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28 APR 1981

Response to Mobay Letter (6/27/80) Concerning EEB Data Request for Namacur Uses on Tobacco and Non-Bearing Fruit Trees (3125-236 3125-237 3125-283).

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Ecological Effects Branch Hazard Evaluation Division TS-769

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Registration Division TS-767

HRU: Henry T. Craven, Head, Section 4, Ecological Effects Branch HED

HRU: Clayton Bushong, Chief, Ecological Effects Branch, HED

The Ecological Effects Branch has discussed with Mobay (9/17/80 meeting) much of what is contained in their 6/27/80 letter. EEB's current position regarding field testing of Namacur is that full-scale field monitoring is needed as there is a lack of utility in additional small-pen simulated field tests. Previous studies have established that Namacur kills avian wildlife in small-pen tests.

The assertion by Mobay that there is no possibility that a soil application of Namacur could have an effect on beneficial insects is unsupported. Namacur is known to be toxic to some beneficial insects and it is systemic. With several beneficial insects present in both tobacco fields and fruit orchards, there is a "possibility" of an adverse effect. Previously submitted studies pertaining to non-toxic insects have not adequately addressed the potential hazards of Namacur soil applications. However, EEB does not require non-target insect studies prior to a conditional registration of Namacur on tobacco and non-bearing fruit trees.

The Ecological Effects Branch does not currently require a large-pen field test with an avian reproduction study. This study could likely be required pending the outcome of the avian studies already initiated by Mobay.

To summarize, the Ecological Effects Branch only requires an avian acute oral LD50 study and a field monitoring study prior to its completion of a hazard assessment for the proposed uses (tobacco and non-bearing

AND
BEAR
FRUIT



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June 27, 1980

Subject: ©NEMACUR 10% Granular, EPA Reg. No. 3125-237
NEMACUR 15% Granular, EPA Reg. No. 3125-236
NEMACUR 3, EPA Reg. No. 3125-283
Applications to Add Claims for Use on Tobacco and
Non-Bearing Deciduous Fruit Trees

Dear Mr. Jacoby:

We have your letter of January 30, 1980 outlining the additional data on fowl and beneficial insects which are to be required to support the subject applications for tobacco and non-bearing fruit trees. We have the following comments on these additional data requirements as set forth in Items 1 through 4 of your letter:

1. We have no objection to conducting an additional acute oral LD₅₀ study on bobwhite quail or mallard duck.
2. As you probably know, a small pen simulated field study has also been requested to support other applications for amended registration of NEMACUR which are pending before the Agency. You have indicated that this type of study must be conducted using one of the granular formulations at the maximum rate recommended in the proposed labeling. In order to avoid having to do a separate study to support each of our pending applications, which would be prohibitive, we want to design a single study which the Agency could accept to support all the proposed uses of NEMACUR. We expect to have a protocol for such a study available soon for discussion with the Agency.
3. We request that the Agency waive the requirement for information on the toxic nature of NEMACUR and its sulfoxide and sulfone metabolites to beneficial insects. We still contend that such data are not at all relevant to the proposed use of NEMACUR in soil applications on tobacco and non-bearing fruit trees. There is no possibility that a soil application of NEMACUR, as proposed, could have any effect on beneficial insects.

In connection with this request we wish to point out that we have previously submitted three studies which contain some information on beneficial insects including parasites, predators and bees. This information may be found in Mobay Reports No. 23757, 24211 and 26431 in our brochure titled: NEMACUR - The Effects on the Environment dated February 1, 1973 which is filed under EPA Accession No. 091689 and/or 120301. These studies support our contention that use of NEMACUR as proposed is unlikely to have any effect on beneficial insects.

Mr. Henry Jacoby
Registration Division
EPA, Washington, D.C.

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4. We request that the Agency defer the requirement for an avian reproduction study in conjunction with a large pen field test. Laboratory reproduction studies on two species are in progress at this time. The requirement for a large pen field study should be reevaluated after the present studies have been reviewed by the Agency.

Under the authority conferred to the Administrator under Section 3(c)(7) of FIFRA, as amended, 40 CFR 162.18-1(a) and 40 CFR 162.18-4(a), we request that EPA issue conditional registration for NEMACUR 3, NEMACUR 10% Granular and NEMACUR 15% Granular on tobacco and non-bearing deciduous fruit trees. Agency approval of this request for conditional registrations would be consistent with the criteria set forth at 40 CFR 162.18-4(a)(1), (2) and (3).

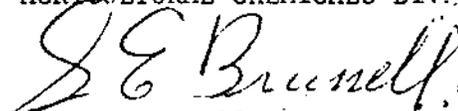
Finally, we wish to address your comments on the precautionary labeling for the subject products. On July 30, 1974 we submitted applications for the 10% and 15% granular formulations along with acute oral toxicity data (Mobay Report No. 40984) to change the signal word from "Warning" to "Danger." The data in our report indicated that the acute oral LD₅₀ was 10 to 14 mg/kg for rats (NEMACUR 15% Granular). On the basis of this study both granular formulations were placed in Toxicity Category I. This change in the signal word was accepted by the Agency on September 17, 1974. A copy of the acceptance letters and our submissions is enclosed.

For the granular formulations we do not agree that the precautionary statements pertaining to inhalation should be deleted. All granular pesticide products will contain "fines" or dust which is unavoidable in shipping and handling. It is this dust which may be toxic if inhaled, particularly for a Category I pesticide. For this reason, we wish to retain the precautionary statements for inhalation hazard as shown in the enclosed photocopies of the printed label for NEMACUR 15% Granular.

As shown in the enclosed photocopies of the printed label for NEMACUR 3, the eye hazard statement reads, "Causes eye damage."

Yours very truly,

MOBAY CHEMICAL CORPORATION
AGRICULTURAL CHEMICALS DIVISION


G. E. Brussell, Manager
Registrations
Research & Development

GEB:RPH:brh

Enclosures