10/OPP # 54144 (52PP)

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

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OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

March 27, 1998

MEMORANDUM:

SUBJECT: Ethoprop (041101), Reregistration Case No. 0106. Product and Residue Chemistry Chapters for the Reregistration Eligibility Decision (RED). DP Barcode No. D239294, No MRID.

FROM: John Abbotts, Chemist [signature] for
Chemistry and Exposure Branch I
Health Effects Division [7509C]

THRU: Francis B. Suhre, Branch Senior Scientist [signature]
Chemistry and Exposure Branch I
Health Effects Division [7509C]

TO: Kit Farwell
Reregistration Branch I
Health Effects Division [7509C]

and

Judith Loranger
Reregistration Branch III
Special Review and Reregistration Division [7508W]

The Product and Residue Chemistry chapters for the Ethoprop RED are attached. The chapters were assembled by Dynamac Corporation under the supervision of CEBI, HED. The data assessment has undergone secondary review in the branch and has been revised to reflect Agency policies.

With regard to Product Chemistry, additional data are required for the 95.9% T to meet the new requirement concerning UV/visible absorption (OPPTS GLN 830.7050). Provided that the registrant submits the required data, and either certifies that the suppliers of beginning materials and the manufacturing processes have not changed since the last comprehensive product chemistry review, or submits completed updated product chemistry data packages, the Branch has no objections to the reregistration of Ethoprop with respect to product chemistry data requirements.

With regard to Residue Chemistry, requirements for plant and livestock metabolism have been satisfied. Requirements for field trials have been satisfied for a few crops. For other crops, submitted field trial data are not entirely consistent with maximum label use patterns; requirements may be satisfied by appropriate label amendments or additional residue data. Processing data are satisfied for most crops. Further details are provided in the endnotes to Table B in the Residue Chemistry chapter. Data also remain outstanding for field rotational crops; however, data requirements could be reduced by appropriate label restrictions on rotational crops. For several crops not being supported for reregistration, data requirements will be waived provided tolerances are revoked.

Tolerances are not established for livestock commodities, and will not be required at present. However, once adequate residue data are available on all livestock feed items, the requirement for livestock feeding studies will be reevaluated to determine if additional data are needed.

With regard to dietary exposure assessment, the HED Metabolism Committee has determined that parent and three metabolites are residues of concern. Magnitude of the residue data have been submitted at most for parent and one metabolite. HED has previously made a commitment to conduct dietary exposure assessment using the best available data, making conservative assumptions from metabolism data to estimate all residues of concern. With the data available, it should be feasible to conduct a reasonably reliable dietary exposure assessment.

If additional information is required, please advise.

Attachment 1: Reregistration Eligibility Decision: Product Chemistry Considerations
Attachment 2: Reregistration Eligibility Decision: Residue Chemistry Considerations

cc(without Attachments):RF
cc(with Attachments): Abbotts, Ethoprop List A File
RDI:FBSuhre:3/23/98:ChemSAC:3/18/98
7509C:CEBI:JAbbotts:CM-2:Rm805B:305-6230: [3/27/98]
Ethoprop.red

ETHOPROP
Shaughnessy No. 041101; Case 0106

Reregistration Eligibility Decision

January 16, 1998

Contract No. 68-D4-0010

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

Submitted by:
Dynamac Corporation
1910 Sedwick Road
Building 100, Suite B
Durham, NC 27713

ETHOPROP

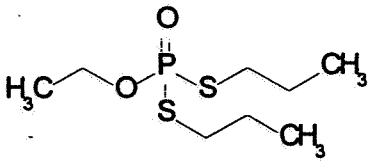
REREGISTRATION ELIGIBILITY DECISION

PRODUCT CHEMISTRY CONSIDERATIONS

Shaughnessy No. 041101; Case No. 0106

DESCRIPTION OF CHEMICAL

Ethoprop (O-ethyl S,S-dipropyl phosphorodithioate) is a nematicide and insecticide registered for use on various fruit and vegetable crops.



Empirical Formula:	$C_8H_{19}O_2PS_2$
Molecular Weight:	242.3
CAS Registry No.:	13194-48-4
Shaughnessy No.:	041101

IDENTIFICATION OF ACTIVE INGREDIENT

Ethoprop is a colorless to yellow tinted liquid with a strong mercaptan odor and a boiling point of 86-91 C at 0.2 mm Hg. Ethoprop is only slightly soluble in water (843 ppm at 21 C), but is soluble in most organic solvents (hexane, xylene, acetone, and ethanol).

MANUFACTURING-USE PRODUCTS

A search of the Reference Files System (REFS) conducted 11/10/97 identified a single ethoprop manufacturing-use product (MP) registered under Shaughnessy No. 041101: the Rhone-Poulenc Ag Company 95.9% technical product (T; EPA Reg. No. 264-456). Only the Rhone-Poulenc 95.9% T is subject to a reregistration eligibility decision.

REGULATORY BACKGROUND

Additional generic and product-specific product chemistry data for ethoprop were required in a registration standard issued 2/28/83 and a guidance document issued 6/83. The Ethoprop Final Registration Standard and Tolerance Reassessment (FRSTR) dated 10/20/87 and the subsequent Ethoprop Guidance Document dated 6/88 required that new or updated product chemistry data be submitted for the reregistration of ethoprop.

The current status of the product chemistry data requirements for the ethoprop 95.9% T is presented in the attached data summary table.

CONCLUSIONS

Pertinent data requirements have been satisfied for the Rhone-Poulenc 95.9% T (EPA Reg. No. 264-456), except that data are required concerning UV/visible absorption for the PAI (OPPTS 830.7050). Provided that the registrant submits the data required in the attached data summary table for the 95.9% T, and either certifies that the suppliers of beginning materials and the manufacturing process for the ethoprop MP have not changed since the last comprehensive product chemistry review or submits a complete updated product chemistry data package, CBRS has no objections to the reregistration of ethoprop with respect to product chemistry data requirements.

AGENCY MEMORANDA CITED IN THIS DOCUMENT

CBRS No(s).:	5114
Subject:	Rhone-Poulenc Ag Company - Response to Ethoprop Final Registration Standard and Tolerance Reassessment Document - Product Chemistry.
From:	G. Makhijani
To:	J. Ellenberger/B. Briscoe and W. Miller
Dated:	4/17/89
MRID(s):	41004401

CBRS No(s).:	5303
Subject:	EPA Reg. No. 264-456: Ethoprop. Response to Final Registration Standard and Tolerance Reassessment. Additional Product Chemistry.
From:	J. Garbus
To:	B. Briscoe
Dated:	9/19/89
MRID(s):	41055301

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CBRS No(s).: 8767
DP Barcode(s): D169998
Subject: Ethoprop. Rhone-Poulenc Response to the Guidance Document Dated 6/88. Storage Stability.
From: L. Cheng
To: L. Rossi
Dated: 5/1/92
MRID(s): 42044801

CBRS No(s).: 12397
DP Barcode(s): D194353
Subject: Ethoprop. Data Waiver of Guideline 63-10.
From: F. Fort
To: S. Jennings/L. Schnaubelt
Dated: 9/29/93
MRID(s): 41055301

CBRS No(s).: 12705
DP Barcode(s): D195967
Subject: Ethoprop Reregistration: List A Chemical No. 041101; Case No. 0106. Rhone-Poulenc: Response to Data Requirements Regarding Color (GLN No. 63-2) for Reregistration of Ethoprop T/MP (EPA Reg. No. 264-456).
From: F. Toghrol
To: W. Waldrop
Dated: 11/19/93
MRID(s): 42953501

CBRS No(s).: 12396
DP Barcode(s): D194202
Subject: Response to the Ethoprop Reregistration Standard: Product Chemistry.
From: R. Perfetti
To: E. Saito
Dated: 7/21/94
MRID(s): 41211203

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CBRS No(s).: 14437
DP Barcode(s): D207680
Subject: Ethoprop Reregistration. Rhone-Poulenc's Undated Response [62-2 data: CSF] to R. Perfetti 7/21/94 Review.
From: K. Dockter
To: L. Schnaubelt/S. Jennings
Dated: 5/8/95
MRID(s): Undated CSF

PRODUCT CHEMISTRY CITATIONS

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

References (cited):

00142272 Orth, D. (1984) Product Chemistry Testing for Ethoprop Technical and Granular Formulation (MOCAP 10G): Final Report: Project Number 84-PL-34; 84-PL-28. Unpublished study prepared by Biospherics Inc. 12 p.

00152115 Beche, R. (1984) Ethoprop, Technical Grade Analysis and Certification of Product Ingredients. Unpublished study prepared by Rhone-Poulenc Agrochimie. 118 p.

41004401 Murayama, S. (1989) Ethoprop Technical: Product Identity and Composition: Proj. ID 783C10. Unpublished study prepared by Rhone-Poulenc Ag Co. 83 p.

41055301 Murayama, S. (1989) Ethoprop Technical: The Technical Grade of the Active Ingredient and the Manufacturing-Use Product: Physical and Chemical Properties: Project ID; 783C10; File No. 40485. Unpublished study prepared by Battelle, Columbus Div. 74 p.

