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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

30 JUN 1986

Memorandum

Subject: Monitor: Registrant 90 day response to 3c2B letter

To: William Miller
Product Manager
Registration Division

From: M. Rostker
Ecological Effects Branch
Hazard Evaluation Division

Thru: Michael Slimak
Chief
Ecological Effects Branch

Thru: Harry Craven
Section Head
Ecological Effects Branch

Regarding the Registration Standard of Methamidophos (Monitor), a 3(c)2(B) letter was sent to the registrants amending the standard to include field residue monitoring and field testing for avian hazards. The data required for residue monitoring include measured residues on soil, vegetation, nontarget insects and water, over a one year period, on the five crops of cotton, cabbage, celery, sugarbeets and potatoes. Also required is the regular collection of nontarget wildlife in these five crops and the analysis of the wildlife for residues and brain and blood cholinesterase levels.

The registrant has submitted crop residue data with claims that the data adequately describe the profile of methamidophos residues under field use conditions. The data pertain to cabbage, celery, collards, endive, kale, lettuce, mustard, spinach, and turnips (a total of 10 crops). According to Table 1 of the data submission (Crop Summary of Residues), the upper limits of the residue ranges exceed the Bobwhite Quail Reproductive No Effect Level of Less Than 5 ppm for the following crops: cabbage on day 0; celery on day 14; collards on day 7; endive on day 14; kale on day 7; lettuce on day 14; mustard on day 14; spinach on day 14; and turnips on day 14.

Crops with residues nearing or exceeding the Bobwhite Quail LC_{50} = 42 ppm are: collards on day 3; endive on day 7; kale on day 3; lettuce on day 3; mustard on day 3; spinach on day 3; and turnips on day 7.

These data show that lethal residues are available to foraging birds for periods up to one week after final application of 1 lb ai/A. Reproductive effect levels are exceeded for periods of at least two weeks after final application of 1 lb ai/A.

The residue monitoring requirement is not fulfilled by the data submitted by the registrant. No soil, water, insect or wildlife samples were reported. Further, the crops of cotton, sugarbeets, and potatoes were not monitored.

The second data requirement in the amendment to the Registration Standard is that of actual field testing in cotton and cabbage. These crops are representative of, in the case of cotton, a large acreage crop with potential for risk to both fish and wildlife. Cabbage represents an important forage source for birds and one found in ecologically diverse areas. Minimum test parameters must include nest box monitoring, cholinesterase analysis and behavioral monitoring. These studies must use at least one site per crop and include a one-year baseline study and two treatment years. Protocols must be specific to proposed sites and methodology. Protocols should be submitted at least 90 days prior to the anticipated initiation of the studies. Other details and rationale for this requirement are contained in the 3(c)2(B) letter. It is especially important that proposed sites must be identified in the submitted protocol in order that EEB may determine the appropriateness of the proposed methodology and sampling regime for the study.

The field testing requirement is not fulfilled nor does this submission constitute fulfillment of the requirement to submit a protocol within six months of receipt of the data requirement letter.

attachments: 1. Table 1 of residue data sumission by Chevron (dated May 9, 1986)

2. 3(c)2(B) (dated February 13, 1986)

3. EEB memo requiring residue and field studies (dated September 23, 1985)

TABLE 1. CROP SUMMARY OF METHAMIDOPHOS (MONITOR) RESIDUE DATA HAZARD EVALUATION - REREGISTRATION

Crop	Interval Between Sprays, Days	lb/A	# Appl.	METHAMIDOPHOS RESIDUES, PPM DAYS AFTER LAST APPLICATION 0	1	3	7	14	21
Cabbage	7-8	1.0	5	0.12-49.9		0.12-0.13	0.06-0.08	0.02-0.03	
Celery	3-7	1.0	8-13	2.3-18.2		0.95-12.6	0.62-10.8	0.31-5.08	
Collards	3-9	1.0	3-6	26.5-147		3.10-97.5	1.12-11.6	0.07-3.84	
Endive	3-8	1.0	5-10	79-145		46-97	17-53	1.7-20	
Kale	7-9	1.0	3-5	18.9-98.0		3.0-38.4	0.86-10.5	0.38-3.84	
Lettuce	6-7	1.0	2-5	12.6-87		30-34	5.8-19.7	2.97-18.7	
Mustard	4-9	1.0	3-6	84.6-312		6.01-151	1.59-10.4	0.53-10.7	
Spinach	7-8	1.0	3-4	34-90.8		36.8-94	6.0-29	1.1-30	
Turnips	3-7	1.0	3-8	23.6-307		13.1-52.0	4.1-45	1.02-14.3	

Are these for Monitor 4 or 6 ?

