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

MAR 23 1995

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Chlorpropham. (0118301) Results of Tolerance Method Validation (TMV) on Potatoes and Processed Potato Commodities. DP Barcode: D213081; CBRS No.: 15122; No MRID No; Rereg. Case No.: 0271.

FROM: David J. Miller, SA HSO U.S. Public Health Service *DM*
Special Review Section II
Chemistry Branch II, Reregistration Support
Health Effects Division (7509C)

THRU: Susan V. Hummel, Acting Section Head *Susan V. Hummel*
Chemistry Branch II, Reregistration Support
Health Effects Division (7509C)

TO: Venus Eagle, PM Team 71
Reregistration Branch
Special Review and Reregistration Division (7508W)

CBRS requested through a memorandum dated 10/24/94 (D. Miller) that ACL perform a Tolerance Method Validation (TMV) on the following method:

Analytical Method for Magnitude of the Residues in Stored Potatoes from Post-Harvest Treatments of Chlorpropham. Effective Date: 8/11/94. No MRID No.

The results of the TMV and the TMV Pre-review are appended to this memorandum as Attachments 1 & 2.



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Results

The average recovery in raw tubers was 97% (range: 81.3 to 107%); in dehydrated potatoes, average recovery was 85% (range: 62 to 98.8%); and in french fries average recovery was 92% (range: 77.6 to 111%). Two experienced chemists can process six samples in 8 hours. Samples containing oil such as french fries require gel permeation chromatography cleanup and increase analysis time by one hour per sample. GC quantitation takes about 1 hour per injection.

Conclusions

The recoveries of chlorpropham in raw tubers, dehydrated flakes, and french fries are acceptable. The following significant comments were made by ACL in the PMV results (Memo, D. Swineford 3/2/95):

- 1) The chlorpropham standard is available from the EPA repository in RTP.
- 2) Analysis of three brands of dehydrated potatoes found chlorpropham in all controls. The control sample of french fried potatoes also contained chlorpropham. Control raw tubers were also found to contain detectable levels of chlorpropham as well.
- 3) The limit of detection from visual inspection of the chromatograms is estimated to be 0.05 ppm for the three matrices.
- 4) ACL used a DB-5 column (5% Phenylmethyl Polysiloxane, 0.53 mm id x 30m, 0.5 um film thickness, J&W Scientific) without a guard column. Operating conditions were as follows:

Gas Flow Rates: Helium carrier: 20 mL/min; Hydrogen: 4 mL/min; Air: 100 mL/min;

Oven Operating Conditions: Initial 100°C hold for 0.5 minutes; Rate 1: 10°C/min to 190°C hold 6 min.; Rate 2: 40°C/min. to 300°C hold 2 min.

CBRS recommends that this equipment and these operating procedures be added to the written method as an alternative means of GC analysis.

The following additional significant comments were made by ACL in the TMV Pre-review

(Memo, E. Greer, Jr. 11/14/94):

1. Re: V Sample Prep

- a) Re: A, B, C, and D: An inordinate amount of detail is included in the sample preparation section of this method. Specific instructions such as glassware washing and potato peeling and washing can be deleted from a tolerance enforcement method unless an analysis requires procedures that are not normally practiced in a pesticide residue laboratory.
- b) Re: E. Sample Extraction: An alternate method for evaporating solvents should be provided for laboratories that are not equipped with a Turbo Vap.
- c) Re: F. GPC Cleanup

#2,3: After the evaporation step, the volume of the solvent is adjusted to "exactly 10 mL." The next step instructs the analyst to "draw at least 10 mL into a 10 mL syringe." It would be virtually impossible to draw up "at least 10 mL" from a flask containing exactly 10 mL.

#9: The statement instructing the analyst to fill out the GPC notebook should be deleted from the method. Individual laboratories have their own quality assurance and/or instrument log requirements.

#14 At the end of the section the analyst is instructed to "follow steps a. through m.", but these steps are not included in this method.

2. Re: VI. Sample Analysis

- a) Re: B.: References to a particular standard operating procedures manual should be deleted.
- b) Re: C.: Specific instructions for archiving data should be deleted from the method.

If the above comments are taken into consideration and incorporated, the method would meet

GDLN 171-4(c) requirements for an analytical enforcement method.

Recommendations

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. The revised method, when received, will be forwarded to FDA for publication in PAM II.

