

The Eco-Efficiency Label Requirements



Requirements

1. Accomplished Eco-Efficiency Analysis according to the methodology certified by TÜV Rhineland/ Berlin-Brandenburg, Germany.
2. Verification of the investigated product to be more eco-efficient for the defined customer benefit than other alternatives as result of the analysis.
3. Presentation of a third party evaluation (so-called Critical Review according ISO 14040 et seq.).
4. Publication of the results via internet on website www.oeea.de, which is referred to on the label.
5. Payment of the license fee for the duration of three years.



Eco-Efficiency

Eco-Efficiency Label Certificate



CERTIFICATE

Eco-Efficiency Analysis "Non-Phthalate Plasticizers for PVC Applications"



The evaluation of environmental and economic effects of non-phthalate plasticizers for PVC toys and soft articles using an eco-efficiency analysis according to the validated method is certified.

BASF SE

is granted the right to use the Eco-Efficiency Label in the presented form for

Hexamol® DINCH

for a duration of three years.

The main results are published under www.ocea.de.

Ludwigshafen, 01.06.2008

Ronald Drews
Dr. R. Drews
Director Product Safety

Dr. P. Saling
Dr. P. Saling
Group Leader Eco-Efficiency

□ - BASF



Eco-Efficiency

Dr. A. Grosse-Sommer

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Eco-Efficiency Label Hexamoll® DINCH



The Eco-Efficiency label can be awarded to the listed PVC products using Hexamoll® DINCH as a plasticizer. It was shown that they are more eco-efficient than the alternative systems.

The graphic is a large, rounded rectangular badge. The top half is white with a black border. Inside, the text 'ÖKOEFFIZIENZ - ANALYSE' is written in black, uppercase letters along the top curve. In the center is a black square containing a white stylized 'E' with an arrow pointing up and to the right. Along the right curve, the text 'ANALYSIS' is written in black, uppercase letters. The bottom half of the badge is black with white text. It reads: '1st place' in a large font, followed by 'in an environmental and economic evaluation according to the BASF method for use as a PVC plasticizer for toys and soft PVC articles' in a smaller font, and 'www.oeea.de' at the bottom.



Eco-Efficiency

Expert Opinion: Critical Review TÜV Rheinland



Critical Reviewers: Dr. Christoph Lutermann, TÜV Rheinland BioTech GmbH
Bernhard Priesemuth, TÜV Rheinland Cert GmbH

After critical review of the report titled 'Non-Phthalate Platicizers for PVC Applications: Hexamoll® DINCH' and the supporting inventory and impact assessment calculations, the main conclusions of the critical reviewers are as follows:

- the input data is detailed and up-to-date and is treated according to the methodology following DIN ISO 14040 et seq.
- the system boundaries are appropriate and the alternatives are clearly and sufficiently modelled.
- the analysis shows that Hexamoll® DINCH is the most eco-efficient plasticizer for the described applications, having the lowest total environmental impact.

Excerpt:

„Die Prozessketten und die dafür erforderlichen Input-Daten wurden detailliert erfasst und gemäß dem Bewertungsverfahren aufbereitet... Die verwendeten Datenquellen sind ausreichend und aktuell... Entsprechend der vorgesehenen Anwendung und der getroffenen Annahmen wurden die Systemgrenzen richtig gesetzt, das System ausreichend und deutlich beschrieben und die erhaltenen Daten entsprechend der Methode aggregiert. Durchgeführte Sensitivitätsbetrachtungen stützen das vorliegende Ergebnis...

Im Ergebnis zeigt sich, dass Hexamoll® DINCH der ökoeffizienteste Weichmacher für die vorgesehenen Anwendungen, mit den niedrigsten gesamten Umweltauswirkungen, ist.“



Eco-Efficiency



validated
eco-efficiency
method

 **BASF**
The Chemical Company

Eco-Efficiency Analysis



Non-Phthalate Plasticizers for PVC Applications: Hexamoll® DINCH

Ludwigshafen, April 1, 2008



Objectives and Use of the Eco-Efficiency Study



- This eco-efficiency study compared various non-phthalate plasticizers for different PVC applications. The alternative in focus was Hexamoll® DINCH.
- The study used the methodology of the eco-efficiency analysis, developed by BASF as a life-cycle tool to show and assess different parts of the life-cycle of the chemical reactions and related materials which are required to achieve the desired product. It is one method between others that are able to assess environmental data over the whole life cycle.
- The ecological calculations of the single results in each category are following the ISO-rules 14040 et seq. in the main points. The quantitative weighting step to get the ecological fingerprint and the portfolio are not covered with the ISO-rules. The eco-efficiency analysis has more features than are mentioned in the ISO rules.
- The methodology has been approved by the German TÜV. This methodology was used by the "Öko-Institut - Institute for applied ecology" in Freiburg Germany in different APME-studies. Öko-Institut uses a quite similar methodology with a different weighting system ("Ecograde"). TNO in the Netherlands using the BASF standard method with a different weighting system. The Wuppertal Institute accepts the method: "Basically, the large number of indicators used in the eco-efficiency analysis of BASF make relatively reliable statements possible ...". The method was initially developed by BASF and Roland Berger Consulting, Munich.



**Validated
Eco-Efficiency
Analysis method**



Eco-Efficiency

User benefit

user benefit

BASF alternative

other alternatives

Production and use of 1000 PVC toy balls for the German market

- Hexamoll® DINCH

- acetyltributyl citrate (ASE)
- diethylhexylterephthalate (DEHTP)
- acetylated castor oil derivative
- alkylsulphonic phenyl ester (ATBC)



Eco-Efficiency

Abbreviations



Hexamoll® DINCH or DINCH – diisononylcyclohexane dicarboxylate (BASF product)

