



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

OFFICE OF  
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

AUG 17 1982

TO: Robert Taylor (25)  
Registration Division (TS-767)  
and  
Residue Chemistry Branch  
Hazard Evaluation Division (TS-769)

SUBJECT: Bladex; EPA Reg.#201-279, 201-281; PP#9F2232; Bladex  
in/on Soybeans CASWELL#188C

Recommendations:

1. The submitted comments regarding the previously reviewed rat teratology study do not adequately address the concerns of Toxicology Branch.

It is not clear that the incidence of a range of 0-5% for anophthalmia and 0-7.4% for microphthalmia is on Fischer 344 rats.

Additionally, Toxicology Branch requires the number of these findings per total number of fetuses and per total number of litters. The actual data supporting these findings would also need to be submitted if it were to be considered.

The referenced Anderson (1949) report indicating the baseline incidence of diaphragmatic hernias to be 2.7-10.8% in albino rat fetuses is not an historical incidence for Fischer 344 rat fetuses. Only historical data within two years of the study from the same rat strain obtained from the same supplier would be appropriate. The suggestive findings in the Bladex teratology study have also been noted in the positive control group and teratology studies other than with Bladex which have been considered teratogenic.

Toxicology Branch concludes that the suggestive teratogenic effects of Bladex in Fischer 344 rats can only be addressed by adequate historical data from the Westhollow Research Center or by repeating the teratology study.

*William Dykstra*

William Dykstra, Ph.D  
Toxicology Branch

Hazard Evaluation Division (TS-769) 8/15/82

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*8/11/82*  
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