1803 BUILDING
April 18, 2012

The Dow Chemical Company
Midland, Michigan 48674
USA

Mark W. Townsend, Chief
HPV Chemicals Branch
USEPA Headquarters
Ariel Rios Building
1200 Pennsylvania Avenue, N. W.
Mail Code: 7403M
Washington, DC 20460

Dear Mr. Townsend:

Please find enclosed a IUCLID study summary for 2-Amino-2-hydroxymethyl-1,3-propandiol (THAM; CAS=77-86-1). The robust study summaries provide information on a recently completed OECD Reproductive/Developmental Toxicity Screening Test. The information is being submitted to you as a follow up to our revision of the test plan and IUCLID for THAM previously submitted to EPA and revised July 2009. Previously, we used a read across approach from 2-Amino-2-methyl propanol (AMP; CAS=124-68-5) to provide reproductive and developmental information on THAM. As a result of the data we have collected on the reproductive and developmental toxicity of various amino alcohols, it was apparent that AMP did not represent a true surrogate for THAM. The read across approach was withdrawn and we offered to conduct an OECD 421 at EPA's discretion or to forward such information should we be required to conduct the study for REACH.

In the OECD 421 study, rats were administered 0, 100, 300, and 1000 kg/kg/day THAM via oral gavage. Treatment-related parental toxicity was limited to point of contact irritation in the stomach of animals given 300 and 1000 mg/kg/day. There were no treatment-related histopathologic changes in the stomach of males and females given 100 mg/kg/day. There were no effects on any parameter of reproductive performance or offspring survival at any dose level tested. Therefore, based on the histopathologic stomach effects, the no-observed-effect level (NOEL) for parental toxicity was 100 mg/kg/day (local effects). The NOEL for reproductive effects or offspring growth and survival was 1000 mg/kg/day, the highest dose tested.

Unless you need further information or actions on our part, we consider our obligations under the HPV program for THAM completed. Please contact me at (989) 636-9870 or via E-mail at bhughes2@dow.com if you have any questions.

Sincerely,

Brian J. Hughes, PhD, DABT
Toxicologist
The Dow Chemical Company

Enclosure