7-28-88

Shaughnessy No.: 103301

Date Out of EAB: 7/28/1988

TO: W. H. Miller/M. Mautz
Product Manager (16/3)
Registration Division (TS-767C)

FROM: Frank L. Davido, Chief Frank L. Davido
Field Studies and Special Projects Section #5
Exposure Assessment Branch/HED (TS-769C)

THRU: Paul F. Schuda, Chief
Exposure Assessment Branch/HED (TS-769C) Paul F. Schuda

Attached, please find the EAB review of...

Reg./File # : 239-2471

Chemical Name: ACEPHATE

Type Product : Insecticide

Product Name : Orthene, 75% SC/S

Company Name : Chevron

Purpose : Submission of soil and foliar dislodgeable residue data in response to data required under 40 CFR § 158.390 and by the Registration Standard for Acephate and to fulfill Guidelines Requirement 132-1.

Action Code: 660

EAB #(s) : 80451

Date Received: 2/25/1988

TAIS Code: 50

Date Completed: 7/28/1988

Total Reviewing Time: 12 days

Monitoring study requested: No

Monitoring study voluntarily: No

Deferrals to:

No Ecological Effects Branch

No Residue Chemistry Branch

No Toxicology Branch

(1)

REVIEW OF REENTRY DATA

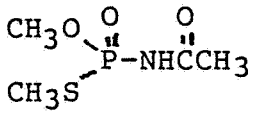
1. CHEMICAL:

Common name: Acephate

Product names: Orthene, Ortho 12420, Ortran

Chemical name: O,S-Dimethyl acetylphosphoramidothioate

Structure: $C_4H_{10}NO_3PS$ MWt 183.18



Other names: Chevron RE 12420, ENT 27822, ORTHENE-755, Ortran, Ortril, CAS: 30560-19-1, RTECS # TB4760000

Formulations: Soluble concentrate solids, soluble concentrate liquids, granulars, pressurized liquids, and an 85% cartridge.

2. TEST MATERIAL:

Orthene, 75% SC/S [75% Soluble concentrate/solid]

3. STUDY/ACTION TYPE:

Submission of foliar and soil dissipation data for reentry hazard assessment to support the registration of Acephate

4. STUDY IDENTIFICATION:

Reg. File No. 239-2471
Record No. 214636
Accession Nos. 40504821 and 40504822

5. REVIEWED BY:

James D. Adams, Chemist
Field Studies and Special Projects Section #5 James D. Adams 7/28/1988

6. APPROVED BY:

Frank Davido, Chief
Field Studies and Special Projects Section #5
Exposure Assessment Branch, HED (TS-769) Frank L. Davido 7/28/1988

7. CONCLUSIONS:

Since the Toxicology issues for acephate have not been fully resolved, it will not be possible now to determine the need for reentry intervals nor to set a reentry interval for cauliflower.

The soil residue study is unacceptable because the soil sampling

technique was inadequate. Insufficient sample sizes may have compromised the results.

8. RECOMMENDATIONS:

At the conclusion of the evaluation of the brain-cholinesterase inhibition data, the appropriate Allowable Exposure Level must be calculated and combined with the exposure data presented here to determine the need for an acephate reentry interval for cauliflower. The Registrant should repeat the dissipation study of acephate residues on peanut soil.

9. BACKGROUND:

Acephate is a systemic, broad spectrum, organophosphate insecticide registered for use on terrestrial food crops, terrestrial nonfood, forestry, indoor (both commercial and residential), and greenhouse sites. Acephate is formulated into soluble concentrate solids, soluble concentrate liquids, granulars, pressurized liquids, and an 85% cartridge. There are 23 products registered in the United States; these include 18 single active ingredient formulations and 5 multiple active ingredient formulations. The methods of application include aerial, ground, injection (into tree trunks), and dip treatment (for ornamentals). It has higher water solubility than most organophosphorus insecticides.

