



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

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CASWELL FILE

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

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MEMORANDUM

SUBJECT: Review of Protocols for EPTC (Eptam); #748-222/223.

TO: Robert Taylor
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Registration Division (TS-769C)

THRU: Christine F. Chaisson, Ph.D. *Christine F. Chaisson*
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Action Requested:

PPG Industries Inc. has submitted for review 3 protocols on EPTC (Eptam). These protocols were submitted in response to the Guidance Package for reregistration in which the Agency advised the registrants to incorporate into the protocol designs special tests for clotting function and hematology. The following protocols were submitted:

- 1) Oncogenicity Study in Mice with EPTC; Hazleton Laboratories, Protocol #TP3160, Study #6100-104.
- 2) Two-year Oral Feeding Study of the Oncogenicity and Chronic Toxicity of EPTC in Rats; Hazleton Laboratories, Protocol #TP3141, Study #6100-106.
- 3) Two-Generation Reproduction Study with EPTC in Rats; Hazleton Laboratories, Protocol #TP4031, Study #6100-108.

Review and Conclusions:

The following items are of note in each of the above 3 protocols:

1) The mouse oncogenicity was already underway at the time the protocol was submitted. Therefore, a review of this protocol is not appropriate, i.e., after initiation of the study. The completed study, including the protocol, will be reviewed when the final report is submitted.

2) The chronic/oncogenic rat feeding study was also already underway at the time the protocol was submitted. Therefore, a review of this protocol is not appropriate, i.e., after initiation of the study. However, it is noted that the protocol does contain special tests for clotting function (prothrombin time) and hematology (including platelet counts and red cell indices) as required in the Agency Reregistration Guidance Package. The completed study, including the protocol, will be reviewed when the final report is submitted.

3) The protocol for the two-generation reproduction study in rats was reviewed. The protocol included special tests for clotting function (prothrombin time) and hematology (including platelet counts and red cell indices) as required in the Agency Reregistration Guidance Package. In addition to the above special tests, the protocol meets the intent of the EPA Guidelines, November 1982, Subdivision F, 183-4.

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