

2-14-96

MEMORANDUM

SUBJECT: Myclobutanil (RH-3866) formulation Nova 40W/Systhane 2E: Review of Turf Dissipation Study (MRID 430879-04, Guideline 164-1)

TO: Connie Welch, PM 21, and Carl Grable, PM Team Reviewer
Registration Branch (7505C)

FROM: Alex T. Clem, Environmental Scientist
Environmental Chemistry, Review Section 3, EFGWB

THRU: Akiva D. Abramovitch, Ph. D., Head
Environmental Chemistry, Review Section 3, EFGWB

Henry Jacoby, Chief, EFGWB

Alex Clem

Akiva D. Abramovitch

Henry Jacoby
2/14/96

Study Background. According to a 12 Jan 94 letter from Rohm and Haas Product Registration Manager Richard Costlow to former PM Sydney Jackson (see attached copy which the Branch recently obtained from PM Team Reviewer Carl Grable), and a recent telephone conversation with Costlow (see below), this study was intended only to provide EEB with a quick, rough estimate of foliar dissipation on turf grass of a single 0.67 pound/acre application of the fungicide myclobutanil. (In actual use up to 12 applications for a total of about 7.8 pounds/acre per season could be applied.) According to Costlow's letter, this intermediate study was prompted by a disagreement with EFED "over the half-life of myclobutanil on environmentally relevant foliar matrices". At a meeting referred to in the letter, EFED, in principle, apparently agreed to consider the current submission.

With the information from this study Costlow says he "hopes" to obtain a "conditional" registration for myclobutanil on turf pending completion of a full-blown turf field dissipation study now in progress.

So that there can be no misunderstanding, this study in no way serves the purpose of a bona fide turf field dissipation study, as discussed in the DER. In addition to major design deficiencies, other essential data was missing (see DER). Therefore, EFGWB (with the prior knowledge of current PM Connie Welch) inquired via telephone on January 29 and 30, 1996, of Costlow and R. Batra (Study Director) if these data were retrievable for our use. A very limited amount of additional data and other information was subsequently mailed to EFGWB. In case you need a record of this correspondence, we have attached the original which was mailed directly to the Branch by Batra. With the additional information, EFGWB was able to make some useful observations and reach the following conclusions:

Conclusions. *This study (MRID 430879-04) is ancillary and partially satisfies the data requirement. This review supersedes a previous preliminary evaluation¹.*

- * *Large quantities of the fungicide myclobutanil wash off grass.* Foliar dissipation during the study was almost strictly a function of rainfall or irrigation water available in quantities sufficient to cause run off from leaf surfaces. There was little or no loss of parent compound from the leaf blades during the study by any other means. This specific mechanism of dissipation does not lend itself to the curve fitting approach used by the registrant to calculate an apparent foliar dissipation half-life of six days. Depending upon the vagaries of rainfall and irrigation scheduling, another study at other times and places would yield entirely different results. In this context, *the six day foliar dissipation half-life assigned by the registrant is not generally applicable and does not represent intrinsic behavior of the chemical formulation.* The registrant did not assign any routes of dissipation, and evidently did not recognize the primary importance of wash off from the grass.

EFGWB makes the additional casual observation that roughly one-half to one inch of rain falling during a typical rainfall event would wash off about half of any myclobutanil remaining on leaf surfaces.

- * By day 11 of the study most of the initially measured amount of myclobutanil had been transferred essentially undiminished (within experimental limits) from the growing grass to the combined thatch/0-3 inch soil core sample (with some also to deeper increments). From day 11 through the end of the 60 day study, *EFGWB estimates tenuously that the apparent soil dissipation half-life was around 30 days (thatch could also be involved).* Degradation was not investigated, analysis was only for parent. *Some of the disappearance can be attributed to leaching losses* as we discuss in the next paragraph.
- * There was noteworthy movement of myclobutanil down the soil profile with the input of water. This was especially evident as water in the profile on day 6 redistributed itself from day 6 to day 11. During this time *leaching occurred into the 18-24 inch interval, the greatest depth sampled.* From the data presented there was no way to determine if there were runoff losses.

Recapitulating the main points: 1) The reported six day foliar dissipation half-life is not valid in general, but rather myclobutanil remained on leaf surfaces until it washed off; 2) this compound dissipated in the soil (possibly also in thatch) with an apparent half-life estimated tenuously by EFGWB to be about 30 days; and 3) at least some of the soil dissipation was due to leaching.

