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PRODUCT MANAGER, NO. G. LaRocca (15)

PRODUCT NAME(S) Abamectin

COMPANY NAME Merck, Sharp and Dohme

SUBMISSION PURPOSE Registrant Response to Previous EEB Review Relative to Conditional Reg. (granted by RD without EEB concurrence) for Cotton and Citrus

SHAUGHNESSEY NO.	CHEMICAL	% A.I.

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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM August 8, 1989

SUBJECT: Registrant Response to EEB Review on Use of Abamectin on Citrus and Cotton
Reg No: 618-97

FROM: James W. Akerman, Chief
Ecological Effects Branch
Environmental Fate and Effects Division H7507C

TO: George LaRocca PM 15
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Registration Division H7505C

Merck, Sharp and Dohme recently obtained a conditional registration for use of abamectin on citrus and cotton. As part of that conditional registration, they were required to perform field testing for both aquatic and mammal effects. Now, they are challenging these requirements.

Aquatic

Merck is claiming the EEB used the wrong values in running the SWRRB-EXAMS models when determining aquatic exposure. Specifically, the values they disagree with are:

1. Soil halflife - We used 56 days, they propose that 0.5 days be used. Our value is derived from a soil metabolism study using construction sand. Other halflife values derived for soil metabolism were 20 to 47 days, depending on the type of soil. The EEB is resolved to use a soil metabolism halflife, not a soil photodegradation halflife, for the soil decay rate. And in that vein, we will use the most conservative value.

2. Soil binding constant - We used 24.6, they propose to use 83. Note that the value of 24.6 is within the range of measured Kd values from 147 in high organic soil (4.8%), to 80.2 in moderately organic soil (2.1%) to 17.4 in low organic soil (0.1%). Again, EEB prefers to use the most conservative value. If we run the models again, we will use the 17.4 Kd value.

3. They also disagree with the application interval we used (14 days). The registrant prefers 21 days, which they refer to as typical. The label does not specify any time interval. The EEB felt 14 days was very realistic and still believes it represents a potential exposure.

4. They do not disagree with our estimation of drift; however, they again indicate that because the typical interval is 21 days that chronic exposure will not occur.

With regards to the application interval, EEB will use the interval they feel is appropriate if the label fails to specify the interval. Note that EEB is intent on assessing not only typical exposure conditions, but also conditions which maximize exposure including those instances when a grower may feel inclined to apply abamectin at shorter intervals. If the label is strictly observed, there is nothing to prevent use at intervals shorter than 14 days: for example 7 days. With this in mind, the EEB requires that a range of exposures based on various intervals (from 7 to 21 days) be determined and that the field study address each of those exposure levels. As an alternative, the registrant may modify the label to indicate a minimum interval of 21 days; the value for the model can be changed and EEB will use that value in our assessment. However, specifying a 21-day interval will not eliminate the need for an aquatic field study.

This strategy - testing a variety of exposure levels based on varying conditions - should be enlarged to include other factors influencing exposure such as photodegradation rate, soil metabolism halflife, and Kd value. But among the exposure levels tested must be one based on conditions which maximize exposure levels, i.e. the level EEB has already estimated. Nothing in the registrant's submission changes our estimate of aquatic exposure.

The registrant has also indicated that they are conducting and will submit the results of a sediment bioassay. The value of that will depend on how it was conducted and how EEB believes it relates to chronic effects caused by bound residues in the sediment.

Aquatic Summary

The aquatic field study is still required as indicated in the April 4, 1989 review.

Terrestrial

The registrant challenged EEB's exposure estimate and their use of the available toxicological data.

1. Exposure - The disagreement over exposure was based on some measured values on celery. The registrant claims the value

estimated using Kenaga's publications are too high because the measured residues on celery are much lower than those estimated on leafy crops (which, according to Merck includes celery). However, in light of the measured residues on cotton, and in keeping with Branch policy, EEB will use the estimates from the nomograph based on Kenega's publications.

Again the issue of application interval is important. Since the label does not specify a minimum interval, EEB will use the shortest one considered reasonable. In this case, 14 days is used. As with the aquatic discussion, it is possible, if the label is followed strictly, for a user to apply abamectin at 7-day intervals. Therefore, EEB does not believe the 14-day interval is unreasonable. Thus, repeated exposure to levels estimated using the nomograph are expected to result in acute and chronic hazards to mammals. Specifying a 21-day interval will not eliminate the need for a field study for mammals.

2. Toxicity - The primary concern is apparently EEB's use of the NOEL from the materno-toxicity test rather than some LC50 derived from several studies. The EEB will continue to use the NOEL and will not use an LC50 or LD50 value developed from several different studies conducted at different times.

In our previous review we suggested that, rather than a chronic effect requiring 10 days to materialize, the results of the materno-toxicity test in which mortality occurred after 3 and 4 doses should be treated as an acute effect. The EEB still maintains this position. Therefore, our initial assessment remains unchanged.

Terrestrial Summary

The field testing for acute and chronic effects to mammals dwelling in and adjacent to citrus and cotton growing areas is still required.

Conclusion

The data submitted by the registrant have been reviewed and do not alter EEB's previous conclusion. The EEB is willing to meet with the registrant; however, no such meeting is considered necessary (by EEB) until the registrant has formulated some strategy or protocol for conducting the required testing. If you have questions, call Daniel Rieder.