42044801 Eubanks, M. (1991) Ethoprop Technical: Storage Stability Study: Lab Project Number: AC-90-016: 41033. Unpublished study prepared by Rhone-Poulenc Ag Co. 54 p.

42953501 Helfant, L. (1993) Ethoprop Technical: Product Chemistry Physical and Chemical Properties Series 63, Guideline 63-2 (Color); Lab Project Number: 44206: 93010LJH. Unpublished study prepared by Rhone-Poulenc Ag Co. 9 p.

41211203 Murayama, S. (1989) Ethoprop Technical: The Technical Grade of the Active Ingredient and the Manufacturing Use Product: Analysis and Certification of Product Ingredients: Laboratory Project ID 783C10. Unpublished study prepared by Rhone-Poulenc Ag Co. 103 p.

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(1)

Case No. 0106
Chemical No. 041101

Case Name: Ethoprop
Registrant: Rhone-Poulenc Ag Company
Product(s): 95.9% T (EPA Reg. No. 264-456)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? [1]	MRID Number [2]
830.1550	Product Identity and Disclosure of Ingredients	Y	**00152115**, 41004401
830.1600	Starting Materials and Manufacturing Process	Y	41004401
830.1620			
830.1650			
830.1670	Discussion of Formation of Impurities	Y	**00152115**, 41004401
830.1700	Preliminary Analysis	Y	**00152115**, 41211203 [3]
830.1750	Certification of Ingredient Limits	Y	**00152115**, 41211203 [3], Undated CSF [4], CSF 8/21/96 [5]
830.1800	Analytical Methods to Verify the Certified Limits	Y	**00152115**, 41211203 [3]
830.6302	Color	Y	41055301 [6], 42953501 [7]
830.6303	Physical State	Y	41055301 [6]
830.6304	Odor	Y	41055301 [6]
830.6313	Stability	Y	41055301 [6]
830.6314	Oxidation/Reduction	Y	**00142272**
830.6315	Flammability	Y	**00142272**
830.6316	Explodability	Y	**00142272**, **00152115**
830.6317	Storage Stability	Y	42044801 [8]
830.6319	Miscibility	Y	**00142272**, 41055301 [6]
830.6320	Corrosion Characteristics	Y	**00142272**
830.7000	pH	Y	**00142272**
830.7050	UV/Visible Absorption	N [9]	
830.7100	Viscosity	Y	**00142272**
830.7200	Melting Point/Melting Range	N/A [10]	
830.7220	Boiling Point/Boiling Range	Y	41055301 [6]
830.7300	Density/Relative Density/Bulk Density	Y	**00142272**
830.7370	Dissociation Constant in Water	N/A [11]	
830.7550	Partition Coefficient (Octanol/Water)	Y	**00142272**
830.7560			
830.7570			
830.7840	Solubility	Y	**00142272**
830.7860			
830.7950	Vapor Pressure	Y	**00142272**

[1] Y = Yes; N = No; N/A = Not Applicable.

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(8)

[2] **Bolded** references were reviewed in the Ethoprop FRSTR dated 10/20/87; underlined references were reviewed under CBRS No. 5114, dated 4/17/89, by G. Makhijani; and all other references were reviewed as noted.

[3] CBRS No. 12396, D194202, 7/21/94, R. Perfetti.

[4] CBRS No. 14437, D207680, 5/8/95, K. Dockter.

[5] CSF obtained from the product jacket.

[6] CBRS No. 5303, 9/19/89, J. Garbus.

[7] CBRS No. 12705, D195967, 11/19/93, F. Toghrol.

[8] CBRS No. 8767, D169998, 5/1/92, L. Cheng.

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

[10] Data are not required because the TGAI/MP is a liquid at room temperature.

[11] Data requirements were waived (CBRS No. 12397, D194353, 9/29/93, F. Fort) because ethoprop does not contain any ionizable functional groups and does not dissociate in water.

ETHOPROP

REREGISTRATION ELIGIBILITY DECISION

RESIDUE CHEMISTRY CONSIDERATIONS

Shaughnessy No. 041101; Case 0106

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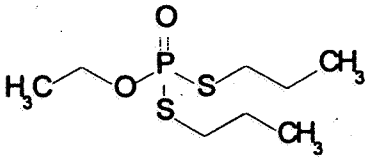
ETHOPROP



REREGISTRATION ELIGIBILITY DOCUMENT

RESIDUE CHEMISTRY CONSIDERATIONS

Shaughnessy No. 041101; Case 0106

INTRODUCTION

Ethoprop [*S,S*-dipropyl *O*-ethyl phosphorodithioate] is an insecticide/nematicide registered for use on bananas/plantains, beans (lima and snap), cabbage, citrus (non-bearing), corn, cucumbers, peanuts, pineapples, potatoes, sugarcane, sweet potatoes, and tobacco. Ethoprop is manufactured by Rhône-Poulenc Ag Company, the basic producer, under the trade name Mocap®. Ethoprop formulations registered for use on food/feed crops include emulsifiable concentrate (EC), soluble concentrate (SC/L), and granular (G) formulations. These products may be applied as broadcast or banded preplant to preemergence applications and as banded postemergence applications directed to the soil. Use directions specify the use of only ground equipment, except on potatoes where aerial applications are allowed.

REGULATORY BACKGROUND

Ethoprop is a List A reregistration chemical and was the subject of a Registration Standard dated 2/28/83, a Final Registration Standard and Tolerance Reassessment (FRSTR) dated 10/20/87, and their associated Guidance Documents (dated 6/83 and 6/88). These documents summarized regulatory conclusions on the available residue chemistry data and specified that additional data were required for reregistration purposes. Numerous submissions of data have been received since the FRSTR was issued. The information contained in this document outlines the current Residue Chemistry Science Assessments with respect to the reregistration of ethoprop.

Tolerances for ethoprop residues in/on food/feed commodities are currently expressed in terms of ethoprop, *O*-ethyl-*S,S*-dipropylphosphorodithioate, [40 CFR §185.262 (a) and (b)] and are 0.02 ppm (negligible residues) in/on all plant commodities. No tolerances have been

established for residues in livestock commodities. Adequate methods are available for the enforcement of established tolerances, as currently defined.

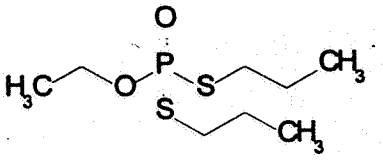
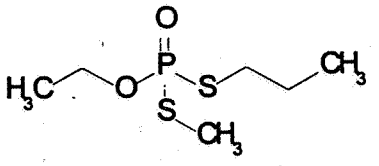
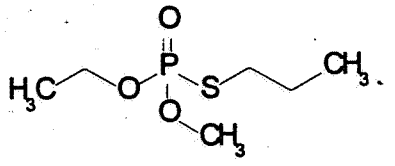
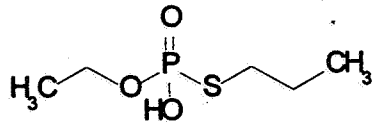
The HED Metabolism Committee (J. Abbotts, 10/17/96) concluded that the residues of toxicological concern for primary and rotational crops are ethoprop and Metabolites II, III and IV (see Figure A), and analytical methods capable of determining all residues of concern, as well as storage stability data, crop field trials, and processing studies reflecting determination of these residues, would be needed for reregistration. Following a meeting with the registrant regarding residue chemistry data requirements for reregistration, the Agency concluded that for the present, entirely new crop field trials and processing studies determining all residues of concern would not be required (Memos of 12/4/96 and 2/12/97, J. Abbotts). HED would conduct dietary exposure assessment using the available data on ethoprop and Metabolite IV, and making conservative assumptions regarding the levels of Metabolites II and III using data from the metabolism studies. However, for any field or processing studies initiated after 12/3/96, data would be required on all residues of concern along with methods for determining all residues of concern and supporting storage stability data.

The HED Metabolism Committee subsequently revised its conclusions (Memo, 2/6/98, K. Farwell). The Committee found that for acute and chronic non-cancer dietary risk, the residues of concern in crops were parent and metabolites II and III; for cancer dietary risk, residues of concern are parent and metabolites II through IV (see Figure A).

Regarding the regulation of ethoprop residues in livestock commodities, HED previously determined that a Category 3 situation [40 CFR 180.6(a)(3)] exists for livestock commodities based upon review of the livestock metabolism studies (R. Perfetti, 6/22/94). However, based on results from the confined rotational crop study, the Agency concluded that requirements for livestock feeding studies should be reevaluated once adequate field trial and processing data are received on all significant feed items.

The chemical names and structures of ethoprop and its metabolites of concern are depicted in Figure A.

Figure A. Chemical name and structure of ethoprop and its residues of concern in primary and rotational crops.

