

June 28, 1999

MEMORANDUM

SUBJECT: Dicrotophos; PC No. 035201, Case No. 0145. The Product Chemistry and Residue Chemistry Chapters for the Reregistration Eligibility Document. DP Barcode D241592.

FROM: Gary Otakie, Chemist
Chemistry and Exposure Branch 2
Health Effects Division (7509C)

THRU: Susan V. Hummel, Senior Scientist
Chemistry and Exposure Branch 2
Health Effects Division (7509C)

TO: Stephanie Willet/Michael Nieves
Reregistration Branch 1
Special Review and Reregistration Division (7508W)

The Product Chemistry and the Residue Chemistry Chapter for the Reregistration Eligibility Decision document were prepared by the Dynamac Corporation according to current Agency guidelines, and the documents have undergone review and modification by HED. The two chapters are attached. Several product chemistry requirements for reregistration have not been fulfilled for dicrotophos. HED has no objections to the reregistration of dicrotophos with respect to product chemistry provided the registrant agrees to satisfy the outstanding data requirements.

All residue chemistry data requirements for the reregistration of dicrotophos have been fulfilled, except for submission of revised labeling to specify a maximum seasonal application rate, the removal of existing feeding and grazing restrictions and Agency validation of a PAM Vol. II lettered method for plant commodities. HED has no objections to the reregistration of dicrotophos with respect to residue chemistry data requirements pending agreement to submit their required revised labeling. The only food related use currently being supported is for use on cotton. The residue of concern in cotton consists of the parent dicrotophos and the metabolite monocrotophos. The current tolerance expression and tolerance of 0.05 ppm for residues of dicrotophos per se in/on cottonseed need to be revised to 0.2 ppm for cottonseed and a new tolerance established of 2.0 ppm in/on cotton gin byproducts for the combined residues of dicrotophos and the metabolite monocrotophos, expressed as dicrotophos.

cc: Chem F, Chron F. GOtakie
RDI:Team: 5/25/99; SVH:6/28/99
Otakie, Rm.824A CM2,305-6991, mail code7509c

DICROTOPHOS

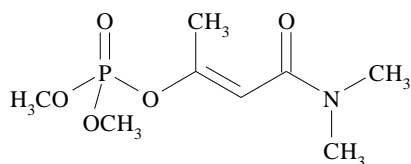
REREGISTRATION ELIGIBILITY DECISION:

PRODUCT CHEMISTRY CONSIDERATIONS

PC Code 035201; Case No. 0145

DESCRIPTION OF CHEMICAL

Dicrotophos (dimethyl phosphate of 3-hydroxy-N,N-dimethyl-cis-crotonamide) is a contact, systemic acaricide/insecticide registered for use on cotton.



Empirical Formula:	C ₈ H ₁₆ NO ₅ P
Molecular Weight:	237.21
CAS Registry No.:	141-66-2
PC Code:	035201

IDENTIFICATION OF ACTIVE INGREDIENT

Dicrotophos is a mixture of the E- and Z-isomers in which the E-isomer is pesticidally active. Technical dicrotophos is a yellow to dark amber liquid at room temperature with a boiling point of 111-112 C at 0.022 mm Hg (extrapolated to 398-399 C at 760 mm Hg), density of 1.19-1.22 g/mL at 20 C, octanol/water partition coefficient (K_{OW} of PAI) of 2.445 (E-isomer) and 0.000481 (Z-isomer), and vapor pressure of 1 x 10⁻⁴ mm Hg at 20 C. Dicrotophos is miscible (mixable in all proportions) with water, acetone, alcohol, acetonitrile, chloroform, methylene chloride, and xylene. Dicrotophos is only slightly soluble in kerosene and diesel fuel.

MANUFACTURING-USE PRODUCTS

A search of the Reference Files System (REFS) conducted 3/17/99 identified a single dicrotophos manufacturing-use product (MP) registered under PC Code 035201: the Amvac

Chemical Corporation 82% technical (T; EPA Reg. No. 5481-447). This product was originally registered to Shell Chemical Company (EPA Reg. No. 201-142), and was subsequently transferred to E. I. du Pont de Nemours and Company (EPA Reg. No. 352-456; 10/29/86), and then to Amvac (12/20/93). Only the Amvac T/TGAI is subject to a reregistration eligibility decision.

REGULATORY BACKGROUND

The Dicrotophos Reregistration Standard dated 11/25/81 required that additional generic and product-specific product chemistry data be submitted for dicrotophos registered to Shell Chemical Company. Data submitted in response to the Reregistration Standard were reviewed in the Addenda to the Dicrotophos Reregistration Standard dated 9/28/84. Amvac has since submitted updated information concerning the 82% T to support the reregistration of dicrotophos.

The current status of the product chemistry data requirements for the dicrotophos manufacturing-use product is presented in the attached data summary table. Refer to this table for a listing of the outstanding product chemistry data requirements.

CONCLUSIONS

Pertinent product chemistry data requirements remain unfulfilled for the Amvac 82% T/TGAI; additional data are required concerning product identity, preliminary analysis, certified limits, enforcement analytical methods, stability, explodability, UV/visible absorption, and viscosity (OPPTS 830.1550, 1700, 1750, 1800, 6313, 6316, 7050, and 7100). Provided that the registrant submits the data required in the attached data summary table for the 82% T, and either certifies that the suppliers of beginning materials and the manufacturing process for the dicrotophos technical product have not changed since the last comprehensive product chemistry review or submits a complete updated product chemistry data package, HED has no objections to the reregistration of dicrotophos with respect to product chemistry data requirements.

AGENCY MEMORANDA CITED IN THIS DOCUMENT

CBRS No(s): None
Subject: Addenda to the Dicrotophos Registration Standard Product and Residue Chemistry Chapters. (Reg. No. 201-142)
From: G. Makhijani
To: W. Miller
Dated: 9/28/84
MRID(s): 00115285 and 00126056

DP Barcode(s): D219352

Subject: Product Chemistry Data submitted by Amvac for the 82% T (EPA Reg. No. 5481-447)
From: G. Otakie
To: S. Willet
Dated: 6/28/99
MRID(s): 43603201-43603205 and 43772301-43772310

PRODUCT CHEMISTRY CITATIONS

Bibliographic citations include only MRIDs containing data which fulfill data requirements.

