TSCA NON-CONFIDENTIAL BUSINESS INFORMATION

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American Chemistry Council

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October 6, 2009

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Document Processing Center (Mail Code 7407M)
Attn: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460-0001

Re: Phenol, 4,4'-(1-methylethylidene)bis-, CASRN 80-05-7
Follow-up information regarding 8EHQ-08-17275

The following information is being submitted on behalf of the Polycarbonate/BPA Global Group of the American Chemistry Council. The Polycarbonate/BPA Global Group includes the following companies that manufacture the subject chemical in the US: Bayer MaterialScience LLC, The Dow Chemical Company, SABIC Innovative Plastics, and Sunoco, Inc (R&M).

A TSCA 8(e) submission dated September 25, 2008 (8EHQ-08-17275) provided preliminary information on a developmental neurotoxicity study that was being conducted on the subject chemical. Enclosed with this letter is a CD that contains the final report from that study titled:

"A Dietary Developmental Neurotoxicity Study of Bisphenol A in Rats"

The developmental neurotoxicity study was conducted in accordance with and exceeded OECD Test Guideline 426 and U.S. EPA OPPTS Guideline 870.6300, and was in conformance with Good Laboratory Practice Regulations (40 CFR Part 792) and the OECD Principles of Good Laboratory Practice [C(97) 186/Final].

Details on the study outline are provided in the summary section of the final report, which is also attached to this letter. Based on reductions in mean body weight and body weight gain in dams and offspring, the no-observed-adverse-effect level (NOAEL) for systemic toxicity was set at the dietary concentration of 75 ppm (5.85 mg/kg/day and 13.1 mg/kg/day during gestation and lactation respectively).

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There was no evidence of developmental neurotoxicity at any dietary concentration. The NOAEL for developmental neurotoxicity was set at the highest dietary concentration tested of 2250 ppm (164 mg/kg/day and 410 mg/kg/day during gestation and lactation, respectively).

Based on the conditions of this study, the authors of the final report concluded there was no evidence that bisphenol A is a developmental neurotoxicant in rats.

The preliminary clinical observations reported in the TSCA 8(e) submission 8EHQ-08-17275 were further examined in a focused follow-up study under conditions designed to replicate, as closely as possible, the original developmental neurotoxicity study. The observations reported earlier were not reproduced at an exposure level of 2250 ppm, which corresponds to the highest dietary concentration tested in the original study. The follow-up study, which supports the conclusions of the original study, is incorporated as Volumes 13-15 of the final report for the original study submitted with this letter.

A manuscript based on the report is now under development and the study will be published in the peer-reviewed scientific literature as soon as practicable.

Please contact me if you have any questions.

Regards,

Steven G. Hentges, Ph.D.
Senior Director
Polycarbonate/BPA Global Group

Enclosure: A Dietary Developmental Neurotoxicity Study of Bisphenol A in Rats