Attachment 1- Memo, D. Swineford 3/2/95
Attachment 2- Memo, E. Greer, Jr. 11/14/94

cc: RF, SF, Rereg. Std. File, Circ., M. Exton (SRRD), DJM.
RDI: SHummel:3/16/95;MMetzger:3/22/95;FSuhre:3/22/95.

ATTACHMENT 1

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

Analytical Chemistry Section
Building 306, BARC-East
Beltsville, Maryland 20705

MAR -2 1995

MEMORANDUM

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT: Chlorpropham. Request for EPA-Beltsville Method Try-out. No DP Barcode. No CBRS No.; No MRID No.; Case No.: 0271

FROM: Douglas Swineford, Chemist *DS*
Analytical Chemistry Section

THRU: Harvey K. Hundley, Head *HK*
Analytical Chemistry Section

THRU: Donald A. Marlow, Chief *DM*
Analytical Chemistry Branch
Biological and Economic Analysis Division (7503W)

TO: F. B. Suhre, Section Head
Special Review Section II,
Chemistry Branch II - Reregistration Support
Health Effects Division (7509C)

Introduction

The Analytical Chemistry Laboratory (ACL) validated the method: "Analytical Method for Magnitude of Residues on Stored Potatoes from Postharvest Treatments of Chlorpropham" sponsored by The Chlorpropham Task Force. The matrices validated were raw tuber, french fried and dehydrated granular potatoes.

Method Summary

Samples were extracted with methanol or a methanol/water mixture, depending on the matrix. The analyte in the methanol/water extract is partitioned into dichloromethane. Sodium chloride saturated phosphate buffer (pH 6.5) is then added to the methanol/water extract and any remaining analyte is again partitioned into dichloromethane.

The two dichloromethane partitions are combined and concentrated. After a n-hexane solvent exchange the samples are quantitated by gas chromatography (GC) using a nitrogen-phosphorous detector.

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Comments

1. Analyses of three brands of dehydrated potatoes found Chlorpropham (CIPC) in all controls (no spike). The CIPC was confirmed by mass spectrometry (MS). Validation recovery study of the method was performed using the sample containing the least CIPC (0.50ppm). The sample of french fried potatoes contained CIPC (also MS confirmed) at 0.08ppm. Recoveries include data for corrected and uncorrected values CIPC found in the samples.

2. ACL used a DB-5^o (5% Phenylmethyl Polysiloxane, 0.53mm id x 30m, 0.5 μ m film thickness, J&W Scientific) without a guard column.

Gas flow rates. Helium carrier: 20 ml/min.; Hydrogen: 4ml/min; Air: 100 ml/min. G.C. oven operating conditions: Initial 100^oC hold 0.5 min. Rate 1: 10^oC/min. to 190^oC hold 6 min.; Rate: 2: 40^oC/min. to 300^oC hold 2 min.

3. A set of six samples can be processed in 8 hours by two experienced chemists. Samples containing oil such as french fries require gel permeation chromatography (GPC) clean-up and increase analyses time by 1 hour per sample. GC quantitation takes about 1 hour per injection.

4. The limit of detection from visual inspection of the chromatogram is estimated to be 0.05 ppm for the three matrices.

5. No special safety hazards were noticed. Normal laboratory safety procedures were followed.

6. Chemistry Branch Registration Support (CBRS) expressed concern (memorandum dated October 13, 1994) that curve-splitting for determining the linearity of the GC nitrogen-phosphorus (NP) detector may not be acceptable. ACL feels that this does not pose a problem as long as the samples are quantitated against a standard of similar concentration and therefore are in the same linear portion of the calibration curve.

Comments (Cont'd.)

7. The standard is available from the EPA repository in RTP, North Carolina.
8. If the above comments are taken into consideration and incorporated, the method would meet 40 CFR 158 and EPA's requirements as published in the Pesticide Assessment Guidelines, Subdivision "O" for Residue Chemistry, Part 171-4(b) as an enforcement method.
9. Recovery data, example chromatograms, pre-review checklist and pre-review comments are attached.

