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

JUL -2 1992

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Poly (hexamethylenebiguanide); PHMB.

Caswell No: 676
DP Barcode: D179343
Submission: S419506

FROM: Timothy F. McMahon, Ph.D., Toxicologist
Review Section I, Toxicology Branch II
Health Effects Division (H7509C)

T. McMahon 6/27/92

TO: Linda Deluise / PM 52
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THRU: Yiannakis M. Ioannou, Ph.D., Section Head
Review Section I, Toxicology Branch II
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Y.M. Ioannou 6/29/92

and

Marcia Van Gemert, Ph.D., Branch Chief
Toxicology Branch II
Health Effects Division (H7509C)

M. Van Gemert 6/30/92

Registrant: ICI Specialty Chemicals, Wilmington, Delaware

Action Requested: Review of proposals put forth by ICI for the conduct of Toxicology studies with PHMB.



Summary:

A meeting between representatives of ICI (Ian Bailey, M.D. Stonard, D.W. Kudner, M.E. Burt) and EPA (Marcia VanGemert, Mike Ioannou, Tim McMahon) was held on May 21, 1992 to discuss technical problems surrounding the conduct of chronic studies with PHMB. Evidence was presented by ICI stating the difficulty in conducting dietary analyses of PHMB due to the inability of extracting this compound from the diet. While drinking water studies were initiated (as PHMB is water soluble, making analysis feasible), significant palatability problems were encountered, necessitating early sacrifice of significant numbers of animals on study. ICI proposes the following in order to conduct updated Toxicology studies with PHMB:

- 1) Use the dietary route of administration for PHMB, as higher dose levels can be achieved by this route.
- 2) Perform gravimetric analysis of the dietary mixtures in order to adequately demonstrate the dose levels achieved.
- 3) Perform homogeneity analyses through addition of a dye to dietary premixes and measuring distribution of the dye.
- 4) Conduct a bioavailability study in one species to demonstrate absorption of PHMB.
- 5) Send protocols on metabolism of PHMB for Agency review.

As agreed to in the meeting of 5/21/92, Toxicology Branch II has no objection to these proposals for PHMB. It is agreed that the registrant will perform the necessary studies for reregistration of PHMB as outlined above.