



Pamela G. Bailey
President & CEO

June 2, 2005

Dr. Scott A. Masten
Office of Chemical Nomination and Selection
NIEHS/NTP
111 T.W. Alexander Drive
P.O. Box 12233
Research Triangle Park, NC 27709

RE: Request for Additional Information on Toxicological Study Nominations to the National Toxicology Program (70 Federal Register 23877): Imidazolidinyl Urea

Dear Dr. Masten,

The Cosmetic, Toiletry, and Fragrance Association¹ (CTFA) appreciates the opportunity to provide additional information on the above referenced topic. Imidazolidinyl Urea is used as a preservative within the personal care products industry, and thus its nomination for study is of interest to CTFA members. When reading the NTP background document on Imidazolidinyl Urea, we noted that data on Diazolidinyl Urea are also included. The background document cites the Cosmetic Ingredient Review (CIR) as finding that Diazolidinyl Urea was not mutagenic in *S. typhimurium* and that it does not induce micronuclei, but that no technical details were available.

The three unpublished studies regarding genotoxicity of Diazolidinyl Urea cited in the CIR report are enclosed. These papers are listed as follows in the reference section of the CIR report.

33. Microbiological Associates. (July 29, 1983). Salmonella/mammalian-microsome mutagenicity assay. Submission of unpublished data by CTFA.

34. Microbiological Associates (September 15, 1983). Salmonella/mammalian-microsome mutagenicity assay. Submission of unpublished data by CTFA.

35. Pharmakon Research International, Inc. (December 12, 1986). Micronucleus test. Submission of unpublished data by CTFA.

¹Based in Washington, D.C., CTFA is the trade association representing the cosmetic, toiletry, and fragrance 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.

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Unpublished data cited in CIR reports are available from CIR upon request. In the future, if unpublished data cited in CIR reports are needed by the NTP, please contact Dr. Carol Eisenmann, at CTFA (eisenmannc@ctfa.org) and she will assist you in getting this information.

Sincerely,

A handwritten signature in black ink, appearing to read "Gerald N. McEwen, Jr.", with a period at the end.

Gerald N. McEwen, Jr., Ph.D., J.D.
Vice President - Science