VALIDATION REPORT CHLORPROPHAM (CIPC)

| <u>Commodity</u> | <u>Chemical Added</u> | <u>PPM Added</u> | <u>PPM Found</u> | <u>%Recovery</u> |
|------------------------|-----------------------|------------------|------------------|------------------|
| Potato (Raw Tubers) | Control | 0 | N.D.* | --- |
| | Control | 0 | N.D.* | --- |
| | Chlorpropham | 0.50 | 0.407 | 81.3 |
| | Chlorpropham | 0.50 | 0.534 | 107. |
| | Chlorpropham | 1.00 | 0.995 | 99.5 |
| | Chlorpropham | 1.00 | 0.949 | 94.9 |
| | Chlorpropham | 10.0 | 9.94 | 99.4 |
| | Chlorpropham | 10.0 | 10.7 | 107. |
| | Chlorpropham | 30.0 | 26.7 | 89.0 |
| | Chlorpropham | 30.0 | 30.5 | 102. |

* N.D. = < 0.05 ppm

| <u>Commodity</u> | <u>Chemical Added</u> | <u>PPM Added</u> | <u>PPM Found</u> | <u>%Recovery</u> | <u>Corrected %Recovery*</u> |
|------------------------|-----------------------|------------------|------------------|------------------|-----------------------------|
| Potato (Dehydrated) | Control | 0 | 0.564 | --- | --- |
| | Control | 0 | 0.436 | --- | --- |
| | Chlorpropham | 0.50 | 0.810 | 162. | 62.0 |
| | Chlorpropham | 0.50 | 0.994 | 198. | 98.8 |
| | Chlorpropham | 1.00 | 1.45 | 145. | 94.7 |
| | Chlorpropham | 1.00 | 1.49 | 149. | 98.8 |
| | Chlorpropham | 10.0 | 8.26 | 82.6 | 77.6 |
| | Chlorpropham | 10.0 | 7.42 | 74.2 | 69.2 |
| | Chlorpropham | 30.0 | 27.7 | 92.3 | 90.7 |
| | Chlorpropham | 30.0 | 27.8 | 92.8 | 91.2 |

* Results corrected by subtracting average ppm found in controls.

VALIDATION REPORT CHLORPROPHAM (CIPC) (Cont'd.)

| <u>Commodity</u> | <u>Chemical Added</u> | <u>PPM Added</u> | <u>PPM Found</u> | <u>%Recovery</u> | <u>Corrected %Recovery*</u> |
|--------------------------|-----------------------|------------------|------------------|------------------|-----------------------------|
| Potato (French Fries) | Control | 0 | 0.0730 | --- | --- |
| | Control | 0 | 0.0894 | --- | --- |
| | Chlorpropham | 0.50 | 0.533 | 107. | 90.3 |
| | Chlorpropham | 0.50 | 0.636 | 127. | 111. |
| | Chlorpropham | 1.0 | 1.025 | 103. | 94.3 |
| | Chlorpropham | 1.0 | 0.947 | 94.7 | 86.5 |
| | Chlorpropham | 10 | 7.84 | 78.4 | 77.6 |
| | Chlorpropham | 10 | 8.74 | 87.4 | 86.5 |
| | Chlorpropham | 30 | 28.6 | 95.2 | 95.0 |
| | Chlorpropham | 30 | 29.7 | 99.0 | 98.7 |

* Results corrected by subtracting average ppm found in controls.

Modifications to method:

None.

Special precautions to be taken:

Handle all chemicals in a safe manner.

Source of analytical standard:

Hazleton Wisconsin, Madison, Wisconsin 23707.

If derivatized standard, give source:

N/A.

Instrument for quantitation:

GC/NPD

Instrument for confirmation:

Mass Spectrometer.

If instrument parameters differ from those given in method, list parameters used:

See comments section of report.

Commercial sources of any special chemicals or apparatus:

N/A

Additional comments:

None.

Chromatograms:

Copies attached.

ATTACHMENT 2

c:\wp51\final\clr14.wpd:00:3-22-95:DJM:djm.

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TMV Pre-review of Chlorpropham in Potatoes

Reviewed By: Everett S. Greer, Jr. *EGJ*

Date: 11-14-94

Laboratory assignment numbers: 95-9,10

Analyte: Chlorpropham

Commodities: Potatoes, french fries and dehydrated granules

Method: Analytical Method for Magnitude of Residues in Stored Potatoes from Postharvest Treatments of Chlorpropham

V Sample preparation

A.B.C.D

An inordinate amount detail is included in the sample preparation section of the method. Specific instructions such as glassware washing and potato peeling and washing can be deleted from a tolerance enforcement method unless an analysis requires procedures that are not normally practiced in a pesticide residue laboratory.

E. Sample extraction

An alternate method for evaporating solvents should be provided for laboratories that are not equipped with a Turbo Vap[®].