DEHTP – diethylhexylterephthalate

ASE – alkylsulphonic phenyl ester

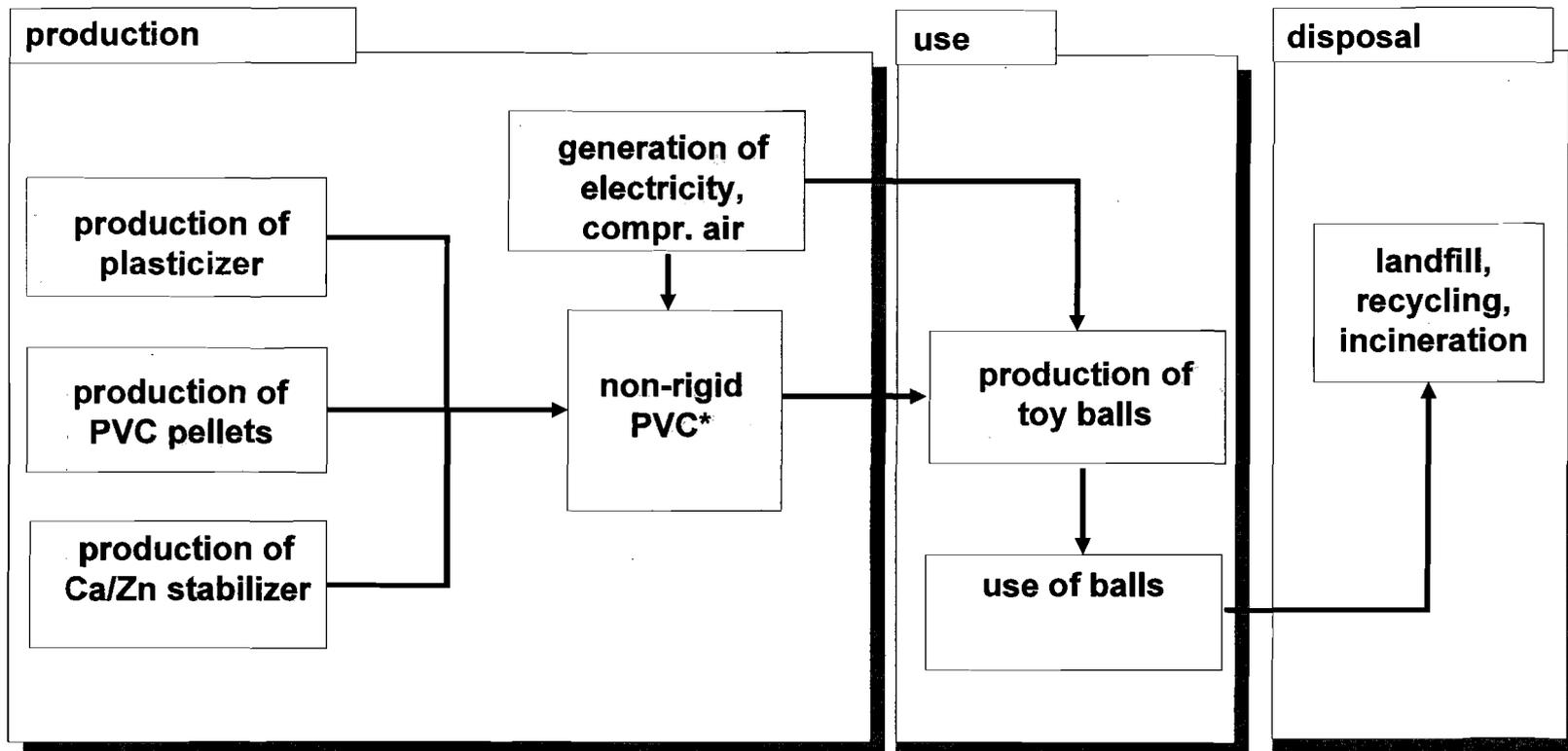
ATBC – acetyltributyl citrate

ESO – epoxidized soybean oil



Eco-Efficiency

General System Boundaries



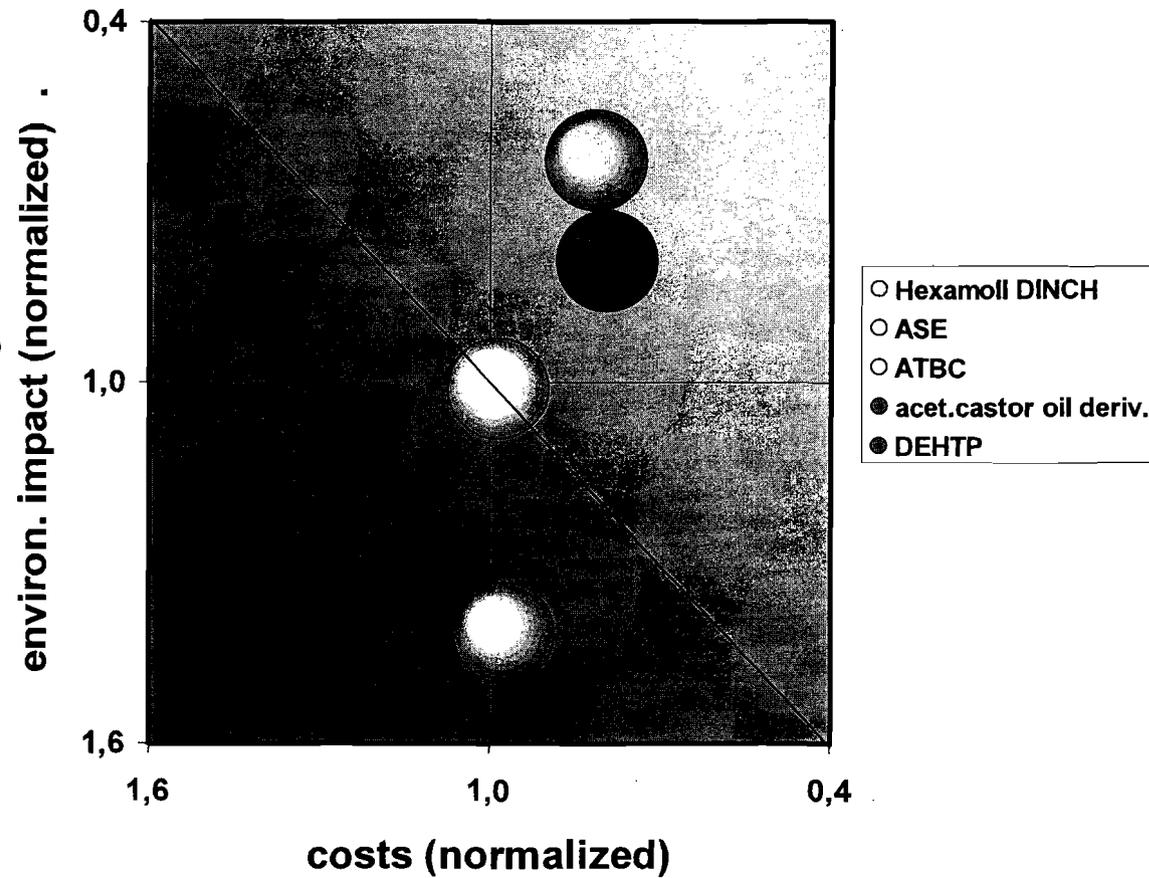
*only differences in PVC weight were considered!



Eco-Efficiency Portfolio: Base Case

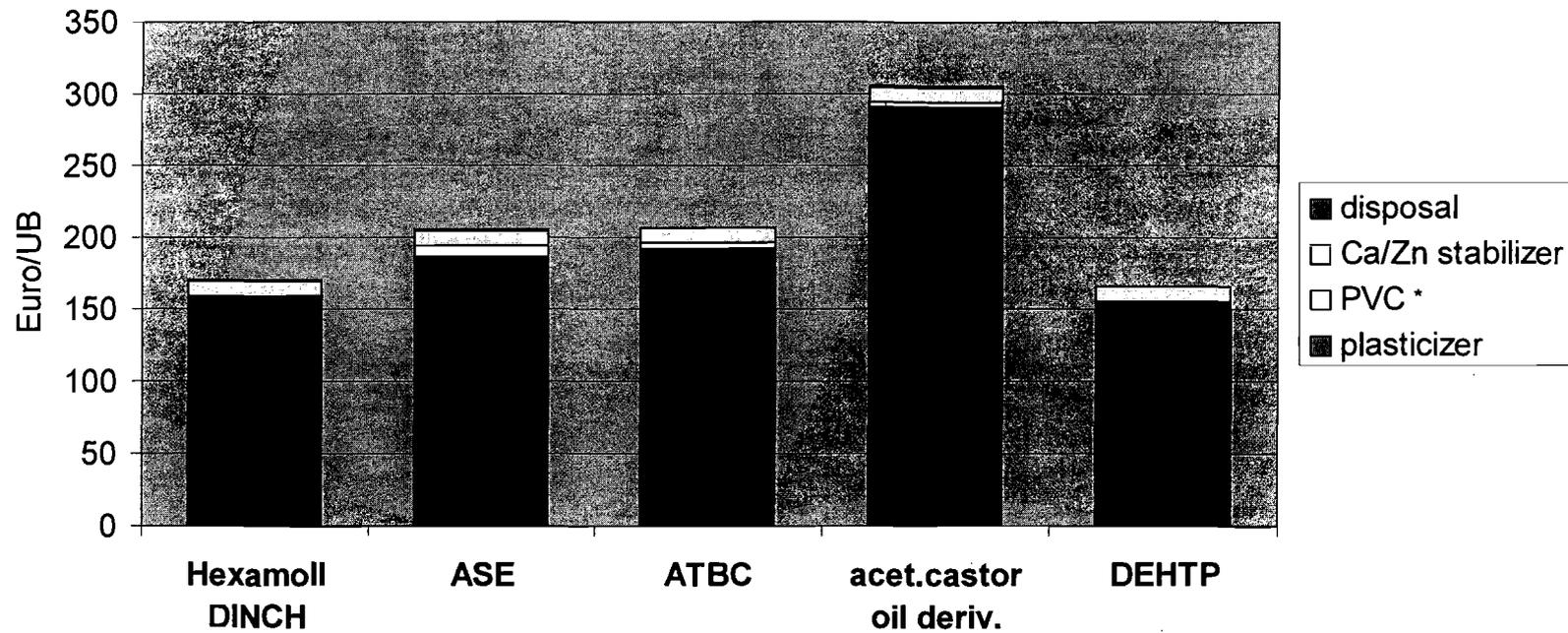
user benefit:

