

US EPA ARCHIVE DOCUMENT

Final Report

CHLORPROPHAM
Shaughnessy No. 018301
Case No. 0271

TASK 2B
Reregistration Eligibility Document:
Residue Chemistry Considerations

June 3, 1994
Revised: June 28, 1994

Contract No. 68-D2-0053

Submitted to:
U.S. Environmental Protection Agency
Arlington, VA 22202

Submitted by:
Dynamac Corporation
The Dynamac Building
2275 Research Boulevard
Rockville, MD 20850-3268

/

CHLORPROPHAM

REREGISTRATION ELIGIBILITY DOCUMENT

RESIDUE CHEMISTRY CONSIDERATIONS

(Shaughnessy No. 018301; Case No. 0271)

TASK 2B

<u>TABLE OF CONTENTS</u>		<u>page</u>
INTRODUCTION		1
REGULATORY BACKGROUND		1
SUMMARY OF SCIENCE FINDINGS		1
GLN 171-3: Directions for use		2
GLN 171-4 (a): Plant Metabolism		2
GLN 171-4 (b): Animal Metabolism		10
GLN 171-4 (c) and (d): Residue Analytical Methods-Plants and Animals		12
GLN 171-4 (e): Storage Stability		12
GLN 171-4 (k): Magnitude of the Residue in Plants		13
GLN 171-4 (l): Magnitude of the Residue in Processed Food/Feed		13
GLN 171-4 (j): Magnitude of the Residue in Meat, Milk, Poultry, and Eggs		13
GLNs 165-1 and 165-2: Confined/Field Rotational Crops		14
TOLERANCE REASSESSMENT SUMMARY		14
Tolerances Listed Under 40 CFR §180.181		14
Tolerances Listed Under 40 CFR §180.319 (interim tolerances)		14
Food and Feed Additive Tolerances to be Proposed (40 CFR §185.xxxx and §186.xxxx)		15
DIETARY EXPOSURE ASSESSMENT SUMMARY		15
Exposure Assessment for Chlorpropham <i>per se</i>		19
Exposure Assessment for 3-Chloroaniline		19
AGENCY MEMORANDA CITED IN THIS DOCUMENT		23
MASTER RECORD IDENTIFICATION NUMBERS		28

2

CHLORPROPHAM

REREGISTRATION ELIGIBILITY DOCUMENT

RESIDUE CHEMISTRY CONSIDERATIONS

(Shaughnessy No. 018301; Case No. 0271)

TASK 2B

INTRODUCTION

Chlorpropham (isopropyl *m*-chlorocarbanilate) is a plant growth regulator used to inhibit sprout formation on stored potato. Chlorpropham is formulated as an emulsifiable concentrate (EC) or ready-to-use solution (RTU) by Aceto Agricultural Chemicals Corporation and Elf Atochem N.A. Inc., the basic producers.

REGULATORY BACKGROUND

The Chlorpropham Reregistration Standard Guidance Document was issued 12/87 and was based on the Chlorpropham Reregistration Standard Science Chapter dated 8/19/87. The Chlorpropham Product and Residue Chemistry Reregistration Standard Update was completed 10/16/91. The information contained in this document outlines the Residue Chemistry Science Assessments with respect to the reregistration of chlorpropham.

Tolerances are established for residues of chlorpropham and its metabolite 1-hydroxy-2-propyl-3'-chlorocarbanilate, calculated as chlorpropham, in/on potato (from post-harvest use) at 50 ppm and soybeans at 0.2 ppm [*Source: 40 CFR §180.181*]. Interim tolerances have been established for residues of chlorpropham in/on plant and animal commodities [*Source: 40 CFR §180.319*]. Interim tolerances range from 0.05 ppm in meat, milk, and eggs to 50.0 ppm in the hay of alfalfa, clover, and grass. No food/feed additive tolerances have been established. Adequate enforcement methods are available for the determination of these regulated compounds in/on plant commodities and milk.

SUMMARY OF SCIENCE FINDINGS

The summaries of residue chemistry guidelines and topics listed below are based on the present regulatory status where the only food/feed use of chlorpropham that will be supported by the registrants is postharvest application to stored potato. CBRS reserves the right to require additional studies for each applicable guideline and topic if additional registrations on food/feed crops other than stored potato are sought, or if a tolerance increase is proposed.

GLN 171-3: Directions for use

A REFS search conducted 3/22/94 indicated that there are eight chlorpropham end-use products (EPs) with food/feed uses which are registered to Aceto Agricultural Chemicals Corp., Elf Atochem N.A., Inc., Platte Chemical Company, Inc., and Pin Nip Inc. These EPs are presented below.

Registrant EPA Reg. No.	Acceptance Date	Formulation Class	Product Name
Aceto Agricultural Chemicals Corp.			
2749-70	9/85	3 lb/gal EC	Spud Nic-3
2749-264 ^a	10/89	4 lb/gal RTU	Spud Nic-4
Elf Atochem N.A., Inc.			
2792-40	2/80	2 lb/gal EC	Decco 276 EC
2792-41	1/90	4.3 lb/gal RTU	Pennwalt Decco 273 Aerosol Potato Sprout Inhibitor
ND85000900 ^b	--	7 lb/gal RTU	Decco 257 Sprout Inhibitor
Platte Chemical Company, Inc.			
34704-612	1/77	4 lb/gal RTU	Sprout Nip Ag
34704-613 ^c	9/82	3 lb/gal EC	Sprout Nip Emulsifiable Concentrate
34704-614	6/86	7 lb/gal RTU	Sprout Nip 7A
Pin Nip Inc.			
65726-1	10/7/93	7 lb/gal RTU	Pin Nip 7A Aerosol Grade - Potato Sprout Inhibitor

^a Including SLN Nos. ND82002100, OR85004700, and WA82006500.

^b This SLN registration has no parent product.

^c Including SLN Nos. DE91000100, MD91000800, NJ91000100, and VA91000400.

A comprehensive summary of the registered food/feed use patterns of chlorpropham, based on these product labels, is presented in Table A. A tabular summary of the residue chemistry science assessments for reregistration of chlorpropham is presented in Table B. The conclusions regarding the reregistration eligibility of chlorpropham on the crops listed in Table B are based on the use patterns registered by the basic producers, Aceto Agricultural Chemicals and Elf Atochem. When end-use product DCIs are developed (e.g., at issuance of the RED), RD should require that all end-use product labels (e.g., MAI labels, SLNs, and products subject to the generic data exemption) be amended such that they are consistent with the basic producer labels.

GLN 171-4 (a): Plant Metabolism

The qualitative nature of the residue in stored potato treated postharvest is adequately understood. The parent chlorpropham was found to be the major residue, representing 96% of the total radioactive residues (TRR), in potato stored for 52 weeks following treatment

Table A. Registered Food/Feed Uses of Chlorpropham.

Site	Application Type Application Timing Application Equipment	Form (EPA Reg. No.)	Max. Single Application Rate (lb ai/A)	Max. # Apps.	Use Limitations
Potato					
Aqueous spray Postharvest Ground equipment	2 lb/gal EC (2792-40) 3 lb/gal EC (2749-70, 34704-613)	0.01 lb ai/1000 lb potato	1	Application is made as an aqueous spray to potato moving along a conveyor belt. Potato must be cured (allowing at least two weeks for cuts and bruises to heal) and washed prior to application. Not for application in field or to seed potato.	
Aerosol application Postharvest Aerosol generator with forced air recirculation	4.3 lb/gal RTU (2792-41) 7 lb/gal RTU (34704-614, 65726-1, ND850009)	0.044 lb ai/1000 lb potato	2 (@ 0.022)	Application at the maximum application rate is to be made to potato which will be stored for long periods. Forced air recirculation at 83 cubic feet per minute/1000 lb potato must be used until fog settles. The storage area must be kept closed during treatment and for 48 hours following treatment. Not for application in field or to seed potato.	
Aerosol application Postharvest Aerosol generator with forced air recirculation	4 lb/gal RTU (2749-264, 34704-612) 7 lb/gal RTU (34704-614, 65726-1) 7 lb/gal RTU (34704-614, 65726-1)	0.017 lb ai/1000 lb potato 0.013-0.028 lb ai/1000 lb potato	1 1	Forced air recirculation at 83 cubic feet per minute/1000 lb potato must be used until fog settles. The storage area must be kept closed during treatment and for 48 hours following treatment. Not for application in field or to seed potato. 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 and for 4 hours following treatment or until fog settles. Not for application in field or to seed potato.	