00013435 Shell Chemical Company (19??) Bidrin Insecticide. (Unpublished study received Jan 28, 1966 under 201-142; CDL:000834-A)

00013513 Shell Oil Company (1976) [Properties, Manufacturing Process, and Preparation of Technical Bidrin]. (Unpublished study received Feb 3, 1977 under 201-274; CDL:095828-L)

00013814 Shell Chemical Company (1962) Manufacture of Bidrin Insecticide. (Unpublished study received Jan 24, 1963 under 201-274; CDL: 000970-B)

00014001 Shell Oil Company (1970) Technical Data Bulletin: Summary of Basic Data for Bidrin Insecticide: ACD: 62-2R. Rev. (Unpublished study received Nov 18, 1970 under 1F1062; CDL:093373-A)

00115285 Shell Chemical Co. (1981) [Chemistry of Bidrin Dicrotophos]. (Compilation; unpublished study received Oct 7, 1982 under 201-142; CDL:248514-A)

00126056 Shell Chemical Co. (1962) [Chemistry of Bidrin]. (Compilation; unpublished study received Jan 28, 1983 under 201-142; CDL: 249412-A)

43603201 Braden, G. (1995) Water Solubility of BIDRIN Insecticide. Unpublished study prepared by AMVAC Chemical Corp. 9 p.

43603202 Braden, G. (1995) Solubility of BIDRIN Insecticide in Selected Organic Solvents. Unpublished study prepared by AMVAC Chemical Corp. 22 p.

43603203 Gonzalez, J. (1995) Vapor Pressure of BIDRIN Technical Insecticide. Unpublished study prepared by AMVAC Chemical Corp. 11 p.

43603204 Gonzalez, J. (1995) Partition Coefficient (n-Octanol/Water) for BIDRIN Insecticide: Lab Project Number: KOW 003-1. Unpublished study prepared by AMVAC Chemical Corp. 20 p.

43603205 Gonzalez, J. (1995) Stability of BIDRIN Technical Insecticide at 50 (degrees) C: Lab Project Number: STO-003/005. Unpublished study prepared by AMVAC Chemical Corp. 19 p.

- 43772301 Brady, K. (1995) Product Identity and Composition of BIDRIN Insecticide. Unpublished study prepared by AMVAC Chemical Corp. 33 p.
- 43772302 Brady, K. (1995) Preliminary Analysis of BIDRIN Insecticide. Unpublished study prepared by AMVAC Chemical Corp. 11 p.
- 43772303 Brady, K. (1995) Color of BIDRIN Insecticide. Unpublished study prepared by AMVAC Chemical Corp. 6 p.
- 43772304 Brady, K. (1995) Physical State of BIDRIN Insecticide. Unpublished study prepared by AMVAC Chemical Corp. 6 p.
- 43772305 Brady, K. (1995) Odor of BIDRIN Insecticide. Unpublished study prepared by AMVAC Chemical Corp. 6 p.
- 43772306 Gonzalez, J. (1995) Melting Point of BIDRIN Insecticide. Unpublished study prepared by AMVAC Chemical Corp. 7 p.
- 43772307 Braden, G. (1995) Boiling Point of BIDRIN Insecticide. Unpublished study prepared by AMVAC Chemical Corp. 11 p.
- 43772308 Brady, K. (1995) Density of BIDRIN Insecticide. Unpublished study prepared by AMVAC Chemical Corp. 7 p.
- 43772309 Brady, K. (1995) Dissociation Constant of BIDRIN Insecticide. Unpublished study prepared by AMVAC Chemical Corp. 5 p.
- 43772310 Braden, G. (1995) pH of BIDRIN Insecticide. Unpublished study prepared by AMVAC Chemical Corp. 13 p.

Case No. 0145
 Chemical No. 035201

Case Name: Dicrotophos
 Registrant: Amvac Chemical Corporation
 Product(s): 82% T (EPA Reg. No. 5481-447)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement fulfilled? ¹	Are Data Requirements MRID Number ²	
830.1550	Product identity and composition	N ³	<u>00126056</u> , 43772301
830.1600	Description of materials used to produce the product	Y	00013513 , 00013814 , <u>00126056</u> , 43772301
830.1620	Description of production process	Y	00013513 , 00013814 , <u>00126056</u> , 43772301
830.1670	Discussion of formation of impurities	Y	<u>00115285</u> , 43772301
830.1700	Preliminary analysis	N ⁴	43772302
830.1750	Certified limits	N ³	43772301
830.1800	Enforcement analytical method	N ⁵	00014001 , <u>Article</u> , 43772302
830.6302	Color	Y	00013435 , <u>00115285</u> , 43772303
830.6303	Physical state	Y	00013435 , 43772304
830.6304	Odor	Y	00013435 , <u>00115285</u> , 43772305
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	N ⁶	00013435 , 43603205
830.6314	Oxidation/reduction: chemical incompatibility	N/A ⁷	<u>00115285</u>
830.6315	Flammability	Y	<u>00115285</u>
830.6316	Explosibility	N	
830.6317	Storage stability	Y	<u>00115285</u>
830.6319	Miscibility	Y	<u>00115285</u>
830.6320	Corrosion characteristics	Y	<u>00115285</u>
830.7000	pH	Y	<u>00126056</u> , 43772310
830.7050	UV/Visible absorption	N ⁸	
830.7100	Viscosity	N	
830.7200	Melting point/melting range	N/A ⁹	
830.7220	Boiling point/boiling range	Y	00013435 , 43772307
830.7300	Density/relative density/bulk density	Y	00013435 , <u>00115285</u> , 43772308
830.7370	Dissociation constants in water	N/A ¹⁰	43772309
830.7550	Partition coefficient (n-octanol/water), shake flask method	Y	43603204
830.7840	Water solubility: column elution method; shake flask method	Y	00013435 , 43603201, 43603202
830.7950	Vapor pressure	Y	00013435 , 43603203

¹ Y = Yes; N = No; N/A = Not Applicable. Data references include data submitted by Shell Chemical Company.

² **Bolded** references were reviewed in the Dicrotophos Reregistration Standard dated 11/25/81; underlined references were reviewed in the Addenda to the Dicrotophos Reregistration Standard dated 9/28/84; and all the remaining references were reviewed under D219352.

