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

EXPEDITE

Memorandum

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Subject: Acephate dietary exposure assessment;
MRID No. 405048-01 and 405048-03 thru
405048-09; DEB No. 4419.

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This review is being expedited (due date 2-1-89) at the request of E. Tinsworth, Director, Special Review and Reregistration Division (memo dated 9-28-88).

The Special Review and Reregistration Division (RD) has requested the Dietary Exposure Branch (DEB) prepare a dietary exposure assessment for acephate. TOX will compare DEB's estimated acephate dietary burden to the Acephate ADI (0.0012 ug/kg body wt/day; see G. Ghali, TB, memo dated 9-29-88).

This dietary exposure assessment will utilize FDA domestic and import surveillance data from FY 1986-88, and acephate residue data from field trials conducted in support of established tolerances. In cases where both FDA surveillance data, and field trial data are available for the same commodity, the FDA surveillance data will be used.

A Registration Standard has been issued for Acephate (Guidance document dated 9-87).

Tolerances are established (40 CFR 180.108) for combined residues of the insecticide acephate (O,S-dimethyl acetylphosphoramidothioate) and its cholinesterase-inhibiting metabolite methamidophos (O,S-dimethyl phosphoramidothioate) as follows:

<u>Commodity</u>	<u>Combined (acephate/methamidophos) Tolerance</u>
(Crops)	
Beans (succulent and dry)	3.0 ppm, of which not more than 1.0 ppm is methamidophos.
Brussel sprouts	3.0 ppm, of which not more than 0.5 ppm is methamidophos.
Cauliflower	2.0 ppm, of which not more than 0.5 ppm is methamidophos.
Celery	10.0 ppm, of which not more than 1.0 ppm is methamidophos.
Cottonseed	2.0 ppm
Cranberries	0.5 ppm, of which not more than 0.1 ppm is methamidophos.
Grass (pasture and range)	15.0 ppm
Grass (hay)	15.0 ppm
Lettuce (head)	10.0 ppm, of which not more than 1.0 ppm is methamidophos.
Macadamia nuts	0.05 ppm
Mint hay	15.0 ppm, of which not more than 1.0 ppm is methamidophos.
Peanuts	0.2 ppm
Peanut hulls	5.0 ppm
Peppers	4.0 ppm, of which not more than 1.0 ppm is methamidophos.
Soybeans	1.0 ppm

Table Continued:

<u>Commodity</u>	<u>Combined (acephate/methamidophos) Tolerance</u>
(Animals)	
Meat, fat, and mby of cattle, goats, hogs, horses, poultry, and sheep.	0.1 ppm
Eggs	0.1 ppm
Milk	0.1 ppm

Feed Additive Tolerances are established (21 CFR 561.20) for combined residues of acephate and its cholinesterase inhibiting metabolite (methamidophos) as follows:

<u>Feed item</u>	<u>Combined (acephate/methamidophos) Tolerance</u>
Cottonseed	
(meal)	8.0 ppm
(hulls)	4.0 ppm
Soybean	
(meal)	4.0 ppm

Separate tolerances are also established for residues of methamidophos (see 40 CFR 180.315, 21 CFR 561.277 and 21 CFR 193.10). Please note that in the Acephate Guidance Document (9-87), the Agency recommended that 40 CFR 180.108 and 21 CFR 561.20 be revised to refer only to acephate per se, with references (indicating that tolerances for methamidophos are also in effect) to sections 40 CFR 180.315 and 21 CFR 561.277. DEB supports this recommendation; particularly since the current combined tolerance expressions for acephate/methamidophos (40 CFR 180.108 and 40 CFR 561.20) are either redundant or contradict established tolerances for methamidophos (40 CFR 180.108, 21 CFR 561.20, and 21 CFR 190.10).

CONCLUSIONS

1. Acephate is a systemic, organophosphate, insecticide. Its metabolic nature in plants and animals is adequately understood; the residues of concern are the parent compound (acephate) and its metabolite, methamidophos.

Note to PM: Since the purpose of this review is to provide TOX with an acephate dietary exposure estimate (personal communication with E. Budd), DEB will limit this review to the parent (acephate) compound.

2a. Cooking/processing studies on beans (succulent and dry) indicate that non-commercial preparations (rinsing and boiling) may reduce acephate residues by up to 50% (0 to 50% reduction depending on the study), while commercial canning may reduce acephate residues levels by as much as 90% (75 to 90% reduction depending on the study).

2b. Processing studies on bean, mint and milk indicate that acephate residues do not concentrate in processed food/feed items.

