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

OCT 27 1994

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

Subject: PP#9F3787. Abamectin (Avermectin B_1) for Use in/on Pears. Review of Additional Residue Data Submitted in Support of Reducing the Pending Tolerance from 0.05 to 0.02 ppm.
MRID# 430054-01 (6 volumes).
DP Barcode# D196855.
CBTS# 12836.

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Merck and Co., Inc. is requesting the establishment of a permanent tolerance for abamectin (avermectin B_1) insecticide/miticide and its delta-8,9-isomer in/on pears at 0.020 ppm based on a rate of 0.025 lbs.ai./A. and a 28 day PHI. Previously, Merck had requested a 0.035 ppm tolerance based on the same rate of 0.025 lbs.ai./A. and initially a 14 day PHI and later a 21 day PHI.

The lone remaining deficiency concerning the Section 3 registration and establishment of a permanent tolerance for avermectin on pears (PP#9F3787) concerned the proposed Section F (see memo of G.J. Herndon dated 12/16/93). Based on the residue data and proposed label that had been submitted, CBTS recommended a new Section F proposing a 0.05 ppm tolerance (see memo of J.B.

Stokes dated 11/26/92). Rather than accept CBTS's proposed 0.05 ppm tolerance, Merck has chosen to support an even lower 0.02 ppm tolerance by submitting new field trial data and a new label that specifies a maximum of 2 treatments separated by at least 21 days and a 28 day PHI.

Conclusions and Recommendations

Based on the proposed changes to the AGRI-MEK 0.015 EC label and the new residue data submitted, CBTS can recommend in favor a Section 3 registration and permanent tolerance of 0.02 ppm on pears **provided the Beltsville lab can show that Method 8000, Rev. 4 is adequate to enforce this new, lower tolerance**. The proposed enforcement method was sent to Beltsville on 10/21/94 and, once CBTS receives results of their validation, will issue a final memo recommending for the registration (or alternatively, recommending proposed changes be made to the method).

CBTS notes that the proposed label does not vary the application rate for concentrated sprays according to tree height, as CBTS has discussed with Merck with regard to the registrations of avermectin on tree nuts and citrus. Since this was not noted in previous memos concerning avermectin on pears, and Merck was previously informed that, with the exception of the proposed Section F, they had satisfied all of CBTS's concerns regarding the registration of avermectin on pears, CBTS will not require additional label changes and/or data at this time. **However, if at a later date Merck wishes to amend the registration for the application of avermectin to pears, CBTS will require that Merck either:**

1. submit a new label proposing that, for concentrated sprays, the rate of avermectin be varied according to tree height

or

2. generate new residue data using young trees just coming into bearing age.

This will also be required for any future Section 3 registrations of avermectin on other tree crops (such as apples).

Detailed Considerations

Proposed Use

Merck has made the following changes to the proposed label:

- Allow a minimum of 21 days between applications (No minimum was stated on the original proposed label dated 7/24/89).
- Allow a minimum 28 day PHI (On the original proposed label dated 7/24/89, the PHI was 14 days).

Residue Data

Magnitude of the Residue

New Data (MRID# 430054-01, vols. 1-6)

Four residue trials were conducted on Bartlett pear trees in California in 1992 to determine the residue levels in pears at 0 and 21 day PHIs. A rate of 0.024 lbs.ai./A. (1X) along with 1 gal./A. of Volck Supreme spray oil was used in the trials. Applications were made using airblast orchard sprayers. The results are shown in Table 1.

Table 1

Residues of Avermectin on Pears from 4 Trials in 1992

site	study	# applications	interval between applications (days)	spray volume (gal/A.)	rate in lbs.ai./A. (vs. proposed rate)	PHI (days)	maximum residue (ppb)*
Stanislaus Co., CA	001-92-6016R	2	14	75	0.024 (1X)	0	30.7
						21	3.9
San Benito Co., CA	001-92-6017R	2	14	75	0.024 (1X)	0	15.2
						21	5.9
Solano Co., CA	001-92-6018R	2	14	75	0.024 (1X)	1	33.3
						21	8.9
Yolo Co., CA	001-92-6019R	2	14	75	0.024 (1X)	0	23.3
						21	10.6

* - uncorrected for method recoveries

Comments (1992 trials)

None of the samples were harvested at the proposed 28 day PHI, but even at a 21 day PHI, all the residue values were below the proposed 0.020 ppm tolerance. The maximum residue measured from the 4 studies from two applications of avermectin 14 days apart (the proposed label states a minimum of 21 days) at the 1X rate and a 21 day PHI was only 0.011 ppm. The method recoveries performed in conjunction with these field trials were acceptable; at fortifications ranging from 0.002 to 0.050 ppm, recoveries varied from 79 to 105%, with an average of 93%.

