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

OCT 25 1995

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: ID# 081601. **Folpet-** Field Residue Data for Grapes, Apples, Strawberries, Cucumbers and Melons. Barcodes D219204 & D219367. CBTS#s 16207 & 16256. MRID#s 437745-01 thru -07, 437870-01 and 437755-01.

FROM: G.F. Kramer, Ph.D., Chemist
Tolerance Petition Section I
Chemistry Branch I, Tolerance Support
Health Effects Division (7509C)

THRU: F.B. Suhre, Acting Section Head
Chemistry Branch I, Tolerance Support
Health Effects Division (7509C)

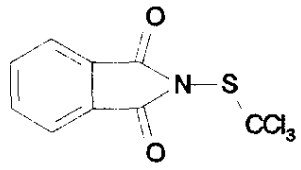
TO: Jack Housenger, Branch Chief
Special Review Branch
Special Review and Reregistration Division (7508W)

Makhteshim-Agan is in the process of developing the data required for establishing tolerances for folpet on imported commodities. CBTS and the registrant have agreed upon the number and location of the residue trials required to set tolerances on imported apples, cucumbers, lettuce, melons, strawberries, tomatoes, onions, cranberries and grapes (Memo, G. Kramer 7/26/95). This program includes eight apple trials to be conducted in Argentina, Canada and Chile; six melon trials to be conducted in Mexico, Honduras and Guatemala; eight grape trials to be conducted in Argentina, Italy, France, Argentina and Chile; and three strawberry trials to be conducted in Mexico.

The present submission consists of apple residue trials conducted in Israel, Chile and Argentina; strawberry residue trials conducted in Brazil and Uruguay; grape residue trials conducted in Spain, Chile and Argentina; a melon residue trial conducted in Spain; and a cucumber residue trial conducted in Turkey. As confirmatory data are not needed to set the import tolerance for strawberries and

apples, the studies related to these crops will not be reviewed at this time. Should these data become relevant in the future, a full review will be conducted at such time.

The structure of folpet is shown below:



Folpet

CONCLUSIONS

1a. A single cucumber residue trial was conducted in Turkey. The application rate was 2.5 kg ai/ha and a total of five applications were performed. Samples were harvested 0, 3 and 7 days after the final application. This information was included in a field trial protocol and an actual field trial report was not included. Sample analysis for folpet and phthalimide was performed using Method FP/15/91 which, based on the narrative description, appears to be identical to Method FP/15/93 (for a review of this method, see Memo, G. Kramer 8/16/95). The maximum folpet residue was 0.28 ppm (0-day PHI).

1b. The following information must be submitted before the acceptability of this cucumber residue trial can be assessed:

i) The Folpan label for Turkey was not provided. The registrant must submit a copy of this label (and an English translation) so that we can determine whether the use patterns in this trial correspond to the maximum use rate, minimum spray volume and minimum PHI.

ii) The registrant must provide a field trial report for this trial. This report should include all data as specified in *Subdivision O Addendum on Data Reporting #2, Magnitude of the Residue: Crop Field Trials*.

iii) The registrant should provide the shipping dates from the field sites to Makhteshim-Agan, the arrival dates at Makhteshim-Agan, the shipping dates to the analytical lab and details of the storage conditions at Makhteshim-Agan.

iv) The registrant should provide a protocol of Method FP/15/91 so that we can assess the adequacy of this method for data gathering purposes.

v) Representative chromatograms of control and treated samples should be submitted for each time point.

2a. A single melon residue trial was conducted in Spain. The application rate and number were not specified. Samples were harvested from each treated plot 0, 7 and 13 days after the final application. Sample analysis for folpet was performed using the method of Anderson (1986). Validation data were not provided. The residues of folpet were nondetectable at all time points.

2b. The following information must be submitted before the acceptability of this melon residue trial can be assessed:

i) The Folpan label for Spain was not provided. The registrant must submit a copy of this label (and an English translation) so that we can determine whether the use patterns in this trial correspond to the maximum use rate, minimum spray volume and minimum PHI.

ii) The registrant must provide complete details of the application procedures including the use rate, number of applications, the between application intervals, the spray volume and the identity of any adjuvants employed.

iii) The registrant should provide the arrival dates at the analytical lab, details of the storage conditions and the dates of analysis. If the samples were stored for longer than one month prior to analysis, then evidence of storage stability must be provided.

iv) The registrant should provide a protocol and validation data for the method of Anderson (1986) so that we can assess the adequacy of this procedure for data gathering purposes.

v) Representative chromatograms of treated and control samples should be submitted for each time point.