3a. The dietary exposure estimates reported below (see recommendations) are based on the best available data. FDA domestic monitoring data were used when available, otherwise, residue data from field studies (conducted in support of established tolerances) were used for estimation purposes. Residue estimates derived from field trials reflect the percent of crop treated (with the exception of macadamia nuts and mint oil, where we assumed a 100% treatment).

3b. Residue data used in this dietary exposure assessment were generated utilizing methodology based on conventional extraction/cleanup techniques and GC/NPD or FPD detection (phosphorus mode).

4a. Acephate residues in and on raw agricultural commodities are stable under frozen storage conditions.

4b. The half life of acephate residues in or on pasture grass ranged from 2 to 8 days.

RECOMMENDATIONS

DEB recommends that a Tolerance Assessment System (TAS) analysis be conducted using the acephate residue values and associated food items presented below:

<u>Commodity</u>	<u>Average Acephate Residues in ppm</u>	<u>% of Crop Treated^a</u>
Beans, fresh ^b	0.05	*
Beans, cooked ^c	0.05	*
Beans, canned ^c	0.013	*
Brussels sprouts, fresh ^b	<0.01	*
Brussels sprouts, cooked ^c	<0.01	*
Brussels sprouts, canned ^c	<0.003	*
Cauliflower, fresh ^b	<0.01	*
Cauliflower, cooked ^c	<0.01	*
Celery, fresh ^b	0.07	*
Cottonseed ^d	0.22	10%
Cottonseed meal ^d	0.33	10%
Cranberries, fresh ^b	<0.01	*
Cranberries, canned ^c	<0.003	*
Lettuce ^b	0.01	*
Macadamia nuts ^d	<0.01	*
Mint oil ^d	<0.02	*
Peanuts ^d	<0.01	10%
Peppers, fresh ^b	0.2	*
Peppers, cooked ^c	0.2	*
Soybeans ^d	0.06	<1.0%
Soybean flour ^d	<0.01	<1.0%
Meat, fat and mbyp of cattle, goats, hogs, horses, and sheep ^e	<0.001 [<0.002 for beef kidney]	
Poultry ^e	<0.001	
Eggs ^e	<0.001	
Milk ^e	<0.0001	

a. % of crop treated is provided for values obtained from residue field trials only (see foot notes b and d); for the TAS analysis use 100% for the commodities marked with an *.

- b. Average residue values from FDA surveillance monitoring (FY 86-88); values reflect treated and non-treated crops.
- c. Residue levels may be affected by non-commercial processing (0 to 50% reduction), and commercial canning (75-90% reduction); values reported above reflect 0% and 75% reductions from cooking and canning, respectively.
- d. Average values from residue field trials; values reflect treated crops only.
- e. Extrapolated from animal feeding studies and average residue in or on feed items (pasture hay for cattle, and soybeans for poultry). Extrapolated values reflect the % of crop (feed item) treated (<1% for pasture grass and soybeans).

DETAILED CONSIDERATIONS

Nature of the Metabolism

The metabolic nature of acephate in plants and animals is adequately understood; the residues of concern are acephate and its metabolite, methamidophos. For a detailed description of plant and animal metabolism please refer to the Residue Chemistry Chapter of the Acephate Registration Standard.

Registered uses

Acephate is registered for use: on agricultural crops, ornamentals, forest, chaparral, nonagricultural and wastelands; and in domestic dwellings, medical facilities, schools, and commercial establishments. For a complete description of all registered uses please refer to the EPA Compendium of Acceptable Uses in the Acephate Guidance Document (Sept. 1987). Registered uses, applicable to this dietary exposure estimate are summarized in Table 1 below:

Table 1: Registered food-uses of Acephate.

Agr. Crop	Rate lbs. a.i./ Acre	Method/ Timing	PHI (days)	Max. lbs. a.i./ season; and restrictions
Beans (dry)	0.5	foliar, ground or aerial repeat as needed	14	Max. not stated; do not feed trt. vines to livestock.
	0.5-1.0 WI and east of Mississippi river.	foliar, ground; repeat as needed at 7 to 10 day interval	14	Max. not stated; do not feed trt. vines to livestock.
Beans (succulent, lima)	0.5	foliar, ground or aerial; repeat as needed	0	Max. not stated; do not feed trt. vines to livestock.
	0.5-1.0 WI and east of Mississippi river.	foliar, ground; repeat as needed at 7 to 10 day interval	0	Max. not stated; do not feed trt. vines to livestock.
Beans (succulent, other than lima)	0.5	foliar, ground or aerial; repeat as needed	14	Max. not stated; do not feed trt. vines to livestock.
	0.5-1.0 WI and east of Mississippi river.	foliar, ground; repeat as needed at 7 to 10 day interval	14	Max. not stated; do not feed trt. vines to livestock.