Methamidophos [O,S-dimethyl phosphoramidothiolate] is a toxic metabolite, environmental-alteration product, and contaminant of acephate. That is, it is found on surfaces immediately after acephate application, and it is generated from acephate in the environment and in vivo. Dislodgeable residues of this material must also be considered as part of the exposure hazard to field-workers.

10. DISCUSSION OF INDIVIDUAL TESTS OR STUDIES:

There are two separate studies in this submission, and they will have to be reviewed separately.

10-1. Lai, J.C. 1987a. Dislodgeable residues of acephate and its metabolite methamidophos on cauliflower leaves. Laboratory Project I.D. R-12T6878DR. Chevron Chemical Co., Ortho Research Center, Richmond, CA. (Accession Number 405048-21).

A. MATERIALS AND METHODS

Acephate (Orthene, 75% SC/S, Chevron Chemical Co.) was applied, using ground equipment (ground rig sprayer), to a field plot (20 x 350 feet) of cauliflower located in Fresno, CA. The pesticide was applied six times, at 1.0 lb ai/A (6.0 lbs ai/A total), at one-week intervals between April 28 and June 2, 1987. An additional, untreated plot of cauliflower served as a control. The treated and control plots were each divided into three subplots, and replicate samples of 48 leaf-discs were collected from each

subplot, using a leaf-punch (2.54 cm in diameter), on day 0 after each application, and on days 2, 3, 7, 10, 14, 21, 28, and 35 after the last application.

Leaf-disc samples collected at all but five intervals during the study were kept in a refrigerator or a cooler containing blue ice, and were transported to the lab for removal of dislodgeable residues. Within 24 hours of collection, samples were washed three times (15 minutes each time), on a mechanical shaker, with a detergent solution of Triton X-100 in deionized water, and the three washes were combined and immediately prepared for analysis.

Leaf-disc samples collected on days 2, 3, 14, and 28 after the last application, and one of two composite samples collected on day 0 after the fourth application were washed at the test site with a detergent solution of Triton B-1956 (a commercial preparation of Triton X-100 with an antifoam agent added) in deionized water, using the procedure described above. The leaf-wash samples were frozen and transported to the lab, where they were stored in a freezer at -20°C until analysis.

Aliquots of all leaf-wash samples were mixed with sodium sulfate, then extracted three times with ethyl acetate and filtered after each extraction. The filtrates were combined, evaporated to dryness, and redissolved in acetone. Leaf-wash extracts were analyzed for acephate and its degradate methamidophos using GC with flame photometric detection. Average recovery of acephate and methamidophos from method validation detergent solutions spiked with 6.25-125 ug acephate and 2.5-50 ug methamidophos ranged from 97.4 to 116 and 86.8 to 99.2% of the applied, respectively. Recovery of acephate and methamidophos from detergent solutions spiked with 12.5 ug acephate and 5.0 ug methamidophos and stored frozen at -20°C for one to six days ranged from 93 to 100 and 94 to 100% of the applied respectively. In addition, following the analysis of an aliquot of a test leaf-wash sample, a second aliquot of the same sample was stored frozen at -20°C for 14 days; following the storage period, the concentrations of acephate and methamidophos were 102 and 100%, respectively, of the concentrations of each compound measured in the initial analysis.

B. REPORTED RESULTS

Air temperature and wind speed at the time of each application and samling interval during the study ranged from 68 to 103°F and from 2 to 10 mph, respectively (no additional meteorological data were provided).

Average dislodgeable residues of acephate and methamidophos on the leaves (one-sided leaf residues) of cauliflower treated with acephate six times, at 1.0 lb ai/A (6.0 lbs ai/A total), ranged from 0.2687 to 0.7353 and 0.0105 to 0.0400 ug/cm^2, respectively, on day 0 after each of the first five treatments, and were 0.1071 and 0.0278 ug/cm^2, respectively, on day 0 after the last treatment (Table 1). Dislodgeable residues of acephate dissipated with a

