September 29, 1995

NOTE:

SUBJECT: Comments on Paladin Associates Evaluation of a Foliar Dislodgeable Residue Study of Propiconazole Dissipation on Corn.

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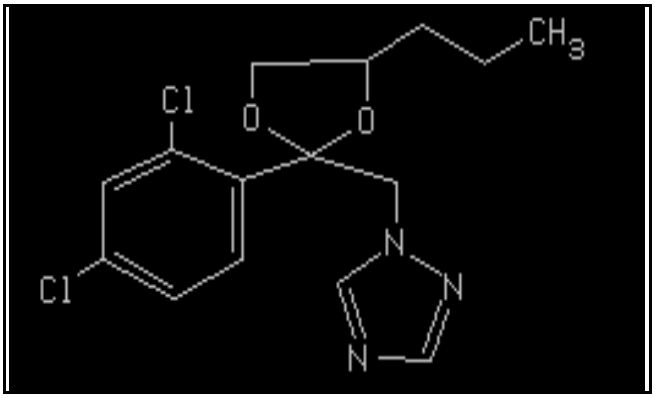
As you requested, I have compared the Propaconizole submission [MRID numbers 425640-01, 425640-02, 425640-03] with the 9/28/94 draft of the comments from Palladin Associates on that submission. Evidently there were other parts to the submission since the Registrant numbered these three parts as; "2 of 7, 3 of 7, and 4 of 7", but these are the only parts sent to Palladin Associates and covered by their review draft. My comments here are restricted to Palladin Associates' discussions of the submission's "reentry" data and calculations required by 40 CFR 158.390 and detailed in Subdivision



Propiconazole

K of the Guidelines.

With the exception of a few points covered below, the review by Palladin Associates is very well done. They have covered the guideline requirements point by point with data from the submission in an organized approach. This aids the Agency's reviewer in preparing the final review and suggestions for the Registration Division's decisions. The Contrator's comments on the submission are lucid, logical, and succinct, but there are a few omissions and/or questionable points. The following paragraphs cover those points and the omissions that could have been treated in the review.

In MRID #425640-01, there is a double negative in the first phrase of the second sentence of ¶ 3.1 on page 6; "Propaconazole is **not** acutely, subchronically, or chronically relatively **non**-toxic....."

SITE LOCATION AND ENVIRONMENTAL CONDITIONS

The State of Georgia site for the foliar residue dissipation study is questionable. Environmental conditions have a very strong affect on the rate of foliar residue dissipation which in turn strongly affects the fieldworker exposure rate. States in the northern mid-west [e.g. Indiana, Illinois, Iowa, Wisconsin, Minnesota] have been prime areas for seed-corn production. In fact, the major reentry poisoning episodes with detasseling operations have occurred in some of those states --- but with other pesticides. [A major complaint with the other pesticides has been dermatitis.] Environmental conditions in those mid-western states are often drier and cooler than in Georgia so the foliar residue levels of Propiconazole there could be higher on a date after application than in Georgia. This would constitute a higher hazard for fieldworkers.

On the other hand, it was summer, and environmental conditions during the submission's tests could be consistent with summer conditions in the mid-west. The review mentions a lack of adequate data on environmental conditions in the submission so it is not possible to make a judgement here except to say that the submitted reentry data is not adequate for assessment of dissipation of foliar dislodgeable residues for the entire United States.

FOLIAR DISLODGEABLE RESIDUES

The foliar sampling is good, but treatment of the resulting data may be misleading. That is, both the Registrant and Palladin Associates did a linear regression of the foliar dislodgeable residue data using log of residues vs linear time. Implicit in this type of regression is the assumption that dissipation is a first order process. This is usually not the case with dissipation of foliar

residues. The plot of foliar residue dissipation [on page 38 of MRID 425640-07] shows a definite curvature and, thus, indicates that linear regression of this data should not be used to predict residue levels at dates not sampled.

THE REENTRY EXPOSURE PROCESS AND TRANSFER COEFFICIENT

It has been common practice for mid-western seed-corn companies to hire large groups (to more than 100) of high school students to detassel corn plants in large fields during the summer vacations. These operations continue for several weeks, and premiums have been offered to those students who will complete the season.

On page 13 of the submission's MRID #425640-01, it is assumed for all 3 exposure scenarios that the detasselers work for 6 days/season. A six day detasseling season may be the practice in Georgia, but teen-agers in the mid-west can detassel corn for several weeks. The submission's reentry exposure estimates are not appropriate for a maximum exposure scenario with respect to the number of days worked.

There are three modes of detasseling corn mentioned in the submission and the review. These are: detasseling mechanically; detasseling manually while on foot; manual detasseling while standing on a platiform on a machine driven through the field. Of the three modes, past complaints of toxic affects indicate that manual detasseling while on a machine presents the greatest exposure. Therefore, the exposure scenario that must be addressed is manual detasseling while riding on a machine.

In the manual-detasseling on a machine that has been common in the mid-west, the corn is planted in a 10-row repeating pattern with only rows 2 through 9 to be detasseled [i.e. 8 rows]. The machines have a very narrow, powered tractor-unit in the center with an overhead support for 2 platforms on each side. These platforms hang down from the support at about a foot from the ground. They are spaced to pass between adjacent rows as the machine passes through the field. Two detasselers stand on a platform to detassel one row each. The machine moves at about the rate a person can walk. Workers can be exposed from head to foot to foliage moving past them at that rate.

It is common for the boys to wear no shirts and for girls to wear shorts and a “halter” so a great deal of body surface may be exposed. Thus, the exposure scenario of greatest exposure, and the one that must be addressed, is for a scantily clad teen-ager. Therefore, the 20% penetration through clothing is questionable and not acceptable without further data. The exposure estimates in the review's Table 1 include 20% penetration for clothing.

Another questionable area in the review's Table 1 has to do with hand exposure to residues on tassels. For lack of appropriate exposure data, the review assumes that all of the dislodgeable pesticide residue transfers to the workers' hands. Since there is no appropriate data to calculate this, the review's hand exposure estimate is the best available - though certainly conservative - estimate. Residue-to-hand transfer data should be provided in future submissions of this type. The importance of this is apparent when the hand exposure at day 14 [0.19 mg/kg/day] is compared to the total dermal exposure at day 7 [0.34 mg/kg/day]. The estimated hand-exposure appears to be 56% [(0.19/0.34)(100)] of the total dermal exposure.

Incidently, the Registrant has submitted soil-residue data that is not required for this exposure scenario. Title 40 of the Code of Federal Regulations, Part 158.390 [40 CFR §158.390(b)(iii)(4)] says; "Soil dissipation data [are] required if agricultural practice involves human tasks that would cause substantial exposure to residues sorbed to soil." The seed-corn tasks do not involve direct "substantial exposure" to soil.

Much of the information provided in this note was not available to Palladin Associates for their review of the data.