7-26-90

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

JUL 26 1990

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Review of addenda to reentry studies submitted in response to requirements of the Reregistration Guidance Document for Acephate (HED Project # 9-1353)

TO: W.H. Miller/M. Mautz
Product Manager 16/3
Registration Division (H7505C)

FROM: Peg Perreault Peg Perreault
Field Studies and Special Projects Section
Non-Dietary Exposure Branch
Health Effects Division (H7509C)

THRU: Alan P. Nielsen, Chief Al Nielsen
Field Studies and Special Projects Section
Non-Dietary Exposure Branch
Health Effects Division (H7509C)

Charles L. Trichilo, Ph.D., Chief
Non-Dietary Exposure Branch
Health Effects Division (H7509C) C L Trichilo

Please find below the NDEB review of ....

RD Record #: 243087

Caswell #: 2A

Date Received: 4/26/89 Review Time: 10 days

Deferral to: _____ Biological Analysis Branch/BEAD

_____ Science Analysis and Coordination Branch

__X__ TB - Insecticide/Rodenticide Support Section

_____ TB - Herbicide/Fungicide/Antimicrobial Support Section

1/20

1.0 INTRODUCTION

In July 1988, NDEB/EAB evaluated two studies submitted by Chevron Chemical Company measuring dislodgeable residues of acephate and its metabolite methamidophos on cauliflower leaves (MRID 405048-21) and peanut soil dust (MRID 405048-22) following foliar applications of acephate. The studies were submitted in response to requirements of the Reregistration Guidance Document for Acephate, under 40 CFR 158.390, to fulfill Guidelines Requirement 132-1. The review (EAB review No. 80451) is attached as Appendix A. The reviewer concluded that the cauliflower foliar dislodgeable residue study provides supplementary reentry data for acephate but does not completely fulfill data requirements because complete meteorological data for conditions during the study were not provided. The peanut soil residue dissipation study was considered unacceptable because the reviewer concluded that the soil sampling technique was inadequate and insufficient sample sizes may have compromised the results. In addition, some control soil samples may have been contaminated with acephate residues and several deficiencies were noted, including inadequate freezer storage stability data and incomplete meteorological data. The reviewer recommended that when the Agency's toxicological evaluation of acephate is complete, the appropriate Allowable Exposure Level must be calculated and combined with the exposure data from these studies to determine reentry intervals for acephate.

In response to the NDEB/EAB review, the registrant has submitted addenda to the original studies (MRIDs 410235-01 and 410235-02) which contain additional data and responses to the reviewer's comments. These addenda are reviewed in Section 4 of this document.

2.0 CONCLUSIONS

NDEB has reviewed the addenda to the cauliflower foliar dislodgeable residue and peanut soil dust residue dissipation studies for their adequacy in addressing deficiencies identified in the NDEB/EAB review of the of the original studies. The irrigation data presented in the addendum to the cauliflower FDR study indicate that irrigation practices during the study, specifically the use of sprinkler irrigation during the period in which the first four foliar applications of the pesticide were made, may have compromised the results. Based on the additional data submitted in the addendum, NDEB now considers this study unacceptable. In the addendum to the peanut soil dust residue study, the registrant attempted to justify the adequacy of the soil sampling technique (a portable vacuum was used to collect wet soil fines) by providing additional data on the weights of soil dust samples collected during the study. However, since soil samples were not obtained at all scheduled sampling

intervals, NDEB continues to believe that the use of a portable vacuum was an inadequate technique in this particular study. In addition, the reported data for soil residues immediately following separate applications of the pesticide were highly variable. Therefore, this study is still considered unacceptable and should be repeated using an alternative sampling technique.

3.0 RECOMMENDATIONS

Reentry protection data as per 40 CFR 158.390 (reentry protection) are required for use by the Agency in assessing the safety of agricultural workers who may be exposed to acephate and to set appropriate reentry intervals. The registrant is required to develop and submit reentry data for representative acephate product formulations. Studies submitted by Chevron Chemical Co. to date on foliar dislodgeable residue and soil residue dissipation of acephate (MRIDs 405048-21 and 405048-22, respectively) are unacceptable. In addition to meeting the requirements for those studies, the registrant must also conduct dermal exposure studies.

Thus, two types of data are required: 1) foliar dislodgeable residue (FDR) and soil residue dissipation data (guidelines reference No. 132-1 and -2, respectively); and 2) dermal exposure data (guidelines reference No. 133-3).

