DYNAMAC
CORPORATION

8-8-91

Final Report

ACEPHATE
Shaughnessy No. 103301
Task 4: Residue Chemistry
Reregistration Standard Update

August 8, 1991

Contract No. 68-D8-0080

Submitted to:
Environmental Protection Agency
Arlington, VA 22202

Submitted by:
Dynamac Corporation
The Dynamac Building
2275 Research Boulevard
Rockville, MD 20850-3268

ACEPHATE

(SHAUGHNESSY NO. 103301)

REREGISTRATION STANDARD UPDATE

RESIDUE CHEMISTRY

Task 4

Table of Contents

ACEPHATE

(SHAUGHNESSY NO. 103301)

REREGISTRATION STANDARD UPDATE

RESIDUE CHEMISTRY

Task 4

INTRODUCTION

The Product Site Listing (SP05, dated 2/4/91) identifies registered food/feed uses for the insecticide acephate (O,S-dimethyl acetylphosphoramidothioate) on the following crops: beans (dry and succulent), celery, cotton, head lettuce, pasture and rangeland grasses, peanuts, peppermint, peppers (bell), soybeans, and spearmint. Acephate is also federally registered for use on air-cured, dark fired, and flue-cured tobacco. Special Local Need registrations (SLNs) are held for use of acephate on nonbearing citrus in FL and TX, lettuce (seed crop) in CA, grain and sweet lupine in WA, macadamia nuts in HI, onions (seed crop) in CA, radishes (seed crop) in OR and WA, burley tobacco in TN, and winter wheat in CO, OK, and TX. It should be noted that uses of acephate on Brussels sprouts, cauliflower, and cranberries appear on the product label for EPA Reg. No. 59639-26 (submitted in response to the Product Label Data Call-In, dated 10/6/89) but not in the SP05.

Acephate formulations registered for food/feed uses include the 90% emulsifiable concentrate (EC), the 97% liquid soluble concentrate (SC/L), and the 75% solid soluble concentrate (SC/S). These formulations are registered for foliar, greenhouse, nursery, plant bed, seed crop, seed treatment, soil, and transplant bed applications.

The Acephate Guidance Document, dated 9/87, identifies residue chemistry data requirements for storage stability, magnitude of the residue in grass and grass hay, tobacco, and the processed commodities of beans (succulent and dry) and soybeans, and the magnitude of the residue in milk. In addition, the Toxicology Branch has expressed concern over the residues of methylthioacetate (MTA), an impurity in an acephate manufacturing process, and requested that CBRS determine levels of MTA in or on acephate-treated food crops (J. Whalan, EPA Memorandum, dated 9/5/85). Accordingly, CBRS identified additional data requirements for residues of MTA in or on beans, cotton, grass and grass hay, lettuce, and peppers. In addition, requirements for the determination of residues in the processed commodities of cottonseed and for feeding studies were reserved (W. J. Hazel, Addendum to Registration Standard, dated 9/23/85).

In response to these requirements, Chevron Chemical Company submitted data pertaining to storage stability (MRIDs 40504802, 40874102, 40874103, and 41137902); the magnitude of the residue in beans (MRID 40504805), pasture and rangeland grass (MRID 40504804), mint hay (MRID 40504803), soybeans (MRID 40504805), and tobacco (MRID 40504809), and the processed commodities of soybeans (MRIDs 40504805 and 41137903); the magnitude of the residue in the meat and milk of dairy cattle (MRID 40504806); and calculations regarding MTA levels in treated crops (MRID 40504801).

We note that MRID Nos. 40504809 and 40504803 through 40504808 were reviewed by the Agency (F.B. Suhre, EPA Memorandum CBRS No. 4419, dated 1/12/89) for dietary assessment for acephate, and it was concluded that a Tolerance Assessment System (TAS) analysis should be conducted.

The available data up to 5/10/91 are reviewed here for their adequacy in fulfilling outstanding data requirements.

Tolerances in food and feed commodities are expressed in terms of combined residues of acephate (O,S-dimethyl acetylphosphor-amidothioate) and its cholinesterase-inhibiting metabolite methamidophos (O,S-dimethyl phosphoramidothioate) [40 CFR §180.108 (a) and (b), 40 CFR §185.100, and 40 CFR §186.100].

SUMMARY

The following residue chemistry data requirements remain outstanding:

- Additional data depicting the metabolism of acephate in plants and animals.
- Additional data pertaining to residue analytical methods.
- Additional storage stability data on tobacco, the processed commodities of cotton, mint, peanuts, and soybeans, the liver of dairy cattle, and poultry tissues.
- Additional residue data on wheat forage, grass forage, and grass hay, radishes, and mint hay.
- Processing studies on beans, soybeans, and peanuts.
- A pyrolysis study on tobacco.

QUALITATIVE NATURE OF THE RESIDUE IN PLANTS

Conclusions:

The qualitative nature of the residue in plants is not adequately understood. Data concerning the metabolism of acephate in plants were reviewed in the Acephate Residue Chemistry Chapter, dated 1/82, and were found to adequately delineate the nature of the residue. However subsequent Agency interpretation of existing guidelines have required a more complete characterization of the total radioactive residue. Available studies do not sufficiently quantitatively characterize the total radioactive residue (TRR). In addition, in the studies with cotton and root crops, application was done in a sufficiently different manner (than the registered uses) such that the Agency questions the applicability of the data to current uses; in the study of the root crop radishes only a small amount of the TRR was identified; in the study with beans, only acetonitrile-soluble residues were characterized; in the studies with cabbage, only "extractable" residues were characterized; and in the study with tomatoes, mature commodities were not analyzed. The study with alfalfa can be considered supporting information only, since acephate is not registered for use on alfalfa or any member of the non-grass animal feeds group.

Thus the available data are inadequate to describe the nature of the residue in plants. Only acephate and methamidophos were detected in the residues that were extracted and characterized, though some data suggest that insignificant residues of acephate and methamidophos are conjugated.

The following additional data are required:

- Data depicting the uptake, distribution, and metabolism of S-methyl-labeled and carbonyl-labeled [^{14}C]acephate in a leafy vegetable, in a legume vegetable, and in cotton. The radiolabeled test substance must be applied under conditions representing normal cropping practices and at rates high enough to permit characterization of ^{14}C-residues. The identities and quantities of residues in mature plant parts must be determined in order to elucidate terminal residues. Data depicting all terminal residue components in commodities at the time of harvest should be expressed as the percentage of the total recovered radioactivity (TRR) and concentration (ppm). Confirmation of the identities of residues using a suitable method such as MS is required. Representative samples from these studies must also be analyzed by the residue analytical methods developed for data collection and tolerance enforcement to assure that these methods

are capable of adequately recovering all metabolites of concern.

References (used):

N/A.

Discussion of the data:

N/A.

QUALITATIVE NATURE OF THE RESIDUE IN ANIMALS

The qualitative nature of the residue in animals is not adequately understood. Data concerning the metabolism of acephate in animals were reviewed in the Acephate Residue Chemistry Chapter, dated 1/82, and were found to adequately delineate the nature of the residue. However, Agency interpretation of existing guidelines has become more strict in recent years. Specifically, the two available studies are inadequate because in one study, only residues in excreta were determined and in the other study, residues were not quantitatively identified. In addition, no data are available depicting the metabolism of acephate in poultry. Although the studies are inadequate, the data indicate that methamidophos is not the major metabolite of acephate in animals and that both acephate and methamidophos undergo S-demethylation in the mammary glands. The following additional data are required:

- Data are required depicting metabolism of acephate in ruminants and poultry. Animals must be dosed orally for a minimum of 3 days with S-methyl-labeled and carbonyl-labeled [^{14}C]acephate at a level sufficient to make residue identification and quantification possible. Milk and eggs must be collected twice a day during the dosing period and animals must be sacrificed within 24 hours of the final dose. The distribution, characterization, and identification of radioactive residues must be determined in milk, eggs, liver, kidney (except poultry), muscle, and fat. The amount of radioactivity identified, characterized, or lost must be accounted for. Results describing all terminal residue components should be expressed as total recovered radioactivity (TRR) and concentration (ppm). Confirmation of the identities of residues using a suitable method such as MS is required. Representative samples from these studies must also be analyzed by the residue analytical methods developed for data collection and tolerance enforcement to assure that these methods are capable of adequately recovering all metabolites of concern.

References (used):

N/A.

Discussion of the data:

N/A.

RESIDUE ANALYTICAL METHODS

Conclusions:

The Acephate Guidance Document, dated 9/87, does not require any additional data concerning analytical methodology. The Acephate Residue Chemistry Chapter, dated 1/82, discusses a gas-liquid chromatography (GLC) method, Chevron Method RM-12A, used to analyze for residues of acephate and methamidophos in/on plant and animal commodities; samples are extracted with ethyl acetate, cleaned on a silica column, and analyzed using a thermionic detector. This method is published in the Pesticide Analytical Manual (PAM) Vol. II as Method I, with modifications in reagents, column type, and detector type and is considered suitable for enforcement of tolerances. A confirmatory thin-layer chromatography (TLC) method, Chevron Method RM-12B and PAM Vol. II, Method A, is also described in the Residue Chemistry Chapter.

Toxicology Branch has expressed concern over the residues of methylthioacetate (MTA), an impurity in an acephate manufacturing process, and requested that CBRS determine levels of MTA in or on acephate-treated food crops (J. Whalan, 9/5/85). Accordingly, CBRS identified additional data requirements for residues of MTA in or on several crops (W.J. Hazel, EPA Memorandum dated 9/23/85). In addition, a description of the method(s) used to determine MTA residues was required. Based on subsequent toxicology and product chemistry data submissions Toxicology Branch does not believe potential MTA residues are not of sufficient magnitude to be of concern so these data are no longer required (personal communication C. Olinger to K. Locke 1/09/92). Should the manufacturing process change at a later date which would considerably increase the amount of MTA impurity, then additional studies would be required.

According to the Pestrak data base (11/6/90; PAM Vol. I, Appendix), acephate, and its metabolite methamidophos, are completely recovered (>80%) using FDA Multiresidue Protocol D and partially recovered using PAM Vol. I method 232.2.

Chevron Method RM-12A-6 was used to obtain the storage stability data, the snap and pinto bean data, the mint data, the grass forage and grass hay data, the 1987 soybean and soybean processing data and the feeding study data discussed in this

update. This method is a modification of RM-12A and includes separate extraction procedures for crops, milk and water, oil, dry crops, oily crops, cured tobacco, and cotton lint. Crop, milk, and water samples are extracted three times with ethyl acetate, filtered, and evaporated to dryness; deionized water is added to dry crops and cured tobacco before extraction in the same manner. Oil and oily crops are mixed with acetonitrile and hexane and the phases allowed to separate; the acetonitrile phase is washed twice with hexane and evaporated to dryness. Cotton lint samples are packed in a column, enough water is added to wet the entire column, and the column is extracted with acetone; the acetone is evaporated and the remaining water is extracted as above for water samples. Extracts undergo a silica gel column clean-up and residues are determined using GLC with a nitrogen-phosphorus detector (NPD) or a flame photometric detector (FPD). The stated limits of detection are 0.01 ppm for both acephate and methamidophos. However, for the analyses of samples discussed in this update, the detection limits for acephate were 0.01-0.05 ppm, depending on the day of analysis; in future submissions, the registrant should clearly explain the reasons for using a different detection limit from the one stated in the method.

Chevron Method RM-12A-5 was used to obtain the 1978 soybean and soybean processing data discussed in this update. This method is essentially the same as RM-12A-6 with slight differences in the GLC operating conditions. The limits of detection are 0.02 ppm for acephate and 0.01 ppm for methamidophos.

The following data are required:

- The qualitative nature of the residues in plants and animals has not been adequately described; therefore, the adequacy of the available methods cannot be ascertained. If the requested data on plant and animal metabolism indicate the presence of additional metabolites of toxicological concern, additional analytical methods will be required. If radiolabeled validation of existing analytical methodology for plants and animals (refer to "Qualitative Nature of the Residue in Plants" and "Qualitative Nature of the Residue in Animals" for additional details) indicates that a major portion of the total radioactive residue is not recovered and identified by the available methods, radiolabeled validation of new proposed methodology will be required.

References (used):

N/A.

Discussion of the data:

N/A.

STORAGE STABILITY DATA

Conclusions:

The Acephate Guidance Document, dated 9/87, concludes that the frozen storage stability of acephate residues appears to be dependent upon the stored, treated commodity. Data depicting the frozen storage stability of acephate residues in or on lettuce and Brussels sprouts are the only data available for crops with acephate tolerances. Therefore, the Guidance Document requires data depicting the stability of weathered residues of acephate, and its metabolite methamidophos, in or on beans, celery, cottonseed, grass, lettuce, eggs, milk, and animal tissues immediately prior to storage and at intervals approximating the maximum period of storage at subfreezing temperatures.

In response to the data requirements, Chevron Chemical Company submitted data depicting the stability of the combined residues of acephate and methamidophos during frozen storage in or on bell peppers, Bermuda grass (fresh and dry), Brussels sprouts, grass (forage and hay), lettuce, pigeon peas, rice (grain and straw), spearmint (fresh and spent hay), eggs, and the milk, kidney, and pectoral muscle of dairy cattle (1988 MRID 40504802); cottonseed (1988; MRID 40874102); celery (1988; MRID 40874103); and pinto beans and snap beans (1989; MRID 41137902). The maximum frozen storage intervals of crop, egg, milk, and animal tissue samples during which the combined residues of acephate and methamidophos are stable, as determined by these storage stability studies, are presented in Table 1. No data are available depicting the stability of acephate and methamidophos in or on tobacco leaves, in any processed commodities, in the liver of dairy cattle, or in any poultry tissues.

