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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

May 4, 1999

Memorandum

SUBJECT: HED's Review of the Folpet Avocado Postapplication Exposure Studies (DFR and Worker); MRIDs 421220-19 and 20. PC Code 081601. DP Barcode D172924.

FROM: Tim Leighton, Environmental Health Scientist Susan Hummel for
Reregistration Branch 4
Health Effects Division (7509C)

THRU: Susan Hummel, Branch Senior Scientist Susan Hummel
Reregistration Branch 4
Health Effects Division (7509C)

TO: David Hrdy, Chemist
Reregistration Branch 4
Health Effects Division (7509C)

Attached is a review of the occupational reentry (avocado harvesting) exposure and DFR data submitted by the registrant (MRID Nos. 421220-19 and 20.). This review was completed by Paladin Associates, Inc. on October 26, 1992, under supervision of HED. It has undergone secondary review in the branch and has been revised to reflect Agency policies.

Executive Summary

The study did not meet all of the Subdivision K requirements. Noted deficiencies included one application was used, yet the label allows for seven applications per season, spread 14 days apart; the submission did not indicate how soon after application the day zero sample was collected; the sample shipping procedure was not described; the quantification limit was not provided or described; the study did not indicate the number of field fortifications per monitoring period; and workers wore an *optional* outer garment over the t-shirt dosimeter, while HED requires that specific clothing attire and material type be provided. Nonetheless, the data are of sufficient scientific quality to be used to determine reentry intervals (REI).

Summary

As required, dislodgeable foliar residue (DFR) studies and concurrent worker exposure monitoring (inhalation and dermal exposure) were conducted for folpet use in avocado orchards. The DFR study was entitled *Folpet Dislodgeable Foliar Residue Study in Avocados* (MRID 421220-19), and the worker exposure study was entitled Folpet: Field Worker Exposure Study in Avocado Harvesting Operations (MRID 421220-20).

For both the DFR study and the worker exposure study, approximately 3.0 lbs ai/acre of Folpet 50WP (e.g., 47.6% active ingredient by weight), formulated as a wettable powder in 200 gallons of spray solution per acre was applied to avocado trees once using an airblast spray system. Four different sprayers placed on trailers were each hitched to 4 different tractors in order to spray 47.5 acres of avocado trees (i.e., the total acres for the three different sites) located at Goulds, Florida. Applications were made on November 4, 1989. Rainfall was measured as a "trace" amount on November 6, 0.24 inches on November 8, and intermittently throughout the study (trace to 0.44 inches per event).

MRID 421220-19: Folpet Dislodgeable Foliar Residue Study in Avocados

For the DFR study, six avocado leaf samples (e.g., each sample consisting of 50 leaf discs measuring 10 cm^2) were taken at each sampling interval from each site. Three of the samples were used for measuring folpet dislodgeable foliar residues, and three samples were used for measuring total residues. The leaf disc samples were collected from the trees at the height of approximately six feet. The folpet residues were dislodged using a detergent solution (an aqueous dilution of Aerosol OT-75). Foliage samples were collected at 0, 1, 3, 7, 9, 13, 21, 28, and 35 days after treatment (DAT).

Quality control samples were generated and treated identically to the foliage samples. Duplicate blank samples were collected for both the leaf punch and the wash solution before initiating the study to serve as negative controls. In addition, duplicates of the leaf punch and wash solutions were fortified in the field with 10, 100, and 1000 micrograms (μg) of folpet to serve as positive controls. The mean laboratory recovery for the fortified samples was 91.4 percent and the mean field recovery was 63.5 percent. The mean storage stability is 53.3 percent after being stored 114 days. Three aliquots from the tank load were also taken as a control sample.

The study did not meet all of the Subdivision K requirements. Noted deficiencies included one application was used, yet the label allows for seven applications per season, spread 14 days apart; the submission did not indicate how soon after application the day zero sample was collected; and the sample shipping procedure was not described.

MRID 421220-20: Folpet: Field Worker Exposure Study in Avocado Harvesting Operations.

For the worker exposure study, thirty workers were monitored while harvesting avocados from trees that had been treated once with folpet. Ten volunteers worked in each grove. Thus, the study contained a total of 10 replicate measurements for calculating folpet inhalation and dermal

exposure at three sampling intervals. The sampling interval was different at each site. The sampling was performed on 6 days after treatment (DAT) at site one, 9 DAT at site two, and 13 DAT at site three.

