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TO: P. O. Hutton/ M. L. Mendelsohn
Product Manager 17
Registration Division (H7505C)

FROM: Michael Barrett, Acting Chief *Michael Barrett*
Ground-Water Section
Environmental Fate & Ground-Water Branch/EFED (H7507C)

THRU: Henry Jacoby, Chief *Henry Jacoby*
Environmental Fate & Ground-Water Branch/EFED (H7507C)

Attached, please find the EFGWB review of:

Reg./File #: 100-654

Chemical Name: Cyromazine

Type Product: Insecticide

Company Name: CIBA-GEIGY Corporation

Purpose: Review protocol for small-scale prospective
ground-water monitoring study

Date Received: 6/8/90; 7/31/90 ACTION CODE: 192

Date Completed: 12/7/90 EFGWB #(s): 900604; 900721

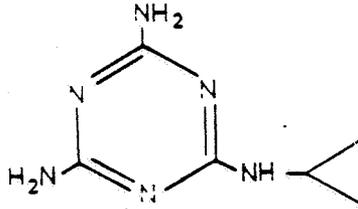
Monitoring study requested: x Total Review Time: 10 days

Monitoring study voluntarily:

Deferrals To: Biological Effects Branch
 Science Integration & Policy Staff, EFED
 Non-Dietary Exposure Branch, HED
 Dietary Exposure Branch, HED
 Toxicology Branch, HED

1. CHEMICAL:

Chemical name: N-cyclopropyl-1,3,5-triazine-2,4,6-triamine
 Common name: Cyromazine
 Trade name: Trigard
 Structure:

2. TEST MATERIAL:

Trigard 75W.

3. STUDY/ACTION TYPE:

Review of protocol for small-scale prospective ground-water monitoring study.

4. STUDY IDENTIFICATION:

Title(s): 1. Prospective ground-water monitoring study for cyromazine.
 2. Protocol amendments #1, #2, and #3 for the above study.

Author(s): Patrick W. Holden
 Richard A. McLaughlin

Submitted by: Blasland & Bouck Engineers
 751 Miller Dr. SE
 Suite D-1A
 Leesburg, VA 22075

for: CIBA-GEIGY Corporation
 Agricultural Division
 P. O. Box 18300
 Greensboro, NC 27419-8300

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5. REVIEWED BY:Larry Liu
ChemistSignature: S J Liu
OPP/EFED/EFGBW/Ground-Water SectionDate: 12-7-906. APPROVED BY:Michael Barrett
Acting ChiefSignature: M Barrett
OPP/EFED/EFGBW/Ground-Water SectionDate: 12/7/907. CONCLUSIONS:

Overall, the body of the report and general methodology for site characterization and study conduction are complete, and appropriate. More site specific information and analytical results will be generated by the registrant. These information and data must be reviewed by the Ground-Water Section before a final decision can be made to terminate the study.

Details regarding the type and number of Quality Control samples were not given in the protocol. The storage stability study presented is inadequate. With the addition of Quality Control samples (such as field and laboratory spike samples) and two storage stability studies (one for the storage of the samples in the cool conditions and the other for the holding time of the extract), this monitoring study would produce data with integrity and meet the GLP requirements.

Field fortification samples are used to check the laboratory's ability to recover the test substance and the test substance stability during shipment. No analysis of matrix spike samples was proposed in the protocol. Matrix spike samples are a check on the laboratory's ability to recover the matrix. Spikes of standard compounds may be added to samples in the laboratory to determine if the ground-water constituents are interfering with test substance identification or quantification. Such analyses may also point to systematic errors and lack of sensitivity of analytical equipment.

Equipment blank analysis provides a check on sampling procedures. An equipment blank is made with pure water by exposing it to the sampling processes (e.g., bailer). The pure water will be poured into the bailer (which has been decontaminated and is ready for sampling) and then into the sampling program for each day's collection of groundwater samples and will be analyzed for the same suite of constituents as the groundwater samples. Duplicate samples

are collected for the same matrix in the field and analyzed to check on laboratory reproducibility.

8. RECOMMENDATIONS:

1. The shallow "skimming" wells should be installed with the screened interval at 3-8 feet whereas the deep wells should be installed with the screened interval of 8-13 feet.
2. Tomatoes should be harvested as they mature during the conduction of the study. If the study continues into a second growing season, tomatoes should be planted again and cyromazine applied according to label recommendations.
3. The registrant must conduct two storage stability studies prior to the analysis of the samples. The first study is to determine the maximum length of time that the soil and water samples can be stored in the refrigerator or freezer prior to extraction. The second study is to determine the holding time of the extract after sample extraction. Sample analyses must be completed within the predetermined sample and extract holding time. According to the Groundwater Monitoring Guidelines, the fortification levels should be detectable and in the range of expected concentration.
4. The applicator or the field person must bring the remaining concentrated test compound back and store it at adequate facility as indicated on the label. The rinse and the remaining dilute solution from the test compound must be properly disposed of. Adequate documentation is required.
5. The SOP for the bail test must be submitted to the Agency.
6. Adequate analytical method with acceptable recovery for the analysis of cyromazine and melamine in soil and water samples must be developed.
7. If the tomatoes show water stress during the conduction of the study, irrigation system(s) must be used in order to simulate the real agricultural practice. The amounts of water applied through these systems need to be estimated and reported. A detailed map to illustrate the design and spacial distribution of the system would be useful.
8. The registrant must report how the tank mix was prepared and the equipment used, etc. for each application.

