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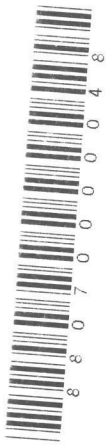
EPA East – Room 6428 Attn: Section 8(e)
Office of Pollution Prevention and Toxics
US EPA
1200 Pennsylvania Avenue NW
Washington DC 20460-0001

Re: TSCA 8(e) Substantial Risk Notice on: Bisphenol A-diglycidyl ether methacrylate (Bis-GMA; CAS No. 1565-94-2)

To whom it may concern:

3M has received data for a 14-day repeated dose oral toxicity rangefinding study in Crl:CD1(ICR) mice conducted on a raw material (Bisphenol A-diglycidyl ether methacrylate (Bis-GMA); CAS No. 1565-94-2). The study was performed at Charles River Laboratories, Horsham, PA for the purpose of establishing dosage for an upcoming definitive reproductive toxicity study of Bis-GMA.



Solutions of the test article (Bis-GMA) or the vehicle (0.8% ethanol in deionized water) were administered once daily to male and female mice (5/sex/group) via oral gavage for 14 consecutive days. The administered doses were 0 (vehicle), 0.008, 0.08, and 0.8 mg/kg-day. At study termination, the 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 when compared with weights obtained for the control group. All other absolute organ weights, as well as the ratios of organ weights to terminal body weights and brain weights, were generally comparable among the groups.

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.

The functional significance of these findings is currently unclear; however, 3M anticipates obtaining additional relevant information in the definitive 28-day reproductive toxicity study scheduled for initiation in November, 2006. Upon receipt, the final report for this study will be forwarded.

If you have any questions, please contact Deanna Luebker at (651) 737-1374.

Sincerely,

Katherine E. Reed (DR)

Katherine E. Reed
Staff Vice President, Environmental, Health and Safety Operations

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