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

JUL 24 1986

Memorandum

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Subject: Phosmet Dietary Exposure Resulting from Residues in Apples, Citrus, Peaches and Pears.

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RCB has been asked to determine the human dietary exposure resulting from total residues of phosmet found in apples, citrus, peaches, pears, and in the processed commodities derived from these fruits. Residues on these four crops lead to the highest potential dietary exposure. Residues on other crops to which phosmet is applied will be evaluated in the future.

A dietary exposure assessment of this type may be based on residues found in these commodities as a result of pesticide applications at the maximum label rates since the pesticides could be applied at these rates. Alternatively, the assessment could be based on extensive monitoring data from the FDA which would accurately reflect the actual residues being found in these foods. Such monitoring data are not currently available. As a third alternative, the dietary exposure could be assessed based on "common practices" of application of phosmet (typical uses) to these fruits. What these "common practices" are would have to be thoroughly researched prior to undertaking a dietary exposure assessment in order for a reasonable assessment to be made; and even with adequate research on "common practices" accomplished, these practices could change as a result of several factors including increased insect infestation due to weather conditions or increased insect resistance to the pesticide requiring higher application rates.

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RCB has been asked to determine a range of possible dietary exposures resulting from applications of phosmet to the subject fruits. This range extends from the lowest likely exposure resulting from application rates determined from "common practices" to the likely exposure resulting from applications of phosmet at the maximum label rates. RCB believes that a dietary exposure assessment based on application rates less than the maximum label rates would be tenuous and should be considered so when these residue levels are used to make a risk assessment.

With these limitations in mind, the dietary exposure assessment (range) will be made.

Formulation

The phosmet formulation registered for use on apples, citrus (lemons and oranges), peaches and pears is Imidan® 50 WP, a 50% active ingredient wettable powder (EPA Reg. No. 476-1917) manufactured by Stauffer Chemical Company.

Tolerances

Tolerances are currently established for the cholinesterase-inhibiting residues of phosmet [(mercaptomethyl)phthalimide S-(O,O-dimethylphosphorodithioate)] and its oxygen analog N-(mercaptomethyl)phthalimide S-(O,O-dimethylphosphorothioate) ranging from 0.1 ppm in or on cottonseed, nuts and potatoes to 40 ppm on alfalfa; and include the following:

Raw Agricultural Commodity	Tolerance (ppm)
Apples	10
Citrus Fruits	5
Peaches	10
Pears	10

No tolerances are currently pending (40 CFR 180.261).

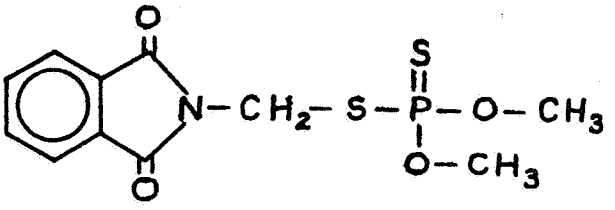
Metabolism

The metabolism of phosmet in plants and animals was last reviewed by M.J. Nelson (6/24/74) and M. Bradley (1/11/82). Phosmet is considered a weakly systemic insecticide which can be absorbed and translocated after soil and foliar applications. Metabolism occurs primarily through oxidation and hydrolysis steps. The parent is oxidized to imidoxon (the oxygen analog) followed by stepwise hydrolysis yielding hydroxymethyl phthalimide, phthalimide, phthalamic acid and phthalic acid. Decarboxylation to form benzoic acid, p-hydroxybenzoic acid and benzimide may also occur.

The metabolism of phosmet in plants was also examined in the Residue Chemistry Chapter of the Phosmet Registration Standard. It was concluded that the plant metabolism of phosmet was not adequately understood because: (i) the metabolites of phosmet have not been completely quantified or identified, (ii) metabolism studies exist for only one crop (cotton), and (iii) no data regarding the efficiency of extraction of ^{14}C residues from crops bearing weathered residues were submitted.

In the absence of adequate metabolism data, and for the purposes of this dietary exposure assessment only, we consider the residue of concern to include parent phosmet (below) and its oxygen analog.

