

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DATE: October 12, 1978

SUBJECT: Conference with ICI representatives regarding Baqnacil Swimming Pool Sanitizer; 10182-EUP-11. Caswell#676 (PHMB)

FROM: William Dykstra, Ph.D.  
TOX/HED TS-769 10/12/78 WAD

TO: A.E. Castillo  
Product Manager#34

Persons in AttendanceEPA

William Dykstra/TOX  
A.E. Castillo

ICI

Gordon A. Thomas  
Allan G. Wheeler  
William P. Long  
Judith Gleave

The registrant has submitted additional information previously requested by TB regarding the incidence of hepatic tumors in Alderley Park mice from the historical data maintained on this mouse strain by ICI Central Toxicology Laboratory. A summarized account of the historical data on 6 groups of Alderly Park mice used as controls in studies, initiated from 1965-1972, shows that the range of all types of liver tumors in females is 0-8% and in males is 8-27%. The overall incidence of liver tumors in controls of both sexes is 9.9%. These ranges of hepatic tumors in controls mice from the historical data are equal to or greater than the incidence of hepatic tumors in the high-dose mice in the 80 week skin painting study and life-time feeding study in mice with PHMB. The conclusions originally reported on the potential oncogenicity of PHMB in the 80 week skin painting study and the life-time feeding study need to be changed. PHMB is not considered oncogenic in either the 80 week skin painting study or the life-time feeding study in mice. No oncogenic RPAR criteria have been triggered. The EUP is toxicologically supported.

TOX/HED:th:R.Engler:10/11/78

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