Common Name/Chemical Name	Chemical Structure
Ethoprop *O*-ethyl-*S,S*-dipropylphosphorodithioate	
Metabolite II *O*-ethyl-*S*-methyl-S-propylphosphorodithioate	
Metabolite III *O*-ethyl-*O*-methyl-*S*-propylphosphorothioate	
Metabolite IV; M1 *O*-ethyl-*S*-propylphosphorothioate	

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SUMMARY OF SCIENCE FINDINGS

OPPTS GLN 860.1200: Directions for Use

A search of the Agency's Reference Files System (REFS) on 12/12/97 indicates that there are seven ethoprop end-use products (EPs) with uses on food/feed crops and two EPs with uses on tobacco registered to Rhône-Poulenc Ag Co. These EPs are presented below.

EPA Reg No.	Label Acceptance Date	Formulation Class	Product Name
264-457	6/93	15% G	MOCAP® 15% Granular Nematicide-Insecticide
264-458 [a]	8/95	6 lb/gal EC	MOCAP® EC Nematicide-Insecticide
264-459 [b]	6/93	10% G	MOCAP® Plus Nematicide-Insecticide
264-464 [b]	12/93	4 lb/gal EC	MOCAP® Plus 4-2 EC Nematicide-Insecticide
264-465 [c]	11/95	10% G	MOCAP® 10% Granular Nematicide-Insecticide
264-469	11/95	20 % G	MOCAP® 20% Granular Nematicide-Insecticide
264-475 [d]	12/93	3% G	MOCAP® PCNB 3-10 Granular Nematicide-Insecticide
264-521 [e]	4/93	10% G	HOLDEM® Brand Granular Nematicide-Insecticide
264-541	6/96	6 lb/gal SC/L	MOCAP® GEL Nematicide-Insecticide

[a] Includes the associated SLNs FL870001 and OR960018.
[b] These products are MAIs that also include disulfoton (5% G or 2 lb/gal EC) and are registered for use only on tobacco.
[c] Includes the associated SLNs FL850001, ME930003, OR840010, OR960017, PR920002, and WA 850008.
[d] This product is a MAI that also contains PCNB (10% G) and is registered for use only on peanuts.
[e] This product is a MAI that also contains Phorate (10% G) and is registered for use only on potatoes.

A review of the above labels and supporting residue data indicate that the following label amendments are required:

Use directions for potatoes and sweet potatoes on all labels should be amended to specify a maximum rate equivalent to 12 lb ai/treated acre for banded applications.

The label for the 15% G formulation (EPA Reg No. 264-457) must be amended to specify a REI.

Use directions for field and sweet corn should be amended to specify pre-plant or at planting application only. Additional residue data are required to support applications later in the season.

Use directions for peanuts on labels for the 3%, 10% and 15% G formulations (EPA Reg. Nos. 264-475, 264-465, and 264-457) should be amended to specify one pre-plant or at planting application.

Available data on sugarcane are adequate to support an application at planting at 15 lb ai/A. Labels should be limited to this effective rate per treated A at planting, or additional field trial data are required.

Data from the limited field rotational crop studies indicate that labels must be amended to include rotational crop restrictions, including a limit of 12 lb ai/A applied to primary crops.

A tabular summary of the residue chemistry science assessments for reregistration of ethoprop is presented in Table B. The conclusions listed in Table B regarding the reregistration eligibility of ethoprop food/feed uses are based on the use patterns registered by the basic producer, Rhône-Poulenc Ag Co., and apply to data on residues of parent and/or metabolite IV. 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's labels.

OPPTS GLN 860.1300: Nature of the Residue in Plants

The qualitative nature of the residue in plants is adequately understood based on cabbage, corn, and potato metabolism studies. The HED Metabolism Committee (Memo, 2/6/98, K. Farwell) found that for acute and chronic non-cancer dietary risk, the residues of concern in crops were parent and metabolites II and III; for cancer dietary risk, residues of concern are parent and metabolites II through IV (see Figure A). The Metabolism Committee earlier concluded that the metabolite ethyl phosphate is not a residue of concern (Memo, 10/17/96, J. Abbotts).

OPPTS GLN 860.1300: Nature of the Residue in Livestock

The qualitative nature of the residue in livestock is adequately understood based upon acceptable ruminant and poultry metabolism studies. The Agency (R. Perfetti, 6/22/94) concluded that the data from the metabolism studies indicate that a Category 3 situation [40 CFR 180.6(a)(3)] exists for livestock commodities. Ethoprop was not detected in milk, eggs or tissues from goats and hens dosed orally for seven consecutive days with [^{14}C]ethoprop at levels equivalent to 32 ppm (865x) and 2.09 ppm (105x), respectively, in the diet. Maximum total radioactive residues were 9.26 ppm in goat liver and 1.22 ppm in chicken liver. Residues of potential concern detected were metabolites III and/or IV which together accounted for ≤2% of the total radioactive residues in liver of hens and goats.

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OPPTS GLN 860.1340: Residue Analytical Methods

Adequate analytical methodology is available for data collection and enforcing tolerances of ethoprop as currently defined. Method I in the Pesticide Analytical Manual (PAM), Vol. II, is a GLC/ sulfur microcoulometric detection method that has undergone a successful EPA method validation. This method involves solvent extraction and clean-up by sweep co-distillation. Residues of ethoprop are determined by GLC using a sulfur microcoulometric detector. PAM, Vol. II also lists Method A, which uses the same principles as Method I, but employs different parameters for extraction and gas chromatography. The limit of quantitation for ethoprop in or on plant commodities is 0.01 ppm in each method.

A newer GC/FPD method has also been proposed as an enforcement method for determining residues of ethoprop and Metabolite IV in plant commodities. In this method, residues of ethoprop and Metabolite IV are extracted with methanol, filtered, and cleaned up using cation exchange resin and nuchar/attaclay. Residues are concentrated and redissolved in methanol. Diazomethane is added to methylate residues of Metabolite IV. Ethoprop and methylated Metabolite IV are partitioned into methylene chloride, concentrated, dissolved in methylene chloride, and further cleaned up using gel permeation and/or silica gel chromatography prior to analysis using GC/FPD in the phosphorus mode. This method was validated by an independent laboratory, with limits of quantitation at 0.01 ppm for each analyte in plant commodities. Review has noted that it could prove to the registrant's advantage to demonstrate that the methylation step does not alter metabolite III, since metabolite IV is converted to III by methylation (Figure A). Because of these uncertainties over the method's full capabilities, the method has not yet been submitted for Agency validation.

Data from analysis of ethoprop residues in plants have been collected using Method I and modifications of Method I, or more recently using variations of the GC/FPD method that has been proposed as an enforcement method.

Adequate methodology for determining Metabolites II and III in or on plant commodities is required in conjunction with any new residue studies.

OPPTS GLN 860.1360: Multiresidue Method Testing

The FDA PESTDATA database indicates that ethoprop is completely recovered using FDA Multiresidue Protocol D (PAM I Section 232.4) and partially recovered using FDA Multiresidue Protocol E for non-oily matrices (PAM I Section 211.1). Recovery of ethoprop using Protocol E for oily matrices (PAM I Section 212.1) is small. The registrant has submitted data pertaining to the recovery of Metabolite IV through FDA Multiresidue Protocols, and these data have been forwarded to the FDA for review.

OPPTS GLN 860.1380: Storage Stability Data

For purposes of reregistration, the requirements for supporting storage stability data are satisfied for all acceptable residue studies. Generally, residues of ethoprop *per se* are more stable in frozen storage than are residues of Metabolite IV. Residues of ethoprop *per se* were stable in most matrices for at least 6 months of frozen storage; however, Metabolite IV was not stable in the majority of matrices following 3 months of storage at either -5 or -20 C. No storage stability data are presently available on the other two residues of concern, Metabolites II and III.

The available storage stability data indicate that ethoprop *per se* is stable in cabbage, potato, pineapple commodities, peanut commodities (except meal), and corn commodities for up to 6 to 12 months at -20 C, and in peanut meal for up to 3 months at -20 C. At storage temperatures of -5 C, ethoprop *per se* is stable for 6 to 12 months in the above commodities except for pineapple bran and pulp, peanut hulls, and corn grain dust, in which ethoprop is stable for <3 months.

Metabolite IV is stable for 6 to 12 months in the following matrices stored at -20 C: cabbage, potatoes, pineapple commodities (except bran), peanut oil and nutmeats, and corn forage, meal, oil, and grain dust. Metabolite IV is stable for ≤ 3 months at -20 C in pineapple bran, corn grain, corn fodder, corn starch, and in peanut meal, vine, hay, and hulls. At storage temperatures of -5 C, Metabolite IV is stable for up to 12 months in cabbage, pineapple juice, peanut nutmeat, peanut crude oil, and corn crude oil. Metabolite IV is stable at -5 C for ≤ 3 months in potatoes; pineapple fruit, bran, and pulp; peanut meal, vine, hay, hull, and refined oil; and corn grain, forage, fodder, starch, meal, grain dust, and refined oil.

Adequate storage stability data have also been submitted indicating that ethoprop and Metabolite IV are stable at -20 C in sugarcane and its processed commodities stored for up to 15 months.

The Agency has advised that concurrent storage stability studies should be conducted with any required field or processing studies; the demonstrated stability problems of Metabolite IV during frozen storage reinforce this requirement.