³ The product identity and proposed nominal concentrations and certified limits listed on the CSF dated 3/24/95 cannot be evaluated until the outstanding preliminary analysis data are received.

⁴ Preliminary analysis data were not included in the submitted MRID; data reflecting analysis of five batches of the TGAI for components present at $\geq 0.1\%$ are required.

⁵ A description of an HPLC/UV method for determination of dicrotophos, along with supporting precision data have been submitted. If this method is intended for enforcement purposes, additional validation data (i.e., method recoveries) are required. In addition, the registrant must confirm that an old method referenced in the Addenda to the Dicrotophos Reregistration Standard for the impurities of dicrotophos is the current enforcement method. Pending identification of the impurities present at $>0.1\%$ in the outstanding preliminary analysis, the Agency will determine the adequacy of the method for enforcement purposes.

⁶ Quantitative data demonstrating the stability of the TGAI upon exposure to metals and metal ions are required.

⁷ The product does not contain oxidizing or reducing agents.

⁸ The OPPTS Series 830, Product Properties Test Guidelines require data pertaining to UV/visible absorption for the PAI.

⁹ Data are not required because the TGAI is a liquid at room temperature.

¹⁰ Data are not required because the TGAI is a fully esterified phosphate with no dissociable ions.

DICROTOPHOS

REREGISTRATION ELIGIBILITY DECISION

RESIDUE CHEMISTRY CONSIDERATIONS

PC Code No. 035201; Case 0145

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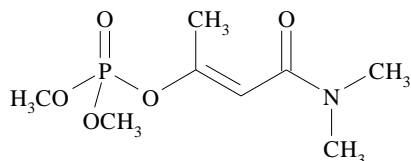
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DICROTOPHOS



REREGISTRATION ELIGIBILITY DECISION

RESIDUE CHEMISTRY CONSIDERATIONS

PC Code No. 035201; Case 0145

INTRODUCTION

Dicrotophos (dimethyl phosphate of 3-hydroxy-N,N-dimethyl-cis-crotonamide) is a contact, systemic acaricide/insecticide registered for use on cotton. The reregistration of dicrotophos is being supported by Amvac Chemical Corporation, the basic producer. Dicrotophos end-use products are marketed in the United States under the trade name Bidrin®; the only dicrotophos end-use formulation currently registered is a water-miscible formulation which may be applied foliarly to established cotton plants.

REGULATORY BACKGROUND

Dicrotophos was the subject of a Reregistration Standard Guidance Document dated 6/30/82; the Residue Chemistry Science Chapter of the Guidance Document was dated 11/25/81. Subsequent addenda to the Dicrotophos Reregistration Standard were issued 9/28/84. These documents summarized the status of residue chemistry data requirements with respect to the reregistration of dicrotophos.

Tolerances have been established under 40 CFR §180.299 for residues of dicrotophos *per se* in/on cottonseed and pecans, each at 0.05 ppm. It is noted that monocrotophos (dimethyl phosphate of 3-hydroxy-N-methyl-cis-crotonamide; PC Code No. 058901; Case 0154) is a residue of concern of dicrotophos. There are currently no registered food or non-food uses of monocrotophos in the United States. Because monocrotophos is highly toxic to avian species, the major producers of monocrotophos requested voluntary cancellation of all registrations containing this active ingredient on 6/13/88, and the Agency subsequently proposed [58 FR 32320, 6/9/93] to revoke all monocrotophos tolerances. Presently, tolerances remain established under 40 CFR §180.296 for residues of monocrotophos *per se* in/on cottonseed at 0.1 ppm, peanut hulls at 0.5 ppm, peanuts at 0.05 ppm, potatoes at 0.1 ppm, sugarcane at 0.1 ppm, and

tomatoes at 0.5 ppm, and under 40 CFR §185.2250 for residues in concentrated tomato products at 2 ppm.

SUMMARY OF SCIENCE FINDINGS

GLN 860.1200: Directions for Use

A search of the Agency's REFS database, conducted on 1/11/99, identified one active end-use product (EP) of dicotophos (DuPont Bidrin® 8 Water Miscible Insecticide; EPA Reg. No. 5481-448, dated 1/94) registered under FIFRA Section 3 to Amvac Chemical Corporation. This EP was originally registered to E.I. DuPont under EPA Reg. No. 352-466 but was transferred to Amvac on 12/20/93. There are no Special Local Need (SLN) registrations associated with this EP.

The 8 lb/gal water-miscible formulation is registered for multiple foliar applications to cotton. Early-season application is permitted at a maximum rate of 0.2 lb ai/A/application. Middle- to late-season applications may be made at a maximum rate of 0.5 lb ai/A/application. Applications are to be made in sufficient water to provide uniform coverage; application through any type of irrigation system is prohibited. A maximum of three foliar applications may be made per growing season. A PHI of 30 days has been established. The feeding of gin trash to livestock or grazing of livestock on treated fields is prohibited.

A review of the dicotophos label and supporting residue data suggests that label amendments are required for the 8 lb/gal water-miscible formulation (EPA Reg. No. 5481-448) to specify a maximum seasonal application rate and to remove the existing feeding/grazing restrictions. Based on the submitted cotton field trial data, the label should be amended to establish one early-season application at a maximum of 0.2 lb ai/A followed by two middle- to late-season applications at a maximum of 0.5 lb ai/A/application for a maximum seasonal rate of 1.2 lb ai/A. In addition, because the Agency considers the restriction which prohibits the feeding of cotton gin trash to livestock animals or the grazing of livestock animals on treated fields to be impractical and unenforceable, this restriction should be deleted from the label.