Two harvesting techniques were monitored in this study. Using the first technique, workers used a machine similar to a "cherry picker". In this type of harvesting, a worker stands on a platform which is raised and lowered by the "cherry picker" as the worker picks avocados by hand so that he/she can pick avocados at different heights of the tree. The platform contains a bucket where the avocados are stored. When the bucket becomes full, the "cherry picker" lowers the platform so that the worker can empty the bucket of avocados into a set of wooden crates placed in a tractor-drawn trailer. In the second harvesting technique, workers pick avocados from the ground or pick up avocados dropped on the ground by workers using the picker machine (the first harvesting technique), collecting the avocados into crates and driving the trucks containing the crates of avocados to a storage facility.

Each test subject wore whole-body dosimeters (i.e., ankle length tights and a long sleeved t-shirt), a personal air sampling pump fitted with a foam filter (run at a "breathing rate" of 2 L/min.), and two head patches attached to a hat. The whole-body dosimeters were reportedly worn underneath "freshly laundered long pants" and underneath "freshly laundered outer garment or as the upper body garment". A soap solution hand wash was performed on each hand of each test subject after the work period. The work period was approximately 4 hours for each test subject. The dermal dosimeters (i.e., ankle length tights, long-sleeved t-shirt, and head patches) were stored in separate heat sealable bags. Hand wash and filter samples were double-bagged for added integrity during shipment and storage.

Duplicate blanks of each matrix were exposed to the environment at each site, although the duration of exposure was not specified. Field recovery samples were prepared by spiking samples of each matrix with 10, 100, or 1000 μg of folpet. Fortified samples were then placed in heat-sealable bags, placed in ice, and taken to the laboratory. Field recoveries for the polyurethane foam, head patch, cotton t-shirt, and cotton tights ranged from 77.6 to 94.8 percent. Laboratory recoveries were determined for each set of samples analyzed. Control samples were fortified at the method limits and at levels above those measured on field samples. Laboratory recoveries for the polyurethane foam, head patch, cotton t-shirt, and cotton tights ranged from 88.2 to 112.4 percent. A storage stability test was conducted by spiking the matrix at the same fortification levels as the field recovery samples. Storage stability recoveries for all matrixes ranged from 73.5 to 103 percent.

Like the DFR study, the exposure monitoring study did not meet all of Subdivision K requirements. Noted deficiencies include: only one application was used, yet the label allows 7 applications per season, spread 14 days apart; the quantification limit was not provided or described; the study did not indicate the number of field fortifications per monitoring period; and workers wore an *optional* outer garment over the t-shirt dosimeter, while HED requires that specific clothing attire and material type be provided.

Dissipation was calculated using measured dislodgeable foliar residue (DFR) data from sites 1 through 3, correcting the data for a field recovery of 63.5 percent, and averaging the results of the three sites together. The average transfer coefficient is based on the average exposure of cherry harvesters at three different sites. The results of the individual site data are as follows:

- DAT 6: dermal exposure = 16,050 μg/hr; Tc = 42,237 cm^2/hr,
- DAT 9: dermal exposure = 5,210 μg/hr; Tc = 13,359 cm^2/hr, and
- DAT 13: dermal exposure = 17,225 μg/hr; Tc = 34,450 cm^2/hr.

Attachment

Attachment 1

Paladin Associates Review Memo dated October 26, 1992

coefficient of variation for the stability data can not be presented since the entire data set was not presented in the submission.

M. Formulation analysis: Lot No. 772218-298 was used for this study. It was analyzed and found to contain 47.6% by weight active ingredient.

N. Recent history of pesticide use at the site: No information was provided in the submission.

O. Summary of results: The first samples were taken at an unspecified time on day 0 post-application. For the three sites, the initial results are as follows.

Site	FDR ($\mu g/cm^2$)
1	0.77
2	1.10
3	0.98

These results are based on two-sided leaves and have not been corrected for recovery values. Table 1 of this chapter contains the mean foliar dislodgeable residue dissipation data from the three sites.

II. Summary of Standard Evaluation Procedure

A. Summary of review procedure used

1. Review of protocol relative to Subdivision K Reentry Guidelines: The report was examined to determine the extent to which it met the requirements of Subdivision K. The required elements include the following.

a. A typical end use product must be used.

This criterion was met by the use of Folpet 50WP, which is a commercial formulation used on avocados.

b. The site at which the study was conducted must possess a climate similar to those in which the product is likely to be used.

