PC 125301

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

AUG 30 1993

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM:

SUBJECT: **PP#0G3879**. Fenoxycarb in/on Pears. Amendment in response to review of 11/2/90. CBTS# 11,395. DP Barcode D188206. MRID#'s 426042-03, -04, -05.

FROM: José J. Morales, Chemist
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José J. Morales 8/30/93

THROUGH: Elizabeth T. Haeberer, Section Head
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TO: Rita Kumar/Marion Johnson, PM Team 10
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and
Albin Kocialski, Section Head
Registration Section
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BACKGROUND

Maag Agrochemicals originally requested an experimental use permit (EUP) for the use of the insect growth regulator Insegar® [active ingredient: fenoxycarb (ethyl-[2-(p-phenoxyphenoxy) ethyl] carbamate] on pears and at the same time proposed the establishment of a temporary tolerance of 0.5 ppm for residues of fenoxycarb in/on the raw agricultural commodity pears. CBRS recommended against the temporary tolerance request because the use directions were insufficient in that the schedule of application is ambiguous and must be clearly defined, the use terminology (i.e. degree days) may not be understood by all

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applicators, and an independent laboratory validation was not provided (D. McNeilly's memo of 11/2/90).

Ciba-Geigy, upon purchasing Maag Agrochemicals, intends to amend the original EUP request by modifying the use directions to reflect a different use pattern, by proposing a lower tolerance for residues of fenoxycarb in/on pears, and addressing some deficiencies cited in the CBRS review of 11/2/90.

SUMMARY OF DEFICIENCIES THAT NEED TO BE RESOLVED

1. A final copy of the enforcement analytical method ADC Project #1103,in which the suggestions made by Ciba-Geigy Residue Chemistry Department are incorporated, must be submitted to the Agency prior recommendation for a temporary tolerance and initiation of the EPA Method Validation.

2. A revised Section B is needed.

CONCLUSIONS AND RECOMMENDATIONS

1. CBTS concludes that the proposed label is not adequate. The petitioner has not proposed a PHI and this information should be added to the proposed label. A revised Section B is needed.

2. The submitted residue data indicates that the proposed tolerance of 0.10 ppm for residues of fenoxycarb (parent only) in or on pears is adequate to cover the use proposed in the experimental use permit (EUP). However, additional data will be required for a permanent tolerance if the HED Metabolism Committee determines that other metabolites should need to be included in the tolerance expression.

3. Acceptable fenoxycarb recoveries were submitted by the petitioner. The submitted data show that the limit of quantification in pears is 0.01 ppm. However, we cannot recommend an EPA Method Validation for method ADC Project #1103 at this moment. The petitioner needs to submit a final copy of the enforcement analytical method ADC Project #1103, in which the suggestions made by Ciba-Geigy Residue Chemistry Department are incorporated, prior recommendation for a temporary tolerance and initiation of the EPA Method Validation. Also, additional methods will need EPA method validation, for a permanent tolerance, if it is determined that other metabolites should appear in the tolerance expression. Note that any additional enforcement methodology must be validated by an independent laboratory prior to submitting to EPA (see PR Notice 88-5).

CBTS recommends against this temporary tolerance request for reasons given in Conclusions 1 and 3.

DETAILED CONSIDERATIONS

The deficiencies listed in CBTS memo of 11/2/90 are outlined below followed by the petitioner's responses and CBTS comments.

CBTS Deficiency #3

The use directions for treatment of pears are not clear; use directions must clearly state the schedule of application and should not use terminology (i.e., degree days) that may not be understood by all personnel applying the product.

Petitioner's Response to Deficiency #3

Maag Agrochemicals, Inc. submitted an application for Experimental Use Permit (EUP) and petition for temporary tolerance for Insegar® (fenoxycarb 25WP) in/on pears at 0.5 ppm. Ciba-Geigy, upon purchasing Maag Agrochemicals, has examined the EUP review and elected to respond to the review with the additional information required, as well to amend the EUP and the petition for temporary tolerance.

