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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)

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

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

M. Sochard
10-31-85
Budd
10/31/85
WFO
10/31/85

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.