The following additional data are required:

- The sample storage intervals and conditions must be supplied for all residue data submitted in support of tolerances, whether previously submitted or required in this update. Storage stability data in support of previously submitted residue data are required only for those samples deemed to be useful for tolerance assessment. Data are also required which depict the decline in levels of combined residues of acephate and methamidophos in green and cured tobacco leaves, in the processed commodities of cottonseed, mint, peanuts, and soybeans, in dairy cattle liver, and in poultry tissues stored under the range of conditions and for the range of intervals specified. Samples of tobacco leaves and processed commodities bearing measurable, weathered residues or fortified with acephate residues of concern, and fortified dairy cattle liver and poultry tissue samples, must be analyzed immediately after processing or

fortification and again after storage intervals that allow for reasonable unforeseen delays in sample analysis. In laboratory tests using fortified samples, the pure active ingredient and pure metabolites must be used. However, if field-weathered samples are used, the test substance must be a typical end-use product. For additional guidance on conducting storage stability studies, the registrant is referred to an August, 1987 Position Document on the Effects of Storage Validity of Pesticide Residue Data available from NTIS under order no. PB 88112362/AS.

- The nature of the residue in plants and animals is not adequately understood. If the requested data on plant and animal metabolism indicate the presence of additional metabolites of toxicological concern, data depicting stability of these residues during storage will be required.

References (used):

MRID(s): 40504802. 40874102. 40874103. 41137902.

Table 1. Summary of maximum storage intervals, at -20°C, during which the combined residues of acephate and methamidophos are stable in samples of eggs, milk, and animal tissues and in or on various crop samples.

Commodity	Maximum storage interval (days)
Eggs, shelled	181
Milk, cow	204
Kidney, cow	175
Muscle, cow	195
Beans, pinto	461
Beans, snap	548
Brussels sprouts	273
Celery	369
Cottonseed	286
Grass, Bermuda	
forage	63
hay	62
Grass, pasture	
forage	272
Lettuce	508
Peppers, bell	391
Pidgeon peas	423
Rice	
grain	512
straw	511
Spearmint	
fresh hay	59
spent hay	59

Discussion of the data:

Chevron Chemical Company submitted data depicting the stability of residues of acephate and methamidophos during frozen storage in or on bell peppers, Brussels sprouts, Bermuda grass and pasture grass (forage and hay), lettuce, pigeon peas, rice (grain and straw), spearmint (fresh and spent hay), eggs, and the milk, kidney, and pectoral muscle of dairy cattle (1988; MRID 40504802); cottonseed (1988; MRID 40874102); celery (1988; MRID 40874103); and pinto and snap beans (1989; MRID 41137902). All crop samples, except pinto beans, were from field studies in which the 75% SC/S formulation or a 5% Bait formulation (not currently registered for use) were applied. Samples of pinto beans receiving six applications of acephate at 1.0 lb ai/A/application bore nondetectable residues; therefore, pinto bean samples were fortified with 0.25 ppm acephate and 0.10 ppm

methamidophos. The rates of acephate applied to the crops are presented in Table 2.

Milk and cow tissues were obtained from dairy cattle administered doses of acephate and methamidophos at ca. 15-60 ppm and 3-12 ppm, respectively, for 28 days. Shelled egg samples were fortified in the laboratory; the fortification level was not specified. All crop and animal samples were macerated and stored at -20°C prior to analysis. Frozen storage stability data for residues of acephate and methamidophos in crop samples are presented in Table 3. Frozen storage stability data for residues of acephate and methamidophos in eggs, milk, and animal tissues are presented in Table 4.

Table 2. Rates of acephate (lb ai/A) applied to crops used for storage stability studies; data from MRIDs 40504802, 40874102, 40874103, and 41137902.

Commodity	Formulation	Rate (lb ai/A/ application)	No. of applications	PHI
Beans,				
pinto	n/a[a]	n/a	n/a	n/a
snap	75% SC/S	1.0	2	14
Brussels sprouts	75% SC/S	1.0	6	14
Celery	75% SC/S	1.0	3	21
Cottonseed	75% SC/S	1.0	9	14
Grass, Bermuda	75% SC/S	0.125	1	1
Grass, pasture	5% Bait[b]	2.0	2	22
Lettuce	75% SC/S	0.56 + 1.0	2	21, 22
Peppers, bell	75% SC/S	1.3	7	9
Pigeon peas	75% SC/S	1.0	4	14
Rice	75% SC/S	0.5	2	21
Spearmint	75% SC/S	1.0	1	14

[a] Pinto beans treated with 6 applications of acephate at 1.0 lb ai/A/application bore nondetectable residues; therefore, pinto bean samples were fortified with 0.25 ppm of acephate and 0.1 ppm methamidophos to determine storage stability.

[b] This formulation is not currently registered for use on any site.

Table 3. Stability of the combined weathered residues of acephate and methamidophos in or on crop samples stored at -20°C; data from MRIDs 40504802, 40874102, 40874103, and 41137902.[a]

Sample	Storage Interval (days)	Combined residues (ppm)	Recovery (%)[b]
Beans, pinto[c]	5	0.32, 0.34	91, 97
	69	0.27, 0.27	77
	118	0.32, 0.30	86, 91
	168	0.25, 0.27	71, 77
	281	0.23, --[d]	66
	385	0.27, 0.27	77
	461	0.28, 0.27	77, 80
Beans, snap	0	0.42, 0.54	--
	70	0.31, 0.46	74, 85
	175	0.40, 0.57	95, 106
	272	0.28, 0.47	67, 87
	359	0.39, 0.55	93, 102
	469	0.33, 0.51	79, 94
	548	0.32, 0.44	76, 81
Brussels sprouts	3	1.64, 2.09	--
	32	1.87, 1.98	95, 114
	118	1.83, 1.76	84, 112
	182	1.67, 2.14	102
	273	1.44, 1.76	84, 88
Celery	3	0.28, 4.39, 4.69	--
	14	0.25, 4.62, 4.34	89-105
	97	0.34, 4.75, 5.38	108-121
	171	0.28, 3.88, 5.33	88-114
	284	0.31, 4.50, 5.10	103-111
	369	0.29, 4.18, 4.94	95-105
Cottonseed	5	0.40, 0.85	--
	11	0.41, 0.64	75, 103
	54	<0.35,<0.62	--[e]
	84	0.45, 0.68	80, 113
	202	0.47, 0.55	65, 118
	286	0.43, 0.58	68, 108
Grass, Bermuda forage	2	0.73, 0.84	--
	34	0.62, 0.74	86
	63	0.79, 1.02	110, 119

(Continued, footnotes follow)

Table 3. Stability of the combined weathered residues of acephate and methamidophos in or on crop samples stored at -20 C; data from MRIDs 40504802, 40874102, 40874103, and 41137902 (continued).[a]

Sample	Storage Interval (days)	Combined residues (ppm)	Recovery (%)[b]
Grass, Bermuda hay	1	2.19, 3.29	--
	33	2.17, 2.65	81, 99
	62	2.24, 3.25	99, 102
Grass, pasture forage	4	0.62, 0.84	--
	26	0.71, 0.79	94, 115
	111	0.65, 0.68	81, 105
	179	0.76, 0.99	118, 123
	272	0.61, 0.66	79, 98
Lettuce	11	0.31, 0.33	--
	97	0.23,<0.26	74
	272	<0.20, 0.22	67
	355	0.20, 0.26	65, 79
	508	0.28, 0.28	85, 90
Peppers, bell	14	4.20, 4.34	--
	253	4.18, 3.81	88, 100
	310	4.10, 4.39	98, 101
	391	4.84, 4.60	106, 115
Pigeon peas	17	9.05,10.81	--
	46	9.68, 9.31	86, 107
	110	10.35,10.73	99, 114
	202	9.27,10.47	97, 102
	285	10.12,11.61	107, 112
	423	9.94,11.26	104, 110
Rice, grain	3	1.30, 1.42	--
	52	1.43, 1.33	94, 110
	100	1.10, 0.86	61, 85
	197	1.48, 1.75	114, 124
	512	1.63, 1.18	83, 125

(Continued, footnotes follow)

Table 3. Stability of the combined weathered residues of acephate and methamidophos in or on crop samples stored at -20 C; data from MRIDs 40504802, 40874102, 40874103, and 41137902 (continued).[a]

Sample	Storage Interval (days)	Combined residues (ppm)	Recovery (%)[b]
Rice, straw	3	0.23, 0.27	--
	52	0.21, 0.24	89, 91
	99	0.18, 0.22	78, 81
	196	0.20, 0.24	87, 89
	511	0.21, 0.24	89, 91
Spearmint, fresh hay	2	7.39, 7.85	--
	28	7.15, 6.39	76, 81
	59	6.33, 5.67	96
Spearmint, spent hay	3	3.17, 3.24	--
	28	2.41, 2.61	89, 97
	59	3.04, 3.10	72, 86

[a] For each commodity except celery, two samples were analyzed at each storage interval; three samples of celery were analyzed at each storage interval.
[b] Percent of initial combined residues.
[c] Samples of pinto beans treated with acephate contained nondetectable residues; therefore, pinto bean samples were fortified with 0.25 ppm acephate and 0.10 ppm methamidophos prior to storage.
[d] This sample was lost during analysis.
[e] Recoveries cannot be determined; samples bore nondetectable residues of methamidophos.

Table 4. Stability of combined residues of acephate and methamidophos in fortified samples of eggs and samples of-kidney, milk, muscle from dairy cattle fed acephate and methamidophos in the diet stored at -20°C; data from MRID 40504802.

Sample[a]	Storage Interval (days)	Combined residues (ppm)	Recovery (%)[b]
Eggs, shelled(2)	1	0.23, 0.23	--
	23	0.26, 0.24	104, 113
	128	<0.14,<0.13	--[c]
	181	0.23, 0.22	96, 100
Milk(3)[d]	2	0.16, 0.29, 0.91	--
	43	0.21, 0.31, 0.89	98-131
	104	0.17, 0.27, 0.73	80-106
	204	0.20, 0.29, 0.85	93-125
Kidney(3)	4	0.28, 0.68, 0.80	--
	33	0.23, 0.52, 0.65	76-82
	133	0.22, 0.51, 0.62	75-79
	175	0.20, 0.49, 0.56	70-72
Muscle(3)[d]	6	0.22, 0.39, 0.43	--
	39	0.19, 0.35, 0.44	86-102
	71	0.18, 0.35, 0.46	82-107
	195	0.20, 0.35, 0.48	90-112

[a] Number of samples in parentheses.
[b] Percent of initial combined residues.
[c] Recoveries cannot be determined; samples bore nondetectable residues of methamidophos.
[d] A fourth sample bore nondetectable initial residues of methamidophos.

Data were collected using a GLC method with NPD or FPD detection (Chevron Method RM-12A-6). The stated limits of detection for this method are 0.01 ppm for both acephate and methamidophos. However, in these studies the limits of detection were 0.01, 0.02, and 0.05 ppm for residues of acephate and 0.01 and 0.02 ppm for residues of methamidophos, depending on the day of analysis. Method recoveries for crop and animal tissues are presented in Table 5.

Table 5. Method recoveries of acephate and methamidophos from fortified crop and animal commodities; data from MRIDs 40504802, 40874102, 40874103, and 41137902.

Sample	No. of Samples	Acephate Fort.[a] (ppm)	Acephate Recovery (%)	Methamidophos Fort. (ppm)	Methamidophos Recovery (%)
Beans,					
pinto	10	0.025, 0.25	80-106	0.01, 0.1	77-92
snap	7	0.25	85-120	0.1	82-119
Brussels sprouts	5	0.25, 0.5	88-110	0.1, 0.2	84-105
Celery	6	0.25	65-104	0.1	70-95
Cottonseed	6	0.25	83-119	0.1	67-86
Grass, Bermuda					
forage	3	0.25	85-107	0.1	76-101
hay	3	0.25	94-108	0.1	90-99
Grass, pasture forage	5	0.25, 0.625	78-113	0.1, 0.25	68-106
Lettuce	5	0.25	80-102	0.1	63-105
Peppers, bell	4	0.25	93-109	0.1	70-101
Pigeon peas	6	0.25, 0.5	82-108	0.1, 0.2	62-92
Rice					
grain	5	0.25	85-99	0.1	80-99
straw	5	0.25	93-107	0.1	88-96
Spearmint					
fresh hay	3	0.25	102-108	0.1	94-109
spent hay	3	0.25	96-112	0.1	85-108
Eggs, shelled	5	0.2, 0.25	78-95	0.1	68-78
Milk, cow	4	0.125	90-104	0.05	86-89
Kidney, cow	4	0.25	85-106	0.1	65-100
Muscle, cow	4	0.25, 0.5	90-97	0.1, 0.2	81-96

[a] Fortification level.

The available data indicate that the combined residues of acephate and methamidophos are quite stable during frozen storage. The maximum frozen storage intervals of crop, egg, milk, and animal tissue samples during which the combined residues of acephate and methamidophos are stable, as determined by these storage stability studies, are presented in Table 1. No data are available depicting the stability of acephate and methamidophos residues in or on tobacco leaves, in any processed commodities, in the liver of dairy cattle, or in poultry tissues. Additional data are required.

MAGNITUDE OF THE RESIDUE IN PLANTS

The Acephate Guidance Document, dated 9/87, identifies residue chemistry data requirements for magnitude of the residue in grass and grass hay and tobacco and in the processed commodities of beans (succulent and dry) and soybeans.

In response to these requirements, Chevron Chemical Company submitted data pertaining to beans (MRID 40504805), grass (MRID 40504804), mint (40504803), soybeans and soybean processed commodities (MRIDs 40504805 and 41137903) and tobacco (MRID 40504809).

The Toxicology Branch has expressed concern over the residues of methylthioacetate (MTA), an impurity in an acephate manufacturing process, and requested that CBRS determine levels of MTA in or on acephate-treated food crops (J. Whalan, EPA Memorandum, dated 9/5/85). Accordingly, CBRS identified additional data requirements for residues of MTA in or on beans, cotton, grass and grass hay, lettuce, and peppers (W. J. Hazel, Addendum to Registration Standard, dated 9/23/85). In addition, requirements for the determination of residues in the processed commodities of cottonseed and for feeding studies were reserved. In response to these requirements, Chevron Chemical Company (1988; MRID 40504801) submitted calculations indicating that residues of MTA would not exceed 1 ppb in or on crops treated with acephate. However, no residue data were submitted; therefore MTA data requirements remain outstanding. Based on subsequent toxicology and product chemistry data submissions Toxicology Branch does not believe potential MTA residues are not of sufficient magnitude to be of concern so these data are no longer required (personal communication C. Olinger to K. Locke 1/09/92). Should the manufacturing process change at a later date which would considerably increase the amount of MTA impurity, then additional studies would be required.

