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04/OPP # 34144

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PREVENTION, PESTICIDES, AND  
TOXIC SUBSTANCES

April 29, 1998

ADDENDUM MEMORANDUM

SUBJECT: Ethoprop (041101). Anticipated Residues for Chronic  
(Cancer) Dietary Exposure.  
MRID None. DP Barcode D245524.

FROM: Sheila Piper, Chemist *Sheila Piper*  
Chemistry & Exposure Branch 1 (CEB-1)  
Health Effects Division (7509C)

THROUGH: Francis B. Suhre, Branch Senior Scientist *Francis Suhre*  
Chemistry & Exposure Branch 1 (CEB-1)  
Health Effects Division (7509C)

TO: Kit Farwell, D.V.M.  
Reregistration Branch 1  
Health Effects Division (7509C)

**Action Requested**

Generate anticipated residue estimates to assess chronic (cancer) dietary risk for ethoprop in support of the Reregistration Eligibility Decision Document (J.Abbotts, 3/23/98).

**Residue Information**

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. Adequate methods are available for the enforcement of established tolerances, as currently defined.

The HED Metabolism Committee recently determined the residues to be regulated are parent

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ethoprop (O-ethyl-S,S-dipropylphosphorodithioate) plus metabolites designated as Metabolite II (O-ethyl-S-methyl-S-propylphosphorodithioate), Metabolite III (O-ethyl-O-methyl-S-propyl phosphorothioate), and Metabolite IV (O-ethyl-S-propylphosphorothioate) (see memo of J.Abbotts, 10/29/96). However, submitted magnitude of the residue studies contained only the parent or parent and Metabolite IV; studies accepted by the FRSTR reported data on parent only (10/20/87). According to the Residue Chemistry Chapter of the ethoprop RED (J. Abbotts, 3/23/98), tolerances will be reassessed based on combined residues of parent and metabolite IV and making conservative assumptions regarding levels of metabolites II and III using data from the metabolism studies.

The HED Metabolism Committee found that for acute and chronic (non-cancer) dietary risk, the residues of concern in crops are parent and metabolites II and III; for cancer dietary risk, residues of concern are parent and metabolites II through IV (J.Abbotts 10/29/96).

### Dietary Exposure

To account for all metabolites of concern for cancer risk identified by the HED metabolism committee (parent + metabolites II, III, and IV), data from ethoprop metabolism and crop rotation studies were used to derive residue adjustment factors by dividing residues of (parent + metabolites II, III, and IV) by residues of (parent + metabolite IV). These adjustment factors were then used to convert data from residue field trials (parent + metabolite IV) to anticipated residues reflecting the total residue of concern (parent + metabolites II, III, and IV): Adjustment factors ranged from 1.0x to 5.3x with the average being 2.1x (see Tables 1-5).

Table 1: Ethoprop and metabolites of concern in corn.

Residue	Forage:		Fodder:	
	%TRR	ppm	%TRR	ppm
Ethoprop	7.8	0.17	0.5	0.01
Metabolite II. O-ethyl-S-methyl-S-propylphosphorodithioate	0.3	0.01	1.1	0.02
Metabolite III. O-ethyl-O-methyl-S-propylphosphorothioate	0.8	0.02	1.8	0.03
Metabolite IV. O-ethyl-S-propylphosphorothioate	2.3	0.05	0.8	0.01
Total Residues of Concern for Cancer (Ethoprop + Met II + III + IV)	11.2	0.25	4.2	0.07
Sum of Ethoprop + Metabolite IV	10.1	0.22	1.3	0.02
Ratio of Total Residues of Concern to Ethoprop + Metabolite IV (ppm)	<b>1.1X</b>		<b>3.5X</b>	

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Table 2: Ethoprop and metabolites of concern in cabbage

Metabolite	Cabbage leaves		Cabbage heads	
	%TRR	ppm	%TRR	ppm
Ethoprop	4.0	0.62	0.8	0.02
Metabolite II. O-ethyl-S-methyl-S-propylphosphorodithioate	0.6	0.09	0.4	0.01
Metabolite III. O-ethyl-O-methyl-S-propylphosphorothioate	1.7	0.26	1.7	0.05
Metabolite IV. O-ethyl-S-propylphosphorothioate	2.5	0.39	0.3	0.01
Total Residues of Concern for Cancer (Ethoprop + Met II + III + IV)	8.8	1.36	2.9	0.09
Sum of Ethoprop + Metabolite IV	6.5	1.01	1.1	0.03
Ratio of Total Residues of Concern to Ethoprop + Metabolite IV (ppm)	<b>1.3X</b>		<b>3.0X</b>	

Table 3: Summary of characterized/identified residues in radish roots rotated from aged sandy loam soil treated with [<sup>14</sup>C]ethoprop at 1x the maximum seasonal rate for annual crops.

