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SHAUGHNESSEY NO.

27
REVIEW NO.

EEB REVIEW

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PETITION OR EXP. NO.

DATE OF SUBMISSION 5.22.85

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RD ACTION CODE/TYPE OF REVIEW 660/Reg. Std. Follow-up

TYPE PRODUCT(S) : I, D, H, F, N, R, S Insecticide

DATA ACCESSION NO(S).

PRODUCT MANAGER NO. W. Miller (16)

PRODUCT NAME(S) Monitor

COMPANY NAME Chevron Chemical Company

SUBMISSION PURPOSE Submission of data relative to registration
standard; see PM's comments/questions

SHAUGHNESSEY NO.	CHEMICAL, & FORMULATION	% A.I.
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

23 SEP 1985

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Methamidophos Data Submissions and New Data Requirements

FROM: Margaret Rostker *Margaret Rostker*
Ecological Effects Branch
Hazard Evaluation Division (TS-769)

THRU: Michael Slimak, Chief *Michael Slimak* 9/20/85
Ecological Effects Branch
Hazard Evaluation Division (TS-769)

and

Harry Craven 9/19/85
Harry Craven
Ecological Effects Branch
Hazard Evaluation Division (TS-769)

TO: William Miller, PM 16
Insecticide-Rodenticide Branch
Registration Division (TS-767)

EEB has reviewed the following four studies:

1. Biospherics, Inc. 1983. The Acute Toxicity of Methamidophos (technical) to Mysidopsis bahia (bay shrimp). Submitted by Mobay Chemical Corporation, Stillwell, Kansas, EPA Registration No. 239-2452; EPA Accession No. 258108.
2. Biospherics, Inc. 1983. The Acute Toxicity of Methamidophos (technical) to sheepshead minnow (Cyprinodon variegatus). Submitted by Mobay Chemical Corporation, Stillwell, Kansas. EPA Registration No. 239-2452; EPA Accession No. 258108.
3. Biospherics, Inc. 1985. Shell deposition in eastern oyster (Crassostrea virginica) exposed to Monitor 4® in a static test system. Submitted by Mobay Chemical Corporation, Stillwell, Kansas. EPA Registration No. 239-2452, EPA Accession No. 258108.

4. Mobay Chemical Corp. 1985. Simulated field study of Monitor 4® toxicity to bobwhite quail. Submitted by Mobay Chemical Corporation, Stillwell, Kansas. EPA Registration No. 239-2452. EPA Accession No. 258108.

The studies will be discussed individually below.

1. The acute toxicity of methamidophos (technical) to Mysidopsis bahia (bay shrimp).

This study fulfills guideline requirements for an acute toxicity test with technical product for an estuarine/marine invertebrate.

2. The acute toxicity of methamidophos (technical) to sheepshead minnow (Cyprinodon variegatus).

This study fulfills guideline requirements for an acute toxicity test with technical product for an estuarine/marine fish.

3. Shell deposition in eastern oyster (Crassostrea virginica) exposed to Monitor 4® in a static test system.

The study is invalid and does not fulfill guideline requirements. It cannot be repaired to meet guideline requirements. A new study must be submitted that is in accordance with guidelines. The major flaws in the present submission are: 1) a static system was employed whereas the guidelines specify a flow-through system; 2) the test oysters exceeded guideline size specifications; 3) test oysters were too crowded in the test vessels (biological loading exceeded guideline specifications); 4) control oysters did not exhibit minimum growth as specified in the guidelines; and 5) the study used an end-formulation whereas the data requirement in the registration standard specified technical material testing.

4. Simulated field study of Monitor 4® toxicity to bobwhite quail.

The study is invalid and does not fulfill guideline requirements. It cannot be repaired to meet guideline requirements. The major irreparable flaws in the submitted study are: 1) the study used the end-formulation Monitor 4® whereas the data requirement in the registration

standard specified the study must use Monitor 6 Spray; 2) the study was not conducted on a registered crop for Monitor; 3) birds and pens were removed during the pesticide application, contrary to guideline specifications that the birds and pens are to be exposed during application; and 4) food and water was available in all test and control pens, contrary to guideline specifications that one-half the test and control pens are to be without food and water for 12 hours following pesticide application.

EEB required this pen study because of concerns for unreasonable avian hazard from use of methamidophos. Methamidophos is very highly acutely toxic to birds and has been shown to negatively effect avian reproduction at very low concentrations. Also, at least one bird kill has been reported to EEB.

For these reasons, and because methamidophos is registered on a variety of crops that are known avian food sources, EEB has determined additional data are required.

EEB will not require the small pen test be re-done. EEB does not consider that another small pen test will be likely to adequately address the important features of actual field use and the effects of field exposure. EEB has determined that actual field testing for safety is necessary. Therefore, EEB is no longer requiring a valid small pen study with Monitor 6 Spray. EEB is requiring the following data:

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, non-target 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, sugar beets and potatoes. Free-living, non-target wildlife will 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. These data are due 18 months after receipt of the Amendment to the Registration Standard for methamidophos.

2. §71-5: Actual Field Testing.

This study will involve a full-scale actual field test of avian populations 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 non-target 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 interspersed 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 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 avian populations on the study sites.

This study will entail a one year baseline study wherein nest boxes are established and the non-target 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. This study is due 48 months after receipt of the Amendment to the Registration Standard for methamidophos.

Protocols for both the residue monitoring and full field test, including study site selection, must be approved by EEB prior to initiation of the studies.

CONCLUSION/SUMMARY

EEB finds that:

- 1) the data gaps of a 96-hour acute toxicity test for a marine fish and marine invertebrate (sheepshead minnow and mysid shrimp, respectively) are fulfilled.
- 2) The oyster shell deposition test is invalid, does not fulfill the data gap, and the requirement remains outstanding.
- 3) The small pen study with Bobwhite Quail is invalid, however EEB is removing that test as a data requirement.
- 4) In the place of the pen study, and in response to concerns for nontarget hazards, especially avian, EEB is requiring two new studies:

§70-1. Special Test: Field Residue Monitoring
and
§71-5. Actual Field Testing.

The residue test is to specifically address short-term, acute toxicity hazards, and the actual field test is to address chronic, sublethal hazard and potential for avian population reduction. Both tests are to be conducted with typical end-products, employing normal agricultural practices and maximum use rates. The protocols, including test site selection, must be approved by EEB prior to test initiation. The residue monitoring study (\$70-1) is due in 18 months and the actual field test (\$71-5) is due in 48 months.