9. Adequate number of laboratory quality control samples (such as standard matrix spike, sample matrix spike, method blank, trip blank, equipment blank, duplicate, and field fortification) must be included and analyzed as discussed elsewhere in this review.
10. This study is conducted based on the registrant's intention to change the label from 12 and 8 applications for celery and lettuce, respectively, to 6 applications for all crops (including tomato). Should the label remain unchanged, the study would become invalid.
11. A map to describe the on-site and off-site features that could influence the groundwater flow needs to be submitted.

9. BACKGROUND:

Cyromazine is currently registered on celery and lettuce (head only) for leafminer control. According to the Label Acceptance Statement dated January 30, 1990, the following use direction has been accepted by EPA. The 75W formulation is applied at the rate of 0.125 lb ai/A as a foliar spray in a minimum of 5 gallons of water by air as leafminers first appear. Applications can be repeated as needed at 7-day intervals. No more than 12 and 8 applications can be made to celery and lettuce, respectively. In order to avoid residue problems, no applications should be made within 7 days of harvest. All registered crops on the label may be planted following harvest of a Trigard 75W-treated crop. Rotation to any other crop, except sweet corn or radishes is not permitted. Sweet corn and radishes may not be planted within three months after last application.

The registrant would like to expand the uses to include several other crops, including tomatoes, mushrooms, peppers, and chrysanthemums. EFGWB recommended that no further registrations for new uses of cyromazine be granted based on the persistence and mobility data for cyromazine until the impact of current use on ground water were assessed (see memo dated September 7, 1988 from Catherine Eiden to Phillip Hutton). The EFGWB recommended requiring a small-scale ground-water monitoring study (prospective or retrospective) to determine if the current uses of cyromazine are impacting ground water.

In a meeting held on June 6, 1989, with CIBA-GEIGY, EFGWB, and RD, the following agreements were made. A small-scale prospective ground-water monitoring study will be conducted on tomatoes in Florida as the worst scenario possible for leaching of cyromazine. Depending upon the results of the

small-scale prospective study, a retrospective study may be required for the current uses on celery and head lettuce (see memo dated July 26, 1989 from Catherine Eiden to Phillip Hutton).

The ground-water DCI has been sent out in January, 1990 (see memo dated January 4, 1990 from Phillip Hutton to Henry Jacoby). Results from the tomato/ground water study will be assessed to apply to the existing head lettuce and celery uses as well as the pending tomato, pepper, and mushroom uses.

The registrant submitted a protocol for the "Prospective Ground-Water Monitoring Study for Cyromazine" for approval by EPA. This protocol was received by EFGWB on June 8, 1990.

In the letter of July 23, 1990, the registrant expressed their intention to change the use directions of cyromazine on the label. For all crops they intend to support no more than six applications per growing season apparently at a rate no higher than 0.17 lb ai/A. No more than two applications would be in "sequence". "Sequence" means, presumably, that the interval between two applications is less than 7 days. Based on this letter, applications for the monitoring study will conform to the proposed changes.

10. DISCUSSION:

The objective of this review is to assess a proposed protocol for a small-scale prospective ground-water study of cyromazine.

A. Test System Selection

In order to represent a "realistic worst-case" scenario, a field site in southern Hillsborough County, Florida was selected for the conduction of the ground-water monitoring study. The selection was based on the following reasons: (1) Florida has the largest area for the production of tomatoes in the US; (2) the depth to ground water at the field site is three to four feet; and (3) the surface soil is a Myakka fine sand. The DRASTIC score for Hillsborough County is 231, indicating the high vulnerability of the site to pesticide contamination. The study plot will be a 2-acre section of a 10 acre field site. The exact location for the 2-acre plot has not determined. A shallow, dry ditch is located on the north edge of the field site. However, no site maps were included in the protocol to locate any offsite features that could possibly influence the groundwater flow at the site (irrigation wells, drainage ditches, ponds, etc). The field site is rectangular in

shape and is currently covered with low vegetation. In general, the slope of the field is to the southwest. Information on the slope of the field and the usage of the test chemical in the past was not reported. According to the Groundwater Monitoring Guidelines, the site selected should be (1) as level as possible and (2) no prior usage of the chemical in question. Using ground water to irrigate tomatoes is a typical farming practice in Florida. The site is irrigated using a semi-closed seepage system that raises the water table to within 12-18 inches of the land surface.