OPPTS GLN 860.1500: Magnitude of the Residue in Crop Plants

For purposes of reregistration, requirements for magnitude of the residue data in/on plants are fulfilled for the following crops, for residues of parent and/or metabolite IV: banana, beans (lima and snap), cabbage, cucumbers, and pineapples. Adequate field trial data depicting ethoprop residues in/on these crops following applications made according to the maximum or proposed use patterns have been submitted. Geographical representation was adequate with sufficient numbers of trials reflecting representative formulation classes.

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Available data on peanuts are adequate for residues of parent and/or metabolite IV, provided use directions for peanuts are amended to specify a single pre-plant or at-planting application. Residue data on field and sweet corn are adequate for residues of parent and metabolite IV, for applications at plant or earlier.

As noted above under Guideline 860.1200, residue data are adequate to support use on potatoes and sugarcane, at specified rates and conditions. Labels should be limited to these rates and conditions, or additional field trials will be required for all residues of concern.

OPPTS GLN 860.1500: Magnitude of the Residue in Crop Plants - Pending Petitions

PP#5E04491: The Interregional Research Project-4 submitted a petition for establishing tolerances for ethoprop in/on mint hay at 0.02 ppm. The proposed use pattern for mint specifies a single broadcast application of ethoprop (EC or G) at 6 lb ai/A to mint following the last harvest of the season. Following application, ethoprop would be incorporated into the soil using either irrigation or mechanical mixing. The proposed label would allow only one application per year and specify a 225 day PHI. This petition is currently in reject status (G. Otakie, 8/11/95 and 9/20/95) based upon the dietary exposure analysis. In addition, in response to a proposal that this use be considered at nonfood use, the Agency (W.J. Hazel, 9/16/97) has determined that the proposed use on mint is a food use.

OPPTS GLN 860.1520: Magnitude of the Residue in Processed Food/Feed

The reregistration requirements for processed food/feed commodities are fulfilled for residues of parent and metabolite IV for corn, peanut, pineapple, potato, and sugarcane. Adequate processing studies are available for corn, pineapple, potato, and sugarcane indicating that residues of ethoprop and Metabolite IV did not concentrate in processed commodities of these crops.

Two processing studies are also available for peanuts; however, neither study was deemed wholly acceptable (J. Abbotts, 9/4/97). In the first peanut processing study, peanut oil and meal were stored frozen prior to analysis for periods longer than ethoprop residues are stable in these commodities. In the second peanut processing study conducted at a 5x application rate, residues of ethoprop and metabolite IV were each <0.01 in peanut nutmeats and meal., and were respectively 0.018 ppm and <0.01 ppm in peanut oil. Frozen nutmeats were analyzed within 66 days of harvest and meal and oil samples were analyzed within 46 days of processing. Based upon these data, the Agency concluded that residues of ethoprop and metabolite IV do not concentrate in meal and that residues of ethoprop concentrate by ≥ 1.8x in oil; however, concentration of metabolite IV in oil could not be determined due to questions about storage stability. The Agency concluded that the maximum theoretical concentration factor for peanut oil (2.8x) would be used for exposure assessment for peanut oil.

Based upon a 2.8x concentration factor for peanut oil, the 5x application rate used in the processing study, and the fact that residues of ethoprop and metabolite IV resulting from the **at-planting use** on peanuts are each nondetectable (<0.01 ppm), anticipated residues in peanut oil would be below the established tolerance for peanut nutmeats. Therefore a tolerance for residues in peanut oil is not required.

OPPTS GLN 860.1480: Magnitude of the Residue in Meat, Milk, Poultry, and Eggs

No tolerances have been established for ethoprop residues in livestock commodities. The Agency (R. Perfetti, 6/22/94) concluded that the data from the metabolism studies indicates that a Category 3 situation [40 CFR 180.6(a)(3)] exists for livestock commodities. Ethoprop was not detected in milk, eggs or tissues from goats and hens dosed orally for seven consecutive days with [^{14}C]ethoprop at levels equivalent to 32 ppm and 2.09 ppm, respectively, in the diet. Maximum total radioactive residues were 9.26 ppm in goat liver and 1.22 ppm in chicken liver. Residues of potential concern detected were metabolites III and/or IV which together accounted for ≤2% of the total radioactive residues in liver of hens and goats.

Based upon the currently registered uses and current or reassessed tolerances, the calculated maximum theoretical dietary burdens are 0.037 ppm for cattle and 0.02 ppm for poultry (see below). Therefore, feeding levels of ethoprop in the goat and poultry metabolism studies represent 865x and 105x the maximum theoretical dietary exposures, respectively..

Feed Commodity	% Dry Matter [a]	% Diet [a]	Tolerance (ppm) [b]	Dietary Contribution (ppm) [c]
Beef Cattle				
corn forage	40	40	0.02	0.02
corn grain	88	45	0.02	0.01
peanut meal	85	15	0.02	0.004
TOTAL BURDEN		100		**0.034**
Dairy Cattle				
corn forage	40	50	0.02	0.025
corn grain	88	35	0.02	0.008
peanut meal	85	15	0.02	0.004
TOTAL BURDEN		100		**0.037**
Poultry				
corn grain	N/A	80	0.02	0.016
peanut meal	N/A	20	0.02	0.004
TOTAL BURDEN		100		**0.02**
Swine				
corn grain	N/A	45	0.02	0.009
potato culls	N/A	40	0.02	0.008
peanut meal	N/A	15	0.02	0.003
TOTAL BURDEN		100		**0.02**

[a] Table 1 (August 1996).
[b] Current tolerance level from Table C.
[c] Contribution = [Reassessed tolerance / % DM (if cattle)] X % diet).

This information would support the conclusion that a Category 3 situation [40 CFR 180.6(a)(3)] exists for livestock commodities. However, data from the confined rotational crop study suggest that residues of concern may be present at higher levels in livestock feed items than indicated by current tolerances on primary crops. For the current time, tolerances for livestock commodities will not be required. However, the requirements for livestock feeding studies will be reevaluated once adequate field trial data and processing data are received on all significant feed items, including rotational feed crops.

OPPTS GLN 860.1400: Magnitude of the Residue in Water, Fish, and Irrigated Crops

Ethoprop is not registered for use on potable water or aquatic food and feed crops; therefore, no residue chemistry data are required under these guideline topics.

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OPPTS GLN 860.1460: Magnitude of the Residue in Food-Handling Establishments

Ethoprop is not registered for use in food handling establishments; therefore, no residue chemistry data are required under these guideline topics.

OPPTS GLN 860.1850: Confined Accumulation in Rotational Crops

An adequate confined rotational crop study is available and indicates that residues of ethoprop in rotational crops are qualitatively similar to the residues resulting from the direct application of ethoprop to the primary crops. Ethoprop residues of concern were detected at >0.01 ppm in/on spinach from the 31-day plant-back interval (PBI), radish roots and wheat straw from 31- and 123-day PBIs, and wheat forage from 31-, 123, and 365-day PBIs. Based upon results of the confined rotational crop study, limited field accumulation studies in rotational crops were required.

OPPTS GLN 860.1900: Field Accumulation in Rotational Crops:

None of the registrant's labels currently specify any rotational crop restrictions pertaining to ethoprop. However, data from rotational crop limited field trials indicate that labels must be amended to include rotational crop restrictions. Depending on the restrictions placed on labels, extensive rotational crop field trials may be required.

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TABLE A. FOOD/FEED USE PATTERNS SUBJECT TO REREGISTRATION FOR ETHOPROP (CASE).

Site Application Type Application Timing Application Equipment [a]	Formulation [EPA Reg. No./ SLN No.]	Max. Single Application Rate [b] (ai)	Max. # Apps. [c]	Minimum Retreatment Interval (Days)	Use Limitations [d]
Food/Feed Crop Uses					
Bananas/Plantains					
Basal application to soil within 30 inches of stem Ground equipment	10% G [264-465] 15% G [264-457] 6 lb/gal EC [264-458]	0.2 oz/plant	NS	6 months	
Beans (Lima and Snap)					
Broadcast preplant or at planting application Ground equipment	10% G [264-465] 15% G [264-457] 6 lb/gal EC [264-458] 6 lb/gal SC/L [264-541]	8 lb/A	1	NA	Labels for the 6 lb/gal EC and SC/L allow only one application per crop.
Banded preplant or at planting application Ground equipment	10% G [264-465] 15% G [264-457]	9 lb/treated acre (12" band)			
	6 lb/gal EC [264-458] 6 lb/gal SC/L [264-541]	8 lb/treated acre (12" band)			

(continued; footnotes follow)

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Table A. Continued.