(continued; footnotes follow)

5

Table A (continued).

Site Application Type Application Timing Application Equipment	Form (EPA Reg. No.)	Max. Single Application Rate (lb ai/A)	Max. # Apps.	Use Limitations
Potato (continued)				
Aerosol application Postharvest Aerosol generator with forced air recirculation	4 lb/gal RTU (ND820021, OR850047, WA820065)	0.025-0.033 lb ai/1000 lb potato	1	Use lower rate for storage up to 3 months and higher rate for storage up to six months. A maximum of 0.033 lb ai/1000 lb potato may be applied during any six month period. Forced air recirculation at 83 cubic feet per minute/1000 lb potato must be used until fog settles. The storage area must be kept closed during treatment and for 48 hours following treatment. Not for application in field or to seed potato.
Spinach				
Broadcast application Dormant Ground equipment	3 lb/gal EC (DE910001, MD910008, NJ910001, VA910004)	1	1	A 30-day PHI has been established.

Table B. Residue Chemistry Science Assessments for the Reregistration of Chlorpropham.

GLN: Data Requirements	Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References ¹
171-3: Directions for Use	N/A = Not Applicable		(see Table A)
171-4 (a): Plant Metabolism	N/A	No	42085601 ²
171-4 (b): Animal Metabolism	N/A	No ³	00114700, 00114701, 00114739, 42112201 ^{2,4} , 42130401 ²
171-4 (c/d): Residue Analytical Methods	N/A	Yes ⁵	00035896, 00045294, 00045295, 00114710, 00114715, 00114718, 00114739, 00114741, 00114751, 00114785, 00115388, 05016141, 42123101 ² , 42653401 ⁶ , 42778901 ⁷
171-4 (e): Storage Stability	N/A	R ⁸	00054672, 42660101 ⁶ , 42958301 ⁹ , 43053601 ¹⁰
171-4 (k): Magnitude of the Residue in Plants			
<u>Root and Tuber Vegetables Group</u>			
- Carrot	0.1 [180.319]	N/A ¹¹	00114725, 00115388
- Potato	50 [180.181]	No ¹²	00083155, 00114695, 00114718, 00114741, 00114747, 00114750, 00114777, 00114785, 00114795, 42566801 ^{13,14} , 42610301 ⁶ , 42653601 ⁶ , 42653801 ⁶ , 42653901 ⁶
- Sugar beet, root	0.1 [180.319]	N/A ¹⁵	00051824, 00114794, 00115388
<u>Leaves of Root and Tuber Vegetables Group</u>			
- Sugar beet, tops	0.3 [180.319]	N/A ¹⁵	00051824, 00114794, 00115388
<u>Bulb Vegetable Group</u>			
- Garlic	0.1 [180.319]	N/A ¹⁵	00051834, 00114725
- Onion (green and dry bulb)	0.1 [180.319]	N/A ¹⁵	00083158, 00114725, 00115388
<u>Leafy Vegetables (except Brassica) Group</u>			

1

Table B (continued).

GLN: Data Requirements	Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References ¹
- Spinach	0.3 [180.319]	N/A ¹⁶	00114710, 00114715, 00114794
<u>Legume Vegetables (Succulent or Dried) Group</u>			
- Bean (succulent and dried)	0.3 [180.319]	N/A ¹⁵	00051812, 00051822, 00114715, 00115388
- Pea (succulent and dried)	0.3 [180.319]	N/A ¹⁵	
- Soybean	0.2 [180.181]	N/A ¹⁷	00030995, 00036642, 00037035, 00037037, 00037038, 00037042, 00037043, 00051815, 00051817, 00106293, 00114715, 00114717, 00114778
<u>Foliage of Legume Vegetables Group</u>			
- Bean forage and hay		N/A ¹⁸	
- Pea vines and hay		N/A ¹⁸	
- Soybean forage and hay		N/A ¹⁸	PP#2F1276, 00036382, 00114715, 00114778
<u>Fruiting Vegetables (except cucurbits) Group</u>			
- Tomato	0.1 [180.319]	N/A ¹⁵	00114710, 00114725, 00051838
<u>Small Fruits and Berries Group</u>			
- Blackberry	0.3 [180.319]	N/A ¹⁵	00051807
- Blueberry	0.3 [180.319]	N/A ¹⁵	00114710
- Cranberry	0.3 [180.319]	N/A ¹⁵	00051861, 00114715, 00114725, 00114737, 00114748
- Raspberry	0.3 [180.319]	N/A ¹⁵	00114710
<u>Cereal Grains Group</u>			
- Rice grain	0.1 [180.319]	N/A ¹⁵	
<u>Forage, Fodder, and Straw of Cereal Grains Group</u>			
- Rice straw		N/A ¹⁸	
<u>Grass Forage, Fodder, and Hay Group</u>			

8

Table B (continued).

GLN: Data Requirements	Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References ¹
- Grass forage and hay	20 (forage) 50 (hay) [180.319]	N/A ¹⁵	00114715, 00114737, 00114794
<u>Non-grass Animal Feeds Group</u>			
- Alfalfa forage and hay	20 (forage) 50 (hay) [180.319]	N/A ¹⁵	00051851, 00051852, 00051853, 00051854, 00051855, 00114710, 00114725, 00114737, 00114794
- Clover forage and hay	20 (forage) 50 (hay) [180.319]	N/A ¹⁵	00036390, 00036392, 00037285, 00058143, 00058147, 00114725, 00114737
<u>Miscellaneous Commodities</u>			
- Safflower seed	0.1 [180.319]	N/A ¹⁵	00114710, 00114715, 00114725
- Tobacco		N/A ¹⁸	
171-4(l): Magnitude of the Residue in Processed Food/Feed			
- Bean		N/A ¹⁸	
- Potato		Yes ¹⁹	42566801 ^{13,14} , 42653701 ⁶ , 42660201 ⁶
- Rice		No ¹⁸	
- Safflower		No ¹⁸	
- Soybeans		No ¹⁸	00037045
- Sugar beets		No ¹⁸	00114725
- Tomato		No ¹⁸	
171-4 (j): Magnitude of the Residue in Meat, Milk, Poultry, and Eggs			
- Cattle, goats, hogs, horses, poultry, and sheep	0.05 [180.319]	Yes ^{20,21}	
- Milk	0.05 [180.319]	Yes ²⁰	00037029, 00054669
- Eggs	0.05 [180.319]	No ²¹	
171-4 (f): Nature and Magnitude of the Residue in Potable Water			
171-4 (g): Nature and Magnitude of the Residue in Fish			
165-1: Rotational Crops (Confined)			
		N/A ²²	

9

Table B (continued).

