



March 12, 2009

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**Via Messenger Delivery**

TSCA Confidential Business Information Center (7407M)  
EPA East – Room 6428, Attn: Section 8(e)  
U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460-0001



RE: TSCA 8(e) Submission: 1,6-Hexamethylene Diacrylate (HDDA; CAS # 13048-33-4)

Dear TSCA 8(e) Coordinator:

Pursuant to Section 8(e) of the Toxic Substances Control Act (TSCA), the Specialty Acrylates and Methacrylates (SAM) Panel of the American Chemistry Council hereby submits this letter on behalf of its member companies that produce 1,6-Hexamethylene Diacrylate (also known as HDDA; CAS # 13048-33-4).<sup>1</sup> The letter is intended to inform EPA of certain findings from a “Combined Repeated Dose Toxicity Study and Reproduction/Developmental Toxicity Screening Test” in which rats were administered HDDA by oral (gavage) exposure (OECD 422, US EPA OPPTS 870.3650). Although the information is being submitted in accordance with the Agency’s interpretation of relevant TSCA 8(e) requirements, the Panel has not made a determination as to whether a significant risk or injury to health or the environment is actually presented by the findings.

**Study Findings:**

In the reproductive screening portion of this study, the mean number of implantation sites was statistically lower ( $p < .05$ ) in the females in the high dose group (750 mg/kg/day) compared to the control group. This difference in number of implantation sites resulted in a lower number of pups delivered per litter (11.4 vs. 14.8 in controls), although this difference did not reach statistical significance. No other treatment-related findings were observed for reproductive parameters at any dose in this screening study. The following table summarizes the results:

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<sup>1</sup> The member companies of the SAM Panel that produce HDDA are: BASF Corporation, Cognis Corporation, Cytec Industries Inc., and Sartomer Company, Inc.



Summary of Gestation and Delivery Data

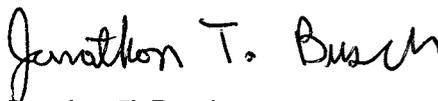
Dose (mg/kg/day)	0	75	250	750
Duration of gestation (days) (SD)	21.6 (1.0)	21.3 (0.5)	21.2 (1.0)	22.3 (0.5)
Mean number of <i>corpora lutea</i> (SD)	17.9 (2.0)	18.4 (3.0)	17.4 (3.6)	16.0 (5.4)
Mean number of implantation sites per litter (SD)	15.8 (1.5)	14.4 (2.5)	15.4 (2.7)	11.8* (5.0)
Mean number of pups delivered (SD)	14.8 (2.0)	13.1 (3.8)	14.7 (2.5)	11.4 (5.0)
Mean number of pups alive on day 1 (SD)	14.7 (1.9)	13.1 (3.8)	14.7 (2.5)	11.4 (5.0)
Mean number of pups alive on day 5 (SD)	14.5 (2.1)	13.0 (3.8)	14.7 (2.5)	10.9 (4.6)

\*:  $p < 0.05$ .

The laboratory testing facility was the Centre International de Toxicologie (CIT) in Evreux France. The results presented in the table above are from a draft study report that has not been fully audited. When available, a copy of the audited, final study report will be provided by the Panel to EPA as a follow-up to this letter.

If you have any questions regarding this submission, please contact me at (703) 741-5633, or at [jon\\_busch@americanchemistry.com](mailto:jon_busch@americanchemistry.com).

Sincerely,



Jonathon T. Busch  
Manager, SAM Panel  
Director, Chemical Products & Technology Division