



Personal Care Products Council
Committed to Safety,
Quality & Innovation

May 23, 2008

Dr. Barbara Shane
Executive Secretary for the NTP BSC
NTP Office of Liaison, Policy and Review
NIEHS
P.O. Box 12233
MD A3-01
Research Triangle Park, NC 27709

RE: Request for Additional Information on NTP Testing Program - 2-Ethylhexyl-*p*-Methoxycinnamate Proposed Research Project - 73 Federal Register 20289

Dear Dr. Shane,

The Personal Care Products Council¹ (Council) appreciates the opportunity to provide additional information on the above referenced topic. 2-Ethylhexyl-*p*-methoxycinnamate is used as a sunscreen within the personal care products industry, and thus its nomination for study is of interest to Council members.

Enclosed are two publications which are not cited in the background documents for 2-ethylhexyl-*p*-methoxycinnamate.

In the first publication², a study in hairless mice to measure the potential of 2-ethylhexyl-*p*-methoxycinnamate to protect against photocarcinogenesis induced by simulated solar ultraviolet radiation is reported. A dose-dependent protective effect of 2-ethylhexyl-*p*-methoxycinnamate was demonstrated. The potential for 2-ethylhexyl-*p*-methoxycinnamate to act as a tumor initiator in a two-stage model of tumorigenesis was also evaluated, and no initiating activity was seen.

¹Based in Washington, D.C., the Personal Care Products Council (formerly the Cosmetics, Toiletry and Fragrance Association (CTFA)) is the trade association representing the cosmetic and personal care products industry in the United States and globally. Founded in 1894, CTFA has a membership of nearly 600 companies including manufacturers, distributors, and suppliers for the vast majority of finished personal care products marketed in the United States.

²Forbes, P.D., Davies, R.E., Sambuco, C.P., and Urbach, F. (1989) Inhibition of Ultraviolet Radiation-Induced Skin Tumors in Hairless Mice by Topical Application of the Sunscreen 2-Ethyl Hexyl-*p*-Methoxycinnamate. *J. Toxicol – Cut. & Ocular Toxicol.* 8(2):209-226.

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In the second publication³, the ability of 2-ethylhexyl-*p*-methoxycinnamate to provide photoprotection in a UV-induced skin carcinogenesis study was measured in hairless mice, and protection against the tumorigenic effects of UV was again demonstrated. This study also measured the ability of 2-ethylhexyl-*p*-methoxycinnamate to act as an initiator of carcinogenesis, and there was again no evidence of initiating potential.

Thank you for the opportunity to provide information relevant to the 2-ethylhexyl-*p*-methoxycinnamate study nomination.

Sincerely,

Linda Loretz, Ph.D., D.A.B.T.
Director, Safety and Regulatory Toxicology – Science

Enclosures

³ Reeve, V.E., Greenoak, G.E., Gallagher, C.H., Canfield, P.J. and Wilkinson, F.J. (1985) Effect of immunosuppressive agents and sunscreens on UV carcinogenesis in the hairless mouse, *Aust. J. Exp. Biol. Med. Sci.* **63**:655-665.