

US EPA ARCHIVE DOCUMENT



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

July 1, 1999

**MEMORANDUM**

**SUBJECT:** Chlorpropham (018301), Addendum to the Chemistry Chapter of the RED; Analytical Method Requirements [HPLC/UV Method for Data Collection] (860.1340), DP Barcode D240103, MRID No. 44397101, Case No. 0271.

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

**Through:** Steve Knizner, Senior Scientist  
Reregistration Branch 3  
Health Effects Division [7509C]

**To:** Patricia Moe, Chemical Review Manager  
Reregistration Branch 3  
Special Review and Reregistration Division [7508C]

Attached is a review of an E.R. Butts International, Inc. submission (on behalf of Pin Nip, Inc) entitled "Analytical Method in the Plant - Analysis of Chlorpropham and 3-Chloroaniline in Potato Peels, Pulp, Chips, and Granules" (1997, MRID 44397101). The accompanying 8/14/97 transmittal letter stated that the submission is intended to satisfy reregistration requirements under OPP GLN 171-4(c); this GLN is now referred to as OPPTS GLN 860.1340.

This information was initially reviewed by Dynamac Corporation and underwent secondary review by HED. HED makes the following conclusions with respect to the submitted studies:

HED acknowledges receipt of Pin Nip's descriptions of an HPLC/UV method that was used in the analysis of samples collected in studies pertaining to magnitude of the residue in postharvest potatoes and potato processed commodities. These residue studies along with the data collection method were previously reviewed by the Agency (DP Barcode D185464, 4/16/93, J. Abbotts; and DP Barcode D193416, 8/11/93, J. Abbotts). The data collection method was adequately described and deemed acceptable based on acceptable recoveries of chlorpropham and 3-chloroaniline. However, the latter review required that the method be subjected to further method validation (preferably using radiolabeled samples from metabolism studies) for its ability to detect conjugated 3-chloroaniline. This requirement was subsequently waived by HED's Greybeard Committee (D235550, 6/12/97) based on the consideration that 3-chloroaniline is no longer considered to be of regulatory concern and is not a metabolite named in the tolerance expression (DP Barcode D239919, 10/27/97, D. Miller).

HED reiterates that the submitted HPLC/UV method (MRID 44397101) had been previously described and deemed adequate for *data collection* purposes. HED concludes that a GC/NPD method is available for the purpose of enforcing tolerances for residues of chlorpropham *per se* in/on plant commodities.

cc: RF, List B File, S.Knizner, D. Drew, R. Hawks, P. Moe (SRRD).  
RDI: Seve Knizner 7/9/99.

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**CHLORPROPHAM**  
**PC Code 018301; Case No. 0271**  
**(DP Barcode D240103)**

**Addendum To The Residue Chemistry Chapter Of The**  
**Reregistration Eligibility Decision (RED) Document**

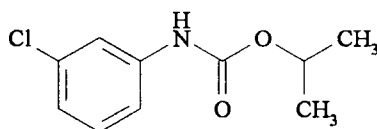
**April 5, 1999**

**Contract No. 68-D4-0010**

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

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

## CHLORPROPHAM



PC Code 018301; Case No. 0271

(DP Barcode D240103)

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

#### INTRODUCTION

E.R. Butts International, Inc., on behalf of Pin Nip, Inc., and in support of reregistration has submitted descriptions of an HPLC/UV method (1997; MRID 44397101) entitled "Analytical Method in the Plant - Analysis of Chlorpropham and 3-chloroaniline in Potato Peels, Pulp, Chips, and Granules". The accompanying 8/14/97 transmittal letter stated that the submission is intended to satisfy reregistration requirements under OPP GLN 171-4(c); this GLN is now referred to as OPPTS GLN 860.1340.

The Product and Residue Chemistry Chapters for Chlorpropham RED were issued 7/1/94. According to the Residue Chemistry Chapter for 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 Elf Atochem N.A., Inc., the basic producers. Pin Nip, Inc. is also actively but separately pursuing the reregistration of its chlorpropham end-use product (EPA Reg. No. 65726-1).

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).

Tolerances are currently 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 and soybeans at 0.2 ppm [40 CFR §180.181]. Interim tolerances have been established for residues of chlorpropham in/on plant and animal commodities [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,

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and grass. No food/feed additive tolerances have been established. No Codex MRLs are established or proposed for residues of chlorpropham. 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

HED acknowledges receipt of Pin Nip's descriptions of an HPLC/UV method that was used in the analysis of samples collected in studies pertaining to magnitude of the residue in postharvest potatoes and potato processed commodities. These residue studies along with the data-collection method were previously reviewed by the Agency (DP Barcode D185464, 4/16/93, J. Abbotts; and DP Barcode D193416, 8/11/93, J. Abbotts). The data-collection method was adequately described and deemed acceptable based on acceptable recoveries of chlorpropham and 3-chloroaniline. However, the latter review required that the method be subjected to further method validation (preferably using radiolabeled samples from metabolism studies) for its ability to detect conjugated 3-chloroaniline. This requirement was subsequently waived by HED's Greybeard Committee (D235550, 6/12/97) based on the consideration that 3-chloroaniline is no

longer considered to be of regulatory concern and is not a metabolite named in the tolerance expression (DP Barcode D239919, 10/27/97, D. Miller).

HED reiterates that the submitted HPLC/UV method (MRID 44397101) had been previously described and deemed adequate for *data collection* purposes. HED concludes that a GC/NPD method is available for the purpose of enforcing tolerances for residues of chlorpropham *per se* in/on plant commodities.

AGENCY MEMORANDA CITED IN THIS REVIEW

CBRS Nos.: 11008  
DP Barcodes: 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 Nos.: 12273  
DP Barcodes: 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

DP Barcode: D239919  
Subject: Chlorpropham,. Request by PIN-NIP for Waiver of Enforcement Analytical Method for 3-Chloroaniline Metabolite in Potatoes.  
From: D. Millers  
To: S. Jennings  
Dated: 10/27/97  
MRID(s): None

MASTER RECORD IDENTIFICATION NUMBERS

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

44397101 Freudenthal, R. (1997) Analytical Method in the Plant--Analysis of Chlorpropham and 3-Chloroaniline in Potato Peels, Pulp, Chips, and Granules. Unpublished study prepared by Pin Nip, Inc. 17 p.