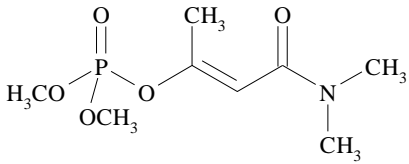
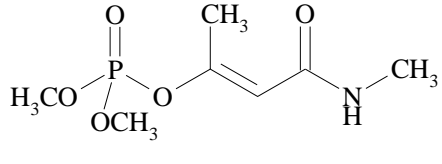
A tabular summary of the residue chemistry science assessments for reregistration of dicotophos is presented in Table A. The status of reregistration requirements for each guideline topic listed in Table A is based on the use patterns registered by the basic producer, Amvac Chemical Corporation. When 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 860.1300: Nature of the Residue - Plants

The reregistration requirements for plant metabolism are fulfilled based on an acceptable cotton metabolism study. In the cotton study, [¹⁴C]dicotophos was applied three times as a broadcast spray to the plant surfaces at a combined seasonal rate of 1.25 lb ai/A. The total radioactive

residues (TRR; expressed as dicrotophos equivalents) were 0.06 ppm in/on cottonseed, 6.11 ppm in/on cotton leaves, and 0.13 ppm in/on cotton stems. Dicrotophos broke down completely in cottonseed and leaf, and to a large extent in cotton stem. Based on the metabolites identified, the major pathway is the stepwise demethylation and hydrolysis of the phosphate group, with subsequent conjugation of acetoacetamide, monocrotophos, and N-methylacetoacetamide. The results of the cotton metabolism study were presented to the HED Metabolism Committee. Members of the HED Metabolism Committee concluded that, based on cholinesterase inhibition as the end point, both dicrotophos and its metabolite monocrotophos should be included in the tolerance expression, and both compounds should be included for dietary exposure assessment. If additional toxicology data indicate another end point, additional metabolites may need to be regulated and assessed. The chemical names and structures of dicrotophos and monocrotophos are depicted in Figure 1.

Figure 1. Chemical Names and Structures of Dicrotophos Residues of Concern in Plant Commodities.

Common Name Chemical Name	Chemical Structure	Common Name Chemical Name	Chemical Structure
Dicrotophos		Monocrotophos	
dimethyl phosphate of 3-hydroxy-N,N-dimethyl-cis-crotonamide		dimethyl phosphate of 3-hydroxy-N-methyl-cis-crotonamide	

GLN 860.1300: Nature of the Residue - Animals

The reregistration requirements for animal metabolism are fulfilled. Acceptable goat and hen metabolism studies have been submitted and evaluated. Neither dicrotophos nor monocrotophos were detected in eggs and poultry tissues, or milk and ruminant tissues; the metabolites found in animals are structurally similar to those found in cotton. Since the HED Metabolism Committee previously concluded that dicrotophos and monocrotophos are the residues of concern, HED concluded that tolerances are not needed in animals.

In the ruminant metabolism study, a lactating goat was administered [¹⁴C]dicrotophos orally for three consecutive days at 10.1 ppm (21x the maximum theoretical dietary burden assuming feed of 20% cottonseed hulls and 20% cotton gin byproducts). At sacrifice, the TRR were 0.251 ppm in liver, 0.103 ppm in kidney, 0.031 ppm in muscle, 0.006 ppm in fat, and 0.134-0.395 ppm in milk. The characterization data from the metabolism study indicate no single identifiable residue of concern would be detectable from the current use on cotton. In the poultry metabolism study, laying hens were also administered [¹⁴C]dicrotophos orally for three consecutive days at 10.1 ppm (1000x the maximum theoretical dietary burden). At sacrifice, the TRR were 0.823 ppm in

liver, 0.074 ppm in muscle, 0.045 ppm in skin/fat, 0.010-0.116 ppm in egg yolk, and 0.049-0.195 ppm in egg white. Both studies adequately characterized radioactive residues in animal commodities. The main metabolites identified included N-methyl-3-hydroxybutyramide, 3-hydroxybutyramide, 3-hydroxybutyric acid and its conjugates. [¹⁴C]Lactose and [¹⁴C]cholesterol were identified in milk and egg yolk, respectively, demonstrating the incorporation of radioactivity into natural products.

GLN 860.1340: Residue Analytical Methods

The recommended change in tolerance expression requires that an appropriate enforcement method be available to determine all dicotophos residues of concern in/on plant commodities. For the purpose of reregistration, adequate methods are available for the enforcement of plant commodity tolerances. Analytical methods for determination of dicotophos residues of concern in animal commodities are not needed because tolerances need not be proposed for eggs, milk, and edible livestock tissues. The Pesticide Analytical Manual (PAM) Volume II (Section 180.299) lists two GLC methods (designated as Methods A and B) with KCl thermionic detection. Both of these methods detect residues of dicotophos and monocotophos, but not other cholinesterase-inhibiting metabolites.

In Method A, residues are extracted with ethyl acetate and cleaned up using a charcoal adsorbent procedure. The eluate from the charcoal column is concentrated and analyzed by GLC using KCl thermionic detection. The reported sensitivity of Method A is 0.02 ppm for the determination of residues in/on cottonseed. In conjunction with a potato petition, PP#0F0912, Method A was subjected to independent laboratory validations, and the results were satisfactory. The Agency's analytical laboratory performed a method tryout of Method A with minor modifications to eliminate interferences by fats and oils on cottonseed. Cottonseed was fortified with monocotophos at 0.05 ppm and 0.10 ppm. A preliminary verbal report by the Agency laboratory indicated that the method tryout was successful; a report of the method tryout and its modifications was supposed to have been issued but was apparently lost in the process. The Agency's laboratory reported monocotophos recoveries of 76% and 90% at the 0.05-ppm level, and 80% and 84% at the 0.10-ppm level. In conjunction with the cotton petition, PP#1F1062, the Agency concluded that another method tryout using cottonseed fortified with dicotophos would not be necessary because dicotophos is closely related to monocotophos, and the method will be equally adequate for determining residues of dicotophos at tolerance level.

Method B is capable of determining residues of dicotophos and monocotophos simultaneously. Residues are extracted with acetone or hexane (depending on the fat content of the crop), and the extract is partitioned into chloroform. The chloroform extract is concentrated and exchanged into ethyl acetate. Residues are determined by GLC with KCl-thermionic detection. The reported sensitivity of Method B is 0.01 ppm for determination of residues in/on cottonseed. Recoveries of dicotophos were 90-140% from cottonseed fortified at 0.01 ppm and 0.02 ppm before and after extraction. Recoveries from cottonseed byproducts (linters, oil, meal, and soapstock) fortified at the same levels were 60-140%.

Samples collected from recently evaluated cotton field and processing studies were analyzed for

dicotophos and monocotophos residues using a GC/FPD-P method (designated as Method DIC- AM-001) with a stated quantitation limit of 0.01 ppm for each analyte. This method has been subjected to a successful independent laboratory validation. Because the enforcement methods listed in PAM Vol. II are lettered methods, HED recommends that Method DIC-AM-001 be forwarded to EPA's Analytical Chemistry Laboratory (Beltsville, MD) for additional method validation by Agency chemists. The Agency will withhold a final conclusion on the adequacy of this method as an analytical enforcement method pending receipt of the Agency method validation report.