Since issuance of the Guidance Document, a tolerance with regional registration has been established for the combined residues of acephate and its metabolite methamidophos in or on macadamia nuts at 0.05 ppm [40 CFR §180.108 (b)]. Data submitted (1981; MRID 00138156) in support of this tolerance were reviewed and accepted by CBTS (L. Kutney, EPA Memorandum, dated 7/8/84).

Acephate is currently registered for use on winter wheat in CO, OK, and TX under SLN registrations CO790009, OK810020, and TX810035. There is currently no tolerance for the residues of acephate of concern in or on winter wheat forage and hay. The registrant must propose a tolerance for residues of acephate and methamidophos in or on wheat forage and hay, which must be supported by appropriate residue data. Alternatively, the registrant may elect to cancel SLNs CO790009, OK810020, and TX810035.

Tolerance petitions for residues of acephate and its metabolite methamidophos are currently pending for almonds (PP#4E3043), asparagus (PP#7E3562 and PP#8E3581), avocados (PP#4E3029), blueberries (PP#4E3091), corn grain, forage, and kernels plus cobs with husks removed (PP#5F3231), grapes (PP#3E2867), peas (PP#6E3406), pineapple (PP#6E3448, PP#6E3450, PP#6H5509, and PP#6H5510), sorghum grain (PP#4G3063), sugarcane (PP#4E3106), and wheat (PP#4G3067). Of these, CBRS has recommended for the establishment of separate tolerances for the residues of acephate and methamidophos in or on avocados at 1 ppm for residues of acephate and 1 ppm for residues of methamidophos, blueberries at 8 ppm for residues of acephate and 0.3 ppm for residues of methamidophos, and grapes at 5 ppm for residues of acephate and 0.5 ppm for residues of methamidophos.

The use patterns discussed in this Reregistration Standard Update are based on the products registered by Chevron Chemical Company, Gustafson, Inc., and Valent USA Corp. When end-use product DCIs are developed (eg. at issuance of the RED), RD should require that all end-use product labels (e.g., any unamended basic producer labels, SLNs, and products covered under the generic data exemption) be amended such that they are consistent with the amended basic producer labels.

Legume Vegetables Group

Beans

Tolerance(s):

A tolerance of 3 ppm has been established for the combined residues of the insecticide O,S-dimethyl acetylphosphoramidothioate (acephate) and its cholinesterase-inhibiting metabolite, O,S-dimethyl phosphoramidothioate (methamidophos) in or on beans, of which no more than 1 ppm is O,S-dimethyl phosphoramidothioate [40 CFR §180.108].

Use directions and limitations:

The 75% SC/S formulation is registered for multiple foliar applications to beans and lima beans (dry and succulent) at 0.25-1 lb ai/A/application at 7 to 10 day intervals. Application is made in 20-100 gal/A using ground equipment or in a minimum of 2 gal/A using aerial equipment. The feeding of treated vines to livestock is prohibited. A 0-day PHI has been established for lima beans in succulent form and a 14-day PHI has been established for snap beans and dry beans. There is no maximum number of applications per season or maximum seasonal rate. These use directions were obtained from the product label of EPA Reg. No. 59639-26 submitted in response to the Product Label Data Call-In (dated 10/6/89).

Conclusions:

The Acephate Guidance Document, dated 9/87, requires data pertaining to the cooking and canning of succulent and dry beans bearing field-weathered residues. In addition, data depicting the residues of MTA in or on beans are required (W. J. Hazel, Addendum to Registration Standard, dated 9/23/85). In response to these requirements, Chevron Chemical Co. submitted data (1988; MRID 40504805) pertaining to the residues of acephate and methamidophos in or on beans and in cooked and canned beans.

The available cooking and canning data indicate that the combined residues of acephate and methamidophos in or on snap beans are reduced by cooking (ca. 0-50%) and canning (ca. 70-90%). No conclusions can be made about pinto bean residue reduction data because the raw agricultural commodity did not bear detectable residues. The available data are adequate to satisfy the specific residue reduction requirements of the Guidance Document. However, the available data are inadequate to assess the established tolerance because no data are available depicting residues of acephate and methamidophos in cannery residue processed from treated beans. In addition, the registrant must submit revised product labels which specify a maximum number of applications per season and/or a maximum seasonal application rate. No data were submitted depicting residues of MTA in or on beans. Based on subsequent toxicology and product chemistry data submissions Toxicology Branch does not believe potential MTA residues are not of sufficient magnitude to be of concern so these data are no longer required (personal communication C. Olinger to K. Locke 1/09/92). Should the manufacturing process change at a later date which would considerably increase the amount of MTA impurity, then additional studies would be required. The following additional data are required:

- The registrant(s) must submit revised product labels which specify a maximum number of applications per season and/or a maximum seasonal application rate supported by appropriate residue data. The available data support a maximum of two applications at 1 lb ai/A/application to lima beans, a maximum of three applications at 1 lb ai/A/application to succulent beans, and a maximum of six applications at 1 lb ai/A/application to dry beans.

- Data depicting the potential for concentration of acephate and methamidophos residues in cannery residue prepared from beans bearing measurable weathered residues. If residues concentrate in this feed item, an appropriate feed additive tolerance must be proposed.

References (used):

MRID(s): 40504805.

Discussion of the data:

Chevron Chemical Company submitted data (1988; 40504805) from three studies in CA, IL, and WI depicting residues of acephate and methamidophos in or on fresh, washed, cooked, and canned snap and pinto beans and in the washing, cooking, and canning water. Snap beans in WI were harvested 14 days following the second of two broadcast foliar applications of the 75% SC/S formulation at 1 lb ai/A/application (1x the maximum registered single application rate) using ground equipment. Snap beans in IL were harvested 22 days following the last of four broadcast foliar applications of the 75% SC/S at 0.75 lb ai/A/application (0.75x the maximum registered single application rate) using aerial equipment. Pinto beans in CA were harvested 14 days following the last of six broadcast foliar applications of the 75% SC/S formulation at 1 lb ai/A/application (1x the maximum registered single application rate) using ground equipment; the beans were allowed to dry in the field for 10 days. Fresh beans were rinsed then cooked for 35 minutes prior to analysis; portions of the rinse water and cooking water were analyzed. Beans were canned at a commercial cannery. Residues of acephate and methamidophos in or on snap and pinto beans after washing, cooking, or canning are presented in Table 6.

Table 6. Residues of acephate and methamidophos in or on fresh, washed, cooked, and canned snap and pinto beans and in the rinse, cooking, and canning water.

Commodity	Location of study[a]	Residues (ppm)		
		Acephate	Methamidophos	Total
Treated snap beans:				
Fresh	IL(3)[b]	0.37-0.43	0.11-0.13	0.48,0.55
	WI(4)[c]	0.19-0.39	0.09-0.15	0.28-0.54
Rinsed	IL(1)	0.39	0.12	0.51[d]
	WI(1)	0.23	0.11	0.34[e]
Cooked	IL(1)	0.20	0.07	0.27[f]
	WI(1)	0.17	0.09	0.26[g]
Canned	IL(1)	0.03	0.03	0.06[h]
	WI(1)	0.08	0.05	0.13[i]
Water:				
Rinse (before cooking)				
	IL(1)	0.05	0.01	0.06
	WI(1)	<0.01[j]	<0.005[j]	<0.02
Cooking	IL(1)	0.02	0.07	0.09
	WI(1)	0.14	0.07	0.21
Rinse (before canning)				
	IL(1)	0.01	<0.005	<0.02
Canning	IL(1)	0.02	0.02	0.04
	WI(1)	0.08	0.05	0.13
Untreated snap beans:[k]				
Fresh	WI(3)	<0.02[j]	<0.01[j]	<0.03
Rinsed	WI(1)	<0.02	<0.01	<0.03
Cooked	WI(1)	<0.02	<0.005	<0.03
Canned	WI(1)	<0.02	<0.01	<0.03
Water:				
Rinse (before cooking)				
	WI(1)	<0.01	<0.005	<0.02
Cooking	WI(1)	<0.02	<0.005	<0.03
Rinse (before canning)				
	IL(1)	<0.01	<0.005	<0.02
Canning	WI(1)	<0.02	<0.005	<0.03
Treated pinto beans:[l]				
Bean	CA(4)	<0.01	<0.01	<0.02
Rinsed	CA(1)	<0.01	<0.01	<0.02
Cooked	CA(1)	<0.01	<0.01	<0.02
Soaked and rinsed at cannery				
	CA(1)	<0.01	<0.01	<0.02
Canned	CA(1)	<0.02	<0.01	<0.02

(Continued, footnotes follow)

Table 6. Residues of acephate and methamidophos in or on fresh, washed, cooked, and canned snap and pinto beans and in the washing, cooking, and canning water (continued).

Commodity	Location of study[a]	Residues, ppm	
		Acephate	Methamidophos
Treated pinto beans:[l]			
Water:			
Rinse (before cooking)	CA(1)	<0.01	<0.01 <0.02
Cooking	CA(1)	<0.01	<0.01 <0.02
Canning	CA(1)	<0.01	<0.01 <0.02
Untreated pinto beans:			
Bean	CA(2)	<0.01-0.02	<0.01 <0.02-<0.03
Rinsed	CA(1)	<0.01	<0.01 <0.02
Cooked	CA(1)	<0.01	<0.01 <0.02
Soaked and rinsed at cannery	CA(1)	<0.01	<0.01 <0.02
Canned	CA(1)	<0.02	<0.01 <0.02
Water:			
Rinse (before cooking)	CA(1)	<0.01	<0.01 <0.02
Cooking	CA(1)	0.01	<0.01 <0.02
Canning	CA(1)	<0.01	<0.01 <0.02

[a] Number of samples in parentheses.
[b] Beans in IL were harvested 22 days following the last of four broadcast foliar applications of the 75% SC/S formulation at 0.75 lb ai/A/application (0.75x the maximum registered single application rate) using aerial equipment.
[c] Beans in WI were harvested 14 days following the second of two broadcast foliar applications of the 75% SC/S formulation at 1 lb ai/A/application (1x the maximum registered single application rate) using ground equipment.
[d] Reducing ca. 7%.
[e] Not reduced.
[f] Reducing ca. 50%.
[g] Reducing ca. 7%.
[h] Reducing ca. 90%.
[i] Reducing ca. 70%.
[j] Not detected.
[k] No control samples from IL were analyzed.
[l] Beans in CA were harvested 14 days following the last of six broadcast foliar applications of the 75% SC/S formulation at 1 lb ai/A/application (1x the maximum registered single application rate) using ground equipment; the beans were allowed to dry in the field for 10 days.

Data were collected using a GLC method with NPD or FPD detection (Chevron method RM-12A-6). The limits of detection were 0.01 and 0.02 ppm for residues of acephate and 0.01 ppm for residues of methamidophos. Method recoveries are presented in Table 7. Samples were stored at ca. -20°C for 8-105 days prior to analysis by Chevron. These data are supported by adequate storage stability data.

Table 7. Method recoveries of acephate and methamidophos from samples of fresh, cooked, and canned snap and pinto beans and rinse, canning, and cooking water fortified with acephate and methamidophos.

	Acephate		Methamidophos	
Commodity	Fortification (ppm)	Recovery (%)	Fortification (ppm)	Recovery (%)
Snap beans	0.25	97	0.1	92
Snap beans	0.25	102	0.1	94
Cooked snap beans	0.25	104	0.1	100
Canned snap beans	0.25	109	0.1	101
Rinse water	0.13	120	0.05	114
Rinse water (before canning)	0.13	86	0.05	86
Canning water	0.13	116	0.05	112
Pinto beans	0.25	104	0.1	91
Cooked pinto beans	0.25	90	0.1	76
Cooking water	0.13	95	0.05	91

The available cooking and canning data indicate that the combined residues of acephate and methamidophos in or on snap beans are reduced by cooking (ca. 0-50%) and canning (ca. 70-90%). No conclusions can be made about pinto bean residue reduction data because the raw agricultural commodity did not bear detectable residues. The available data are adequate to satisfy the specific residue reduction requirements of the Guidance Document. However, the available data are inadequate to assess the established tolerance because no data are available depicting residues of acephate and methamidophos in cannery residue processed from treated beans. In addition, the registrant must submit revised product labels which specify a maximum number of applications per season and/or a maximum seasonal application rate. Additional data are required.

Soybeans

Tolerance(s):

Tolerances of 1 ppm and 4 ppm have been established for the combined residues of the insecticide O,S-dimethyl acetylphosphoramidothioate (acephate) and its cholinesterase-inhibiting metabolite, O,S-dimethyl phosphoramidothioate (methamidophos) in or on soybeans and soybean meal, respectively [40 CFR §180.108 and 40 CFR §186.100].

Use directions and limitations:

The 75% SC/S formulation is registered for multiple foliar applications to soybeans at 0.25-1 lb ai/A/application in 10-50 gal/A using ground equipment or 2-10/A gal using aerial equipment. The grazing of livestock or cutting of vines for hay or forage is prohibited. A 14-day PHI is in effect. There is no maximum number of applications per season or maximum seasonal rate. These use directions were obtained from the product label for EPA Reg. No. 59639-26 submitted in response to the Product Label Data Call-In (dated 10/6/89).

The 75% SC/S formulation is also registered for planter box seed treatment of soybeans at 0.5 lb ai/A under an SLN registration in MS (MS820023).

