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Document Title	INITIAL SUBMISSION: LTR FR AMER CHEM COUNCIL TO USEPA REPORTING INFO FR AN NTP DERMAL STUDY OF PENTAERYTHRITOL TRIACRYLATE & TRIMETHYLOL*, DTD 042401		
Chemical Category	PENTAERYTHRITOL TRIACRYLATE & TRIMETHYLOLPROPANE TRIACRYLATE		

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April 24, 2001

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Office of Pollution Prevention and Toxics  
U.S. Environmental Protection Agency  
401 M Street, S.W.  
Washington, D.C. 20460



BEHQ-01-14916

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Re: TSCA 8(e) Submission



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Dear Sir or Madam:

The Specialty Acrylates and Methacrylates Panel (Panel) of the American Chemistry Council is reporting information received from the National Toxicology Program (NTP) on pentaerythritol triacrylate (PETA) (CAS No. 3524-68-3) and trimethylolpropane triacrylate (TMPTA) (CAS No. 15625-89-5) on behalf of Panel member who manufacture, process or import PETA or TMPTA, in accordance with the EPA's interpretation of section 8(e) of the Toxic Substances Control Act. The Panel is in receipt of NTP data tables from its study entitled "26-Week Subchronic Study in Hemizygous, Tg.AC Mice Administered by Dermal Application." We have been informed by NTP staff that these tables have been sent previously to the TSCA Docket and various other government agency contacts. No report analyzing or summarizing these data is available from NTP.

The principle neoplastic findings for the PETA-treated animals of both sexes identified in these data tables were dose-related, statistically significant increases in squamous cell papillomas at the site of test substance application (SOA) for the three highest dosages (3, 6, and 12 mg/kg/dose). In addition, a slight increase in the incidence of keratoacanthoma at the SOA for males in the high dose group, and a statistically significant dose-related trend (but not incidence) for squamous cell carcinomas in males were noted. No tumors were noted in the two lowest dose groups (0.75 and 1.5 mg/kg/dose).

Based on incidence (no individual data were available for direct correlation), the occurrence of neoplasms for PETA-treated animals was associated with a dose-related increase in skin irritation at the SOA, identified as hyperkeratosis, chronic active inflammation, and/or hyperplasia. A low incidence of irritation was noted for the 1.5 mg/kg/dose group. An increase in non-neoplastic "hematopoietic cell proliferation" was also noted in the higher dose groups.

Neoplasia in TMPTA-treated animals included a dose-related, statistically significant increase in squamous cell papillomas at the SOA for both sexes at the two highest dosages (6 and 12 mg/kg/dose). In addition, for females, the data tables indicate a slight, statistically significant

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increase in squamous cell papillomas in the stomach and malignant lymphoma in all tissues for the high dose, and in odontogenic tumors in the low dose. No tumors were noted in the three lower dose groups (0.75, 1.5, and 3 mg/kg/dose). As noted for PETA-treated animals, neoplasia for TMPTA-treated animals was associated with a dose-related increase in skin irritation at the SOA, and minimal irritation was observed in the 1.5 and 3 mg/kg/dose groups.

The Panel is reporting these data on behalf of its members who manufacture, process or import PETA and TMPTA even though this assay has not been validated for human risk assessment. We therefore express no views at this time concerning the relevance of these data for human risk assessment. Whereas we do not believe these findings themselves represent a significant risk to humans, we are reporting because these data are the first report of such effects in genetically engineered mice. The Tg.AC bioassay and other transgenic assays were the subject of a session at the recent Society of Toxicology meeting on March 29.

Please direct any questions to the Panel Manager, Anne LeHuray at (703) 741-5630 or via email at [anne\\_lehuray@americanchemistry.com](mailto:anne_lehuray@americanchemistry.com).

Sincerely yours,

*Courtney M. Price/HCS*

Courtney M. Price  
Vice President, CHEMSTAR

cc: SAM Panel Members