Unfortunately, not enough field trials or geographic diversity were presented from the 1992 trials to support a Section 3 registration and permanent tolerance for the use of avermectin on pears. Therefore, data from field trials performed in 1987 and 1988 will need to be reexamined.

Old Data

1987

Residue trials were conducted on pear trees at 9 sites in 1987. Four applications at approximately 30 day intervals at rates of 0.025 (1X) and 0.05 lbs.ai./A. (2X). Samples were harvested at various PHIs ranging from 0 to 14 days. Various spray rates (both concentrated and dilute) were applied per acre but in all cases paraffinic oil was tank mixed at the rate of 1 gallon per acre. Applications were made using either high pressure hydraulic handguns or airblast orchard sprayers. The results are shown in Table 2.

Table 2

Residues of Avermectin on Pears from Trials Conducted in 1987

site	study	variety	# applications	interval between applications (days)	spray volume (gal/A.)	rate in lbs.ai./A. (vs. proposed rate)	PHI (days)	residue (ppb) average	residue (ppb) maximum
Placerville, CA	001-87-5007R	Bartlett	4	30 days for all	300-400	0.025 (1X)	0	13.1	22.5
							1	12.6	14.5
							3	8.4	13.9
							7	6.2	8.3
							14	6.7	9.2
						0.05 (2X)	0	41.0	76.8
							1	32.6	49.7
							3	30.6	66.1
							7	14.6	26.4
							14	11.9	19.0
Hood River, OR	001-87-5008R	de Anjou	4	25/32/30 days	400	0.025 (1X)	1	14.9	19.6
							3	7.1	10.3
							14	7.2	9.5
						0.05 (2X)	0	36.1	50.3
							1	33.2	50.1
							3	20.2	31.1
							7	28.7	37.4
							14	16.5	19.5
Delta Co., CO	001-87-5009R	Bartlett	4	32/30/29	300	0.025 (1X)	0	16.2	21.6
							1	8.4	11.8
							3	8.9	10.6
							7	6.2	10.0
							14	4.0	5.8
						0.05 (2X)	0	29.6	35.2
							1	16.0	18.9
							3	14.1	16.8
							7	16.5	20.8
							14	11.5	13.3

site	study	variety	# applications	interval between applications (days)	spray volume (gal/A.)	rate in lbs.ai./A. (vs. proposed rate)	PHI (days)	residue (ppb) average	residue (ppb) maximum
Orefield, PA	001-87-5010R	Bartlett	4	27/33/30	300	0.025 (1X)	0	24.4	30.6
							1	15.3	17.7
							3	9.8	10.1
							7	11.2	13.1
							14	8.2	10.4
						0.05 (2X)	0	48.0	59.4
							1	37.1	45.8
							3	22.9	27.7
							7	17.0	19.2
							14	14.8	22.2
Medford, OR	001-87-5011R	Bosc	4	30 for all	360	0.025 (1X)	0	11.6	15.4
							7	2.5	5
Yakima, WA	001-87-5012R	Bosc	4	30 for all	400	0.025 (1X)	0	17.2	19.3
							7	3.8	5
				29/34/28	40	0.025 (1X)	0	13.5	18.6
							7	3.8	5
Alton, NY	001-87-5013R	Bartlett	4	35/25/28	400	0.025 (1X)	0	40.8	44.0
							1	20.9	24.9
							3	8.6	9.1
							7	5.4	5.6
							14	5	5
						0.05 (2X)	0	51.8	64.9
							1	33.1	37.6
							3	15.0	24.2
							7	8.3	9.7
							14	5.8	8.1
					40	0.025 (1X)	0	40.6	53.0
							1	37.7	44.2
							3	31.1	39.4
							7	25.5	28.6
							14	15.4	18.9
						0.05 (2X)	0	73.4	88.4
							1	55.7	73.6
							3	45.4	51.3
							7	34.4	39.2
							14	22.5	30.8

