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EPA East – Room 6428 Attn: Section 8(e)  
Office of Pollution Prevention and Toxics  
US EPA  
1200 Pennsylvania Avenue NW  
Washington DC 20460-0001



Re: TSCA 8(e) Substantial Risk Notice: Supplemental to Docket No. 8EHQ-06-16630;  
Bisphenol A-diglycidyl ether methacrylate (Bis-GMA; CAS No. 1565-94-2)

To whom it may concern:

On October 26, 2006 3M notified the EPA that data for a 14-day repeated dose oral toxicity rangefinding study in CrI:CD1(ICR) mice conducted on Bisphenol A-diglycidyl ether methacrylate (Bis-GMA), CAS No. 1565-94-2, had been received. The study was performed for the purpose of establishing dose levels for a definitive reproductive toxicity study of Bis-GMA.

At termination of the rangefinding study, mean absolute weights for the right and left testes were increased by 15% and 19%, respectively, in males dosed with 0.8 mg/kg-day (high dose group) when compared with weights obtained for the control group. In a subsequent histopathological examination, minimal or mild test article-related multifocal spermatid degeneration was observed in both testes of 4/5 male mice from the 0.8 mg/kg-day group. The number and size of affected spermatids/residual bodies were notably increased in the mice of the test article treatment group when compared to the control group and were thus considered to be test article related.

At the time the EPA was notified of these results, the functional significance of these findings was unclear and the definitive 28-day reproductive toxicity study had not yet been conducted.

The definitive 28-day reproductive toxicity study is now complete. Data from this study do not show an increase in testes weight in treated groups as compared to control, and spermatid degeneration was not observed; furthermore, no adverse effects were observed in any evaluated endpoint. Based on this information, 3M finds no evidence that supports functional significance of the findings observed in the rangefinding study. For this reason, the final report for this study (including the rangefinder) will not be forwarded to the EPA.

If you have any questions, please contact me at (651) 737-1374 or [djluebker@mmm.com](mailto:djluebker@mmm.com).

Sincerely,

Deanna J. Luebker, PhD  
3M TSCA 8(e) Coordinator

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