GLN 860.1360: Multiresidue Methods

The reregistration requirements for multiresidue method testing are fulfilled. The 2/97 FDA PESTDATA database (PAM Volume I, Appendix I) indicates that dicotophos is completely recovered (>80%) using Multiresidue Methods Section 302 (Luke Method; Protocol D) but is not recovered using Multiresidue Methods Section 303 (Mills, Onley, Gaither Method; Protocol E, nonfatty foods).

Monocotophos is completely recovered (>80%) using Multiresidue Methods Section 302 (Luke Method; Protocol D) but is not recovered using method Sections 303 (Mills, Onley, and Gaither Method; Protocol E for nonfatty food) and 304 (Mills method; Protocol E for fatty food).

GLN 860.1380: Storage Stability Data

The reregistration requirements for storage stability data are satisfied. The total storage intervals between harvest and analysis of samples from previously evaluated cotton field and processing studies were ~5 months. Recently submitted storage stability data indicate that fortified residues of dicotophos and monocotophos are stable during frozen storage (<-20 ±5 C) for up to 6 months in/on undelinted cottonseed, cotton gin trash, and cottonseed processed commodities. These storage stability data are adequate to support the storage intervals and conditions of samples collected from the cottonseed field and processing studies.

According to data from Accession No. 248514 located in "Addenda to the Dicotophos Registration Standard Product and Residue Chemistry Chapters," residues of dicotophos *per se* are stable during frozen storage (-20 C) for up to 20 months in/on alfalfa, apples, bean foliage, melons, and oranges. The Residue Chemistry Science Chapter to the Monocotophos Reregistration Standard dated 12/6/84 reported that residues of monocotophos *per se* are relatively stable in/on plant commodities under frozen storage conditions for up to 8 months; however, residues of monocotophos declined by 50% after 22 months of frozen storage.

GLN 860.1500: Crop Field Trials

HED has evaluated residue data depicting the magnitude of dicotophos residues of concern in/on cottonseed and cotton gin byproducts. Twelve field trials were conducted in the states of

AK (1), CA (3), GA (1), LA (1), MS (1), NM (1), OK (1), and TX (3); the number of trials per state are in parentheses. The 8 lb/gal water-miscible formulation of dicotophos was applied to cotton plants using ground equipment and according to the following treatment schedule: one early-season application at 0.24-0.26 lb ai/A followed by two mid-/late-season applications at 0.48-0.53 lb ai/A/application. The application rates represent 1x the maximum registered rates for early and mid-/late-season treatments, respectively. Samples were collected at preharvest intervals of 28 to 36 days. The combined residues of dicotophos and monocotophos in/on treated cottonseed ranged from <0.02 ppm (nondetectable) to 0.13 ppm. The combined residues of dicotophos and monocotophos in/on treated cotton gin byproducts ranged from 0.12 ppm to 1.8 ppm.

The reregistration requirements for magnitude of the residue in/on cottonseed and cotton gin byproducts will be considered fulfilled pending label revisions and/or tolerance adjustments. The results of the cotton field trials indicate that the existing dicotophos tolerance of 0.05 ppm in/on cottonseed is too low and that the registrant needs to propose a tolerance for dicotophos residues of concern in/on cotton gin byproducts. Refer to the "Tolerance Reassessment Summary" section for recommendations regarding appropriate tolerance levels.

The use of dicotophos on pecans is not being supported by the basic producer which has deleted this crop as a site from their Section 3 EP label. Therefore, no additional field trial data are required for pecans.

GLN 860.1520: Processed Food/Feed

HED has evaluated residue data pertaining to the potential for concentration of dicotophos residues of concern in the processed commodities of cotton. The cotton processing data indicate that dicotophos and monocotophos residues did not concentrate in hulls, meal, and refined oil processed from cottonseed bearing detectable dicotophos residues and nondetectable monocotophos residues. Tolerances are, therefore, not required for the processed commodities of cotton.

GLN 860.1480: Meat, Milk, Poultry, Eggs

The reregistration requirements for studies pertaining to magnitude of the residue in milk, eggs, and tissues of animals are waived. Based on the results of dicotophos animal metabolism studies, there is no reasonable expectation of residues in milk, eggs, and tissues of animals [Category 3 of 40 CFR §180.6(a)] when dicotophos is applied according to registered use directions. Therefore, tolerances for residues of dicotophos in animal commodities need not be proposed.

GLN 860.1400: Water, Fish, and Irrigated Crops

Dicotophos is presently not registered for direct use on water and aquatic food and feed crops; therefore, no residue chemistry data are required under these guideline topics. The HED

Metabolism Committee concluded that since dicrotophos acid had been found in environmental fate studies, the exposure assessment in drinking water should include dicrotophos, monocrotophos, and dicrotophos acid if the acid is present in significant amounts.

GLN 860.1460: Food Handling

Dicrotophos is presently not registered for use in food-handling establishments; therefore, no residue chemistry data are required under this guideline topic.

GLN 860.1850 and 860.1900: Confined/Field Accumulation in Rotational Crops

The reregistration requirements for confined/field rotational crop studies are fulfilled. The available confined rotational crop data indicate that the metabolism of dicrotophos in rotational crops is similar to that in primary plants. Because no residues of dicrotophos or monocrotophos were detected in any rotational crop commodity at any plantback interval, no field rotational crop studies are required. In addition, no rotational crop tolerances or restrictions need be established.

Table A. Residue Chemistry Science Assessments for Reregistration of Dicrotophos.