Conclusions:

The Acephate Guidance Document, dated 9/87, requires data depicting residues of acephate and methamidophos in crude oil, refined oil, and defatted flour processed from soybeans containing field-weathered residues. In response to these requirements, Chevron Chemical Company submitted data (1988 and 1989; MRIDs 40504805 and 41137903) depicting residues of acephate and methamidophos in or on soybeans and in the processed commodities of soybeans.

The available field data indicate that the combined residues of acephate and methamidophos will not exceed the established tolerance in or on soybeans harvested 13 and 14 days following the last of three applications of the 75% SC/S formulation at 1 or 2 lb ai/A/application (1 or 2x the maximum registered single application rate) using ground equipment. The registrant(s) must submit revised product labels specifying a maximum number of applications per season and/or a maximum seasonal application rate.

The available processing data indicate that the combined residues of acephate and methamidophos do not concentrate in full fat flour, defatted flour, crude oil, degummed oil, refined oil, crude lecithin, and soapstock. The data also indicate that

residues of acephate and methamidophos concentrate in hulls, up to 8x, and in soybean meal, up to 1.5x. The registrant must propose a tolerance for residues of acephate and methamidophos in soybean hulls. In addition, no data are available pertaining to acephate and methamidophos residues in soybean grain dust.

The following additional data are required:

- The registrant(s) must submit revised product labels which specify a maximum number of applications per season and/or a maximum seasonal application rate supported by appropriate residue data. The available data support a maximum of three applications at 1 lb ai/A/application per season.

- A processing study depicting the potential for concentration of residues of acephate and methamidophos in grain dust processed from soybeans bearing measurable, weathered residues. If residues concentrate in this item, an appropriate feed additive tolerance must be proposed.

- The registrant(s) must propose a feed additive tolerance for the combined residues of acephate and methamidophos in soybean hulls.

References (used):

MRID(s): 40504805. 41137903.

Discussion of the data:

Chevron Chemical Company submitted data (1988; MRID 40504805) from two field studies conducted in MS in 1978 and 1987. Soybeans were harvested 13-22 days following the last of three broadcast foliar applications of the 75% SC/S formulation at 1 or 2 lb ai/A/application (1 or 2x the maximum registered single application rate) using ground equipment. Residues of acephate and methamidophos are presented in Table 8.

Table 8. Residues of acephate and methamidophos in or on soybeans treated with three applications of the 75% SC/S formulation.

Application rate (lb ai/A)	PHI (days)	Residues (ppm)		
		Acephate	Methamidophos	Total
Treated soybeans:[a]				
1	13	0.04	<0.01[b]	<0.05
1	14	<0.02[b]	<0.01	<0.03
1	21	<0.02	<0.01	<0.03
2	13	0.12,0.17	<0.01	<0.13,<0.18
2	21	<0.02	<0.01	<0.03
Untreated soybeans:[c]				
--	--	<0.02	<0.01	<0.03

[a] Two samples of soybeans at each treatment level and PHI.
[b] Not detected.
[c] Three samples of untreated soybeans.

Data were collected using GLC methods with NPD or FPD detection (Chevron methods RM-12A-5 and RM-12A-6). The limits of detection were 0.02 ppm for residues of acephate and 0.01 ppm for residues of methamidophos. Recoveries of acephate were 99% and 103% from two samples fortified with 0.25 ppm. Recoveries of methamidophos were 74% and 90% from two samples fortified with 0.1 ppm. Samples were stored frozen (ca. -20°C) for 13-367 days prior to analysis by Chevron. These data are supported by adequate storage stability data.

The available field data indicate that the combined residues of acephate and methamidophos will not exceed the established tolerance in or on soybeans harvested 13 and 14 days following the last of three applications of the 75% SC/S formulation at 1 or 2 lb ai/A/application (1 or 2x the maximum registered single application rate) using ground equipment.

The same submission also contained data pertaining to a soybean processing study conducted in 1978. Soybeans were harvested 14 and 22 days following the last of three broadcast foliar applications of the 75% SC/S formulation at 1 or 2 lb ai/A/application (1 or 2x the maximum registered single application rate) using ground equipment and processed (using an unspecified procedure) into meal, crude oil, and hulls. Residues of acephate and methamidophos are presented in Table 9.

Table 9. Residues of acephate and methamidophos in or on soybeans and in meal, crude oil, and hulls processed from soybeans treated with three applications of the 75% SC/S formulation.

Commodity	Application rate (lb ai/A)	PHI (days)	Residues (ppm) Acephate	Methamidophos	Total
Treated:[a]					
Soybeans	1	14	0.02,0.03	0.01,0.02	0.03,0.05
	1	22	<0.02[b],0.02	0.01	<0.03,0.03
	2	14	0.09,0.13	0.06	0.15,0.19
	2	22	0.04,0.05	0.03	0.07,0.08
Soybean meal	1	14	0.02,0.04	0.02,0.03	0.04,0.07[c]
	1	22	<0.02	0.01	<0.03
	2	14	0.03,0.04	0.05	0.08,0.09
	2	22	0.02,0.05	0.04,0.05	0.06,0.10
Crude oil	1	14	<0.02	<0.01[b]	<0.03
	1	22	<0.02	<0.01	<0.03
	2	14	<0.02	<0.01	<0.03
	2	22	<0.02,0.03	<0.01	<0.03,<0.04
Hulls	1	14	0.19,0.33	0.04,0.05	0.23,0.38[d]
	1	22	0.04	0.01	0.05[e]
	2	14	0.46,0.77	0.11,0.14	0.57,0.91[f]
	2	22	0.18,0.19	0.05	0.23,0.24[g]
Untreated:[h]					
Soybeans	--	--	<0.02	<0.01	<0.03
Soybean meal	--	--	<0.02	<0.01	<0.03
Crude oil	--	--	<0.02	<0.01	<0.03
Hulls	--	--	0.03	<0.01	<0.04

[a] Two samples of each commodity at each treatment level and PHI.
[b] Not detected.
[c] Concentrating ca. 1.5x. [d] Concentrating ca. 8x.
[e] Concentrating ca. 2x. [f] Concentrating ca. 4.5x.
[g] Concentrating ca. 3x. [h] Two untreated samples of each commodity.

Data were collected using GLC methods with NPD or FPD detection (Chevron methods RM-12A-5 and RM-12A-6). The limits of detection were 0.02 ppm for residues of acephate and 0.01 ppm for residues of methamidophos. Recoveries were: (i) 68% from one sample of soybeans, 78% from one sample of soybean meal, and 90% from one sample of crude oil fortified with 0.25 ppm acephate; (ii) 98% from one sample of hulls fortified with 0.5 ppm acephate; (iii) 66% from one sample of soybeans, 80% from one sample of soybean meal, and 82% from one sample of crude oil fortified with 0.1 ppm methamidophos; and (iv) 91% from one sample of hulls fortified with 0.2 ppm methamidophos. Samples

were stored frozen (ca. -20°C) for 593-602 days prior to analysis by Chevron. No data depicting the stability of the processed commodities of soybean during frozen storage are available.

Chevron Chemical Company also submitted data (1989; MRID 41137903) from a processing study conducted in 1987. Three treated and two untreated samples of soybeans were harvested seven days following the last of 11 broadcast foliar applications of the 75% SC/S formulation at 2 lb ai/A/application (2x the maximum registered single application rate) using ground equipment. Two treated samples and one untreated sample were sent for analysis; one treated and one untreated sample were sent to the Seed Fractionation Laboratory at Texas A & M University for processing according to commercial practices. Residues of acephate and methamidophos in the processed commodities of acephate treated soybeans are presented in Table 10. Apparent residues of acephate and methamidophos were <0.02(ND) ppm and <0.01(ND) ppm, respectively, in or on three samples of untreated soybeans and one sample each of hulls, full fat flour, meal, crude oil, degummed oil, crude lecithin, refined oil, and defatted flour processed from untreated soybeans.

Table 10. Residues of acephate and methamidophos in the processed commodities of soybeans harvested seven days following the last of 11 applications of the 75% SC/S formulation at 2 lb ai/A/application.

Commodity	No. of samples	Residues (ppm)		
		Acephate	Methamidophos	Total
Soybeans from field	2	0.03,0.04	0.01,0.02	0.04,0.06
Soybeans before processing	1	0.03	0.013[a]	0.043
Meal	1	<0.02	0.02	<0.04
Full fat flour	1	0.02	0.01	0.03
Defatted flour	1	<0.02	0.01	<0.03
Crude oil	1	<0.02	<0.01	<0.03
Degummed oil	1	<0.02	<0.01	<0.03
Refined oil	1	<0.02	<0.01	<0.03
Crude lecithin	1	<0.02	<0.01	<0.03
Hulls	1	0.08	0.02	0.10[b]
Soapstock	1	<0.02	<0.01	<0.03

[a] Average of three determinations at 0.01, 0.01, and 0.02 ppm.
[b] Concentrating ca. 2x.

Data were collected using a GLC method with NPD or FPD detection (Chevron Method RM-12A-6). The detection limits were 0.02 ppm

for acephate and 0.01 ppm for methamidophos. Method recoveries are presented in Table 11.

Table 11. Method recoveries of acephate and methamidophos from samples of soybeans and soybean processed commodities fortified with acephate and methamidophos.

	Acephate		Methamidophos	
Commodity[a]	Fortification (ppm)	Recovery (%)	Fortification (ppm)	Recovery (%)
Soybeans(1)	0.02	78	0.01	62
Soybeans(4)	0.25	73-82	0.1	70-81
Meal(1)	0.25	83	0.1	79
Full fat flour(1)	0.25	73	0.1	74
Defatted flour(1)	0.25	74	0.1	70
Crude oil(1)	0.25	96	0.1	96
Degummed oil(1)	0.25	96	0.1	91
Refined oil(1)	0.25	88	0.1	82
Crude lecithin(1)	0.63	88	0.1	86
Hulls(1)	0.25	90	0.1	89
Soapstock(2)	0.25	96,104	0.1	104,113

[a] Number of samples in parentheses.

The available processing data indicate that the combined residues of acephate and methamidophos do not concentrate in full fat flour, defatted flour, crude oil, degummed oil, refined oil, crude lecithin, and soapstock. The data also indicate that residues of acephate and methamidophos concentrate in hulls, up to 8x, and in soybean meal, up to 1.5x. The registrant must propose a tolerance for residues of acephate and methamidophos in soybean hulls. In addition, no data are available pertaining to acephate and methamidophos residues in soybean grain dust. Additional data are required.

Grass Forage, Fodder, and Hay Group

Pasture and Rangeland Grasses

Tolerance(s):

A tolerance of 15 ppm has been established for the combined residues of the insecticide O,S-dimethyl acetylphosphoramidothioate (acephate) and its cholinesterase-inhibiting metabolite, O,S-dimethyl phosphoramidothioate (methamidophos) in or on grass forage and grass hay [40 CFR §180.108 and 40 CFR §186.100].

Use directions and limitations:

The 97% SC/L and the 75% SC/S formulations are registered for application to pasture and rangeland grass at 0.094-0.125 lb ai/A in a minimum of 0.5 gal/A using aerial equipment or, for the 75% SC/S only, in 10-20 gal/A using ground equipment. No more than one application per season may be made.

The 75% SC/S formulation is also registered for application to pasture and rangeland grass at 0.188 lb ai/A in CO only under SLN registration CO790009 and at 0.125 to 0.25 lb ai/A in NM, OK, and TX only under SLN registrations NM800010, OK810020, and TX810035. Application is made in 0.5 gal/A using aerial equipment. There is no maximum number of applications per season or maximum seasonal rate.

The 75% SC/S is registered for application to fire ant mounds in pasture and rangeland grass in AR only under SLN AR840013 and to harvester ant mounds in OK only under SLN OK890004. Treatment in AR is made at 0.005-0.01 lb ai dry over the mound or 0.01 lb ai/gal/mound (drench) with a maximum treatment of 13 mounds per acre (0.13 lb ai/A). Treatment in OK is made at 0.06 lb ai dry over the mound or 0.06 lb ai/gal/mound (drench) with a maximum treatment of 13 mounds per acre (0.78 lb ai/A) and one treatment per season.

The following restrictions apply to all methods of treatment: A 21-day PHI has been established for grass forage cut for hay. Application when lactating dairy cattle are present is prohibited. The pasturing of or feeding of treated hay to lactating dairy cattle within 21 days after application is prohibited. If meat animals were present at application or grazed treated areas within 21 days after application, they must be removed from treated areas at least one day before slaughter.

These use directions were obtained from the product labels of EPA Reg. Nos. 59639-26 and 59639-30 submitted in response to the Product Label Data Call-In (dated 10/6/89) and from the SLN labels.

Conclusions:

The Acephate Guidance Document, dated 9/87, states that the established tolerance for residues of acephate in milk are likely to be exceeded if maximum levels of grass hay are included in the dairy animal diet; therefore, the registrant(s) must either propose a lower tolerance, establish a feeding/grazing restriction for grass forage and grass hay to dairy animals, or amend product labels to specify pregrazing and preharvest intervals longer than 21 days. Appropriate residue data must be submitted to support either of these actions. In addition, data are required depicting residues of MTA in or on grass forage and grass hay (W. J. Hazel, Addendum to Registration Standard, dated 9/23/85). Based on subsequent toxicology and product chemistry data submissions Toxicology Branch does not believe potential MTA residues are not of sufficient magnitude to be of concern so these data are no longer required (personal communication C. Olinger to K. Locke 1/09/92). Should the manufacturing process change at a later date which would considerably increase the amount of MTA impurity, then additional studies would be required.

In response to these requirements, Chevron Chemical Co. submitted data (1987; MRID 40504804) pertaining to residues of acephate and methamidophos in or on grass forage and grass hay. The available data indicate the established tolerance for the combined residues of acephate and methamidophos will not be exceeded in or on grass forage harvested at 0-day or grass hay harvested at 21-days following a single application of the 75% SC/S formulation at 0.125 lb ai/A. These data (acephate data only) were also reviewed by CBRS (F.B. Suhre, EPA Memorandum CBRS No. 4419, dated 1/12/89) for dietary assessment of acephate, the reviewer stated that the registrant has requested the establishment of a 7 day feeding/grazing restriction for treated grass forage. The available data indicate that the combined residues of acephate and methamidophos will be 8.05 ppm and 10.6 ppm in or on grass forage and grass hay harvested 7 days following a single application of the 75% SC/S formulation at 0.125 lb ai/A. However, the available data are inadequate for reregistration because of the following: (i) no data were submitted representing geographic areas of production in the northeastern, southeastern, and western regions of the U.S.; and (ii) no data were submitted reflecting application of acephate to ant mounds in pastures and rangeland.