The petitioner explained that the use pattern for the previous EUP application was for post-harvest, pre-bloom and late spring and summer applications of fenoxycarb 25WP at 6 to 12 ounces formulated product per acre (1.4 to 3 ounces ai/A) in 50 to 500 gallons of water to control codling moth, pear psylla, and western tentiform leafminer. A 21 day PHI was specified. The revised directions for use are for 8 ounces of formulated product (2 ounces ai) per acre, in one of two regimes: 1) two applications in the late winter/early spring (one at delayed dormant and one at pre-bloom), or 2) two applications in late spring/early summer (one at petal fall and one within 28 days after petal fall application). The two earlier applications are directed at pear psylla, while the later two will control late nymphs of pear psylla, codling moth and western tentiform leafminer. The maximum number of applications per site per year is two.

In residue trials conducted with a treatment consisting of two applications of 2 oz. ai/A, applied two weeks after petal fall and again approximately 28 days after the first, no residue (<0.01 ppm) was detected on any sample from this treatment. The preharvest intervals ranged from 76 to 106 days. The petitioner stated that this treatment regime represents the later application timing in this

revised EUP, and would represent a greater opportunity for residue than the earlier timing (delayed dormant and pre-bloom). Maag Agrochemicals, Inc. had originally petitioned the Agency for a temporary tolerance of 0.5 ppm. Based on the residue data provided, Ciba-Geigy is amending the petition for temporary tolerance by proposing a 0.1 ppm tolerance for residues of fenoxycarb in pears.

CBTS Comments

The residue data submitted in support of this submission was generated using the fenoxycarb formulation Tactic®. In a 2/24/93 letter from Ciba-Geigy to the PM, the petitioner stated that due to trademark issues Tactic® (formerly Insegar® by Maag Agrochemicals, Inc.) will now be known as Comply®. Comply® (EPA Experimental Use Permit No. 100-EUP-94) is a wettable powder, packaged in 8 ounce water soluble packets, containing 25% of ai and 75% of inerts.

The following directions apply for Comply®:

Pre-bloom applications

For control of pear psylla, apply Comply® at a rate of 8 ounces [1 packet = 2 ounces ai (equivalent to 56.8 g ai)] of formulated product per acre, in 50 to 400 gallons of water per acre. Complete coverage of the tree is essential to achieve control.

Applications should be made pre-bloom, at the delayed dormant (stages 1-2) and at bud burst (stages 3-4). Comply® controls pear psylla by preventing newly laid eggs from hatching. It must be applied prior to egg laying so that the eggs are laid on treated plant parts. In addition, Comply® prevents nymphs of pear psylla from becoming adults.

Late spring and summer applications

For control of codling moth, western tentiform leafminer and pear psylla in pears, apply Comply® at a rate of 8 ounces [1 packet = 2 ounces ai (equivalent to 56.8 g ai)] of formulated product per acre in 50 to 400 gallons of water per acre. Complete coverage of the fruit and the foliage in all areas of the tree is essential to achieve control.

Timing of application is extremely important because Comply® controls codling moth, western tentiform leafminer and pear psylla by preventing newly laid eggs from hatching. It must be applied prior to egg laying so that the eggs

are laid on treated plant parts. In addition, Comply® prevents late nymphs of the pear psylla leafminer from becoming tissue feeders.

First application should be made approximately 1 to 2 weeks after petal fall and is 10 to 14 days earlier than the timing used for conventional insecticides. The second application should be made about 21 to 28 days after the first.

The label specifies a maximum of two applications of Comply® may be made per year.

CBTS concludes that the proposed label is not adequate. The petitioner has not proposed a PHI and this information should be added to the proposed label. A revised Section B is needed.