site	study	variety	# applications	interval between applications (days)	spray volume (gal/A.)	rate in lbs.ai./A. (vs. proposed rate)	PHI (days)	residue (ppb) average	residue (ppb) maximum
Fennville, MI	001-87-5014R	Bartlett	4	34/30/32	250	0.025 (1X)	0	20.7	27.0
							1	6.5	7.5
							3	5.8	7.2
							7	5	5
							14	5.0	5.2
						0.05 (2X)	0	37.2	42.6
							1	13.6	17.3
							3	8.4	10.8
							7	8.4	11.7
							14	6.4	7.3
				30/30/32	40	0.025 (1X)	0	27.6	46.9
							1	9.6	13.8
							3	9.7	12.99
							7	8.4	10.8
							14	6.0	7.8
						0.05 (2X)	0	46.5	56.6
							1	15.3	27.2
							3	16.8	20.4
							7	11.9	15.1
							14	15.2	29.3
Yuba City, CA	001-87-5015R	Bartlett	4	30/30/32	400	0.025 (1X)	0	14.6	22.9
							1	6.0	8.0
							3	5.8	8.3
							7	6.2	9.2
							14	4.1	6.5
						0.05 (2X)	0	37.6	45.5
							1	17.3	23.8
							3	18.2	24.3
							7	7.2	11.4
							14	19.5	33.9
					40	0.025 (1X)	0	33.2	37.2
							1	14.9	18.4
							3	12.0	14.5
							7	12.5	14.8
							14	10.7	13.6
						0.05 (2X)	0	48.4	69.4
							1	28.4	43.4
							3	33.3	32.4
							7	32.0	60.4
							14	38.9	41.4

Comments (1987 trials)

None of the samples were harvested at the proposed 28 day PHI. The maximum residue measured from the 1987 studies from 4 applications of avermectin about 30 days apart (the proposed label states a maximum of 2 applications and a minimum interval between sprayings of 21 days) at the 1X rate and a 14 day PHI was 0.019 ppm (0.041 ppm for the 2X rate). Taking the residue values from the trial that exhibited the 0.019 ppm residue value at a 14 day PHI (trial 001-87-5013R, 40 gal./A.), and plugging 5 data points into a linear regression curve, a theoretical value of 0.007 ppm is calculated for an extrapolated 28 day PHI.

1988

Residue trials were conducted on pear trees at 5 sites in 1988. Three applications at approximately 21 day intervals at rates of 0.025 (1X) and 0.05 lbs.ai./A. (2X). Samples were harvested at 0 and 7 day PHIs. Various spray rates (both concentrated and dilute) were applied per acre but in all cases paraffinic oil was tank mixed at the rate of 1 gallon per acre. Applications were made using either high pressure hydraulic handguns or airblast orchard sprayers. The results are shown in Table 3.

Table 3

Residues of Avermectin on Pears from Trials Conducted in 1988

site	study	variety	# applications	interval between applications (days)	spray volume (gal/A.)	rate in lbs.ai./A. (vs. proposed rate)	PHI (days)	residue (ppb) average	residue (ppb) maximum
Hood River, OR	001-88-1009	Bartlett	3	21 / 21	40	0.025 (1X)	0	N/A	49.1
							7	28.3	30.5
Hood River, OR	001-88-1010R	Bartlett	3	21 / 21	400	0.025 (1X)	0	N/A	37.2
							7	22.8	25.5
Yakima, WA	001-88-1018R	Bartlett	3	21 / 21	400	0.025 (1X)	0	N/A	31.6
							7	15.1	15.2
Yakima, WA	001-88-1024R	Bartlett	3	22 / 20	37.5	0.025 (1X)	0	N/A	21.6
							7	14.4	15.3
Rochester, NY	001-88-3019R	Bartlett	3	21 / 21	400	0.025 (1X)	0	N/A	23.9
							7	12.6	16.2
Upper Black Eddy, PA	001-88-3020R	Bartlett	3	21 / 21	300	0.025 (1X)	0	N/A	36.9
							7	7.0	7.6
Fairfield, CA	001-88-6047R	Bartlett	3	21 / 21	250	0.025 (1X)	0	N/A	5.0
							7	< 2.0	< 2.0

Comments (1988 trials)

The field trial residue data from 1988 is of minimal value due to the 7 day PHI of the harvested samples. The maximum residue value from a 1X rate was 0.031 ppm.

Overall Magnitude of the Residue Comments

The existing and newly submitted residue data indicate that, when applied at a maximum label rate of 0.023 lb.ai./A./application, with a maximum of 2 applications at least 21 days apart, residues of avermectin are not likely to exceed 0.02 ppm at a 28 day PHI.

Method 8000, Rev. 4 was sent to the EPA Beltsville lab on 10/21/94 to be validated at the newly proposed, lower 0.020 ppm tolerance. Provided that Beltsville can show that the method is adequate to enforce the 0.02 ppm tolerance, CBTS can recommend that RD issue a Section 3 registration and permanent tolerance. Once CBTS receives results of their validation, a final memo will be issued recommending for the registration (or alternatively, recommending proposed changes be made to the method).

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