Table 1 Continued:

Agr. Crop	Rate lbs. a.i./ Acre	Method/ Timing	PHI (days)	Max. lbs. a.i./ season; and restrictions
Brussel sprouts	0.5-1.0	foliar, ground or aerial; repeat as needed	14	6.0 lbs ai/A; do not feed or graze livestock
Cauliflower	0.5-1.0	foliar, ground or aerial; repeat as needed	14	Max. not stated; do not graze or feed livestock
Celery	0.5-1.0 limited to CA and FL	foliar, ground; repeat as needed at 3 to 7 days in FL, and 3 to 10 days in CA.	21	Max. not stated; Plants should be marketed trimmed; do not feed tops to livestock
Cotton	0.5-1.0	foliar, aerial and ground; early, mid, and late season	21	Max. not stated; do not use threshings as feed, do not graze livestock
	0.4 lbs./ 100 lbs. seeds seeds	Apply with sufficient water for thorough coverage	N/A	0.4 lbs./ 100 lbs. seeds; do not use treated seeds for food/feed. Trt. seeds must be colored

Table 1 Continued:

Agr. Crop	Rate lbs. a.i./ Acre	Method/ Timing	PHI (days)	Max. lbs. a.i./ season; and restrictions
Cranberries	1.0	foliar, ground or aerial; repeat as necessary	90	Max. not stated
Lettuce (head)	0.5-1.0	Foliar, aerial and ground; repeat as needed; do not apply after 1st head is formed.	21	5 lbs.; do not feed trimmings to livestock, or graze trt. areas
Macadamia nuts	0.5-1.0	foliar, ground or aerial	120	Max. not stated
Pasture grass	0.094- 0.125	foliar, ground or aerial	21 days for dairy cattle; 0 days for beef cattle	0.125 lbs/ A/season; 1 day pre- slaughter interval for beef cattle
Peanuts	0.25- 1.0	foliar, ground or aerial	14	Max. not stated; do not feed or graze livestock
Pepper (bell)	0.5-1.0	foliar, ground; repeat as needed	7	Max. not stated

Table 1 Continued:

Agr. Crop	Rate lbs. a.i./ Acre	Method/ Timing	PHI (days)	Max. lbs. a.i./ season; and restrictions
Peppermint	1.0	foliar, ground or aerial	14	2.0 lbs./ A/season; do not feed or graze livestock
Rangeland grass		same as pasture grass		
Soybeans	0.25-1.0	foliar, aerial and ground.	14	Max. not stated; do not graze, or use treated vines for hay.
Spearmint		same as peppermint		
Tobacco	0.25-0.75	foliar, aerial and ground; repeat as needed at 7 day intervals	3	Max. not stated

Magnitude of the residue

ANALYTICAL METHODS

Analytical methods used in conjunction with established acephate tolerances, include:

Method RM-12: Orthene Residue Analysis by Thermionic Gas Chromatography. Received 2-23-72 from Chevron Chemical Co. in connection with PP#2G1248.

Method RM-12A: Orthene and the Metabolite Ortho 9006 Residue Analysis by Thermionic Gas Chromatography. Received 9-12-72 from Chevron Chemical Co. in connection with PP#3F1375.

Method RM-12A-3: Orthene and the Metabolite 9006 Residue Analysis by Thermionic Gas Chromatography. Chevron Chemical Co., dated 9-12-72.

Method RM-12A-4: Orthene and the Metabolite 9006 Residue Analysis by Thermionic Gas Chromatography. Chevron Chemical Co., dated 4-25-74.

Method RM-12A-5: Residue Analysis of Acephate and Methamidophos in Crops, Soil, Water, and Milk. Chevron Chemical Co. (1-25-78).

Method RM-12B: Analysis of Orthene Residues by Thin-layer Chromatography. Chevron Chemical Co. (1-21-72); submitted in connection with PP#2G1248.

Methods RM-12A and RM-12B are described in PAM Vol. II, and are considered adequate for enforcement purposes. Method RM-12A-3, RM-12A-4, and RM-12A-5 are similar to RM-12A, with minor modifications to the extraction/cleanup schemes. Method RM-12 contains extraction procedures applicable to cottonseed, eggs, meat, milk, soil, soybeans, and vegetables. Following extraction the sample workup is subjected to silica gel cleanup, then analyzed for acephate/methamidophos by Gas Chromatography utilizing flame photometric detection (phosphorus mode). RM-12 has a limit of detection of 0.01 ppm for acephate, and 0.04 ppm for methamidophos.