Site Application Type Application Timing Application Equipment [a]	Formulation [EPA Reg. No./ SLN No.]	Max. Single Application Rate [b] (ai)	Max. # Apps. [c]	Minimum Retreatment Interval (Days)	Use Limitations [d]
Cabbage					
Broadcast preplant or at planting application Ground equipment	10% G [264-465] 15% G [264-457] 6 lb/gal EC [264-458] 6 lb/gal SC/L [264-541]	5 lb/A	1	NA	Labels for the 6 lb/gal EC and SC/L allow only one application per crop.
Banded at planting application Ground equipment		5 lb/treated acre (12-15" band)			
Corn (field and sweet)					
Broadcast preplant or at-planting application Ground equipment	10% G [264-465] 15% G [264-457] 20% G [264-469]]	6 lb/A	1	NA	No PHI is specified. Labels for the 20% G and 6 lb/gal EC and SC/L allow only one application per crop.
Banded applications at planting through lay-by Ground Equipment		6.5 lb/treated acre (6" band)	NS	NS	
Banded application at planting Ground Equipment	6 lb/gal EC [264-458] 6 lb/gal SC/L [264-541]	6 lb/treated acre (6"-12" band)	1	NA	
Cucumbers					
Banded preplant or at planting application Ground equipment	10% G [264-465] 15% G [264-457]	14 lb/treated acre (12" band)	1	NA	Labels for the 6 lb/gal EC and SC/L allow only one application per crop.
	6 lb/gal EC [264-458] 6 lb/gal SC/L [264-541]	10.8 lb/treated acre (12" band)			

(continued; footnotes follow)

Table A. Continued.

Site Application Type Application Timing Application Equipment [a]	Formulation [EPA Reg. No./ SLN No.]	Max. Single Application Rate [b] (ai)	Max. # Apps. [c]	Minimum Retreatment Interval (Days)	Use Limitations [d]
Peanuts					
Broadcast preplant or at planting application Ground equipment	10% G [264-465] 15% G [264-457] 6 lb/gal EC [264-458] 6 lb/gal SC/L [264-541]	6 lb/A	1	NA	Label for the 6 lb/gal EC and SC/L specify one application per crop.
Banded preplant or at planting application Ground equipment		12 lb/treated acre (12" band)			
Banded application at pegging Ground equipment	10% G [264-465] 15% G [264-457]	7.3 lb/treated acre (15" band)	1	NA	No PHI is specified.
Postemergence broadcast or banded application at early pegging incorporated into the soil. Ground equipment	3% G [264-475]	3 lb/A 8.8 lb/treated acre (12" band)	1	NA	No PHI is specified.
Pineapple					
Chemigation through drip irrigation system beginning at planting.	6 lb/gal EC [264-458] 6 lb/gal SC/L [264-541]	6 lb/A	8 - planting crop 5 - ratoon crop	2 months	For use only in Hawaii. A 120-day PHI is specified. A maximum of 8 applications or 48 lb ai/A can be applied to the planting crop and 5 applications or 30 lb ai/A can be applied to the ratoon crop.
Banded preplant application over planting beds, with spot applications allowed 3-6 months after planting Ground equipment	10% G [PR920002]	12 lb/A	NS	3 months	A 120-day PHI is specified. For use only in Puerto Rico.

(continued; footnotes follow)

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Table A. Continued.

Site Application Type Application Timing Application Equipment [a]	Formulation [EPA Reg. No./ SLN No.]	Max. Single Application Rate [b] (ai)	Max. # Apps. [c]	Minimum Retreatment Interval (Days)	Use Limitations [d]
Potatoes					
Broadcast preplant to preemergence application Ground or aerial equipment	10% G [264-465] [OR840010] [WA850008] 15% G [264-457] 20% G [264-469] 6 lb/gal EC [264-458] 6 lb/gal SC/L [264-541]	12 lb/A	1	NA	Do not exceed 12 lb ai/A per season. Labels for the 6 lb/gal EC and SC/L specify one application per crop and prohibit aerial application. The label for the 15% G restricts the use to potatoes grown East of the Rocky Mountains. SLN ME930003 specifies one application per crop.
Banded application at planting Ground equipment	10% G [264-465] 20% G [264-469] 6 lb/gal EC [264-458] 6 lb/gal SC/L [264-541]	9 lb/treated acre (12" band)			
	15% G [264-457]	11 lb/treated acre (12" band)			
	10% G [ME930003]	22 lb/treated acre (5" band)			
Banded application into open furrow at planting Ground equipment	10% G [264-521]	18.3 lb/treated acre (6" band)	1	NA	A 90-day PHI is specified. Do not apply more than once per year. Use a minimum row spacing of 32 inches

(continued; footnotes follow)

Table A. Continued.

Site Application Type Application Timing Application Equipment [a]	Formulation [EPA Reg. No./ SLN No.]	Max. Single Application Rate [b] (ai)	Max. # Apps. [c]	Minimum Retreatment Interval (Days)	Use Limitations [d]
Sugarcane					
Broadcast application at planting Ground equipment	10% G [FL850001]	6 lb/A	1	NA	Labels for the 6 lb/gal EC and SC/L allow only one application per crop.
Banded application at planting Ground equipment	10% G [264-465] [FL850001] 15% G [264-457] 20% G [264-469] 6 lb/gal EC [264-458] 6 lb/gal SC/L [264-541]	24 lb/treated acre (12" band)			
Sweet Potatoes					
Broadcast preplant application Ground equipment	10% G [264-465] 15% G [264-457] 6 lb/gal EC [264-458] 6 lb/gal SC/L [264-541]	8 lb/A	1	NA	Labels for the 6 lb/gal EC and SC/L allow only one application per crop.
Banded preplant application Ground equipment		14 lb/treated acre (12" band)			
Non food/feed Uses					
Citrus (seedlings or non-bearing trees)					
30 minute bare root dip or soil drench of potted plants	6 lb/gal EC [264-458]	0.375 lb/50 gal	NS	NS	

(*continued; footnotes follow*)

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Table A. Continued.

Site Application Type Application Timing Application Equipment [a]	Formulation [EPA Reg. No./ SLN No.]	Max. Single Application Rate [b] (ai)	Max. # Apps. [c]	Minimum Retreatment Interval (Days)	Use Limitations [d]
Banded application to soil between tree rows Ground equipment	6 lb/gal EC [FL870001]	5 lb/treated acre	2	NS	Apply only to non-bearing trees (trees that will not produce marketable fruit within 12 months). Do not apply more than twice per season.
Tobacco					
Broadcast application preplant or at planting Ground equipment	10% G [264-459] 4 lb/gal EC [264-464]	8 lb/A	1	NA	Label for the 6 lb/gal EC and SC/L allow only one application per crop. The label for the 4 lb/gal EC prohibits applications through any type of irrigation system.
	10% G [264-465] 15% G [264-457] 6 lb/gal EC [264-458] 6 lb/gal SC/L [264-541]	12 lb/A			
Banded application preplant or at planting Ground equipment	10% G [264-459] 4 lb/gal EC [264-464]	14 lb/treated acre (18" band)			
	15% G [264-457] 10% G [264-465] 6 lb/gal EC [264-458] 6 lb/gal SC/L [264-541]	28 lb/treated acre (18" band)			

(continued; footnotes follow)

Table A. Continued.

[a] Labels for the 6 lb/gal EC (264-458) and the 6 lb/gal SC/L (264-541) allow applications through the following types of irrigation systems: center pivot, lateral move end tow, side (wheel) roll, traveler, big gun, solid set, or hand move sprinkler systems, or drip (trickle) irrigation systems.

[b] For banded applications, the maximum rate is expressed on a treated acre basis, and is calculated using the maximum rate per 1000 ft row and the minimum band width as follows: [(lb ai/1,000 ft row) ÷ (band width in feet)] * 43.56 = lb ai/treated acre.

[c] Maximum number of applications at the maximum single application rate.

[d] Ethoprop must be incorporated into the soil with mechanical or irrigation equipment following application.

Labels for EPA Reg. Nos. 264-459 and -521 specify a 24-hour restricted entry interval (REI). The labels for EPA Reg. Nos. 264-458, -464, -465, -469, -475, and -541 specify a 48-hour REI in areas receiving ≥25 inches of rain/year and 72-hour REI in areas receiving <25 inches of rain/year, except when material has been soil incorporated. The label for EPA Reg. No. 264-457 does not specify a REI.

The following labels prohibit application in Long Island, NY: EPA Reg. Nos. 264-457, -458, -459, -464, -465, -469 and -541.

None of the labels contain rotational crop restrictions pertaining to ethoprop.

Table B. Residue Chemistry Science Assessments for Reregistration of Ethoprop.

OPPTS GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References[1]
860.1200: Directions for Use	N/A	Yes[2]	See Table A.
860.1300: Nature of the Residue			
- Plants	N/A	No	*00040380* **00075252** **00075253** **00075254** **00075255** **00075256** **00092103** **40653205** 41691001[3] 41814001[3] 41840801[3] 41946001[4] 43836401[5] 43868701[6]
- Livestock	N/A	No	**00092070** 42923201[7] 42962701[7] 43209001[8]
860.1340: Residue Analytical Methods	N/A	Yes[9]	**00075245** *00075246* *00092079* **00092080** *00125395* *00125397* *00129928* *00145970* *00153065* *00153326* *00154203* *00160441* 42220601[10] 43277502[11] 43373601[11] 44321501[12]
860.1360: Multiresidue Method	N/A	No	41270701[13] 42242101[14]
860.1380: Storage Stability	N/A	No[15]	*00160441* 43539401[16] 43971501[17]
860.1500: Magnitude of the Residue in Crop Plants			
Root and Tuber Vegetables Group			
- Potatoes	0.02 (N) [§180.262(a)]	No	*00153065* *40028502*
- Sweet potatoes	0.02 (N) [§180.262(a)]	No	**00075252**
Brassica (Cole) Leafy Vegetables Group			
- Cabbage	0.02 (N) [§180.262(a)]	No	**00092068** *00125397* 43583201[18]
Legume Vegetables (Succulent or Dried) Group			
- Beans, lima	0.02 (N) [§180.262(a)]	No	**40653204** 43539601[19]
- Beans, snap	0.02 (N) [§180.262 (a)]	No	**40653204** 43538601[19]
- Soybeans	0.02 (N) [§180.262(a)]	Yes[20]	*00076720* **00092072** **00092074**
Foliage of Legume Vegetables Group			
- Beans, lima and snap, forage	0.02 (N) [§180.262(a)]	No[21]	**40653204**

(continued; footnotes follow)

Table B. (*continued*).

