Rate (lbs ai/60,000 lb of potato)		% of Max Rate	
Bottom Sampling Location										
eastern ID/ commercial storage area/1998	Russet Burbank	potato peel	RTU	2.0	1	NA	2.0	200%	0	<0.056, <0.056, <0.056
									1	4.511, 5.261, 5.89
									15	5.833, 7.058, 9.213
									30	5.375, 6.884, 7.192
									60	3.541, 3.790, 4.360
									90	3.42, 4.830, 5.489
									0	<0.056, <0.056, 0.113
									1	3.282, 3.666, 3.820
									15	3.239, 3.631, 4.261
									30	4.190, 5.918, 6.583
60	2.024, 2.708, 3.658									
90	4.719, 6.073, 7.047									

The sampling time represents the time potato samples were collected post-fumigation.
Bolded residues resulted from applications at the maximum proposed application rates.

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Comments:

The submitted study is deemed supplemental. According to the Residue Chemistry Chapter of Chlorpropham RED, the reregistration requirements for data depicting magnitude of the residue on stored potatoes and its processed commodities, are fulfilled based on adequate residue data previously submitted by the Chlorpropham Task Force.

III. CONCLUSIONS

Chlorpropham was applied as a single postharvest fog treatment to a commercial storage facility containing approximately 2,400,000 lbs of potatoes at a rate of 1.0 lb ai/60,000 lbs of potatoes (1.0x the maximum single application rate registered to Pin/Nip). A second potato storage facility, containing 1,800,000 lbs of potatoes was also treated once as above at a rate of 2.0 lb ai/60,000 lbs of potatoes (2.0x). Samples of treated and untreated potatoes from the top, middle, and bottom portions of storage facilities were collected at intervals of 0, 1, 15, 30, 60, and 90 days posttreatment.

The ranges of chlorpropham residues in/on 1.0x-treated potato skin, collected from the top, middle, and bottom portions of the storage facility, were: (i) <0.056-4.556 ppm; (ii) <0.056-4.602 ppm; and (iii) <0.056-7.047 ppm. The ranges of chlorpropham residues in/on 2.0x-treated potato skin, respectively collected from the top, middle, and bottom portions of the storage facility, were: (i) <0.056-11.335 ppm; (ii) <0.056-9.651 ppm; and (iii) <0.056-9.213 ppm.

These data support the reassessed RAC tolerance of 30 ppm.

IV. STUDY DEFICIENCIES

Although concurrent method recovery data and information pertaining to sample storage conditions and intervals were not provided, they are not required because the study is classified as supplemental. The registrant is reminded that these types of supporting data are required for the conduct future field residue studies.

V. REFERENCES

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
Date: 4/16/93
MRIDs: 42566801

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GL: OPPTS 860.1500

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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
Date: 8/11/93
MRIDs: None

DP Barcode: D188707
Subject: Chlorpropham. Product Chemistry Chapter and Residue Chemistry Chapter for the Reregistration Eligibility Document (RED).
From: D. Miller
To: V. Eagle and F. Chow
Date: 7/1/94
MRIDs: None

DP Barcode: D240103
Subject: Chlorpropham (018301). Addendum to the Chemistry Chapter of the RED; Analytical Method Requirements [HPLC/UV Method for Data Collection].
From: D. Drew
To: P. Moe
Date: 7/1/99
MRIDs: 44397101

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