Production and
use of 1000 toy
PVC balls



Eco-Efficiency

Costs: Base Case



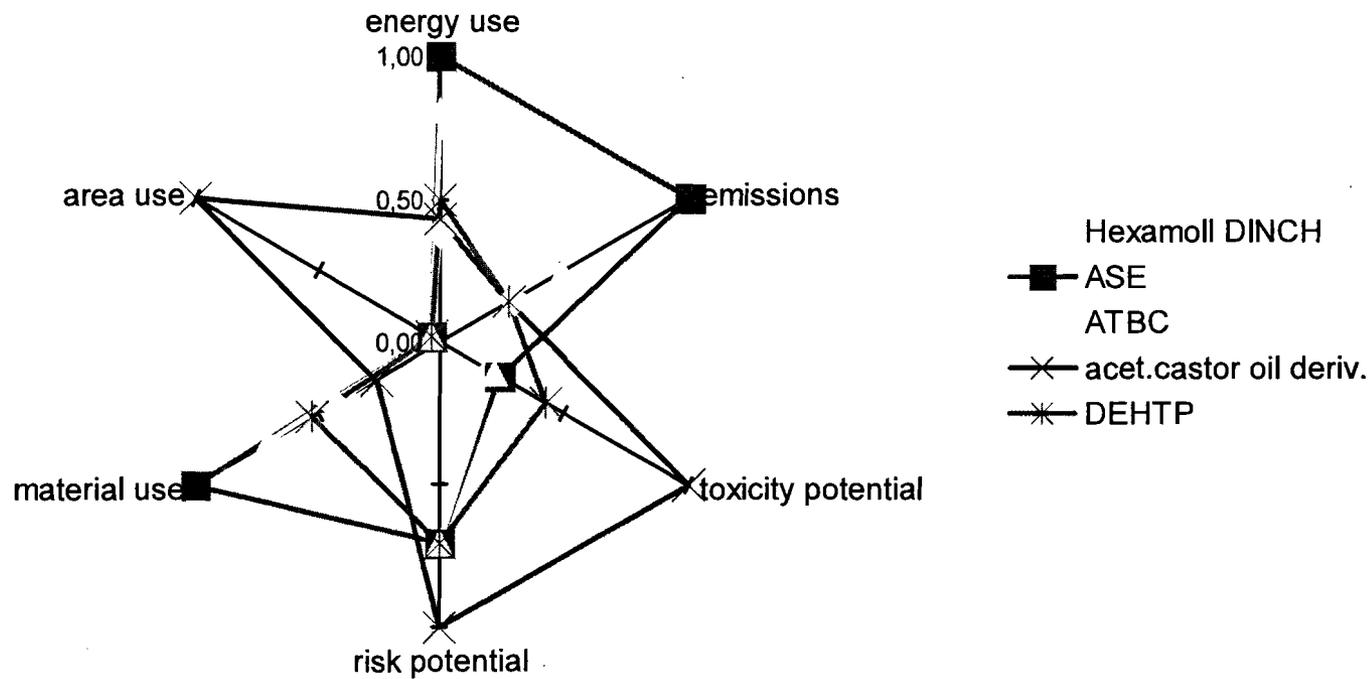
UB- user/user benefit

*differential approach



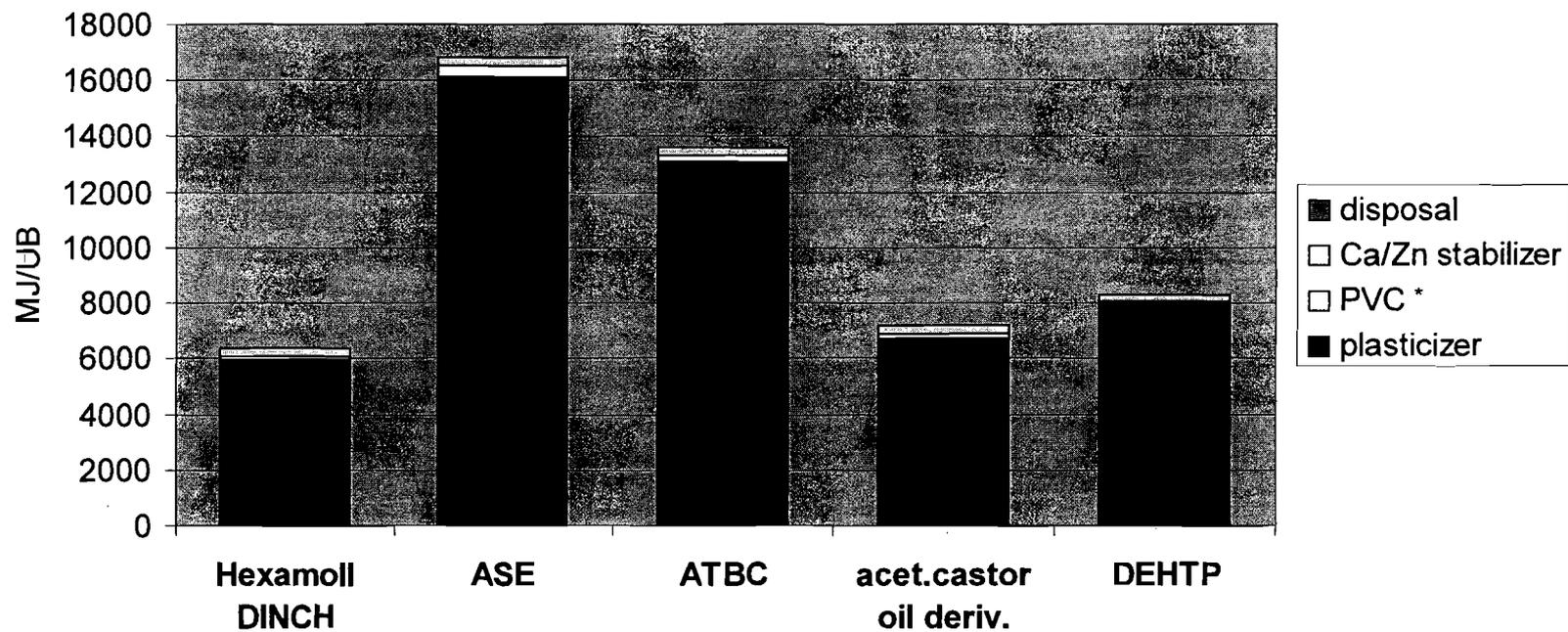
Eco-Efficiency

Base Case: Environmental Fingerprint



1: maximum environmental impact
0: minimum environmental impact

