Plasticizers and the CPSIA

U.S. Consumer Product Safety Commission
Bethesda, MD
July 16, 2009

This presentation includes forward-looking statements. Actual future conditions (including economic conditions, energy demand, and energy supply) could differ materially due to changes in technology, the development of new supply sources, political events, demographic changes, and other factors discussed herein (and in Item 1 of ExxonMobil’s latest report on Form 10-K). This material is not to be reproduced without the permission of Exxon Mobil Corporation.
Agenda

• Background
• CPSIA Support
• Commercial Plasticizers which can be used in toys
• Differences in Phthalates
• CHAP Review
• Scientific DINP/DIDP Review
• Cumulative Risk Assessment
• Next Steps
Background

- **ExxonMobil investment in product safety is substantial**
  - Biomedical Sciences staff perform health and toxicology studies in support of product safety
  - ExxonMobil has spent over $30M testing DIMP and DIDP and has been producing these products for more than 40 years
  - Testing and prior independent governmental reviews have demonstrated that DIMP and DIDP are safe for their intended uses including toys and childcare articles

- **Basic principles of consumer safety requires:**
  - Restricting dangerous substances
  - Allowing the use of well tested and evaluated substances which have been shown to be safe
  - Subjecting all substances which can be used in a particular application to the same standards with regard to testing requirements, degree of evaluation, and ultimate application of federal standard
ExxonMobil Supports CPSIA

• ExxonMobil is the world’s largest plasticizer producer and supports several key principles contained in the CPSIA

• CPSIA differentiates between high molecular weight phthalates (DINP/DIDP) and low molecular weight phthalates (DEHP/BBP/DBP)

• Establishes a federal regulation which preempts state rules

• Mandates Chronic Hazard Advisory Panel to review science on plasticizers and issue report to CPSC
  – Final regulation to be based on sound science
  – Requires all plasticizers used in toys to be subject to same level of scrutiny
## Commercial Plasticizers

- **Phthalates**
  - 90% (5.4 MT) of global plasticizer demand
  - Used to make PVC plastic soft and flexible
  - Most common plasticizer due to excellent balance of cost and performance
  - Also includes terephthalates (DOTP)

- **Adipates**
  - Used in food wrap and low temperature applications

- **Epoxy**
  - Epoxidized soybean oil is most common plasticizer in this group
  - Inexpensive but generally poor performance

- **Trimellitates**
  - Low volatility, excellent high temperature performance
  - Commonly used in PVC wire insulation
  - Expensive raw material trimellitic anhydride

- **Benzoates**
  - Specialty plasticizers
  - Used in adhesives, caulks and sealants
  - Used in combination with phthalates for vinyl flooring

- **Other**
  - Includes citrates, DINCH, many others

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**2005 Global Plasticizer Demand = 6.0 M metric tons**

Source: SRI 2007 Plasticizer CEH Report
U.S. Commercial Plasticizers

2005 US Plasticizer Demands

- DEHP
- DINP/DIDP
- Linear
- BBP
- Other Phthalates
- Non-Phthalates

Total Market = 907 K metric tons

Source: SRI 2007 Plasticizer CEH Report

2010 US Plasticizer Demands

- DEHP
- DINP/DIDP
- Linear
- BBP
- Other Phthalates
- Non-Phthalates

Total Market = 958 K metric tons

Source: SRI 2007 Plasticizer CEH Report

Market Trends (SRI consultant 2007 report)

- Plasticizer market growth below GDP due to finished good imports
- DPHP growing; partially replacing linear phthalates
Plasticizers and PVC Toys

### Evaluations

<table>
<thead>
<tr>
<th>Plasticisers</th>
<th>LMW phthalates</th>
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<tr>
<td></td>
<td>DEHP, DBP, BBP</td>
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<td>DINP, DIP</td>
<td>DPHP</td>
<td>Linear 810, 911</td>
<td>BIP, DOTP</td>
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<td></td>
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<td>DOA, DIB, DIA, DOZ, DOS, DIN, Dibenzoates, Monobenzoates, Alkylsulphonic ester of phenol, TBC, TEC, DINCH, Polymerics, Triglyceride esters of castor oil</td>
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### EU Risk Assessment

