

US EPA ARCHIVE DOCUMENT



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CASWELL FILE
272E

007283

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

JUN 29 1989

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Cyproconazole: Response to the Evaluation of an In Vivo Mouse Micronucleus Assay (Accession no. 406077-28; Laboratory Project ID 249.215.005)

TO: Lewis/Grable PM 21
Registration Division (H7505C)

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EPA ID No.: 55947-RGE
Project No.: 9-1151
Caswell No.: 272E
Registrant: Sandoz Corp.

Requested Action

Evaluate registrant's response

Background

The subject study was part of a toxicity data package that was submitted to support the simultaneous registration of Cyproconazole technical (for manufacturing use only) and Cyproconazole WG 40, the end use product which is a formulation of the fungicide proposed for use on golf course and sod farm turf. The data package has been evaluated (EPA memorandum, Swentzel, TB, to Rossi, RD, January 17, 1989) and the subject study was evaluated by Backus, Chen and Rowe (Date of final signature on the DER: December 6, 1988). The reviewers concluded that the study (which was negative) was unacceptable because the purity of the test material (technical) was not provided. Additionally, the supplier of the test animals was not indicated.

Response

The purity of SAN 619F, batch 8405, is reported to be 94.4%. The supplier of the mice was "Central Experimental Animal Farm" (noted as "CPB" in the report).

Conclusion

TB now considers this study to be acceptable.

Tox Chem No. 272E File Last Updated _____ Current Date 6/28/89

EPA
MRID/Acc.
No.

LD50, LC50, PIS, NOEL, LEL

Results:

Material

Study/Lab/Study #/Date

TOX
Category

CORE Grade/
Doc. No.

Mouse micronucleus assay
Litton Bionetics/
Lab.ID 249.215.005/
1/10/85

Technical
94.48

No mutagenic response;
Doses: 16.7, 55.7 & 167.0 mg/kg
Study may be upgraded to acceptable
because the purity of the test
material and the supplier of the
mice were provided.

Acceptable