GLN: Data Requirements	Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References ¹
165-2: Rotational Crops (Field)		N/A ²²	
<ol style="list-style-type: none"> 1. References were reviewed in the Residue Chemistry Science Chapter of the Reregistration Standard, dated 8/19/87, unless otherwise noted. 2. CBRS Nos. 8942, 9137, 9166, and 9171, DP Barcodes D171613, D172569, D172742, and D172739, 3/10/93, J. Abbotts. 3. Reference 2, Reference 4, and CBRS No. 13232, DP Barcode D199308, 5/18/94, D. Miller. 4. CBRS No. 12452, DP Barcode D194640, 10/8/93, J. Abbotts. 5. An enforcement analytical method capable of adequately detecting residues of chlorpropham and 4-hydroxychlorpropham-O-sulfonic acid in animal commodities must be developed and validated using radiolabeled samples from the goat metabolism study (no CBRS No. 12/17/93, J. Abbotts). 6. CBRS Nos. 11217, 11422, and 11428, DP Barcodes D186971, D188291, and D188292, 6/21/93, J. Abbotts. 7. CBRS No. 11948, DP Barcode D191727, 7/8/93, J. Abbotts. 8. No storage stability data are available for animal commodities. A ruminant feeding study remains outstanding. Unless tissue and milk samples from the feeding study are analyzed within two weeks of sample collection, storage stability data for residues of chlorpropham and 4-hydroxychlorpropham-O-sulfonic acid in animal commodities will be required. 9. CBRS No. 12695, DP Barcode D195985, 12/9/93, J. Abbotts. 10. These data are currently under review at CBRS (DP Barcode D198109). 11. The USDA had previously indicated that it would support use of chlorpropham on carrots; however, USDA has stated that it does not intend to support this use (Reference 6). Unless the Agency receives notification from USDA or other party of an intent to support reregistration, the interim tolerance for carrot should be revoked. 12. The submitted data pertaining to magnitude of the residue in potato indicate that the established tolerance may be reduced from 50 ppm to 30 ppm (Reference 6); use must be limited to the following maximum use rates: <ul style="list-style-type: none"> • aerosol fog at 0.022 lb ai/1000 lbs potato in each of two applications 90 days apart followed by direct spray at 0.0104 lb ai/1000 lbs potato; or • aerosol fog at 0.033 lbs ai/1000 lbs potato and a second aerosol fog 140 days later at 0.017 lb ai/1000 lbs potato. 13. CBRS No. 11008, DP Barcode D185464, 4/16/93, J. Abbotts. 14. CBRS No. 12273, DP Barcode D193416, 8/11/93, J. Abbotts. 			

10

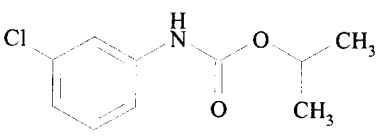
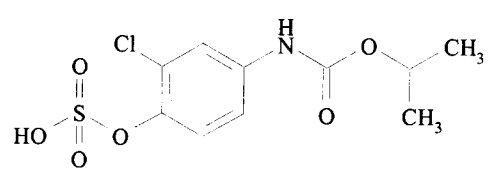
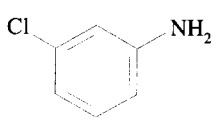
Table B (continued).

15. There are currently no registered uses of chlorpropham on this commodity. We recommend that the interim tolerance for this commodity be revoked.
16. Although SLNs for use of chlorpropham on spinach remain active (DE910001, MD910008, NJ910001, and VA910004), the registrants (Aceto, Elf Atochem, Platte, and Pin Nip) have indicated that they do not wish to support this use. In addition, USDA, which had previously indicated that it would support use of chlorpropham on spinach, has now stated that it does not intend to support this use (Reference 6). Unless the Agency receives notification from USDA or other party of an intent to support reregistration, the interim tolerance for spinach should be revoked.
17. There are currently no registered uses of chlorpropham on soybean. We recommend that established tolerance for soybean be canceled.
18. There are currently no registered uses of chlorpropham on this commodity. We recommend that the tolerance be revoked.
19. The submitted processing studies indicate that food additive tolerances must be proposed for wet peel at 150 ppm and dry peel at 330 ppm, and a feed additive tolerance must be proposed for processed potato waste at 330 ppm (Reference 6)].
20. A ruminant feeding study, reflecting feeding levels of 1x, 3x, and 10x the maximum theoretical dietary burden, is required (Reference 2).
21. Because potato commodities are not significant poultry feed items, a poultry feeding study is not required and the interim tolerance for the eggs, fat, meat, and meat byproducts of poultry should be revoked (Reference 2).
22. The registrants only intend to support postharvest use on stored potatoes. Rotational crop studies are not required to support this use.

with [¹⁴]chlorpropham at 2.4x the maximum registered rate. Although this indicates that little metabolism of chlorpropham occurs in stored potato, some metabolites of chlorpropham were detected (each at <1.3% of TRR), indicating that chlorpropham may metabolize through hydroxylation of the aniline ring or the isopropyl side chain, with subsequent conjugation with carbohydrates or amino acids. Decarbanilation also occurs, forming 3-chloroaniline. The regulated metabolite (1-hydroxy-2-propyl-3-chlorocarbanilate) was not detected, but an oligosaccharide conjugate of this metabolite was detected at 0.03% TRR. The 3-chloroaniline metabolite and its glucose conjugate were also identified at a combined level of 0.58% TRR.

The HED Metabolism Committee has determined that the metabolite 1-hydroxy-2-propyl-3-chlorocarbanilate does not need to be included in the tolerance expression for potato (J. Abbotts, 4/16/93). The Committee also judged that the tolerance expression in potatoes should *not* include the 3-chloroaniline compound, but that a risk assessment for this metabolite should be included in the RED document (D. Miller, 6/1/94). This risk assessment should be performed using anticipated residues of 3-chloroaniline along with the q* associated with 4-chloroaniline. The Committee recognized that this latter assumption may overestimate the risk associated with 3-chloroaniline, but believed that no reliable information exists at this time to refute this assumption. The chemical structures of chlorpropham and 3-chloroaniline are presented in Figure A.

Figure A. Chemical structures of chlorpropham, 4-hydroxychlorpropham-O-sulfonic acid (a residue of concern in animal commodities), and 3-chloroaniline (a potential residue of concern in potato and animal commodities).

Structure Metabolite: Chemical Name	Structure Metabolite: Chemical Name
 <p>Chlorpropham: isopropyl <i>m</i>-chlorocarbanilate</p>	 <p>4-Hydroxychlorpropham-O-sulfonic acid</p>
 <p>3-Chloroaniline</p>	

GLN 171-4 (b): Animal Metabolism

The qualitative nature of the residue in poultry is adequately understood for the purposes of the limited use of chlorpropham. The qualitative nature of the residue in ruminants is adequately understood. The HED Metabolism Committee has determined that the residues to be regulated in animal commodities are chlorpropham and the metabolite 4-hydroxychlorpropham-O-sulfonic acid (J. Abbotts, 12/17/93). The Committee has judged that although 3-chloroaniline should *not* be

included in the tolerance expression, the dietary risk assessment should include the 3-chloroaniline metabolite.

In the poultry metabolism study, laying hens received a single dose of ring-labeled [¹⁴C]chlorpropham at 50 ppm by capsule for seven consecutive days (according to the Table II Update (June 1994), potato commodities are not fed to poultry). The total radioactive residues were 0.468 ppm in liver, 0.455 ppm in kidney, <0.028 ppm in muscle, 0.186 ppm in fat, and 0.153 ppm in skin. Radioactivity levels were highest in day-6 egg yolk and white (0.074 and 0.199 ppm, respectively). The major metabolite isolated from kidney was 4-hydroxychlorpropham-O-glucuronic acid at 9% of TRR. Kidney and liver residues representing 25% and 64% of TRR, respectively, were characterized as 3-chloro-4-hydroxyaniline related compounds. The major residue identified in skin and fat was chlorpropham at 68% and 92% of TRR, respectively. The metabolite 4-hydroxychlorpropham-O-sulfonic acid accounted for 19% of TRR in skin. The major metabolite in egg whites was 3-chloro-4-hydroxyaniline-O-sulfonic acid (22% of TRR) and the major residues in egg yolks were chlorpropham (20% of TRR) and 4-hydroxychlorpropham-O-sulfonic acid (32% of TRR). Chlorpropham was also detected in egg whites (3% of TRR), liver (0.5% of TRR), and kidney (7% of TRR).

