12-3-92

MEMORANDUM

Subject: Reregistration of Imazalil. Time Extension Requests for Nature of the Residue in Poultry and Wheat Field Trial/Processing. DP Barcode D184389. MRID No. None. CBRS No. 10839.

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Poultry Metabolism

The Janssen Pharmaceutica protocol for the determination of the nature of the residue in poultry from the feeding of radiolabeled imazalil was reviewed previously (S. Funk, CBRS No. 10026, 08/06/92; Addendum, 09/24/92). The registrant's proposal to label imazalil at the C-2 ethyl carbon was rejected, and the registrant was requested to use imazalil uniformly ^{14}C-labeled in the phenyl ring. This position was reiterated in the Addendum of 09/24/92.
The registrant now reports that the earliest possible start date for the study is 02/93. The delay is caused by the need to acquire ^{14}C-phenyl labeled imazalil. A nine month extension to 12/31/93 is suggested.

CBRS notes that ^{14}C-phenyl labeled imazalil was not used in previous studies and that the registrant could not have anticipated the need for this radiolabeled chemical. Therefore, the requested time extension is reasonable, but the granting of time extension requests is in the purview of SRRD.

Wheat Field Trial/Processing

The registrant's protocol for winter wheat trials was previously reviewed (S. Funk, CBRS No. 8108, 07/16/91). One trial was to be conducted at an approximate 7X exaggerated rate to generate grain for a processing study. Janssen Pharmaceutica now reports that an exaggerated rate planting (10X) in Kansas was destroyed in 05/92 by the operator, Servi-Tech. Serv-Tech decided to discontinue research operations. The 10X rate has been planted in North Dakota on spring wheat. If germination is poor, the registrant plans to conduct a 7X rate in Kansas in the fall of 1993. The registrant requests a time extension to 12/94 if the Kansas trial is needed.

CBRS agrees that a time extension may be required if germination is unsatisfactory and recommends for the extension to 12/94. If adequate wheat grain crop is available from even a poor germination rate and if analysis of that grain shows no residues, then no additional work would be required. If germination is so poor as to provide no reasonable yield, then more plantings at lower exaggerated rates will be required. To prevent repeated requests for extensions as the result of phytotoxicity problems, CBRS recommends that several exaggerated trials at a given location be conducted in the fall of 1993, such as 3X, 5X, and 7X. The highest exaggerated rate with acceptable germination may be utilized for the processing study. Alternatively, the registrant may perform small-scale greenhouse studies to determine the highest rate with reasonable (40%) germination and use that exaggerated rate for the next field trial.

Recommendation

CBRS recommends for the time extension for the poultry metabolism study to 12/93. CBRS also recommends for a time extension for the exaggerated wheat field trial for a processing study until 12/94. In the latter case, the registrant should either determine the germination rates as related to the application rate or conduct several exaggerated rate field trials (3X, 5X, 7X) simultaneously to preclude repeated requests for time extensions. CBRS recognizes that the granting of time extensions is in the purview of SRRD.

Figure 1: Structure of Imazalil

cc: Imazalil Reregistration File, RF, circ., S. Funk.
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