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<td>evaluation for use in toys</td>
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<td>Yes (Toy safety Directive)</td>
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<td>No</td>
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<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

- The table shows commercial plasticizers which are used in PVC toys, have the potential to be used in PVC toys, or which have been restricted in PVC toys.
- Not all of the substances with the potential to be used are necessarily used in PVC toys.
- The table also shows the Category 2 CMR phthalates.
- Among all the non-Category 2 CMR plasticizers available, DINP and DIDP are the only plasticizers which have been risk assessed and found to be safe for use in toys.
## Differences in Phthalates

### Low molecular weight
- DEHP, BBP, DBP
- C3 to C8 alcohol + Phthalic Acid
- Cat 2 Reproductive Agents
- Risk reduction required
- REACH Candidate List
- Fertility effects – likely ED

### High molecular weight
- DINP & DIDP
- C9 & C10 Alcohol + Phthalic Acid
- Not CMR
- Not classified and labelled
- No risk reduction required
- Not Endocrine disrupters

- PVC+DINP, DIDP: safe, flexible, durable, cost effective, can be recycled
Differences Explained by Structure

- Tendency to oversimplify by treating all phthalates as a “class” but they are different chemically
- Orthophthalate toxicity to rodents depends on number of carbon atoms in the alcohol side chain
- Total carbon – C4-C8 – Category 2 CMR (carcinogenic, mutagenic, reproductive)

![Chemical Structure](image)

- Total carbon C4-C8 (alcohol backbone C3-C6) DBP, BBP, DEHP Category 2 CMR
- Total carbon C9-C13 (alcohol backbone C7 and above) DINP, DIDP not classified
# EU Classification and Labeling

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<th>ALCOHOL BACKBONE</th>
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<td>DPP</td>
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</tr>
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<td>Cat 2, T; R61</td>
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<tr>
<td>711P (Highly branched)</td>
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<td>10 - 11</td>
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<td>DTDP</td>
<td>11 - 13</td>
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<td>79P (Slightly branched)</td>
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<tr>
<td>911P (Slightly branched)</td>
<td>9 - 11</td>
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</tbody>
</table>

CHAP Review

• CHAP review should be fair, swift and unbiased
  – Sound science as the basis of decision making

• Review of all commercial plasticizers is required
  – Evaluate safe use levels for all commercial phthalates and non-phthalates which may be used in toys
  – Conduct a cumulative risk assessment on total exposure to phthalates using appropriate and consistent endpoints.

• ExxonMobil Biomedical Sciences fully supports the CHAP
  – Willing to submit all available toxicological and environmental data on DINP and DIDP
New DINP/DIDP Data post-CHAP

- Toxicity studies since 2002 confirm that DINP/DIDP are safe
  - 2003 report completed by the National Toxicology Program’s Center for the Evaluation of Risks to Human Reproduction determined
    - DINP presents “minimal concern” for both developmental and reproductive adverse effects
    - DIDP presents “minimal concern” for developmental adverse effects and “negligible concern” for reproductive adverse effects
  - 2005 US CDC (2005) study showed that the general population has low ppb levels of DINP metabolites in urine
    - Recent research shows ppb levels for both DINP and DIDP metabolites - indicative of exposure well within safe limits
  - 2006 report from European Chemical Bureau’s Risk assessment concluded “no risk reduction required” for DINP and DIDP
  - 2006 Oslo-Paris North-East Atlantic Commission for protection of the marine environment concludes “DINP and DIDP are not PBT substances and “there is no indication of potential for endocrine disruption”
  - Toxicological Literature search by EMBSI since 2002 indicates no new science to shift the opinion on DINP or DIDP
    - 31 studies on HMW phthalate (DINP/DIDP/DPHP) toxicology. References submitted by ExxonMobil in public comments to CPSC on January 12, 2009.
  - Recent “Review of Recent Scientific Data on DINP and Risk Characterization for its Use in Toys and Childcare Articles” completed by EMBSI
    - Submitted to European Commission for re-evaluation of DINP/DIDP in the Article 2 Toy Directive
    - Report clearly demonstrates that there is an adequate margin of safety for DINP in mouthing toys
Hazard data on DINP/DIDP

