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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

AUG 20 1992

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Myclobutanil-- Response to Rebuttals on Turf Review/
Necessity of Further Avian Reproduction Studies
DP Barcodes: D179904, D169912
ID Nos: 000707 -00221 and -00215

FROM: Douglas J. Urban, Acting Chief
Ecological Effects Branch
Environmental Fate and Effects Division (H7507C)

TO: Susan Lewis, PM 21
Fungicide\Herbicide Branch
Registration Division (H7505C)

BACKGROUND

Two avian reproduction studies, both labeled as Acc. No. 265744, were reviewed in 1987. The tests were only conducted up to 60 ppm and although they were found to fulfill guideline requirements, the reviewer noted that if chronic dietary exposure levels are expected to exceed 60 ppm, additional reproductive testing would be in order. Thus far, this has proved to be the case for the following uses of myclobutanil: plums and prunes, pome fruits, grapes, almonds, and turf.

Rohm and Haas Company submitted a rebuttal to the EEB August 15, 1990 review of myclobutanil use on turf grasses. Rohm and Haas feels that the avian reproduction studies need not be repeated because: (1) the estimated environmental concentration (EEC) is lower than predicted by EEB and (2) the actual exposure of avian species to myclobutanil will be reduced by dietary and behavioral factors. The company also contends that the values EEB uses in aquatic exposure calculations do not accurately characterize myclobutanil's behavior.

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CONCURRENCES

SYMBOL	H7507C	H7507C	H7507C					
SURNAME	H. Mansfield	Vaughan	Cook for DJU					
DATE	8/10/92	8.18.92	8.19.92					

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DISCUSSION

Two studies were submitted to EFGWB to support EECs lower than EEB's initial calculation -- a runoff study and a residue study. EEB received a summary of these studies and copies of studies/articles that detail that are referenced in attachment one. Because the actual studies have not yet been evaluated and may not be by the due date of this expedited review, EEB may not yet respond to each issue that the registrant has posed. The following are EEB's responses to some of the issues raised by Rohm and Haas, in the order in which they were presented:

Rohm and Haas: "...the primary use pattern of most turf fungicides is on golf courses, particularly greens and tees (6% of total average golf course area), with substantially less use on larger areas such as fairways and roughs"

EEB Response: Even if the primary use pattern of turf fungicides is on golf courses, it must be considered that myclobutanil may also be used on turf nurseries, seed or sod farms, cemeteries, athletic fields, roadway right of ways, educational facilities, and residential lawns. Lawn care operators use a substantial percentage of the total fungicides sold. If Rohm and Haas wishes EEB to consider that myclobutanil is used only on golf courses, the company must submit a label indicating this limitation.

Although EEB concurs that golf course fungicide use is the most extensive on greens and tees, in terms of acreage, fairways account for the most use. Again, if Rohm and Haas wishes EEB to consider that myclobutanil is only used on greens and tees, the company must submit a label indicating this limitation.

Rohm and Haas: "...non-target organisms must reach well-travelled, localized areas of golf courses to be in contact with myclobutanil applied to turf..."

EEB Response: Geese and other birds that feed on golf courses may be accustomed to humans and not fearful of their presence. Further, the birds may feed early in the morning or at other times when people are either scarce or not present. Humans may not be counted on as a factor in limiting non-target organism exposure to myclobutanil. Numerous bird kills have occurred on golf courses from the use of other pesticides.

Rohm and Haas: "Aerobic soil metabolism exhibits a half-life of 61 to 71 days (average = 66 days).....A recently completed Rohm and Haas field study submitted to USEPA with this report has shown that the dissipation half-life of myclobutanil on turf ranges from 3.8 to 5.6 days (average half-life = 4.5 days). The Rohm and Haas half-life was obtained from replicate tests located in three representative areas- Northeast (Chalfont, PA),

Southeast (Douglasville, FA), and Midwest (Columbus, OH). The USEPA EEB-assumed plant average half-life of 66 days (an average of aerobic soil half-lives) is not a suitable surrogate for the average turf half-life parameter and should not be used to estimate exposure now that measured true half-life data are available."

EEB Response: The recently submitted study concerning myclobutanil's half-life on turf has not yet been evaluated. EEB routinely uses the aerobic soil metabolism half-life to calculate both residues, both on feed items and in ponds resulting from multiple applications. However, EEB concurs with Rohm and Haas that actual residue accumulation/dissipation data is more appropriate. If the submitted study is validated by EFGWB, then the half-life data may be used to determine expected terrestrial residues from repeat applications of myclobutanil.