3a. A single grape residue trial was conducted in Spain. The application rate was 0.4 kg ai/ha and a total of three applications were performed. Samples were harvested 0, 10 and 20 days after the final application. The analytical report consisted of a series of "Analysis Bulletins," of which only one was in English.

3b. The following information must be submitted before the acceptability of this grape residue trial can be assessed:

i) The Folpan label for Spain was not provided. The registrant must submit a copy of this label (and an English translation) so that we can determine whether the use patterns in this trial correspond to the maximum use rate, minimum spray volume and minimum PHI.

ii) The registrant must provide a analytical report for the trial which includes the protocol, validation data and representative chromatograms of treated and control samples

for each time point.

iii) The registrant should provide the arrival dates at the analytical lab, details of the storage conditions and the dates of analysis. If the samples were stored for longer than one month prior to analysis, then evidence of storage stability must be provided.

4a. Two grape residue trials were conducted in Argentina. In the first trial (wine grapes), the application rate was 1.28 kg ai/ha and a total of three applications were performed. Samples were harvested 20 days after the final application. In the second trial (table grapes), the application rate was 1.66 kg ai/ha and a total of five applications were performed. Samples were harvested 7 days after the final application. Sample analysis for folpet was performed using a method which, based on the protocol submitted, is similar in principle to Method FP/15/93. The maximum folpet residue was 0.06 ppm in wine grapes and 0.57 ppm in table grapes.

4b. The following information must be submitted before the acceptability of these grape residue trials can be assessed:

i) The Folpan label for Argentina was not provided. The registrant must submit a copy of this label (and an English translation) so that we can determine whether the use patterns in these trials correspond to the maximum use rate, minimum spray volume and minimum PHI.

ii) The registrant should provide further details of the analytical method validation; i.e. were fortified controls employed and what were the values in ppm.

5a. A single grape residue trial was conducted in Chile. The application rate was 2.88-3.6 kg ai/ha and a total of three applications were performed with a between application interval of 3 weeks. Samples were harvested 15 days after the final application. Sample analysis for folpet was performed using Method CAC/PR-7-1984. The maximum folpet residue was 25.2 ppm.

5b. The following information must be submitted before the acceptability of this grape residue trial can be assessed:

i) The Folpan label for Chile was not provided. The registrant must submit a copy of this label (and an English translation) so that we can determine whether the use patterns in this trial correspond to the maximum use rate, minimum spray volume and minimum PHI.

ii) The registrant must provide further details of the field portion of the study, including the spray volume and the identity of any adjuvants employed for each application, weather data, and the conditions of sample storage between

harvest (3/24) and the arrival at the analytical lab (4/8).

iii) As the samples were stored for longer than one month prior to analysis, evidence of storage stability must be provided.

iv) The registrant should provide a protocol and validation data for Method CAC/PR-7-1984 so that we can assess the adequacy of this procedure for data gathering purposes.

v) Chromatograms (with English labels) of each treated and control sample should be submitted.

Recommendations

Further data must be submitted before the adequacy of the cucumber, melon and grape residue data can be assessed (Conclusions 1b, 2b, 3b, 4b and 5b).

Detailed Considerations

Magnitude of Residue- Cucumbers and Melons

CBTS has agreed to consider these residue trials in regards to establishing a tolerance on imported cucumbers and melons (Memo, G. Kramer 6/13/95). The registrant has committed to performing the additional trials required.

Cucumbers:

Submitted with this petition:

> Determination of Folpan and Phthalimide Residues in Cucumbers (Turkey). MRID# 437745-03. Performing Laboratory: Analyst, Ltd.

A single field residue trial was conducted in 1993 in Turkey using Folpan 50WP. The application rate was 2.5 kg ai/ha and a total of five applications were performed with a between application interval of 7 days. The spray volume was 3000 l/ha. Four replicate samples were harvested from each treated plot 0, 3 and 7 days after the final application. This information was included in a field trial protocol and an actual field trial report was not included. The samples were analyzed within one month of harvest.