Phosmet



Phosmet Registration Standard

A Registration Standard for phosmet (Residue Chemistry Chapter) was completed 4/15/86. Numerous deficiencies in the residue data were identified. These include the following:

(1) The metabolism of phosmet in plants is not adequately understood as described previously.
(2) The metabolism of phosmet in animals is not adequately understood. The available ruminant metabolism study reflects only dermal applications of ^{14}C phosmet and is inadequate because residues were not characterized in tissues. No studies concerning oral administration of phosmet are available.
(3) The available residue data do not support the established tolerances for the following crops: potatoes, sweet potatoes, peas (dry and succulent), pea vines and hay, citrus fruits, apricots, nectarines , plums, tree nuts and cottonseed oil.
(4) Adequate processing studies are not available for potatoes, apples, plums, grapes, field corn grain and cottonseed.

The Registration Standard also provides a summary of phosmet residues found in apples and peaches from the FDA Total Diet Studies from 1982-1984. Two detectable residues were found in apples (0.029 ppm and 0.03 ppm) with a mean value for all analyses of 0.007 ppm. Four detectable residues were found for peaches ranging from trace (<0.004 ppm) to 0.029 ppm with a mean value of 0.04 ppm.

Uses

Imidan® 50WP is registered for use as a foliar spray on the subject fruit trees. In the following paragraphs, we will describe both the currently registered label rates and the application rates considered "common practice" for each commodity. These "common practice" application rates were obtained from one of the following two sources: (1) from recommended uses described in state or regional bulletins (1986 Georgia Farm Chemical Handbook, Cooperative Extension Service, University of Georgia; 1984 South Carolina Agricultural Chemicals Handbook; Pacific Northwest Insect Control Handbook, Extension Entomologists from Oregon State University, University of Idaho and Washington State University, 1985; and 1985 Cornell Recommendations for Commercial Fruit Tree Production); or (2) from personal communication with Y. Ng (Science Support Branch). It should be pointed out that the "common practice" application rates have not been substantiated by a survey or by communication with farmers actually using the pesticide, nor are these rates limiting in any way, restricting or recommending against use at higher rates under certain circumstances.

Apples

Label Use: Apply 1-1.5 lbs product (0.5-0.75 lbs.a.i.)/100 gallons water or a maximum of 8 lbs. product (4 lbs.a.i.)/A/application. Apply as necessary up to 7 days prior to harvest. No timing or maximum number of applications is given. In California use a minimum of 4 lbs. product (2 lbs.a.i.)/A/application. When low volume sprays are used, apply the recommended rate in proportionally lower volumes of water.
Dormant applications can be made at 1 lb. (0.5 lbs.a.i.)/100 gallons water with no rate or number of applications specified.
"Common Practice" Use: Apply 1-1.5 lbs. product (0.5-0.75 lbs.a.i.)/100 gallons water or 6 lbs. Product (3 lbs.a.i.)/A/application at petal fall and at 7-10 day intervals for 3-4 additional applications (effective PHI of approximately 90 days).

Citrus

Label Use: Apply 1.0 lb. product (0.5 lbs.a.i.)/100 gallons of water plus a minimum of 1 qt. of a suitable spray oil/100 gallons of water or a maximum of 30 lbs. product (15 lbs.a.i.)/A/application for a maximum of 3 applications per season at 30 day intervals. A PHI of 7 days is required, and applications should be made as full cover sprays using ground equipment only. Phosmet use on citrus is restricted to the states of CA, AR and TX.
"Common practice" use: Y. Ng of the Science Support Branch reports that there is no (or very limited) use of phosmet on citrus fruit. Therefore, we will not calculate residues reflecting "common practice" use of phosmet.