calculated half-life of 7.5 days on the surface of cauliflower leaves, and declined to nondetectable levels (<0.001 ug/cm^2) by day 35 after the last treatment. Average dislodgeable residues of methamidophos were detected at a level of 0.0016 ug/cm^2 on day 35 after the last treatment. Corresponding fieldworker exposure rates, derived from average dislodgeable residue data and EAB's surrogate exposure data base ranged from 3,250 to 10,250 ug/hour for acephate and from 78 to 360 ug/hour for methamidophos on day 0 after each of the first five treatments, and were 1,150 and 230 ug/hour for acephate and methamidophos, respectively, on day 0 after the last treatment. Rates of exposure to both acephate and methamidophos declined to <10 ug/hour by day 35 after the last treatment.

C. STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES

The Registrant concludes that the submitted data, "demonstrate that acephate residues found on cauliflower leaf surfaces grown under actual field conditions are low (0.733 ug/sq. cm or less) and dissipate rapidly with a half life of 7.5 days. No significant accumulation of methamidophos residues from acephate treatment occurs on the leaf surfaces."

D. REVIEWER'S DISCUSSION AND INTERPRETATION OF STUDY RESULTS

This study is scientifically sound and provides supplemental reentry data for acephate, but it does not completely fulfill EPA Data Requirements for Registering Pesticides (Exposure:Reentry). The Registrant did not provide complete meteorological data for conditions during the study. Occurrence or lack of rainfall during the study should have been reported. However, examination of the submitted data does not show any substantial discontinuities in the graph of the data and, therefore, there was not sufficient rainfall during the study to increase the residue dissipation rate significantly.

Average dislodgeable residues of acephate (Orthene, 75% SC/S) and its degradate methamidophos on leaves (one-sided leaf residues) of cauliflower treated with acephate six times, at 1.0 lb ai/A (6.0 lbs ai/A total), ranged from 0.5600 to 0.7353 and 0.0105 to 0.0400 ug/cm^2, respectively, on day 0 after each of the first five treatments, and were 0.1071 and 0.0278 ug/cm^2, respectively, on day 0 after the last treatment. Dislodgeable residues of acephate dissipated with a calculated half-life of 7.5 days on the surface of cauliflower leaves, and declined to nondetectable levels (<0.001 ug/cm^2) by day 35 after the last treatment. Corresponding fieldworker exposure rates ranged from 3,250 to 10,250 ug/hour for acephate, and from 78 to 360 ug/hour for methamidophos on day 0 after each of the first five treatments, and were 1,150 and 230 ug/hour for acephate and methamidophos, respectively, on day 0 after the last treatment. Rates of exposure to both acephate and methamidophos declined to <10 ug/hour by day 35 after the last treatment.

Table 1 contains averages of the Registrant's 3 reported foliar disslodgeable residue levels for both acephate and methamidophos. Those values are based on two sides of the leaf. There is no question that the leaves have two sides, but the EAB surrogate exposure data base for reentry exposure has been based on values calculated on one side of leaves as originally calculated and reported by several of the researchers in reentry exposure. In order to use the Registrant's data, it was converted into "one sided" data, and those values are also contained in Table 1. The "one-sided" data were then used to estimate exposure levels assuming reentry at the sampling dates.

The reported foliar dislodgeable residues of acephate on the days of application do not show an increase with the number of applications indicating that there is no significant tendency for those residues to accumulate on the foliage. The fact that the initial residues not only don't increase but actually appear to decrease with number of applications is unexpected. There is evidence that the low value after the last application may have been due to the normal variability of field applications and measurements. This is supported by the fact that the 3 samples taken on the day of and after the sixth application were all in the low range but within range of the other individual samples. Also, extrapolation of the first order graph of residue dissipation with time indicates that the initial (0 day) value was low. See the attached Figure 1.

Linear regression analysis of the foliar dislodgeable residue data shows that the dissipation kinetics for acephate approximate a first-order process with a half-life of 7.5 days. Dissipation of foliar dislodgeable residues for other pesticides usually do not follow first order kinetics, and strictly speaking, there would be no half-life for other pesticide residues.

