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### **HUMAN EXPOSURE TO DEHP**

#### **■ The Affect of DEHP Exposure on Rats vs. Humans**

“Human absorption and breakdown of DEHP in the body is different from that of rats and mice. Therefore, many of the effects seen in rats and mice after exposures to DEHP may not occur in humans and higher animals like monkeys (primates).”<sup>1</sup>

*Agency for Toxic Substances and Disease Registry (ATSDR)  
U.S. Department of Health & Human Services*

#### **■ The Issue of DEHP as a Cancer Hazard to Humans**

“The mechanism by which DEHP increases the evidence of hepatocellular tumours (*sic*) in rats and mice is not relevant to humans.”<sup>2</sup> Consequently, in February 2000, DEHP was downgraded to a classification category reserved for chemicals with no evidence of cancer causing potential in humans.

*World Health Organization's  
International Agency for Research on Cancer (IARC)*

DEHP “shall not be classified or labeled as a carcinogenic or an irritant substance.”<sup>3</sup>

*Commission of the European Communities*

“[B]is(2-ethylhexyl)phthalate<sup>4</sup> has been classified in Group IV (‘Unlikely to be Carcinogenic to Humans’) of the classification scheme for carcinogenicity developed for the assessment of ‘toxic’ under Paragraph 11(c) of CEPA [the Canadian Environmental Protection Act].<sup>5</sup>

*Health Canada*

“Currently there is not sufficient evidence to suggest that DEHP is a potential human carcinogen.”<sup>6</sup>

*World Health Organization*

“Comparative studies of a number of related compounds have established that the hepatocarcinogenicity of DEHA and other 2-ethylhexyl-containing compounds [such as DEHP] is associated with hepatic peroxisome proliferation. As human liver cells are refractory to induction of peroxisome proliferation, *the relevance of the liver tumors in rodents induced by peroxisome proliferation appears to be questionable in humans.*”<sup>7</sup>

*U.S. Environmental Protection Agency*

“Mechanistic and exposure information may modulate significantly the case for human carcinogenicity.” Specifically, “[DEHP] may produce tumors by processes not relevant to humans.”<sup>8</sup>

*U.S. Environmental Protection Agency*

*April 2000*

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<sup>1</sup> ATSDR (1993). *Toxicity Profile for Di(2-ethylhexyl)phthalate (DEHP)*, AT 4-5.

<sup>2</sup> IARC monographs on the *Evaluation of Carcinogenic Risks to Humans*. February, 2000. Available at <http://193.51.164.11/htdocs/announcements/vol77.htm>.

<sup>3</sup> Commission Decision of 25 July 1990 on the classification and labeling of di(2-ethylhexyl)phthalate in accordance with Article 23 of Council Directive 67/548/EEC, *Official Journal of the European Communities* No. L 222/49 (Aug. 17, 1990)

<sup>4</sup> DEHP is referred to as both bis(2-ethylhexyl)phthalate and di(2-ethylhexyl)phthalate.

<sup>5</sup> Health Canada (undated), *Priority Substances List Assessment Report: Bis(2-ethylhexyl) Phthalate*, 26.

<sup>6</sup> World Health Organization (1992). *Environmental Health Criteria 131: Diethylhexyl Phthalate*. International Programme on Chemical Safety, page 18.

<sup>7</sup> 60 Fed. Reg. 3912 (Aug. 1, 1995) [bracketed text and emphasis added].

<sup>8</sup> Letter from Victor Kimm, deputy director, EPA’s Office of Prevention, Pesticides, and Toxic Substances, and William Farland, director, EPA’s Office of Health and Environmental Assessment, to Kenneth Olden, director, National Toxicology Program (June 9, 1992).