Base Case: Energy Consumption



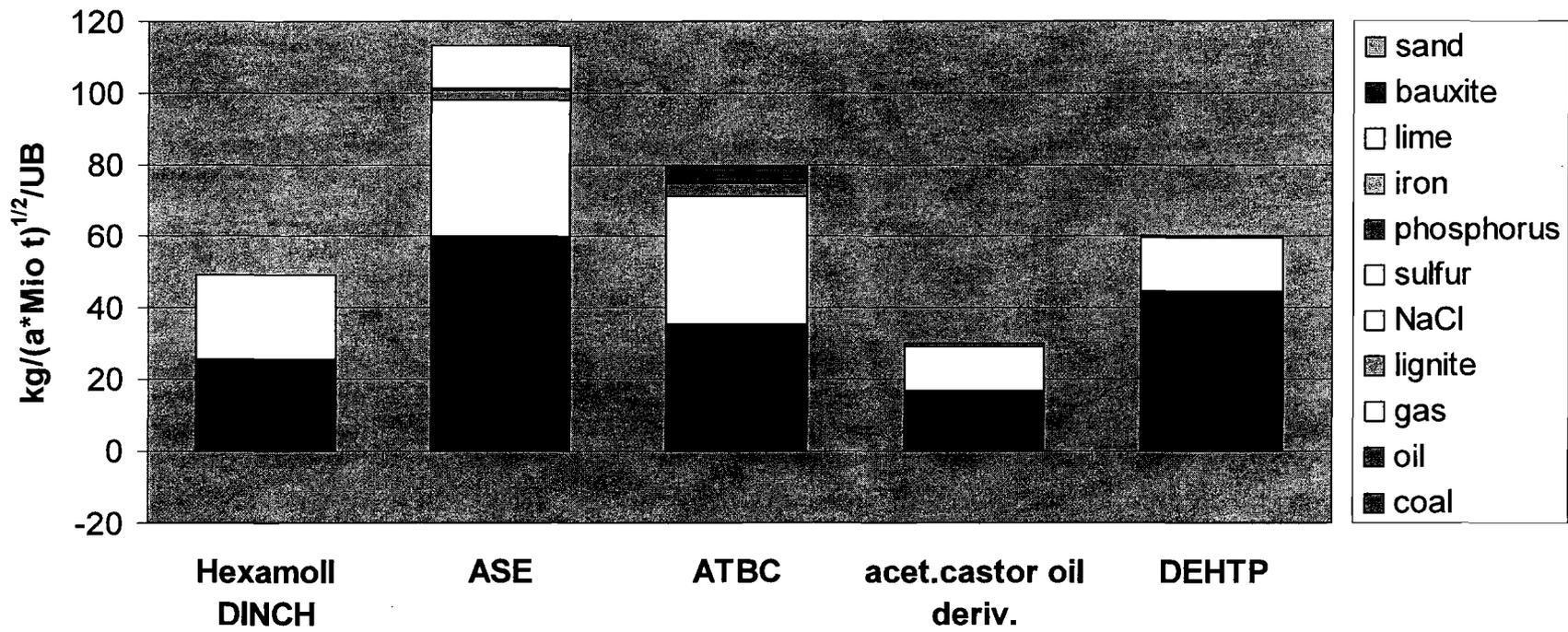
UB- user benefit

*differential approach



Eco-Efficiency

Resource Consumption: Base Case

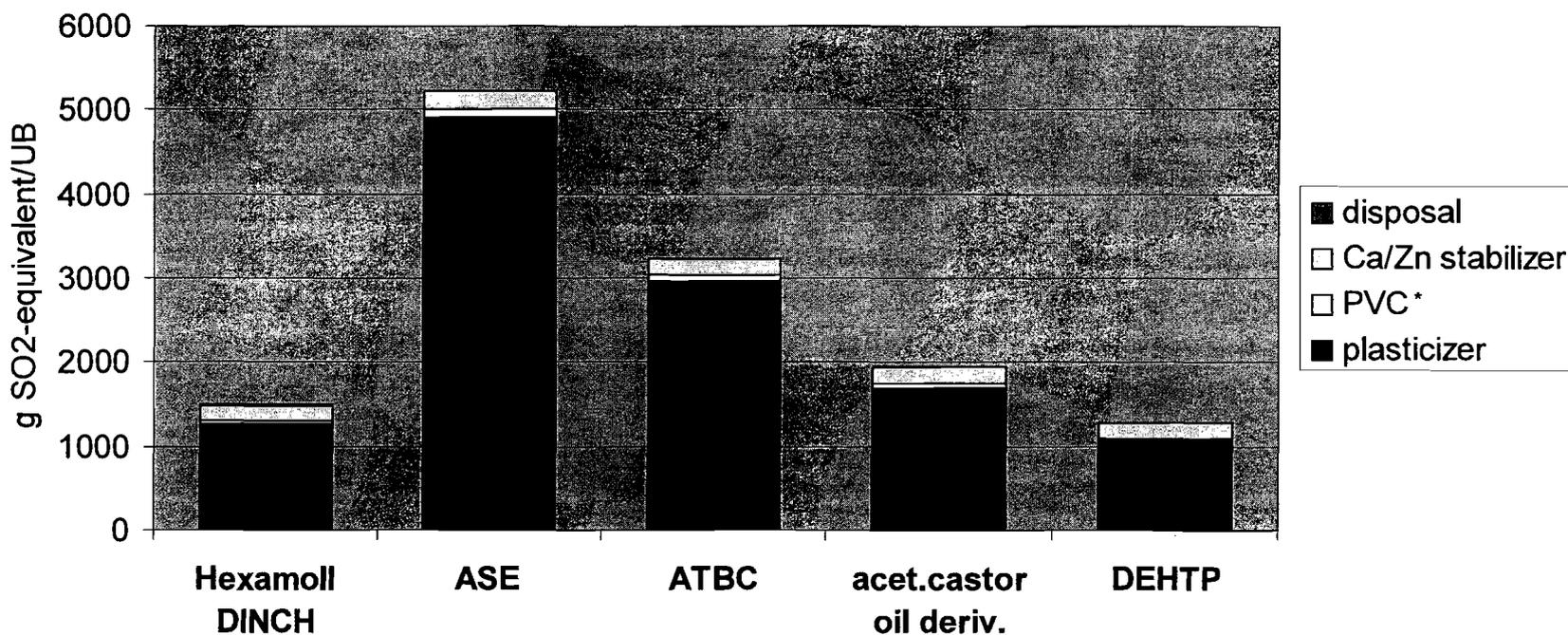


UB- user benefit



Eco-Efficiency

Air Emissions: Base Case Acidification Potential (AP)