Since acephate may be applied 6 times per season at 7 days (or greater) intervals and the half-life is 7.5 days, a short term accumulation of the residues should occur. That is, at the second application, the dissipation kinetics predict that there would be foliar dislodgeable residues almost equivalent to 1 + 0.5 times the first application's; at the third application there would be 1 + 0.25 + 0.5; 1 + 0.125 + 0.25 + 0.5 at the fourth; 1 + 0.0625 + 0.125 + 0.25 + 0.50 at the fifth; and 1 + 0.03125 + 0.0625 + 0.125 + 0.25 + 0.50 at the sixth application. Accumulation of acephate residues would approach but never equal twice the residue level at the first application. As discussed above, the measured residue levels at those applications do not show this accumulation effect. The problem here is related to the normal variability of the residue measurements. That is, the accumulation predicted by the kinetics is so small compared to the variability of the data, that the effect is not apparent.

On the other hand, methamidophos residues do not dissipate as rapidly as acephate residues. The methamidophos residues start lower than acephate, but do not dissipate rapidly during the 35-day test.

TABLE 1.

Average foliar dislodgeable residues of, and fieldworker exposure rates to acephate and its degradate methamidophos on the leaves of cauliflower treated with acephate six times, at 1.0 lb ai/A (6.0 lbs ai/A total).[a]

Number of applications[b]	Sampling interval (days)	Foliar Dislodgeable residues, (ug/cm^2)				Fieldworker exposure rates (ug/hour)[d]	
		Acephate		Methamidophos			
		Two-sided leaves	One-sided leaves[c]	Two-sided leaves	One-sided leaves	Acephate	Methamidophos
1	0	0.2800	0.5600	0.0052	0.0105	7,500	78
2	0	0.3677	0.7353	0.0200	0.0400	10,250	360
3	0	0.1430	0.2860	0.0169	0.0337	3,450	280
4	0	0.1413	0.2827	0.0126	0.0252	3,400	210
5	0	0.1343	0.2687	0.0102	0.0203	3,250	165
6	0	0.0535	0.1071	0.0139	0.0278	1,150	230
	2	0.0377	0.0753	0.0072	0.0143	760	111
	3	0.0397	0.0793	0.0073	0.0146	790	114
	7	0.0150	0.0301	0.0071	0.0142	260	110
	10	0.0116	0.0232	0.0052	0.0103	190	75
	14	0.0083	0.0167	0.0058	0.0115	125	85
	21	0.0068	0.0136	0.0047	0.0095	100	70
	28	0.0026	0.0053	0.0021	0.0042	33	27
	35	ND[e]	ND	0.0008	0.0016	<10	<10

[a] Average of three replicate leaf-disc samples.

[b] The pesticide was applied six times, at one-week intervals, from April 28 to June 2, 1987.

[c] Calculated by the reviewer from data reported for two-sided leaf residues as follows: ug/cm^2 (one-side) = ug/cm^2 (two-sides) x 2.