Residue data, submitted in response to the Acephate Registration Standard DCI, were generated utilizing method RM-12A-6 (MRID No. 405048). Method RM-12A-6 includes separate extraction/cleanup procedures for: crops, milk and water, oily crops, oil, dry crops, cured tobacco, and cotton lint. FDA surveillance data were generated utilizing the PAM I, 232.3 charcoal column cleanup procedure, and GLC/NPD or FPD detection (phosphorus mode).

Residue data

The 1986-88 FDA domestic and import surveillance monitoring data for acephate are summarized in Tables 2 and 3 below:

Table 2: FDA domestic surveillance data (86-88) for residues of acephate

<u>Commodity</u>	<u>No. of Samples</u>	<u>Average Residue (ppm)</u>	<u>Upper 95% Confidence limit</u>
Beans succulent	208	0.04	0.05
Brussel sprouts	37	ND (<0.01)	n/a (not/applicable)
Cauliflower	284	ND (<0.01)	n/a
Celery	238	0.07	0.08
Cranberries	89	ND (<0.01)	n/a
Lettuce	1523	0.01	0.02
Peppers	235	0.20	0.25

Table 3: FDA import surveillance data (86-88) for residues of acephate

<u>Commodity</u>	<u>No. of Samples</u>	<u>Average Residue (ppm)</u>	<u>Upper 95% Confidence limit</u>
Beans succulent	387	ND (<0.01)	n/a
Brussel sprouts	110	ND (<0.01)	n/a
Cauliflower	74	ND (<0.01)	n/a
Celery	58	0.16	0.23
Cranberries	2	ND (<0.01)	n/a
Lettuce	149	0.02	0.03
Peppers	1802	0.05	0.06

Residue data (data reflects registered uses) from field trials conducted in support of established tolerances are summarized in Table 4 below:

Table 4: Residue data generated in support of established tolerances:

<u>RAC/ Petition</u>	<u>No. of samples</u>	<u>Average Residue(ppm)</u>	<u>% of Crop Treated ^a</u>
Cottonseed/ PP#3F1375			ca. 10%
seed	6	0.22	
meal	4	0.33	
Soybeans/ PP#3F1375			< 1%
beans	4	0.06	
flour	4	ND (<0.01)	
Peanuts/ PP#2F2632			ca. 10%
nutmeat	185	ND (<0.01)	
hulls	11	0.539	
Grass/ (MRID no. 405048-04)			< 1%
fresh/ 0 day PHI		14	
1 day PHI		14	
3 day PHI		9	
7 day PHI		7	
14 day PHI		8	
21 day PHI		1.5	
hay/ 0 day PHI		15	
1 day PHI		14	
3 day PHI		10	
7 day PHI		8	
14 day PHI		8	
21 day PHI		3	
Macadamia nuts/ PP#4E3028	7	ND (<0.01 ppm)	not available
Mint (MRID No. 4056048-03)			
fresh	6	14	not available
spent	4	3	
oil	2	ND (<0.02)	

a. personal communication (R. Torla, BEAD).

STORAGE STABILITY DATA

The storage stability of "weathered" commodities was cited as a data gap in the Acephate Registration Standard DCI, i.e.:

"Weathered residues of acephate and methamidophos must be determined in or on the following commodities immediately prior to storage and at intervals approximating the maximum period of storage at subfreezing temperatures: beans, celery, cottonseed, grass, and lettuce. In addition, eggs, milk, and animal tissues must be similarly tested."

In response to this data gap, Chevron Chemical Co. submitted a storage stability study entitled: Storage Stability of Acephate in Frozen Crops, Milk, and Tissues; Laboratory Project Identification R12-1987SS, Dated 12-9-87 (MRID No. 405048-02).

In this study the registrant provided storage (frozen conditions) stability data for residues resulting from "weathered" crops, animal feeding studies, and an egg fortification study.

Weathered samples from field trials in which ORTHENE 75 S (10 trials) or ORTHENE 5% BAIT (1 trial) was applied (0.125 to 2.0 lbs. ai/A) were harvested (0-28 days after last treatment), packed in dry ice and transported to Chevron's Ortho Research Laboratory. Each commodity was immediately analyzed for acephate placed in frozen storage (-20°C), and periodically re-analyzed. All assays were performed using Method RM-12A-6 (see, MRID 405048-02). The stability of acephate residues in weathered crop samples, under frozen storage conditions, are summarized in Table 5 below:

Table 5: Stability of Acephate residues under frozen storage conditions:

<u>Crop Commodity^a</u>	<u>Days in Storage</u>	<u>% Residue Remaining Acephate</u>
Snap beans	69	79
Pigeon Peas	418	107
Bell Peppers	386	108
Brussel Sprouts	272	86
Celery	94	111
Cottonseed	48	80
Grass	269	89
Fresh Grass	61	115
Dry Grass	60	100

Table 5 Continued:

Mint Hay	58	79
Spent Mint Hay	58	96
Lettuce	504	89
Rice Grain	506	104
Rice Straw	507	92

Milk and tissue samples containing acephate were obtained from a 28 day feeding study in which dairy cattle were fed 15, 30, and 60 ppm ORTHENE. The stability of acephate residues in incurred animal tissue during frozen storage are summarized in Table 6 below:

Table 6: Stability of Acephate and residues in cattle tissue under frozen storage conditions.