Environmental Fate Assessment. The Branch will not update our most recent fate assessment

¹Results of the preliminary review were included in the EFGWB memorandum of 11 Jan 95 (JB, DP Barcode 208244) which primarily dealt with study MRID 421881-01.

for myclobutanil (11 Jan 95) until the full-blown turf dissipation study is submitted. At that time we will revisit all the data. However, we note that previous evaluations may have underestimated mobility.

Recommendations

- 1) Please notify the registrant of the results of our evaluation of this study. The registrant should apply the relevant comments given in the DER to the turf dissipation study now in progress. Furthermore, for the study now in progress, the soil and its hydraulic properties throughout the sampled profile (and appropriately beyond) should be characterized. All rainfall and irrigation data should be prominently displayed and a reasonable water balance presented (see DER).
- 2) Costlow in his 12 Jan 94 letter also asks for our opinion on a proposed special use pattern for turf which would be invoked during times of high disease susceptibility or in susceptible areas. The proposal is for a single application at double the present rate (1.3 vs. 0.65 lb a.i. per acre), but to maintain the currently proposed maximal seasonal rate of 7.8 lb a.i. per acre.

Our reply, based on 1) the current study results, 2) potential use under diverse environmental conditions and diverse cultural practices, and 3) present modelling limitations for turf, is that EEC's and risk assessments would be based on a simple, undiminished double rate for the special application to foliar surfaces. Historical rainfall data for selected regions of the country might then be applied to wash off data which the registrant could provide. Better information related to wash off in the turf study now underway could also be applicable.

- 3) In addition, as we communicated to R. Batra via telephone on 7 Feb 96, the adsorption/desorption study which was reviewed on 26 Mar 85 (Acc. No. 072909. Allen, S.S. May, 1984. Adsorptive and Desorptive Properties of RH-3866 on Soils. Rohm and Haas, Philadelphia, PA. Report No. 310-85-05) has anomalous results which need to be explained or a new study performed. In particular, how can it be that desorption coefficients are markedly lower than those for adsorption? Without reliable mobility data we cannot assess the fate of myclobutanil.

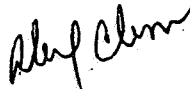
Attachments: DER
Referenced letter from Costlow
Recent correspondence and data from Batra

DATA EVALUATION REPORT

RH-3866 (Myclobutanil) Single Application Turf Residue Decline
(Formulation Nova 40W/Systhane 2E, Guideline 164-1)
MRID 430879-04

CITATION: Batra, R.. RH-3866 (Myclobutanil) Single Application Turf Residue Decline. 10 Jan 1994. Laboratory Project ID: Rohm and Haas Co. Technical Report No. TR 34-93-125. Performing Laboratories: 1) Centre Analytical Laboratories; 3048 Research Drive; State College, PA 16801; 2) Rohm and Haas Company; 727 Norristown Rd., P.O. Box 904; Spring House, PA 19477-0904; 3) Crop Management Strategies, Inc.; P.O. Box 510; Hereford, PA 18056. Sponsored by Rohm and Haas Company; 727 Norristown Rd., P.O. Box 904; Spring House, PA 19477-0904.

REVIEWER: Alex T. Clem, Environmental Scientist, CRS 3
EFGWB/EFED/OPP/OPPTS/USEPA



Study Background (see cover memo).

CONCLUSIONS. *This study is ancillary and partially satisfies the data requirement. This review supersedes a previous preliminary evaluation¹.*

This study in no way serves the purpose of a bona fide turf field dissipation study and was not intended to do so as discussed in the Study Background Section of the cover memo. Even though it suffers from major design deficiencies, EFGWB is able to make these observations:

- * *Large quantities of the fungicide myclobutanil wash off the grass with water.* This was most evident from differences in the samples collected on days 5 and 6 for which soil moisture content dramatically increased from about 9 to 27% in the top layer of soil (see Comments on rainfall and irrigation). During this interval over half of the existing amount of myclobutanil was transferred to the soil. On previous days the concentration of fungicide in the grass essentially remained unchanged, while soil moisture dwindled. Similar behavior is observable after periods of significant rainfall.

This specific wash-off mechanism of dissipation does not lend itself to the curve fitting approach used by the registrant to calculate an apparent foliar dissipation half-life of six days. Depending upon the vagaries of rainfall and irrigation scheduling, another study at other times and places would yield entirely different results. In this context, *the six day foliar dissipation half-life assigned by the registrant is not generally applicable and*

¹Results of the screen were included in the EFGWB memorandum of 11 Jan 95 (JB, DP Barcode 208244) which primarily dealt with study MRID 421881-01.

does not represent intrinsic behavior of the chemical formulation. The registrant analyzed only for parent and did not assign any routes of dissipation. Evidently they did not recognize the primary importance of wash off from the grass.