Dermal exposure studies representing each crop group/formulation type category must be conducted for a minimum of three days at one site per crop selected. Studies should include testing at maximum application rates, maximum number of treatments on the label, minimum interval on the label between each treatment, and geographical sites and climatological conditions where residue decay is expected to be at a minimum.

On each of the three days per site, per crop, ten replicates of dermal exposure monitoring must be conducted measuring the activity likely to lead to the highest exposure (generally hand harvesting, pruning, or hand weeding, and varying with crop). Also, dermal exposure monitoring must include the early morning period if normal work practices include morning activities. Whole body dosimeters should be worn under the usual clothing worn by workers entering fields treated with acephate. Clothing scenarios should reflect practical field conditions. Data reports must clearly define the type of clothing that is worn by participants during the study.

As part of the final data report, raw data must be submitted as well as sample calculations converting these to final values. Representative chromatograms or other instrument printouts must be submitted. Climatic data must also be provided.

The protocol must address the above as well as QA/QC, i.e., the

precision and accuracy of the data, and the use of good laboratory practice (GLP) requirements.

Data should also be developed bridging foliar and/or soil dissipation data to dermal exposure data for the purpose of estimating exposure at various post-application intervals. FDR and/or soil residue data must be generated concurrently with the dermal exposure study.

The registrant must propose the exact intervals they wish to use, along with the rationale behind them, in a protocol submitted for approval by the Agency. Time intervals will vary with practices used, but at least three different times must be measured. This will allow an estimation of the dissipation/decay of the FDR and soil residue with time, and provide the bridging data necessary to estimate dermal exposure using FDR and soil residue data. The registrant must assure that these intervals encompass the dissipation span of acephate so that appropriate reentry intervals can be calculated. If this is not accomplished, this factor will be among those that could cause a study to be found unaccepatable.

In addition, pesticide use data must be submitted. Data on maximum and typical application rates, number of treatments per year, minimum and typical intervals between treatments, harvester and other reentry practice information, including type of activity, hours per day, days per year, and harvester productivity rates must be submitted.

Due to a lack of adequate reentry data, NDEB cannot calculate final reentry intervals for acephate; however, we recommend that the existing reentry interval of 24 hours for all crops treated with acephate continue to be enforced. In addition, in order to calculate final reentry intervals, NDEB must have the appropriate toxicity data (brain ChE NOELs for both acephate and its metabolite methamidophos) from which to calculate an Allowable Exposure Level (AEL). A brain ChE NOEL for acephate has been established; however, since fieldworker exposure to methamidophos must also be considered when determining a reentry interval for acephate, NDEB must be provided with toxicity data for methamidophos as well. We defer to the Toxicology Branch to determine the brain ChE NOEL for methamidophos.

The reentry data that were required by the Reregistration Guidance Document and the types of data that are considered by NDEB to remain data gaps are presented in Table 1.

4.0 REVIEW OF ADDENDA TO STUDIES SUBMITTED BY CHEVRON CHEMICAL COMPANY IN RESPONSE TO THE NDEB/EAB REVIEW OF PREVIOUSLY SUBMITTED STUDIES

NDEB/EAB has reviewed two studies submitted by Chevron Chemical

Company in response to the Reregistration Guidance Document for Acephate dated September 1987. The NDEB/EAB review dated 7/28/88 is attached as Appendix A. The registrant has submitted addenda to these studies which are reviewed below for their adequacy in addressing the deficiencies identified in the review of the original studies.

4.1 REENTRY - FOLIAR DISLODGEABLE RESIDUES ON CAULIFLOWER

CITATION: Dislodgeable Residues of Acephate and its Metabolite Methamidophos on Cauliflower Leaves (Addendum). Chevron Chemical Company Report R-12T6878DR. MRID 410235-01 (Addendum), 405048-21 (Previous submission).

The previously submitted study was considered supplementary and does not completely fulfill data requirements because complete meteorological data for conditions during the study were not provided. Additional meteorological data and information concerning irrigation practices during the study have been submitted in the addendum. The meteorological data indicate that climatic conditions during the study, including rainfall, would not have increased foliar residue dissipation significantly. However, the irrigation data indicate that although furrow irrigation was employed from May 27 through July 15 (day 2 after the fifth application through day 45 after the sixth and last application), the plots were irrigated by sprinkler at intervals of one to six days between April 6 and May 18, 1987, during which time the first four applications of the pesticide were made (April 28, May 5, May 12, and May 18, 1987). The use of sprinkler irrigation during this period may have increased foliar residue dissipation significantly, resulting in a decrease in the accumulation of residues from one application to the next and, thus, lower foliar residue levels of both acephate and its metabolite methamidophos during the entire study.

