(12a)

Shaughnessy Number: 128857

Date out of EAB: NOV 10 1988

no studies

comments on field dissipation

To: Lois Rossi
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From: Emil Regelman, Supervisory Chemist
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Environmental Fate and Effects Division (TS 769C)

Thru: Hank Jacoby, Acting Chief
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Attached, please find the EAB review of...

Reg./File #: 707-EUP-RO

Chemical Name: Myclobutanil

Type Product: fungicide

Company Name: Rohm and Haas

Purpose: EUP on stone fruit

Date Received: 9/7/88 Action Code: 750

Date Completed: _____ EFGWB#(s): 81002

Total Reviewing Time (decimal days): 1.5 days

Deferrals to: ___Ecological Effects Branch, EFED

___Science Integration and Policy Staff, EFED

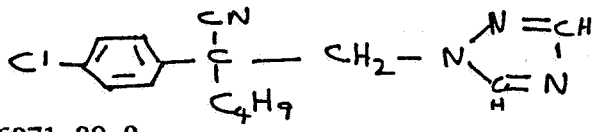
___Non-Dietary Exposure Branch, HED

___Dietary Exposure Branch, HED

___Toxicology Branch, HED

1. CHEMICAL:

chemical name: [α-butyl-α(4-chlorophenyl)-1H-1,2-triazole-1-propanenitrile
common name: Myclobutanil
trade name: Systhane, Rally
structure:



CAS #: 66871-89-0
Shaughnessy #: 128857

2. TEST MATERIAL:

3. STUDY/ACTION TYPE: response to EFGWB comments

4. STUDY IDENTIFICATION: n.a.

5. REVIEWED BY:

Typed Name: E. Brinson Conerly
Title: Chemist, Review Section 2
Organization: EFGWB/EFED/OPP

E. B. Conerly 9/23/88

SEP 27 1988

6. APPROVED BY:

Typed Name: Emil Regelman
Title: Supervisory Chemist, Review Section 2
Organization: EFGWB/EFED/OPP

SEP 27 1988

7. CONCLUSIONS:

The studies discussed in this review are not acceptable.

8. RECOMMENDATIONS:

EFGWB recommends that the applicant agree to perform a field dissipation study on myclobutanil as a condition of registration, after submitting and obtaining approval for the protocol. This should include pre- and post-application day-zero samples, multiple core samples at each time period, and shorter intervals between samples. At least three sites should be used, including one without a cover crop. Application should be at the maximum label rate, or, at the applicant's option, a 2 or 3x rate. EFGWB reserves any further data requirement on triazole at this time. EFGWB defers the following matters on myclobutanil and its triazole metabolite:

to the Residue and Toxicology Branches for an assessment of the dietary risk potential
to the ground water team for a ground water assessment

9. BACKGROUND:

The status of data requirements is as follows:

hydrolysis -- satisfied -- stable at pHs 5, 7, 9
photolysis in water -- satisfied -- stable to photolysis in water
photolysis in soil -- satisfied -- extrapolated $t_{\frac{1}{2}}$ ca. 143 days
aerobic soil metabolism -- satisfied -- $t_{\frac{1}{2}}$ 61-71 days -- major product is 1,2,4-triazole up to ca 15%, with CO_2 and unextractables in lesser amounts
anaerobic soil metabolism -- satisfied -- resistant to anaerobic metabolism -- no detectable degradation after ca. 60 days
leaching - satisfied for parent -- moderately mobile -- k_ds 1.46 - 9.77 for adsorption, 0.47-4.18 for desorption in five soils: clay loam, sand, silt loam, sandy loam, clay -- additional data required re "aged" compound (degradates must be identified and quantified).
terrestrial field dissipation -- discussed below
fish bioaccumulation -- waived, based on low k_{ow}s for parent and degradates. The compound is not expected to bioaccumulate.

These data indicate the following:

1) A major route of disappearance of myclobutanil will be diffusion/dilution since it appears to be resistant to most environmental breakdown processes.
2) A ground water evaluation may be necessary, based on toxicology and residue concerns, since the compound is stable and somewhat mobile.

The terrestrial field dissipation study was previously deemed unacceptable, due to inadequacy of sampling; to lack of immediate post-treatment sampling of the PA site (which means that application rate was not confirmed); a difference of almost an order of magnitude in soil concentration between the two sites, in what should have been comparable samples; and apparent difficulties with the analytical method. The applicant has provided additional discussion relative to these deficiencies:

Studies on the parent:

Rohm and Haas:

1) Zero-day samples are unnecessary since the data are not used quantitatively, and no conclusions would be changed were these data available.
2) ... Since the material is foliarly applied, any material which reaches the soil does so by accident....
3) one should not expect to obtain the same result under ... varied conditions. Rather, the observations should be used to demonstrate the range of initial levels, and the focus should be on the rate of decline.

4) [Rohm and Haas] ... analyzed for free 1,2,4-triazole as well as for parent compound... Triazole was the only

metabolite noted ... at a sufficient level to warrant analysis in the field study. ... the carboxylate metabolite... is a low level, transient material.

EFGWB response [item numbers corresponding to above]:

1) Zero-day samples are used to demonstrate that the specific application under discussion was uniform and at the correct rate. Without this information the other analytical results cannot be adequately assessed.
2) Myclobutanil can reach the soil by means other than incidental contact when foliar application is made. Since the compound is long-lived, a substantial amount could reach the soil through leaf litter and other material from treated crops. However, this type of residue is not presently an issue.
3) We agree that this type of study should be used to demonstrate the range of initial levels and rate of decline of the parent compound. We do not believe that this particular study accomplished that purpose. The apparent difference in rates of decline between these two sites is greater than an order of magnitude. We do not believe that from these data a statement can be made about a probable range of soil concentrations or typical rate of dissipation.
4) We agree with the applicant's position on this issue.

On reexamination of the study report, it appears that the results and conclusions were based on a single core sample at each time period. If this is true, the study is unacceptable. A single core sample is not sufficient, and the analytical results derived from it cannot be used with confidence to draw any conclusions.

A previous review (EBC 5/19/87) also noted that at the first post-application sampling in PA (day 24), ca 80% of the parent had dissipated. While EFGWB agrees that this tends to demonstrate that parent compound would not accumulate in the soil, data from intermediate times would be useful for confirmation.

At the MS site, the apparent soil $t_{\frac{1}{2}}$ was ca 5.5 months (160 days), more than an order of magnitude greater than that in PA.

Studies on Triazole everywhere

Because the results are so variable, the Agency has questioned the validity of the analyses on various samples from this study. The applicant defends these results as follows [EFGWB paraphrase]:

Rohm and Haas:

1) Naturally occurring background levels, experimental levels, and detection limits of the method are all of

the same order of magnitude.

2) Sample values were corrected by subtracting corresponding control values.
3) Since these values were of the same magnitude, apparent variability was increased when this "correction" was applied.
4) The values reported were toxicologically insignificant.

EFGWB response :

We have reexamined the original triazole study. It appears that the results and the conclusions are based on one core sample per sampling period. This is unacceptable, since the variability of the application and sampling procedures cannot be assessed without duplicate sampling. The reported values do indicate generally low concentrations of triazine, but there are several samples which are much higher than background. It is doubtful whether a new, similar study would yield much additional information to clarify the situation. If toxicological and residue evaluations indicate a need for the information, a bare-ground exaggerated-rate study would probably be more useful.

10. DISCUSSION OF INDIVIDUAL TESTS OR STUDIES: n.a.

11. COMPLETION OF ONE-LINER: attached

12. CBI APPENDIX: n.a.