REVIEWER

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

JUL 22 1992

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OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: 625. Pentachloronitrobenzene (PCNB). Preliminary Notification of Adverse Effects in 21-Day Dermal Study

Tox. Chem. No. 640
Project No. D179789

TO: Susan Cerrelli, PM Team # 73
Special Review and
Reregistration Division (H7508W)

FROM: Pamela M. Hurley, Toxicologist Pamela M. Hurley 7/11/92
Section I, Toxicology Branch I
Health Effects Division (H7509C)

THRU: Roger L. Gardner, Section Head
Section I, Toxicology Branch I Roger Gardner KP 7/17/92
Health Effects Division (H7509C) 7/15/92

Submission: S420276

Background and Request:

Amvac Chemical Corporation is in the process of conducting a 21-day dermal study in the rat in response to a Data Call-In requirement for PCNB. On the basis of a range-finding study, the dose levels that were selected for this study were 0, 100, 300 and 1000 mg/kg/day. The in-life phase of the study has been completed and the microscopic examinations are in progress. Amvac has submitted to the Agency a preliminary 6(a)(2) notification letter stating that there is evidence of hypertrophy and hyperplasia of the follicular epithelium of the thyroid gland in the high dose males (4/5 tested). The Registrant expects to submit the final report to the Agency in August, 1992. The letter was sent to the Toxicology Branch (TB-I) as an FYI. TB-I was not asked to officially respond to the letter.

Toxicology Branch Response:

TB-I acknowledges the receipt of the preliminary notification of the possible 6(a)(2) data for the 21-day dermal study on PCNB. As the instructions state on the bean sheet, TB-I will wait for the final report before commenting on the results from the study.

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