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

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MEMORANDUM

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Propiconazole: Liver Tumor Response Document

TO: Lewis/Stone, PM 21
Registration Division (H7505C)

FROM: Byron T. Backus, Ph.D., Toxicologist Byron T. Backus 9/10/90
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THROUGH: K. Clark Swentzel K. Clark Swentzel 9/11/90
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and

Marcia van Gemert, Ph.D., Branch Chief Marcia van Gemert 9/14/90
Herbicide/Fungicide/Antimicrobial Toxicology Branch
HED (H7509C)

EPA Record No. 249050

Project No. 9-1891

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Tox. Chem. 323EE

Action Requested:

Review and comment on a document from Ciba-Geigy titled: "Perspective: Liver Tumor Response Noted in Male Mice after the Administration of an Excessive Level of Propiconazole."

Comments and Recommendations:

1. Much of the focus of this document is on interpretation of the findings of the Huntingdon mouse carcinogenicity study conducted with propiconazole. This includes a statement (p. 8: "Therefore, the conclusion in the original Huntingdon Report concerning the relationship between the incidence of swollen abdomens and liver tumors in propiconazole treated males is both incorrect and misleading.") that takes issue with the original reporting of the study by the contracting laboratory.

2. Propiconazole has been the subject of four Peer Reviews by the Health Effects Division Peer Review Committee. At the most recent meeting (July 12, 1989) the Committee affirmed its previous decision that propiconazole should remain classified as a Group C carcinogen with a quantification of estimated potential human risk. At this time, it is our understanding that Ciba-Geigy is conducting a 90-day mouse feeding study with propiconazole in order to resolve the MTD issue associated with the mouse carcinogenicity study. New data, rather than reinterpretations of the Huntingdon study, is needed before propiconazole can be considered for reclassification.

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