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References ¹
860.1200: Directions for Use	N/A = Not Applicable	Yes ²	Product label for EPA Reg. No. 5481-448
860.1300: Plant Metabolism	N/A	No	00013451, 00013506, 00013684, 00013998, 05013986, 05014733, 44169401 ³
860.1300: Animal Metabolism	N/A	No	05012698, 05014733, 43962401 ⁴ , 44031201 ⁴
<u>860.1340: Residue Analytical Methods</u>			
- Plant commodities	N/A	Yes ⁵	00013453, 00013456, 00013472, 00013474, 00013516, 00013517, 00013682, 00013703, 00013967, 00013969, 00013999, 00014005, 00014006, 05002358, 44750301 ⁶
- Animal commodities	N/A	No	00013453, 00013472, 00013474, 00013682, 00013703, 00013967
860.1360: Multiresidue Methods	N/A	No	
860.1380: Storage Stability Data	N/A	No	44728501 ⁶
<u>860.1500: Crop Field Trials</u>			
<u>Tree Nuts Group</u>			
- Pecans	0.05 [§180.299]	No ⁷	PP#0E2415
<u>Miscellaneous Commodities</u>			
- Cotton, seed and gin byproducts	0.05, cottonseed [§180.299]	No	00013684, 00013997, 00014000, 44614701 ⁸
<u>860.1520: Processed Food/Feed</u>			
- Cotton, seed	None established	No	00013684, 44614702 ⁹
<u>860.1480: Meat, Milk, Poultry, Eggs</u>			
- Milk and the Fat, Meat, and Meat Byproducts of Cattle, Goats, Hogs, Horses, and Sheep	None established	No	00013440, 05012698
- Eggs and the Fat, Meat, and Meat Byproducts of Poultry	None established	No	
860.1400: Water, Fish, and Irrigated Crops	N/A	N/A	
860.1460: Food Handling	N/A	N/A	
860.1850: Confined Rotational Crops	N/A	No	44101001 ¹⁰
860.1900: Field Rotational Crops	None established	No	

(continued; footnotes follow)

(continued; footnotes follow)

TOLERANCE REASSESSMENT SUMMARY

Tolerances for residues in/on plant commodities are established under 40 CFR §180.299 and are currently expressed in terms of residues of dicrotophos *per se* (dimethyl phosphate of 3-hydroxy-N,N-dimethyl-cis-crotonamide). The qualitative nature of the residue in plants is adequately understood. The HED Metabolism Committee has determined that dicrotophos and monocrotophos (dimethyl phosphate of 3-hydroxy-N-dimethyl-cis-crotonamide) are the residues that warrant regulation in plant commodities. The tolerance expression should be revised to include monocrotophos and should be expressed in terms of the combined residues of dicrotophos and its metabolite monocrotophos (calculated as dicrotophos).

The qualitative nature of the residue in animals is adequately understood. There is no reasonable expectation of residues in milk, eggs, and tissues of animals [Category 3 of 40 CFR §180.6(a)] when dicrotophos is applied according to registered use directions. Therefore, tolerances for residues of dicrotophos in animal commodities need not be proposed.

We note that although all registered uses of monocrotophos have been canceled, tolerances remain established for residues of monocrotophos *per se* under 40 CFR §180.296 in/on cottonseed at 0.1 ppm, peanut hulls at 0.5 ppm, peanuts at 0.05 ppm, potatoes at 0.1 ppm, sugarcane at 0.1 ppm, and tomatoes at 0.5 ppm, and under 40 CFR §185.2250 in concentrated tomato products at 2 ppm. The revocation of all monocrotophos tolerances was earlier proposed by the Agency [58 FR 32320, 6/9/93] but this proposal was put on hold because certain monocrotophos registrants expressed interest in the establishment of import tolerances for cottonseed, potatoes, and sugarcane. Novartis Corporation, the only company that supports monocrotophos worldwide, has indicated that the pesticide's last year of sale will occur during 1999 in Mexico and agreed to tolerance revocation for monocrotophos (see OPP Weekly Activity Report for Week Ending 1/29/99, M. Mulkey, 2/16/99)

A summary of dicrotophos tolerance reassessments is presented in Table B. The reassessments of tolerances are contingent upon the implementation of the requested label revision.

Tolerances Listed Under 40 CFR §180.299:

Sufficient field trial data are available to reassess the established tolerance for cottonseed. These data suggest that the existing dicrotophos tolerance of 0.05 ppm in/on cottonseed is too low. The combined residues of dicrotophos and monocrotophos in/on cottonseed samples treated and harvested according to the maximum label use directions ranged from <0.02 ppm to 0.13 ppm. HED recommends that the tolerance for dicrotophos and its metabolite monocrotophos in/on cottonseed be reassessed at 0.2 ppm.

No registrant has committed to support dicrotophos use on pecans, and this site has been removed from the basic producer's product label. Therefore, the established tolerance for pecans should be revoked.

Tolerance to be Proposed Under 40 CFR §180.299:

Sufficient field trial data have been submitted and reviewed for cotton gin byproducts. These

data indicate that the combined residues of dicrotophos and monocrotophos in/on treated cotton gin byproducts ranged from 0.12 to 1.8 ppm following treatments according to the maximum label use directions. The registrant should propose a tolerance for the combined residues of dicrotophos and its metabolite monocrotophos (calculated as dicrotophos) in/on cotton gin byproducts at 2.0 ppm.

Based on the available cottonseed processing study which demonstrated that residues of dicrotophos and monocrotophos do not concentrate in cottonseed hulls, meal or refined oil, tolerances are not required for these processed commodities.

Table B. Tolerance Reassessment Summary for Dicrotophos.

Commodity	Current Tolerance, ppm	Reassessed Tolerance, ppm	Comment [Correct Commodity Definition]
Tolerances Listed Under 40 CFR §180.299			
Cottonseed	0.05	0.2 ^a	[Cotton, undelinted seed]
Pecans	0.05	Revoke	Use of dicrotophos on pecans is not being supported for reregistration.
Tolerance To Be Proposed Under 40 CFR §180.299			
Cotton, gin byproducts	--	2.0 ^a	

^a The reassessed tolerance for cottonseed and the recommended tolerance for cotton gin byproducts are contingent upon the implementation of the requested label revision.

CODEX HARMONIZATION

The Codex Alimentarius Commission has not established or proposed maximum residue limits (MRLs) for residues of dicrotophos. Therefore, there are no issues regarding compatibility of U.S. tolerances with Codex MRLs.

DIETARY EXPOSURE ASSESSMENT

Adequate residue data for food commodities are available for registration and risk assessment purposes. A risk assessment for the use of dicrotophos on food can be conducted at this time using the proposed 0.2 ppm tolerance for cottonseed. The tolerance is based on the highest cotton field trial residue data of 0.13 ppm (or 0.11 ppm for the average of two replicate samples) rounded up to the nearest tenth of a ppm. Averaging the combined dicrotophos and monocrotophos residue levels in samples from the cotton field trials, results in an anticipated residue for combined residues of dicrotophos and monocrotophos of 0.04 ppm in cottonseed. Based on the available data HED concludes there is no reasonable expectation of finding quantifiable secondary residues of dicrotophos/monocrotophos in animal commodities from the approved use on cotton.