Residue data originally submitted in support of this EUP appear in D. McNeilly's memo of 11/2/90. Eight residue trials were conducted in NY (2), WA (2), OR (2), CA (1), and MI (1). Four applications of fenoxycarb were made at varying rates from 60 g (2 oz.) ai/A to 800 g (28 oz.) ai/A (240 g (8.4 oz.) ai/A/year to 3200 g (112 oz.) ai/A/year) with PHI's ranging from 0 to 28 days. A temporary tolerance of 0.5 ppm for fenoxycarb was proposed based on the submitted data. This temporary tolerance proposal is currently in reject status.

Currently, residue data reflecting the new application pattern of fenoxycarb to pears appear in the following report:

> "Fenoxycarb - Magnitude of the residue in or on pears following postemergence foliar applications of fenoxycarb 25WP"; R. Speth; 12/18/92; Laboratory Project ID No. ABR-92082. Performing Laboratory was Residue Chemistry Department, Plant Protection Division, Ciba-Geigy Corporation, Greensboro, NC (MRID# 426042-03).

Eight field trials were conducted during 1990 in Oregon (3), New York (2), Washington (2), and California (1). According to Agricultural Statistics, 1988, these states accounted for at least 97% of the pear production in the U.S. Fenoxycarb was applied to pear trees in one of the following treatments: a) treatment 1: four applications of fenoxycarb 25WP, each at the rate of 2 oz. ai/A. The first application was two weeks after petal fall, and three subsequent applications were made at approximately 28 day intervals. The PHI ranged from 21 to 49 days; b) treatment 2: two applications of fenoxycarb 25WP, each at the rate of 2 oz. ai/A. The first application was two weeks after petal fall, and the second application was approximately 28 days after the first. The PHI ranged from 76 to 106 days; and c) treatment 3: two applications of

fenoxycarb 25WP, each at the rate of 3 oz. ai/A. The application timing was similar to treatment 2. The PHI ranged from 76 to 106 days. After collection, samples were frozen and shipped to Analytical Development Corporation, Colorado Springs, CO. Also, samples from each treatment group were shipped to National Food Laboratories, Dublin, CA, where they were processed into pear slices and pear puree. After processing, the samples were sent to Analytical Development Corporation for analysis.

CBTS concludes that geographic representation of residue data is adequate for the proposed use on pears.

Residues of fenoxycarb were shown to be stable when stored at ≤-20°C for up to 18 months. Samples of pears were analyzed for fenoxycarb residues up to almost 6 months after harvest. Maximum interval between extraction and analysis was 3 months.

CBTS concludes that the storage stability data of fenoxycarb on pears are adequate to support the subject tolerance petition.

The analytical method used to determine fenoxycarb residues (parent only) in pears and pear fractions is described in ADC Research Report 1204-8 "Determination of Residues of Fenoxycarb in Whole Pears and Pear Commodities of Pear Slices and Pear Puree" (MRID# 426042-03). Briefly, samples of pear and pear fractions are extracted with acetone and partitioned with sodium chloride and hexane. The organic layer is reduced in volume and cleaned-up on a silica gel column. Fenoxycarb residues are detected using HPLC with UV detection at 230 nm. The detection limit is 0.01 ppm. Although, this method is similar to the one previously submitted by the petitioner in support of this EUP, "The determination of Fenoxycarb Residues in Pears by High Performance Liquid Chromatography" (ADC Project No. 1103), the limit of detection was lowered from 0.05 ppm to 0.01 ppm and pear fractions were included in the new method.

Recovery data were obtained from untreated samples of whole pears fortified with fenoxycarb at the level of 0.01 ppm and 0.10 ppm prior to extraction. Recovery values ranged from 75% to 120% for samples fortified at the 0.01 ppm level and from 75% to 116% for samples fortified at the 0.10 ppm level. Recoveries for samples of pear slices and pear puree fortified with fenoxycarb at the level of 0.02 ppm and 0.20 ppm ranged from 101% to 109% for pear slices and from 96% to 114% for pear puree. Submitted chromatograms show well resolved peaks in support of these data.

The residue data are summarized in Table I.