FXK:kt/P-9
4/25/86

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

mailed 2/13/86

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

Subject: Amendment to the September 1982 Guidance Document for the Reregistration of Manufacturing-Use Products and Certain End-Use Products Containing Methamidophos as the Single Active Ingredient

This Notice is to inform you that the Guidance Document for the registration of methamidophos is being amended to require registrants of manufacturing-use products to submit certain data not previously required in the September 1982 Methamidophos Guidance Document.

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt from doing so, then the registration(s) of your product(s) subject to this Notice will be suspended. We have provided a list of all of your products subject to this Notice (Attachment A), as well as a list of all registrants who have received this Notice (Attachment B).

The authority for this Notice is Section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. §136a(c)(2)(B).

WHY YOU ARE RECEIVING THIS NOTICE NOW

Additional data are needed to fully assess the potential hazard to avian species from the use of methamidophos. The submitted small pen (simulated field study) on birds which was required under the September 1982 Guidance Document to address this potential hazard, has been evaluated and has been found to contain major unrepairable deficiencies.

Instead of requiring that the pen study be repeated, the Agency believes that more useful data can be obtained from actual field testing and residue monitoring studies. Therefore, the Agency is requiring residue monitoring and actual field testing to address the potential hazard to avian species resulting from the use of methamidophos.

The residue test is required to specifically address short-term, acute toxicity hazards, and the actual field test is required to address chronic, sublethal hazard and potential for avian population reduction. Both tests are to be conducted with typical end-use products, employing normal agricultural practices and maximum use rates. The protocols, including test site selection, must be approved by the Agency prior to test initiation.

DATA REQUIRED

A. Data Needed

1. §70-1: Special Tests: Field Residue Monitoring.

This study will involve monitoring of methamidophos residues on avian food items in selected field crops. A major objective of this study is to determine the acute, short-term hazard to birds from methamidophos residues on avian food items. Soil, vegetation, nontarget insects and water should be monitored for residues over a full year's time on a minimum of the following five crops: cotton, cabbage, celery, sugarbeets, and potatoes. Free-living, nontarget wildlife will be collected on a regular basis in these crops, and analyzed for brain and blood cholinesterase, and residue levels. Selected avian species sampling will be of special emphasis.

2. §71-5: Actual Field Testing.

This study will involve a full-scale actual field test of avian population in selected field crops. A major objective of this study is to determine the

chronic, sublethal effects and the population reduction hazard to birds from use of methamidophos. The multiple-year study should be conducted on a minimum of the following two crops: cotton and cabbage. These crops are selected as representative of, in the case of cotton, a large acreage crop with potential for nontarget risk to both aquatic and terrestrial organisms. Cabbage is selected as a representative of a potentially important forage source for birds and one that is found in ecologically diverse areas with considerable interspersion of wildlife habitat throughout the production areas. Cabbage also is important because it is grown year round in areas frequented by nesting and/or migratory birds. Minimum test parameters should include nest box monitoring for sublethal, chronic effects, avian brain, blood and carcass analysis for residues and/or cholinesterase depression, behavioral monitoring for sublethal, chronic effects, and individual fate determinations for selected, marked individuals of avian populations on the study sites.

This study will entail a one-year baseline study wherein nest boxes are established and the nontarget wildlife community is characterized and quantified. No methamidophos will be used the first year. In the second and third year methamidophos will be used and the wildlife, soil, vegetation, water and nest boxes monitored for the appropriate parameters. The data thus generated will permit comparison between a pre- and post-treatment data set to statistically determine chronic risk and population reduction hazards.

B. Schedules for Submission of Data

Data must be submitted according to the following schedules:

1. §70-1 Special Tests - Field Residue Monitoring

Your proposed protocol for this study must be submitted within 6 months from date of receipt of this Notice. The study must be submitted within 15 months from date of acceptance of the protocol by the Agency.

2. §71-5 Actual Field Testing

Your proposed protocol for this study must be submitted within 6 months from date of receipt of this Notice. The study must be submitted within 42 months from date of acceptance of the protocol by the Agency.

COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

Within 90 days of receiving this Notice, you must submit for each of your products subject to this Notice a completed copy of the "FIFRA section 3(c)(2)(B) Summary Sheet," (EPA Form 8580-1, Attachment C). On that sheet you must state which option(s) you have selected to comply with this Notice. At the same time, you must also submit any additional documents required to support the option(s) chosen. The Summary Sheet and other attachments are provided to assist you in accurately and quickly responding to this Notice. Do not alter the printed material.