In the ruminant metabolism study, two goats were dosed with ring-labeled [¹⁴C]chlorpropham at ca. 34 ppm for seven consecutive days.¹ Total radioactive residues ranged up to 0.341 ppm in liver, to 0.061 ppm in kidney, <0.03 ppm in muscle, and up to 0.041 ppm in fat. Radioactivity levels were highest in day-6 milk of one goat (0.483 ppm) and in day-1 milk of the other goat (0.325 ppm). The major metabolite identified in milk and kidney was 4-hydroxychlorpropham-O-sulfonic acid at 78% of TRR and 32% of TRR, respectively. The major residue in fat was chlorpropham at 84% of TRR. In liver, the major residue identified was 3-chloroaniline, which accounted for 11% of TRR; however, because of the severity of the extraction procedure used to release the 3-chloroaniline residue, it may have been conjugated in the tissue. Minor residues that were identified (each at <10% of TRR) were 4-hydroxychlorpropham (milk and liver), 1,4-dihydroxychlorpropham (liver), 1,4-dihydroxychlorpropham-4-O-sulfonic acid (milk and kidney), 3-chloroacetanilide (kidney and liver), 3-chloro-4-hydroxyacetanilide (kidney), 3-chloro-6-hydroxyaniline (kidney), 3-chloro-4-hydroxyacetanilide-O-sulfonic acid (milk, kidney, and liver), chlorpropham (kidney), chlorpropham carboxylic acid (liver), p-methoxychlorpropham (kidney), and 4-hydroxychlorpropham-O-glucuronic (milk and kidney).

The metabolism of chlorpropham in ruminants and poultry is proposed to proceed through oxidation to 4-hydroxychlorpropham or degradation to 3-chloroaniline. The hydroxychlorpropham is then

¹ Assuming that a typical ruminant diet might consist of 70% to 90% dry matter, this represents a dose rate of ca. 0.15x [i.e., (34 ppm/70% to 90% DM)/280 ppm].

further metabolized to 4-hydroxychlorpropham-O-sulfonic acid or 4-hydroxychlorpropham-O-glucuronide and the aniline is further metabolized to 3-chloro-4-hydroxyaniline-O-sulfonic acid.

GLN 171-4 (c) and (d): Residue Analytical Methods-Plants and Animals

The Pesticide Analytical Manual (PAM) Vol. II list several methods as available for the enforcement of chlorpropham tolerances in 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 Residue Chemistry Science Chapter to the Chlorpropham Reregistration Standard concluded that data collection and enforcement methodology should include hydrolysis steps in order to detect free and conjugated side-chain modified metabolites, such as 1-hydroxy-2-propyl-3-chlorocarbanilate and 3-chloroaniline. The HED Metabolism Committee has determined that the tolerance should be expressed in terms of chlorpropham *per se* at this time, but the RED document should include a discussion of the risk associated with both chlorpropham and the 3-chloroaniline metabolite. A GC method with nitrogen-phosphorus detection has been submitted for the determination of chlorpropham and 3-chloroaniline in potato commodities. The limits of detection are 0.08 ppm for potato, potato pulp, potato peel, and processed wet peel; 0.38 ppm for granules and dried potato peel; and 0.45 ppm for potato chips. Two independent laboratory validations of this method were unsuccessful; therefore, this requirement remains outstanding before this method can be consider adequate for enforcement purposes.

The HED Metabolism Committee has determined that the residues to be included in the tolerance expression in animal commodities are chlorpropham and 4-hydroxychlorpropham-O-sulfonic acid. An enforcement analytical method capable of adequately detecting these residues in animal commodities must be developed and validated using radiolabeled samples from the goat metabolism study.

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).

GLN 171-4 (e): Storage Stability

All data requirements pertaining to chlorpropham storage stability *per se* have been evaluated and deemed adequate. Residues of chlorpropham *per se* are stable during frozen storage at -4°C in potato and wet potato peel for 13 months, in potato chips for 8 months, in potato granules for 9 months, and in processed dry peels for 12 months (D. Miller, CBRS No. 13088).

No storage stability data are available for animal commodities. A ruminant feeding study remains outstanding. Unless tissue and milk samples from the feeding study are analyzed within two weeks of sample collection, storage stability data for residues of chlorpropham and 4-hydroxychlorpropham-O-sulfonic acid in animal commodities will be required.

GLN 171-4 (k): Magnitude of the Residue in Plants

All data requirements pertaining to the magnitude of chlorpropham residue in stored potato have been evaluated and deemed adequate. The submitted data indicate that the established tolerance for potato may be reduced from 50 ppm to 30 ppm, provided that the following treatment rates are not exceeded:

- aerosol fog at 0.022 lb ai/1000 lbs potato in each of two applications 90 days apart followed by direct spray at 0.0104 lb ai/1000 lbs potato; or
- aerosol fog at 0.033 lbs ai/1000 lbs potato and a second aerosol fog 140 days later at 0.017 lb ai/1000 lbs potato.

Data pertaining to 3-chloroaniline residues in potato have also been submitted. However, the HED Metabolism Committee has determined that the tolerance expression will consist of chlorpropham only, and *not* the 3-chloroaniline metabolite. Instead, the magnitude of the 3-chloroaniline residue in potatoes will be incorporated into the risk assessment: adequate magnitude of the 3-chloroaniline residue data for a risk assessment has been submitted.

Adequate magnitude of the residue data are available to support the SLN uses of chlorpropham on spinach. However, chlorpropham registrants have indicated that they intend to support use of chlorpropham on stored potato only and the conclusions of this RED chapter regarding the status of residue chemistry data requirements only reflect that use. If an interested party wishes to support the use of chlorpropham on spinach, then additional residue chemistry data pertaining to plant metabolism, residue analytical methods, storage stability, and rotational crop studies would be required.

GLN 171-4 (l): Magnitude of the Residue in Processed Food/Feed

All data requirements pertaining to the magnitude of chlorpropham residue in processed potato commodities have been evaluated and deemed adequate. Food additive tolerances must be proposed for wet peel at 150 ppm and dry peel at 330 ppm, and a feed additive tolerance must be proposed for processed potato waste at 330 ppm.

GLN 171-4 (j): Magnitude of the Residue in Meat, Milk, Poultry, and Eggs

A ruminant feeding study remains outstanding. Since potato commodities are not significant poultry feed items, a poultry feeding study is not required and tolerances for poultry commodities will not be necessary.

The maximum theoretical dietary burden of chlorpropham for ruminants is estimated to be 280 ppm (dry matter basis) based on a diet consisting of 75% processed potato waste (dry peel) consisting of 88.6% dry matter.

GLNs 165-1 and 165-2: Confined/Field Rotational Crops

Rotational crop studies are not required to support use of chlorpropham on stored potato.

TOLERANCE REASSESSMENT SUMMARY

The HED Metabolism Committee has determined that the residue to be included in the tolerance expression for stored potato is chlorpropham *per se* and that the residues to be regulated in the tolerance expression for ruminant and swine commodities are chlorpropham and 4-hydroxychlorpropham-O-sulfonic acid.

Tolerances Listed Under 40 CFR §180.181:

The tolerances listed in 40 CFR §180.181 are expressed in terms of the combined residues of chlorpropham and 1-hydroxy-2-propyl-3-chlorocarbanilate. The tolerance expression should be revised to reflect residues of chlorpropham *per se*. Sufficient data are available to assess the adequacy of the established tolerance for potato. The data indicate that the tolerance may be reduced from 50 ppm to 30 ppm, provided that the following treatment rates are not exceeded:

- aerosol fog at 0.022 lb ai/1000 lbs potato in each of two applications 90 days apart followed by direct spray at 0.0104 lb ai/1000 lbs potato; or
- aerosol fog at 0.033 lbs ai/1000 lbs potato and a second aerosol fog 140 days later at 0.017 lb ai/1000 lbs potato.