The following additional data are required:

- The registrant may propose a lower tolerance for the combined residues of acephate and methamidophos in or on grass forage and grass hay, and amend product labels to increase the established PHI. Tolerance and product label amendments must be supported by the following data.

Data depicting residues of concern in or on Bermuda grass and bromegrass (or fescue) forage and hay harvested at the proposed PHI and pregrazing/feeding interval following a single application of the 75% SC/S formulation at 0.125 lb ai/A. Applications must be made using ground and aerial equipment. (Aerial data are not required if label specifies application with more than 2 gal. spray solution/A.) Tests must be conducted in the major pasture and rangeland growing regions of the U.S.

- Data depicting residues of acephate and methamidophos in or on Bermuda grass and bromegrass (or fescue) forage and hay following treatment of 13 ant mounds/A in AR and OK with the SC/S formulation at 0.06 lb ai/mound. Tests must reflect dry and drench applications. Alternately, the registrant may cancel these SLNs (AR840013 and OK890004).

- The registrant must amend SLN labels AR840013, CO790009, NM800010, OK810020, and TX810035 to specify that no more than one application per season may be made. In addition, all SLN labels must be amended to include a 21-day PHI for grass hay for all livestock.

References (used):

MRID(s): 40504804.

Discussion of the data:

Chevron Chemical Company submitted data (1987; MRID 40504804) from two field studies conducted in OK and TX pertaining to residues of acephate and methamidophos in or on Bermuda grass forage and hay. Samples of Bermuda grass forage were harvested 0-21 days following a single broadcast foliar application of the 75% SC/S formulation at 0.125 lb ai/A; hay samples were obtained by allowing grass samples to dry for one or two days in the field. Residues of acephate and methamidophos are presented in Table 12.

Table 12. Residues of acephate and methamidophos in or on Bermuda grass forage and hay treated with a single application of the 75% SC/S formulation at 0.125 lb ai/A.

Commodity	PHI (days)	Residues (ppm)		
		Acephate	Methamidophos	Total
Treated:[a]				
Forage	0	6.50-14.5	0.32-0.48	6.82-15.0
	1	0.62-13.9	0.11-0.59	0.73-14.5
	3	0.42-8.93	0.10-0.69	0.52-9.62
	7	0.05-7.38	0.02-0.69	0.07-8.05
	14	<0.02[b]-9.42	<0.01[b]-0.72	<0.03-10.1
	21	<0.02-1.50	<0.01-0.27	<0.03-1.76
Hay	0	9.47-14.8	0.31-1.06	10.4-15.1[c]
	1	1.88-13.9	0.31-0.44	2.19-14.2
	3	0.84-10.9	0.23-0.35	1.07-11.3
	7	0.12-10.2	0.04-0.35	0.16-10.6
	14	0.02-8.82	<0.01-0.47	<0.03-9.29
	21	<0.02-3.95	<0.01-0.72	<0.03-4.67
Untreated:[d]				
Forage	--	<0.02-0.26	<0.01,0.01	<0.03-0.27
Hay	--	<0.02-0.13	<0.01	<0.03-<0.14

[a] Four samples of each commodity at each PHI.
[b] Not detected.
[c] Includes one sample bearing tolerance-exceeding combined residues of 15.1 ppm.
[d] Four samples of each commodity.

Data were collected using a GLC method with NPD or FPD detection (Chevron method RM-12A-6). The detection limits were 0.02 ppm and 0.01 ppm for residues of acephate and methamidophos, respectively. Method recoveries are presented in Table 13. Samples were stored frozen (ca. -20°C) for 72-121 days prior to analysis by Chevron. These data are adequately supported by storage stability data.

Table 13. Method recoveries of acephate and methamidophos from Bermuda grass forage and hay samples fortified with acephate and methamidophos.

Commodity[a]	Acephate Fortification (ppm)	Acephate Recovery (%)	Methamidophos Fortification (ppm)	Methamidophos Recovery (%)
Forage(2)	0.25	85,109	0.1	77,99
Hay(2)	0.25	97,108	0.1	87,99

[a] Number of samples in parentheses.

Geographic representation is inadequate since the test states of OK(3%) and TX(4%) plus the surrounding states of AR(1%), CO(3%), KS(4%), LA(1%), and NM(1%) only accounted for ca. 20% of the 1988 U.S. production of hay. The available data indicate the established tolerance for the combined residues of acephate and methamidophos will not be exceeded in or on grass forage harvested at 0-day or grass hay harvested at 21-days following a single application of the 75% SC/S formulation at 0.125 lb ai/A. These data (acephate data only) were also reviewed by CBRS (F.B. Suhre, EPA Memorandum CBRS No. 4419, dated 1/12/89) for dietary assessment for acephate, the reviewer stated that the registrant has requested the establishment of a 7 day feeding/grazing restriction for treated grass forage. The available data indicate that the combined residues of acephate and methamidophos will be 8.05 ppm and 10.6 ppm in or on grass forage and grass hay harvested 7 days following a single application of the 75% SC/S formulation at 0.125 lb ai/A. However, the available data are inadequate for reregistration because of the following: (i) no data were submitted representing geographic areas of production in the northeastern, southeastern, and western regions of the U.S.; (ii) no data were submitted reflecting application of acephate to ant mounds in pastures and rangeland. Additional data are required.

Miscellaneous Commodities

Mint

Tolerance(s):

A tolerance of 15 ppm has been established for the combined residues of the insecticide O,S-dimethyl acetylphosphoramidothioate (acephate) and its cholinesterase-inhibiting metabolite, O,S-dimethyl phosphoramidothioate (methamidophos) in or on mint hay, of which no more than 1 ppm is O,S-dimethyl phosphoramidothioate [40 CFR §180.108].

Use directions and limitations:

The 75% SC/S formulation is registered for up to two applications to peppermint and spearmint at 1 lb ai/A/application. Application is made in 5-10 gal/A using aerial equipment or 20-100 gal/A using ground equipment. A 14-day PHI is in effect. These use directions were obtained from the product label of EPA Reg. No. 59639-26 submitted in response to the Product Label Data Call-In (dated 10/6/89).

Conclusions:

The Acephate Guidance Document, dated 9/87, concludes that the available data support the established tolerance for residues of acephate and methamidophos in or on mint hay. However, the Guidance Document concludes that acephate residues in milk are likely to exceed the established tolerance if maximum levels of spent mint hay are included in the dairy animal diet and requires that a restriction against the feeding of spent mint hay to dairy cattle be established.

Chevron Chemical Company submitted data (1987; 40504803) depicting residues of acephate and methamidophos in or on fresh mint hay and in spent mint hay and mint oil. Pending the submission of adequate storage stability data, the available processing data indicate that residues of acephate and methamidophos do not concentrate in spent hay or mint oil. However, the available field data indicate that the established tolerance may be too low. Residues exceeded the tolerance (up to 27.8 ppm) in or on two fresh hay samples harvested 14 days following a single application of the 75% SC/S formulation at 1 lb ai/A (0.5x the maximum registered seasonal application rate) using aerial equipment. These data (acephate data only) were also reviewed by CBRS (F.B. Suhre, EPA Memorandum CBRS No. 4419, dated 1/12/89) for dietary assessment for acephate, the reviewer stated that the registrant has requested that the feeding restriction for spent mint hay (treated with acephate) be reconsidered by the Agency. Upon submission of adequate storage stability data for spent mint hay and field data for mint hay, the need for a feeding restriction for spent mint hay will be reconsidered. The following additional data are required:

- The registrant must propose label restrictions lengthening the PHI, reducing the maximum number of foliar applications per growing season or the maximum seasonal rate, and/or reducing the maximum registered single application rate, which must be efficacious, and submit data depicting residues of concern at the proposed PHI using the proposed number of applications of the 75% SC/S formulation at the proposed maximum single application rate. The tests must be conducted using ground and aerial equipment in OR(53%) and WA(26%),

accounting for ca. 80% of the 1988 U.S. production of peppermint. Alternately, the registrant may amend product labels limiting the method of application to ground equipment only.

References (used):

MRID(s): 40504803.

Discussion of the data:

Chevron Chemical Company submitted data (1987; MRID 40504803) from four field studies conducted in OR(2) and WA(2) depicting residues of acephate and methamidophos in or on fresh peppermint and spearmint hay. A processing study was included in the submission in which residues of acephate and methamidophos were determined in spent hay and mint oil. Hay samples were harvested 14 days following a single broadcast foliar application of the 75% SC/S formulation at 1 lb ai/A (0.5x the maximum registered seasonal application rate) using ground and aerial equipment. Hay samples were distilled to obtain spent hay and mint oil samples. Residues of acephate and methamidophos are presented in Table 14.

Table 14. Residues of acephate and methamidophos in or on mint hay and in the processed commodities of mint hay harvested 14 days following a single application of the 75% SC/S formulation at 1 lb ai/A.

Commodity[a]	Method of application	Residues (ppm)		
		Acephate	Methamidophos	Total
Treated:				
Fresh hay(2)	ground	6.85,7.36	0.49,0.54	7.39,7.85
Spent hay(2)	ground	2.81,2.91	0.33,0.36	3.17,3.24
Fresh hay(6)	aerial	0.57-26.2	0.07-1.62	0.64-27.8[b]
Spent hay(6)	aerial	0.03-3.98	0.03-0.77	0.06-4.75
Oil(2)	aerial	<0.02[c]	<0.01[c]	<0.03
Untreated:				
Fresh hay(4)	--	<0.02-0.13	<0.01-0.02	<0.03-0.15
Spent hay(4)	--	<0.02-0.40	<0.01-0.15	<0.03-0.55
Oil(2)	--	<0.02	<0.01	<0.03

[a] Number of samples in parentheses.
[b] Includes two samples bearing tolerance exceeding combined residues of 20.8 and 27.8 ppm.
[c] Not detected.

Data were collected using a GLC method with NPD or FPD detection (Chevron method RM-12A-6). The detection limits were 0.02 and 0.01 ppm for residues of acephate and methamidophos, respectively. Recoveries of acephate from samples fortified with 0.25 ppm of acephate were: (i) 112 and 128% from two fresh hay samples; (ii) 108 and 110% from two spent hay samples; and (iii) 84% from one oil sample. Recoveries of methamidophos from samples fortified with 0.1 ppm of methamidophos were: (i) 108 and 124% from two fresh hay samples; (ii) 109 and 114% from two spent hay samples; and (iii) 77% from one oil sample. Samples were stored frozen (ca. -20°C) for 42-115 days prior to analysis by Chevron. The fresh and spent hay data are adequately supported by storage stability data; no data are available depicting the stability of acephate and methamidophos residues in mint oil.

Geographic representation is adequate since the test states of OR(53%) and WA(26%) accounted for ca. 80% of the 1988 U.S. production of peppermint and OR(6%) and WA(72%) accounted for ca. 80% of the production of spearmint. Pending the submission of adequate storage stability data, the available processing data indicate that residues of acephate and methamidophos do not concentrate in spent hay or mint oil. However, the available field data indicate that the established tolerance may be too low. Residues exceeded the tolerance (up to 27.8 ppm) in or on two fresh hay samples harvested 14 days following a single application of the 75% SC/S formulation at 1 lb ai/A (0.5x the maximum registered seasonal application rate) using aerial equipment. Additional data are required.

Peanuts

Conclusions:

The Acephate Guidance Document, dated 9/87, concludes that the available data are adequate to assess the established tolerances for residues of acephate and methamidophos in or on peanuts and peanut hulls. However, Agency interpretation of existing guidelines has become more strict in recent years. The available processing study is no longer adequate to determine the potential for concentration of acephate residues of concern because only one sample of the seven peanut samples which were processed bore detectable residues. The following additional data are required:

- A processing study depicting the potential for concentration of acephate residues of concern in meal, soapstock, crude oil, and refined oil processed from peanuts bearing measurable, weathered residues. If residues concentrate in any product, appropriate food/feed additive tolerances must be proposed.

References (used):

N/A.

Discussion of the data:

N/A.

Tobacco

Tolerance(s):

No tolerances have been established for residues of acephate and its metabolite methamidophos in or on tobacco.

Use directions and limitations:

The 75% SC/S formulation is registered for the following methods of application: (i) transplant water application to tobacco at 0.75 lb ai/A in a minimum of 100 gal/A; (ii) multiple foliar applications to flue-cured, air-cured, and dark fire-cured tobacco at 0.25-0.75 lb ai/A/application at seven day intervals in 10-50 gal/A using ground equipment or in a minimum of 3 gal/A using aerial equipment; (iii) plant bed application at 0.75 lb ai/A; and (iv) a single soil application for removal of fire ants at 0.01-0.02 lb ai (dry) over the mound or 0.01 lb ai/gal/mound with a maximum of 13 mounds per acre (0.26 lb ai/A). A 3-day PHI is in effect. There is no maximum number of applications per season and/or maximum seasonal application rate. These use directions were obtained from the product label for EPA Reg. No. 59639-37 submitted in response to the Product Label Data Call-In (dated 10/6/89).

The 75% SC/S formulation is also registered under SLN registration TN870014 for a transplant water application to burley tobacco in TN only at 1.5 lb ai/A in a minimum of 200 gal/A.

Conclusions:

The Acephate Guidance Document, dated 9/87, requires data depicting residues of acephate and methamidophos in or on tobacco following aerial applications of acephate. In response to these requirements, Chevron Chemical Co. submitted data (1987; MRID 40504809) pertaining to residues of acephate and methamidophos in or on tobacco following treatment with the 75% SC/S formulation using aerial equipment. The available data indicate that combined residues of acephate and methamidophos will exceed 0.1 ppm in or on green and cured tobacco leaves. Therefore, data depicting the pyrolysis products of acephate in smoke are required. In addition, the registrant must submit revised product labels which specify a maximum number of applications per season and/or a maximum seasonal rate.