Since the study was conducted in Florida, a state in which avocados are grown, this criterion was met.

c. The test substance must be applied in a manner consistent with the approved application methods specified for the end-use product and at the least dilution and highest permissible rate.

The label does not provide sufficient information to determine a maximum use rate or frequency and least dilution. Thus, it could not be determined whether this criterion was met. The label should be amended to correct this deficiency.

d. The test period must coincide with the time of year or season during which the product will likely be used to satisfactorily control the pest.

The study took place in the fall, which is a normal time of the year to harvest avocados. Thus, this criterion appears to have been met.

e. The study must include meteorological data obtained at or near the location of the test site.

Insufficient meteorological data were presented. There are no relative humidity or wind speed data. This criterion was not met.

f. Duplicate foliage/soil samples must be collected periodically during the study.

This criterion was met.

g. The first round of samples must be taken as soon as feasible following the final application (i.e., when the dust has settled or when the spray has dried).

Insufficient information was presented to determine whether this criterion was met. All that was stated was that samples were taken on day 0 post-application.

h. Sampling intervals must be short at first and may subsequently increase.

This criterion was met.

i. Soil samples must be taken whenever there is the potential for worker exposure to the product by virtue of its presence in the soil.

This criterion is not relevant to this study of avocado foliage.

j. Storage of samples must take place only when necessary, and must be performed in such a way as to minimize residue dissipation.

This criterion was met.

k. Foliage residue data must be reported in units of $\mu g/cm^2$ of leaf surface, and soil residue data in units of ppm.

This criterion was met.

l. Soil samples must be taken from the upper 1 cm of soil.

This criterion is not relevant to this study of avocado foliage.

Data gaps are listed in Section III.G.

2. Review of Quality Assurance/Quality Control Procedures: These procedures were reviewed to ensure that the data were collected in accordance with GLPs and requirements outlined in Subdivision K of the Pesticide Assessment Guidelines. Among these elements are: proper blanks and recovery spike samples, appropriate replicate samples, maintenance of sample identity and integrity, proper chain of custody and documentation procedures, and a description of the quality assurance unit of the investigating organization and analytical laboratory.
3. Verification of calculations: Calculations explicitly presented or implicit in the presentation of data such as means, standard deviations, and correlation coefficients were checked. When available, chromatograms were spot checked (approximately 10% of chromatograms) to determine if the indicated concentrations agreed with any raw data that were presented. When raw data were included in the report, the extent of their agreement with the finished, tabulated data was determined.

III. Study Evaluation Summary

A. Nature/purpose of study: This study was conducted by Agrisearch, Inc., to generate avocado foliar dislodgeable residue dissipation and worker re-entry exposure data, and to meet the requirements of the EPA Pesticide Assessment Guidelines Subdivision K, 132-1 Exposure: Reentry Protection.

B. Verification of calculations: Chromatograms and raw data for selected samples were presented. The raw data results for these samples correspond to the compiled data in the tables in the text of the submission and with the associated chromatograms. Dissipation half-lives for the data

from all three sites were calculated by this reviewer and are presented in Section IV.

C. Adequacy of study protocol: The protocol and submission were reviewed for scientific soundness. Adherence to design requirements outlined in Subdivision K was also determined. There are several minor design flaws in the protocol for this study. The meteorological data are insufficient. Consequently, this study does not meet all the requirements of Subdivision K.

D. Adequacy of recovery data: Since not all the storage stability and field recovery data were presented, coefficients of variation for these data could not be calculated. Thus, it is not possible to determine the adequacy of these data. The mean folpet laboratory recovery value is 91.4% and the coefficient of variation is 31%. The laboratory recoveries are acceptable.

E. Acceptability of field and laboratory QA procedures: Review of reported QA/QC procedures relative to U.S. EPA GLP and other QA/QC requirements and standards, such as outlined in Subdivision K, Reentry Protection, of the Pesticide Assessment Guidelines, indicates that the field and laboratory QA/QC procedures are acceptable.