AGENCY MEMORANDA RELEVANT TO REREGISTRATION

CB No.: 239
Subject: ID #201-142: Dicrotophos (Bidrin® Insecticide) Registration Standard - Protocol for cotton metabolism study - Letter of October 15, 1985
From: A. Smith
To: W. Miller and Toxicology Branch
Dated: 1/24/86
MRID(s): None

CB No.: 1049
Subject: EPA Accession Number 263099. Response to Registration Standard on Bidrin (Dicrotophos). Submissions of Cotton Metabolism Study. Letter of 5/30/86.
From: R. Cook
To: W. Miller and Toxicology Branch
Dated: 8/18/86
MRID(s): None

CBRS No.: 11765
DP Barcode: D190400
Subject: Dicrotophos: Possible Detection in Rice.
From: L. Cheng
To: M. Mautz
Dated: 4/30/93
MRID(s): None

CB No. 17690
DP Barcode: D232021
Subject: Dicrotophos. Case 0145. Metabolism on Cotton.
From: L. Cheng
To: D. McCall
Dated: 3/21/97
MRID(s): 44169401

DP Barcode: None
Subject: Dicrotophos. Case 0145. Metabolism in Cotton. To be Presented to the HED Metabolism Committee.
From: L. Cheng
To: The HED Metabolism Committee
Dated: 4/2/97
MRID(s): None

DP Barcode: None
Subject: Dicrotophos. Metabolism in Cotton. The Metabolism Committee Meeting Held on April 21, 1997.
From: L. Cheng
To: The HED Metabolism Committee
Dated: 4/22/97
MRID(s): None

CB Nos. 17830 and 17831
DP Barcodes: D234328 and D233998
Subject: Dicrotophos. Case 0145. Residues to be Measured in Cotton Field Trials.
From: L. Cheng
To: P. Deschamp
Dated: 5/1/97
MRID(s): None

DP Barcodes: D227121, D229636, and D228047
Subject: Dicrotophos. Case 0145. PC Code 035201. Metabolism in Laying Hens and Lactating Goat.
From: L. Cheng
To: K. Whitby
Dated: 11/25/97
MRID(s): 44031201 and 43962401

DP Barcode: D248565
Subject: Dicrotophos: Magnitude of the Residue in Cottonseed and Cotton Gin Byproducts. Chemical No. 035201. Case No. 0145.
From: S. Law
To: T. Luminello
Dated: 9/18/98
MRID(s): 44614701
DP Barcode: D248407
Subject: Dicrotophos: Magnitude of the Residue in Cotton Processed Commodities. Chemical No. 035201. Case No. 0145.
From: S. Law
To: S. Willett
Dated: 10/6/98
MRID(s): 44614702

DP Barcode: D245297
Subject: Dicrotophos. Confined Rotational Crop Study

From: S. Law
To: S. Willett
Dated: 12/8/98
MRID(s): 44101001

DP Barcode D252921
Subject Response to Residue Chemistry Data Requirements
From: G. Otakie
To: S. Willett
Dated: 6/28/99
MRID(s) 44750301 and 44728501

MASTER RECORD IDENTIFICATION NUMBERS

References Used To Support Reregistration

00013440 Pankaskie, J.E. (1962) Summary Report on Field Performance of SD 3562: 3-(Dimethoxyphosphinyloxy)-N,N-dimethyl-cis-crotonamide: Technical Report No. M-17-62. (Unpublished study received Jan 28, 1966 under 201-142; submitted by Shell Chemical Co., Washington, D.C.; CDL:000834-F)

00013451 Shell Oil Company (19??) Isolation and Characterization of a Product Formed from Bidrin Insecticide in Plants (Bull's and Lindquist's Unknown A). (Unpublished study received Jan 28, 1966 under 201-142; CDL:000834-S)

00013453 Shell Development Company (1965) Determination of Traces of Bidrin Insecticide and Three Possible Metabolites, Azodrin Insecticide, SD 12657, and SD 12210 in Crops and Milk: Total Enzyme Inhibition-Spectrophotometric Method. Method MMS-65/65 dated Aug 1965. (Unpublished study received Jan 28, 1966 under 201-142; CDL:000834-U)

00013440 Pankaskie, J.E. (1962) Summary Report on Field Performance of SD 3562: 3-(Dimethoxyphosphinyloxy)-N,N-dimethyl-cis-crotonamide: Technical Report No. M-17-62. (Unpublished study received Jan 28, 1966 under 201-142; submitted by Shell Chemical Co., Washington, D.C.; CDL:000834-F)

00013472 Shell Development Company (1963) Determination of Bidrin Insecticide in Crops and Animal Products: Enzyme Inhibition-Spectrophotometric Method. Method MMS-40/63 dated Aug 29, 1963. (Unpublished study received Jan 28, 1966 under 201-142; CDL:000834-AQ)

00013474 Shell Development Company (1965) Determination of Bidrin Insecticide Residues in Crops and Milk--A Specific Enzymatic Method. Method MMS-66/65 dated Sep 1965. (Unpublished study received Jan 28, 1966 under 201-142; CDL:000834-AS)

00013506 Shell Chemical Company (1965?) Identification of Unknown 4. (Unpublished study received May 13, 1966 under 6G0497; CDL: 090571-O)

00013516 Shell Development Company (1973) Determination of Azodrin and/or Bidrin Insecticides in Water, Soil and Agricultural Commodities: AFID/Flame Photometric-GLC Method. Method MMS-R-332-1 dated Nov 1973. (Unpublished study received Feb 3, 1977 under 201-274; CDL:095828-R)

00013517 Shell Development Company (1975) Determination of Bidrin Insecticide Metabolite SD 12210 Occurring as Glycosides in Crops: TLC-Enzyme Inhibition Method. Method MMS-R-245-2 dated Jul 1975. (Unpublished study received Feb 3, 1977 under 201-274; CDL:095828-T)

