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CASWELL FILE

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

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OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Iprodione - Dermal Sensitization Study in Guinea Pigs
Response to Review

TO: Barbara Briscoe PM 51
SRRD (H7508W)

FROM: K. Clark Swentzel K. Clark Swentzel 1/22/93
Section Head, Section 2
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HED (H7509C)

THROUGH: Marcia van Gemert, Ph.D. Marcia van Gemert 1/26/93
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ID NO.	109801-000264
CASE	816345
BARCODE:	D184831
SUBMISSION:	S429691
PC NO.	109801
MRID	425246-01
CASWELL NO.	470A
REGISTRANT:	Rhone-Poulenc Co.

Requested Action

Review the attached data submitted to upgrade the existing study, MRID 405676-02.

Background

TB II concluded that since the registrant's last response to the review of the subject study did not include information on the pH and preparation frequency of dosing solutions, as well as the stability, uniformity and concentration of test material in the vehicle, the study should remain classified Core-supplementary (EPA Memorandum, Whitby to Briscoe, May 5, 1992).

Registrant's Response

The following itemized responses were included in the registrant's submission:

Frequency of preparation of the dosing solution: Dosing solutions were prepared 11 times during the study, one for each exposure.

Stability of the dosing solution: The stability of the dosing solution was not checked during the study. Dosing solutions were prepared on the same day of dosing for the third induction and rechallenge exposures and on the day prior to dosing for all other exposures.

pH of the dosing solution: The pH of the dosing solution was not checked during the course of the study. However, the pH of an acetone solution containing 10% iprodione technical was determined retrospectively and found to be 6.5. The registrant indicated that no significant difference in pH was found between pure acetone and an acetone solution containing 10% iprodione technical.

Analyses of stability, uniformity and concentration of iprodione in the vehicle:

These analyses were not performed during the course of the study, however, the registrant argued that stability should not have been a problem since the time between the preparation and use of the dosing solutions was 24 hours or less and studies of solubility of iprodione in acetone had previously been conducted.

The registrant also indicated that uniformity should not have been a problem since the solubility of iprodione in acetone is greater than 30% while the concentration of the dosing solutions did not exceed 10%.

Although the registrant did not provide data for the analyses of iprodione in acetone, gravimetric and volumetric data indicating how the dosing solutions were prepared are included in this submission.

Conclusion

The information in the current submission from the registrant has adequately satisfied the concerns previously expressed by TB II regarding the subject study. Therefore this study (Study No. 209821/MRD-098; MRID 405676-02) should be upgraded to Core-minimum.