OPPTS GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References[1]
- Soybean, forage and hay	0.02 (N) [§180.262(a)]	Yes[20]	*00076720* **40653201**
Cucurbit Vegetables Group			
- Cucumbers	0.02 (N) [§180.262(a)]	No	**40653204** 43484001[22]
Cereal Grains Group			
- Corn, fresh (inc. sweet) (K+CWHR)	0.02 (N) [§180.262(a)]	Yes[23]	*00075249* **00075250** *00092108* *00092109* *00092135* **40653207** 43491001[24] 43748203[12]
- Corn, grain (inc. pop)	0.02 (N) [§180.262(a)]	Yes[23]	*00075249* **00075250** *00092108* *00092109* *00092135* **40653207** 43530901[25] 43748201[12]
Forage, Fodder, and Straw of Cereal Grains Group			
- Corn forage and fodder	0.02 (N) [§180.262(a)]	Yes[23]	*00075249* **00075250** *00092108* *00092109* *00092135* **40653207** 43530901[25]
Miscellaneous Commodities			
- Banana	0.02 (N) [§180.262(a)]	No	**40653206**
- Mushrooms	0.02 [§180.262(a)]	Yes[26]	00030481[27] 00030482[27]
- Okra	0.02 [§180.262(b)]	Yes[26]	*00125395*
- Peanut	0.02 (N) [§180.262(a)]	Yes[28]	*00092106* *00092116* *00129928* *00141494* **40653202** 43539701[28] 44062401[28]
- Peanut hay	0.02 (N) [§180.262(a)]	Yes[28]	*00092106* *00092116* *00129928* *00141494* **40653202** 43539701[28] 44062401[28]
- Pineapple	0.02 (N) [§180.262(a)]	No	**00092070** *00154203* 42901601[29]
- Pineapple, fodder and forage	0.02 (N) [§180.262(a)]	No[30]	**00092070** *00154203*
- Sugarcane	0.02 (N) [§180.262(a)]	Yes[31]	**40653203**
- Sugarcane, fodder and forage	0.02 (N) [§180.262(a)]	No[30]	**40653203**

(*continued; footnotes follow*)

Table B. (*continued*).

OPPTS GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References[1]
- Tobacco	NA	No	*00145970 00153065* 41809601[32]
860.1520: Magnitude of the Residues in Processed Food/Feed			
- Corn	None	No	43748202[12]
- Peanut	None	No	43539801[16] 44003301[18]
- Pineapple	None	No	42945501[29]
- Potato	None	No	43373601[11]
- Soybean	None	Yes[20]	
- Sugarcane	None	No	43277501[33] 43971501[17]
860.1480: Magnitude of the Residue in Meat, Milk, Poultry, and Eggs	None	Reserved[34]	**00092101**
860.1400: Magnitude of the Residue in water, fish, and irrigated crops	N/A	N/A	
860.1460: Magnitude of the Residue in Food Handling Establishments	N/A	N/A	
860.1850: Confined Accumulation in Rotational Crops	N/A	No	42197601[7]
860.1900: Field Accumulation in Rotational Crops	None	Yes[35]	44350201[12]

[1] **Bolded** references were cited in the Ethoprop Registration Standard dated 2/28/83 and *italicized* references were reviewed/cited in the Ethoprop FRSTR dated 10/20/87; Other references were reviewed as noted.

[2] Based upon the available residue data, the Agency is recommending specific changes to label directions for uses on peanuts. The peanut residue data are adequate to support application at plant. If any registrant desires to support application at-pegging, additional field trials are required. Labels for uses on field and sweet corn should be amended to limit application to at plant or earlier. Labels for use on potatoes, sweet potatoes, and sugarcane should be amended to limit application rates. Otherwise, additional field trial data are required. In addition, results from rotational crop limited field trials indicate that rotational crop restrictions are required. The recommended label amendments are listed in the SUMMARY OF SCIENCE FINDINGS, under OPPTS GLN 860.1200: Directions for Use.
Requirements for magnitude of the residue studies in this Table are pertinent to data on parent and/or metabolite IV (Figure A).

[3] CBRS Nos. 7407, 7795, and 7933; DP Barcodes D149067, D163011, and D163888; 1/24/92; C. Olinger.

[4] CBRS No. 8330, DP Barcode D167017, 4/22/92, J. Abbotts.

[5] CBRS No. 16699, DP Barcode D221052, 7/11/96, J. Abbotts.

[6] CBRS No. 16678, DP Barcode D221951, 7/11/96, J. Abbotts.

(*continued; footnotes follow*)

Table B. (*continued*).

7 CBRS Nos. 11533, 12610, and 12797; DP Barcodes D188915, D195286, and D196126; 6/22/94; R. Perfetti.

8 CBRS No. 13604, DP Barcode D202608, 9/29/94, R. Perfetti.

9 A proposed GC/FPD enforcement method for determining residues of ethoprop and metabolite IV in plant commodities has been validated by an independent laboratory. Review has advised that it would be in the registrant's interests to determine if this method can also successfully determine residues of metabolite III. In addition, adequate methodology for determining metabolites II and III in or on plant commodities is required in conjunction with any new residue studies.

10 CBRS No. 9568, DP Barcode D175797,7/16/92, B. Cropp-Kohlligian.

11 CBRS Nos. 14535 and 13949, DP Barcodes D207805 and D204975, 8/3/95, R. Perfetti.

12 MRID 44321501 on analytical method was reviewed in D237651, 11/26/97, J. Abbotts.
MRIDs 43748201 on field corn, 43748203 on sweet corn, 43748202 on corn processing were reviewed in D218411, 235686, 1/8/98, J. Abbotts; data were adequate to support application at plant or earlier.
MRID 44350201 on limited rotational crop field trials was reviewed in D238977, 1/23/98, J. Abbotts.

13 CB No. 6009, 1/19/90, M. Nelson.

14 CBRS No. 9812, DP Barcode D177243, 5/28/92, L. Cheng.

15 No additional storage stability data are required to support the existing field and processing studies; however, the Agency recommends conducting concurrent storage stability studies with any new residue studies.

16 CBRS No. 15114, DP Barcode D212132, 12/21/95, S. Knizner.

17 CBRS No. 17211, DP Barcode D225648, 11/14/97, J. Abbotts.

18 CBRS Nos. 15401 and 17234, DP Barcodes D213957 and D226333, 9/4/97, J. Abbotts.

19 CBRS No. 15264, DP Barcode D213113, 10/22/97, J. Abbotts.

20 Uses on soybeans have been deleted from the registrant's labels. Provided tolerances are revoked, no data will be required.

21 Forage of lima and snap beans is no longer considered a significant livestock feed item; therefore, residue data on these commodities are not required.

22 CBRS No. 14917, DP Barcode D210696, 3/13/97, C. Eiden.

23 Data on corn are adequate to support application at plant or earlier. Additional field trials and data on aspirated grain fractions are required to support applications later in the season.

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Table B. (*continued*).

[24] CBRS No. 14917, DP Barcode D210696, 3/13/97, C. Eiden.

[25] CBRS No. 15114, DP Barcode D212132, 12/21/95, S. Knizner.

[26] The basic producer, Rhone Poulenc, has no registered uses on mushrooms or okra. Provided tolerances on these crops are revoked, residue data will not be required.

[27] Reviews of these data could not be located.

[28] DP Barcode D235830, 9/22/97, J. Abbotts. The data are adequate to support application at plant. If any registrant desires to support application at-pegging, additional field trials are required.

[29] CBRS Nos. 12706 and 12578, DP Barcodes D195968 and D195127, 2/18/94, R. Perfetti.

[30] Residue data on forage and fodder of pineapple and sugarcane are not required as these commodities are not considered to be significant livestock feed items (Table 1, OPPTS Guideline 860.1000).

[31] In reviewing the registrant's response to the Ethoprop FRSTR, the Agency (R. Perfetti, 7/3/90) noted that residue data are available supporting application of ethoprop to sugarcane at rates up to 15 lb ai/A. However, current label directions for sugarcane allow for a banded application at a rate equivalent to 24 lb ai/treated acre. Residue data are required depicting all ethoprop residues of concern in/on sugarcane harvested at normal maturity following an at planting application of ethoprop at 1x the maximum label rate (24 lb ai/treated acre). Field trials should be conducted in accordance with current Agency guidelines (OPPTS Guideline 860.1500).

