

Meeting Log

Meeting: Presentation on Phthalates in Toys at Toy Manufacturers of America's Toy Safety Seminar

Date: February, 11, 1999

Place: Marriott Marquis, New York, NY

Submitted by: Marilyn L. Wind, Ph.D.

Attached are the slides used in the presentation.

CPSA 6 (b)(1) Cleared  
No. of Mfrs/Products 2/44  
Products Identified  
Exempted by  
Firms identified  
Comments provided

CPSC/OFFICE OF  
THE SECRETARY  
1999 JUL 26 P 2:59



**A Commission Update on Polyvinyl Chloride  
in Toys**

Marilyn L. Wind, Ph.D.



\* The opinions expressed by the author, a present employee of the Consumer Product Safety Commission, do not necessarily represent the views of the Commission.

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**Phthalates Working Group**

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**Phthalate Esters**

- Plasticizers in children's PVC products
  - Teethers, rattles, & soft toys
  - Pacifiers & bottle nipples
- Not covalently bound

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## Background

- DEHP
  - Primary Plasticizer in Early 80's
  - Carcinogen
  - Teratogen
  - Removed Voluntarily from Pacifiers, Teethers, and Rattles

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## Voluntary Standard

Pacifiers, rattles, and teethers shall not intentionally contain Di(2-ethylhexyl) phthalate. To prevent trace amounts of DEHP from affecting analysis, up to 3% of total solid content will be accepted in the result when tested in accordance with Practice D 3421.

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## Federal Hazardous Substances Act

- Hazardous Substance
  - Toxic
    - acute
    - chronic
  - Causes substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children.

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### Diisononyl Phthalate (DINP)

- Primary phthalate in children's products
- Present in 31/35 products CPSC tested
- Mixture of branched chain isomers

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### Health Effects of DINP

- Two-year feeding studies in rat & mouse
- Toxic to the liver & kidney
- NOAEL = 15 mg/kg-d
  - (Lington et al., 1997)
- Acceptable daily intake (ADI)
  - 0.15 mg/kg-d or 150 µg/kg-d

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### Carcinogenicity

- Hepatocellular tumors in rat & mouse
  - Covance, 1998
- Dose response similar to DEHP
- Non-genotoxic
- Lack of chronic stimulation of cell proliferation

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### Exposure Assessment

- Laboratory migration studies
- Validation of the laboratory method
- Duration of exposure

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### CPSC Impaction Method

- Immerse intact product in saliva simulant
  - Dulbecco's PBS + mucin
- Impact with piston
  - 6 pounds force at 37 °C for 6 hours.
- Measure DINP by GC-MS
- Normalize to 11 cm<sup>2</sup>

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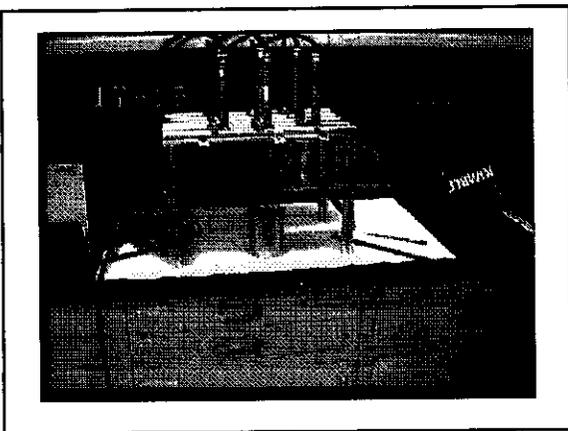
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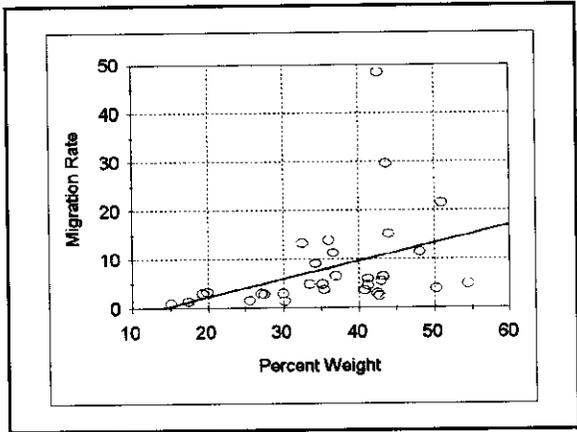
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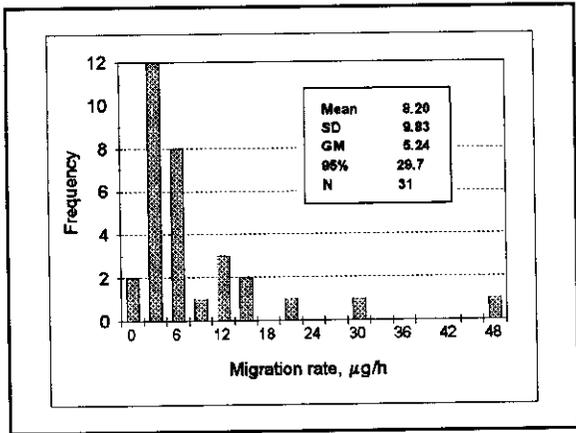
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### Other Migration Methods

- Several migration methods worldwide
  - Shaking, impaction, tumbling, ultrasound
- Broad range of migration rates
- Few inter-lab comparisons
- Need for a standard method

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## Human Subjects Testing

- Dutch Consensus Group conducted tests with adults.
  - Volunteers would mouth or chew the test article and collect saliva.
- 39.5-fold factor between human subjects & CPSC impaction method.

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## Exposure Duration

- Dutch Consensus Group studied mouthing behavior.
  - Pacifiers, teethers, toys, etc.
- Teethers and Toys
  - 3 -- 12 months       $12.0 \pm 2.55$  min/d
  - 13 -- 26 months       $2.1 \pm 1.75$  min/d

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$$DE = \frac{M \times S \times T}{BW}$$

where:

DE = daily exposure      M = migration rate

S = scaling factor      T = duration

BW = body weight

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<b>Teethers &amp; Toys</b>		
<b>Age (months)</b>	<b>Exposure (<math>\mu\text{g}/\text{kg}\cdot\text{d}</math>)</b>	
	<b>Median</b>	<b>95 %</b>
3 -- 12	5.7	94.3
13 -- 26	0.7	7.6

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- Conclusions**
- Median & 95th percentile exposures < ADI
  - Significant sources of uncertainty
    - Migration Method
    - Duration of Exposure
    - Background Levels of Phthalates
    - Cancer Risk

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- Toy Manufacturers**
- Voluntary reformulation of:
    - teethers
    - rattles
    - pacifiers & bottle nipples
  - Phthalates still used in soft toys

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CPSC

- Chronic Hazard Advisory Panel (CHAP)
- Larger observational study
- Laboratory method development & validation
- Petition

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