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CTFA
Cosmetic, Toiletry, and Fragrance Association

Pamela G. Bailey
President & CEO

May 10, 2007

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

RE: Toxicological Study Nomination to the NTP: Diethyl Phthalate (72 Federal Register 14816)

Dear Dr. Masten,

The Cosmetic, Toiletry, and Fragrance Association[1] (CTFA) appreciates the opportunity to provide comments on the above referenced topic. Diethyl phthalate (DEP) is used within the personal care products industry, and thus, its nomination for toxicological studies is of significant interest to CTFA members.

The National Toxicology Program (NTP) has nominated DEP for multigeneration oral reproductive and developmental toxicity studies, and toxicokinetic studies by the oral and dermal routes. The cited rationale for the nomination is "(w)idespread consumer exposure through use in cosmetics and personal care products; insufficient toxicity data to assess potential reproductive hazard".

CTFA agrees with and seconds the comments submitted by the Phthalate Esters Panel (Panel) of the American Chemistry Council (ACC) that the existing toxicological database is sufficient to conclude that DEP is not a reproductive or developmental toxicant, and therefore, that additional testing of DEP is not necessary. The Panel's comments provide a summary of the relevant testing done with DEP. It is not our intention to discuss those data here as they are well-described and referenced in the ACC Panel comments. We would simply reiterate that the database is robust, including two multi-generation studies conducted at different laboratories; developmental toxicity studies, including one designed to directly address concerns about the developing male

[1]Based 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 of the vast majority of finished personal care products marketed in the United States.

reproductive tract; and in vitro studies evaluating gene expression and testosterone production. The results of all of these studies support the conclusion that DEP is neither a reproductive nor a developmental toxicant.

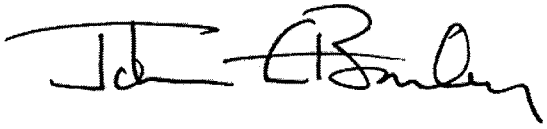
NTP's DEP Chemical Information Profile describes the most recent two generation reproduction study as 'well-conducted', but suggests there were 'limitations' in its design. We note that the totality and consistency of the database would compensate for any limitations in a single study.

Consumer exposure is cited as a justification for the proposed testing. However, the levels reported in the Centers for Disease Control and Prevention (CDC) biomonitoring data are far below the reference dose set by EPA based on non-reproductive effects in rats, as is also discussed further in the ACC Panel comments. These low levels do not indicate a need for additional studies.

In conclusion, CTFA believes that additional testing of DEP is unnecessary due to the sufficient existing database, which consistently indicates that DEP is not a developmental or reproductive toxicant. The proposed testing would require the expenditure of significant resources, and would involve the sacrifice of a considerable number of animals. We believe that these resources could be put to better use.

Thank you for your consideration of our comments. Please contact us if we can provide further information.

Sincerely,



John Bailey, Ph.D
Executive Vice President – Science

cc: Marian Stanley, American Chemistry Council