The following additional data are required:

- The pyrolysis products of acephate must be characterized and the level of the residue in smoke must be quantified. Tobacco leaves fortified with [^{14}C]acephate must be used for the pyrolysis studies.

- The registrant must submit revised product labels which specify a maximum number of foliar applications per season and/or a maximum seasonal application rate.

References (used):

MRID(s): 40504809.

Discussion of the data:

Chevron Chemical Company submitted data (1987; 40504809) from two field studies in KY and NC depicting residues of acephate and methamidophos in or on the green leaves and cured leaves of tobacco. Tobacco leaves were harvested 3 and 6 days following the last of a single transplant application of the 75% SC/S formulation at 0.75 lb ai/A (1x the maximum registered application rate) and five or seven foliar applications of the same formulation at 0.75 lb ai/A/application (1x the maximum registered single application rate) using aerial equipment. Tobacco leaves in KY were cured for 50 days in a barn; tobacco leaves in NC were cured for seven days at 32-71 C. Residues of acephate and methamidophos are presented in Table 15.

Table 15. Residues of acephate and methamidophos in or on green and cured tobacco leaves following a single transplant application at 0.75 lb ai/A and multiple broadcast foliar applications at 0.75 lb ai/A/application using aerial equipment.

Commodity	Location of study	Residues (ppm)		
		Acephate	Methamidophos	Total
Treated:[a]				
Green leaves	KY[b]	2.76,2.99	0.97,0.98	3.73,3.97
	NC[c]	18.5,19.2	2.58,2.72	21.1,21.9
Cured leaves	KY	0.08,0.09	2.45,2.48	2.53,2.57
	NC	<0.02[d]	0.18,0.22	<0.20,<0.24
Untreated:[e]				
Green leaves		<0.02	<0.01[d]	<0.03
Cured leaves		<0.02	<0.01	<0.03

[a] Two samples of each commodity at each location.
[b] Tobacco samples in KY were harvested 6 days after the last of a single transplant application and five foliar applications; leaves were cured for 50 days at ambient temperatures.
[c] Tobacco samples in NC were harvested 3 days after the last of a single transplant application and seven foliar applications; leaves were cured for 7 days at elevated temperatures.
[d] Not detected.
[e] Two samples of each commodity.

Data were collected using a GLC method with NPD or FPD detection (Chevron method RM-12A-6). The detection limits were 0.02 and 0.01 ppm for residues of acephate and methamidophos, respectively. Recoveries were 72 and 102% from two samples of green leaves and 77 and 79% from two samples of cured leaves fortified with 0.25 ppm of acephate. Recoveries were 79 and 91% from two samples of green leaves and 80% from one sample of cured leaves fortified with 0.1 ppm of methamidophos. Samples were stored frozen (ca. -20°C) for 27-69 days prior to analysis by Chevron. No data are available depicting the storage stability of residues of acephate and methamidophos in or on tobacco leaves.

Geographic representation is adequate since the test states of KY(26%) and NC(40%) accounted for ca. 70% of the 1988 U.S. production of tobacco (Agricultural Statistics Board, NASS, USDA Crop Database, Aug. 1989). The available data indicate that combined residues of acephate and methamidophos will exceed 0.1 ppm in or on green and cured tobacco leaves. Additional data are required.

Crops Grown For Seed Only

Radishes

Conclusions:

There are currently no established tolerances for residues of acephate and methamidophos in or on radishes. Acephate is registered for use on radishes grown for seed in OR and WA under SLN registrations OR830040 and WA810064; the use directions are identical. The WA registration was reviewed by CBRS (R. Loranger, EPA Memorandum, dated 12/22/83); it was concluded that this use is not a non-food use since application may occur early in the season when radishes would still be harvestable for human consumption. Therefore, the registrant must submit data reflecting residues of acephate and methamidophos in or on radishes grown for seed following treatment with acephate. The following data are required:

- Data depicting residues of acephate and methamidophos following multiple broadcast applications of an SC/S formulation at 1 lb ai/A/application before peak bloom period. Tests must be conducted in OR and WA since this use is limited to OR and WA. Alternatively, the registrant may elect to cancel SLN registrations OR830040 and WA810064.

References (used):

N/A.

Discussion of the data:

N/A.

MAGNITUDE OF THE RESIDUE IN ANIMALS

Milk and the Fat, Meat, and Meat Byproducts of Cattle, Goats, Hogs, Horses, and Sheep

Tolerance(s):

Tolerances of 0.1 ppm have been established for the combined residues of the insecticide O,S-dimethyl acetylphosphor-amidothioate (acephate) and its cholinesterase-inhibiting metabolite, O,S-dimethyl phosphoramidothioate (methamidophos) in milk, and the fat, meat, and meat byproducts of cattle, goats, hogs, horses, and sheep [40 CFR §180.108].

Conclusions:

The Acephate Guidance Document, dated 9/87, required a dairy cattle feeding study in which cattle are fed acephate and methamidophos, at a ratio of ca. 5:1, in the diet at a level high enough to result in detectable residues in milk. The data requirement stated that residues of acephate and methamidophos must be determined in whole raw milk, pasteurized milk, and in nonfat milk solids, milk fat solids, and milk sugar.

In response to these requirements, Chevron Chemical Company submitted data (1987; MRID 40504806) depicting residues of acephate and methamidophos in the milk, fat, kidney, liver, and muscle of lactating dairy cattle. The available milk processing data indicate that residues of acephate do not concentrate in pasteurized milk, non-fat milk solids, milk fat solids, milk sugar (lactose), and protein processed from the milk of cows fed 60 ppm acephate and 12 ppm methamidophos in the diet. The milk data are adequate to satisfy the specific requirements of the Guidance Document pertaining to residues of acephate and methamidophos in the processed fractions of milk. The acephate data in this submission were reviewed by CBRS to assess acephate dietary exposure (F.B. Suhre, EPA Memorandum CBRS No. 4419, dated 1/12/89) who concluded that acephate residues are not significantly affected by pasteurization and do not concentrate in nonfat milk solids, milk fat solids, milk sugar, and milk protein.

The adequacy of the feeding study cannot be ascertained because the nature of the residue in plants and animals is not adequately understood and data gaps exist for feed commodities. Upon receipt of data requested in "Qualitative Nature of the Residue in Plants", "Qualitative Nature of the Residue in Animals", and "Magnitude of the Residue in Plants", the adequacy of the established tolerances will be assessed, the expected dietary intake will be calculated and the need for additional feeding studies will be reevaluated.

References (used):

MRID(s): 40504806.

Discussion of the data:

Chevron Chemical Company submitted data (1987; MRID 40504806) pertaining to residues of acephate and methamidophos in the tissues and milk of lactating dairy cattle. Twelve cows (four per dose group) received twice daily capsular doses of acephate and methamidophos at target levels equivalent to 15, 30, and 60 ppm acephate and 3, 6, and 12 ppm methamidophos in the diet for 28 consecutive days. While acephate levels were close to the target doses it appears that the actual level of methamidophos

fed may have been as low as 45% of the targeted dose, based on analysis of the dosing solution. An additional group of two cows served as control animals and did not receive acephate or methamidophos. Milk samples were collected on days 0, 1, 4, 8, 12, 16, 20, 24, 28, 29, and 30. Milk samples were also collected from the high dose group on days 25, 26, and 27, pooled, and processed to obtain pasteurized milk, non-fat milk solids, milk fat solids, milk sugar, and milk protein. On day 28, three cows from each dose group and one control cow were sacrificed and samples of fat (peritoneal and subcutaneous), kidney, liver, and muscle were collected. On day 31, the remaining animals (one per group and one control cow) were sacrificed and tissue samples were collected; however, the tissues of the control cow were not analyzed.

Residues of acephate and methamidophos in the milk of cows fed acephate and methamidophos are presented in Table 16. Residues of acephate and methamidophos in the processed fractions of milk are presented in Table 17. Apparent residues of acephate and methamidophos were nondetectable in the milk and the processed fractions of milk collected from the control cows.

Residues of acephate and methamidophos in the tissues of cattle fed acephate and methamidophos for 28 days and sacrificed on day 28 are presented in Table 18. Residues of acephate and methamidophos were nondetectable in the tissues of cows sacrificed after a three day withdrawal period except for a single pectoral muscle sample which bore acephate residues of 0.01 ppm. Apparent residues of acephate and methamidophos were nondetectable in the tissues of the control cow sacrificed on day 28.

Table 16. Residues of acephate and methamidophos in the milk of cows fed acephate, at 15, 30, and 60 ppm, and methamidophos, at 3, 6, and 12 ppm, in the diet for 28 days.[a]

Day of Study	Acephate residues (ppm) Feeding dose (ppm) 15	30	60	Methamidophos residues (ppm) Feeding dose (ppm) 3	6	12	Total residues (ppm) Feeding dose (ppm) 15/3	30/6	60/12
0	0.01-0.02	0.04-0.11	0.13-0.19	<0.01[b]	<0.01-0.01	0.02-0.05	<0.02, <0.03	<0.05-0.12	0.15-0.24
1	0.12-0.16	0.20-0.31	0.66-0.71	<0.01, 0.01	0.02, 0.03	0.02-0.07	<0.13-0.17	0.22-0.34	0.67-0.81
4	0.11-0.14	0.28-0.45	0.79-0.95	<0.01, 0.01	0.02, 0.03	0.05-0.08	<0.12-<0.15	0.30-0.48	0.84-1.03
8	0.14-0.15	0.23-0.33	0.88-0.98	<0.01, 0.01	0.02, 0.03	0.06-0.09	0.15-0.16	0.26-0.31	0.94-1.07
12	0.12-0.14	0.27-0.31	0.79-0.98	<0.01	0.02	0.04, 0.06	<0.13-<0.15	0.29-0.33	0.83-1.07
16	0.14, 0.15	0.23-0.32	0.81-0.97	<0.01, 0.01	0.02	0.05, 0.06	0.15-<0.16	0.25-0.34	0.86-1.03
20	0.13-0.17	0.31-0.42	0.75-0.86	<0.01, 0.01	0.01, 0.02	0.04, 0.05	<0.14-0.18	0.32-0.43	0.79-0.90
24	0.17-0.20	0.36-0.44	0.77-0.92	0.01	0.02	0.06, 0.07	0.18-0.21	0.38-0.46	0.83-0.99
28	0.12-0.22	0.23-0.36	0.65-0.88	<0.01, 0.01	0.01, 0.02	0.04-0.06	<0.13-0.23	0.24-0.38	0.69-0.94
29	0.01	0.03	0.08	<0.01	<0.01	<0.01	<0.02	<0.04	<0.09
30	<0.01	<0.01	0.07	<0.01	<0.01	<0.01	<0.02	<0.02	<0.08

[a] Four samples of milk from each dose group on each day up to day 28; one sample of milk from each dose group on days 29 and 30.

[b] Not detected.

Table 17. Residues of acephate and methamidophos in the processed fractions of milk collected from dairy cattle fed 60 ppm acephate and 12 ppm methamidophos in the diet.

Milk fraction	Residues (ppm)		
	Acephate	Methamidophos	Total
Unprocessed milk[a]	0.66-0.97	0.04-0.07	0.72-1.04
Pasteurized milk	0.83	0.06	0.89
Nonfat milk solids	0.62	0.06	0.68
Milk fat solids	0.06	<0.01[b]	<0.07
Milk sugar (lactose)	0.45	0.04	0.49
Milk protein	0.44	0.03	0.47

[a] Milk collected from each cow in the high dose group on days 25, 26, and 27 for a total of 12 samples; these samples were pooled for processing.
[b] Not detected.

Table 18. Residues of acephate and methamidophos in the fat, kidney, liver, and muscle of cows fed acephate, at 15, 30, and 60 ppm, and methamidophos, at 3, 6, and 12 ppm, in the diet for 28 days.[a]

	Acephate residues (ppm)			Methamidophos residues (ppm)			Total residues (ppm)		
	Feeding dose (ppm)			Feeding dose (ppm)			Feeding dose (ppm)		
Tissue	15	30	60	3	6	12	15/3	30/6	60/12
Fat, subcutaneous and peritoneal	0.05, 0.10	0.09-0.15	0.17-0.40	<0.01[b]	<0.01	<0.01, 0.02	<0.06, <0.11	<0.10-<0.16	<0.18-0.42
Kidney	0.19, 0.26	0.34, 0.40	0.63-0.85	0.01, 0.02	0.02-0.04	0.05, 0.07	0.20, 0.28	0.36-0.44	0.68-0.92
Liver	0.02	0.03, 0.04	0.06-0.15	<0.01	<0.01	0.01, 0.02	<0.03	<0.04, <0.05	0.07-0.11
Muscle, adductor	0.08-0.12	0.15-0.18	0.29-0.42	<0.01, 0.01	0.01	0.02, 0.03	<0.09-<0.13	0.16-0.19	0.31-0.45
Muscle, cardial	0.07-0.11	0.13-0.16	0.28-0.40	<0.01, 0.01	0.01, 0.02	0.03, 0.04	<0.08-0.12	0.14-0.18	0.31-0.44
Muscle, pectoral	0.09-0.12	0.15-0.21	0.29-0.40	<0.01	<0.01, 0.01	0.02, 0.03	<0.10-<0.13	<0.16-0.22	0.31-0.43

[a] Three samples of each tissue in each dose group.
[b] Not detected.

Data were collected using a GLC method with NPD or FPD detection (Chevron Method RM-12A-6). The limits of detection are 0.01 and 0.02 ppm for residues of acephate, depending on the day of the analysis, and 0.01 ppm for residues of methamidophos. Method recoveries are presented in Table 19. Tissue samples were stored frozen (ca. -20°C) for 37-56 days and milk samples for 7-51 days prior to analysis by Chevron. The milk, kidney, and muscle data are adequately supported by storage stability data. Because no storage stability data are available for fat, the fat samples were reanalyzed ca. 4 months after the original analyses; residues of acephate and methamidophos were equal to or slightly greater than those of the original analyses. No storage stability data are available for liver.

