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OFFICE OF
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AND TOXIC SUBSTANCES

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OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

MEMORANDUM

SUBJECT: **Chlorpropham (CIPC)** (018301), Determination of Reside Data Used to Support Registration. DP Barcode D283698, no MRID.

From: Danette Drew, Chemist
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As requested by the Registration Division, HED has examined the residue chemistry data that were available to support chlorpropham registrations in 1995. Specifically, data available to support the post-harvest use of chlorpropham on potatoes were investigated for fulfillment of the residue chemistry guidelines 860.1300 [formerly 171-4(a) and (b)], 860.1340 [171-4(c) and (d)], 860.1380 [171-4(e)], 860.1480 [171-4 (j)], 860.1500 [171-4 (k)], and 860.1520 [171-4(l)]. Data submissions cited below do not include those reviewed in the Residue Chemistry Science Chapter of the Reregistration Standard dated 8/18/87, but reflect only those submissions received after the issuance of that document.

Residue Chemistry

171-4 (a) (GLN 860.1300) Nature of Residue in Plants: According to the Residue Chemistry Chapter of the RED dated 7/1/94 (D188707, D. Miller), which was incorporated into the 1/95 HED Chapter of the RED, MRID 42085601, submitted by the CIPC Task Force (CTF) in 1991, satisfied the 171-4 (a) [860.1300] requirement. There do not appear to be any Pin Nip submissions for this guideline.

(The 1996 DCI required plant metabolism data to support the use of chloropham on spinach, *which is no longer a registered use*. There do not appear to have been any plant metabolism data submissions in response to that DCI.)

171-4 (b) (GLN 860.1300) Nature of Residue in Livestock: According to the 7/1/94 Chemistry Chapter of the RED, livestock metabolism data requirements were fulfilled and the following MRIDs cited: 42130401, 42112201(both submitted by the CTF in 1991). There do not appear to be any Pin Nip submissions for this guideline.

171-4(c) (GLN 860.1340) Residue Analytical Method- Plants: According to the 7/94 Chemistry chapter, three studies were submitted by the CTF under this guideline (MRIDs 42123101, 42653401, 42778901; submitted in 1991, 1993, and 1993, respectively and reveiwed by HED in 3/93, 6/93, and 7/93, respectively.). As of the 7/94 Chemistry chapter, the requirement for RAM for plants remained unfulfilled as a successful ILV (independent laboratory validation) had not been submitted. Also submitted by the CTF in 1994, but not referenced in the chapter, was MRID 43160101, which was reviewed 6/94 and determined to be an inadequate ILV study. The CTF submitted a response to that review (no MRID) on 8/22/94. HED determined that the CTF response addressed the deficiencies for an ILV and that the ILV requirements for a plant method (potatoes) were now fulfilled (D207719, 10/12/94) and that the Agency's Analytical Chemistry Laboratory (ACL) would perform a TMV (tolerance method validation; requested on 10/24/94).

As a result of the TMV, the ACL made several comments (memos of 3/2/95,D. Swineford, and 11/14/95, E. Greer, Jr.) and the Agency concluded that the *"registrant should submit a revised version of the proposed analytical enforcement method which meets the aforementioned requirements. Until receipt of the revised method, the requirements for analytical enforcement methodology will remain unfulfilled"*(D213081, 3/22/95). To date, there do not appear to be any CTF submissions that address that deficiency; therefore, the requirements for an analytical method (plant) remain unfulfilled.

In 1997 Pin Nip submitted an analytical method for plants (potatoes). The submitted study (MRID 44397101) was a summary of a method used in a previously submitted magnitude of the residue (860.1500) study (MRID 42566801, submitted 1992, and a follow-up letter from Pin Nip dated 7/16/93). The method was determined to be adequate for data collection purposes only. (8/10/93, D193416). The method was recently reviewed for adequacy as a *tolerance enforcement* residue analytical method (6/3/02, D283302) and was found to have the following deficiencies:

> *The internal standard was added to the sample along with the extracting solvent prior to extraction. The method should be modified to stipulate the addition of the internal standard to the final extract just prior to injection on the column.*
>
> *Prior to final approval, the proposed enforcement method will need to be radiovalidated, undergo a confirmatory method to determine specificity, and undergo a successful independent laboratory validation. The method will then be submitted to the EPA's Analytical Chemistry Branch for Agency validation.*

The requirements for an analytical method (plant) remain unfulfilled.

(The 1996 DCI required residue analytical method data to support the use of chlopropham on spinach, *which is no longer a registered use*. There do not appear to have been any method data submissions in response to that DCI.)

171-4(d) (GLN 860.1340) Residue Analytical Method- Livestock: As of the issuance of the 7/1/94 Chapter, no data had been submitted for this guideline. The 1994 DCI required residue analytical method data for animals. Data were subsequently submitted by the CTF in 1995 (MRIDs 43677001, 43760301). Those data were reviewed 9/27/95 (D218755) and it was determined that a successful ILV is required before the Agency will initiate a method validation. The requirement for residue analytical method for ruminants remains unfulfilled. Pin Nip has not submitted any livestock analytical method data to date.