Chlorpropham registrants have indicated that they wish to support use of chlorpropham only on stored potato. Therefore, the established tolerance for soybeans should be revoked.

Tolerances Listed Under 40 CFR §180.319 (interim tolerances):

The tolerances listed in 40 CFR §180.319 for chlorpropham are expressed in terms of residues of chlorpropham *per se*.

Insufficient data are available to assess the adequacy of the interim tolerances for milk, and the fat, meat, and meat byproducts of cattle, goats, hogs, horses, and sheep. A ruminant feeding study remains outstanding. At such time that appropriate tolerance levels for these commodities are determined, the interim tolerances should be revoked and tolerances for combined residues of

chlorpropham and 4-hydroxychlorpropham-O-sulfonic acid in these commodities should be established under 40 CFR §180.181.

Chlorpropham registrants have indicated that they wish to support use of chlorpropham only on stored potato. Therefore, the interim tolerances for alfalfa, alfalfa hay, beans (dry and succulent), blackberries, blueberries, carrots, clover, clover hay, cranberries, garlic, grass, grass hay, onions, peas (dry and succulent), raspberries, rice grain, safflower seed, spinach, sugar beet roots and tops, and tomatoes should be revoked.

CBRS has determined that tolerances for poultry commodities are not required since potato commodities are not a significant poultry feed item. Therefore, the interim tolerances for eggs, and the fat, meat, and meat byproducts of poultry should be revoked.

Food and Feed Additive Tolerances to be Proposed (40 CFR §185.xxxx and §186.xxxx):

An adequate potato processing study has been conducted. Food additive tolerances must be proposed for residues of chlorpropham *per se* in potato wet peel at 150 ppm and in potato dry peel at 330 ppm. A feed additive tolerance must be proposed for residues of chlorpropham *per se* in processed potato waste at 330 ppm.

A summary of chlorpropham tolerance reassessment is presented in Table C.

CODEX HARMONIZATION

There are no Codex MRLs established or proposed for residues of chlorpropham. Therefore, there are no questions with respect to compatibility of U.S. tolerances with Codex MRLs.

DIETARY EXPOSURE ASSESSMENT SUMMARY

As part of the Chlorpropham RED process, a dietary exposure assessment is needed for residues of chlorpropham and its 3-chloroaniline metabolite as a result of treatment with chlorpropham. We recommend that the re-assessed tolerance levels for chlorpropham and the anticipated residues for the 3-chloroaniline metabolite be used by DRES to estimate dietary risk.

CBRS has estimated exposures to both chlorpropham *per se* and to the 3-chloroaniline metabolite which was detected in certain commodities during the plant and animal metabolism studies. These exposure estimates are described in more detail below.

Table C. Tolerance Reassessment Summary for Chlorpropham			
Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/Correct Commodity Definition
Tolerances listed under 40 CFR §180.181			
Potatoes (POST-H)	50	30	Potato
Soybeans	0.2	Revoke	No registered uses
Tolerances listed under 40 CFR §180.319 (interim tolerances)			
Alfalfa	20	Revoke	No registered uses
Alfalfa hay	50	Revoke	No registered uses
Beans (dry and succulent)	0.3	Revoke	No registered uses
Blackberries	0.3	Revoke	No registered uses
Blueberries	0.3	Revoke	No registered uses
Carrots	0.1	Revoke	No registered uses
Cattle, fat	0.05	To be determined	To be determined following ruminant feeding study
Cattle, mbyop	0.05	To be determined	To be determined following ruminant feeding study
Cattle, meat	0.05	To be determined	To be determined following ruminant feeding study
Clover	20	Revoke	No registered uses
Clover hay	50	Revoke	No registered uses
Cranberries	0.3	Revoke	No registered uses
Eggs	0.05	Revoke	Tolerances for poultry commodities are not required.
Garlic	0.1	Revoke	No registered uses
Goats, fat	0.05	To be determined	To be determined following ruminant feeding study
Goats, mbyop	0.05	To be determined	To be determined following ruminant feeding study
Goats, meat	0.05	To be determined	To be determined following ruminant feeding study
Grass	20	Revoke	No registered uses
Grass hay	50	Revoke	No registered uses
Hogs, fat	0.05	To be determined	To be determined following ruminant feeding study
Hogs, mbyop	0.05	To be determined	To be determined following ruminant feeding study
Hogs, meat	0.05	To be determined	To be determined following ruminant feeding study

Table C (continued).

Table C. Tolerance Reassessment Summary for Chlorpropham			
Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/Correct Commodity Definition
Horses, fat	0.05	To be determined	To be determined following ruminant feeding study
Horses, mbyop	0.05	To be determined	To be determined following ruminant feeding study
Horses, meat	0.05	To be determined	To be determined following ruminant feeding study
Milk	0.05	To be determined	To be determined following ruminant feeding study
Onions	0.1	Revoke	No registered uses
Peas (dry and succulent)	0.3	Revoke	No registered uses
Poultry, fat	0.05	Revoke	Tolerances for poultry commodities are not required.
Poultry, mbyop	0.05	Revoke	Tolerances for poultry commodities are not required.
Poultry, meat	0.05	Revoke	Tolerances for poultry commodities are not required.
Raspberries	0.3	Revoke	No registered uses
Rice grain	0.1	Revoke	No registered uses
Safflower seed	0.1	Revoke	No registered uses
Sheep, fat	0.05	To be determined	To be determined following ruminant feeding study
Sheep, mbyop	0.05	To be determined	To be determined following ruminant feeding study
Sheep, meat	0.05	To be determined	To be determined following ruminant feeding study
Spinach	0.3	Revoke	No registered uses
Sugar beet roots	0.1	Revoke	No registered uses
Sugar beet tops	0.3	Revoke	No registered uses
Tomatoes	0.1	Revoke	No registered uses
Tolerances to be proposed			
Potato, wet peel	N/A	150	
Potato, dry peel	N/A	330	
Potato, waste from processing	N/A	330	

19

Table D. Summary of Re-assessed (and Current) Tolerances for Chlorpropham for Use in DRES Analysis ^a	
Commodity	Reassessed (or Current) Tolerance (ppm)
Potatoes	30
Cattle, fat	(0.05) ^a
Cattle, mbyp	(0.05) ^a
Cattle, meat	(0.05) ^a
Goats, fat	(0.05) ^a
Goats, mbyp	(0.05) ^a
Goats, meat	(0.05) ^a
Hogs, fat	(0.05) ^a
Hogs, mbyp	(0.05) ^a
Hogs, meat	(0.05) ^a
Horses, fat	(0.05) ^a
Horses, mbyp	(0.05) ^a
Horses, meat	(0.05) ^a
Milk	(0.05) ^a
Sheep, fat	(0.05) ^a
Sheep, mbyp	(0.05) ^a
Sheep, meat	(0.05) ^a
Potato, wet peel	150
Potato, dry peel	330
Potato, processing waste	330
^a Those tolerances appearing in parenthesis are current CFR interim tolerances. These will be reassessed when the information from ruminant feeding studies becomes available.	

20

Exposure Assessment for Chlorpropham *per se*

We recommend that the reassessed tolerances for chlorpropham in potato and processed potato commodities be used to estimate dietary risk from chlorpropham *per se*. Reassessment of the tolerances associated with meat and milk products is not possible at this time since feeding studies with cattle ("Magnitude of the Residue in Ruminants") have not yet been performed by the registrant. When this information becomes available, the current tolerances associated with these commodities will be reassessed. Table D provides a summary of these reassessed tolerances as well as the current tolerances for those commodities for which adequate information is not available. This information should be used by DRES to estimate risks associated with chlorpropham *per se*.