- **Hazard data**
  - DINP is not classified as a reproductive or developmental toxicant
    - Standard two generation test, no effects on fertility
    - Standard dev tox (dosing: gd 6 – 15), no marked developmental effects
    - No effects on gonads from repeat dose studies
  - DIDP is not classified as a reproductive or developmental toxicant
    - Standard two generation test, no effects on fertility, decrease in pup survival indices at high doses in second generation (0.2% in diet or greater). No effects on pup development.
    - Standard dev tox (dosing: gd 6-15 ), no marked developmental effects, skeletal variations noted.
    - No effects on gonads from repeated dose studies

- **Relevant End Points**
  - Previous CHAP selected spongiosis hepatis as the key endpoint for risk assessment, however new studies regard spongiosis hepatis as a rat specific lesion without a counterpart in human pathology
  - Primate studies clearly show that rats are much more sensitive to phthalates; NOAELs in primates are 500 mg/kg/day; using rat NOAEL of 88 mg/kg-bw/d as identified in the European Risk Assessment is therefore already a conservative approach
Toxicology Study Methodology

• **What we look for when assessing toxicology studies**
  – Performed under GLP
  – Standardized guideline testing (ex. OECD)
  – If not guideline, well-documented and generally accepted methodology
  – Appropriate statistical methods and analysis
  – Comprehensive and appropriate use of controls
  – Thorough data reporting
  – Conclusions based on accurate scientific evidence and not speculation or over-extended data interpretation.

• **Selected NOAELs should be based on relevant human end-points**
Epidemiology Study Methodology

- Urinary metabolite analysis makes epidemiology studies possible

- Some studies have tried to correlate exposure of phthalates with pathological effects in humans but DINP and DIDP have not been associated with the following:
  - Anogenital distance, sperm counts, reproductive outcomes, early onset of puberty, endometriosis, asthmas, etc.

- In reviewing these studies there are a number of issues that need to be considered
  - Were the proper maker substances measured?
    - Mono-esters is correct vs. di-esters
  - Was the investigated population representative?
    - Children with asthmas, patients from infertility clinics?
  - Were the statistical methods appropriate?
    - Multiple comparisons versus common control?
  - Was the outcome legitimate?
    - Has the effect been sufficiently investigated?
  - Was the outcome plausible?
    - Are the results consistent with other work and knowledge?
  - Do the results agree with the toxicology information
    - Was the toxicology data properly presented?

- DINP and DIDP have not been correlated to adverse human effects
Exposure to DINP/DIDP

• **Exposure based on Biomonitoring**
  – Significant biomonitoring data from both the US and Europe which show that exposures to the general population are significantly lower than those used in the EU Risk Assessment
    • US Center for Disease Control (2005)
    • Wittasek et al, 2007
    • Wittasek and Angerer, 2008
    • These papers address “uncertainties in the evaluation of exposure…to emissions from other sources”

• **Exposure estimated from mouthing studies**
  – Three new exposure papers on children and toys/childcare articles which show that exposures of infants to DINP from toys are significantly lower than those used by CSTEE and the EU RA
    • CPSC (2001)
    • Babich et al 2004
    • Sugita et al 2003
  – Actual exposure to DINP and DIDP exposure is significantly lower than previously estimated
Cumulative Risk Approach

- Cumulative Risk is an emerging area of toxicology
  - Examine key effects and identifying the NOAEL/LOAEL from the appropriate study
    - Repeated Dose Effects, Developmental Effects (Anti-androgenicity, Fetal Toxicity, Malformations) and Fertility
  - Calculate a Margin of Safety (MOS) based on exposure data and a reference dose for each individual phthalate
  - Calculate a MOS for the aggregate exposure factoring potency of each phthalate for the key effect