Rohm and Haas: "A reasonable avian reproduction structure-activity relationship (SAR) can be developed based on avian toxicity information on the following triazole based fungicides: flusizole, a silicon, difluorophenyl triazole; fenbuconazole-a chlorophenyl, phenyl, nitrile triazole; triadimefon, a chlorophenoxy triazole; propiconazole, a chlorophenyl dioxolan triazole;and myclobutanil, a chlorophenyl, nitrile triazole."

EEB Response: EEB does not consider the structure-activity relationships between chemicals in performing a risk assessment. Extrapolations from the toxicity of one chemical to another may not be relied upon.

Rohm and Haas: "Because avian diet contributes to exposure, E-FATE input concentrations should be modified by diet composition to provide a more environmentally realistic estimate of avian wildlife dietary exposure (i.e. ppm per day)... Grass shoots are reasonable surrogate vegetation for turf, and when various grass species are included, the dietary contribution of grass shoots during reproduction was 60% in geese (Prevett et al., 1985). Therefore, a more realistic maximum residue concentration for representative avian species can be estimated by multiplying the measured field residue concentration (127 ppm) by .60 (60%), resulting in 76 ppm."

EEB Response: Laboratory data provides a gross approximation of the toxicity of a compound to specific indicator species. This data is used to help set levels of acceptable risk for field use. It is not possible to calculate the exposure/risk from use of myclobutanil to each individual of each species. EEB's intent is that the laboratory toxicity data and the exposure calculations for indicator species will protect the broad spectrum of avian life. Exposure estimates provide a general "safety net" for species that may be affected by a chemical differently than the indicator species. Any calculation involved in assessing the

risk of pesticide use to nontarget organisms must, therefore, assume that 100% of the organism's diet will be food that has been treated or contaminated by the pesticide. Many factors may influence how nontarget organisms are affected by pesticide use. Field studies can be done to ascertain the hazard from actual use.

Rohm and Haas: "Based on the field residue dissipation data obtained in the Rohm and Haas field application study, the actual first-order dissipation rate of myclobutanil is faster than what is predicted with a "conventional" first-order exponential curve (Rohm and Haas half-life = 4.5 days). The first-order fit of In residue concentration versus In time is better...The first order half-life based on the log-log curve is 1.7 days."

EEB Response: This additional information will be considered when the turf residue dissipation data has been reviewed.

Rohm and Haas: "An aquatic half-life of 15 days for myclobutanil due to photolysis has been demonstrated (Accession No. 256773). Therefore, myclobutanil is not resistant to degradation in the aquatic environment as stated in the USEPA EEB review."

EEB Response: The reviewer of the study corresponding to Accession No. 256773 concluded that the study did not fulfill the guideline requirements. The study was later repeated and myclobutanil was characterized as stable to photolysis.

Rohm and Haas: "...Assuming extreme worst-case 5% runoff (ESEPA EEB), 1% runoff (Rohm and Haas worst-case), and a more realistic .05% runoff (Rohm and Haas runoff simulation study using GLEAMS; Weeks, 1990) ..."

EEB Response: EEB's position on Rohm and Haas' worst-case runoff is the same as EEB's position on Rohm and Haas' terrestrial half-life: EEB will consider the 1% runoff value from Rohm and Haas' study **if** the study is considered valid by EFGWB and is determined to reflect a worst-case scenario.

OVERALL CONCLUSIONS

(1) EEB concurs with Rohm and Haas that the residue accumulation/dissipation on turf and runoff data are more appropriate for performing a risk assessment than the surrogates that EEB has used up to this point. If evaluation of the two studies confirms that they reflect the worst-case and the data is valid, then the turf half-life and confidence limits may be used in calculating terrestrial residues from repeat applications and the percent runoff may be used in place of the runoff value derived from myclobutanil's solubility in water.

(2) It can not be assumed that non-target organism exposure to myclobutanil will be limited by the presence of humans or variation in diet. Numerous variables may influence how nontarget organisms are affected by pesticide use. To be general enough to protect a broad spectrum of nontarget organisms and their varied life habits, EEB must consider the worst case of the effect of a pesticide, where 100% of an organism's diet is contaminated by that pesticide.

(3) EPA reviews of the half-life of myclobutanil in water support the conclusion that the chemical is stable to both photolysis and hydrolysis.

(4) EEB does not consider the structure-activity relationships between chemicals when evaluating hazard.

If you have any questions, please call Heather Mansfield at 305-5064.

Administrative Materials References (enclosed):

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