<u>Tissue Commodity</u>	<u>Days in Storage</u>	<u>% Residue Remaining Acephate</u>
Milk	202	119
Kidney	172	72
Muscle (Pectoral)	193	100

Egg samples containing acephate residues were obtained by fortifying blended shell eggs. The level of acephate in these samples remained constant under frozen storage for up to 175 days.

PROCESSING/COOKING STUDIES

Data gaps pertaining to cooking and/or processing of Raw Agricultural Commodities treated with acephate are cited in the Acephate Registration Standard DCI. Cooking and/or processing studies are required for succulent beans, dry beans, soybean oil, and soybean defatted flour (see, foot note 9 of Table A, §158.125 Residue Chemistry). In response to these data gap, Chevron Chemical Co. submitted a Residue Study entitled:

Magnitude of the Residue in Beans; Laboratory Project
Identification R12T70177091, Dated 11-24-87 (MRID No. 405048-05).

In this study the registrant provided acephate residue data from "weathered" bean crops (succulent, dry, and soybean) following cooking/processing, as follows:

Snap beans

Two field trials (1 each in WI and IL) were conducted during 1987. The WI field trial involved two postemergence foliar applications of ORTHENE 75S (1.0 lb. acephate a.i./A; 7 day interval between applications) using a tractor drawn boom sprayer. The crop was mechanically harvested 14 days after the final treatment. The IL field trial involved 4 aerial applications of ORTHENE 75S (0.75 lb acephate a.i./A; 5-6 day interval between applications). The crop was harvested 22 days after the final treatment. Harvested samples were refrigerated (fresh beans) and shipped to either the laboratory or cannery. A small representative sample of harvested beans was frozen to determine "at harvest" residue levels.

Cooking: Fresh beans (Succulent beans with pods) received by the laboratory were rinsed with water and a portion of the rinsed beans were then cooked for 35 minutes. The rinse water and cooking water were saved for analysis along with the cooked beans.

Canning: Fresh beans received by the cannery were sampled then frozen prior to canning.

Analytical methods RM-12A-5 and RM-12A-6 were used to assay all samples; results are summarized in Tables 7 and 8 below:

Table 7: Acephate residues in or on snap beans, resulting from ground applications (2) of 1.0 lbs acephate a.i./A and a 14 day PHI (WI trial); and aerial applications (4) of 0.75 lbs. ai/A and a 22 day PHI (IL trial).

<u>RAC</u>	<u>Acephate Residues in ppm</u>	
	<u>WI</u>	<u>IL</u>
Succulent bean with pod at harvest ^a	0.35	0.40
<u>COOKING</u>		
Fresh Beans (unfrozen)	0.19	0.42
Fresh Beans (washed)	0.23	0.39
Wash water	<0.01	0.07
Fresh Beans (cooked)	0.17	0.20
Cooking water	0.09	0.19

COMMERCIAL PROCESSING

Succulent Beans with pod	0.32	0.40
Canned Beans	0.08	0.03
Water from canned Beans	0.08	0.02

The above data show a 0 to 50% residue reduction resulting from non-commercial preparation/cooking, and a 75-93% reduction resulting from commercial canning.

Dry pinto beans

One field trial in CA was conducted during 1987. Six foliar applications of ORTHENE 75 S (1.0 lb. acephate a.i./A.) were made using a backpack boom sprayer. Bean vines were cut 14 days after the final treatment and were allowed to field dry for 10 days before being hand threshed. No acephate residues were found in the dry shelled beans or any processed fractions (cooked or canned).