The previous reviewer noted that since acephate may be applied six times per season at intervals of 7 days (or greater) and the half-life is 7.5 days, a short term accumulation of these residues should occur. However, the reported data do not show an increase in foliar dislodgeable residues with the number of applications. In fact, initial residues on the days of application actually appear to decrease with the number of applications. The reviewer concluded that these unexpected results could be attributed to the normal variability of field applications and residue measurements; however, based on the additional irrigation data submitted in the addendum, it can be concluded that irrigation practices during the study may have compromised the results, i.e. the use of sprinkler irrigation during the period in which the first four applications of the pesticide were made may have prevented the accumulation of foliar dislodgeable residues from one application to the next.

Therefore, this study cannot be considered acceptable.

In addition, the registrant provided calculated estimates of cauliflower harvester exposure and margins of safety. The margins of safety are based on a NOEL of 0.1 mg/kg/day for acephate brain cholinesterase inhibition; however, the Toxicology Branch considers the acephate brain ChE NOEL to be 0.004 mg/kg/day and has not yet established a brain ChE NOEL for the toxic metabolite methamidophos. Fieldworker exposure to methamidophos must also be considered when determining a reentry interval for acephate.

4.2 REENTRY: RESIDUES IN/ON PEANUT SOIL DUST

CITATION: Dissipation of Residues of Acephate and its Metabolite Methamidophos in/on Peanut Soil Dust (Addendum). Chevron Chemical Company Project R-12T6879RE. MRID 410235-02 (Addendum), 40504822 (Previous submission).

The previously submitted study was considered unacceptable because the reviewer concluded that the soil sampling technique was inadequate and insufficient sample sizes may have compromised the results. The registant responded that the soil sampling technique was not inadequate and provided additional data in the addendum on the weights of soil dust samples collected during the study using a portable vacuum cleaner. Although the data indicate that sufficient sample sizes were obtained at most sampling intervals during the study, the fact remains that soil samples were not collected on day 0 after the second and fifth applications due to high soil moisture content. In addition, the soil dust residue data from samples collected on day 0 following the first, third, fourth, and sixth applications are highly variable. Residues of both acephate and metahmidophos were found at much higher levels in soil samples collected after the first, third, and fourth applications than in samples collected after the sixth and last application. No explaination for this data variability was provided and, if soil dust residue levels after the sixth application had been comparable to residues found following previous applications, then residues during the dissipation portion of the study would have been significantly higher as well. NDEB continues to believe that the use of a portable vacuum cleaner for soil sample collection was an inadequate technique in this particular study; therefore, this study is unacceptable and should be repeated using an alternative sampling technique.

Attachments: Table 1
Appendix A

cc: Peg Perreault/NDEB (H7509C)
Krystyna Locke/TB-1/IR (H7509C)
Acephate File
Circulation
Correspondence File

Table 1. Reentry Data for Acephate Required by the Reregistration Guidance Document dated September, 1987.

Data Requirement	Test Substance	Crops	Study Received	Data Gap
158.390 Reentry Protection				
132-1 Foliar Dissipation	TEP	Cauliflower[1]	Yes[2]	Yes
132-2 Soil Dissipation	TEP	Peanuts[3]	Yes[2]	Yes
133-3 Dermal Exposure	TEP	Cauliflower	No	Yes
		Peanuts	No	Yes
133-4 Inhalation Exposure	TEP		No	No

[1] FDR data are required for cauliflower as a representative crop since, among the crops on which acephate is registered for use as described in the Guidance Document, cauliflower is considered to be representative of a worst case in terms of the likelihood of fieldworker exposure to residues during reentry activities.

[2] Study received, considered unacceptable by NDEB.

[3] Soil dissipation data are required for use on peanuts because the registered use of acephate on peanuts as described in the Guidance Document involves reentry activities that could cause fieldworker exposure to residues adsorbed to soil.

