12-21-79

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DATE: December 18, 1979

SUBJECT: 6(a)(2) Data on Terbutryn and Propazine Caswell No.: 125D + 184

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Recommendations:

1. At the higher dose of terbutryn (3000 ppm) in rats, preliminary results show in the males an increased incidence of interstitial cell adenoma of the testis and increased incidence of adenoma, fibroadenoma and adenocarcinoma in mammary gland. In females, the high dose of terbutryn, caused increased incidence of adenoma and hepatocellular carcinoma in female livers. Histological evaluation of the two intermediate levels (2 and 300 ppm) is in progress. The final report of the 2-year rat study with terbutryn should be given priority review status.

2. At the high-dose of propazine (100 ppm) in rats there was a significant increase in mammary adenocarcinomas in female rats. The final report of the 2-year rat study with propazine should be given priority review status.

Review

1. Terbutryn Herbicide

Ciba-Geigy contracted with IRDC 2-year rat and mouse studies, IRDC subcontracted histopathology on the 2-year rat study to experimental pathology laboratories (EFL) Preliminary findings are being reported to EPA.

In summary, the results (in rats) are as follows:

MALES

Increased incidence of interstitial cell adenoma of the testis.

Controls	High Dose (3000 PPM)
13/59 (22.0%)	23/57 (40.4%)

Increased incidence of adenoma, fibrodenoma, and adenocarcinoma in mammary gland:

	Controls	High Dose (3000 PPM)
Adenoma	12/57 (21.1%)	18/55 (32.7%)
Fibrodenoma	6/57 (10.5%)	15/55 (27.3%)
Adenocarcinoma	15/57 (26.3%)	20/55 (36.4%)

Animals with any of the above-24/57 (42.1%) 34/55 (61.8%)

FEMALES

Increased incidence of adenoma and hepatocellular carcinoma in female livers.

	Controls	High Dose (3000 PPM)
Adenoma Hepatocellular	3/57 (5.3%)	12/56 (21.4%)
Carcinoma	2/57 (3.5%)	4/56 (7.1%)

Histological evaluation of the two intermediate levels (2 and 300 ppm) is in progress.

2. Propazine Herbicide

Ciba-Geigy contracted with IRDC 2-year rat and mouse studies.

In summary, the preliminary results in rats are as follows:

FEMALES

	Controls	High Dose (1000 PPM)
Mammary Adenocarcinoma	6/60	20/60

Histological examination of the two intermediate doses (3 and 100 ppm) is in progress.

per
Linda Butler