F. Adequacy of analytical technique: One hundred and fifty milliliters of a solution consisting of 20 mL of 2% (w/v) Aerosol OT-75 (Fischer) in 3980 mL of distilled water were used to dislodge the folpet residues from the foliage samples. Dislodged samples were stored frozen until analysis. The samples were thawed, and 75 mL aliquots were removed and extracted with three successive 75 mL volumes of 20:80 (v:v) methylene chloride in hexane. The organic layers were pooled and dried with anhydrous sodium sulfate and evaporated to dryness. The residues were dissolved in appropriate amounts of hexane and subjected to gas chromatography. A Shimadzu GC-9A gas chromatograph with an AOC-9 autoinjector and a Shimadzu CR4A computing integrator was used to analyze the samples. An electron capture detector was used. The submission states that the method limit is 0.01 $\mu g/cm^2$, but it was not specified whether this is a detection or a quantification limit. The submission contains several standard solution chromatograms that show no apparent interferences. A standard curve was included that shows good linearity, and some calibration data were included that yielded a satisfactory correlation coefficient. On the basis of this information, these analytical methods are adequate.

G. Data gaps: There are several data gaps in this submission. Wind speed and relative humidity data are required. There is no information concerning the recent use of other agricultural products at the site.

H. Issues/items requiring submitter's clarification: A reference is made to Craven Laboratories, Inc. use of mastication (sic) to analyze the total folpet residues in the foliage samples. In view of the controversy surrounding this laboratory, the submitter should clearly indicate what role,

if any, Craven Laboratories, Inc. played in generating the analytical data described in this submission. Also, the submitter should indicate how early on day 0 post-application the first samples were taken.

I. Miscellaneous evaluations of FDR data (from Subdivision K): None.

IV. Summary and Discussion

Representative chromatograms for the field samples were presented, and correspond well to the raw data that was presented. The raw data that were presented were accurately compiled into the finished tables in the body of the submission. Half-life values for the dissipation of folpet from the avocado foliage in the three sites were calculated by this reviewer. It appears that the dissipation process is biphasic. Using all the data, the half-lives for the three sites are 12, 11, and 22 days, respectively. The associated correlation coefficients range from 0.696-0.879. Using only the first four data points, which appear to correspond to the first phase of dissipation, the half-lives are all 3 days. The correlation coefficients for the first 4 data points obtained from linear regression calculations range from 0.884-0.910. It is likely that these lower half-life values are more useful as a predictor of the rate of folpet dissipation.

Total folpet residues were also quantified in this study. Since these data are not predictors of potential exposure to pesticide residues, they are not relevant to the derivation of reentry intervals. As such, they have not been discussed in this report.

The study does not meet all the Subdivision K requirements. None of the missing information (wind speed and relative humidity data) is sufficiently important to invalidate the data. Also, since the proposed label does not provide sufficient details concerning the maximum application rate and number of applications, it could not be determined whether the application procedures used in this study are consistent with these maxima. Finally, it appears that Craven Laboratories, Inc. played some role in the generation of the data. The submitter must specify what this role was, and whether Craven Laboratories generated any foliar dislodgeable residue data. Therefore, it is concluded that these data should be tentatively considered to be acceptable for the purpose of the re-registration of folpet for use on avocados.

Table 1. Average foliar dislodgeable residue dissipation data from avocado foliage following the application of Folpet 50WP at 3 lb ai/acre.

Study Day	Average residue ($\mu g/cm^2$)		
	Site I	Site II	Site III
0	0.77	1.09	0.98
1	1.19	1.13	0.94
3	0.56	0.35	0.33
6	0.24	0.32	0.30
9	0.25	0.25	0.35
13	0.38	0.28	0.32
21	0.15	0.18	0.20
28	0.13	0.21	0.25
35	0.11	0.07	0.27

CHAPTER 4. Exposure Study, Folpet on Avocados - Worker Reentry Study

This study examined worker exposure under reentry conditions pertaining to harvesting of avocados which had been previously treated with folpet via a commercial air-blast sprayer.

I. Description of Study

A. Study identifier: 1990. "Folpet: Field Worker Exposure Study in Avocado Harvesting Operations" Authored by D. Larry Merricks, Agrisearch, Inc., Frederick, MD, sponsored by Makhteshim-Agan (America), Inc. Performing laboratory: Agrisearch, Inc., Frederick, MD. EPA MRID/Accession No. 421220-20.

B. Site description: The study was conducted in three commercial avocado groves totalling 47.5 acres, located in Goulds, FL. Acreage of each site was not given. A companion DFR study was also conducted at each site. The substrate was not described.

Weather conditions were provided for the three reentry days of the study, as collected from the site using a portable weather station. Air data for the three days (November 10, 13, and 17, 1989) is as follows:

	Air Temp. (°C)		% Humidity		Wind Speed	
Day	Max	Min	Max	Min	Max	Min
11/10	31.7	22.2	87	65	7	0
11/13	28.9	23.9	79	60	10	4
11/17	22.5	11.0	75	65	8	5

C. Number of sites: Three sites were used.

D. Number of replicates (total and per site): Thirty workers took part in the study, harvesting avocados from trees that had been treated once with folpet. Ten volunteers worked in each grove. Thus, the study contained a total of 10 replicate measurements for calculating folpet inhalation and dermal exposure under different reentry intervals.