00013682 Shell Development Company (1962) Determination of SD 3562 in Crops and Animal Products: Enzyme Inhibition-Spectrophotometric Method. Method MMS-40/61 dated Feb 23, 1962. (Unpublished study received Mar 5, 1962 under unknown admin. no.; CDL:121262-B)

00013684 Shell Chemical Company (1962) Cottonseed and Cottonseed Products: Analysis of Seed Cotton, Cottonseed, and Processed Cottonseed Products Following Application of Bidrin Insecticide to the Plant Foliage. (Unpublished study received Feb 21, 1963 under unknown admin. no.; CDL:121265-E)

00013703 Shell Development Company (1964) Determination of Bidrin Insecticide in Crops and Animal Products: Enzyme Inhibition-Spectrophotometric Method. Method MMS-40/64 dated Jul 1964. (Unpublished study received Jul 1, 1964 under unknown admin. no.; CDL:129695-A)

00013967 Shell Development Company (1966) Determination of Traces of Bidrin Insecticide and Three Possible Metabolites, Azodrin Insecticide, SD 12657, and SD 12210 in Crops and Milk: Total Enzyme Inhibition-Spectrophotometric Method. Method MMS-65/66 dated Mar 1966. (Unpublished study received Dec 2, 1966 under 7G0571; CDL:090721-J)

00013997 Shell Chemical Company (1969) Residues of Bidrin(R) Insecticide on Cotton. (Unpublished study received on unknown date under 1F1062; CDL:091828-AB)

00013998 Lindquist, D.A.; Bull, D.L.; Ridgway, R.L. (1965) Systemic activity of Bidrin in the

cotton plant. *Journal of Economic Entomology* 58(2): 200-203. (Also In unpublished submission received Jan 28, 1966 under 1F1062; submitted by Shell Chemical Co., Washington, D.C.; CDL:091828-AG)

00014000 Shell Chemical Company (1968) Experimental Data on Determination of Bidrin Insecticide Residues on Cottonseed. (Unpublished study received on unknown date under 1F1062; CDL:091828-AK)

05012698 Johnson, J.C., Jr.; Bowman, M.C. (1968) Fate of Bidrin and Imidan when fed in silage to lactating dairy cows. *Journal of Dairy Science* 51(8): 1225-1228.

05013986 Bull, D.L.; Lindquist, D.A. (1964) Metabolism of 3-hydroxy-N,N-dimethylcrotonamide dimethyl phosphate by cotton plants, insects, and rats. *Journal of Agricultural and Food Chemistry* 12(4): 310-317.

05014733 Menzer, R.E.; Casida, J.E. (1965) Nature of toxic metabolites formed in mammals, insects, and plants from 3-(dimethoxyphosphinyloxy)-N,N-dimethyl-cis-crotonamide and its N-methyl analog. *Journal of Agricultural and Food Chemistry* 13(2): 102-112.

43962401 Krautter, G.; Marsh, J.; Downs, J. (1996) The Metabolism of (carbon 14)-Dicrotophos in the Lactating Goat: Lab Project Number: 834: 1674. Unpublished study prepared by PTRL East, Inc. 176 p.

44031201 Krautter, G.; Downs, J.; Marsh, J. (1996) The Metabolism of (carbon 14)Dicrotophos in the Laying Hen: Lab Project Number: 835: 1890. Unpublished study prepared by PTRL East, Inc. 168 p.

44101001 O'Neal, S. (1996) A Confined Rotational Crop Study with (carbon 13)(carbon 14)-Dicrotophos: Lab Project Number: 868: 1897. Unpublished study prepared by PTRL East, Inc. 199 p.

44169401 O'Neal, S. (1996) Metabolic Fate and Distribution of (carbon-13,14)-Dicrotophos in Cotton: (Final Report): Lab Project Number: 847: 1914. Unpublished study prepared by North Carolina State University and PTRL East, Inc. 125 p.

44614701 Prochaska, L. (1998) Magnitude of Dicrotophos Residues in Cotton Raw Agricultural Commodities: Lab Project Number: SARS-97-30: SARS-97-AR-30: SARS-97-CA-30A. Unpublished study prepared by Morse Laboratories Stewart Agricultural Research Services, Inc. 324 p. {OPPTS 860.1500}

44614702 Prochaska, L. (1998) Magnitude of Dicrotophos Residues in Cotton Processed Commodities: Lab Project Number: SARS-97-31: ML97-0701-AMV: DIC-AM-001. Unpublished study prepared by Morse Laboratories, Inc. Stewart Agricultural Research Services, Inc. 210 p. {OPPTS 860.1520}

1. References without endnotes were reviewed in the Residue Chemistry Science Chapter of the Dicrotophos Guidance Document, dated 11/25/81. Otherwise, references were reviewed as noted.

2. Label amendments are required for the 8 lb/gal water-miscible formulation (EPA Reg. No. 5481-448) to specify a maximum seasonal application rate and to remove the existing feeding/grazing restrictions. Based on the submitted cotton field trial data, the label should be amended to establish one early-season application at a maximum of 0.2 lb ai/A followed by two middle- to late-season applications at a maximum of 0.5 lb ai/A/application for a maximum seasonal rate of 1.2 lb ai/A. In addition, because the Agency considers the restrictions prohibiting the feeding of cotton gin trash to livestock animals or the grazing of livestock animals on treated fields to be impractical and unenforceable, this restriction should be deleted from the label.
3. CB No. 17690, DP Barcode D232021, 3/21/97, L. Cheng.
4. DP Barcodes D227121, D229636, and D228047, 11/25/97, L. Cheng.
5. Because the enforcement methods listed in PAM Vol. II are lettered methods, HED recommends that Method DIC-AM-001 be forwarded to EPA's Analytical Chemistry Laboratory (Beltsville, MD) for additional method validation by Agency chemists. The Agency will withhold a final conclusion on the adequacy of this method as an analytical enforcement method pending receipt of the Agency method validation report.
6. DP Barcodes D252921 and D25328.
7. The registrant does not intend to support dicotophos use on pecans; therefore the established tolerance for pecans should be revoked.
8. DP Barcode D248565, 9/18/98, S. Law.
9. DP Barcode D248407, 10/6/98, S. Law.

10. DP Barcode D245297, 12/8/98, S. Law.
10. DP Barcode D245297, 12/8/98, S. Law.