EFGWB makes the additional casual observation that roughly one-half to one inch of rain falling during a typical rainfall event would wash off about half of any myclobutanil remaining on leaf surfaces.

- * By day 11 almost all of the initially measured amount of myclobutanil had been transferred essentially undiminished from the growing grass to the combined thatch/0-3 inch soil core sample (with some travel to greater depths, see below). From day 11 through the end of the 60 day study, *EFGWB estimates tenuously that the apparent soil dissipation half-life was around 30 days*. Degradation was not investigated. However, *some of the disappearance can be attributed to leaching losses* as we discuss in the next paragraph.
- * There was noteworthy movement of myclobutanil down the soil profile. This was especially evident as water in the profile on day 6 redistributed itself from day 6 to day 11. During this time *leaching occurred into the 18-24 inch interval, the greatest depth sampled*. From the data presented there was no way to determine if there were runoff losses.

EXPERIMENTAL (details provided by the registrant in Study Section 3 of the submission are attached)

This was an *unreplicated, single application, 60 day study* conducted in Bapistown, New Jersey, on a silt loam soil (Penn soil series, see attached, incomplete characterization from page 75 of submission). The approximately 20 by 60 ft. test plot was a cool season mixture of one year old Kentucky Bluegrass sod/turf which had been obtained from a farm in Pennsylvania. The transplanted sod was well-established at the test site by the 24 Jun 93 application date. An adjacent contingency plot and a nearby untreated control plot were also maintained. Conventional cultural practices were observed, but plots were not mowed or irrigated (accidental irrigation may have occurred, see Comments). Plots were last mowed three days before treatment, but were not mowed during the experiment. There were no quantitative data or descriptive indication of how the well the grass grew.

There was but a *single application* of the myclobutanil (RH-3866) formulation Nova 40W/Systhane 2E at a targeted rate of 0.67 lb a.i./acre (rate not verified, see Comments). A carbon dioxide pressurized backpack sprayer with handheld boom with flat fan nozzles spaced 20 inches apart was used to spray broadcast 80 inch swaths on the grass foliage.

Turf and soil were sampled from the treated plots at the following intervals: three days pre-treatment, post application days 0, 1, 2, 3, 4, 5, 6, 7, 11 (10?), 14, 22, 28, 35, and 60. Squares of grass 12 inches on edge were harvested. One inch diameter soil cores were then

taken within clipped areas down to 24 inches using a special extraction sequence (see attached). At each randomly selected grid point, six soil samples were taken and composited for each sampling day. Thatch was included with a 0-3 inch subsample of the top 6 inches of soil core. Soil intervals analyzed were 0-3, 3-6, 6-12, 12-18, and 18-24 inches.

Samples of turf and soil were analyzed only for parent compound using RH-3866 method TR 34S-88-21. Modifications to this procedure are described in Appendix I, pages 60-63 of the submission. The sample analysis scheme is attached. Final analysis was by GC with a reported limit of quantitation 0.01 ppm with a detection limit of 0.003 ppm. Ten gram subsamples of grass and soil were analyzed. Only one composite subsample was analyzed for each sampling interval. Average analytical recovery was $96\% \pm 14\%$ (N=63). Total grass sample weights were not recorded. Therefore, verification of application rate could not be made. An indirect, ersatz estimate indicates that about 60 to 80% of the applied was recovered from the grass (see Comments for these and other related considerations). Furthermore, since total sample weights were not ever recorded we have no quantitative measure of myclobutanil dilution due to plant growth.

Registrant Tables 1 and 2 and corresponding Figures 1 and 2 contain the myclobutanil (RH-3866) residue data as a function of time in turf and soil, respectively. Without careful analysis and interpretation of the study as a whole, casual inspection of these data is apt to be misleading. Important soil moisture data and residue concentrations of myclobutanil in the soil profile are attached (registrant's Appendix IV).

COMMENTS

- ▶ There were no treatment replications--only one composite sample was analyzed for each sampling interval. Furthermore, of these samples only one subsample was quantitated.
- ▶ The study was conducted for 60 days only.
- ▶ Verification of the day 0 application rate was not given, nor was the essential numeric data (total weights of each of the 12 inch by 12 inch turf grass samples and any relevant thatch/soil sample weights) to allow its *absolute* computation. Furthermore, because total grass sample weights were not given for any sample interval we had no measure of myclobutanil dilution as a function of grass growth.