Peaches

Label use: Apply 1-1.5 lbs (0.5-0.75 lbs.a.i.)/100 gallons water or a maximum of 6 lbs. (3 lbs.a.i.)/A/application as a full cover spray using ground or aerial equipment. Repeat applications as necessary up to 14 days prior to harvest. In CA use a minimum of 4 lbs. (2 lbs.a.i.)/A/application. Dormant use same as for dormant use on apples.
"Common practice" use: Apply 1-1.5 lbs. (0.5-0.75 lbs.a.i.)/100 gallons water or 3 lbs. (1.5 lbs.a.i.)/A/application at petal fall and for 3-4 additional applications after petal fall (effective PHI = approximately 60 days).

Pears

Label use: Apply 1-1.5 lbs (0.5-0.75 lbs.a.i.)/100 gallons water or a maximum of 10 lbs. (5 lbs.a.i.)/A/application as a full cover spray using ground or aerial equipment. Repeat as necessary up to 7 days prior to harvest. In CA use a minimum of 4 lbs. (2 lbs.a.i.)/A/application.

Dormant use same as dormant use on apples.
"Common practice" use: Apply 1-1.5 lbs. (0.5-0.75 lbs.a.i.)/100 gallons water or 3 lbs. (1.5 lbs.a.i.)/A/application at petal fall and for 3-4 additional applications at 7-10 day intervals after petal fall (effective PHI = approximately 90 days).

Additional Use Information

The Economic Analysis Branch (BUD) prepared a paper entitled, "Preliminary Quantitative Usage Analysis of Phosmet (Imidan®)", in which they summarized the percentages of active ingredient used on various raw agricultural commodities and the percentages of sites (or commodities)

treated per year, for all major commodities to which phosmet is applied. These data state that phosmet is not used on citrus (probably <1%) supporting the earlier "not used" statement for "common practice" use of phosmet on citrus. The information for apples, pears and peaches is reproduced below.

Agricultural Site	Approximate Quantity A.I. Lbs.a.i. (X 1000)	Percentage of Total a.i. Used	Percentage of Sites Treated/Year
Apples	1400-1850	80	70-90
Pears	90- 160	5-7	15-40
Peaches	20- 60	1	1-15

Analytical Methods

Analytical methods used to dertermine residues of phosmet and its oxygen analog in crops are numerous including methods based on both GC and cholinesterase inhibition. Various methods were used in the residue studies reviewed in conjunction with this dietary exposure assessment. These have been reviewed previously in tolerance petitions for each commodity and will not be reviewed here (see PP#6G0455, PP#7F0523, PP#8F0699 for apples, pears and peaches; and PP#4F1464 for citrus fruit).

The analytical methods used for most of the peach studies analyzed for parent only. Additionally, corrections were made to the reported residue levels for the 90% average recovery for the method. The analytical methods for apples, pears and citrus measure both parent and oxygen analog residues and were not corrected for recovery. Total phosmet residues in all four commodities can be quantitated using PAM II, Method III.

Residue Data

Residue data were utilized from both field studies submitted with tolerance petitions and from FDA monitoring data. These are discussed separately.

Field Studies

Apples

Residue studies reflecting applications of Imidan® 50WP to apples were submitted with PP#6G0455 and PP#7F0523. Imidan® 50WP was applied at rates of 1.5-5.625 lbs.a.i./A

for 1-9 applications. PHI's ranged from 0-49 days. These data are summarized in Table 1. Based on these data, we conclude that residues are not likely to exceed 10 ppm as a result of applications of phosmet at the maximum label rates, and are not likely to exceed 1 ppm as a result of "common practice" use.

Although no processing studies were submitted for apples, studies were submitted which suggest that greater than 80% of the total phosmet residue is found in the peel. Assuming that cider and wet pomace comprise 80% and 20% respectively of raw apples by weight, and assuming a dry-down factor of 5X in producing dry from wet pomace, we calculate the following residues likely to be found in apples and processed apple commodities.

