



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

JUL 11 1990

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Developmental Toxicity Protocol for a Study with Bronopol in Rats.

Tox. Chem. No.: 116A
HED Project No.: 0-1222
EPA ID No.: 33753-5
Record No.: 260814

TO: John Lee, PM #31
Registration Division (H7505C)

FROM: Roger Gardner, Acting Section Head
Review Section I
Toxicology Branch I (Insecticide/Rodenticide Support)
Health Effects Division (H7509C)
Roger Gardner 7-2-90

THRU: Karl Baetcke, Ph. D., Chief
Toxicology Branch I (Insecticide/Rodenticide Support)
Health Effects Division (H7509C)
Karl Baetcke 7/9/90

Actions Requested

Review of a developmental toxicity study with Bronopol in rats (Toxicology Data Requirement 83-3).

Conclusion

The protocol as presented is unacceptable because procedures were described by reference to Standard Operating Procedures with limited details on the observations to be made during the study.

Discussions

There was no statement in the protocol to indicate an intention to comply with Subdivision F testing guidelines (83-3). The procedures to be followed were described by reference to Standard Operating Procedures for the testing facility with only a limited description of details. There was no indication that the numbers of corpora lutea, implantation sites, resorptions (early and late), and gravid uterine weights would be reported. Other observations that were not mentioned in the protocol included the number of non-gravid dams and dams with total litter loss.

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