Mint

Chevron Chemical Co. also submitted a mint processing study entitled: Magnitude of the Residue in Mint; Laboratory Project Identification R12T70297035, dated 11-3-87 (MRID No. 405048-03). In this study the registrant provided acephate/methamidophos residue data for fresh mint hay, spent mint hay, and mint oil, as follows:

Four field trials (2 in WA, and 2 in OR) were conducted during 1987. Peppermint and spearmint fields were treated with a single ground (1 trial) or aerial (3 trials) application of acephate at 1.0 lb. a.i per acre. Mint was harvested 14 days after treatment. Green hay and spent hay were analyzed from each site, while mint oil was processed and analyzed from only 2 of the test sites. All samples were analyzed using Method RM-12A-6. The method's limit of sensitivity is 0.02 ppm for acephate in or on mint hay and oil. Recovery of acephate from control mint samples fortified at 0.25 ppm were reported to be: 128% for green hay, 110% for spent hay, and 84% for mint oil. Analytical results are summarized in Table 8 below:

Table 8: Acephate residues mint (fresh, spent hay, and oil)

<u>Mint</u> <u>Hay</u>	<u>No. of</u> <u>Samples</u>	<u>Average</u> <u>Residue</u>
Green hay	6	14 ppm
Spent hay	4	3.0 ppm (max. residue was 4.0 ppm)

<u>Fraction</u>	<u>Treatment Site</u>	
	<u>OR; R-12-7035</u>	<u>WA; R-127029</u>
Green hay	5.2 ppm	--
Spent hay	0.05 ppm	1.2 ppm
Mint oil	ND (<0.02 ppm)	ND (<0.02 ppm)

The above data indicate that acephate residues in or on fresh mint do not concentrate during processing. Based on these data the registrant requested that the label restriction against feeding spent mint hay to dairy cattle be reconsidered.

Meat, Milk, Poultry, and Eggs

To support current meat and milk tolerances, the registrant previously submitted a dairy cattle feeding study entitled:

Meat and Milk Residue Study with Orthene and Ortho 9006 in Dairy Cattle, January 11, 1973, Chevron File No. 741.11 (MRID 00015225).

In this study, 3 cows were dosed with acephate and methamidophos (5:1) for 30 consecutive days at levels of 3 to 30 ppm acephate and 0.6 to 6.0 ppm methamidophos. However, since the collected milk was not processed, the study was cited as being incomplete (Acephate Registration Standard DCI), i.e.,

"A dairy cattle feeding study must be conducted in which cattle are fed acephate and methamidophos at approximately 5:1 ratio in the diet. The feeding level should be high enough to result in detectable residues of both acephate and methamidophos in milk. Exaggerated rates would be advantageous. Residues of acephate and methamidophos must be determined in whole raw milk (containing detectable residues of each compound), pasteurized milk, and in nonfat milk solids, milk fat solid, and possibly milk sugar."

In response to this data gap, the registrant submitted a study entitled:

28-Day Milk and Meat Residue Study with Acephate Technical plus Methamidophos Technical in a 5:1 Ratio in Dairy Cattle; Laboratory Project Identification No. R1287MM7, dated 10-19-87. (MRID No. 405048-06)

In this study 3 groups (4 cows per group) of lactating dairy cattle were orally dosed for 28 consecutive days. The daily dose (1/2 at morning and 1/2 at evening milking) was administered in gelatin capsules containing a feed equivalent of 15, 30, and 60 ppm acephate, and 3, 6, and 12 ppm methamidophos. A separate group of 2 cows were used for control purposes. Milk samples were collected from individual animals on day 0, 1, 4, 8, 12, 16, 20, 24, 28, 29, and 30. Milk samples were also collected on day 25, 26, and 27 from the high dose group, pooled and processed to obtain pasteurized milk, non-fat solids, milk fat solids, milk sugar, and protein. On day 28, 3 animals from each group were sacrificed and samples of liver, kidney, fat (peritoneal and subcutaneous) and muscle (adductor, cardinal and pectoral) were collected. On day 31, the remaining animal in each group and one control animal were sacrificed and identical tissue samples were collected. All tissue samples were frozen (packed in dry ice) immediately after collection and shipped to Chevron's Residue Laboratory for analysis. The samples were assayed utilizing Analytical method RM-12A-6. The acephate analytical results from this feeding/processing study are summarized in Tables 9, 10, and 11 below:

Table 9: Acephate residues in milk of dairy cattle.

Day	Feeding Dose		
	15 ppm	30 ppm	60 ppm
0	0.02	0.07	0.15
1	0.14	0.26	0.69
4	0.13	0.33	0.86
8	0.15	0.27	0.92
12	0.13	0.29	0.86
16	0.15	0.28	0.91
20	0.15	0.37	0.81
24	0.18	0.39	0.85
28	0.17	0.33	0.80

The above data clearly show that acephate residues in milk plateau within 4 days, reaching levels of ca 0.15 ppm from the 15 ppm dose; 0.30 ppm from the 30 ppm dose; and 0.90 ppm from the 60 ppm dose.

Table 10: Acephate residues in tissue of dairy cattle.