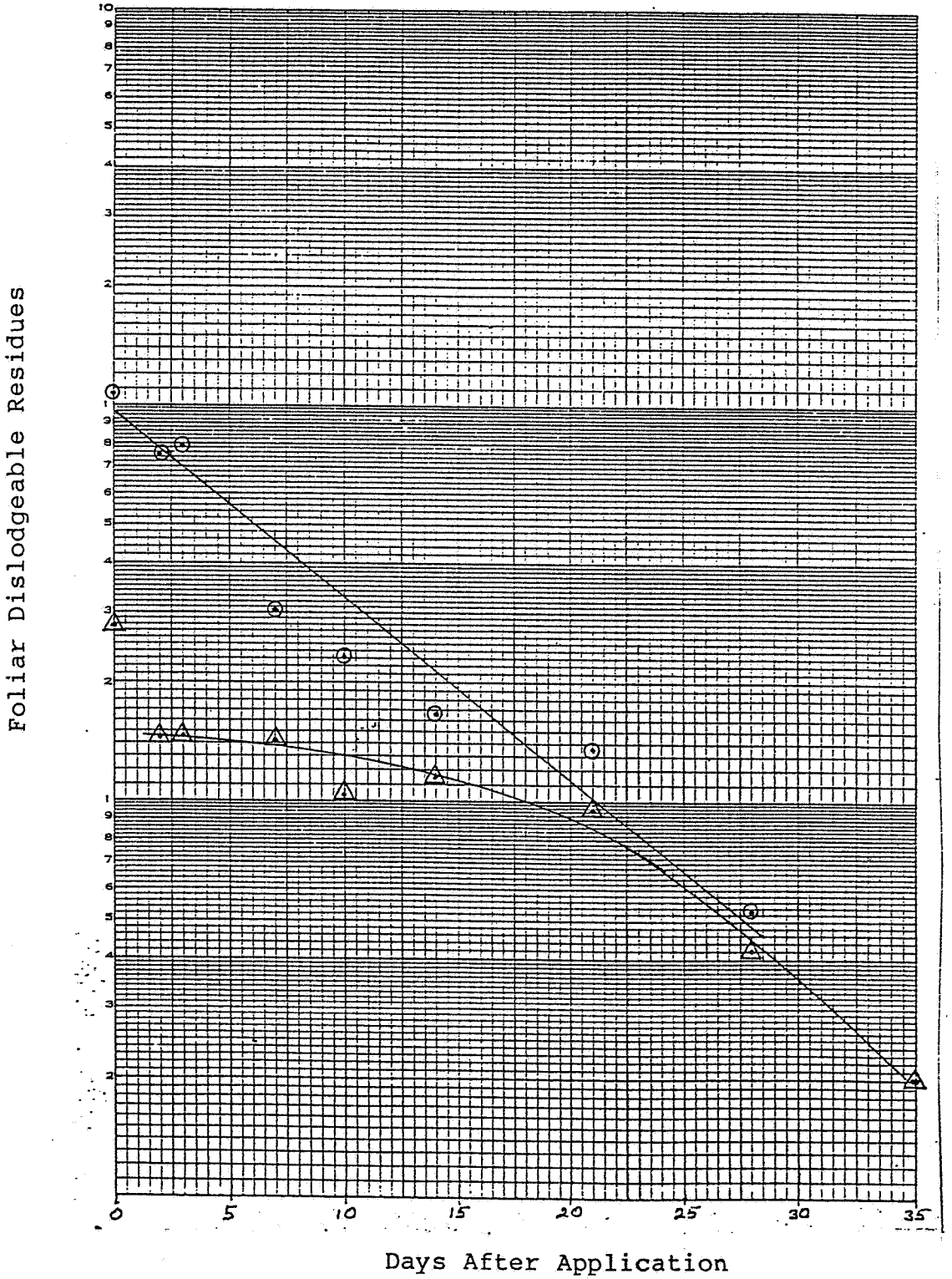
[d] Derived from average dislodgeable residue data and

[e] Not detected; the detection limit was 0.001 ug/cm^2.

Figure 1

Dissipation of Dislodgeable Foliar Residues of

Acephate [⊙] and Methamidophos [△]



The extimated human exposure rates given in Table 1 are derived from data based on measurements of foliar dislodgeable residues and human exposure during work in fruit trees (citrus, apple, etc.). Human exposure in those situations would be to all parts of the body, but exposure in cauliflower would largely be limited to the hands, forearms, thighs, and lower legs. That is, the exposure rates listed in Table 1 are expected to be conservative.

10-2. Lai, J.C. 1987b. Dissipation of residues of acephate and its metabolite methamidophos in/on peanut soil dust. Laboratory Project I.D. R-12T6879RE. Chevron Chemical Co., Ortho Research Center, Richmond, CA (Accession Number 405048-22).