Table 19. Method recoveries of acephate and methamidophos from milk and tissue samples.

	Acephate		Methamidophos	
Commodity	Fortification (ppm)[a]	Recovery (%)	Fortification (ppm)[a]	Recovery (%)
Milk	0.13(13)	79-108	0.05(13)	70-99
Pasteurized milk	0.25(2)	90	0.1(2)	77,81
Nonfat milk solids	0.25(1)	78	0.1(2)	94
Milk fat solids	0.25(1)	76	0.1(1)	82
Milk sugar (lactose)	0.63(1)	86	0.25(1)	86
Milk protein	0.13(1)	86	0.05(1)	75
Fat, subcutaneous and peritoneal	0.25(3)	83-135	0.1(3)	70-120
Kidney	0.25(1)	91	0.1(1)	65
Liver	0.25(1)	95	0.1(1)	60
Muscle, adductor, cardial, and pectoral	0.25(3)	80-92	0.1(3)	75-88
	0.5(1)	96	0.2(1)	81

[a] Number of samples in parentheses.

The available milk data indicate that the combined residues of acephate and methamidophos plateau in milk within four days of the initial dose. The milk processing data indicate that residues of acephate and methamidophos do not concentrate in pasteurized milk, nonfat milk solids, milk fat solids, milk sugar (lactose), and milk protein processed from the milk of cows fed 60 ppm acephate and 12 ppm methamidophos in the diet. The milk

data are adequate to satisfy the specific requirements of the Guidance Document pertaining to residues of acephate and methamidophos in the processed fractions of milk. The acephate data in this submission were reviewed by CBRS to assess acephate dietary exposure (F.B. Suhre, EPA Memorandum CBRS No. 4419, dated 1/12/89) who concluded that acephate residues are not significantly affected by pasteurization and do not concentrate in nonfat milk solids, milk fat solids, milk sugar, and milk protein.

The adequacy of the feeding study cannot be ascertained because the nature of the residue in plants and animals is not adequately understood and data gaps currently exist for feed commodities.

Eggs and the Fat, Meat, and Meat Byproducts of Poultry

Tolerance(s):

Tolerances of 0.1 ppm have been established for the combined residues of the insecticide O,S-dimethyl acetylphosphor-amidothioate (acephate) and its cholinesterase-inhibiting metabolite, O,S-dimethyl phosphoramidothioate (methamidophos) in eggs and the fat, meat, and meat byproducts of poultry [40 CFR §180.108].

Conclusions:

Presently, the nature of the residue in plants and animals is not adequately understood and data gaps exist for feed commodities. Upon receipt of data requested in "Qualitative Nature of the Residue in Animals", "Qualitative Nature of the Residue in Plants", and "Magnitude of the Residue in Plants", the adequacy of the established tolerances will be assessed, the expected dietary intake will be calculated, and the need for additional feeding studies will be reevaluated.

References (used):

N/A.

Discussion of the data:

N/A.

TOLERANCE REASSESSMENT SUMMARY

It should be noted that data gaps exist for plant metabolism, animal metabolism, and storage stability data. Thus, on receipt of the data requested in these sections, the conclusions stated below regarding the adequacy of the established tolerances are subject to change.

Sufficient data are available to support the established tolerances for the combined residues of acephate and methamidophos in or on Brussels sprouts, cauliflower, celery, cranberries, cottonseed, lettuce (head), peanuts, peanut hulls, and peppers.

Insufficient data are available to support the established tolerances for the combined residues of acephate and methamidophos in or on beans (succulent and dry), grass forage (pasture and range), grass hay, mint hay, soybeans, and eggs, milk, and the fat, meat, and meat byproducts of cattle, goats, hogs, horses, poultry, and sheep.

Processing studies are required for beans, soybeans, and peanuts.

Upon receipt of adequate storage stability data, feed additive tolerances must be proposed for residues of acephate and methamidophos in soybean hulls.

Acephate is currently registered for use on winter wheat in CO, OK, and TX under SLN registrations CO790009, OK810020, and TX810035. There is currently no tolerance for the residues of acephate of concern in or on winter wheat forage and straw. The registrant must propose a tolerance for residues of acephate and methamidophos in or on wheat forage and straw, which must be supported by appropriate residue data. Alternatively, the registrant may elect to cancel SLNs CO790009, OK810020, and TX810035.

A change in the residue definition for acephate tolerances is to be initiated by the Agency. Acephate tolerances currently established under 40 CFR §180.108 and §186.100 are to refer only to acephate per se, with references to section 40 CFR §180.315. We note that this separation of tolerances will require that feed additive tolerances be established for residues of methamidophos per se in cottonseed meal, cottonseed hulls, and soybean meal.

Methamidophos tolerances currently established under 40 CFR §180.315 are to be divided into parts (a) and (b) where (a) includes (1) tolerances reflecting use of methamidophos and (2) tolerances where both acephate and methamidophos formulations are used on the same crops, and (b) includes tolerances reflecting

use of acephate formulations alone, i.e., residues of methamidophos resulting from the metabolism of acephate.

The food additive tolerances currently established under 40 CFR §185.100 are to be expressed in terms of only acephate per se, i.e., based on the available data, no residues of the metabolite methamidophos are expected to occur (less than 0.001 ppm) in or on these foods.

These changes in the residue definition would require deletion of the paragraph (d)(8) of 40 CFR §180.3 which states that methamidophos residues may not exceed the higher of the two tolerances established for the use of acephate or methamidophos as a pesticide.

MASTER RECORD IDENTIFICATION NUMBERS

MRID documents containing data which have been reviewed by the Agency are designated in shaded blocks in the following bibliographic listing of Residue Chemistry Citations (used). A summary of the memoranda and their associated MRID documents is presented below.

CBRS No.: none assigned
Subject: OR-830040. Acephate on radishes grown for seed.
From: R. Loranger
To: W. Miller
Dated: 12/22/83
MRID(s): none assigned

CBTS No.: none assigned
Subject: PP#4E3028. Acephate on Macadamia Nuts. Amendment of 6/12/84. (Accession No. 072288)
From: L. L. Kutney
To: H. Jamerson
Dated: 7/8/84
MRID(s): 00138156

CBRS No.: none assigned
Subject: EPA No. 239-2471. Methylthioacetate (MTA). Request for Determination of MTA Residues in/on Food Crops. Tox. Chem. No. 584D and 2A.
From: J. E. Whalan
To: C.L. Trichilo
Dated: 9/5/85
MRID(s): none assigned

CBRS No.: none assigned
Subject: Addendum to the Acephate Registration Standard; Toxicology Branch deferral concerning residues of an acephate impurity, methylthioacetate, in/on food items.
From: W.J. Hazel
To: W.H. Miller
Dated: 9/23/85
MRID(s): none assigned

CBRS No.: 4419
Subject: Acephate dietary exposure assessment; MRID No. 405048-01 and 405048-03 thru 405048-09; DEB No. 4419.
From: F.B. Suhre
To: J. Tice
Dated: 1/12/89
MRID(s): 40504803 through 40504808

Residue Chemistry Citations (used):

00138156 Interregional Research Project No. 4 (1981) The Results of Tests on the Amount of Acephate Residues Remaining in or on Macadamia Nuts, Including a Description of the Analytical Method Used. (Compilation; unpublished study received Jan 13, 1984 under 239-2418; CDL:072288-A)

40504801 Chevron Chemical Co. (1988) Chemical Identity MTA in Crops: Orthene Technical. Unpublished study.

40504802 Lai, J. (1987) Storage Stability of Acephate in Frozen Crops, Milk, and Tissues: Interim Rept. : Proj. ID R12-1987SS. Unpublished study prepared by Chevron Chemical Co. 314 p.

40504803 Lai. J. (1987) Magnitude of the Residue in Mint: Orthene: Proj. ID R12T70297035. Unpublished study prepared by Chevron Chemical Co. 92 p.

40504804 Lai, J. (1987) Magnitude of the Residue in Grass: Orthene Tech. :Proj. ID R12T70397040. Unpublished study prepared by Chevron Chemical Co. 80 p.

40504805 Lai, J. (1987) Magnitude of the Residue in Beans: Orthene Tech. :R12T70177019. Unpublished study prepared by Chevron Chemical Co. 164 p.

40504806 Lai, J. (1987) 28-Day Milk and Meat Residue Study with Acephate Technical Plus Methamidophos Technical in a 5:1 Ratio in Dairy Cattle: Ortho Orthene: R1287MM7. Unpublished study prepared by Chevron Chemical Co. 270 p.

40504809 Lai, J. (1987) Magnitude of the Residue in Tobacco (Aerial Applications): Orthene Tech.: Proj. ID R12T70257026. Unpublished study prepared by Chevron Chemical Co. 64 p.

40874102 Lai, J. (1988) Storage Stability of Acephate in Frozen Cottonseed Macerates: Project ID: R12-T7023SS. Unpublished study prepared by Chevron Chemical Co. 49 p.

40874103 Lai, J. (1988) Storage Stability of Acephate in Frozen Celery Macerates: Project ID: R12-T7037SS. Unpublished study prepared by Chevron Chemical Co. 45 p.

41137902 Lai, J. (1989) Storage Stability of Acephate in Frozen Macerated Beans: Project ID R127017SS. Unpublished study prepared by Chevron Chemical Co. 78 p.

41137903 Lai, J. (1989) Effect of Processing on Acephate Residues in Soybean: Project ID R12T7199PR. Unpublished study prepared by Chevron Chemical Co. 175 p.

Residue Chemistry Citations (not used):

[The following references were not submitted in response to the Guidance Document.]

00148010 Chevron Chemical Co. (19??) Orthene (Acephate) Residue Tolerance Petition: Cucumbers. Unpublished compilation. 129 p.

00157764 Chevron Chemical Co. (1986) Product Chemistry, [Residue Chemistry, Environmental Chemistry, Toxicology, and Exposure Data Regarding Acephate]. Unpublished compilation. 1851 p.

00158277 Chevron Chemical Co. (1983) Summary of Residue Data [of Acephate on Oranges]. Unpublished compilation. 5 p.

00164059 Chevron Chemical Co. (1986) Orthene Fire Ant Bait: Efficacy Data; Residue on Pasture and Turf Grass. Unpublished compilation. 90 p.

00164182 Chevron Chemical Co. (1985) Methamidophos and Acephate: Residues in Rice Grain Resulting from Treatment with Orthene 75 Soluble Powder. Unpublished compilation. 54 p.

40309701 Baron, J. (1987) Acephate and Its Metabolite Methamidophos Magnitude of Residue on Asparagus: Lab. Proj. ID PR-0372. Unpublished study prepared by IR-4 Western Region Analytical Laboratory, Univ. of California. 29 p.

40322501 Rosenburg, D. (1987) Comparative Esterolytic Activity with Methylthioacetate (SX-1724) in Various Tissues of the Rat and Rabbit: Laboratory Project ID: 8712331. Unpublished study prepared by Chevron Environmental Health Centre, Inc. 25 p.

40504807 Lai, J. (1987) Residue Reduction Mint: Orthene Tech. : Proj. IDR12T7029A. Unpublished study. 3 p.

40504808 Lai, J. (1987) Residue Reduction Beans: Orthene Tech. : Proj. ID R12T7017A. Unpublished study. 6 p.

40548301 Lai, J. (1988) Orthene Fire Ant Bait Residue Data Rangeland. Unpublished compilation prepared by Chevron Chemical Co. 59 p.

40874104 Schreckengast, G.; Kreuger, M.; Jaber, M. (1988) Orthene Tobacco Insect Spray: A Residue Monitoring Study in Tobacco to Assess Exposure to Avian Species Under Standard Agricultural Use Conditions in North Carolina: Amended Report: Project ID: WIL Project No. 162-173; Study No. S-2983. Unpublished study prepared by Wildlife International, Ltd. 123 p.

40874105 Johnson, G.; Wallace, M.; Kreuger, H.; et al. (1988) Orthene 75S Soluble Powder: A Residue Monitoring Study in Cotton to Assess Exposure to Avian Species Under Standard Agricultural Use Conditions in Alabama: Project ID: WIL Project No. 162-172; Study No. S-2980. Unpublished study prepared by Wildlife International. 139 p.

41051601 Petersen, B.; Eichoff, J. (1989) Anticipated Residues and Chronic Dietary Exposure Analysis for Acephate Per Se: Project ID VALENT ORT/TAS. 1FXK. Unpublished study prepared by Technical Assessment Systems, Inc. 155 p.

41175401 Lai, J. (1989) Magnitude of the Residue in Sugar Beets: Orthene 75S: Project ID: R69R71MR. Unpublished study prepared by Chevron Chemical Co. 152 p.

41243401 Lai, J. (1988) Effect of Processing on Acephate Residues in Corn: Orthene 75 S Soluble Powder: Project ID R127042. Unpublished study prepared by Chevron Chemical Co. 253 p.

41250901 Danka, R.; Fourrier, L.; Hostetler, N.; et al. (1989) Acephate and Methamidophos Residues in Dead Bees, Honey, and Beeswax from Honey Bee Colonies Treated with 375 ppm Orthene 75 S in Sucrose-Honey Bait: Project ID PRLR 26-208. Unpublished study prepared by USDA-ARS. 6 p.

41250902 Williams, J.; Danka, R. (1989) Effect of Foraging Distance and Acephate Concentration Morality of Honey Bee Colonies Treated with Orthene 75 S in Syrup-Honey Bait: Project ID Acephate Technol. 1988. Unpublished study prepared by USDA-ARS. 3 p.

41733601 Biehn, W. (1988) Acephate and its Metabolite Methamidophos: Magnitude of Residue On Maple Sap Including A Description Of The Analytical Method Used: Lab Project Number: 1026. Unpublished Study prepared by Chevron Chemical Co. 80 p.