<u>Tissue</u>	<u>Feeding Dose</u>		
	<u>15 ppm</u>	<u>30 ppm</u>	<u>60 ppm</u>
Muscle			
Cardinal	0.09	0.15	0.34
Pectoral	0.11	0.18	0.35
Adductor	0.22	0.16	0.35
Fat	0.07	0.11	0.29
Kidney	0.24	0.36	0.74
Liver	0.02	0.03	0.10

Table 11: Acephate residues in processed milk fractions, from dairy cattle fed 60 ppm acephate.

<u>Milk Fraction</u>	<u>Residue in ppm Acephate</u>
Pasteurized Milk	0.83
Non-fat Milk solids	0.62
Milk fat solids	0.06
Milks Sugar (lactose)	0.45
Protein	0.44
Milk	0.78

The above data indicate that acephate residues: are not significantly affected by pasteurization; and do not concentrate in non-fat milk solids, milk fat solids, milk sugar, and milk protein.

Grass, pasture and rangeland

Chevron Chemical Co. submitted a residue field trial entitled: Magnitude of the Residue in Grass (MRID No. 405048-04). This study was conducted in response to the Agency's concern that

residues (at over tolerance levels, >0.1 ppm) may result in milk, if dairy cattle were fed grass containing acephate residues at the established tolerance (15 ppm). This concern led the Agency to require an interim feeding/grazing restriction of 21 days for dairy cattle (see Acephate Registration Standard Guidance Document).

Two field trials (1 each in OK and TX) were conducted during 1987. Grass pastures were treated with a single postemergence application of acephate at 0.125 lb. a.i. per acre utilizing a tractor mounted boom sprayer or CO2 backpack sprayer. Samples were harvested at 0, 1, 3, 7, 14, and 21 days after application. Fresh grass and dried grass (1-2 days drying time) were analyzed from each site. All samples were analyzed using Method RM-12A-6. The method's limit of sensitivity is 0.02 ppm for acephate in or on grass. Recovery of acephate from control grass samples fortified at 0.25 ppm were reported to be 99.8% for grass. The results of this study are summarized in Tables 12 and 13 below:

Table 12: Acephate residues in fresh pasture grass, following a single treatment at 0.125 lb. a.i./A.

<u>PHI</u>	Acephate Residues (ppm)	
	Site	
	<u>OK</u>	<u>TX</u>
0	6.8	14.0
1	0.7	13.5
3	0.5	8.9
7	0.1	6.7
14	ND (<0.02)	7.8
21	ND (<0.02)	1.5
ca. half life	2 days	8 days

Table 13: Acephate residues in dried pasture grass, following a single treatment at 0.125 lb. a.i./A.

Acephate Residues (ppm)		
Site		
<u>PHI</u>	<u>OK</u>	<u>TX</u>
0	10.8	14.5
1	2.4	14.0
3	1.0	9.8
7	0.1	8.2
14	0.1	7.5
21	ND (<0.02)	3.4
ca half life	2 days	11 days

Based on the above data, the registrant concluded that the acephate tolerance in or on grass (15 ppm) will not be exceeded as a result this registered use. Furthermore, the registrant concluded that the acephate milk tolerance (0.1 ppm) will not be exceeded if lactating dairy cattle are fed dried hay, harvested 7 or more days after treatment with acephate at 0.125 lb. a.i./A. The maximum acephate residue on hay, 21 days after treatment was 3.4 ppm.

DEB's estimation of potential acephate residues in milk

Acephate tolerances are established for several raw agricultural commodities used as dairy cattle feed items. It should be noted, however, that most registered uses on potential animal feed items contain restrictions against livestock feeding/grazing, i.e.,

<u>Feed Item</u>	% OF LIVESTOCK DIET		<u>Labeled Use Restrictions</u>
	<u>BEEF</u>	<u>DAIRY</u>	
Beans			
seeds	20	20	Do not feed treated vines to livestock
vines	20	35	
cannery waste	20	20	
hay	20	35	

Table 13 continued:

<u>Feed Item</u>	<u>% OF LIVESTOCK DIET</u>		<u>Labeled Use Restrictions</u>
	<u>BEEF</u>	<u>DAIRY</u>	
Cottonseed			
seeds	25	20	Do not feed threshing or treated seeds to livestock
meal	15	15	
hulls	15	5	
soapstock	5	5	
forage	20	40	
Grass			
fresh	75	70	21 day feeding/ grazing restriction for dairy cattle; 0 days for beef
hay	70	70	

Note to PM: Based on data submitted in response to the Acephate Registration Standard DCI, the registrant has requested that a 7 day feeding/grazing restriction be established for treated grass.

Mint			
spent hay	25	60	Do not feed treated hay to livestock.