A. MATERIALS AND METHODS

Acephate (Orthene, 75% SC/S, Chevron Chemical Co.) was applied, using a carbon dioxide backpack sprayer, to a field plot (48 x 100 feet) of peanuts (Florunner) located in Donalsonville, GA. The pesticide was applied six times, at 1.0 lb ai/A (6.0 lbs ai/A total), at 14- to 15-day intervals between July 14 and September 22, 1987. An additional, untreated plot (24 x 100 feet) of peanuts served as a control. The soil in the treated and control plots was described as Tifton sandy loam soil (78.6% sand, 11.4% silt, 10% clay, 2% organic matter). Three replicate samples of surface soil dust from the treated plot and one soil dust sample from the control plot, each consisting of a composite of 16 subsamples from different sites within the dripline zone of each plot, were collected, using a three-layer sampling screen and a portable vacuum, prior to the first treatment, on day 0 immediately after each treatment (samples were not collected on day 0 after the second and fifth treatments; see Discussion, point No. 1), and on days 1, 3, 7, 11, 15, 22, 28, 35, 42, and 48 after the last treatment. Following collection, soil samples were placed in glass jars, stored frozen at -18°C, and were later shipped on dry ice to the lab, where they were maintained frozen until analysis.

Soil samples were mixed with deionized water and sodium sulfate, then extracted three times with ethyl acetate and filtered after each extraction. The filtrates were combined, evaporated to dryness, and redissolved in acetone. Soil extracts were analyzed for acephate and its degradate methamidophos using GC with flame photometric detection. Recovery of acephate and methamidophos from soil samples (5-20 g) spiked with 1.25-6.25 ug acephate and 0.5-2.5 ug methamidophos ranged from 71.2 to 117 and 75.8 to 118% of the applied, respectively.

B. REPORTED RESULTS

Meteorological data recorded from July 14-September 30, 1987 (day 0 of the first treatment through day 8 after the last treatment) show air temperature ranged from 59.7 to 101.6°F, soil temperature ranged from 69.0 to 115.9°F, and relative humidity ranged from 59.0 to 89.9%. A total of 5.92 inches of rainfall was

recorded during the period from July 14 - September 30, 1987.

Acephate degraded with a calculated half-life of 8.0 days in the surface soil of a plot of peanuts (Donalsonville, GA) treated six times with acephate, at 1.0 lb ai/A (6.0 lbs. ai/A total). Average residues of acephate and its degradate methamidophos in the surface soil ranged from 31.57 to 108.3 ppm (0.0162 to 0.0177 ug/cm^2) and 0.035 to 0.665 ppm, respectively, on day 0 after the first, third, and fourth treatments, and were 2.98 ppm (0.0062 ug/cm^2) and 0.027 ppm, respectively, on day 0 after the last treatment (Table 1). Average residues of acephate and methamidophos increased to 4.37 ppm (0.0070 ug/cm^2) and 0.037 ppm, respectively, on day 1 after the last treatment, and declined to 0.1 ppm (0.0001 ug/cm^2) and 0.01 ppm, respectively, by day 48 after the last treatment.

C. STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES

The Registrant concludes that these submitted data, "demonstrate that acephate residues found on/in soil dust from a Georgia Peanut field treated with six applications of ORTHENE 75 soluble powder at 1.0 lb active ingredient per acre under actual field conditions are 0.026 ug/sq. cm or less and dissipate rapidly with a half-life of 8.0 days. No significant concentrations of methamidophos were observed in soil dust from treatment with ORTHENE."

D. REVIEWER'S DISCUSSION AND INTERPRETATION OF STUDY RESULTS

This study is unacceptable because the soil sampling technique was inadequate and insufficient sample sizes may have compromised the results. Also, soil samples collected from the test and control plots prior to the first treatment and control samples collected at several additional intervals were contaminated with acephate residues. In addition, this study does not fulfill EPA Data Requirements for Registering Pesticides (Exposure:Reentry) because the registrant did not determine an Allowable Exposure Level (AEL) for acephate, a Reentry Level and corresponding Reentry Interval could not be established from the data provided, adequate freezer storage stability data were not provided, and meteorological data for most of the residue dissipation portion of the study were not provided.