APPENDIX A

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

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REVIEW OF REENTRY DATA

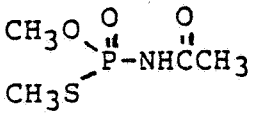
1. CHEMICAL:

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

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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 fieldworkers.

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

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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.

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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.

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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.

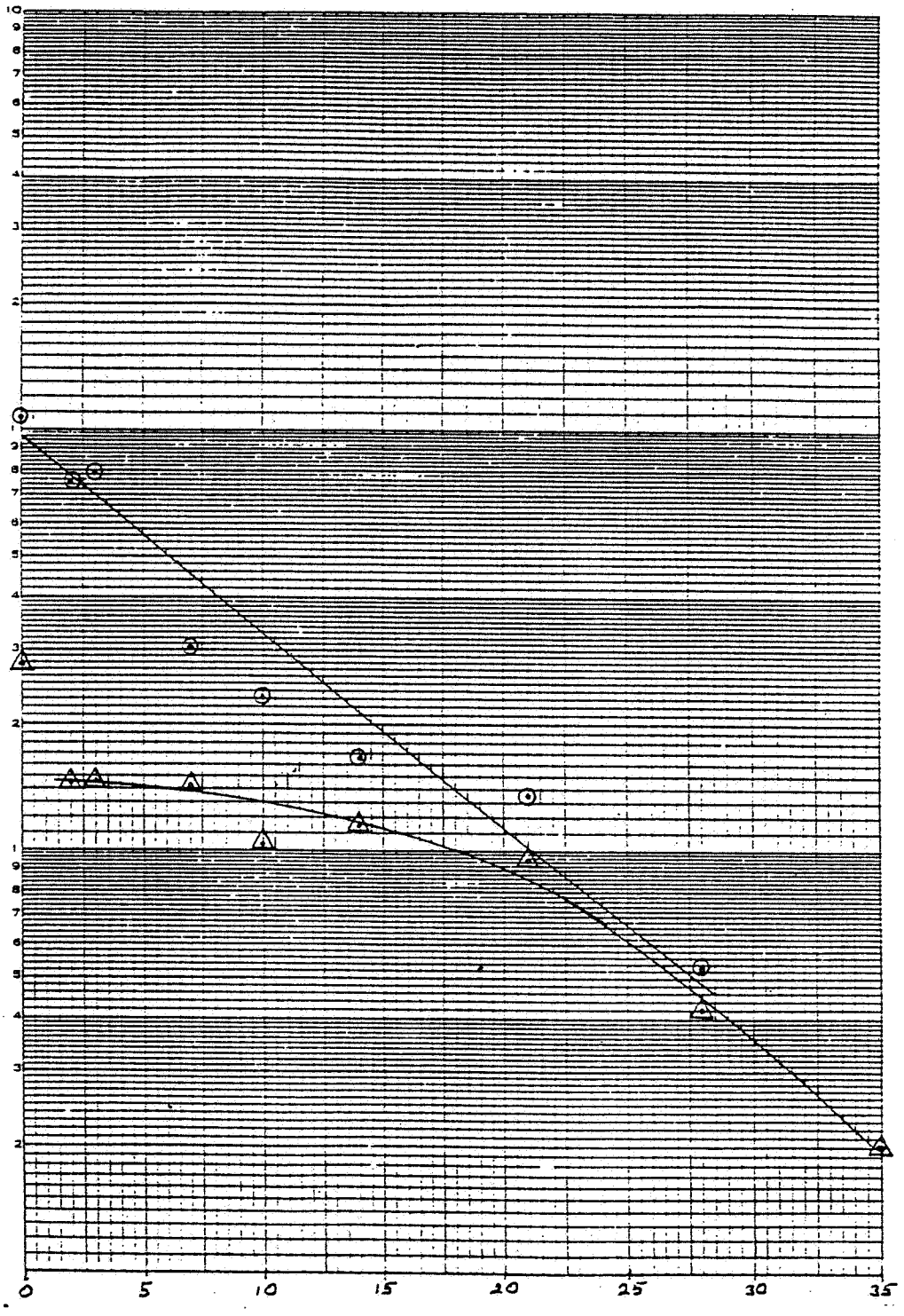
[d] Derived from average dislodgeable residue data and

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

Figure 1

Dissipation of Dislodgeable Foliar Residues of

Acephate [⊙] and Methamidophos [△]



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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

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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

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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.

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.

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