

Phthalates

HEALTH SCIENCES:

Applied Epidemiology

Consumer Products

Environmental Contaminants

Food & Food Ingredients

Food Contact Substances

Industrial Chemicals

Litigation Support

Medical Devices

Nutrition Science & Dietary Exposure

Occupational & Industrial Health & Safety

Pesticides

Pharmaceuticals & Biologics

Risk Assessment & Risk Management

ENVIRONMENTAL SCIENCES & ENGINEERING:

Air Quality Management

Compliance Assistance

Corporate Responsibility

Engineering Design & Construction Management

Environment, Health & Safety Management

Environmental Due Diligence

Environmental Impact and Assessment & Planning

Environmental Technology Assessment

Greenhouse Gas Management

Risk Assessment & Risk Management

Site Characterization & Remediation

Solid & Hazardous Waste Management

Water & Wastewater Quality Management

In The News

Phthalates are a family of related chemicals, used as plasticizers in PVC and other plastics, including food containers. Phthalates have been under regulatory scrutiny for more than 20 years because of questions about carcinogenicity and reproductive toxicity. Such concerns led to the voluntary removal of one phthalate, di(2-ethylhexyl)phthalate (DEHP) from children's teething and toys in 1986, and subsequent pressure to remove others.⁽¹⁾ Since December 1999, toys intended to be placed in the mouth by children under three years of age and containing certain phthalates have been prohibited in the European Union.⁽²⁾ More recently, the state of California has initiated action to potentially ban young children's products containing certain phthalates in concentrations exceeding 0.1%.⁽³⁾ In addition, recent scientific publications suggesting endocrine effects of some phthalates have raised the level of concern.

Recent Research Articles

The International Agency for Research on Cancer (IARC) downgraded its categorization of DEHP from Group 2B, *possibly carcinogenic to humans*, to Group 3, *not classifiable as to carcinogenicity to humans*, citing evidence that the mechanism by which DEHP increases the incidence of liver tumors in rats and mice is not relevant to humans.⁽⁶⁾ Concerns have shifted to possible effects of DEHP on reproduction and fetal development. While there is evidence of reproductive/developmental effects of some phthalates in animals, only recently have studies been published suggesting effects in humans.^(7,8) A 2003 paper by Duty et al.⁽⁹⁾ reported an association between urine concentrations of monobenzyl, monobutyl, and possibly monomethyl phthalates and reduced sperm motility and concentration. A paper by Shanna Swan, and colleagues⁽¹⁰⁾ appeared on May 27, 2005 on the website of the journal, *Environmental Health Perspectives* reporting an association between prenatal phthalate exposure, as measured by the concentration of phthalate metabolites in the mother's urine before birth, and reduced anogenital distance in male human infants. Several phthalates had previously been shown to cause adverse reproductive effects in rodents, including effects on anogenital distance, a

sensitive indicator of prenatal anti-androgen exposure.⁽¹¹⁾

Human Exposure

As part of the ongoing National Health and Nutrition Examination Survey (NHANES), the Centers for Disease Control and Prevention (CDC) published the results of the Second National Report on Human Exposure to Environmental Chemicals in 2003. Phthalates were found in more than 75% of urine samples studied, indicating widespread human exposure.⁽⁴⁾ Recently, *Environmental Health Perspectives* released on its "In Press" website a paper by researchers at the Harvard School of Public Health reporting a correlation between DEHP-containing medical devices in a neonatal intensive care unit and levels of a DEHP metabolite (MEHP) in the infants' urine.⁽⁵⁾

Legislative Activity

A bill (AB319), introduced into the California legislature in March 2005 by Assemblywoman Wilma Chan, D-Oakland, would prohibit the manufacture or sale of "any toy or child care article," if it contains certain phthalates in concentrations exceeding 0.1 percent.⁽³⁾

ENVIRON Services

To assist with risk management decisions, ENVIRON conducts hazard assessments, exposure assessments, and safety (toxicological) assessments for intentional ingredients, unintended byproducts, and incidental or unavoidable contaminants in consumer products. ENVIRON evaluates the available exposure data and constructs credible, exposure models. ENVIRON conducts a critical weight-of-evidence assessment of the entire portfolio of safety studies. ENVIRON's use of its defensible, science-based assessments has served as the foundation for favorable regulatory decisions, successful defense in litigation, and improved market position.

ENVIRON Experience

ENVIRON has extensive experience relevant to phthalates:

- ENVIRON evaluated the potential health risk that might result from the leaching of phthalate plasticizer into liquid carbon dioxide used for beverage carbonation.

Hot Topic Bulletin

Phthalates

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- For a trade association consisting of paper and paperboard mills using recycled fiber, ENVIRON reviewed scientific data on the toxicity of di(2-ethylhexyl)phthalate (DEHP), prepared a safety assessment, and identified a safe concentration of DEHP in the paper and paperboard products for food-contact uses.
 - ENVIRON evaluated the potential risk from di-(2-ethylhexyl)-phthalate (DEHP) leaching from PVC gloves to workers wearing the gloves and to patients receiving medical devices handled with PVC gloves.
 - ENVIRON prepared a risk assessment for certain consumer uses of a plasticizer used widely in infant and children's products.
 - ENVIRON prepared a document examining how information on mechanism of action, pharmacokinetics, etc., could be incorporated into the identification of a no-significant-risk level for DEHP under California's Proposition 65.
 - ENVIRON prepared a peer-reviewed publication describing a risk assessment for the use of DEHP in vinyl toys and teethingers.
8. Federal Register 70(23):6024, February 4, 2005.
9. S.M. Duty, M.J. Silva, D.B. Barr, et al. Phthalate exposure and human semen parameters. *Epidemiology* 2003; 14:269-277.
10. S.H. Swan, K.M. Main, F. Liu, et al. Decrease in anogenital distance among male infants with prenatal phthalate exposure. *Environ. Health Perspect.* (in press) Available at <http://ehp.niehs.nih.gov/members/2005/8100/8100.pdf>
11. L.G. Parks, J.S. Ostby, C.R. Lambright, et al. The plasticizer diethylhexyl phthalate induces malformations by decreasing fetal testosterone synthesis during sexual differentiation in the male rat. *Toxicol. Sci.* 58:339-349 (2000).

Notes and References

1. Available at <http://www.cpsc.gov/library/foia/foia03/petition/ageunder.PDF>
2. Available at <http://europa.eu.int/scadplus/leg/en/lvb/l32033.htm>
3. Available at http://www.aroundthecapitol.com/billtrack/billview.html?bill=ab_319
4. M.J. Silva, D.B. Barr, J.A. Reidy, N.A. Malek, C.C. Hodge, S.P. Caudill, J.W. Brock, L.L. Needham, and A.M. Calafat. Urinary Levels of Seven Phthalate Metabolites in the U.S. Population from the National Health and Nutrition Examination Survey (NHANES) 1999-2000. *Environ Health Perspect* 112:331-338 (2004).
5. R. Green, R. Hauser, A.M. Calafat, et al. Use of di(2-ethylhexyl) phthalate containing medical products and urinary levels of mono(2-ethylhexyl) phthalate in neonatal intensive care infant units. Available at <http://ehp.niehs.nih.gov/members/2005/7932/7932.pdf>
6. International Agency for Research on Cancer, Monographs on the Evaluation of Carcinogenic Risks to Humans, Vol.77, pp.41-148, 2000.
7. Available at <http://cerhr.niehs.nih.gov/news/phthalates/report.html>