Note to PM: Based on data submitted in response to the Acephate Registration Standard DCI, the registrant has requested that the feeding restriction for spent mint hay (treated with acephate) be reconsidered by the Agency.

Peanuts			
meal	15	25	Do not graze or feed treated vines to livestock
vines	20	40	
hay	25	60	
hulls	5	not used	
soapstock	5	5	
Soybeans			
seeds	10	25	Do not graze, or use treated vines for hay
meal	25	25	
hulls	20	10	
ensiled	25	40	
hay	10	40	
straw	10	not used	
forage	20	40	
soapstock	5	5	

Based on the above information, hay from acephate treated pasture grass reflects the most likely source for transfer of acephate residues to meat and milk. Utilizing an acephate residue concentration of 3.4 ppm (maximum residue detected on hay, 21 days after treatment), the daily dietary burden to cattle would be 2.4 ppm ($3.4 \times 70\%$).

By constructing least square linear regression curves (plotting the acephate feeding dose vs. the corresponding acephate concentrations found in milk and tissue from the dairy cattle feeding study), we can estimate (by extrapolation) the level of acephate in the milk and tissue of cattle fed acephate treated pasture grass hay, as follows:

Linear regression curve for acephate residues in milk

<u>Feeding-dose</u>	<u>Residue in milk</u>
15 ppm	0.15 ppm
30 ppm	0.30 ppm
60 ppm	0.90 ppm

Regression curve $Y = mX + b$

$$Y = 0.017 x - 0.15 ; r = 0.990$$

Y = residue concentration in milk

X = acephate dose

m = slope of the curve

b = y intercept when x is 0

r = coefficient of correlation

Estimated acephate concentration in milk of dairy cattle fed hay from acephate treated pasture grass.

PHI	Acephate hay conc.	Dietary Burden ^a	Est. (extrapolated) milk residue ^b
21	3.4	2.4	ND (<0.01 ppm)

a. Reflects a diet of 70% pasture hay.

b. The estimated acephate residue is below the established tolerance for milk at 0.1 ppm. Furthermore, taking into consideration the percent of pasture grass treated with acephate (<1%) the residue values would be further reduced by 2 orders of magnitude to <0.0001 ppm.

Linear regression curve for acephate residues in muscle tissue

<u>Feeding-dose</u>	<u>Acephate Residue in</u>	
	<u>Muscle</u>	<u>Kidney</u>
15 ppm	0.14	0.24
30 ppm	0.16	0.36
60 ppm	0.35	0.74

Regression curve for muscle tissue:

$$Y = mX + b$$

$$Y = 0.005x + 0.045$$

$$r = 0.969$$

Regression curve for kidney tissue:

$$Y = mX + b$$

$$Y = 0.011x + 0.05$$

$$r = 0.995$$

PHI	Dietary Burden ^a	<u>Est. (extrapolated) Acephate Residue^b</u>	
		<u>Muscle</u>	<u>Kidney</u>
0	10.2	0.095	0.17

a. Reflects a diet of 70% pasture hay, and a 0 day PHI.

b. The estimated acephate residue in muscle tissue is below the established tolerances (0.1 ppm); while the estimated acephate residues in kidney tissue exceeds the established tolerance (0.1 ppm). Taking into considerations the percent of crop treated (< 1%) the estimated tissue concentrations become 0.001 and 0.002 ppm for muscle and kidney tissue, respectively.

Poultry and Eggs

Soybean seeds and soybean meal are the poultry feed items most likely to result in the transfer of acephate residues to poultry meat and eggs.

Acephate residue data submitted in support of the established tolerances (see, Acephate Registration Standard) for poultry tissue (0.1 ppm) and eggs are summarized below:

Poultry muscle tissue:

<u>Feeding dose</u>	<u>Acephate Residue (ppm)</u>
10 ppm	ND
30 ppm	0.12

Poultry eggs:

<u>Feeding dose</u>	<u>Acephate Residue (ppm)</u>	
	<u>7 day</u>	<u>14 day</u>
3 ppm	ND (<0.01)	ND (<0.01)
10 ppm	0.07	0.08
30 ppm	0.19	0.19

Based on the available residue data for soybeans treated with acephate, the acephate dietary burden to poultry will be less than 3 ppm, therefore, finite residues (ND < 0.01 ppm) of acephate in poultry tissue and eggs are not expected to occur. Furthermore, taking into consideration the % of the soybean crop treated with acephate (ca. 10%), the estimated acephate residue in poultry tissue and eggs would be <0.001 ppm.

cc:R.F.,S.F.,Circu,Acephate Reg. Std. file ,SACB (Jaeger)
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