



CASWELL FILE

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

MAR 21 1986

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: 86-TX-05; Action Code #500; Section 18 Emergency Exemption
for Use of Propiconazole on Rice in Texas
Caswell #: 323EE

TO: Donald Stubbs (PM #41)
Registration Division, TS-767C
and
Residue Chemistry Branch
Hazard Evaluation Division, TS-769C

FROM: Alan Katz *Alan Katz* 3/21/86
Toxicology Branch
Hazard Evaluation Division, TS-769C

THRU: Clint Skinner, Ph.D. *Clint Skinner*
Head, Review Section III 3-21-86
Toxicology Branch
and
Theodore M. Farber, Ph.D., Chief
Toxicology Branch *11/1 3/21/86*

Background:

Propiconazole is not currently registered for use on food crops. The Texas Department of Agriculture (TDA) has applied for a specific exemption to use Tilt[®] on rice to control sheath blight. The TDA proposes use of 10,000 gallons of propiconazole by aerial application during the 1986 growing season. No new toxicity data were submitted. A copy of the one-liners is attached.

Recommendations/Conclusions:

The Section 18 exemption from provisions of FIFRA is not toxicologically supported, for the following reasons:

1. The active ingredient, CGA 64250, is a liver oncogen in male mice.
2. In a 2-year dietary oncogenicity and chronic toxicity study with CGA 64250 in rats, no NOEL was established for several histological effects. Dermal fibromas in males and thyroid follicular tumors in females may be attributable to exposure to the test compound.
3. The registrant was required to provide additional data to enable the Toxicology Branch to complete its evaluation of a 90-day rat feeding study with the plant metabolite, triazole alanine.
4. Following data evaluation, the oncogenic potential must be addressed by the Toxicology Branch ad hoc committee. It is considered inappropriate to establish an ADI prior to completion of these evaluations.