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

APR 16 1992

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Iprodione - Proposed Supplemental Metabolism Study in Rats

TO: Kathryn Davis/Barbara Briscoe PM 51
SRRD (H7508C)

FROM: K. Clark Swentzel K. Clark Swentzel 4/10/92
Toxicology Branch II
HED (H7509C)

THROUGH: Marcia van Gemert, Ph.D. Marcia van Gemert 4/13/92
Branch Chief
Toxicology Branch II
HED (H7509C)

SUBMISSION:	S414313	**PROJECT NUMBER:**	2-1893
ID NUMBER:	109801-000264	**CASWELL NUMBER:**	470A
BARCODE:	D175844	**REGISTRANT:**	Rhone-Poulenc
CASE:	816345		

Requested Action

Review the proposed study to determine if this approach would be adequate to upgrade the original study (MRID 41346701).

Background

The original study noted above, [Iprodione: Absorption, distribution, metabolism and excretion study in the rat (Unpublished study No. 89/1013 performed by Life Science Research, Ltd., Suffolk, England, for Rhone-Poulenc Agriculture Company, Essex, England: dated December 1, 1989)], was previously reviewed and classified unacceptable (Memorandum, Swentzel to Lewis and Stone, July 9, 1990). It was concluded that this study provided adequate information on the absorption, distribution and excretion of orally administered iprodione in rats. However, since the high-performance liquid chromatography (HPLC) and thin-layer chromatography (TLC) methods used by the investigator failed to identify (1) al least 2 major urinary metabolites and (2) up to 22% of the urinary radioactivity and up to 88% of the fecal

radioactivity, it was concluded that this study provided only supplementary information on the metabolism of iprodione. The issue of unidentified urinary and fecal radioactivity was subsequently resolved (Memorandum, Swentzel to Lewis and Stone, May 1, 1991).

Current submission

The registrant has proposed to upgrade the original study by dosing rats with ^{14}C-iprodione, collecting excreta and performing appropriate analyses in order to identify the metabolites associated with the ^{14}C-residues. A complete guideline metabolism study would not be done.

Response

TB II does not object to the registrant's proposal provided that quantitated parameters (doses, measured levels of ^{14}C-residues, retention times etc.) are comparable to those in the original study. The registrant should submit a test protocol to the agency before initiating the study.