Sample analysis for folpet and phthalimide was performed using Method FP/15/91 which, based on the narrative description, appears to be identical to Method FP/15/93 (for a review of this method, see Memo, G. Kramer 8/16/95). The method was validated over a range of 0.05-0.5 ppm. The average recovery was 102 ± 4.1%. Analysis of the treated samples (Table 1) showed that the maximum folpet residue was 0.28 ppm (0-day PHI).

Conclusions: The following information must be submitted before the acceptability of the cucumber residue trial can be assessed:

1) The Folpan label for Turkey was not provided. The registrant must submit a copy of this label (and an English translation) so that we can determine whether the use patterns in this trial correspond to the maximum use rate, minimum spray volume and minimum PHI.

2) The registrant must provide a field trial report for this trial. This report should include all data as specified in *Subdivision O Addendum on Data Reporting #2, Magnitude of the Residue: Crop Field Trials*.

3) The registrant should provide the shipping dates from the field sites to Makhteshim-Agan, the arrival dates at Makhteshim-Agan, the shipping dates to the analytical lab and details of the storage conditions at Makhteshim-Agan.

4) The registrant should provide a protocol of Method FP/15/91 so that we can assess the adequacy of this method for data gathering purposes.

5) Representative chromatograms of control and treated samples should be submitted for each time point.

Melons:

Submitted with this petition:

> Determination of Folpet and Captan Residues in Melon (Spain). MRID# 437745-01. Performing Laboratory: Territorial Directorate of the Ministry of Agriculture, Spain

A single field residue trial was conducted in 1991 in Turkey. The application rate and number were not specified. Four replicate samples were harvested from each treated plot 0, 7 and 13 days after the final application. Sample analysis for folpet was performed using the method of Anderson (1986). Validation data were not provided. Analysis of the treated samples (Table 1) showed that the residues of folpet were nondetectable at all time points.

Conclusions: The following information must be submitted before the acceptability of the melon residue trial can be assessed:

1) The Folpan label for Spain was not provided. The registrant must submit a copy of this label (and an English translation) so that we can determine whether the use patterns in this trial correspond to the maximum use rate, minimum spray volume and minimum PHI.

2) The registrant must provide complete details of the application procedures including the use rate, number of applications, the between application intervals, the spray volume and the identity of any adjuvants employed.

3) The registrant should provide the arrival dates at the analytical lab, details of the storage conditions and the dates of analysis. If the samples were stored for longer than one month prior to analysis, then evidence of storage stability must be provided.

4) The registrant should provide a protocol and validation data for the method of Anderson (1986) so that we can assess the adequacy of this procedure for data gathering purposes.

5) Representative chromatograms of treated and control samples should be submitted for each time point.

Magnitude of Residue- Grapes

CBTS has agreed to consider these residue data as supplementary in regards to establishing a tolerance on imported grapes (Memo, G. Kramer 6/13/95). The registrant has committed to performing the total number of residue trials required for establishing this tolerance.

Grapes (Spain):

Submitted with this petition:

> Residue Trial Report (Spain). MRID# 437745-07. Performing Laboratory: Territorial Directorate of the Ministry of Agriculture, Spain

A single field residue trial was conducted in 1991 in Spain using Folpan 50WP. The application rate was 0.4 kg ai/ha and a total of three applications were performed with a between application interval of 12 days. The spray volume was 360-400 l/ha. Four replicate samples were harvested from each treated plot 0, 10 and

20 days after the final application. The analytical report consisted of a series of "Analysis Bulletins," of which only one was in English.

Conclusions: The following information must be submitted before the acceptability of this grape residue trial can be assessed:

1) The Folpan label for Spain was not provided. The registrant must submit a copy of this label (and an English translation) so that we can determine whether the use patterns in this trial correspond to the maximum use rate, minimum spray volume and minimum PHI.

2) The registrant must provide a analytical report for the trial which includes the protocol, validation data and representative chromatograms of treated and control samples for each time point.

3) The registrant should provide the arrival dates at the analytical lab, details of the storage conditions and the dates of analysis. If the samples were stored for longer than one month prior to analysis, then evidence of storage stability must be provided.

