## CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

# SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986 (PROPOSITION 65)

# NOTICE OF INTENT TO LIST CHEMICALS April 11, 2003

The Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65) provides two mechanisms for administratively listing chemicals which are known to the State to cause cancer or reproductive toxicity (Health and Safety Code Section 25249.8(b)). One such mechanism by which a chemical may be listed is if a body considered to be authoritative by the state's qualified experts has formally identified it as causing cancer or reproductive toxicity. The following are identified as authoritative bodies for purposes of Proposition 65 as it pertains to chemicals known to cause reproductive toxicity: the U.S. Environmental Protection Agency, the International Agency for Research on Cancer (solely as to transplacental carcinogenicity), the U.S. Food and Drug Administration, the National Institute for Occupational Safety and Health, and the National Toxicology Program (NTP) (solely as to final reports of NTP's Center for Evaluation of Risks to Human Reproduction). The criteria for listing chemicals through the authoritative bodies mechanism are set forth in Title 22, California Code of Regulations (22 CCR), Section 12306.

As the lead agency for the implementation of Proposition 65, the Office of Environmental Health Hazard Assessment (OEHHA) of the California Environmental Protection Agency intends to list *di(2-ethylhexyl) phthalate* as known to the State to cause reproductive toxicity, pursuant to this administrative mechanism as provided in Health and Safety Code Section 25249.8(b) and 22 CCR, Section 12306.

Relevant information on *di(2-ethylhexyl) phthalate* was requested in a notice published in the *California Regulatory Notice Register* on December 4, 1998 (Register 98, No. 49-Z). A public forum was held on January 11, 1999. OEHHA has determined that *di(2-ethylhexyl) phthalate* meets the criteria for listing under 22 CCR, Section 12306, and therefore is issuing a notice of intent to list *di(2-ethylhexyl) phthalate* under Proposition 65. A document providing more detail on the basis for the listing of this chemical can be obtained from OEHHA's Proposition 65 Implementation Office at the address and telephone number indicated below, or from the OEHHA Web site at: <a href="http://www.oehha.ca.gov/">http://www.oehha.ca.gov/</a>. Anyone objecting to the listing of *di(2-ethylhexyl) phthalate* as causing reproductive toxicity on the basis that there is no substantial evidence that the criteria for sufficiency of evidence as causing reproductive toxicity specified in 22 CCR, Section 12306 have been satisfied should provide written comments in triplicate, along with supporting documentation, by mail or by fax to:

### Ms. Cynthia Oshita Office of Environmental Health Hazard Assessment

Street Address: 1001 I Street Sacramento, California 95814 Mailing Address: P.O. Box 4010 Sacramento, California 95812-4010

> Fax No.: (916) 323-8803 Telephone: (916) 445-6900

Comments may also be hand-delivered to Ms. Oshita at the Office of Environmental Health Hazard Assessment at the same address.

In order to be considered, comments must be postmarked (if sent by mail) or received at OEHHA (if hand-delivered or sent by FAX) by 5:00 p.m. on Monday, May 12, 2003.

The following chemical has been determined by OEHHA to meet the criteria set forth in 22 CCR, Section 12306 for listing as causing reproductive toxicity under the authoritative bodies mechanism:

Chemical	CAS No.	Toxicological	Reference
		Endpoint	
Di(2-ethylhexyl) phthalate	117-81-7	Developmental and	NIOSH (1990)
		male reproductive	US FDA (2001)
		toxicity	

#### References

National Institute for Occupational Safety and Health (NIOSH, 1990). *NIOH and NIOSH basis* for an Occupational Health Standard: Di(2-ethylhexyl) phthalate (DEHP). U.S. Department of Health and Human Services. Public Health Service. Centers for Disease Control. NIOSH.

US Food and Drug Administration (US FDA, 2001). Safety Assessment of Di(2-ethylhexyl)phthalate (DEHP) Released from PVC Medical Devices. Centers for Devices and Radiological Health. U.S. Food and Drug Administration. Rockville, MD.