E. Application rate(s): The application rate was stated to have been 3.0 lb. a.i. per acre.

F. Mixing/loading/application procedures: Four commercial airblast sprayers (nozzle type unspecified) delivered 200 gallons of spray per acre at 250 psi.

G. Number of applications: One application was made to each grove on November 4, 1989.

H. Intervals between applications: Not applicable.

I. Interval between application and reentry: The reentry interval was different at each site; the interval between application and reentry was either 6, 9, or 13 days.

J. Monitoring methodologies: All workers were experienced in harvesting avocados. For determining dermal exposure, each worker wore ankle-length tights, long-sleeved t-shirts, and a hat with dosimeter patches attached, and had their hands rinsed at the end of the exposure period. For determining inhalation exposure to folpet, each worker wore a personal sampling pump for respiratory monitoring. The work period was approximately 4 hours for each worker. In one grove, reentry was on day 6, in one grove on day 9, and in one grove on day 13. Harvesters worked at two typical harvest operations. Some workers harvested avocados directly from trees by standing in a cherry picker, which was then unloaded into a tractor-drawn trailer. Other workers picked avocados from the ground and picked up any avocados dropped by harvesters in cherry pickers. These ground workers also drove the tractors through the grove back to the processing plant.

Dermal: Upper body and lower body exposures were estimated by analyzing long-sleeved t-shirts and ankle-length tights, respectively. Tights were worn under long pants and t-shirts under an optional outer garment which was not described. At the end of each of the replicate exposure periods, participants put on rubber gloves to remove their outer clothes, then took the gloves off to remove the t-shirts and tights which they placed in separate heat sealable bags.

Head exposure was assessed by using two dosimeter patches (4 x 4" alpha cellulose), which were attached to the front and back of a cap which was worn by each worker. After sampling, front and back patches were combined for analysis and placed face to face in a heat-sealable bag.

Hand exposures were estimated with rinses of a water/detergent solution (20 ml of 2% (w:v) Aerosol OT75 added to 3980 ml distilled water). After the sampling period, hand rinses were obtained by having each worker place each hand into a separate plastic bag containing 150 ml detergent solution and shaking for one minute. The hand was then rinsed with an additional 50 ml of detergent and the bag was sealed.

All samples were stored in the field, and shipped to the laboratory on dry ice. Times and conditions of field and laboratory storage were not given.

Inhalation: Air samples were collected by attaching sample collectors and personal sampling pumps to each worker. It was not specified where on the worker the collectors were attached. The sample collectors were composed of two polyurethane foam filters in holders. The pumps were calibrated in the field before and after the exposure period, with the sampling rate at 2 L/min. After the sampling period, the two polyurethane filters were removed and combined for analysis in glass vials.

K. Clock times/durations for monitored exposures: The nominal exposure time was four hours. Exact exposure times were recorded and utilized for calculation of exposure rates.

L. Quality Control Data: Duplicate blanks of each matrix were exposed to the environment at each site, although the duration of exposure was not specified. The submission states that each set of samples was analyzed with blank samples, but it is not clear whether these were reagent or method blanks. It was not indicated whether or not folpet was detected in the blanks.

All recovery data are summarized in Table 1 below. Field recovery samples were prepared by spiking samples of each matrix with 10, 100, and 1,000 µg of folpet. Fortified samples were then placed in heat-sealable bags, placed in dry ice, and taken to the laboratory.

Laboratory recoveries were determined for each set of samples analyzed. Control samples were fortified at the method limits and at levels above those measured on field samples. In addition, recovery values incorporated day 0 storage stability samples, which were prepared as described below and were basically laboratory recovery samples.

A storage stability test was conducted by spiking each matrix with 10, 100, and 1000 µg of folpet. Samples were analyzed immediately (day 0) or were frozen for the approximate freezer storage time of field samples (although this information is not given) and then analyzed. Foam filters were stored in a freezer for 184 days, tights for 183 days, t-shirts and patches for 115 days, and handwashes for 114 days. The recoveries given below are only for frozen samples, which are a true measure of storage stability.