171-4 (e) (GLN 860.1380) Storage Stability: According to the 7/1/94 Chemistry Chapter of the RED, storage stability data requirements were fulfilled for potatoes and the following MRIDs cited:42660101, 42958301, 43053601(submitted by the CTF). However, at that time no data on storage stability for animal commodities were available. It was determined that if the samples from the ruminant feeding study (171-4 (j)) were not analyzed within two weeks of collection, storage stability data would be required for residues of CIPC and 4-hydroxychlorpropham-O-sulfonic acid on animal commodities.

The CTF subsequently submitted ruminant storage stability data in 1996 (MRID 43989901, which was an addendum to the ruminant feeding study submitted in 1995, MRID 43884501). The submitted storage stability data were determined to be adequate to validate the storage conditions and intervals of milk and tissue samples from the dairy cattle feeding study (7/9/99, D234818). The requirement for ruminant storage stability data has been fulfilled.

There do not appear to be any Pin Nip submissions for the storage stability guideline requirements. However, it should be noted that storage stability data were not required for the 860.1500/1520 Pin Nip submissions (42566801, 44736001, and 45426101) as the samples were stored less than 30 days prior to analysis.

(The 1996 DCI required storage stability data to support the use of chlopropham on spinach, *which is no longer a registered use*. There do not appear to have been any storage stability data submissions in response to that DCI.)

171-4(j) (GLN 860.1480) Magnitude of the Residue Meat/Milk/Poulry/Eggs: As of the issuance of the 7/1/94 Chapter, no data had been submitted for this guideline. The 1994 DCI required residue data from a *ruminant* feeding study. Data were subsequently submitted by the CTF in 1995 (MRID 43884501).The requirement for a ruminant feeding study has been fulfilled (7/9/99, D222987). There do not appear to be any Pin Nip submissions for this guideline.

171-4 (k) (GLN 860.1500) Crop Field Trials: According to the 7/94 Chemistry Chapter, sufficient crop field trial data to support a 30 ppm chlorpropham tolerance on potatoes had been submitted, provided the following maximum post-harvest application rates are not exceeded (Note: the 1996 DCI required registrants with products whose label rates and timing may result in higher residues to submit supporting data) :

> *aerosol fog at 0.022 lb ai/1000 lbs potato in each of two applications 90 days apart (0.044 lb ai total aerosol) followed by direct spray at 0.0104 lb ai/1000 lbs potato (0.054 lb ai total applied);*
>
> *aerosol fog at 0.033 lb ai/1000 lbs potato and a second aerosol fog 140 days later at 0.017 lb ai/1000 lb potato (0.05 lb ai total aerosol).*

There were five residue studies cited in the 7/94 chapter. The first, MRID 42566801, was submitted by Pin Nip in 1992 and initially reviewed 4/16/93 (D185464). It was determined that the study was inadequate but upgradeable. Additional data was submitted by Pin Nip (no MRID) and the original submission was determined to be upgraded to acceptable to "support the use of an RTU formulation applied by aerosol/fogger at an application rate of 0.017 lb ai/1000 lb potatoes"(8/10/93, D193416).

The other four studies cited in the 7/94 chapter are MRIDs 42610301, 42653601, 42653801, and 42653901 submitted by the CTF (reviewed 6/21/93, D186971, D188291, D188292). These residue data were determined to be adequate to support the maximum rates and minimum retreatment intervals listed in italics above (RTU [aerosol] and EC [direct spray] formulations).

Pin Nip subsequently submitted two additional field trial studies in 1998 (MRID 44736001 [EC formulation] and 45426101 [RTU formulation]). The studies were initially reviewed 12/17/01 and 1/7/02, respectively, and were determined to be inadequate for tolerance reassessment. Pin Nip submitted information in two letters (3/13/02 and 6/17/02; no MRIDs) in an effort to upgrade the studies. While some deficiencies were corrected, the studies still remain inadequate for fulfilling the 860.1500 guidelines for chlorpropham use on potatoes (reviews D281664, 5/6/02 and D283783, 6/25/02).

(The 1996 DCI required crop field trial data to support the use of chlopropham on spinach, *which is no longer a registered use*. There do not appear to have been any residue data submissions in response to that DCI.)

171-4(l) (GLN 860.1520) Processed Food/Feed: According to the 7/1/94 Chemistry Chapter of the RED, data requirements for residues of chlorpropham in processed potato commodities were deemed adequate and the following MRIDs cited: 42566801, 42653701 and 42660201. MRID 42566801 was submitted by Pin Nip in 1992. It was initially reviewed 4/16/93 (D185464) and determined to be inadequate but was upgraded to acceptable 8/10/93 (D193416).MRIDs 42653701 and 42660201 were submitted by the CTF in 1993 and were deemed adequate 6/21/93 (D186971, D188291, D188292).

In a 8/3/95 memo (no Barcode, D.Miller) it was decided, based on calculations from available studies, that a 409 tolerance for processed potato waste would not be required. However, in order to confirm that decision the Agency required that " the registrant perform a pilot- or commercial- scale processing study, with potatoes treated at maximum label rates. Prior to performing this study, the registrant should submit a protocol to the Agency for review and approval". This requirement was stipulated in the 1996 DCI as well. The CTF then submitted a protocol (no MRID) which the Agency commented on in a memo dated 4/29/97 (D234821). The commercial potato processing study was submitted by the CTF in 1998 (MRID 44534501) and determined to be adequate (7/9/99, D210640).

cc: RF, D. Drew, Cynthia Giles-Parker (RD), Gary Mullins (SRRD, mailcode 7508C), Scott Garrison (OGC, mailcode 2333A).
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