

US EPA ARCHIVE DOCUMENT

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Tox Chem # 889

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SUBJECT: TRIFLURALIN ONCOGENICITY STUDIES; RESIDUE TOLERANCE FOR UPLAND CRESS.
PP # 9E2224.

FROM: Roland A. Gessert, D.V.M.; Toxicology Branch

TO: Mr. Clinton Fletcher, Minor Uses Officer, Special Registrations (TS-767)

THRU: William Burnam, Toxicology Branch Chief (Acting) TS-769

I have made a superficial review of the recently submitted chronic toxicity studies of trifluralin in rats and mice.

The study in Charles River B6C3F1 mice indicates that toxic doses of trifluralin do not induce an oncogenic response in these mice. A previous NCI study conducted at Hazelton Laboratories had demonstrated hepatocellular carcinomas and alveolar/bronchiolar adenomas in female mice. The NCI study had deficiencies and variables which may have affected the results; therefore, the present study was conducted.

In the rat study, an increase in malignant renal neoplasms in male rats was observed. Also, a high incidence of renal calculi occurred. Associated with the presence of a high incidence of renal calculi were progressive glomerulonephrosi hyperplasia of the renal epithelium, malignant neoplasms of the kidney, and an increased incidence of neoplasms of the bladder. There was no evidence of an increase in the total incidence of benign or malignant tumors in the groups fed trifluralin. Whether the test substance, or the presence of calculi, or the interaction of the two factors was responsible for the neoplastic response seen in the kidney and bladder cannot be established from the submitted data.

Total incidence of benign and malignant neoplasms was either less than control (females) or not different from control (males).

In two previous rat studies conducted by Lilly, and in an NCI rat study conducted at Hazelton Laboratories, no oncogenicity was demonstrated.

In short, (1) the presently considered mouse study does not support the previous conducted mouse study in which oncogenicity appeared to be present, and (2) the presently considered rat study is not supported in the renal oncogenicity findings ⁱⁿ previously conducted studies.

Regarding your current concern, the present studies should not affect our previous conclusions pertaining to a residue tolerance for trifluralin in or on upland cress.

cc: Mr. Richard Mountfort; Dr. Louis Kasza