F. GPC clean-up (for oil processed samples)

2.1.3.

After the evaporation step, the volume of the solvent is adjusted to "exactly 10 Ml." The next step instructs the analyst to "draw at least 10 Ml into a 10 Ml syringe." It would be virtually impossible to draw up "at least 10 mL" from a flask containing exactly 10 ml.

2.

The statement instructing the analyst to fill out the GPC notebook should be deleted from the method. Individual laboratories have their own quality assurance and/or instrument log requirements.

14.

At the end of this section the analyst is instructed to

"follow steps a. through m.", but these steps are not included in this method.

VI. Sample analysis

B.

References to a particular standard operating procedures manual should be deleted.

C.

Specific instructions for archiving data should be deleted from the method.

Additional reviewers comments

1. This reviewer was informed in a telephone conversation with David J. Miller of CBRS that the matrix used for the french fry analysis should be an oil processed product. This will require the GPC cleanup described in step F.

2. CBRS is recommending a tolerance of 30 ppm be proposed for potatoes, but is asking ACL to validate the method for 0.3 ppm.

3. Validation recovery data is presented as part of Dr. Miller's review of the independent laboratory validation of this method. The only recoveries reported are for potatoes spiked at 2 ppm and 5 ppm. No chromatograms are included. ACL has requested Dr. Miller to supply Beltsville with the ILV report and any additional recovery data that CBRS has obtained from the registrant.

ANALYTICAL CHEMISTRY BRANCH
 SCREEN FOR RESIDUE METHODS FOR TMV

LABORATORY ASSIGNMENT NUMBER: B 95- 9,10,11

PP#: _____

TECHNICAL REVIEWER: Everett S. Greer, Jr.

DATE: 11-19-99

ANALYTES/LEVEL: Chlorpropham / 0.3, 1.0, 10, 30 ppm

COMMODITIES: Potato (raw tuber), French fries, dehydrated granules

METHOD: Analytical Method for Magnitude of Residues in Stored Potatoes from Post Harvest Treatments of Chlorpropham

The Analytical Chemistry Section has been asked to screen the residue chemistry methods submitted by the registrant in order to determine if they contain the essential requirements identified in the Residue Chemistry Guidelines. Full scientific review and laboratory evaluation of those methods will take place after the initial screen. The following items need to be resolved before the analytical method can be evaluated.

| | <u>YES</u> | <u>NO</u> |
|--|--------------------------|-------------------------------------|
| Does the method use exotic equipment and/or supplies that are not commercially available in the U.S.? | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| Does the method require any new equipment before the laboratory work begins? | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| Are chromatograms included? | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| a. Is (are) peak(s) of interest sufficiently resolved from other peaks? | <input type="checkbox"/> | <input type="checkbox"/> <i>NA</i> |
| b. Has registrant included chromatograms of analyses at or below tolerance on all crop types for which tolerance is requested by HED? | <input type="checkbox"/> | <input type="checkbox"/> <i>NA</i> |
| c. Do the control samples have reasonably low levels of the analyte in relation to the proposed tolerance? | <input type="checkbox"/> | <input type="checkbox"/> <i>NA</i> |
| d. Is the method sufficiently sensitive and specific to measure and identify the residues at levels specified by HED in the TMV request? | <input type="checkbox"/> | <input type="checkbox"/> <i>NA</i> |

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YES NO

- 4. Has recovery data been provided to ACL for the residues that are specified in the TMV request? YES NO
- 5. Are recovery values between 70% and 120% at all levels and for all commodity types? YES NO
- 6. Are all procedures clearly written with no ambiguities so that the method can be run without communication with the registrant? YES NO *See handwritten note*
- 7. Does the method require correction for a sample of the untreated commodities or a blank? YES NO
- 8. Does the method require the use of an internal or procedural standard to compensate for lost analyte during analysis? YES NO
- 9. Are 2nd laboratory validation data provided with the method? YES NO *See handwritten note*
- 10. Are there any deficiencies other than those covered above that would prevent ACS from conducting a method trial? YES NO
- 11. Is this method suitable for validation testing? YES NO

Any deficiencies/problems noted for any above items should be addressed in the full scientific review of this method to be attached as an addendum.

[Handwritten Signature]
Signature

11-19-94
Date

The following is to be completed by the analyst performing the TMV.