Commodity	Max. (and average) Residue at Max. Label Rate Use (ppm)	Max. (and average) Residue for "Common Practice" Use (ppm)
Raw Apples	10 (4)	1 (0.4)
Apple Juice	2 (0.8)	0.2 (0.08)
Wet Pomace	2 (0.8)	0.2 (0.08)
Dry Pomace	10 (4)	1 (0.4)
Apple Sauce	2 (0.8)	0.2 (0.08)

Citrus

Residue data for applications of phosmet to oranges and lemons were submitted with PP#4F1464. Imidan® 50WP was applied to lemons at rates of 3, 6, 10 or 13.5 lbs.a.i./A for 1-3 applications and utilizing PHI's of 0-54 days. Imidan® 50WP was applied to oranges at rates of 3-18 lbs.a.i./A for 1-3 applications and utilizing PHI's of 0-166 days. A processing study for oranges was also submitted. Residues found in oranges and lemons are summarized in table 1. Results of the orange processing studies as well as likely residues in processed commodities are summarized below.

Commodity	Average Conc. Factor	Max. (and average) Residue for Appl. at Max. Label Rate
Orange, whole fruit	1	5 (2)
" , juice	0.009	0.05 (0.02)
, dried pulp	0.018	0.10 (0.04)
, molasses	0.04	0.20 (0.08)
, oil	2.95	15 (6)
, peel	2.0	10 (4)
Lemons, whole fruit	-	5 (2)
, oil	2.95	15 (6)

Table 1. Phosmet Residues in Apples, Citrus, Peaches and Pears. From Field Trial Residue Data

Commodity	Application Rate (lbs.a.i./A)	No. Apps.	Residue Range (ppm)
Apples	1.5	9	<0.2 - 3.75
	1.75	2	0.9 - 1.68
	1.875	8	0.26 - 2.47
	2.0	6	1.31 - 5.43
	2.1	1	0.87 - 2.16
	3.375	1	2.92 - 9.98
	3.75	1	0.51 - 4.63
	4.0	1-3	1.03 - 5.67
	5.625	1	1.03 - 6.51
Oranges	3	1	0.66
	4.5	1	0.74
	5.0	1	0.14 - 0.19 (166 day PHI)
	7.5	1	0.19 (166 day PHI)
	10.0	3	0.28 - 0.94
	13.5	1	0.84 - 3.66
	15	2-3	0.85 - 2.24
	18	1	1.16 - 3.66
Lemons	3	2	0.2
	6	3	1.31 - 2.9
	10	2-3	0.03 - 2.68
	13.5	1	0.85 - 2.14
Peaches	1.03	8	<0.1 - 2.09*
	1.5	9	2.29 - 6.96*
	2	1-5	0.48 - 14.3*
	1.65	4	1.93 - 14.11*
Pears	1.5	3	<0.4 - 1.35
	2	1-2	0.52 - 4.31
	2.5	2	0.63 - 2.64
	4.0	2	0.71 - 1.56
	5.0	1	0.99 - 3.39
	6.0	3	2.22 - 6.83
	8.0	3	0.60 - 2.43

*corrected for 90% recovery, parent only

Peaches

Residue data for application of phosmet to peaches were submitted with PP#7F0523 and PP#6G0455. Imidan® 50WP was applied at rates of 1.03125, 1.5, 2 and 2.625 lbs.a.i./A for 1-9 applications, and PHI's ranged from 0-28 days.

These data are summarized in Table 1. Additional data were submitted for peeled and dried peaches suggesting that greater than 80% of the residue in peaches is found in the peel, and suggesting a concentration factor of 2X in dried peaches. Based on these data, we make the following estimations.

Commodity	Max. (and average) Likely Residue for Apps. at Max. Label Rate (ppm)	Max. (and average) Likely Residue for Apps. at "Common Practice" Rate (ppm)
Peaches	10 (3)	1 (0,3)
Peaches, w/o peel	2 (0.6)	0.2 (0.06)
Peaches, dried	20 (6)	2 (0.6)

Pears

Residue data for applications of phosmet to pears were submitted with PP#7F0523 and PP#6G0455. Imidan® 50WP was applied at rates ranging from 1.5-8 lbs.a.i./A for 1-3 applications and utilizing PHI's of 0-22 days. No processing studies were submitted. Residue data are summarized in Table 1. Based on data for apples and peaches, we estimate that greater than 80% of the total residue in pears will be found in the peels. We, therefore, make the following estimations.