- Approach should emphasize and demonstrate which phthalates drive the risk

- Margin of Safety calculated for each phthalate in the mixture
Cumulative Risk Approach

Cumulative Risk Assessment on DBP, BBP, DEHP, DINP, DIDP

Margin of Safety

- Exposure data based on 3rd report of CDC NHANES data

Source: ExxonMobil Biomedical Sciences, 2009; Normalized to MEOHP metabolite
Risk Characterization Conclusions

- EMBSI Risk characterisation shows safe use of DINP and DIDP with margins of safety well above 1000 (safety factor of minimum 100 required)

- Biomonitoring on DINP and DIDP show exposures well below the conservative NOAEL

- These new data confirm the previous CHAP conclusion that DINP can be safely used in toys and childcare articles

- These new data are sufficient to remove conflicts and uncertainties and therefore the precautionary principle no longer needs to be applied
Next Steps / Conclusion

- Clarify CHAP scope, timing, role for ExxonMobil
  - Scientific review of DINP and DIDP with the CHAP scientists
  - Cumulative risk assessment methodology addresses potency

- Establish schedule and topics for future meetings

- ExxonMobil remains committed to CPSIA and the CHAP process to establish swift, fair, and unbiased scientific basis for regulation
Back-up
Commercial Plasticizers

2005 Global Plasticizer Demands

- DEHP
- DPHP
- DINP/DIDP
- Other Phthalates
- Linear
- Non-Phthalates

Total Market = 6.0M metric tons

Source: SRI 2007 Plasticizer CEH Report

2010 Global Plasticizer Demands

- DEHP
- DPHP
- DINP/DIDP
- Other Phthalates
- Linear
- Non-Phthalates

Total Market = 6.8M metric tons

Source: SRI 2007 Plasticizer CEH Report

Global Market Trends

- EU REACH legislation expected to impact DEHP, BBP, and DBP
- New DPHP capacity announced in Europe and China by 2012
- DINCH/DOTP growth due to no listing
## Commercial Plasticizers Producers

<table>
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<tr>
<th>TYPE</th>
<th>ABBREVIATION</th>
<th>NAME</th>
<th>PRODUCERS</th>
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<td>DBP</td>
<td>Dibutyl phthalate</td>
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<td>DIBP</td>
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<td>BBP</td>
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Source: ExxonMobil Marketing Estimates, SRI 2007 Plasticizers CEH report
## Commercial Plasticizers Producers

<table>
<thead>
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<th>TYPE</th>
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Source: ExxonMobil Marketing Estimates, SRI 2007 Plasticizers CEH report
CPSC Statements

• 2001 Kenneth Bogan, chair of CHAP on DINP convened by the CPSC:
  "The risk to reproductive and developmental processes in humans due to DINP exposure is extremely low or non-existent"

• 2002 Dr. Marilyn L. Wind, CPSC Deputy Associate Executive Director
  "Based upon the scientific data ... the staff believes that there is no demonstrated health risk posed by PVC toys or other products intended for children 5 years of age and under"

• 2003 Dr. Marilyn L. Wind
  "The Commission agreed with the staff and voted to deny the petition requesting a ban of PVC in toys and other products."

• 2003 Mary Sheila Gall, CPSC Commissioner:
  "Consumers may have a high level of assurance that soft plastic products pose no risk to children"

• 2004 CPSC Staff:
  "If DINP is to be replaced in children’s products ... the potential risks of the substitutes must be considered. Weaker or more brittle plastics might break and result in a choking hazard. Other plasticizers might not be studied as well as DINP."

• 2007 Jacqueline Elder, CPSC Assistant Executive Director, regarding the safety of DINP and vinyl toys:
  "CPSC staff has kept abreast of the new research and has not seen anything that would cause a change in the staff's position on this issue."

• 2009 Dr Marilyn L. Wind
  "We [CPSC] could not ban DINP because there was not a risk of injury to children."