INQUIRIES AND RESPONSES TO THIS NOTICE

All correspondence or questions concerning this Notice should be directed to:

William H. Miller
Product Manager (16)
Registration Division (TS-767)
U.S. Environmental Protection Agency,
401 M Street SW.,
Washington, DC 20460.
(703) 557-2600

Sincerely,

for Douglas D. Campt, Director
Registration Division

Enclosures:

Attachment A = List of Registrant's Products Containing Methamidophos
B = List of all Registrants Receiving This Notice
C = Section 3(c)(2)(B) Summary Sheet

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

Memorandum

23 SEP 1985

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Subject: Amendment to the Registration Standard for Methamidophos

From: Michael Slimak, Chief
Ecological Effects Branch
Hazard Evaluation Division

To: William Milller, PM 16
Insecticide-Rodenticide Branch
Registration Division

As a result of reviewing data required under the Registration Standard for Methamidophos, EEB has determined additional data are required to address ecological safety concerns. Therefore, EEB seeks to amend the data requirements in the following manner:

1. §72-3. Acute toxicity test for estuarine and marine organisms: Oyster.

The submitted oyster shell deposition test, reviewed in EEB review of September 20, 1985, is invalid. The data requirement is not changed and thus remains outstanding.

2. §71-5. Simulated (small pen) Field Test: Avian (Bobwhite Quail).

The small pen study, reviewed in EEB review of September 20, 1985, is invalid. However, this data requirement has been determined to be insufficient to address EEB concerns for avian risk. EEB removes this data requirement and is no longer requiring this study.

3. §70-1. Special Tests: Field Residue Monitoring: Terrestrial

This study is now required. A primary objective of this data requirement is to determine the acute, short-term hazard to birds from methamidophos residues on avian food. In order to document safety of methamidophos, residues must be monitored for a full year on a minimum of the following 5 crops: cotton, cabbage, celery, sugar beets and potatoes. These crops are selected as being representative of a variety of avian food sources, and of crop acreages located in a variety of ecologically diverse habitats used by birds. Soil,

vegetation, non-target insects, and water should be monitored for residues resulting from normal agricultural application of methamidophos at maximum label rates and maximum numbers of repeat applications in minimum time frames between repeated applications. Free-living, non-target wildlife should be collected on a regular basis in these crops, and analysed for brain and blood cholinesterase, and residue levels. Selected avian species sampling will be of special emphasis. The protocol, including study site selection, must be approved by EEB prior to test initiation. These data are due in 18 months.

4. §71-5. Actual Field Testing: Avian.

This study is now required. A primary objective of this data requirement is to determine the chronic, sublethal effects and the population reduction hazard to birds from use of methamidophos. These data are critical to assessing safety because methamidophos has been shown to negatively effect bird reproduction at very low levels, well below LC_{50} values. The multiple-year study should be conducted on a minimum of the following two crops: cotton and cabbage. These crops are selected as representative of, in the case of cotton, a large acreage crop with potential for non-target risk to both aquatic and terrestrial organisms. Cabbage is representative of an important forage source for birds, and as a crop found in diverse areas containing considerable interspersion with wildlife habitat. Cabbage also is important because it is grown year round in areas frequented by nesting and/or migratory birds. Minimum test parameters will include nest box monitoring for reproductive effects; avian brain, blood, and carcass analysis for residues and/or cholinesterase depression; behavioral monitoring for sublethal, chronic effects; and, individual fate determinations for selected, marked individuals of bird populations on the study sites.

~~This~~ study will entail a one year baseline period wherein nest boxes are established and the non-target wildlife populations ~~characterized and quantified. No methamidophos the first year. In~~ the second and third year, methamidophos will be used at ~~maximum rates~~, with the maximum number of minimally spaced repeat applications. Wildife, soil, vegetation, non-target insects, water and nest boxes will be monitored for the appropriate parameters. The data thus generated will permit comparison between a pre- and post-treatment data set to determine chronic risk and population reduction hazards. The protocol, including study site selection, must be approved by EEB prior to test initiation. This study is due in 48 months.

On the following page EEB is providing an abbreviated Generic Data Requirement Table to illustrate the changes made by EEB to the original Registration Standard data requirement table.

Changes to Table A-5 cont.

5. Testing is required to determine chronic, sublethal effects and population reduction hazard to birds. A multiple-year study is required on the following crops: cotton and cabbage. An initial one year baseline period is required to establish nest boxes and quantify the resident free-living non-target wildlife populations. No methamidophos is to be used the baseline year. In the second and third year of the study methamidophos is to applied at maximal rates with the maximum number of repeat applications over the mimimal time permitted between applications. Minimum test parameters will include nest box establishment and monitoring for reproductive effects; avian brain and blood cholinesterase monitoring; avian carcass residue analysis; behavioral monitoring for sublethal, chronic effects; and individual fate determinations for marked birds within the study site populations. The protocol must be approved by EEB prior to study initiation. The study is due in 48 months.