The use of a portable vacuum for soil sample collection was an inadequate technique in this particular study. At two sampling intervals, day 0 after the second and fifth treatments, high soil moisture content from rainfall prevented collection of soil samples, and, at several intervals during the study, the sampling technique did not provide soil samples of sufficient size to obtain reliable data (samples were < 1 g). In addition, the registrant reported that all soil samples received for analysis were extremely small (< 22 g). Insufficient sample sizes throughout the study may have compromised the results. This study should be repeated using an alternative soil sampling technique. Subdivision K of the Guidelines suggests (p. 32) that sampling

of wet soil fines be done by the soil sampling method contained in a 1981 paper by Berck, et al. [J. Agric. Food Chem. 29:209].

A summary of the submitted soil residue dissipation data is contained in Table 2 below.

Table 2.

Average residues of acephate and methamidophos in surface soil dust of a plot of peanuts (Donalsonville, GA)

Number of applications[b]	Sampling interval (days)	Acephate		Methamidophos[c] ppm
		ppm	ug/cm^2	
0[a]	-	0.14	<0.0001	ND[d]
1[a]	0	32.40	0.0162	0.035
2	0	--[e]	--	--
3	0	31.57	0.0170	0.123
4[a]	0	108.30	0.0177	0.665
5	0	--[e]	--	--
6	0	2.98	0.0062	0.027
	1	4.37	0.0070	0.037
	3	1.78	0.0028	0.01
	7	1.22	0.0026	<0.01
	11	0.35	0.0005	0.01
	15	0.34	0.0005	0.03
	22	0.50	0.0008	0.04
	28	0.27	0.0004	0.02
	35	0.19	0.0003	0.02
	42	0.06	0.0001	<0.01
	48	0.10	0.0001	0.01

[a] Average of three replicate samples, except data for pretreatment and day 0 after the first and fourth treatments; these data are the average of 2 replicate samples because the sample collected at each of these intervals was too small (<1 g) to provide reliable data.

[b] The pesticide was applied at 14- to 15-day intervals between July 14 and August 22, 1987.

[c] Residues of methamidophos in the soil were detected at levels too low to provide meaningful data expressed in ug/cm^2.

[d] Not detected; the detection limit was 0.02 ppm acephate and 0.01 ppm methamidophos.

[e] Soil samples were not collected on day 0 after the second and fifth treatments due to high soil moisture content from rainfall.

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Meteorological data show that a total of 5.92 inches of rainfall occurred during the period from July 14 to September 30, 1987. The application of acephate to low crops in an area with less seasonal and/or annual precipitation would result in higher residues of acephate and methamidophos in the surface soil following treatment.

Soil samples collected from the test and control plots prior to the first treatment and control soil samples collected at several additional intervals during the study were contaminated with acephate residues evidently from previous treatments. Acephate was found at levels of 0.01 to 0.30 ppm in replicate pretreatment samples collected from the test plot and were reportedly detected at levels of < 0.2 ug total (below the detection limit of 1.0 ug total) in control samples at various intervals; however, data for control samples were not provided.

Adequate freezer storage stability data for acephate were not provided. Although freezer storage stability data from a study not yet completed were included in this study as surrogate data, these data cannot be considered acceptable because the study from which the data were obtained has not been reviewed.

The registrant did not determine an AEL for acephate, and the Reentry Level and corresponding Reentry Interval could not be established from the data provided.

Although complete daily meteorological data were provided for the months of July, August, and September, 1987 (day 0 of the first application through day 8 after the last application), no data for most of the soil residue dissipation portion of the study (days 9-48 after the last application) were provided.

11. COMPLETION OF ONE-LINER:

Not Applicable.

12. CBI APPENDIX:

None of the submitted data are considered "company-confidential" by the registrant, and none of the submitted data were retained in the Exposure Assessment Branch files.