

PC 129006

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

APR 14 1995

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#3F4174. Amendment Dated 02/14/95. Chlorethoxyfos (DPX-43898) in/on Corn. (MRID #435503-00. CBTS # 51217. DP Barcode D212808.)

FROM: Jerry B. Stokes, Chemist  
Chemistry Branch I/Tolerance Support  
Health Effects Division (7509C)

*Jerry B. Stokes*  
*R. B. Perfetti*

THRU: R. B. Perfetti, Ph.D., Acting Section Head  
Chemistry Branch I/Tolerance Support  
Health Effects Division (7509C)

TO: Dennis Edwards/Teung Chin, PM# 12  
Insecticide-Rodenticide Branch  
Registration Division (7505C)

and

Jane Smith, Acting Section Head  
Risk Characterization and Analysis Branch  
Health Effects Division (7509C)

E. I. du Pont de Nemours & Company had requested 0.01 ppm permanent tolerances for their insecticide product Fortress 5G containing phosphorothioic acid O,O-diethyl-O-1,2,2,2-tetrachloroethyl ester (DPX-43898) as the active ingredient in/on corn grain; field corn forage, fodder, and silage; popcorn forage and fodder; sweet corn (kernel and cob with husk removed), forage, and fodder. No tolerances are proposed for corn processed commodities. No tolerances are proposed for livestock meat, fat, meat byproducts, milk, or eggs. The acceptable ANSI name is **chlorethoxyfos**.

The registrant has now submitted an amendment dated 02/14/95 in response to deficiency 1b cited in CBTS review (See memo of 01/10/94, J. Stokes). The registrant has also submitted a revised Section B and a revised CSF for the FORTRESS®5G formulation.



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"1b. Since the proposed products are yet not in commercial production, the registrant must submit a deferral request of data submission to include the following:

- i) A statement that the applicant has no facilities for producing the product in commercial quantities and does not intend to construct such facilities until the product is registered;
- ii) A schedule for submitting all data required by 40 CFR 158.150 through 158.190 based upon the commercially produced material;
- iii) A discussion of the formation of impurities in the commercially-produced vs. the pilot-scale, and a discussion of changes in the certified limits for the product which might result from differences between the pilot scale and commercial production processes."

Registrant's Response:

No facilities are presently in production of commercial quantities of chlorethoxyfos. However, the registrant intends to construct such facilities this year in anticipation that registration and tolerances will be granted this year.

The registrant will submit all data required by 40 CFR Parts 158.150 through 158.190 within 1 year of the registration of chlorethoxyfos and the granting of the tolerances.

To date, the registrant has produced three batches, i.e. 2 at 100-gallon scale and 1 at 5000-gallon scale. These three batches were produced using the same process and showed little variation in the impurity profiles. Full-scale commercial production of 10,000-gallon quantities will be conducted using the same procedure. Since the final scale-up involves only a 2-fold increase over the largest pilot-scale, and the first scale-up involved a 50-fold increase with no effect on the impurity profile, no significant change in certified limits or formation of impurities is expected.

CBTS Comment/Conclusion:

This deficiency is now resolved.

CBTS Comment, Memo of 01/10/94, J. Stokes:

"2. CBTS considers the metabolism of chlorethoxyfos in corn (as a result of soil application) to be adequately understood. The residue to be regulated will be determined by the HED Metabolism Committee."

CBTS Conclusion:

Based on the determination of the HED Metabolism Committee (04/11/95), the residue of regulatory concern is chlorethoxyfos.

Other Considerations:

Proposed Use:

The registrant has also submitted a revised Section B to reduce the proposed application rate from 6 to 3 oz of formulation (0.02 lb a.i. to 0.01 lb a.i.) per 1000 row feet of corn for any row spacing. Thus the amount of a.i. applied per acre varies from 0.12 lb to 0.16 lb based on row spacing of 40-30 inches respectively.

The registrant also has limited the use of the proposed product to the Smartbox<sup>™</sup> only, a closed handling and application system.

Analytical Methodology:

CBTS had previously asked for analytical methodology validation data for the oxon analog of chlorethoxyfos (See memo of 03/28/94, J. Stokes). However, since it has been determined that the residue of regulatory concern is chlorethoxyfos only, these data are no longer needed. The submitted analytical methodology is adequate for enforcement purposes at the proposed 0.01 ppm tolerance level.

Confidential Statement of Formula:

The registrant has submitted a revised CSF dated 10/24/94 for the FORTRESS<sup>®</sup>5G formulation. (See Confidential Appendix).

Recommendations:

TOX considerations permitting, and provided a revised Section F is submitted as specified below, CBTS recommends for the establishment of 0.01 ppm permanent tolerances for the insecticide chlorethoxyfos (phosphorothioic acid O,O-diethyl-O-1,2,2,2-tetrachloroethyl ester) in/on corn (field, pop, sweet). Based upon 40 CFR §180.6(a)(3) no tolerances are needed for livestock meat, fat, meat byproducts, milk, or eggs. Likewise no tolerances are needed for corn processed commodities. A DRES run can be initiated.

Revised Section F:

The registrant still needs to submit a revised Section F for the following:

corn grain (field, pop)	0.01 ppm
corn forage (field, sweet)	0.01 ppm
corn fodder (stover) (field, pop, sweet)	0.01 ppm
sweet corn (K + CWHR)	0.01 ppm

Attachment: Confidential Appendix

cc with Attachment: PP#3F4174; J. Stokes (CBTS); R.F.

cc without Attachment: Circu.

RDI: RPerfetti:04/13/95:RLoranger:04/13/95:EZager:04/13/95  
7509C:CBTS:JStokes:js:Rm 803:CM#2:305-7561:04/14/95

# FIFRA

## CONFIDENTIAL BUSINESS INFORMATION DOES NOT CONTAIN NATIONAL SECURITY INFORMATION (EO 12356)

Some information in the attached material may be entitled to treatment as trade secret or proprietary data section 7(d) and section 10 the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) as amended.

Any person handling or using the attached data in any way is responsible for preventing unauthorized disclosure while in his/her possession. Section 12(a)(2)(D) makes it unlawful for any employee to use to his/her own advantage or to reveal any confidential information (except to persons needing the information for the performance of official duties). A penalty of up to \$10,000 fine and up 3 years imprisonment may result from conviction of a violation on section 12(a)(2)(D).

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The attached information is not to be published, reproduced, publicly discussed, included in response to an FOI request or otherwise released without the explicit written authorization of the appropriate division or his designee.

CONFIDENTIAL APPENDIX

Chlorethoxyfos

PP#3F4174

Amendment Dated 02/14/95

RIN 0806-96

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Pages \_\_\_\_\_ through \_\_\_\_\_ are not included.

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The material not included contains the following type of information:

- Identity of product inert ingredients.
  - Identity of product impurities.
  - Description of the product manufacturing process.
  - Description of quality control procedures.
  - Identity of the source of product ingredients.
  - Sales or other commercial/financial information.
  - A draft product label.
  - The product confidential statement of formula.
  - Information about a pending registration action.
  - FIFRA registration data.
  - The document is a duplicate of page(s) \_\_\_\_\_.
  - The document is not responsive to the request.
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The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

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