

Dated: November 10, 2005.

Sandra L. Kusumoto,

Director, Bureau of Consumer Complaints and Licensing.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Toxicology Program (NTP); Center for the Evaluation of Risks to Human Reproduction (CERHR); Announcement of the Availability of the Di-(2-Ethylhexyl)Phthalate (DEHP) Update Expert Panel Report; Request for Public Comment

AGENCY: National Institute for Environmental Health Sciences (NIEHS); National Institutes of Health (NIH).

ACTION: Report availability and request for comment.

SUMMARY: The CERHR announces the availability of the DEHP update expert panel report on November 21, 2005 from the CERHR Web site (<http://cerhr.niehs.nih.gov>) or in print from the CERHR (see **ADDRESSES** below). The expert panel report is an updated evaluation of the reproductive and developmental toxicity of DEHP conducted by an 11-member expert panel composed of scientists from the Federal government, universities, and private organizations. The expert panel met in public on October 10-12, 2005, at the Holiday Inn Old Town Select Alexandria, Virginia to review and revise the draft expert panel report and reach conclusions regarding whether exposure to DEHP is a hazard to human development or reproduction. The expert panel also identified data gaps and research needs. The CERHR invites the submission of public comments on this expert panel report (see **SUPPLEMENTARY INFORMATION** below). The CERHR previously solicited public comment on the draft version of this expert panel report (70 FR 43870-43871, July 29, 2005).

DATES: The final DEHP update expert panel report will be available for public comment on November 21, 2005. Written public comments on this report should be received by January 4, 2006.

ADDRESSES: Comments on the expert panel report and any other correspondence should be sent to Dr. Michael D. Shelby, CERHR Director, NIEHS, P.O. Box 12233, MD EC-32, Research Triangle Park, NC 27709 (mail), (919) 316-4511 (fax), or shelby@niehs.nih.gov (e-mail). Courier address: CERHR, 79 T.W. Alexander

Drive, Building 4401, Room 103, Research Triangle Park, NC 27709.

SUPPLEMENTARY INFORMATION:

Background

The NTP-CERHR convened an expert panel on October 10-12, 2005, to re-evaluate the reproductive and developmental toxicities of di(2-ethylhexyl)phthalate (DEHP, CAS RN: 117-81-7). DEHP is a high production volume chemical used as a plasticizer in the manufacture of a wide variety of consumer products. It is found in many consumer products, such as building products, car products, clothing, food packaging, children's products (but not in toys intended for mouthing), and in some medical devices made of polyvinyl chloride. The public can be exposed to DEHP by ingesting food or drink that has been in contact with DEHP-containing plastics and through medical procedures that use DEHP-containing plastics.

A previous CERHR expert panel evaluated DEHP in 1999-2000. However, since release of the earlier CERHR expert panel report on DEHP, approximately 150 papers relevant to human exposure and reproductive and/or developmental toxicity of DEHP have been published. The CERHR decided to update the evaluation of DEHP because of: (1) Widespread human exposure, (2) public and government interest in potential adverse health effects, and (3) the large number of relevant papers published since the earlier evaluation. Both the original and updated expert panel reports for DEHP are available on the CERHR Web site (<http://cerhr.niehs.nih.gov>). This is the first time a CERHR expert panel was convened to update an evaluation conducted by an earlier expert panel.

Following receipt of public comments on the DEHP update expert panel report, the CERHR staff will prepare an NTP-CERHR monograph on this chemical. NTP-CERHR monographs are divided into four major sections: (1) The NTP Brief which provides the NTP's interpretation of the potential for the chemical to cause adverse reproductive and/or developmental effects in exposed humans, (2) a roster of expert panel members, (3) the final expert panel report, and (4) any public comments received on that report. The NTP Brief is based on the expert panel report, public comments on that report, and any new information that became available after the expert panel meeting.

Request for Comments

The CERHR invites written public comments on the DEHP update expert panel report. Written comments should

be sent to Dr. Michael Shelby at the address provided above. Persons submitting written comments are asked to include their name and contact information (affiliation, mailing address, telephone and facsimile numbers, e-mail, and sponsoring organization, if any). Any comments received will be posted on the CERHR Web site and be included in the NTP CERHR monograph on this chemical. All public comments will be considered by the NTP during preparation of the NTP Brief described above under "Background."

Background Information on the CERHR

The NTP established CERHR in June 1998 [63 FR 68782, Dec. 14, 1998]. CERHR is a publicly accessible resource for information about adverse reproductive and/or developmental health effects associated with exposure to environmental and/or occupational exposures. Expert panels conduct scientific evaluations of agents selected by CERHR in public forums.

CERHR invites the nomination of agents for evaluation or scientists for its expert registry. Information about CERHR and the nomination process can be obtained from its Web site (<http://cerhr.niehs.nih.gov>) or by contacting Dr. Shelby (see **ADDRESSES** above). CERHR selects chemicals for evaluation based upon several factors including production volume, potential for human exposure from use and occurrence in the environment, extent of public concern, and extent of data from reproductive and developmental toxicity studies.

CERHR follows a formal, multi-step process for review and evaluation of selected chemicals. The formal evaluation process was published in the **Federal Register** notice July 16, 2001 (66 FR 37047-37048, July 16, 2001) and is available on the CERHR Web site under "About CERHR" or in printed copy from the CERHR.

Dated: November 3, 2005.

David A. Schwartz,

Director, National Institute of Environmental Health Sciences and the National Toxicology Program.

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