



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

JUL 22 1992

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: 056502. Pentachloronitrobenzene (PCNB). Request for
Cost Sharing Approval for 2-Generation Reproduction
Study

Tox. Chem. No. 640
Project No. 2-C150
DP Barcode: D1E9835

TO: Susan Cerrelli, PM Team # 71
Reregistration Branch
Special Review and
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THRU: Roger L. Gardner, Section Head *Roger Gardner*
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Submission: S404986

Background and Request:

A Data Call-In Notice on PCNB required that a 2-generation reproduction study and a 21-day dermal study be conducted in order to satisfy the regulatory requirements for Technical PCNB. Amvac Chemical Corporation (Amvac) has entered into a "data cost sharing agreement" with Uniroyal Chemical Company, Inc. (Uniroyal) in order to comply with the Data Call-In requirements. Uniroyal has previously conducted a 2-generation reproduction study in the rat on Technical PCNB. However, it was conducted on the Technical material that is manufactured by Uniroyal. Amvac has requested that the Agency review and compare the chemistry data of the Technical grade materials manufactured by Amvac and by Uniroyal to determine whether or not they are similar enough in composition such that the 2-generation reproduction study conducted on the Uniroyal Technical material will be sufficient to satisfy the regulatory requirements for the Amvac Technical material.

Amvac has already decided to conduct the 21-day dermal study with the Amvac Technical material.

The Toxicology Branch (TB-I) has been asked to respond to this request.

Toxicology Branch Conclusions:

After receiving the analysis of the two Technical materials from the Chemistry Branch (memorandum enclosed), TB-I has determined that the composition of the two Technical materials are sufficiently different that the 2-generation reproduction study conducted on the Uniroyal Technical material will not satisfy the regulatory requirement for the Amvac Technical material.

The actual compositions of the two Technical materials are summarized in the Chemistry Branch memorandum and will not be listed here in detail because the data are considered to be confidential business information (CBI). The Technical PCNB from Amvac is 95% pure material and the Technical PCNB from Uniroyal is 99% pure material. TB-I is concerned about the potential toxicological activity of [REDACTED] major impurities in the Amvac Technical product that are not present in the Uniroyal Technical product. Taken together, [REDACTED] impurities represent approximately [REDACTED] of the Technical material. TB-I believes that these impurities represent a sufficiently high percentage of the Technical material that the reproduction study conducted with the Uniroyal Technical material will not satisfy the regulatory requirement for the Amvac Technical material.

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