[The following references were not submitted in response to the Guidance Document. The references were submitted under Guideline No. 171-7: reasonable grounds in support of the petition.]

41081605 Lai, J. (1989) 1984 & 1985 Chevron Market Basket Surveys for Acephate and Methamidophos. Unpublished study prepared by Chevron Chemical Co. 485p.

41081606 Lai, J. (1989) Farm Gate-to-Consumer Studies of Five Orthene Treated Crops. Unpublished study prepared by Chevron Chemical Co. 133 p.

TABLE A. GENERIC DATA REQUIREMENTS FOR ACEPHATE.

Data Requirement	Test Substance[1]	Does EPA have data to satisfy this requirement?	Bibliographic Citation[2]	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?
40 CFR §158.240 Residue Chemistry				
171-2. Chemical Identity[3]				
171-3. Directions for Use[4,5]		(See Index)[6]		
171-4. Nature of the Residue (Metabolism) - Plants	PAIRA	Partially		Yes[7]
171-4. Nature of the Residue (Metabolism) - Livestock	PAIRA & plant metabolites	Partially		Yes[8]
171-4. Residue Analytical Methods	TGAI & metabolites	Partially		Yes[9]
171-4. Storage Stability	TEP & metabolites	Partially	40504802 40874102 40874103 41137902	Yes[10]
171-4. Magnitude of Residue in Plants				
Leafy Vegetables (except Brassica)				
- Celery	TEP	Yes		No
- Lettuce	TEP	Yes		No

(Continued, footnotes follow)

TABLE A. (Continued).

Data Requirement	Test Substance[1]	Does EPA have data to satisfy this requirement?	Bibliographic Citation[2]	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?
Brassica Leafy Vegetables				
- Brussels sprouts	TEP	Yes		No
- Cauliflower	TEP	Yes		No
Legume Vegetables				
- Beans	TEP	Yes	40504805	No
(processed commodities)	TEP	Partially	40504805	Yes[11]
- Soybeans	TEP	Yes	40504805	No
(processed commodities)	TEP	Partially	40504805 41137903	Yes[12]
Fruiting Vegetables (Except Cucurbits)				
- Peppers	TEP	Yes		No
Small Fruits and Berries				
- Cranberries	TEP	Yes		No
Tree Nuts				
- Macadamia nuts	TEP	Yes	00138156	No
Forage, Fodder, and Straw of Cereal Grains				
- Wheat forage and straw	TEP	No		Yes[13]
Grass Forage, Fodder, and Hay				
- Pasture and rangeland forage & hay	TEP	Partially	40504804	Yes[14]
Miscellaneous Commodities				

(Continued, footnotes follow)

TABLE A. (Continued).

Data Requirement	Test Substance[1]	Does EPA have data to satisfy this requirement?	Bibliographic Citation[2]	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?
- Cottonseed	TEP	Yes		No
(processed commodities)	TEP	Yes		No
- Mint	TEP	Partially	40504803	Yes[15]
- Peanuts	TEP	Yes		No
(processed commodities)	TEP	Partially		Yes[16]
- Tobacco	TEP	Partially	40504809	Yes[17]
Crops Grown Solely for Seed				
- Radishes	TEP	No		Yes[18]
171-4. Magnitude of residue in Meat/Milk/Poultry/Eggs	TGAI or plant metabolites	Partially	40504806	Reserved[19]

1. Test substance: PAI = purified active ingredient; PAIRA = purified active ingredient, radiolabeled; TEP = Typical end-use product; TGAI = technical grade of the active ingredient; MP = manufacturing-use product.

2. These references were submitted in response to the Acephate Guidance Document dated 9/87. Underlining indicates documents that have been reviewed for this update.

3. The same chemical identity data are required as under 40 CFR §158.150-190, with emphasis on impurities that could constitute residue problems. Refer to Product Chemistry Data Requirements tables.

(Continued, footnotes follow)

TABLE A. (Continued).

4. All end-use product labels (e.g., any unamended basic producer labels, SLNs, and products covered under the generic data exemption) must be amended such that they are consistent with the amended basic producer labels.

5. The registrant must submit revised product labels which specify a maximum number of applications per season and/or a maximum seasonal application rate for the following crops: beans (dry and succulent), cauliflower, celery, cotton, pasture and rangeland grasses (SLNs AR840013, CO790009, NM800010, OK810020, and TX810035), peanuts, peppers (bell), soybeans, and tobacco. The label amendments must be supported by appropriate residue data. The registrant must also submit revised product labels which establish a restriction against feeding spent mint hay to dairy cattle. In addition, all SLN labels with uses on pasture and rangeland grass must be amended to include a 21-day PHI for grass hay for all livestock.

6. The labels of end-use products registered for food/feed uses were used to determine the use patterns.

7. The available plant metabolism studies are inadequate to delineate the nature of residue in plants because total radioactive residues were not quantitatively identified.

The following additional data are required: Data depicting the uptake, distribution, and metabolism of S-methyl-labeled and carbonyl-labeled [^{14}C]acephate in a leafy vegetable, in a legume vegetable, and in cotton. The radiolabeled test substance must be applied under conditions representing normal cropping practices and at rates high enough to permit characterization of ^{14}C-residues. The identities and quantities of residues in mature plant parts must be determined in order to elucidate terminal residues. Data depicting all terminal residue components in commodities at the time of harvest should be expressed as the percentage of the total recovered radioactivity (TRR) and concentration (ppm). Confirmation of the identities of residues using a suitable method such as MS is required. Representative samples from these studies must also be analyzed by the residue analytical methods developed for data collection and tolerance enforcement to assure that these methods are capable of adequately recovering all metabolites of concern.

8. The available animal metabolism studies discussed in the Acephate Residue Chemistry Chapter, dated 1/28/82, are inadequate to delineate the nature of the residue in animals because residues were not quantitatively identified and no poultry metabolism data are available.

TABLE A. (Continued).

The following additional data are required: Data are required depicting metabolism of acephate in ruminants and poultry. Animals must be dosed orally for a minimum of 3 days with S-methyl-labeled and carbonyl-labeled [^{14}C]acephate at a level sufficient to make residue identification and quantification possible. Milk and eggs must be collected twice a day during the dosing period and animals must be sacrificed within 24 hours of the final dose. The distribution, characterization, and identification of radioactive residues must be determined in milk, eggs, liver, kidney (except poultry), muscle, and fat. The amount of radioactivity identified, characterized, or lost must be accounted for. Results describing all terminal residue components should be expressed as total recovered radioactivity (TRR) and concentration (ppm). Confirmation of the identities of residues using a suitable method such as MS is required. Representative samples from these studies must also be analyzed by the residue analytical methods developed for data collection and tolerance enforcement to assure that these methods are capable of adequately recovering all metabolites of concern.

9. The following additional data are required: the qualitative nature of the residue in plants and animals has not been adequately described, therefore, the adequacy of the available methods cannot be ascertained. If the requested data on plant and animal metabolism indicate the presence of additional metabolites of toxicological concern, additional analytical methods will be required. If radiolabeled validation of existing analytical methodology for plants and animals (refer to "Qualitative Nature of the Residue in Plants" and "Qualitative Nature of the Residue in Animals" for additional details) indicates that a major portion of the total radioactive residue is not recovered and identified by the available methods, radiolabeled validation of new proposed methodology will be required.

10. The storage stability data submitted in response to the Guidance Document are inadequate because no data are available depicting the stability of acephate and methamidophos in tobacco leaves, in any processed commodities, in the liver of dairy cattle, or in poultry tissues.

The following additional data are required: (i) The sample storage intervals and conditions must be supplied for all residue data submitted in support of tolerances, whether previously submitted or required in this update. Storage stability data in support of previously submitted residue data are required only for those samples deemed to be useful for tolerance assessment. Data are also required which depict the decline in levels of combined residues of acephate and methamidophos in green and cured tobacco leaves, in the processed commodities of cottonseed, mint, peanuts, and soybeans, in dairy cattle liver, and in poultry tissues stored under the range of conditions and for the range of intervals specified. Samples of tobacco

89

leaves and processed commodities bearing measurable, weathered residues or fortified with acephate residues of concern, and fortified dairy cattle liver and poultry tissue samples, must be analyzed immediately after processing or fortification and again after storage intervals that allow for reasonable unforeseen delays in sample analysis. In laboratory tests using fortified samples, the pure active ingredient and pure metabolites must be used. However, if field-weathered samples are used, the test substance must be a, typical end-use product. For additional guidance on conducting storage stability studies, the registrant is referred to an August, 1987 Position Document on the Effects of Storage Validity of Pesticide Residue Data available from NTIS under order no. PB 88112362/AS; and (ii) The nature of the residue in plants and animals is not adequately understood. If the requested data on plant and animal metabolism indicate the presence of additional metabolites of toxicological concern, data depicting stability of these residues during storage will be required.

11. The bean processing data submitted in response to the Guidance Document are inadequate because no data were submitted depicting residues in cannery residue.

The following additional data are required: Data depicting the potential for concentration of acephate and methamidophos residues in cannery residue prepared from beans bearing measurable weathered residues. If residues concentrate in this feed item, an appropriate feed additive tolerance must be proposed.

12. The processing studies submitted in response to the Guidance Document indicate that the combined residues of acephate and methamidophos concentrate in soybean hulls; the registrant must propose a feed additive tolerance for soybean hulls. In addition, no processing data are available for grain dust.

The following additional data are required: (i) A processing study depicting the potential for concentration of residues of acephate and methamidophos in grain dust processed from soybeans bearing measurable, weathered residues. If residues concentrate in this item, an appropriate feed additive tolerance must be proposed; and (ii) The registrant(s) must propose a feed additive tolerance for the combined residues of acephate and methamidophos in soybean hulls.

13. Acephate is currently registered for use on winter wheat in CO, OK, and TX under SLN registrations CO790009, OK810020, and TX810035. There is currently no tolerance for the residues of acephate of concern in or on winter wheat forage and straw.

The following data are required: Data depicting acephate residues of concern in or on winter wheat forage and straw harvested 0 (forage) and 21 (straw) days following a single application of the SC/S formulation at 0.125 lb ai/A. Tests must reflect the use of ground and aerial equipment and must be conducted in CO, OK, and TX since this use is limited to these states. The registrant must propose a tolerance for residues of acephate and methamidophos in or on winter wheat forage and straw. Alternatively, the registrant may elect to cancel SLNs CO790009, OK810020, and TX810035.

14. The grass forage and hay data submitted in response to the Guidance Document are inadequate to assess the established tolerances because data were not submitted for the representative members of the grass forage, fodder, and hay crop group.

The following additional data are required: (i) The registrant may propose a lower tolerance for the combined residues of acephate and methamidophos in or on grass forage and grass hay, and amend product labels to increase the established PHI. Tolerance and product label amendments must be supported by the following data. Data depicting residues of concern in or on Bermuda grass and bromegrass (or fescue) forage and hay harvested at the proposed PHI and pregrazing/feeding interval following a single application of the 75% SC/S formulation at 0.125 lb ai/A. Applications must be made using ground and aerial equipment. (Data representing aerial application are not required if application is made with greater than 2 gal. solution/A.) Tests must be conducted in the major pasture and rangeland growing regions of the U.S.; (ii) Data depicting residues of acephate and methamidophos in or on Bermuda grass and bromegrass (or fescue) forage and hay following treatment of 13 ant mounds/A in AR and OK with the SC/S formulation at 0.06 lb ai/mound. Tests must reflect dry and drench applications. Alternately, the registrant may cancel these SLNs (AR840013 and OK890004).

15. The submitted mint data indicate that the established tolerance may be too low.

The following additional data are required: The registrant must propose label restrictions lengthening the PHI, reducing the maximum number of foliar applications per growing season or the maximum seasonal rate, and/or reducing the maximum registered single application rate, which must be efficacious, and submit data depicting residues of concern at the proposed PHI using the proposed number of applications of the 75% SC/S formulation at the proposed maximum single application rate. The tests must be conducted using ground and aerial equipment in OR(53%) and WA(26%), accounting for ca. 80% of the 1988 U.S. production of peppermint.

Alternately, the registrant may amend product labels limiting the method of application to ground equipment only.

16. The available peanut processing data (discussed in the Acephate Residue Chemistry Chapter, dated 1/82) are inadequate to determine the potential for concentration of the combined residues of acephate and methamidophos because only one sample of the seven peanut samples which were processed bore detectable residues.

The following additional data are required: A processing study depicting the potential for concentration of acephate residues of concern in meal, soapstock, crude oil, and refined oil processed from peanuts bearing measurable, weathered residues. If residues concentrate in any product, appropriate food/feed additive tolerances must be proposed.

17. The tobacco data submitted in response to the Guidance Document indicate that combined residues of acephate and methamidophos will exceed 0.1 ppm in or on green and cured tobacco leaves.

The following additional data are required: The pyrolysis products of acephate must be characterized and the level of the residue in smoke must be quantified. Tobacco leaves fortified with [^{14}C]acephate must be used for the pyrolysis studies.

18. The SLN registration of acephate for use on radishes grown for seed in WA (WA810064) was reviewed by CBRS (R. Loranger, EPA Memorandum, dated 12/22/83); it was concluded that this use is not a non-food use since application may occur early in the season when radishes would still be harvestable for human consumption.

The following data are required: Data depicting residues of acephate and methamidophos following multiple broadcast applications of an SC/S formulation at 1 lb ai/A/application before peak bloom period. Tests must be conducted in OR and WA since this use is limited to OR and WA. Alternatively, the registrant may elect to cancel SLN registrations OR830040 and WA810064.

19. The nature of the residue in plants and animals is not understood and data gaps exist for several feed commodities. Upon receipt of data requested in "Qualitative Nature of the Residue in Plants", "Qualitative Nature of the Residue in Animals", and "Magnitude of the Residue in Plants", the adequacy of the established

99

TABLE A. (Continued).

tolerances will be assessed, the expected dietary intake will be calculated and the need for additional feeding studies will be reevaluated.