- 12. Can a set of 6 samples be run within 24 hours? YES NO
- 13. a. Are standards available at RTP repository? YES NO
- b. Are derivatized analytical reference standards available? YES NO *NA*



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

MAR 21 1995

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Chlorpropham. (018301) Use on Spinach.
No DP Barcode. CBRS No.: 15120; No MRID No.; Rereg. Case No.: 0271
D15251

FROM: David J. Miller, SA HSO, U.S. Public Health Service. *DJM*
Special Review Section II
Chemistry Branch II--Reregistration Support
Health Effects Division (7509C)

THRU: Susan V. Hummel, Acting Section Head *Susan V. Hummel*
Special Review Section II
Chemistry Branch II-- Reregistration Support
Health Effects Division (7509C)

TO: Margery Exton, PM Team 71
Reregistration Branch
Special Review and Reregistration Division (7503C)

CBRS was recently requested to explain the status of chlorpropham with respect to use on spinach. It was our original understanding when preparing the Residue Chemistry chapter of the RED that the Chlorpropham Task Force (representing Aceto and Elf-Atochem) intended to restrict use of chlorpropham to post-harvest use on potatoes. We have subsequently been alerted by SRRD that Platte Chemical desires that use be retained on spinach. The current memorandum summarizes our understanding of the outstanding residue chemistry issues associated with spinach. CBRS understands that SRRD has three specific questions relating to the status of chlorpropham use on spinach.

The format of this memorandum is Q&A form, with questions (in bold) followed by CBRS answers. More detailed information is provided in small type following the CBRS answer.



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QUESTION:

From the Nature of the Residue Studies in Leafy Greens Which Were Previously Reviewed, Can CBRS Make Any Conclusions Regarding Expected Concentrations of 3-CA in Spinach?

ANSWER:

Since the 3-chloroaniline metabolite was detected in numerous leafy green crops in two studies reviewed in the Registration Standard and the studies were unable to quantify these amounts in either relative or absolute terms, CBRS can make no conclusions regarding expected 3-CA concentrations in spinach.

The 1987 Chlorpropham Registration Standard concluded that the nature of the residue in field-treated, growing plants is adequately understood. The Registration Standard show that following exposure of roots to hydroponic or soil substrates containing [¹⁴C]Chlorpropham, ¹⁴C-residues appear in the shoots of soybeans, alfalfa, and cucumber. Chlorpropham per se was identified in soybean shoots, with its 6-OH-CIPC, 4-OH-CIPC, isopropyl-OH-CIPC, and 2-OH-CIPC metabolites were detected in soybeans, alfalfa, orchardgrass, and turnips. The 3-chloroaniline metabolite was identified in smartweed, pigweed, tomatoes, and parsnip. CBRS notes that for these latter species in which 3-CA was detected, the studies were deemed inadequate because the relative distribution of total recovered radiolabeled activity in the chloroform-soluble, water-soluble, and insoluble fractions was not stated and thus the percentages of ¹⁴C-activities could not be calculated. Therefore, CBRS can make no conclusions regarding expected concentrations of 3-CA in spinach. CBRS notes that in at least one of these two studies, the treated leaves were collected after only 10 days following treatment which does not simulate the current label directions for treatment (i.e., treatment of dormant spinach during late winter and harvest no sooner than 30 days after treatment).

QUESTION:

From Previously-Submitted Magnitude of the Residue Studies in Spinach, Can CBRS Conclude That The Current Interim Tolerance of Spinach of 0.3 ppm (at a 30-day PHI) Will Not Be Exceeded By the Current SLN Uses in DE, NJ, VA, and MD.

ANSWER:

Given the limited database available for consideration in terms of both geographic diversity/relevance and pre-harvest intervals, CBRS can tentatively conclude that a spinach tolerance of 0.3 ppm will not likely be exceeded if application is limited to 1 lb ai/A with a 30 day PHI label restriction. If the registrant attempts to reregister chlorpropham use on spinach, however, additional field trials in the DE, NJ, VA, and MD will be required.

The 1987 Registration Standard indicated that the submitted data are insufficient to assess the adequacy of the established interim tolerance for residues of chlorpropham *per se* in or on spinach since only two samples satisfied the conditions of maximum use rate and minimum treatment-to-harvest interval. The Registration Standard states that the registrant must submit

Data depicting chlorpropham residues of concern in or on spinach harvested 30 days after postemergence application of the 4 lb/gal EC formulation at 2 lb ai/A at the six to eight leaf growth stage. Tests must be conducted in the states of AR, MD, OK, and VA where special local needs registrations are in effect. The registrants must propose an appropriate tolerance for chlorpropham residues of concern in or on spinach.