Exposure Assessment for 3-Chloroaniline

The HED Metabolism Committee decided that the carcinogenic risk due to the 3-chloroaniline metabolite should be assessed: since no data are available on the cancer potency of the 3-CA metabolite, this risk was to be calculated using the cancer potency factor (i.e., the q^*) available for the 4-CA isomer. The Committee recognized that using the q^* value for 4-CA in place of an actual q^* for 3-CA may overestimate the risk associated with 3-CA, but believed that this approach was appropriate since no information was available to suggest that 3-CA is any less carcinogenic than 4-CA.

CBRS has developed the anticipated residues for use in assessing the dietary risk of the 3-chloroaniline metabolite under two scenarios: these are a "typical" risk scenario which represents an estimate of exposure on a national basis and uses more realistic assumptions, and an upperbound estimate which uses more conservative (i.e., health protective) assumptions to estimate exposures to consumers in a local milkshed. In each case, field trial studies and potato processing studies were reviewed to provide estimates of 3-chloroaniline concentrations following actual post-harvest fumigation of stored potatoes. To provide exposure estimates for populations residing in a local milkshed, metabolism study data was used along with certain assumptions regarding the percent of the potato crop which is treated and the dietary burden. The major differences in the assumptions used in these two scenarios are highlighted in the following matrix:

Risk Scenario	Exposure Scenario	
	Potatoes	Beef and Milk
Local Milkshed Case	<ul style="list-style-type: none"> • 3-CA concentration in potatoes and processed potatoes derived from <u>highest</u> 3-CA field-trial concentration detected • Chlorpropham is assumed to concentrate in processed potato commodities at highest observed concentration factor 	<ul style="list-style-type: none"> • Chlorpropham dietary burden derived from highest chlorpropham field trial concentration • 3-CA assumed to be present in milk at 1/2 the LOD • Chlorpropham is assumed to concentrate in processed potato waste at highest observed concentration factor • Beef and dairy cow diet assumed to consist of 75% and 50% processed potato waste, respectively; no consumption of culled potatoes by cattle is assumed
Typical Case	<ul style="list-style-type: none"> • 3-CA concentration in potatoes and processed potatoes derived from the <u>average</u> of the 3-CA concentrations detected at the 15 day, 30 day, 60 day, 90 day, and 106-day storage period • Chlorpropham is assumed to concentrate in processed potato commodities at highest observed concentration factor 	<ul style="list-style-type: none"> • Assumes that no exposure occurs through beef and milk, since beef and milk production center is not in a local potato shed

CBRS has reviewed the post-harvest fumigation field trial data on potatoes to develop a estimated exposures under the "typical" and "local milkshed" exposure assumptions. The derivation of the anticipated residues and associated risks are detailed in a previous CBRS memorandum (D. Miller, 6/24/94). The anticipated residues under the "local milkshed" and "typical" cases are presented in columns (1) and (2) of Table E, respectively². We recommend that these anticipated residues be used by DRES for risk assessment to estimate the carcinogenic risk associated with 3-chloroaniline.

² Note that livestock commodities are not assumed to contain residues of 3-CA under the "typical" scenario since a typical consumer is not assumed to live in a milkshed in which potato peelings are fed to beef and dairy cattle.

22

Table E. Summary of Anticipated Residue Values for Dietary Risk Assessment Under "Local Milkshed" and "Typical" Case Exposure Scenarios for Use in DRES Analysis			
Food Code	Food Name/Food Form	Anticipated Residue (ppm)	
		(1) Upperbound Case Risk Scenario	(2) Typical Case Risk Scenario
14013AA	Potatoes(White)--Whole		
	10 Raw	0.406	0.059
	20 Cooked NFS	0.406	0.059
	30 Cooked-Fresh Baked	0.406	0.059
14013AB	Potatoes(White)--Unspec. 22 Cooked-Fresh Baked	0.406	0.059
14013AC	Potatoes(White)--Peeled		
	21 Cooked-NFS	0.126 ^a	0.018 ^a
	22 Cooked-Fresh Baked	0.126 ^a	0.018 ^a
	23 Cooked-Fresh Boiled	0.126 ^a	0.018 ^a
	25 Cooked-Fresh Fried	0.284	0.041 ^b
14013DA	Potatoes(White)--Dry		
	10 Raw-Fresh or NFS 31 Cooked-Fr. or Can.	0.406 0.406	0.059 0.059
14013HA	Potatoes(White)--Peel Only 22 Cooked-Fresh Baked	6.58 ^c	0.958 ^c
53001A	Beef(Organ Meats)--Liver		
	25 Cooked-Fresh-Fried 31 Cooked-Fresh or Canned	0.039 0.039	-- --
50000DB	Milk--Non-fat Solids		
	10 Raw-Fresh or NFS	0.002 ^d	--
	21 Cooked-NFS 51 Cooked-Canned	0.002 ^d 0.002 ^d	-- --
50000FA	Milk--Fat Solids		
	10 Raw-Fresh or NFS	0.002 ^d	--
	20 Cooked-NFS 51 Cooked-Canned	0.002 ^d 0.002 ^d	-- --
50000SA	Milk Sugar(Lactose)		
	21 Cooked-NFS 51 Cooked-Canned	0.002 ^d 0.002 ^d	-- --

Table E. Summary of Anticipated Residue Values for Dietary Risk Assessment Under "Local Milkshed" and "Typical" Case Exposure Scenarios for Use in DRES Analysis

^a The registrant did not supply data for concentrations of 3-CA in peeled potatoes. However, an article appearing in *Pesticide Science* demonstrates that approximately 70% of the radioactivity is present in the skin of the tuber (Coxon, DT and A Filmer, 1985, *Pesticide Science* 16:355-63). Thus, the ppm values shown here were calculated by assuming that 70% of the residues are present in 5% of the potato (which represents peel). The calculation also assumes that 60% of the potatoes are treated with chlorpropham.

^b The registrant did not peel the potatoes prior to frying them and determining 3-CA concentrations. CBRS calculated the anticipated residues in fresh fried potatoes by assuming that (i) 70% of the residues are present in the peel; (ii) the peel represents 5% of the whole tuber weight; (iii) 95% of the fresh fried potatoes (french fries and potato chips) are peeled prior to processing. The calculation also assumes that 60% of the potatoes are treated with chlorpropham.

^c This value is assumed to equal the value for processed dry peel.

^d Although 3-CA was not detected in milk during the metabolism study, these upperbound case assumptions are calculated using the one-half the LOD value.

AGENCY MEMORANDA CITED IN THIS DOCUMENT

CBRS No(s): 8942, 9137, 9166, and 9171
DP Barcodes: D171613, D172569, D172742, and D172739
Subject: Chlorpropham. Chlorpropham Task Force Response to the Reregistration Standard: Nature of the Residue in Postharvest Potatoes, Nature of the Residue in Ruminants and Poultry, and Analytical Methods for Potatoes.
From: J. Abbotts, CBRS, HED
To: L Rossi, SRRD
Dated: 3/10/93
MRID(s): 42085601, 42112201, 42123101, and 42130401

CBRS No.: None
DP Barcode: None
Subject: Chlorpropham. Reregistration Case No. 0271. Issues to be Presented at the 3/16/93 Meeting of the HED Metabolism Committee.
From: J. Abbotts, CBRS, HED
To: HED Metabolism Committee
Dated: 3/10/93
MRID(s): None

CBRS No.: None
DP Barcode: None
Subject: Results of the HED Metabolism Committee Meeting Held on 3/22/93: Chlorpropham Metabolism in Potatoes.
From: J. Abbotts, CBRS, HED
To: HED Metabolism Committee
Dated: 3/31/93
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, CBRS, HED
To: V. Eagle, SRRD
Dated: 4/16/93
MRID: 42566801

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, CBRS, HED
To: V. Eagle, SRRD
Dated: 4/16/93
MRID(s): None

CB No.: 11846
DP Barcode: D191079
Subject: Chlorpropham. SLN 24(c) for Use on Overwintered Spinach in the State of Delaware. SLN No. DE-91-0001.
From: M. Flood, CBTS, HED
To: C. Giles-Parker/J. Stone, RD
Dated: 5/24/93
MRID(s): None

CBRS No(s).: 11217, 11422, and 11428
DP Barcodes: D186971, D188291, and D188292
Subject: Chlorpropham. Chlorpropham Task Force Response to the Reregistration Standard: Analytical Method, Magnitude of the Residue in Postharvest Potatoes, Potato Processed Commodities, and Storage Stability.
From: J. Abbotts, CBRS, HED
To: V. Eagle, SRRD
Dated: 6/21/93
MRID(s): 42610301, 42653401, 42653601, 42653701, 42653801, 42653901, 42660101, and 42660201

CBRS No.: 11948
DP Barcode: D191727
Subject: Chlorpropham Reregistration. Independent Laboratory Validation of an Analytical Method.
From: J. Abbotts, CBRS, HED
To: V. Eagle, SRRD
Dated: 7/8/93
MRID: 42778901

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, CBRS, HED

To: V. Eagle, SRRD

Dated: 8/11/93

MRID(s): None

CBRS No.: 12452

DP Barcode: D194640

Subject: Chlorpropham Reregistration. Chlorpropham Task Force Submission of Supplemental Data: Nature of the Residue in Animals.