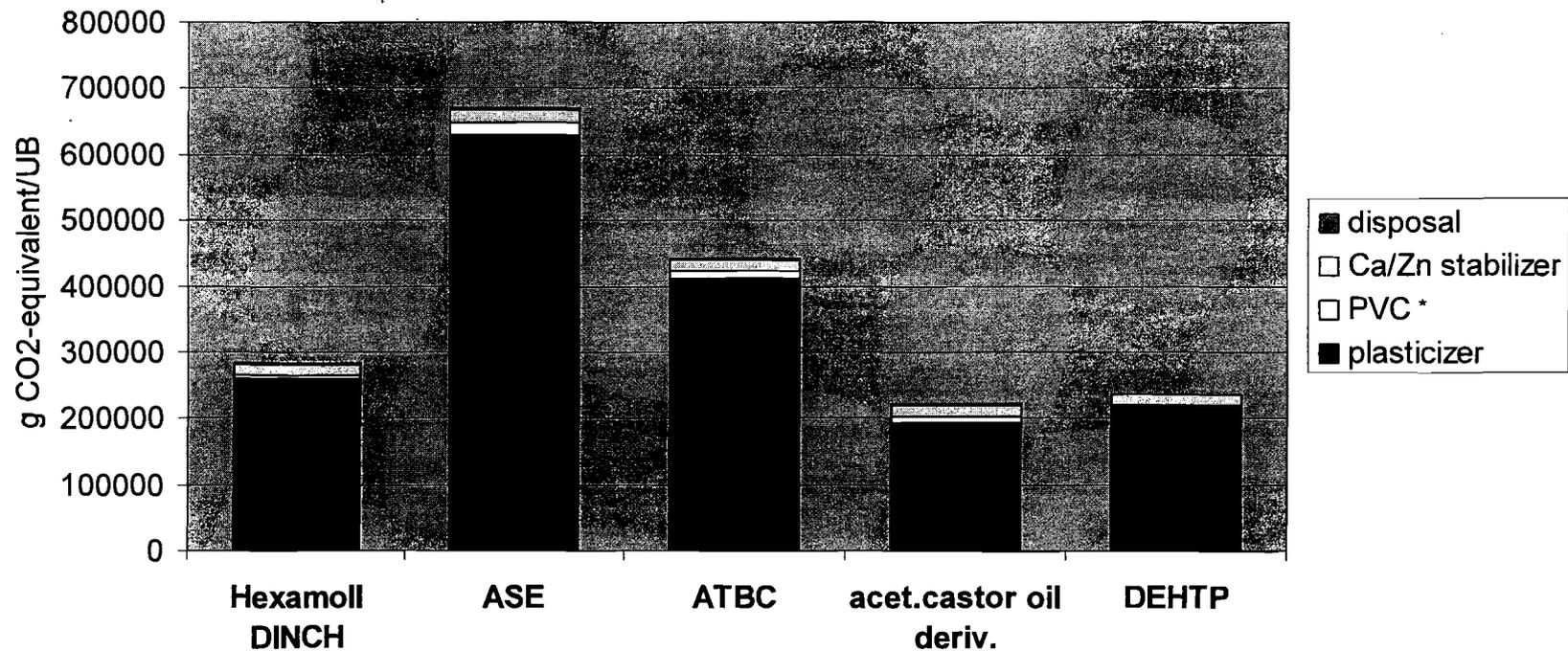
UB- user benefit

*differential approach



Eco-Efficiency

Air Emissions: Base Case Global Warming Potential (GWP)