Commodity	Max. (and average) Likely Residue for Appl. at Max. Label Rate (ppm)	Max. (and average) Likely Residue for Appl. at "Common Practice" Rate (ppm)
Pears	10 (3)	1 (0.3)
Pears, peeled	2 (0.6)	0.2 (0.06)

FDA Monitoring Data

FDA monitoring data for FY'84 and 85 (through 8/31/85) are summarized in the table on the next page.

Commodity	No. Positive Findings FY'84	No. Positive Findings FY'85	Max. Residue* Found (ppm) FY'84	Max. Residue* Found (ppm) FY'85	Ave. Residue* (ppm) FY'84	Ave. Residue* (ppm) FY'85	95% Conf.* Limit FY'84	95% Conf.* Limit FY'85
Apples	6	6	2.4	0.36	0.03	<0.01	0.32	0.05
Pears	6	1	0.8	0.71	0.04	0.01	0.26	0.13
Peaches	3	0	0.01	-	<0.01	-	<0.01	-

* Residues are for parent only.

The total number of analyses done in FY'84 and FY'85 respectively were pears (62,92), apples (216,310), peaches (146,76), oranges (93,112) and lemons (22,21). No detectable residues were found in oranges or lemons during the two year period or in peaches in FY'85. Only three trace (ca. 0.01 ppm) residues were found in peaches in FY'84. These data tend to support the "common practice" uses of phosmet although the total number of analyses is insufficient to completely base a dietary exposure assessment upon. Additionally, the analytical method used determines residues of parent only. Residues are likely to be from 0-30% higher with the oxygen analog residues included.

Meat, Milk, Poultry and Eggs

RCB was asked not to examine phosmet residues in meat, milk, poultry and eggs in conjunction with this dietary exposure assessment. It should, however, be mentioned that tolerances are established for combined residues in the meat, fat and meat by-products of cattle, goats, hogs, horses, poultry and sheep at 0.2 ppm. A cursory inspection of the data indicates that these tolerances are appropriate based on current maximum intake of phosmet residues by these animals. No tolerance has been established for milk. Feeding studies in which cows were fed 100 ppm or 200 ppm phosmet (approx. 0.6-1.3X the maximum possible dietary intake) showed no detectable residues ($\leq$0.03 ppm) of phosmet or its oxygen analog in milk.

Conclusions and Recommendations

The dietary exposure to combined residues of phosmet and its oxygen analog are provided in the table on the next page.

The monitoring data from the FDA are more consistent with residue estimations based upon the "common practice" use rather than with the maximum label rate applications. However, the quantity of FDA data is limited and is not likely to be representative of residues in these crops.

Commodity	Max. (and average) Likely Residue for Appl. at Max. Label Rate (ppm)		Max. (and average) Likely Residue for Appl. at "Common Practice" Rates (ppm)	
Apples, raw	10	(4)	1	(0.4)
" , juice	2	(0.8)	0.2	(0.08)
" , wet pomace	2	(0.8)	0.2	(0.08)
" , dry pomace	10	(4)	1	(0.4)
" , sauce	2	(0.8)	0.2	(0.08)
Orange, whole fruit	5	(2)		
" , juice	0.05	(0.02)		
" , dried pulp	0.10	(0.04)		
" , molasses	0.2	(0.08)		
" , oil	15	(6)		
" , peel	10	(4)		
Lemons	5	(2)		
Peaches, whole fruit	10	(3)	1	(0.3)
" , w/o peel	2	(0.6)	0.2	(0.06)
" , dried	20	(6)	2	(0.6)
Pears, whole fruit	10	(3)	1	(0.3)
" , w/o peel	2	(0.6)	0.2	(0.06)

RCB recommends that a range of risk assessments be made utilizing residue levels from the average residue based on "common practice" use to the highest residue based on use at the maximum label rates.

cc:Phosmet(Imidan®)S.F., R.F.,Special Review S.F., Circu,
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