List B File
10-4-94

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

OCT 4 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: **Iprodione**. Response to CBRS Review of Grape Chemigation Magnitude of the Residue Study. MRID #43034100, 43034101 and 43034102. DP Barcode D198251 CBRS #13135

FROM: Steven A. Knizner, Chemist
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THRU: Edward Zager, Chief
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TO: Bill Wooge, PM Team 52
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In a letter to the Agency dated 11/30/93 (MRID #43034100), Rhone-Poulenc responded to a previous CBRS review (S.Knizner, 10/15/92, CBRS #10507) of an iprodione magnitude of the residue in grapes following chemigation application study (MRID #42437101). The review of MRID #42437101 noted that until resolution of questions about geographical representation, analytical method, reporting of results, and storage stability, the study was not adequate. The registrant responded to these conclusions by submission of MRID #43034101 and 43034102. The deficiencies cited by CBRS and the registrant responses are evaluated below.

Recommendations With the exception of storage stability data, the registrant has adequately addressed all deficiencies noted in the CBRS review of MRID #42437101. CBRS notes that an iprodione storage stability study is currently under review (MRID #43273401, DP Barcode D206161). Until the storage stability data are determined to be adequate, the iprodione grape chemigation study remains inadequate.

Detailed Considerations

Geographic Representation - CBRS concluded that until the registrant provides additional information about the numbers of growers contacted in NY concerning chemigation application of fungicides, and documentation from sources knowledgeable about grape cultivation in NY (e.g., NY Department of Agriculture or NY grape growers trade associations), the geographic representation of this study is not adequate. Alternatively, the registrant could amend the label to prohibit chemigation application in NY. This deficiency is upgradeable.

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Registrant's Response: Product labels have been modified to prohibit chemigation application of iprodione to grapes grown in New York.

CBRS Response: In a memo dated 8/1/94 (S.Knizner, CBRS #13863) CBRS acknowledged that the restrictions concerning chemigation application to grapes grown in New York adequately resolved this point.

Analytical Method - CBRS concluded that a complete copy of the analytical method should be submitted. Additionally:

a. The analytical method was not validated prior to analysis of samples as called for in the study protocol. This was not noted as a deviation from the study protocol. The registrant should explain why the method was not validated prior to sample analysis.

b. Fortified samples were analyzed concurrently with each sample set. Although most recovery values were within an acceptable range (70 to 110%), recovery values of 67% for the isomer and 118.0% for the metabolite were obtained for fortifications at 0.5 ppm (5X the LOQ). These values are outside the range considered acceptable in the study protocol. The protocol stated that should this situation occur, "the results for that bunch of analyses will be rejected and the samples reanalyzed". The registrant needs to explain why the protocol was not followed. This was not noted as a deviation. The registrant should also explain why concurrent fortifications were made at such high levels (5X or 10X the LOQ).

Registrant's Response: The registrant supplied a copy of Rhone-Poulenc Ag Company SOP-90277, entitled "Rovral: Determination of RP26019 and its Metabolites in/on Dry, Succulent, Oily, and Non-Oily Crops by Gas Liquid Chromatography and Thin Layer Chromatography" (MRID #43034102).

The registrant explained that the method was not validated prior to analysis of samples because the analytical director considered the previous successful use of this method on grapes along with the use of fortified samples to be adequate validation. The registrant agreed that after review of the protocol, a protocol deviation should have been noted. They have amended the final report (MRID #43034101) to reflect this deviation.

The registrant also explained that although two recoveries (67% and 118%) were outside the range considered acceptable in the study protocol, the analytical director used average recoveries of the three analytes to determine acceptability of the data. The registrant concluded that once again a protocol deviation occurred, and modified the final report to reflect this deviation. The registrant also noted that the fortification levels of 5X and 10X the LOQ were chosen based on expected levels of residue.

CBRS Response: The analytical method has been previously evaluated (S.Knizner, 8/1/94, CBRS #13863) and found to be adequate for data collection purposes for residues of iprodione, its isomer, and its metabolite in/on grapes. CBRS concludes that the registrant has adequately addressed concerns over recovery results and levels of sample fortification.

Results - CBRS concluded that:

a. Some of the values reported for the isomer and metabolite are below the limit of detection (0.05 ppm). The registrant must either submit evidence of the suitability of the method for

determination of metabolite and isomer in the 0.005-0.05 ppm range or assign 0.05 ppm (LOQ) to those values <0.05 ppm.

b. Chromatograms and raw data were sparse. For any one site (of the three studied) all sample and standard chromatograms and all raw data (peak heights and retention times) must be submitted. The submissions must be clearly labeled with sample/standard number and date of analysis.

Registrant's Response: In the amended final report (MRID #4303341) the registrant has revised all data summary tables. The value of <0.05 ppm was used whenever iprodione was detected, but was below the LOQ. Appendix C of MRID #43034101 contains a complete set of chromatograms from one of the field trials.

CBRS Response: The changes made to the data summary table are acceptable. Sufficient representative chromatograms and raw data were provided.

Storage Stability - Storage stability data are needed. The registrant stated that a storage stability study is presently underway. Samples were stored frozen between 57 and 161 days from harvest until analysis.

Registrant's Response: The registrant did not address storage stability in their present submission.

CBRS Response: Storage stability data remain outstanding. CBRS notes that an iprodione storage stability study is currently under review (MRID #43273401, DP Barcode D206161).

cc: S.F., circ., R.F., List B File, S.Knizner
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