UB- user benefit

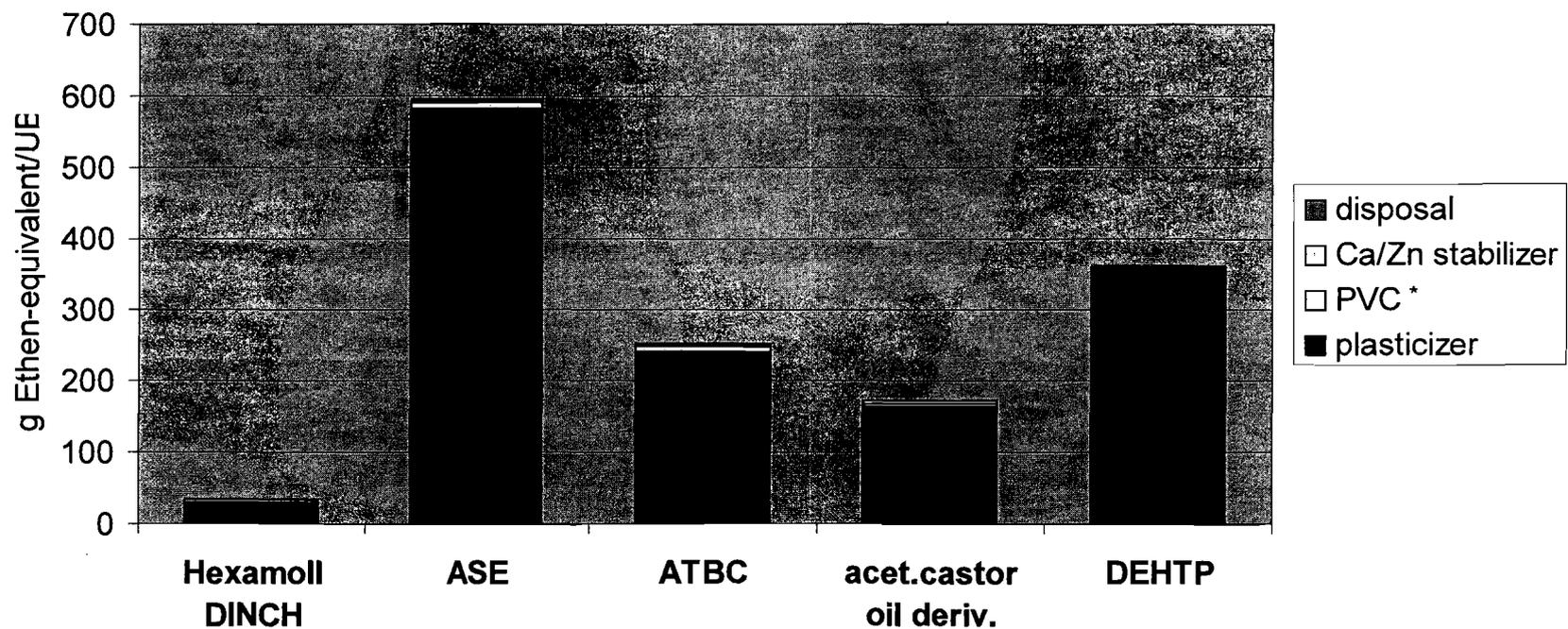
*differential approach



Eco-Efficiency

Air Emissions: Base Case

Photochemical Ozone Creating Potential (POCP) **BASF** The Chemical Company



UB- user benefit

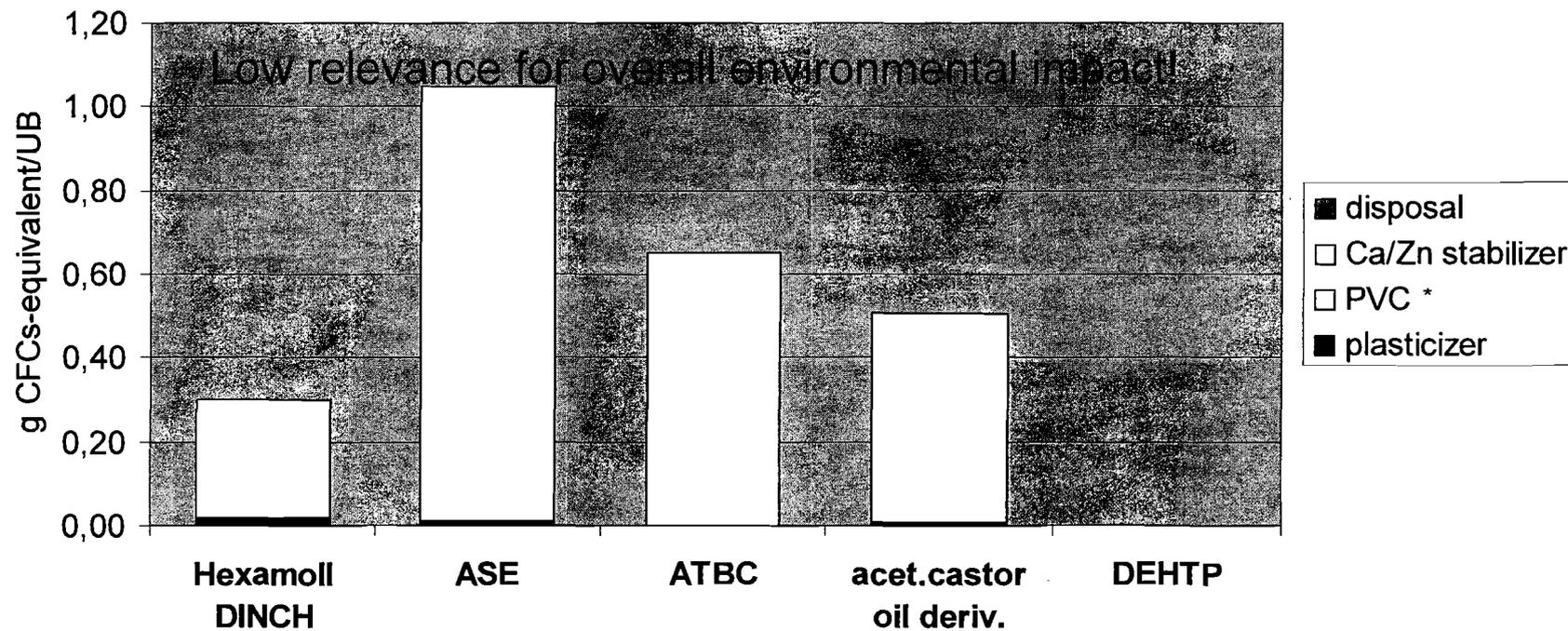
*differential approach



Eco-Efficiency

Air Emissions: Base Case

Ozone Depletion Potential (ODP)



