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@preventharm

Midwest Bioeconomy and Safer Products Summit

19 February 2015
PHTHALATES should be replaced with safer substitutes due to:

- Widespread use and human exposure
- Credible scientific evidence of harm
- Vulnerable: pregnant women & children
- Growing regulatory consensus to act
- Market demand for safer alternatives

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**ortho-PHTHALATES** - a large class of related chemicals

The general chemical structure of an *o*-phthalate. R and R’ are ester side chains that vary in length and structure. The two side chains can be identical, or they can differ, giving different phthalates different properties.

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Widely Used in Everyday Products

- Flooring & Wall Coverings: 20%
- Film & Sheet: 19%
- Wire & Cable: 19%
- Consumer Goods: 9%
- Coated Fabric: 11%
- Others: 22%

Source: SRI, CMAI, BASF estimates
Uses of Phthalates as Plasticizers

Source: Flexible Vinyl Alliance 2010
Excludes Phthalates used exclusively as solvents (i.e. Perfumes, Lotions, etc.)

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<tr>
<th>Segment</th>
<th>Subset</th>
<th>DMP</th>
<th>DEP</th>
<th>DPP</th>
<th>DBP</th>
<th>BBP</th>
<th>DEHP</th>
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Figure 2.2  Estimated phthalate ester exposure (µg/kg-d) for eight phthalates and four subpopulations.
Growing Evidence of Harm

Three independent lines of evidence show consistent adverse effects:

• Hundreds of *animal* studies
• Known *biochemical mechanisms*
  – Hormone disruption: testosterone, thyroid
• Dozens of *human* health studies
PRENATAL Exposure

- Male reproductive health
- Behavioral effects (brain)
- Immune sensitization (asthma & allergies)

Phthalate levels were measured in the mothers and their children were tested later (sometimes years)
Development of male reproductive organs

Interference with testosterone during fetal development:

- Undescended testes
- Shortened penis
- Hypospadias
- Shorter anogenital distance

- Increased risk of low fertility, testicular cancer, prostate cancer

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Behavioral Changes

GIRLS:
• Decreased alertness

BOYS:
• Poorer reflexes
• More feminized play behavior

BOTH SEXES:
• Poorer cognitive score, with clinically withdrawn behavior at 3 years
• Poorer social behavior at 7 to 9 years
• Poorer attention and conduct disorder
CHILDHOOD Exposure

• Sexual development
• Behavior and intellectual function
• Immune function

Phthalate levels were measured in the children near the time of testing
Reproductive Health

• Changes in timing of adolescence in girls (development of pubic hair and breasts, first menstruation)

• Development of breasts in boys (gynecomastia)
Behavioral Changes

- Decreased IQ
- Decreased vocabulary
- Increased ADHD
- More errors in attention and impulsivity
Immune Function

- Increased asthma and wheezing
- Increased biochemical markers for asthma
Human Exposure Continues

DEP, DEHP, DBP, BBP

DINP, DIDP, DNOP

03-04  05-06  07-08  09-10

total median urinary concentration (ug/L)

51% increase  39% decrease

numbers represent the total number of metabolites analyzed

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People are exposed to a variety of chemicals throughout their daily lives. To protect public health, regulators use risk assessments to examine the effects of chemical exposures. This report provides guidance for assessing the risk of phthalates, chemicals found in many consumer products that have been shown to affect the development of the male reproductive system of laboratory animals.

Because people are exposed to multiple phthalates and other chemicals that affect male reproductive development, a cumulative risk assessment should be conducted that evaluates the combined effects of exposure to all these chemicals. The report suggests an approach for cumulative risk assessment that can serve as a model for evaluating the health risks of other types of chemicals.

Phthalates are a class of chemicals used in many consumer products to impart flexibility and durability or used for their solvent properties. Concerns have been raised about some phthalates because studies in laboratory animals have shown that exposure can cause adverse health effects, including effects on development of the male reproductive system. Few data are available on the health effects of phthalates in humans, but studies show widespread human exposure to phthalates. The United States and the European Union have passed legislation to restrict the concentrations of several phthalates in children's toys; the European Union has also banned some phthalates from cosmetics.