The field, laboratory, and storage recovery data can be summarized as follows:

Table 1. Average field, laboratory, and storage stability recoveries of folpet in sample matrices. Range of recoveries given in parentheses.

Matrix	Average % Recovery, Field	Average % Recovery, Laboratory	Average % Recovery, Storage Stability
Polyurethane Foam	94.8 (70.6-100.1)	88.2 (50.8-156.8)	75.5 (61.1-85.1)
Head Patch	89.3 (81.4-130.4)	102 (67.9-145.6)	103 (82.6-123.2)
Cotton T-Shirt	77.6 (61.8-110.4)	95.9 (56-126.3)	73.5 (36.4-110.6)
Cotton Tights	87.9 (77.6-137)	112.4 (69.4-157.3)	93.5 (71-116)

Handwash	76 (53.6-107.9)	92.9 (51.9-152.5)	76.9 (46.8-107)

It is not indicated whether reentry data were corrected for any of the recoveries, although the protocol states that final results will be corrected for laboratory recovery if necessary.

II. Summary of Standard Evaluation Procedure

A. Review of protocol relative to Subdivision K Reentry Guidelines: The report was examined to determine the extent to which it met the applicable requirements of Subdivision K, other technically appropriate guidance, and sound scientific procedure. Required elements under Subdivision K include the following.

a. A typical end use product must be used.

This criterion was met by the use of folpet formulated as a wettable powder (folpet 50WP) on avocados.

b. The test substance must be applied in a manner consistent with the approved application methods specified for the end-use product and at the least dilution and highest permissible rate.

Since the label was not included in the submission, this criterion could not be verified.

c. Dermal and/or inhalation exposure must be monitored by validated methodologies.

This criterion was met as judged against Subdivision K and Agency acceptance of whole body dosimetry.

d. The participants in the study should be engaged in activities consistent with typical accepted agricultural practices.

This criterion was met.

e. The duration of sampling must be sufficient to collect measurable residues, but not so long that residue dissipation could occur.

This criterion was met.

f. At least 10 workers must participate in each sampling period.

This criterion was met.

g. Dermal exposure must be reported for each body area monitored for each individual.

This criterion was met.

h. Total dermal and/or inhalation exposure must be reported for each individual and for the whole group.

This criterion was met.

i. The storage stability, method efficiency for each collection matrix, and the quantitation limit must be provided.

This criterion was not completely met, due to absence of a quantitation limit.

k. At least one field fortification sample per worker per monitoring period per fortification level must be generated for each matrix. There must be at least one field blank per worker per monitoring period for each matrix.

This criterion was questionably met. Although field fortifications were made at three levels per monitoring period, there is no information about the number of field fortifications made during each monitoring period.

Data gaps in the study are enumerated in Section III. H.

B. Review of Quality Assurance/Quality Control Procedures: These procedures were reviewed to ensure that the data were collected in accordance with GLPs and requirements outlined in Subdivision K of the Pesticide Assessment Guidelines. Among these elements are: proper blanks and recovery spike samples, appropriate replicate samples, maintenance of sample identity and integrity, proper chain of custody and documentation procedures, and a description of the quality assurance unit of the investigating organization and analytical laboratory.

C. Verification of calculations: Calculations explicitly presented or implicit in the presentation of data such as means, standard deviations, and coefficients of

variation are checked. When available, chromatograms are spot checked (approximately 10% of chromatograms) to determine if the indicated concentrations agreed with any raw data that were presented. When raw data are included in the report, the extent of their agreement with the finished, tabulated data was determined.

III. Study Evaluation Summary

A. Nature/purpose of study: This study was conducted by Agrisearch, Inc. for Makhteshim-Agan (America), Inc. to generate data on the transfer of folpet from treated avocado trees to dosimeter clothing and patches and to air monitoring filters. The purpose of collecting this data was to calculate dermal and inhalation exposure of workers to folpet under reentry conditions (tree and ground harvesting of avocados) to satisfy Subdivision K requirements.

B. Summary of results: Results were reported for the amount of folpet on dermal and inhalation exposure media for workers exposed to folpet after three different reentry intervals. Results were grouped by site (reentry interval) for each type of harvesting work done; either from a cherry picker or from the ground/tractor; Table 2 and Table 3, respectively. Exposure rates were presented based on µg/day (day=8 hr), and were recalculated by this reviewer based on the more conventional mg/hr (Tables 4-6).