Telephone conversation with registrant representatives (see Background above) revealed these data were not taken and the samples were irretrievable. Therefore, all dissipation data are on a *relative* basis. However, they proffered that similar samples taken for other purposes at other times in nearby plots might give a crude measure of total grass sample weights and a measure of their variability. In this way, the initial application rate might be roughly estimated. This information was subsequently mailed to us for our review and is attached.

Their calculation yielded "83.6%" as the amount of applied which was recovered. However, this was a single sample estimate based on the highest concentration observed. Since all the data from days 0 through 5 are statistically equivalent, these data suggest that that roughly 60 to 80% was recovered. A look at the amounts of parent eventually reaching the soil/thatch shows that a high percentage of the intended application amount reached the soil/thatch. For example, using only the maximum concentration on day 11 and simplifying approximations, 85 to 94% of the intended application would have been recovered in a soil with bulk density in a range of 1.35 or 1.50 g/cm³ (we were not given the actual bulk density of any sample).

- ▶ Why were there background concentrations of myclobutanil of about 0.01 to 0.03 ppm in the turf grass in both the pretreated plot and in the control plot?
- ▶ No degradates were identified.
- ▶ No rainfall/irrigation data was initially provided with the study. All weather data was missing. The registrant, at our request, subsequently mailed us rainfall/irrigation data which is attached. Although we are told that there was no irrigation during the study and no rainfall is indicated between days 5 and 6, the source of the dramatic increase in water content down to approximately one foot during this interval is not clear. We assume that inadvertent irrigation took place, perhaps overlap from adjacent irrigated plots or accidental opening of the wrong irrigation valves.

Water input to the test systems and its soil water redistribution are critical to the understanding of field dissipation studies because water affects both degradation and mobility. EFGWB likes rainfall and irrigation amounts to be plotted on the same figures as those which show time vs. dissipation.

It is important that an estimate of the maximum leaching potential (water movement or movement of an unretained component in the soil profile) be made with methods such as water balance, field moisture instrumentation, or use of tracers.

The soil moisture which was systematically measured by the registrant at all sampled depth intervals served as a useful adjunct. The change in fungicide concentration within the soil moisture profile was a primary indicator of leaching potential.

- ▶ Whether there was runoff from the test plot was not addressed. Slope was stated to be less than 3%. Were buffer areas, especially downslope, sampled?
- ▶ No estimate of the soil dissipation rate was made.
- ▶ Soil core diameters were only one inch. Much larger cores are recommended to reduce spatial variability and to minimize handling and subsampling errors. Some measure of variation and hence reliability of the data must be demonstrated (see also Error treatment

below).

- ▶ Error treatment. No error limits were given for numerical results and no error bars were indicated in data plots. In all studies an error analysis should be given for all determined values. As is almost always true for analytical results, precision in laboratory manipulation and quantitative procedures is secondary when compared to choice of representative samples to analyze. Of utmost importance is some measure of variation of samples collected in complex environmental matrices.

Concerning laboratory precision only, conventional use of significant figures should be observed in reporting final numerical results with error limits indicated for individual results. Hypothetical expected errors can be calculated based on general experimental limitations for the various procedures, concentrations, methods, etc. For example, calculation of a maximum expected error is often a simple procedure, and would be appropriate for many studies. Pooling of precision data from similar samples or established methodologies taken over the course of time (even from other studies or sources) can often be used effectively. Only in this way can the apparent results, variations, and trends be meaningfully interpreted.

It is not unreasonable to expect that considerable effort be devoted to experimental design, sample selection, and assessment of the reliability of experimental results (perhaps as much as data collection?). Otherwise, the data could legitimately be regarded as worthless.

- ▶ References to plot dimensions are inconsistent.
- ▶ Data tables are inconsistent on whether it was day 10 or day 11 on which samples were taken. Soil moisture table indicates day 10.

PERTINENT DATA AND OTHER EXPERIMENTAL INFORMATION

Page _____ is not included in this copy.

Pages 10 through 39 are not included in this copy.

The material not included contains the following type of information:

- Identity of product inert ingredients.
 - Identity of product impurities.
 - Description of the product manufacturing process.
 - Description of quality control procedures.
 - Identity of the source of product ingredients.
 - Sales or other commercial/financial information.
 - A draft product label.
 - The product confidential statement of formula.
 - Information about a pending registration action.
 - FIFRA registration data.
 - The document is a duplicate of page(s) _____.
 - The document is not responsive to the request.
-

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.