From: J. Abbotts, CBRS, HED

To: V. Eagle, SRRD

Dated: 10/8/93

MRID(s): None

CBRS No.: None

DP Barcode: None

Subject: Chlorpropham. Reregistration Case No. 0271. Issues to be Presented at the 11/5/93 Meeting of the HED Metabolism Committee.

From: J. Abbotts, CBRS, HED

To: HED Metabolism Committee

Dated: 11/5/93

MRID(s): None

CBRS No.: 12695

DP Barcode: D195985

Subject: Chlorpropham Reregistration. Chlorpropham Task Force Submission of Additional Data on Storage Stability.

From: J. Abbotts, CBRS, HED

To: V. Eagle, SRRD

Dated: 12/9/93

MRID: 42958301

CBRS No.: None

DP Barcode: None

Subject: Chlorpropham Reregistration. Conclusions of the HED Metabolism Committee.

From: J. Abbotts, CBRS, HED

To: F. Chow, HED

Dated: 12/17/93
MRID(s): None

CBRS No.: None
DP Barcode: None
Subject: Chlorpropham Reregistration. Conclusions of the HED Metabolism Committee.
From: J. Abbotts, CBRS, HED
To: W. Waldrop/V. Eagle, SRRD
Dated: 12/17/93
MRID(s): None

CBRS No.: None
DP Barcode: None
Subject: Chlorpropham. Metabolism Committee Decision Re: Regulation of 3-CA Metabolite.
From: D. Miller, CBRS, HED
To: Metabolism Committee
Dated: 3/30/94
MRID(s): None

CBRS No.: 12232
DP Barcode: D199308
Subject: Response to Chlorpropham Task Force's January 8 1994 Request for Additional Information and Submission of Supplemental Data
From: D. Miller, CBRS, HED
To: V. Eagle, SRRD
Dated: 5/18/94
MRID(s): None

CBRS No.: None
DP Barcode: None
Subject: Chlorpropham. Determination of Anticipated Residues of 3-Chloroaniline Metabolite in Poultry, Beef, and Milk Commodities for Use in DRES Analysis and in the Chlorpropham RED Document.
From: D. Miller, CBRS, HED
To: CBRS Files
Dated: 6/24/94
MRID(s): None

CBRS No.: None
DP Barcode: None
Subject: Chlorpropham. Outcome of 5/19/94 Meeting of HED Metabolism Committee.
From: D. Miller, CBRS, HED
To: HED Metabolism Committee
Dated: 6/1/94
MRID(s): None

CBRS No.: None
DP Barcode: None
Subject: Chlorpropham. Outcome of 6/9/94 Meeting of HED Metabolism Committee Meeting.
From: D. Miller, CBRS, HED
To: HED Metabolism Committee
Dated: --
MRID(s): None

CBRS No.: 13088
DP Barcode: D198109
Subject: Chlorpropham. Storage Stability on Potatoes (whole, dehydrated granules, peels, wet peels, and dry peels).
From: D. Miller, CBRS, HED
To: Venus Eagle, SRRD
Dated: --
MRID(s): 430536-01

MASTER RECORD IDENTIFICATION NUMBERS

References used to support established tolerance for potatoes:

00035896 Wiedmann, J.L.; Pensyl, J. (1975) Proposed Regulatory Method for CIPC Residue (CIPC + Metabolite III): BR 19718. Method dated May 2, 1975. (Unpublished study received May 8, 1975 under 4F1429; submitted by PPG Industries, Inc., Barberton, Ohio; CDL: 093811-D)

00037029 Ware, G.W.; Brakel, W.J. (1963) Excretion of 3-C1-aniline and Isopropyl-N-(3-Chlorophenyl) carbamate (CIPC) in the milk and urine of dairy cows fed CIPC. Journal of Dairy Science XLVI(2): 120-123. (Also in unpublished submission received on unknown date under 4F1429; submitted by Pittsburgh Plate Glass Co., Morristown, N.J.; CDL:093807-P)

00045294 PPG Industries, Incorporated (1969) General Analytical Method for Determining CIPC Residues in Crops Designated in the Summary Table as Being Analyzed by MF (Ext.). (Unpublished study received Dec 31, 1970 under 1F1119; CDL:093430-D)

00045295 PPG Industries, Incorporated (1968) General Analytical Method for Determining CIPC Residues in Crops Designated in the Summary Table as Being Analyzed by the MF (TCH-Dist) Method. (Unpublished study received Dec 31, 1970 under 1F1119; CDL:093430-E)

00054669 Ware, G.W.; Brakel, W.J. (1963) Excretion of 3-Cl-aniline and Isopropyl-N-(3-chlorophenyl) carbamate (CIPC) in the milk and urine of dairy cows fed CIPC. Journal of Dairy Science 46:120-123. (Also in unpublished submission received Aug 26, 1977 under 4581-EX-30; submitted by Pennwalt Corp., Philadelphia, Pa.; CDL: 231831-L)

00054672 Dave, B. (1977) Residue Data of CIPC on Potatoes. (Unpublished study received Aug 26, 1977 under 4581-EX-30; submitted by Pennwalt Corp., Philadelphia, Pa.; CDL:231831-T)

00083155 Gard, L.N. (1959) Determination of isopropyl N-(3-chlorophenyl) carbamate residues in potatoes treated for sprout inhibition. Journal of Agricultural and Food Chemistry 7(5):339-341. (Also in unpublished submission received Dec 1, 1959 under PP0234; submitted by Columbia-Southern Chemical Corp., Pittsburgh, Pa.; CDL:090262-G)

00114695 Fredenburg, R. (1960) Letter sent to E. Plant dated Nov 8, 1960: [Emulsifiable sprout nip: Chloro-IPC]. (Unpublished study received Feb 14, 1961 under 748-182; submitted by PPG Industries, Inc., Barberton, OH; CDL:024269-B)

00114700 Kennedy, G.; Jenkins, D. (1970) Report to PPG Industries, Inc.: Distribution of CIPC in Milk and Tissues of a Lactating Cow: IBT No. J8629A. (Unpublished study received on unknown date under 1F1119; prepared by Industrial Bio-Test Laboratories, Inc., submitted by PPG Industries, Inc., Barberton, OH; CDL:090892-I)

00114701 Kennedy, G. (1970) Report to PPG Industries, Inc.: Tissue and Egg Residue Study of CIPC in White Leghorn Chickens: IBT No. J8630A. (Unpublished study received on unknown date under 1F1119; prepared by Industrial Bio-Test Laboratories, Inc., submitted by PPG Industries, Inc., Barberton, OH; CDL:090892-J)

00114710 Pittsburgh Plate Glass (1967) [Study: CIPC Residue on Selected Crops]. (Compilation; unpublished study received Aug 23, 1967 under 8F0690; CDL:091198-A)