Table I. Fenoxycarb Residues in Pears

Location	Treatment[1]	Application Rate (oz. ai/A)	PHI	Fenoxycarb Residues (ppm)
OR[2]				
	Control	--	--	<0.01
	T1	1 x 2.7 3 x 1.5	21	0.05
	T1	1 x 2.7 3 x 1.5	43	0.04
	T2	1 x 2.7 1 x 1.5	78	<0.01
	T3	2 x 2.25	78	<0.01
	T2	1 x 2.7 1 x 1.5	100	<0.01
	T3	2 x 2.25	100	<0.01
NY				
	control	--	--	<0.01
	T1	4 x 2.0	21	<0.01
	T2	2 x 2.0	77	<0.01
	T3	2 x 3.0	77	0.15
NY				
	control	--	--	<0.01
	T1	4 x 2.0	21	0.19
	T2	2 x 2.0	77	<0.01
	T3	2 x 3.0	77	0.04
WA				
	control	--	--	<0.01
	T1	4 x 2.0	21	0.05
	T1	4 x 2.0	36	0.02

Location	Treatment[1]	Application Rate (oz. ai/A)	PHI	Fenoxycarb Residues (ppm)
	T2	2 x 2.0	76	<0.01
	T3	2 x 3.0	76	<0.01
	T2	2 x 2.0	91	<0.01
	T3	2 x 3.0	91	<0.01
WA				
	control	--	--	<0.01
	T1	4 x 2.0	21	0.04
	T2	2 x 2.0	76	<0.01
	T3	2 x 3.0	76	<0.01
OR				
	control	--	--	<0.01
	T1	4 x 2.0	21	0.09
	T1	4 x 2.0	49	0.04
	T2	2 x 2.0	78	<0.01
	T3	2 x 3.0	78	<0.01
	T2	2 x 2.0	106	<0.01
	T3	2 x 3.0	106	<0.01
OR				
	control	--	--	<0.01
	T1	4 x 2.0	21	0.05
	T1	4 x 2.0	29	0.03
	T2	2 x 2.0	78	<0.01
	T3	2 x 3.0	78	<0.01
	T2	2 x 2.0	86	<0.01
	T3	2 x 3.0	86	<0.01

Location	Treatment[1]	Application Rate (oz. ai/A)	PHI	Fenoxycarb Residues (ppm)
CA				
	control	--	--	<0.01
	T1	4 x 2.0	21	<0.01
	T2	2 x 2.0	77	<0.01
	T3	2 x 3.0	77	0.02

1. T1 - Four applications of fenoxycarb at the rate of 2 oz. ai/A. The first application was two weeks after petal fall, and three subsequent applications were made at approximately 28 day intervals.

   T2 - Two applications of 2 oz. ai/A. The first application was two weeks after petal fall, and the second application was approximately 28 days after the first.

   T3 - Two applications of 3 oz. ai/A. The application timing is similar to T2.

2. Applications were made at erroneous rates.

As can be seen from the Table, fenoxycarb residues ranged from <0.01 ppm to 0.19 ppm for pears that received treatment T1; <0.01 ppm for pears that received treatment T2; and <0.01 ppm to 0.15 ppm for pears receiving treatment T3.

Samples of pears from each treatment group were subjected to pear processing into pear slices and pear puree. Fenoxycarb residues were detected in whole pears (0.05 ppm), unwashed ripened pears (0.03 ppm) and washed ripened pears (0.05 ppm) from treatment T1. Nondetectable (<0.01 ppm) residues were obtained in pears from treatment T2. A 0.01 ppm residue was obtained in unwashed unripe pears from treatment T3. Concentration of fenoxycarb residues in any of the processed pear commodities (slices and puree) was not observed.

CBTS will withhold its conclusions regarding the adequacy of the proposed temporary tolerance at this moment. Pending resolution of the label and analytical methodology issues, CBTS could recommend for a temporary tolerance of 0.10 ppm for fenoxycarb in or on pears for the parent compound for the purpose of this experimental use permit only.