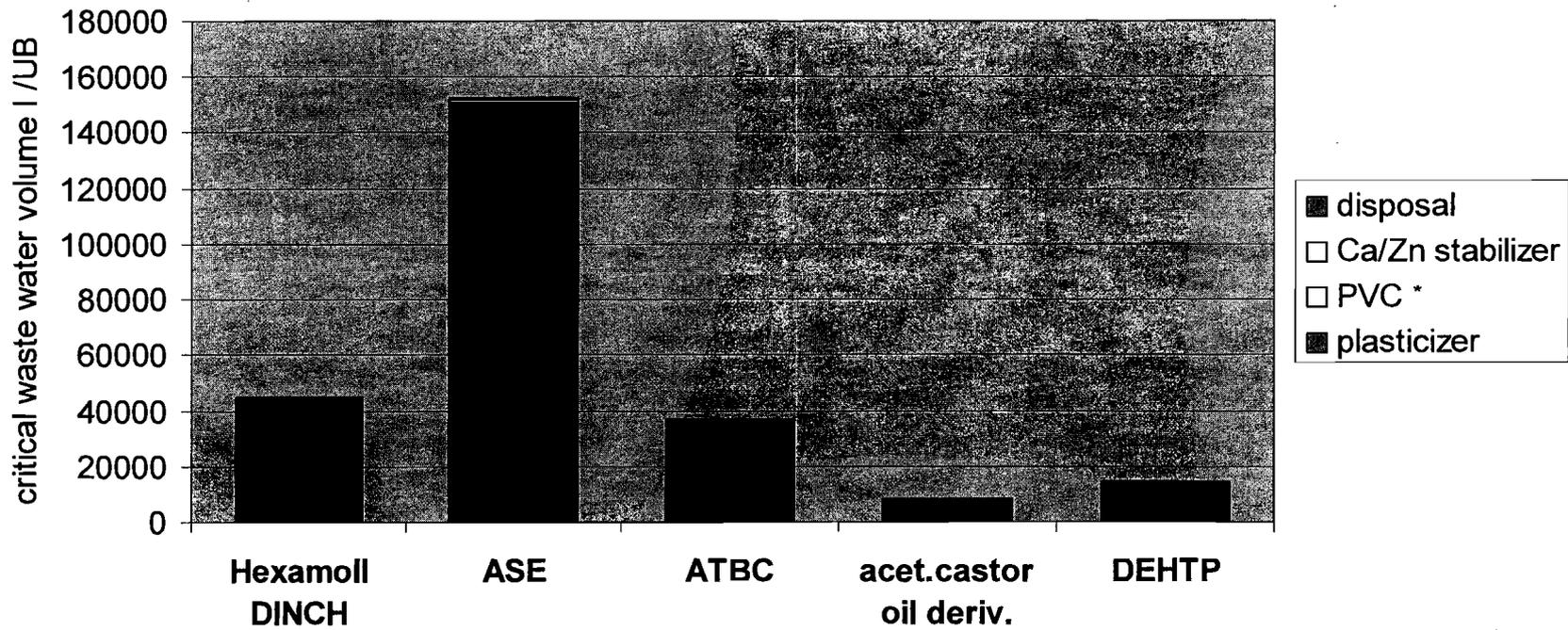
UB- user benefit

*differential approach



Eco-Efficiency

Water Emissions: Base Case



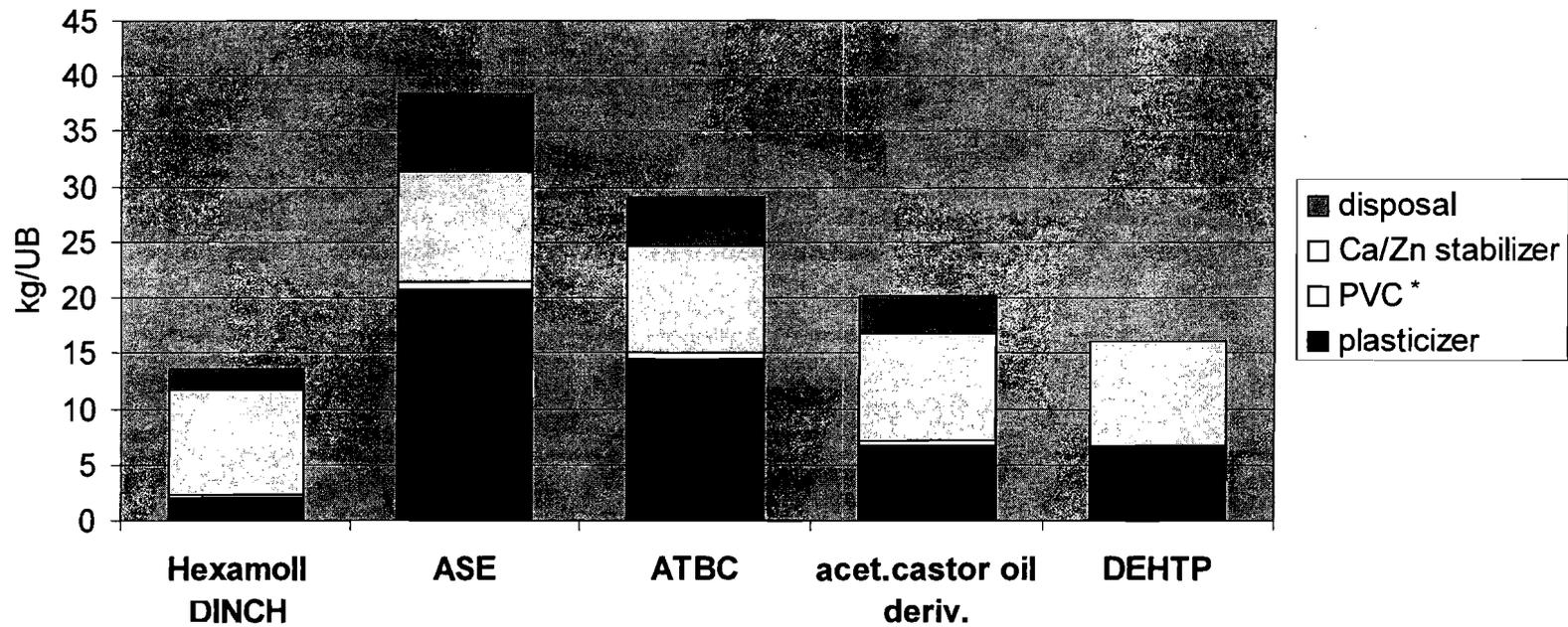
UB- user benefit

*differential approach



Eco-Efficiency

Solid Wastes: Base Case

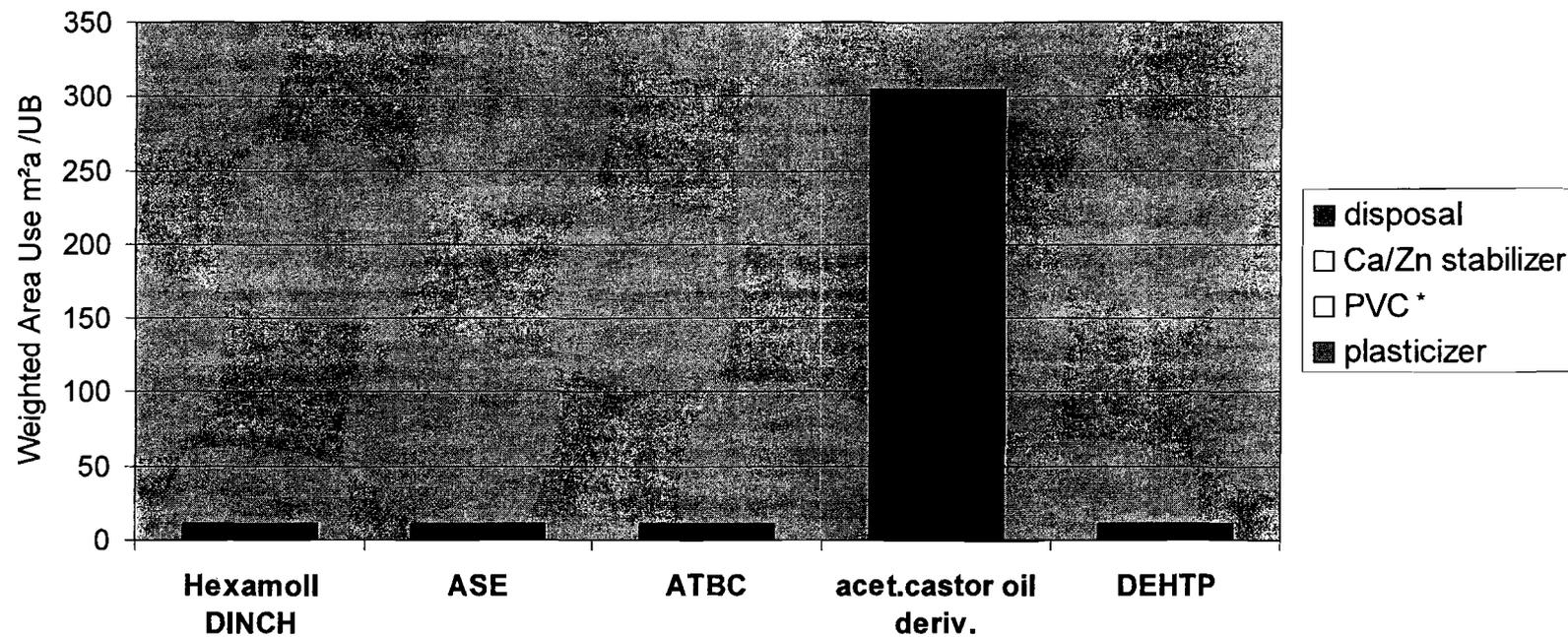


UB- user benefit
*differential approach



Eco-Efficiency

Area Use: Base Case



UB- user benefit

*differential approach

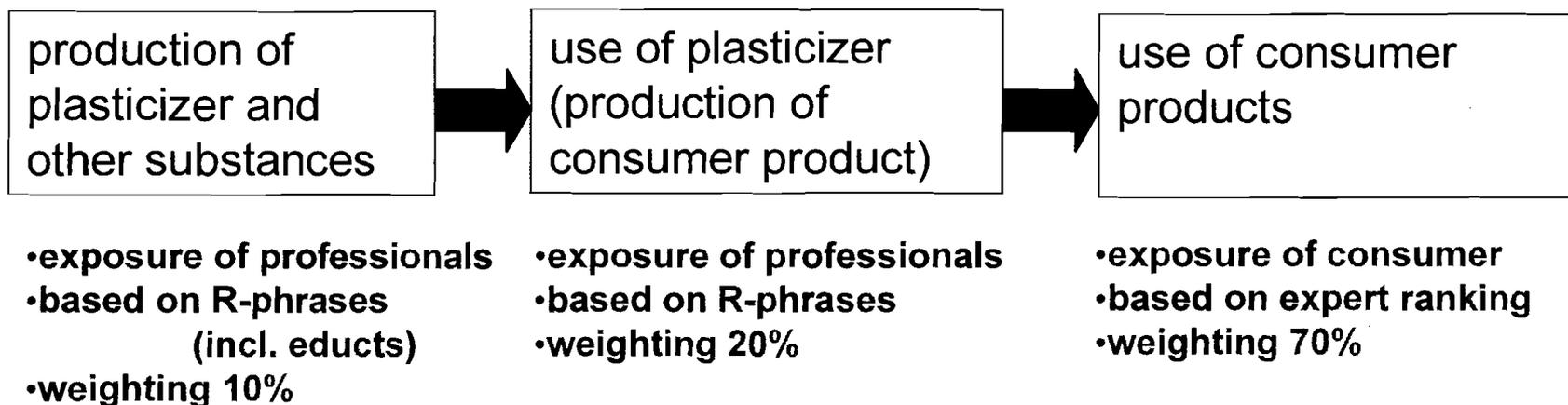


Eco-Efficiency

Toxicity Potential: Determination (1)

The toxicity potential was determined by considering all substances involved in the life cycle of the balls. Exposure of the public to a toxic substance was weighted more heavily than exposure of professionals (see scheme below) since the latter have better training and equipment to deal with critical substances.

