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

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

DATE: December 24, 1981

SUBJECT: TB/HED comment on E. Lilly ltr., oryzalin, 10/22/81, Hill - Taylor.

FROM: Mary L. Quaife, Ph.D.
Toxicology Branch/HED (TS-769)

TO: Registration Division (TS-767)

Caswell No. 623A

E. Lilly & Co., Indianapolis

- Summary:
1. TB/HED agrees that adverse effect of oryzalin on male gonads was not noted in studies listed in A. and B., below (while repeating that dominant-lethal study is unacceptable).
 2. Pending receipt of copies of following original studies (which PM is requested to send to TB/HED), we are unable either to confirm or deny such negative effects: Three-month dog, D-167; 3-month rat, R-686; 3-month mouse, M-9276; 3-month mouse, M-9058; 1-year mouse, M-9137; and 1-year rat, R-157.

Introduction: Petitioner believes that his cited studies which have shown "no effects" on testicular tissue obviate the need for "further study on sperm or sperm cell development." We comment briefly on each study, below.

- Comments:
- A. TB/HED does not dispute Petitioner's claim that the rat dominant-lethal (mutagenicity) study was negative, but TB still judges it unacceptable (as in 1/23/81 and 6/12/81 memos), i.e., Supplementary.
 - B. Statement of "no-effect" on histopathologic examination of male gonads is verified for 42-day rabbit dermal and 21-day rat inhalation studies (B-7256 and R-726) by W. Dykstra, Ph.D., 6/2/78, and for 2-year rat and mouse studies (1/7/81 and 10/7/81) and for 3-generation rat reproduction study (1/23/81 and 6/3/81), latter reviews by this reviewer.
 - C. Ninety-day rat and dog feeding studies (both in reviews and in PP 2G1201) are identified differently than in the Hill letter (as R-1077 and D-100-67 rather than Hill's R-686 and D-167). Therefore we are unable to confirm Petitioner's claimed "no effect."
 - D. Our files do not note reviews of (nor contain copies of studies): 3-month mouse, M-9058; 1-year mouse, M-9137; or 1-year rat, R-157; or 3-month mouse, M-9276.