C. Adequacy of study protocol: The study protocol was reviewed for scientific soundness and adherence to design requirements outlined in the NDEB/OREB-approved study protocol, Subdivision K, and other appropriate criteria. The protocol was determined to be adequate, except it did not require precipitation data. In addition, the protocol calls for correction of results for laboratory recoveries if necessary, but the requirement should not have been conditional, and it should have included corrections for field, laboratory, and storage stability recoveries.

D. Adequacy of recovery data: The field, laboratory, and storage stability recovery data appear to be acceptable. It is not clearly indicated if the analytical results were corrected for the laboratory recoveries.

E. Acceptability of field and laboratory QA procedures: Review of reported QA/QC procedures relative to U.S. EPA GLP and other QA/QC requirements and standards as outlined in Subdivision K indicate that the study QA/QC appears to be acceptable.

F. Adequacy of analytical techniques: A Shimadzu GC-9A gas chromatograph equipped with an electron capture detector and a SP2110 2%/SP2510 1% on Supelcort 100/120 mesh column was used to analyze the sample extracts for folpet. Operating parameters were given for the system. The quantitation limit and detection limit were not given. Examination of the example chromatograms

showed no potential interferences from other substances. Standard curves were not given, so a linear detector response could not be verified. Derivation of the quantitative results could not be verified since only a few example chromatograms and no raw data were given. The overall adequacy of the analytical technique seems acceptable, based on the available information.

G. Data gaps: Precipitation data should have been collected along with the other meteorological data at each site. Raw data and the proposed label should have been included for verification purposes. Quantitation and detection limits should have been given. The label was not included, so the maximum application rate could not be verified.

H. Issues/items requiring submitter's clarification: Times and temperatures of field and laboratory storage of samples need to be specified, there should be an indication of the number of field fortifications made per monitoring period and whether associated field blanks were prepared, whether duplicate spikes were made for field recoveries, and how the quantitation limits were calculated, and whether results were corrected for laboratory recoveries. In addition, information should have been given as to which workers did and did not wear outer garments over t-shirt dosimeters, since this would affect the residue levels found and thus the exposure rate calculated for these workers.

IV. Summary and Discussion

Since raw data was not included in the submission, calculations and transcriptions could not be checked.

Wearing an outer garment over the t-shirt dosimeter was optional during the study, therefore, those workers wearing outer garments would be expected to have less folpet on the t-shirt dosimeter, giving an underestimate of the dermal exposure rate. Workers not wearing outer garments would receive maximal exposure, thus creating a conservative reentry interval. The results from these two situations should not have been pooled as they were in this study, but separated out to determine least and worst case exposure scenarios. However, it can be assumed that the use of an outer garment, such as a work shirt, is a customary work practice and that residues on the t-shirt dosimeters are reflective of actual dermal exposure. Those replicates collected from workers without outer garments are therefore a more conservative, if not worst case, element in the exposure assessment. Therefore, this reporting discrepancy would not prevent the establishment of an adequately protective reentry level.

Residues on the upper body made up 82-91% of the total dermal exposure for both groups of workers at all reentry intervals, while residues on the head made up 6-12%, on hands were 0.7-5%, and on lower body were 1-3% of total dermal exposure. According to the submission, this is consistent with the harvesting operations, in which the upper body and head had the greatest contact with treated foliage. However, it would be expected that hands would also have the greatest

contact with foliage, but the exposure contribution from hands was the lowest, and the authors do not address this.

Total exposure rates are not that different between workers in cherry pickers or on the ground/tractor at Site 1 and Site 2, although the exposure rate of all workers is 2-3 times greater at Site 1. In addition, the exposure rate for workers in cherry pickers at Site 3 was slightly higher than at Site 1, and was 5 times less for workers on the ground/tractor. The authors conclude that dermal exposure is higher for workers in trees than those on the ground, but this was true only at Site 3. The authors suggest that the lower reentry exposure measure at Site 2 was due to a fewer number of trees at that site, requiring more trips between trees and less time harvesting. Respiratory exposure rates were low for all workers at all three sites, at rates less than 1 mg/hr.

As previously noted in this chapter, there are several data gaps and issues requiring submitter's clarification, but in general the submission can be considered acceptable for the registration of folpet on avocados.

Table 2. Average amount of folpet (μg) detected in exposure matrices of workers exposed to folpet treated avocado trees during harvesting operations. Cherry pickers were used to harvest avocados. Results are given for the three different reentry intervals. Ranges are given in parentheses.