B. Site Characterization

In order to determine the presence of pesticide of concern in the soil, permeability of the soil, and the depth of the water table, the following field investigations will be performed:

- o A set of soil samples (the number of soil samples and depth intervals were unspecified) will be collected from the surface to the water table and analyzed for organic matter, cation exchange capacity, bulk density, texture (percent sand, silt, and clay), particle size distribution of sand, silt, and clay as a function of depth, field capacity, and wilting point. The Groundwater Monitoring Guidelines recommends the following sampling scheme: 6-inch increments for the first five feet, and foot-long increments to the water table. The Guidelines also requires geologic description of soil color and structure.
- o The soil samples collected for the site characterization will also be analyzed for background residues of cyromazine and its degradation product melamine.
- o Three piezometers will be installed to determine groundwater flow gradients and depth.
- o Bail tests will be conducted at two or three of the piezometers to estimate the hydraulic conductivity of the aquifer. No detailed SOP for the bail test was submitted with the protocol.

C. Monitoring

Wells - Eight monitoring wells and one upgradient control well will be installed after the site characterization study and prior to the pesticide application. A field observation regarding color and structure of the borehole cuttings should be performed according to the Groundwater Monitoring Guidelines. The monitoring wells will be installed in clusters of two wells at four equal subplots

at the study site. Each cluster consists of one shallow monitoring well screened from the water at the time of installation to 5 feet below the water table, and one deep monitoring screened from approximately 5 to 10 feet below the water table. All wells will be developed to remove fine-grained sediments from the formation materials adjacent to the well screen.

The Agency is concerned that this arrangement of wells may not result in sampling water from the top of the water table where it is possible that there may be a potential for residues to occur at higher concentrations.

Soil and Water sampling - Protocol Amendment #1, pages 10-12. under Post-Application soil Sampling; Line 13; "sampling rounds will revert to a routine schedule of days 0, 1, 3, 7, 14, 28 and then monthly. Day 28 should be Day 30 (see Table 1 in the protocol). However, the proposed sampling schedule can be flexible due to unforeseen conditions. The registrant intends to analyze a composite soil sample from 5 samples collected at the same depth from the 5 sampling holes in one of the three areas in the test site. This design is accordant with the Groundwater Monitoring Guidelines and would provide sufficient information regarding the spacial distribution of the test compound in the soil. The ground-water samples will be analyzed individually.

Suction Lysimeters - Due to the shallow depth of water table at the study site, lysimeters will not be installed. The explanation is acceptable.

Tracer - The study director plans to apply an unspecified ionic tracer immediately following the first application at a rate of 30-40 lbs/acre. A second unspecified ionic tracer will be applied with the test compound after the last application at the same rate. The registrant can choose bromide (or chloride) as the tracer with the first application and chloride (or bromide) with the last application (see Groundwater Monitoring Guidelines).

Chemical Analysis/Quality Control - Protocol Amendment #2, page 2. Test Substance: last paragraph; "All test substance containers and remaining product will be retained on site until study completion".

Protocol Amendment #1, last page, "each control area sample will be analyzed for cyromazine and melamine". This sentence should be expanded to "all samples will be analyzed for cyromazine and melamine".

No analytical method and recovery data as well as detection limit were included in the protocol. In addition, collection and analyses of quality assurance and quality control samples (such as equipment blanks, trip blanks, method blanks, duplicate, standard matrix spike, and sample matrix spike) were not mentioned in the protocol. It would be a good laboratory practice to define the type and number of control samples in the protocol.

D. Study Duration

The prospective study is considered to be a 2-3 year study. Actual study duration is dependent upon review of the analytical results obtained during the study by EPA [see memo dated January 22, 1990 from Henry Jacoby (Chief, Environmental Fate & Groundwater Branch, Environmental Fate Effects Division) to Phillip Hutton (Product manager, Insecticide-Rodenticide Branch, Registration Division)]. It should be noted that the test compound and its degradation products may not reach the monitoring well within one year as proposed by the registrant due to the properties of these compounds in soil and groundwater, soil type, and hydrogeology.

E. Irrigation

The registrant does not plan to use supplemental irrigation at the study site. There was no discussion of whether water stress might occur at the site, or whether irrigation might be needed in order to simulate the normal agricultural practice.

F. Purity of the Test Compound

As stated in the protocol, the registrant proposes to analyze samples collected from the tank mix prior to and after each application. It would be unnecessary for the registrant to analyze all these tank mix samples because the mixing procedure should be the same. Prior to the application, the purity of the test compound must be determined.

G. Storage Stability

The spike levels of 10, 100, and 1000 mg to the matrix samples (soil and water) stated in the protocol are meaningless because the amounts of samples to be spiked were not specified. The analysis scheme reported in the protocol is incorrect. If the registrant finds that the study compound is not stable after the analysis of the spike

sample set #2, it will be too late because the samples collected in the field have already been analyzed.

Although the stability study for the test compound in the extract is not required in the Groundwater Monitoring Guidelines and the registrant did not plan to conduct it, the reviewer believes that this is a very important practice to have integrated data.