Shaughnessy #: 123301

Due Date: 4/18/85

Init:

Out date: APR 18 1985

To: H. Jacoby
Product Manager #21
Registration Division (TS-767)

From: Joseph C. Reinert, Ph.D., Chief
Special Review Section
Environmental Fate Branch
Hazard Evaluation Division (TS-769c)

JCR

Attached please find the EAB review of...

Reg./File No.: 359-706

Chemical: Aliette

Type Product: F

Product Name:

Company Name: Rhone Poulenc

Submission Purpose: Protocol for greenhouse worker exposure study

ZBB Code:

ACTION CODE: 352

Date In: 3/19/85

EAB # 5372

Date Completed: 4/17/85

TAIS (level II)	Days
60	0.5

Deferrals To:

_____ Ecological Effects Branch

_____ Residue Chemistry Branch

_____ Toxicology Branch

112

1.0 INTRODUCTION:

A protocol was submitted by Rhone-Poulenc, Inc. for a greenhouse worker exposure study of the foliar application of Aliette® to greenhouse ornamentals (EPA Reg. #359-706). Dr. Joe Reinert had specified to the company that he wanted to review the protocol. The study was scheduled to be done in cooperation with Rutgers University, beginning March 1, 1985.

2.0 PROTOCOL:

The protocol describes a field study (greenhouse) designed to:

1. Monitor exposure during typical work practices for both loading of equipment and application of product; and

2. Collect sufficient samples to allow estimation of the efficacy of protective work clothing in reducing exposure.

The study described in the protocol meets our requirements for method of sampling, assay, and information to be reported, and it contains the minimally required number of samples to obtain the exposure information needed.

3.0 DISCUSSION:

1. It was not clear from the protocol as to what method of application is to be used, and the size of tank, although the document states that these will be described in the study report.

2. Sampling strategy appears to give a total of 12 sample sets, probably six for mixers and six for applicators. However "work period" and "exposure episode" are not defined; it could be taken to mean that the crew works through four exposure episodes, but the hand rinse and pad collections are taken at the end of the total work period.

3. Residue chemistry lists method development and validation. Some description of how this may be done should be included, as well as what is considered validation of a residue method over a range of residue levels.

4. The protocol states that the study is designed to collect sufficient samples to allow estimation of the efficacy of protective work clothing in reducing exposure. EPA does not recommend that field studies be used for this purpose, since the number of replicates described in this protocol would not be sufficient to evaluate efficacy, and even then any value of protective clothing would apply only to the particular clothing worn and for the specific conditions under which the field study was carried out.

4.0 CONCLUSIONS:

The protocol essentially meets our requirements for producing a study that we can evaluate, and we would have recommended that the company proceed to run it. However we learned from Richard Fenske of Rutgers, who was in charge of the field study that the study has been completed. We believe a comment is in order about the time frame for this review.

The cover letter was sent to EPA on Feb. 7, 1985, and it states that the study was scheduled to begin on March 1, 1985, yet EAB received the protocol for evaluation on March 19. When the registrant goes to the trouble of submitting a protocol three weeks before the study is to begin, we schedule an expedited review in order for them to begin the study on time, and we would appreciate it if Registration Division would attempt to deliver such protocols to us as soon as possible after receipt. It is a waste of our time to comment on the protocol once the study is begun.

If the registrant or study director has any questions, I can be reached at FTS-703/557-3935. Questions regarding studies of efficacy of protective clothing can be answered by Alan Nielson of EAB, FTS-703/557-2067.

Anne R. Keller

Anne R. Keller, Chemist
Special Review Section 2
Exposure Assessment Branch
Hazard Evaluation Division

114