In the data discussion section of the Registration Standard, studies are described in which 28 tests were conducted in AR (7), TN (12), TX (5) and VA (4) reflecting post-emergence applications of chlorpropham to spinach (1974-7); MRID 00114794). At application rates of 2-8 lbs ai/A, residues of chlorpropham plus isopropyl-OH-CIPC in these tests were (i) 0.03-0.59 ppm in three samples harvested 18 days post-treatment; (ii) 0.11 ppm in two samples harvested 30-31 days post treatment; and (iii) <0.01-0.14 ppm in eight samples harvested 59-167 days post-treatment. In addition, a trial conducted in TX at 2 lb ai/A revealed the presence of 0.15 ppm in or on one sample harvested 53 days following application. Residues of chlorpropham plus isopropyl-OH-CIPC were analyzed by an adequate GLC/EC procedure and recovery efficiencies were adequate (86-106%). However, samples were stored frozen for an unspecified interval before analysis.

An additional study is described (1971; MRID 00114715) concerning four trials conducted in VA; in these tests, 0.5 lbs ai/A was applied preemergence followed by 1-2 lbs ai/A postemergence. Six samples harvested 65 days post treatment bore residues of <0.02-0.04 ppm chlorpropham plus isopropyl-OH-CIPC. An adequate analytical method was used and acceptable fortification recoveries (86-94%) were seen. However, samples were stored frozen for an unspecified period.

Subsequent to the issuance of the 1987 Registration Standard CBTS concluded in response to an application for a 24(c) registration for the state of Delaware (DE 910001) that "the available data imply that the tolerance of 0.3 ppm will not be exceeded when the formulation is applied at a maximum seasonal application level of 2-2/3 pints (1 lb ai) per acre. The site of the Virginia field trial--near the eastern shore-- is similar climatically to that of Delaware" (M. Flood, 5/24/93, CB No. 11846--see attached). The CBTS review concluded that "[s]ufficient residue data exist to allow us to conclude that the current interim tolerance of 0.3 ppm will not be exceeded due to the proposed use.

QUESTION:

What additional data are the registrants required to submit to support the existing spinach use of chlorpropham?

ANSWER:

The registrants are required to submit the following residue chemistry generic data to support the existing spinach use of chlorpropham.

- 171-4(a) Plant metabolism (only for spinach). Levels of 3-CA must be quantitated
- 171-4(c) Residue analytical methods to determine chlorpropham and 3-CA and any other residue of concern
- 171-4(e) Storage stability for chlorpropham, 3-CA, and any other residue of concern
- 171-4(k) Crop field trials (2 trials with two independent plots treated at 1x and 2x rates or 3 trials to support SLN uses in DE, MD, NJ, and VA or 8 trials to support nationwide use) including 1 residue decline study. Chlorpropham, 3-CA, and any other residues of concern must be determined.
- 165-1 Confined Rotational Crop (with 165-2 potentially required)

QUESTION:

What additional data are the registrants required to submit to support the existing spinach use of chlorpropham?

ANSWER:

The registrants are required to submit the following residue chemistry generic data to support the existing spinach use of chlorpropham.

- 171-4(1) Plant metabolism (only for spinach). Levels of 3-CA must be quantitated
- 171-4(c) Residue analytical methods to determine chlorpropham and 3-CA and any other residue of concern
- 171-4(e) Storage stability for chlorpropham, 3-CA, and any other residue of concern
- 171-4(k) Crop field trials (2 trials with two independent plots treated at 1x and 2x rates or 3 trials to support SLN uses in DE, MD, NJ, and VA or 8 trials to support nationwide use) including 1 residue decline study. Chlorpropham, 3-CA, and any other residues of concern must be determined.
- 165-1 Confined Rotational Crop (with 165-2 potentially required)

Attach.: M. Flood review (5/24/93, CB No. 11846)

cc: RF, SF, List A Rereg. F., Circ., DJM.
RDI: SHummel:3/13/95;MMetzger:3/14/95;FSuhre:3/17/95.

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

MAY 24 1993

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Chlorpropham. SLN(24C) for Use on Overwintered Spinach
in the State of Delaware. SLN No. DE-91-0001.

DP Barcode D191079. CB # 11846.