[32] CBRS No. 7775, DP Barcode D162702, 1/24/92, C. Olinger; and CBRS No. 12816, DP Barcode D196279, , 7/19/95, C. Olinger.

[33] CBRS Nos. 14535 and 13949, DP Barcodes D207805 and D204975, 8/3/95, R. Perfetti; and CBRS No. 17688, DP Barcode D231955, 2/19/97, J. Abbotts.

[34] Data from the confined rotational crop study suggest that residues of concern may be present at higher levels in livestock feed items than indicated by current tolerances for primary plants (10/29/96, J. Abbotts). Tolerances for livestock commodities are not required at this time, but requirements for livestock feeding studies will be reevaluated once adequate field trial data and processing data are received on all significant feed items, including feed rotational crops.

[35] Data are adequate for rotational crop limited field trials. Extensive field trials are required. Requirements can be reduced by label restrictions on crop rotation.

TOLERANCE REASSESSMENT SUMMARY

Tolerances for residues of ethoprop in/on plant RACs are currently expressed in terms of ethoprop *per se* [40 CFR §180.262 (a) and (b)]. No food/feed tolerances have been established for residues of ethoprop. The HED Metabolism Committee has concluded that the residues of toxicological concern for primary and rotational crops include ethoprop and Metabolites II through IV (Memo, 2/6/98, K. Farwell). However, submitted magnitude of the residue studies contained at best residue data on parent and Metabolite IV; and studies accepted by the FRSTR reported data on parent only. In addition, as noted under discussion on analytical method, it may be the case that methods which methylate Metabolite IV may also determine residues of metabolite III (Figure A).

It seems appropriate to change the current tolerance expression, so that Section 24(c) registrations and amended uses could not be approved on the basis of residue data for parent only. The current Division position is that studies initiated after 12/3/96 should report data on all residues of concern (CBRS 17755, 2/12/97, J. Abbotts). Such requirements should apply to both new and amended uses. In the interim, the tolerance expression for ethoprop should be amended as follows:

Tolerances are established for the combined residues of ethoprop (*O*-ethyl-*S,S*-dipropylphosphorodithioate) and its metabolite *O*-ethyl-*S*-propylphosphorothioate, each expressed as ethoprop.

As data are received on additional residues of concern, and/or as further information become available on the capability of methods to determine residues of metabolite II and III, tolerances can be revised for specific crops to include metabolites II and/or III. At the present, tolerances will be reassessed based on combined residues of parent and metabolite IV. For those crops where residue data on parent only were accepted by the FRSTR, the current tolerances at 0.02 ppm will be doubled to encompass residues of metabolite IV.

In addition, the "(N)" designation for negligible residues should be deleted from all 40 CFR §180.262 entries. A summary of the ethoprop tolerance reassessment and recommended modifications in commodity definitions are presented in Table C.

Tolerances Listed Under 40 CFR §180.262 (a):

Sufficient data are available to ascertain the adequacy of the established tolerances on bananas, beans (lima and snap), cabbage, cucumbers, and pineapples. The available residue data on bananas (parent only), lima beans, and pineapples adequately support the current 0.02 ppm tolerances on these commodities. Residue data on snap beans, cabbage, and cucumbers indicate that tolerances for ethoprop residues in/on these crops should be increased to 0.2, 0.05, and 0.1 ppm, respectively.

As noted above under Guideline 860.1200, label amendments and/or additional field trial data on all residues of concern are necessary before tolerances can be reassessed on corn grain, corn forage, corn fodder, peanuts, potatoes, sweet potatoes by translation from potatoes, and sugarcane.

As there are no registered uses on mushrooms or soybeans, tolerances for residues in/on mushrooms and soybean commodities should be revoked. In addition, tolerances for residues in/on lima and snap bean forage, pineapple fodder and forage, and sugarcane fodder and forage should be revoked as the Agency no longer considers these commodities to be significant livestock feed items (Table 1 in OPPTS Guideline 860.1000).

Tolerances Listed Under 40 CFR §180.262 (b):

A tolerance of 0.02 ppm parent is established with regional registration on okra. As there are currently no registered uses for ethoprop on okra, the tolerance for ethoprop residue in/on okra should be revoked.

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Table C. Tolerance Reassessment Summary for Ethoprop.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Tolerances listed under 40 CFR §180.262 (a):			
Bananas	0.02 (N)	0.04	*Banana*
Beans, lima	0.02 (N)	0.02	*Bean, lima*
Beans, lima, forage	0.02 (N)	Revoke	No longer a regulated feed item.
Beans, snap	0.02 (N)	0.2	*Bean, snap*
Beans, snap, forage	0.02 (N)	Revoke	No longer a regulated feed item.
Cabbage	0.02 (N)	0.05	*Cabbage, fresh w/ wrapper leaves*
Corn, fodder	0.02 (N)	TBD [a]	*Corn, stover*
Corn, forage	0.02 (N)	TBD[a]	
Corn, fresh (inc. sweet) (K+CWHR)	0.02 (N)	TBD[a]	*Corn, sweet, K+CWHR*
Corn, grain	0.02 (N)	TBD[a]	
Cucumbers	0.02 (N)	0.1	*Cucumber*
Mushrooms	0.02	Revoke	No registered uses on mushrooms
Peanuts	0.02 (N)	TBD[a]	*Peanut, nutmeat*
Peanut, hay	0.02 (N)	TBD[a]	
Pineapples	0.02 (N)	0.02	*Pineapple*
Pineapples, fodder	0.02 (N)	Revoke	No longer regulated feed items.
Pineapples, forage	0.02 (N)		
Potatoes	0.02 (N)	TBD[a]	*Potato, tuber*
Soybeans	0.02 (N)	Revoke	Uses on soybeans have been deleted from all the registrant's labels.
Soybeans, forage	0.02 (N)		
Soybeans, hay	0.02 (N)		
Sugarcane	0.02 (N)	TBD[a]	*Sugarcane, cane*
Sugarcane, fodder	0.02 (N)	Revoke	No longer regulated feed items.
Sugarcane, forage	0.02 (N)		
Sweet potatoes	0.02 (N)	TBD[a]	Data can be translated from potatoes. *Sweet potato*
Tolerance with Regional Registration listed under 40 CFR §180.262 (b):			
Okra	0.02	Revoke	No registered uses on okra

[a] TBD = To be determined. Tolerance cannot be determined at this time because label amendments or additional data on all residues of concern are required.

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DIETARY EXPOSURE ASSESSMENT SUMMARY

For reregistration and risk assessment purposes, adequate plant and livestock metabolism data are available. Adequate magnitude of the residue data for ethoprop *per se* and/or for Metabolite IV are available for the registered commodities indicated in Table C. For other commodities, adequate residue data are available for label conditions less stringent than the maximum conditions. Adequate residue data are also available for all processed commodities currently registered in the U.S. As residue data on Metabolites II and III are not available, HED will conduct dietary exposure assessment using the available data on ethoprop and Metabolite IV, and making conservative assumptions regarding the levels of Metabolites II and III using data from the metabolism studies. A reasonably reliable risk assessment for the uses of ethoprop should be feasible at this time using available residue data.

CODEX HARMONIZATION

The Codex Alimentarius Commission has established maximum residue limits (MRLs) for ethoprophos (ethoprop) residues in/on various plant commodities (see *Guide to Codex Maximum Limits For Pesticide Residues, Part A.1, 1995*). Currently, the Codex MRL residue definition includes only parent ethoprophos. With the inclusion of Metabolites II through IV in the U.S. tolerance definition, Codex MRLs and U.S. tolerances will no longer be compatible.

A comparison of the Codex MRLs and the corresponding U.S. tolerances is presented in Table D.

Table D. Codex MRLs for ethoprophos and current U.S. tolerances.

Codex			Current U.S. Tolerance (ppm)	Recommendation and Comments
Commodity (As Defined)	MRL (mg/kg)	Step		
Banana	0.02 (*)[a]	CXL	0.02	
Beetroot	0.02 (*)	CXL	None	Not registered for this use in the U.S.
Cabbages, Head	0.02 (*)	CXL	0.02	
Cucumber	0.02 (*)	CXL	0.02	The tolerance for cucumber includes gherkins in the U.S.
Gherkin	0.02 (*)	CXL		
Grapes	0.02 (*)	CXL	None	Not registered for this use in the U.S.
Lettuce, Head	0.02 (*)	CXL	None	Not registered for this use in the U.S.
Maize	0.02 (*)	CXL	0.02	
Maize fodder	0.02 (*)	CXL		
Maize forage	0.02 (*)	CXL		
Melons, except watermelon	0.02 (*)	CXL	None	Not registered for this use in the U.S.

(continued; footnotes follow)

Table D *(continued)*.

