

US EPA ARCHIVE DOCUMENT

6-2488



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

JUN 24 1988

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Use of Banner ("Tilt") on Home Lawns

TO: Ms. Lois Rossi, PM 21
Registration Division (TS-767C)

FROM: Byron T. Backus, Toxicologist
Toxicology Branch (TS-769C)

Byron T. Backus
05/25/88

THROUGH: Marcia van Gemert, Ph.D.
Section Head, Review Section III
Toxicology Branch (TS-769C)

M. van Gemert
5/26/88

and

Theodore M. Farber, Ph.D., D.A.B.T.
Branch Chief
Toxicology Branch (TS-769C)

W. Farber
6/20/88

EPA Record No. 218788

Project No. 8-0726

Tox. Chem. 323EE

Action Requested:

Comment on the proposed deletion of the statement "Do not use on home lawns" for use of Banner. The Registrant is under the impression that the Agency has recategorized Propiconazole to Category D (without a quantitative risk assessment) in terms of potential carcinogenicity.

Comments and Recommendations:

1. The Agency has reviewed the FIFRA Scientific Advisory Panel recommendations. The Agency's position remains that, based on currently available information, the appropriate classification of Propiconazole is Category C (with a quantitative risk assessment) for carcinogenic risk.
2. The label statement: "Do not use on home lawns" for this product should remain.

FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

SCIENTIFIC ADVISORY PANEL

A Set of Scientific Issues Being Considered by the Agency in
Connection with the Peer Review Classification of
Propiconazole as a Class C Oncogen

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP) has completed review of a set of scientific issues being considered by the Environmental Protection Agency in connection with the peer review classification of Propiconazole as a Class C oncogen. The review was conducted in an open meeting held in Arlington, Virginia, on March 2, 1988. All Panel members, except Dr. Thomas W. Clarkson, were present for the review. In addition, Dr. Wendell W. Kilgore, University of California, Davis, served as an ad hoc member of the Panel.

Public notice of the meeting was published in the Federal Register on Thursday, February 18, 1988.

Oral statements were received from staff of the Environmental Protection Agency and from Mr. John Barnett, Ciba-Geigy and Dr. Seymour Friess representing Ciba-Geigy.

In consideration of all matters brought out during the meeting and careful review of all documents presented by the Agency, the Panel unanimously submits the following report.

REPORT OF PANEL RECOMMENDATIONS

Propiconazole

The Agency requested the Panel to focus its attention upon a scientific issue relating to the Peer Review of Propiconazole. There follows the issue and the Panel's response to the issue:

Propiconazole was classified by the TOX Branch Peer Review Committee as a Category C oncogen based on increased incidence of combined liver adenomas and carcinomas in male mice.

Issue:

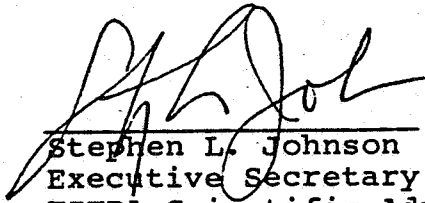
The Agency requests any comments regarding the overall assessment of the weight-of-evidence and classification of this chemical in accordance with the Agency's Guidelines for Carcinogen Risk Assessment.

Panel Response:

The Panel believes there is only minimal evidence for placing propiconazole in the Category C oncogen group. This evidence is based on the incidence of liver tumors in male mice given the agent at a dose that appears to have exceeded the MTD (demonstrated by increased mortality during the first year of study and by the increased SGOT, SAP and SGPT in these animals). Given the totality of the evidence, the Panel recommends placing propiconazole in Category D. Accordingly, a quantitative risk assessment is not in order.

FOR THE CHAIRMAN:

Certified as an accurate report of Findings:



Stephen L. Johnson
Executive Secretary
FIFRA Scientific Advisory Panel

Date: 3-9-88