Given the health concerns about these chemicals, EPA asked the National Research Council to convene a committee to determine whether cumulative risk assessment—an approach that focuses on the health risks posed by multiple chemicals over multiple pathways, routes, and times—of this chemical class should be conducted, and, if so, to identify approaches that could be used for the assessment. However, the committee was not asked to carry out such an assessment in this report.

The committee's report concludes that the risks associated with phthalate exposure should be evaluated using a cumulative risk assessment and provides specific guidance on approaches to that cumulative risk assessment.

The report also considers other chemicals that cause similar effects on male reproductive development, and makes a broader recommendation that the cumulative risk assessment for phthalates should focus on common adverse health outcomes and expand to include these other chemicals. The recommendation to focus on common adverse outcomes represents a shift relative to current practice and is far less restrictive in terms of determining which chemicals to consider for cumulative risk assessments.

What are Phthalates?

Phthalates, or phthalate esters, are diesters of benzenedicarboxylic acid. This report focuses on the most biologically active phthalates.

The general chemical structure of an o-phthalate. R and R' are ester side chains that vary in length and structure. The two side chains can be identical, or they can differ, giving different phthalates different properties. The Tasks Ahead

* Common adverse effects are additive
* Assess cumulative risk from exposure to all phthalates and other anti-androgens

• Chronic Hazard Advisory Panel (CHAP) to U.S. Consumer Product Safety Commission:
• 10% of pregnant women and 5% of infants are exposed to “unsafe” levels of phthalates today
• 5 phthalates: DEHP > DBP, BBP, DINP > DIBP
• Permanent ban on DINP in children’s products
• Recommended ban on 5 additional phthalates

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Increasing Regulatory Pressure

<table>
<thead>
<tr>
<th>POLICY ACTION</th>
<th># PHTHALATES</th>
<th>GOV’T BODIES</th>
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<tbody>
<tr>
<td>Prioritized</td>
<td>41</td>
<td>Many</td>
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<td>Disclosure</td>
<td>32</td>
<td>Canada (28)</td>
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<td>CA (5), WA (8) and ME (4 proposed)</td>
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<td>Restricted</td>
<td>9</td>
<td>European Union, United States</td>
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# Restrictions on Phthalates

<table>
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<tr>
<th>Major Phthalate</th>
<th>BAN in Toys &amp; Child Care Articles (EU, US)</th>
<th>PHASE-OUT All Uses Unless Authorized (EU)</th>
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<tbody>
<tr>
<td>DEP</td>
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<td>(SIN listed as SVHC)</td>
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<td>DBP</td>
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<td>DIBP</td>
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<td>DEHP (DOP)</td>
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<td>BBP</td>
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<td>DNOP</td>
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[www.preventharm.org](http://www.preventharm.org)
DINP is not a safer alternative

- Confirmed anti-androgen (NAS, CHAP)
- Contributes to cumulative risk (NAS, CHAP)
- Banned in children’s products (EU)
- Interim US ban proposed as permanent (CSPC)
- Substance of Very High Concern (SIN list)
- Prop 65 cancer risk warnings (California)
- Use reporting in children’s products (WA state)
- Use reporting in consumer products (Canada)
Phthalate-free Plasticizers in PVC

By Sarah Lott

Safer Substitutes Widely Available

• Alternatives to PVC without plasticizers

• (2014) Six alternative plasticizers identified with safer EH profile

• Two preferred alts:
  * Biobased
  * Well-studied
  * Least toxic

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Why Mind the Store?

Because with great market power comes great responsibility.

TAKEN ACTION: Tell the nation's top ten retailers to get tough on toxic chemicals in consumer products!

www.saferchemicals.org

www.preventharm.org
Task: Phase out all PHTHALATES in favor of safer substitutes