MATRIX	FOLPET MASS (UG)		
	Day 6	Day 9	Day 13
Polyurethane Foam	26 (11-37)	23 (8-46)	75 (44-127)
Head Patches	7,224 (548-19,083)	1,546 (469-2,617)	4,227 (1,038-7,099)
Cotton T-Shirt	55,818 (40,066-74,150)	17,711 (14,464-23,284)	63,028 (50,229-104,088)
Cotton Tights	630 (278-1,021)	508 (328-783)	1,175 (331-3,549)
Handwash	528 (275-1,157)	1,074 (295-2,436)	469 (225-772)
Total	64,226	20,862	68,974

Table 3. Average amount of folpet (μg) detected in exposure matrices of workers exposed to folpet treated avocado trees during harvesting operations. Harvesters worked on the ground or on a tractor. Results are given for the three different reentry times were used. Ranges are given in parentheses.

MATRIX	FOLPET MASS (UG)		
	Day 6	Day 9	Day 13
Polyurethane Foam	18 (14-23)	23 (4-38)	6 (2-8)
Head Patches	6,813 (2,599-10,065)	2,157 (1,789-2,527)	1,658 (431-1,565)
Cotton T-Shirt	48,138 (23,050-62,296)	23,071 (15,014-36,618)	11,332 (3,853-13,869)
Cotton Tights	978 (600-1,336)	833 (62-1,684)	387 (122-506)
Handwash	590 (97-1,366)	1,165 (816-1,479)	494 (484-503)
Total	56,537	27,249	13,877

Table 4. Site 1, Reentry Day 6. Average dermal and inhalation folpet exposure rate (mg/hr) of avocado harvesters working in cherry pickers or on the ground/tractor.

DOSIMETER	EXPOSURE RATE (MG/HR)	
	CHERRY PICKER	GROUND/TRACTOR
Inhalation	0.09	0.06
Head/Neck	1.80	1.70
Upper Body	13.90	11.98
Lower Body	0.16	0.24
Hands (Pair)	0.13	0.15
TOTAL	16.08	14.14

Table 5. Site 2, Reentry Day 9. Average dermal and inhalation folpet exposure rate (mg/hr) of avocado harvesters working in cherry pickers or on the ground/tractor.

DOSIMETER	EXPOSURE RATE (MG/HR)	
	CHERRY PICKER	GROUND/TRACTOR
Inhalation	0.08	0.08
Head/Neck	0.40	0.55
Upper Body	4.52	5.83
Lower Body	0.13	0.21
Hands (Pair)	0.27	0.29
TOTAL	5.40	6.96

Table 6. Site 3, Reentry Day 13. Average dermal and inhalation folpet exposure rate (mg/hr) of avocado harvesters working in cherry pickers or on the ground/tractor.

DOSIMETER	EXPOSURE RATE (MG/HR)	
	CHERRY PICKER	GROUND/TRACTOR
Inhalation	0.27	0.02
Head/Neck	1.20	0.47
Upper Body	17.96	3.21
Lower Body	0.34	0.11
Hands (Pair)	0.13	0.14
TOTAL	19.91	3.95

APPENDIX A

DESCRIPTION	SPRAYER # (a) 554	555	556	560
Manufacturer	Swanson	F.M.C.	F.M.C	Hardi
Model #	DA 500 CUD 26	Speed Sprayer 957 CPD	Speed Sprayer 6757 DOV	800 D58
Tank Size (gal)	500	500	500	500
Vehicle	Ford 80hp	Ford 80hp	Ford 80hp	Ford 80hp
Ground Speed (mph)	1.5	1.5	1.5	1.5
Gallons/Acre	200	200	200	200
Application Rate(b) (lb. a.i./acre)	3.0	3.0	3.0	3.0
Nozzle	Spray Systems 5630	Spray Systems 5630	Spray Systems 5630	Spray Systems 5630
Nozzle Size(c)	D8, D10, D14	D2, D6, D8	D2, D6, D8	D6, D8
Total # Nozzles	15	36	36	32

(a) Kendall Foods Sprayer Identification number. See FIGURES 2 and 3 for additional information. All four sprayers were used during application.
(b) Folpet formulated as a wettable powder (50% a.i.) so 6 lb. of formulation were applied per acre.
(c) See FIGURE 2 for additional information regarding the number of nozzles and their orientation.

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Chemical:	**Folpet (ANSI)**
PC Code:	**081601**
HED File Code	**12000 Exposure Reviews**
Memo Date:	**05/04/99**
File ID:	***DPD172924***
Accession Number:	**412-01-0084**

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