In addition, we note in D. Mcneilly's memo of 11/2/90, that at long PHI's the parent compound is no longer the only compound present in significant amounts. Fenoxycarb metabolite 2-hydroxy-ethyl-[p-(p-hydroxyphenoxy)phenoxy) ethyl] carbamate is present as a residue to almost

the same extent as the parent compound. If this metabolite is determined to be of toxicological significance, a tolerance based on the parent compound only will not be adequate and total toxicological significant residues may exceed the proposed tolerance level. CBTS will defer a decision on the residue (s) to be regulated to the HED Metabolism Committee. Note that for a permanent tolerance, additional residue data will be required if its determined that other metabolites should be included in the tolerance expression.

Deficiency #3 is unresolved.

CBTS Deficiency #5

The analytical method (HPLC) described in PP#0G3879 appears to be adequate for the enforcement of the proposed temporary tolerance for the parent compound, fenoxycarb. However, an independent laboratory validation was not provided. Also, additional methods may be required if metabolites are included in the tolerance expression.

Petitioner's Response to Deficiency #5

The petitioner submitted an independent method validation for the determination of fenoxycarb in pears using ADC Project #1103 "The Determination of Fenoxycarb Residues in Pears by High Performance Liquid Chromatography". Also, a validation report of the analytical method for the determination of fenoxycarb in pears and the pear commodities of pear slices and pear puree was submitted.

CBTS Comments

The independent method validation for fenoxycarb appear in the following report:

> Fenoxycarb: Method Validation Ruggedness Trial for the Determination of Fenoxycarb in Pears using ADC Project #I103: "The Determination of Fenoxycarb Residues in Pears by High Performance Liquid Chromatography"; R. Wurz; 12/18/92; Laboratory Project ID ABR-92087. Performing laboratory was Residue Chemistry Department, Plant Protection Division, Ciba-Geigy Corporation, Greensboro, NC (MRID# 426042-04).

Control pear samples were fortified with fenoxycarb at the level of 0.01 ppm, 0.05 ppm and 0.10 ppm. Recovery values are presented in Table II.

Table II. Fenoxycarb Recoveries on Pears

Fortification Level (ppm)	% Recovery
0.01	82, 81
0.05	84, 95
0.10	87, 91

The validation report of the analytical method for the determination of fenoxycarb residues in pears and the pear commodities of pear slices and pear puree appear in MRID# 426042-03. Validation of whole pears consisted of the analysis of a reagent blank, duplicate controls, and duplicated control fortifications at the level of 0.01 ppm, 0.02 ppm, and 0.10 ppm. Validation of pear slices and pear puree consisted of the analysis of duplicate controls, and duplicated control fortifications at the level of 0.01 ppm, 0.05 ppm, and 0.25 ppm. Recovery values are presented in Table III.

Table III. Method Validation Recoveries in Pear and Pear Commodities

Commodity	Fortification Level (ppm)	% Recovery
Reagent Blank	0.00	--
Whole Pears		
	control	--
	0.01	83, 93
	0.02	78, 98
	0.10	91, 93
Pear Slices		
	control	--
	0.01	72, 93
	0.05	90, 95
	0.25	74, 91
Pear Puree		
	control	--

Commodity	Fortification Level (ppm)	% Recovery
	0.01	93, 100
	0.05	89, 94
	0.25	92, 99

CBTS concludes that acceptable fenoxycarb recoveries were submitted by the petitioner. The submitted data show that the limit of quantification in pears is 0.01 ppm. However, we cannot recommend an EPA Method Validation for method ADC Project #1103 at this moment. The petitioner needs to submit a final copy of the enforcement analytical method ADC Project #1103, in which the suggestions made by Ciba-Geigy Residue Chemistry Department are incorporated, prior recommendation for a temporary tolerance and initiation of the EPA Method Validation. Also, additional methods will need EPA method validation, for a permanent tolerance, if it is determined that other metabolites should appear in the tolerance expression. Note that any additional enforcement methodology must be validated by an independent laboratory prior to submitting to EPA (see PR Notice 88-5).

Deficiency #5 is unresolved.

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