Changes to Table A-5 in Registration Standard for Methamidophos

Guidelines Citation	Name of Test	Composition	Does EPA have data?	Biblio. Citation	Must data be submit?
§72-3	Acute tox. to estuarine/ marine organisms	TG	no	---	yes[3]
§71-5	Simulated Field Testing: Mammals & Birds	Monitor 6 Spray	no	---	no
§70-1	Special Tests: Field Residue Monitoring	TEP	no	---	yes[4]
§71-5	Actual Field Testing: Birds	Monitor 6 Spray	no	---	yes[5]

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3. Testing is required to establish the acute toxicity of the technical pesticide to estuarine or marine invertebrates when the end-use product is expected to enter the estuarine or marine environment in significant concentrations because of its use or mobility pattern. In the case of methamidophos, it is very soluble in water and mobile on the soil and it is used on cotton and on vegetable crops in Florida and other Gulf coastal states adjacent to estuarine and marine habitat.

4. Testing is required to establish actual residue levels in field crops that are utilized by birds and other non-target organisms. A full year of residue monitoring is required on the following 5 crops: cotton, cabbage, celery sugar beets and potatoes. Samples of non-target wildlife, especially birds, soil, vegetation, non-target insects and water must be analysed for residues and/or cholinesterase depression. Maximal application rates and number of repeat applications must be made on the study sites. The protocol must be approved by EEB prior to test initiation. The study is due in 18 months.

Chevron
ORTHO
Chevron Chemical Company
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Research
Agricultural Chemicals Division

15

5/30

May 13, 1986

Methamidophos: Amendment to 1982 Guidance
Document Received February 19, 1986

William H. Miller
Product Manager (16)
Registration Division (TS-767)
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, DC 20460

Dear Mr. Miller:

We wish to provide a 90-day response to the Amended Guidance Document on methamidophos we received from the Agency on February 19, 1986. The Amended Guidance Document requested the following studies: (a) Special Tests: Field Residue Monitoring (70-1) and (b) Actual Field Testing (71-5) to evaluate short term acute and chronic hazard and potential for avian population reduction. The Field Residue Monitoring study required measuring methamidophos residues on avian food items in five field crops while the Actual Field Testing required multi-year nesting box studies in two crops.

The Agency's request for avian field testing appears to be overly extensive, unnecessary and extremely expensive. In addition, it proposes to generate residue monitoring data which already is available and develop biological response information which is already known. We believe that the information on methamidophos requested by the Agency can be obtained from a substantially reduced field testing program. As an alternate proposal to fill the avian testing requirements on methamidophos required in the February 19, 1986 Amended Guidance Document, we submit the attached residue data (3 copies) on several field crops and 3 copies of protocols for a multi-year nesting box study.

The residue data we submit includes an overall crop summary of methamidophos monitoring data (Reference 1), a summary of methamidophos residues on individual crops (Reference 2), and residue trials on the individual crops (References 3 thru 28). The proposal for a multi-year nesting box study (Reference 29) includes a guideline for a site selection procedure, an initial baseline monitoring year survey, and evaluation of potential effects upon wildlife during two consecutive treatment years. Please note that our field study proposal is not site specific. We believe that Agency approval of a general protocol is an essential prerequisite to initiating a site search and developing a site specific protocol.

We believe that our crop residue data adequately describes the profile of methamidophos residues under field use conditions and no further residue monitoring is necessary. We also believe that completion of our proposed multi-year nesting box study on a single crop

under "worst case" conditions (application at maximum label rate of 1.0 lb ai/A) together with our residue monitoring data will provide a suitable data base to evaluate the Agency's concern of hazard of methamidophos to avian species.

We would like to schedule a meeting with the Agency on June 17 to discuss our proposed program to satisfy the data requirements of the March 10, 1986 Amendment to the Reregistration Standard. Please confirm that this date is acceptable to you. If you have any questions, please contact Dr. Nancy J. Rachman at (202) 457-5800.

As required by the 90-day response, I am attaching FIFRA Section 3(C)(2)(B) Summary Sheets for all products affected by the Amended Reregistration Standard. Please be advised we are in a cost share agreement with Mobay.

Sincerely,

Desmond Byrne/jcw

Desmond Byrne, Manager
Registration & Regulatory Affairs

FXK:kt/P-9