FROM: Michael T. Flood, Ph.D., Chemist
Tolerance Petition Section II
Chemistry Branch I -- Tolerance Support
Health Effects Division (H7509C) *Mike Flood*

THROUGH: Elizabeth T. Haebeler, Section Chief *Elizabeth T. Haebeler*
Tolerance Petition Section II
Chemistry Branch I -- Tolerance Support
Health Effects Division (H7509C)

TO: C. Giles-Parker/J. Stone, PM 22
Fungicide-Herbicide Branch
Registration Division (H7505C)

Background

CBTS has been asked whether the existing interim tolerance of 0.3 ppm for chlorpropham in/on spinach will cover the 24C use in Delaware. The 24C has been in effect since 1991. CBTS/CBRS has not commented previously.

The interim tolerance (no expiration date) has been established for chlorpropham (isopropyl *m*-chlorocarbanilate, or CIPC) under 40 CFR 180.319. Chlorpropham is a List A chemical. The Residue Chemistry Chapter of the Registration Standard was issued 8/14/87. The Product and Residue Chemistry Reregistration Standard Updates were issued 10/16/91. The Residue Chemistry Chapter for the RED is scheduled for completion on 7/30/94.

The registrants have voluntarily canceled all uses of the herbicide except post-harvest treatment of potatoes, and CBRS has previously recommended that tolerances for uses not supported for reregistration should be revoked (J. Abbotts, 4/30/93, 3/10/93). USDA had indicated that it would support use on spinach (P. Deschamp, 4/9/91), but has since decided against support (Mike Flood, telecon with Jim Parochetti, USDA, 5/13/93). Therefore, the 0.3 ppm tolerance for chlorpropham in/on spinach will



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22

eventually be revoked.

Conclusion

Sufficient residue data exist to allow us to conclude that the current interim tolerance of 0.3 ppm will not be exceeded due to the proposed use. However, it should be noted that this tolerance will eventually be revoked because the national use is not being supported under reregistration.

Detailed Considerations

DE910001

Chlorpropham is registered as the formulation Sprout Nip Emulsifiable Concentrate, EPA Reg. No. 34704-613, which consists of 36% active ingredient (ai). One gallon contains 3 lbs ai, or 0.375 lb/pint. Sprout Nip is registered by Platte Chemical Co., Fremont, NE.

Sprout Nip should be applied to Fall planted spinach in one application in late winter. Broadcast 1-1/3 to 2-2/3 pints (0.5 - 1 lb ai) in 20 or more gallons of water per acre. Do not apply within 30 days of harvest.

Residue data reflecting postemergence application of chlorpropham are available from VA, AR, TN and TX. In most cases, the formulation applied was Furlon 4E, an emulsifiable concentrate. The one exception was the field trial held in Dilley, TX, where applications were made with Furlon 10G (granular). Those data which correspond to use patterns similar to or more severe than the proposed use are listed in the following table. The analytical procedure used measured parent as well as the metabolite 1-hydroxy-2-propyl-3-chlorocarbanilate.

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Table 1

| Location | Rate (lbs ai/A) | PHI (Days) | Residue (ppm) |
|---------------|-----------------|------------|---------------|
| Painter, VA | 1 | 18 | 0.18 |
| | 2 | | 0.22 |
| | 6 | | 0.59 |
| VanBuren, AR | 1 | 31 | 0.05 |
| | 2 | | 0.11 |
| Dyersburg, TN | 1 | 30 | 0.07 |
| | 2 | | 0.11 |
| Dilley, TX | 8 | 23 | 1.21 |
| | | 52 | 0.60 |
| | 2.2 | 48 | 0.03 |
| Alma, AR | 2.2 | 25 | 0.05 |
| Pearsall, TX | 2 | 15 | 0.03 |
| | | 30 | <0.01 |
| | 4 | 15 | 0.11 |
| | | 30 | <0.01 |

The available data imply that the tolerance of 0.3 ppm will not be exceeded when the formulation is applied at a maximum seasonal application level of 2-2/3 pints (1 lb ai) per acre. The site of the Virginia field trial -- near the eastern shore -- is similar climatically to that of Delaware.

As noted, the interim tolerance of 0.3 ppm will eventually be revoked. Additional residue data requirements, as outlined in the Registration Standard, would be necessary to support the continued registration of this compound on spinach.

cc: 24C file, Mike Flood, E. Haebeler, RF, Circu.. Reg. Std.
File (Chlorpropham).

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