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

OFFICE OF  
PESTICIDES AND TOXIC  
SUBSTANCES

JUL 22 1992

MEMORANDUM

SUBJECT: Poly (hexamethylenebiguanide); Baquacil: Review of additional Toxicology Data Submitted by the Registrant.

Caswell No: 676  
Submission: S420604  
DP Barcode: D179976

FROM: Timothy F. McMahon, Ph.D., Toxicologist *[Signature]* 7/13/92  
Review Section I, Toxicology Branch II  
Health Effects Division (H7509C)

TO: Linda Deluise / PM 52  
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THRU: Yiannakis M. Ioannou, Ph.D., Section Head *[Signature]* 7/13/92  
Review Section I, Toxicology Branch II  
Health Effects Division (H7509C)

and

Marcia Van Gemert, Ph.D., Branch Chief *[Signature]* 7/13/92  
Toxicology Branch II  
Health Effects Division (H7509C)

Registrant: ICI Specialty Chemicals, Wilmington, Delaware

**Action Requested:** Review of additional data submitted in support of MRID # 65131, "PHMB ("Baquacil" SB): A Teratology Study in the Rat by Dietary Administration."

### **Conclusions:**

ICI Specialty Chemicals submitted data with a request for upgrading a rat teratology study with Baquacil. From the Phase IV review of this study, it was determined that the acceptability of this study required submission of data demonstrating the stability, homogeneity, and concentration of test material in the dosing medium. In a subsequent meeting between representatives of ICI and Health Effects Division (May 21, 1992), it was determined that significant technical difficulties existed in detection of Baquacil in dietary mixtures. Thus, this issue was resolved through an agreement that gravimetric analysis would be performed on dietary mixtures to adequately demonstrate the dose levels achieved in long-term studies.

The registrant has requested that the rat teratology study be upgraded to acceptable, based upon this agreement and the fact that the lack of dietary analysis was the only deficiency noted in the rat teratology study. At the present time, Toxicology Branch II recommends against upgrading this study until dietary analysis data as previously agreed to between ICI and Toxicology Branch II are submitted and reviewed by Toxicology Branch II.

### **Classification:**

The acceptability of the rat teratology study (MRID # 65131) remains reserved pending receipt and review of dietary analysis data.