UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

DEC 12 1995

Mark E. Burt, Ph.D.
ZENECA Biocides
1800 Concord Pike
Wilmington, Delaware 19897

SUBJECT: Review of addendum submitted to upgrade status of guideline 72-1a, acute toxicity to bluegill sunfish, for Poly(hexamethylenebiguanide) (PHMB); Case #3122; AI #111801.

Dear Dr. Burt:

This letter is a response to your study (MRID 43759701) and letter submitted as an addendum to upgrade a previously submitted bluegill sunfish acute toxicity study for Vantocil IB (MRID 42722101) for the guideline requirement 72-1a.

The Agency has reviewed your submission and has determined that the status of this study remains invalid for the following reasons:

- Each study should be conducted in such a manner that it can stand on its own merit.
- The Standard Evaluation Procedure states that for a flow-through method, the test solution must be analyzed to determine the exact concentration of pesticide at each dose level.
- Even though a > 70% recovery of nominal concentration for Vantocil IB was shown in a static range-finding test for rainbow trout, a static range-finding test is not designed to represent a flow-through test. A flow-through range-finding test might show less or greater than 70% recovery. For a flow-through system, the Agency needs to know the exact concentrations test animals are exposed to in order to determine the correct toxicity category. (Note: Agency records show that PHMB is a polymer which appears fairly stable in water. This information supports the results obtained in the analyses of stock solutions. However, without some analyses of PHMB in the actual test chambers, one cannot corroborate that diluters were operating properly to support that the 1 to 200 ratio is accurate.)

The Agency concludes that the data found in your addendum are unacceptable to upgrade the bluegill sunfish study from invalid to acceptable. **However, another warmwater, or coldwater, fish study is not required to support reregistration of a 20%, or less, active ingredient product.** We have reviewed the file for PHMB and determined that acceptable data, developed at the Agency's Animal Biology Laboratory, are available for bluegill sunfish and rainbow trout. These data indicate that Baquacil, 20% active ingredient (AI), resulted in 96-hour LC_{50}s of 0.44 ppm AI, and 0.11 ppm AI for bluegill sunfish and rainbow trout, respectively.

Copies of these reports are enclosed. Also enclosed is a chemical review status sheet, as you requested. If you have any other questions concerning this letter or the chemical review status sheet, please call Marie Boucher of the Accelerated Reregistration Branch at (703) 308-8178.

Sincerely Yours,

Bruce Sidwell

Bruce Sidwell, Section Chief
Accelerated Reregistration Branch
Special Review and
Reregistration Division

enclosures
cc: Curtis Laird (EFED/EEB)
Henry Craven (EFED/EEB)

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