CASWELL FILE

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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

OCT 31 1985

MEMORANDUM

SUBJECT: EPA No. 476-2134. Dyfonate (Fonofos). Registrant's Response to Registration Standard (RS)

Tox. Chem No. 454B

TO: W. H. Miller, PM #16
Registration Division (TS-769c)

FROM: M. Sochard, Ph.D.
Section II, Toxicology Branch
Hazard Evaluation Division (TS-769C)

M. Sochard 10-31-85

THRU: Edwin R. Budd, Section Head
Section II, Toxicology Branch
Hazard Evaluation Division (TS-769C)

Bud 10/31/85

10/31/85

Registrant: Stauffer Chemical Co.
1200 South 47th Street
Richmond, CA 94804

Action Requested:

In response to the Fonofos (Dyfonate) RS in which a teratology study in a second species was cited as a data gap, the Registrant has reiterated for a second time that on December 17, 1981, an agreement was reached with EPA to permit the three-generation reproduction study in rats to serve as a teratology study in a second species.

Recommendations:

1) In a response to the above, a memorandum (E. R. Budd, February 20, 1985) indicated that "Neither TB nor PM Team #16 in Registration Division (RD) is aware of or has been able to locate the December 9, 1981 letter referred to by Stauffer. Stauffer should be asked to provide EPA with a copy of the letter." TB is still unable to find this agreement. The registrant has provided no new information on this agreement.

2) A rereview of the three-generation reproduction study in rats indicates deficiencies which exclude the study from use as a teratology study.

3) Deficiencies in the three-generation reproduction study in rats which exclude it from consideration as a teratology study are as follows:

   a) The highest dose tested was not at a level which would produce some toxic effects.

   b) Dietary administration of test article rather than gavage administration.

   c) Administration of test article was not restricted to the critical period of organogenesis in the fetus.

   d) The results of the teratogenic examination of the fetuses were inadequately reported.

   e) Justification was not offered by the Registrant for the use of a second rodent species as the test animal.

Conclusion:

The three-generation reproduction study in rats is not acceptable as a teratogenicity study.