Metabolite	31-DAT		123-DAT	
	%TRR	ppm	%TRR	ppm
I. Ethoprop	7.6	0.33	5.1	0.07
II. O-ethyl-S-methyl-S-propylphosphorodithioate	0.3	0.01	--	--
III. O-ethyl-O-methyl-S-propylphosphorothioate	0.2	0.01	--	--
IV. O-ethyl-S-propylphosphorothioate	21.0	0.91	--	--
Total Residues of Concern for Cancer (Ethoprop + Met II + III + IV)	29.1	1.26	--	--
Sum of Ethoprop + Metabolite IV	28.6	1.24	--	--
Ratio of Total Residues of Concern to Ethoprop + Metabolite IV (ppm)	<b>1.0X</b>		---	

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Table 4: Summary of characterized/identified residues in/on spinach rotated from aged sandy loam soil treated with [<sup>14</sup>C]ethoprop at 1x the maximum seasonal rate for annual crops.

Metabolite	31-DAT	
	%TRR	ppm
I. Ethoprop	0.4	0.08
II. O-ethyl-S-methyl-S-propylphosphorodithioate	1.8	0.34
III. O-ethyl-O-methyl-S-propylphosphorothioate	---	---
IV. O-ethyl-S- propylphosphorothioate	---	---
Total Residues of Concern for Cancer (Ethoprop + Met II + III + IV)	2.2	0.42
Sum of Ethoprop + Metabolite IV	0.4	0.08
Ratio of Total Residues of Concern to Ethoprop + Metabolite IV (ppm)	<b>5.3X</b>	

Table 5: Summary of characterized/identified residues in/on wheat rotated from aged sandy loam soil treated with [<sup>14</sup>C]ethoprop at 1x the maximum seasonal rate for annual crops.

Metabolite	31-DAT		123-DAT	
	%TRR	ppm	%TRR	ppm
<b>Wheat Forage</b>				
I. Ethoprop	6.5	1.82	4.9	0.25
II. O-ethyl-S-methyl-S-propylphosphorodithioate	0.8	0.22	--	--
III. O-ethyl-O-methyl-S-propylphosphorothioate	0.3	0.08	--	--
IV. O-ethyl-S- propylphosphorothioate	--	--	10.5	0.53
Total Residues of Concern for Cancer (Ethoprop + Met II + III + IV)	7.6	2.12	15.4	0.78
Sum of Ethoprop + Metabolite IV	6.5	1.82	15.4	0.78
Ratio of Total Residues of Concern to Ethoprop + Metabolite IV (ppm)	<b>1.2X</b>		<b>1.0X</b>	

Wheat Straw				
I. Ethoprop	1.3	0.62	0.3	0.13
II. O-ethyl-S-methyl-S-propylphosphorodithioate	--	--	0.05	0.02
III. O-ethyl-O-methyl-S-propylphosphorothioate	0.6	0.27	0.4	0.16
IV. O-ethyl-S-propylphosphorothioate	--	--	0.2	0.09
Total Residues of Concern for Cancer (Ethoprop + Met II + III + IV)	1.9	0.89	0.95	0.40
Sum of Ethoprop + Metabolite IV	1.3	0.62	0.5	0.22
Ratio of Total Residues of Concern to Ethoprop + Metabolite IV (ppm)	1.4X		1.8X	

Table Note: DAT= days after treatment for planting. See Table 7 for structures.

### Summary

The average residues from field trial data reflect residues of parent and metabolite IV. Residues reported as none detected ND (LOD=0.002 ppm) were adjusted to one-half the LOD (0.001 ppm). The maximum residues from field trial data were taken from the highest residues found on the crop at the 1x rate. The average adjustment factor is 2.1 and the maximum adjustment factor is 5.3 (see Tables 1-5). Chronic anticipated residues were calculated from the average residues from field trial data multiplied by the average adjustment factor. Acute anticipated residues were calculated from the maximum residues from field trial data multiplied by the maximum adjustment factor. The HED Risk Assessor conducting the DRES analysis should be advised that the Chronic AR and Acute AR in Table 6 are not corrected for percent crop treated.

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Table 6: Ethoprop Anticipated Residues for Acute and Chronic Non-Cancer Dietary Exposure

RAC	Food Items	Tolerance		Average Residues from Field Trial Data <sup>3</sup>	Average Adjustment Factor <sup>4</sup>	Chronic (Cancer) Anticipated Residues <sup>5</sup>	% Crop Treated <sup>6</sup>
		Established <sup>1</sup>	Pending <sup>2</sup>				
Bananas		0.02	0.04	0.04	2.1	0.084	100.0*
Beans, Lima		0.02	0.02	0.004	2.1	0.008	4.00
Beans, Snap		0.02	0.2	0.030	2.1	0.063	4.00
Cabbage		0.02	0.05	0.034	2.1	0.071	1.00
Corn, Sweet		0.02		0.001	2.1	0.002	2.00
Corn, Grain	starch, refined oil, grits, meal & flour	0.02		0.001	2.1	0.002	2.00
Cucumbers		0.02	0.1	0.047	2.1	0.099	1.00
Peanuts(nutmeat)		0.02		0.065	2.1	0.137	2.00
	meal			0.001	2.1	0.002	2.00
	oil, refined			0.012	2.1	0.025	2.00
Pineapples		0.02	0.02	0.02	2.1	0.042	100.0*
	juice			0.02	2.1	0.042	100.0*
Potatoes		0.02		0.001	2.1	0.002	7.00
	granules/flakes, chips peel, wet			0.001	2.1	0.002	7.00