Grapes (Chile):

Submitted with this petition:

> Determination of Folpet and Captan in Red King Oregon Apples and Thompson Seedless Grapes (Chile). MRID# 437870-01. Performing Laboratory: Analab Inc., Chile

A single field residue trial was conducted in 1992 in Chile using Folpan 80 WP. The application rate was 2.88-3.6 kg ai/ha and a total of three applications were performed with a between application interval of 3 weeks. The spray volume was 1200-1500 l/ha. Samples were harvested 15 days after the final application. The samples were stored as homogenates for 4 months prior to analysis. Sample analysis for folpet and phthalimide was performed using Method CAC/PR-7-1984. The method was validated at 0.81 ppm. The recovery was 93.8%. Analysis of the treated samples (Table 1) showed that the maximum folpet residue was 25.2 ppm.

Conclusions: The following information must be submitted before the acceptability of this grape residue trial can be assessed:

1) The Folpan label for Chile was not provided. The registrant must submit a copy of this label (and an English translation) so that we can determine whether the use patterns in this trial correspond to the maximum use rate, minimum spray volume and minimum PHI.

2) The registrant must provide a further details of the field portion of the study, including the spray volume and the identity of any adjuvants employed for each application, weather data, and the conditions of sample storage between harvest (3/24) and the arrival at the analytical lab (4/8).

3) As the samples were stored for longer than one month prior to analysis, evidence of storage stability must be provided.

4) The registrant should provide a protocol and validation data for Method CAC/PR-7-1984 so that we can assess the adequacy of this procedure for data gathering purposes.

5) Chromatograms (with English labels) of each treated and control sample should be submitted.

Grapes (Argentina):

Submitted with this petition:

> Determination of Captan, Folpet and Metabolite Residues in Grape Samples (Argentina). MRID# 437755-01. Performing Laboratory: Sistemas Analiticos Labs., Argentina

Two field residue trials were conducted in 1991/92 in Argentina using Super Folpan WP. In the first trial (wine grapes), the application rate was 1.28 kg ai/ha and a total of three applications were performed with a between application interval of 4-5 weeks. The spray volume was 1050 l/ha. Samples were harvested 20 days after the final application. In the second trial (table grapes), the application rate was 1.66 kg ai/ha and a total of five applications were performed with a between application interval of 3-4 weeks. The spray volume was 1330 l/ha. Samples were harvested 7 days after the final application. The samples were analyzed within one month of harvest. Sample analysis for folpet and phthalimide was performed using a method which, based on the protocol submitted, is similar in principle to Method FP/15/93 (for a review of this method, see Memo, G. Kramer 8/16/95). The method was validated over a range of 0.77-7.70 mg. The average recovery was 86.5 ± 3.1%. Analysis of the treated samples (Table 1) showed that the maximum folpet residue was 0.06 ppm in wine grapes and 0.57 ppm in table grapes.

Conclusions: The following information must be submitted before the acceptability of the grape residue trial can be assessed:

1) The Folpan label for Argentina was not provided. The registrant must submit a copy of this label (and an English translation) so that we can determine whether the use patterns in these trials correspond to the maximum use rate, minimum spray volume and minimum PHI.

2) The registrant should provide further details of the analytical method validation; i.e. were fortified controls employed and what were the values in ppm.

Table 1- Folpet residue data.

Crop (Location)	Application Rate (kg. ai/ha)	# Applications	Between Application Interval (Weeks)	Spray Volume (l/ha)	PHI (Days)	Maximum Residue (ppm)	
						Folpet	Phthalimide
Cucumbers (Turkey)	2.5	5?	1?	3000	0	0.28	<0.1
					3	0.19	<0.1
					7	0.14	<0.1
Melons (Spain)	?	?	?	?	0	N.D.	-
					7	N.D.	-
					13	N.D.	-
Grapes (Chile)	2.88-3.6	3	3	1200-1500	15	25.23	1.91
Wine Grapes (Argentina)	1.28	3	4-5	1050	20	0.063	0.133
ble Grapes (Argentina)	1.66	5	3-4	1330	7	0.566	ND

N.D. = Not Detected
- = Not determined

cc: Folpet Reg. Std. File, Kramer, R.F., Circ.
RDI: F.B. Suhre (10/19/95), R.A. Loranger (10/20/95), M.S. Metzger (10/25/95)
G.F. Kramer:804T:CM#2:(703)305-5079:7509C:CBTS

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