00114715 PPG Industries, Inc. (1972) Petition of PPG Industries, Inc. Pursuant to Section 408 (d)(1) of the Federal Food, Drug and Cosmetic Act with Respect to the Pesticide Chemical Chlorpropham. (Compilation; unpublished study received Jun 1, 1972 under 2F1276; CDL:092107-A)

00114718 Columbia-Southern Chemical Corp. (1960) [Analyses for Residues of CIPC and Other Chemicals in Potatoes]. (Compilation; unpublished study received on unknown date under PP0234; CDL: 092511-A)

00114739 PPG Industries, Inc. (1974) [Analyses for Residues of CIPC Chemicals in Various Products]. (Compilation; unpublished study received on unknown date under 4F1429; CDL:098173-A)

00114741 Columbia Southern Chemical Corp. (1960) [Analyses for Residues of CIPC Chemicals in Potatoes]. (Compilation; unpublished study received on unknown date under PP0234; CDL:098745-A)

00114747 PPG Industries, Inc. (1961) [Analyses for Residues of CIPC in Potatoes]. (Compilation; unpublished study received Mar 17, 1961 under unknown admin. no.; CDL:120933-A)

00114750 Food Machinery and Chemical Corp. (1956) Sprout Control in Irish Potatoes. (Unpublished study received on unknown date under unknown admin. no.; CDL:120940-A)

00114751 Gard, L. (1957?) Determination of ... (CIPC) Residues in Potatoes Treated for Sprout Inhibition. (Unpublished study received Nov 24, 1958 under unknown admin. no.; submitted by PPG Industries, Inc., Barberton, OH; CDL:120941-A)

00114777 Agchem (1978) [Analyses for Residues of CIPC in Potatoes]. (Compilation; unpublished study received Aug 14, 1978 under 4581-EX- 30; CDL:234638-A)

00114785 Agchem (1978) Residue Data of CIPC on Potatoes. (Compilation; unpublished study received Nov 21, 1978 under 4581-338; CDL: 235995-G)

00114795 PPG Industries, Inc. (1979) Summary of 1978-1979 Tests Using Decco Brand CIPC-AR under EPA Permit #4581-EUP-30. (Compilation; unpublished study received Jul 18, 1979 under 4581-EX-30; CDL: 238857-A)

- 00115388 PPG Industries, Inc. (1967) [CIPC: Residues in Milk and Other Subjects]. (Compilation; unpublished study received on unknown date under 1F1120; CDL:090894-A)
- 05016141 Ebing, W. (1972) Routine methode zur Duenschichtchromatographischen Identifizierung der Pestizidrueckstaende aus den Klassen der Triazine, Carbamate, Harnstoffe und Uracile_ [Routine method for identification of pesticide residues of triazine, carbamate, urea, and uracil type compounds by thin-layer chromatography_] Journal of Chromatography 65(3):533-545.
- 42085601 Kim-Kang, H. (1991) Metabolism of Carbon fourteen Chlorpropham in Stored Potatoes: Nature of the Residue in Potatoes: Lab Project Number: XBL 89070: RPT0066. Unpublished study prepared by XenoBiotic Laboratories, Inc. 167 p.
- 42112201 Wu, D. (1991) Metabolism of Carbon 14-Chlorpropham in Lactating Goats: Metabolite Analysis and Quantitation in Milk and Tissues: Final Report: Lab Project Number: XBL 90055: RPT0061. Unpublished study prepared by XenoBiotic Laboratories, Inc. 231 p.
- 42123101 Moller, G. (1991) Analytical Method for Magnitude of Residues in Stored Potatoes from Postharvest Treatments of Chlorpropham: Final Report: Lab Project Number: 91CIPC01. Unpublished study prepared by Univ. of Idaho Analytical Lab, Holm Research Ctr. 87 p.
- 42130401 Wu, D. (1991) Metabolism of Carbon 14-Chlorpropham in Laying Hens: Metabolite Analysis and Quantitation in Eggs and Tissues: Lab Project Number: XBL 90053: RPT0073. Unpublished study prepared XenoBiotic Labs, Inc. 228 p.
- 42566801 Wulf, L. (1992) Final Report: Chlorpropham and 3-Chloroaniline Residue Study on Potatoes, Potato Skins, Potato Chips and Potato Granules After Post-Harvest Fumigation: Lab Project Number: 92-001. Unpublished study prepared by Hibbs Analytical Laboratories, Inc. 51 p.
- 42610301 Kleinkopf, G.; Thomson, C. (1992) In-life Phase Study: Magnitude of Residues in Stored Potatoes from Postharvest Treatments of Chlorpropham: Lab Project Number: 92CIPC02. Unpublished study prepared by University of Idaho. 151 p.
- 42653401 Walker, G.; Goodrick, B.; Haws, R.; et al. (1993) Analytical Method for Magnitude of Residues in Stored Potatoes from Postharvest Treatments of Chlorpropham: An Addendum: Lab Project Number: 92CIPC01. Unpublished study prepared by University of Idaho. 323 p.
- 42653601 Goodrick, B.; Haws, R.; Walker, G.; et al. (1993) Magnitude of the Residues of Chlorpropham and Major Metabolites in or on Stored Potatoes Intended for the Fresh Market: Lab Project Number: 92CIPC04. Unpublished study prepared by University of Idaho. 193 p.
- 42653701 Swanson, B.; Younce, F.; Englar, J.; et al. (1993) Processing of Stored Potatoes Treated Postharvest with Chlorpropham to Determine Magnitude of Residues in Processed Potato Fractions: Lab Project Number: 92CIPC03. Unpublished study prepared by Washington State Univ. 76 p.

42653801 Goodrick, B.; Haws, R.; Walker, G.; et al. (1993) Magnitude of the Residues of Chlorpropham and Major Metabolites in or on Stored Potatoes Intended for Processing into Potato Chips: Lab Project Number: 92CIPC06. Unpublished study prepared by University of Idaho. 181 p.

42653901 Goodrick, B.; Haws, R.; Walker, G.; et al. (1993) Magnitude of the Residues of Chlorpropham and Major Metabolites in or on Stored Potatoes Intended for Processing into Frozen or Dehydrated Products: Lab Project Number: 92CIPC05. Unpublished study prepared by University of Idaho. 181 p.

42660101 Haws, R.; Goodrick, B.; Walker, G.; et al. (1993) Determination of Storage Stability of Field-Incurred Residues of Chlorpropham and Metabolites of Concern in or on Fresh, Stored and Processed Potatoes: Lab Project Number: 92CIPC08. Unpublished study prepared by University of Idaho. 81 p.

42660201 Haws, R.; Goodrick, B.; Walker, G.; et al. (1993) Magnitude of the Residues of Chlorpropham and Major Metabolites in or on Processed Potato Products and Peels: Lab Project Number: 92CIPC07. Unpublished study prepared by University of Idaho. 425 p.

42778901 Boggess, K. (1993) Validation of a Method for the Determination of Chlorpropham (CIPC) and Other Target Analytes from Potato Matrices: Lab Project Number: 3304-F. Unpublished study prepared by Midwest Research Institute. 60 p.

42958301 Haws, R.; Goodrick, B.; Walker, G.; et al. (1993) Addendum 1 to Report 92CIPC08: Determination of Storage Stability of Field-Incurred Residues of Chlorpropham and Metabolites of Concern in or on Fresh, Stored and Processed Potatoes: Lab Project Number: 92CIPC08. Unpublished study prepared by Univ. of Idaho Analytical Lab. 91 p.

43053601 Goodrick, B.; Haws, R.; Moller, G. (1993) Determination of Storage Stability of Fortified Residues of Chlorpropham and Metabolites of Concern in/on Fresh, Stored, and Processed Potatoes: Lab Project Number: 93CIPC02. Unpublished study prepared by University of Idaho Analytical Lab. 273 p.