Codex			Current U.S. Tolerance (ppm)	Recommendation and Comments
Commodity (As Defined)	MRL (mg/kg)	Step		
Onion, Bulb	0.02 (*)	CXL	None	Not registered for this use in the U.S.
Peanut	0.02 (*)	CXL	0.02	
Peanut fodder	0.02 (*)	CXL	0.02	
Peas	0.02 (*)	CXL	None	Not registered for this use in the U.S.
Peppers	0.02 (*)	CXL	None	Not registered for this use in the U.S.
Pineapple	0.02 (*)	CXL	0.02	
Pineapple fodder	0.02 (*)	CXL	None	No longer regulated as feed items in the U.S.
Pineapple forage	0.02 (*)	CXL	None	
Potato	0.02 (*)	CXL	0.02	
Soya bean fodder	0.02 (*)	CXL	None	Not registered for this use in the U.S.; tolerances should be revoked.
Soya bean (dry)	0.02 (*)	CXL	None	
Strawberry	0.02 (*)	CXL	None	Not registered for this use in the U.S.
Sugar cane	0.02 (*)	CXL	0.02	
Sugar cane fodder	0.02 (*)	CXL	None	No longer regulated as feed items in the U.S.
Sugar cane forage	0.02 (*)	CXL	None	
Sweet potato	0.02 (*)	CXL	0.02	
Tomato	0.02 (*)	CXL	None	Not registered for this use in the U.S.
Turnip, Garden	0.02 (*)	CXL	None	Not registered for this use in the U.S.

* An asterisk (*) signifies that the MRL was established at or about the limit of detection.

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AGENCY MEMORANDA CITED IN THIS DOCUMENT

CB No: 6009
DP Barcode: None
Subject: Multiresidue Protocol Data.
From: M. Nelson
To: J. Talarico
Dated: 1/19/90
MRID(s) 41270700 and 41270701

CB No: 6141
DP Barcode: None
Subject: Rhone-Poulenc, Inc. Response to the Ethoprop Reregistration Standard: Residue Chemistry Requirements.
From: R. Perfetti
To: R. Engler/L. Rossi
Dated: 7/3/90
MRID(s) None

CBRS No: 7775
DP Barcode: D162702
Subject: Rhone-Poulenc Ag Company Response to the Reregistration Standard: Residue Chemistry Data.
From: C. Olinger
To: L. Rossi
Dated: 1/24/92
MRID(s) 41809601

CBRS No: 7407, 7795, and 7933
DP Barcode: D14906, D163011, and D163888
Subject: Rhone-Poulenc Ag Company Response to the Reregistration Standard: Plant Metabolism Data.
From: C. Olinger
To: L. Rossi
Dated: 1/24/92
MRID(s) 41691001, 41814001, and 41840801

CBRS No: 8330
DP Barcode: D167017
Subject: Rhone-Poulenc Ag company Response to the Reregistration Standard: Plant Metabolism Data for Cabbage.
From: J. Abbotts
To: L. Rossi
Dated: 4/22/92
MRID(s) 41946001

CBRS No: 9812
DP Barcode: D177243
Subject: Multi-residue Methods Protocol.
From: L. Cheng
To: H. Hundley
Dated: 5/28/92
MRID(s) 42242101

CBRS No: 9568
DP Barcode: D175797
Subject: Reregistration of Ethoprop. Residue Analytical Method - Plants.
From: B. Cropp-Kohlligian
To: L. Rossi/L. Shnaubelt
Dated: 7/16/92
MRID(s) 42220601

CBRS No: 12706 and 12578
DP Barcode: D195968 and D195127
Subject: Response to the Ethoprop Reregistration Standard: Pineapple Residue and Processing Studies.
From: R. Perfetti
To: L. Rossi
Dated: 2/18/94
MRID(s) 42945501 and 42901601

CBRS No: 11533, 12610, and 12797
DP Barcode: D188915, D195286, and D196126
Subject: Response to the Ethoprop Reregistration Standard: Metabolism and rotational Crop Studies.
From: R. Perfetti
To: L. Rossi
Dated: 6/22/94
MRID(s) 42197601, 42923201, and 42962701

CBRS No: 13604
DP Barcode: D202608
Subject: Response to the Ethoprop Reregistration Standard: Metabolism Upgrade.
From: R. Perfetti
To: E. Saito
Dated: 9/29/94
MRID(s) 43209001

CBRS No: 12816
DP Barcode: 196279
Subject: Reregistration of Ethoprop: Response to CBRS Review of a Tobacco Pyrolysis Study.
From: C. Olinger
To: S. Jennings
Dated: 7/19/95
MRID(s) None

CBRS No: 14535 and 13949
DP Barcode: D207805 and D204975
Subject: Response to the Ethoprop Reregistration Standard: Methods and Processing Studies.
From: R. Perfetti
To: S. Jennings
Dated: 8/3/95
MRID(s) 43277501, 43277502, and 43373601

CBRS No: 15410
DP Barcode: D214091
Subject: PP#5E04491 - Ethoprop on Mint - Evaluation of Field Trial and Processing Residue Data.
From: G. Otakie
To: D. Edwards/C. Anderson/W. Hazel
Dated: 8/11/95
MRID(s) 43588801 and 43588802

CBRS No: 16089
DP Barcode: D218587
Subject: PP#5E04491 - Ethoprop on Mint. Evaluation of Revised Section F.
From: G. Otakie
To: H. Jamerson/W. Hazel
Dated: 9/20/95
MRID(s) None

CBRS No: 15114
DP Barcode: D212132

Subject: Magnitude of the Residue in Field Corn, Peanut Processing Study, and Storage Stability.
From: S. Knizner
To: S. Jennings
Dated: 12/21/95
MRID(s) 43539801, 43530901, and 43539401

CBRS No: 16678
DP Barcode: D221951
Subject: Ethoprop (041101). Metabolism in Corn, Supplemental.
From: J. Abbotts
To: P. Deschamp
Dated: 7/11/96
MRID(s) 43868701

CBRS No: 16699
DP Barcode: D221052
Subject: Ethoprop (041101). Metabolism in Potato, Supplemental..
From: J. Abbotts
To: P. Deschamp
Dated: 7/11/96
MRID(s) 43836401

CBRS No: None
DP Barcode: None
Subject: Issues to be presented at the 10/7/96 meeting of the HED Metabolism Committee.
From: J. Abbotts
To: HED Metabolism Committee
Dated: 10/1/96
MRID(s) None

CBRS No: None
DP Barcode: None
Subject: Results of the HED Metabolism Committee Meeting Held on 10/16/96: Ethoprop on Primary and Rotational Crops.
From: J. Abbotts
To: HED Metabolism Committee
Dated: 10/17/96
MRID(s) None

CBRS No: None
DP Barcode: None
Subject: Ethoprop. Decision on the HED Metabolism Committee, Residues to be Regulated in Primary and Rotational Crops.
From: J. Abbotts
To: P. Deschamp
Dated: 10/29/96
MRID(s) None

CBRS No: None
DP Barcode: None
Subject: Ethoprop. Meeting with Registrant Rhone-Poulenc, 12/3/96, on Residue Chemistry Requirements.
From: J. Abbotts
To: P. Deschamp
Dated: 12/4/96
MRID(s) None

CBRS No: 17755
DP Barcode: D232990
Subject: Ethoprop. Registrant Rhone-Poulenc, Letter on Residue Chemistry Requirements.
From: J. Abbotts
To: P. Deschamp
Dated: 2/12/97
MRID(s) None

CBRS No: 17688
DP Barcode: D231955
Subject: Registrant Rhone-Poulenc Ag Company. Sugarcane Processing.
From: J. Abbotts
To: T. Myers
Dated: 2/19/97
MRID(s) None

CBRS No: 14917
DP Barcode: D210696
Subject: Magnitude of the Residue in Sweet Corn and Cucumbers.
From: C. Eiden
To: P. Deschamp/S. Jennings/L. Schnaubelt
Dated: 3/13/97
MRID(s) 4349101 & 43484001

CBRS Nos: 15401 and 17234
DP Barcode: D213957 and D226333
Subject: Ethoprop. Cabbage Field Trials and Peanut Processing Data.
From: J. Abbotts
To: K. Farwell/J. Loranger
Dated: 9/4/97
MRID(s) 43583201 and 44003301

CBRS No: None
DP Barcode: D238745
Subject: Preplant application to mint: Is classification as a nonfood use appropriate?
From: J. Hazel
To: H. Jamerson/R. Forrest
Dated: 9/16/97
MRID(s) None

CBRS No: None
DP Barcode: D235830
Subject: Ethoprop. Peanut Field Trails.
From: J. Abbotts
To: K. Farwell/J. Loranger
Dated: 9/22/97
MRID(s) 43539701 and 44062401

CBRS No: 15264
DP Barcode: D213113
Subject: Ethoprop. Lima and Snap Bean Field Trails.
From: J. Abbotts
To: K. Farwell/J. Loranger
Dated: 9/22/97
MRID(s) 43538601 and 43539601

CBRS No: 17221
DP Barcode: D225648
Subject: Ethoprop. Storage Stability in Sugarcane, Sugarcane Processing.
From: J. Abbotts
To: K. Farwell/J. Loranger
Dated: 11/14/97
MRID(s) 43971501

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