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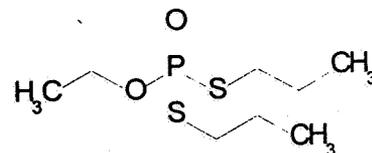
RAC	Food Items	Tolerance		Average Residues from Field Trial Data <sup>3</sup>	Average Adjustment Factor <sup>4</sup>	Chronic (Cancer) Anticipated Residues <sup>5</sup>	% Crop Treated <sup>6</sup>
		Established <sup>1</sup>	Pending <sup>2</sup>				
Sugarcane		0.02		0.001	2.1	0.002	5.00
	molasses, sugar refined			0.001	2.1	0.002	5.00
Sweet Potatoes		0.02		0.001	2.1	0.002	15.00

<sup>1</sup> 40CFR 180.262: Tolerance established on parent only.  
<sup>2</sup> Tolerance are reassessed for parent + Metabolite IV (See RED section 18).  
<sup>3</sup> Data from field trial data: Average of (parent + Metabolite IV). Residues reported as ND (LOD=0.002) were adjusted to one-half LOD (0.001).  
<sup>4</sup> The ratio of the [parent + Metabolite II + III + IV] / [parent + Metabolite IV] from Metabolism studies and Crop Rotation studies.  
<sup>5</sup> The average adjustment factor is 2.1 and the maximum adjustment factor is 5.3.  
<sup>6</sup> Chronic (cancer) AR: Average residues from field trial data multiply by average adjustment factor. Values were not corrected for % crop treated.  
 \* BEAD (4/11/95) supplied the estimates of % crop treated.  
 \* 100% crop treated was assumed in the absence of % crop treated.

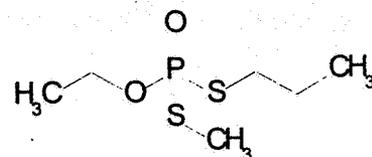
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Table 7: Ethoprop and metabolites identified in primary and rotational crops.

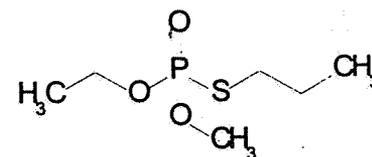
I. O-ethyl-S,S-dipropylphosphorodithioate; ethoprop



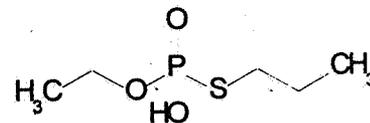
II. O-ethyl-S-methyl-S-propylphosphorodithioate



III. O-ethyl-O-methyl-S-propylphosphorothioate



IV. O-ethyl-S-propylphosphorothioate



cc: Spiper, RF, SF, Reg Std File

RDI: ResChem Team: 4/21/98: ChemSac Mtg: 4/23/98: FBSuhre: 4/29/98

7509C:CEB1:SPiper:CM-2:Rm 718D: 308-2717: Ethoprop

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DP BARCODE: D245524

DATA PACKAGE RECORD  
BEAN SHEET

DATE: 04/28/98  
Page 1 of 1

\* \* \* FREE STANDING DATA PACKAGE \* \* \*

THERE IS NO CASE OR SUBMISSION DATA

\* \* \* DATA PACKAGE INFORMATION \* \* \*

DP BARCODE: 245524 EXPEDITE: N DATE SENT: 04/28/98 DATE RET.: / /  
CHEMICAL: 041101 Ethoprop  
DP TYPE: 999

ASSIGNED TO	CSF: N	DATE	IN	LABEL: N	DATE	OUT	ADMIN DUE DATE:	/	/
DIV : HED		/	/		/	/	NEGOT DATE:	/	/
BRAN: CEB1		/	/		/	/	PROJ DATE:	/	/
SECT: IO		/	/		/	/			
REVR : SPIPER		/	/		/	/			
CONTR:		/	/		/	/			

\* \* \* DATA REVIEW INSTRUCTIONS \* \* \*

Prepare anticipated residue estimates for conducting a dietary cancer risk assessment.

\* \* \* DATA PACKAGE EVALUATION \* \* \*

No evaluation is written for this data package

THERE ARE NO ADDITIONAL DATA PACKAGES

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(9)