For all production steps, the R-phrases (from EU safety data sheets) were used as a measure of toxicity potential. For the consumer use of the ball, an expert ranking of various toxicological and ecotoxicological values (see next page) was used to compare the various plasticizers.



Label

Eco-Efficiency Analysis

Hexamoll® DINCH



May 10th, 2008



Eco-Efficiency

Summary (1)

- This eco-efficiency analysis compares various non-phthalate plasticizers for use in PVC applications in the German market. Plasticizers that were compared included Hexamoll® DINCH (diisononylcyclohexane dicarboxylate), acetyltributyl citrate (ATBC), acetylated castor oil derivative, alkylsulphonic phenyl ester (ASE), and diethylhexylterephthalate (DEHTP).
- Hexamoll® DINCH is the most eco-efficient plasticizer, with the lowest overall environmental impact. DEHTP has a slight cost advantage, but is less eco-efficient primarily due to toxicity considerations. ATBC has an intermediate eco-efficiency. ASE results in comparable costs; however, it has a significantly lower eco-efficiency due to high material consumption, energy use and emissions during plasticizer production. Acetylated castor oil derivative has the lowest eco-efficiency, with low environmental performance at a much higher cost.



Summary (2)

- The results hold not only for balls (base case), but also for garden hoses and medicinal tubing. While these have somewhat different compositions, the eco-efficiency relationships remain essentially unchanged compared to the base case.
- The relative position of acetylated castor oil derivative would not be improved even if the R-phrase (R43) were not applicable.

Communication

- Hexamoll® DINCH is the most eco-efficient non-phthalate plasticizer for PVC applications such as balls, garden hose and medicinal tubing.

- Hexamoll® DINCH and DEHTP are similarly priced, but the former offers significant toxicological advantages over the complete life cycle. Considering only the toxicological risk to the consumer, the advantage of Hexamoll® DINCH is even greater.



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Hexamol® DINCH

for a duration of three years.

The main results are published under www.oeca.de.

Ludwigshafen, 01.06.2008

Ronald Drews

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Director Product Safety

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Group Leader Eco-Efficiency

BASF



Eco-Efficiency

Dr. A. Grosse-Sommer

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Eco-Efficiency Label Hexamoll® DINCH



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Eco-Efficiency

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Im Ergebnis zeigt sich, dass Hexamoll® DINCH der ökoeffizienteste Weichmacher für die vorgesehenen Anwendungen, mit den niedrigsten gesamten Umweltauswirkungen, ist.“



Eco-Efficiency



validated
eco-efficiency
method

BASF

The Chemical Company

Eco-Efficiency Analysis



Non-Phthalate Plasticizers for PVC Applications: Hexamoll® DINCH

Ludwigshafen, April 1, 2008



Objectives and Use of the Eco-Efficiency Study



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**Validated
Eco-Efficiency
Analysis method**



Eco-Efficiency

User benefit

user benefit

BASF alternative

other alternatives

Production and use of 1000 PVC toy balls for the German market

- Hexamoll® DINCH

- acetyltributyl citrate (ASE)
- diethylhexylterephthalate (DEHTP)
- acetylated castor oil derivative
- alkylsulphonic phenyl ester (ATBC)



Eco-Efficiency

Abbreviations



Hexamoll® DINCH or DINCH – diisononylcyclohexane dicarboxylate (BASF product)

DEHTP – diethylhexylterephthalate

ASE – alkylsulphonic phenyl ester

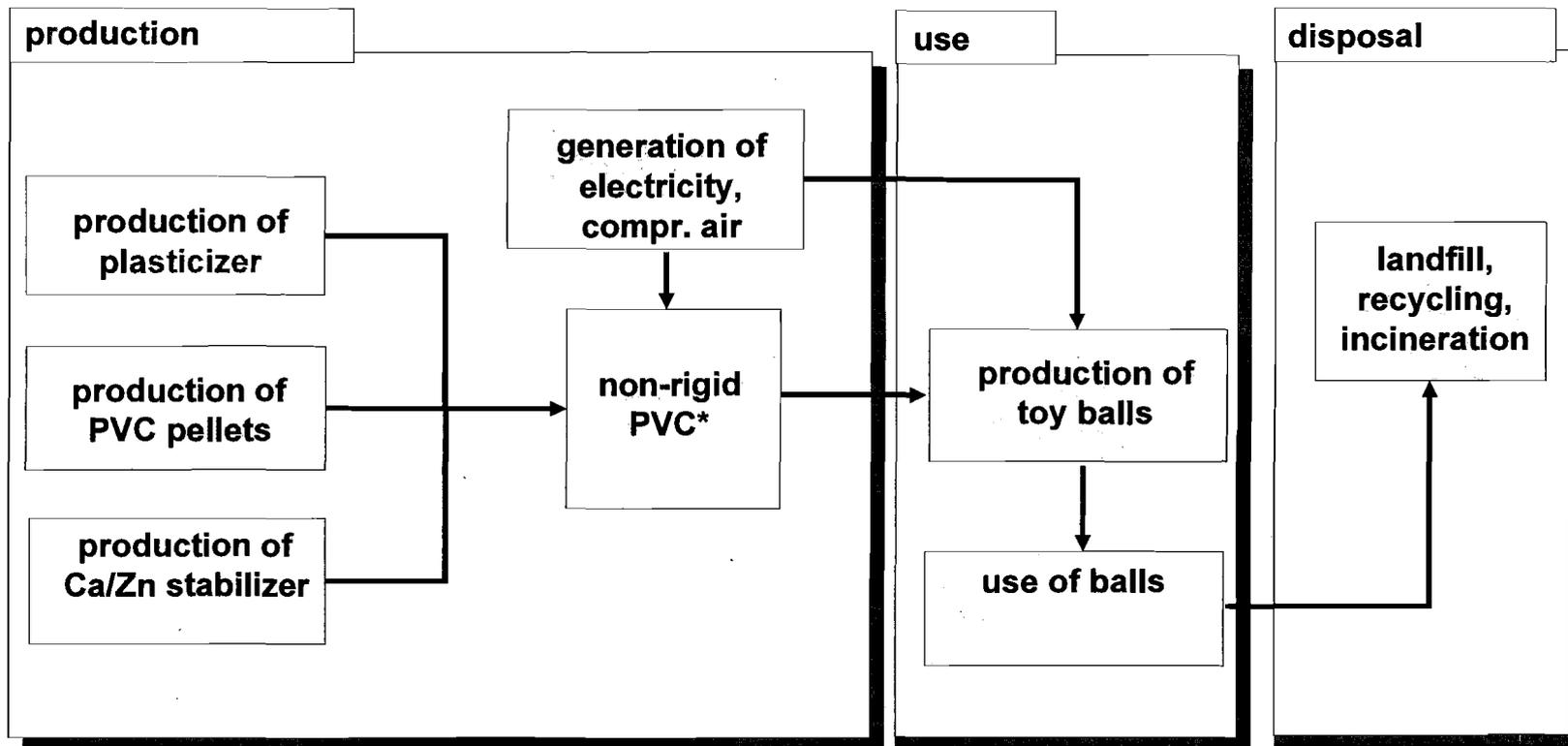
ATBC – acetyltributyl citrate

ESO – epoxidized soybean oil



Eco-Efficiency

General System Boundaries



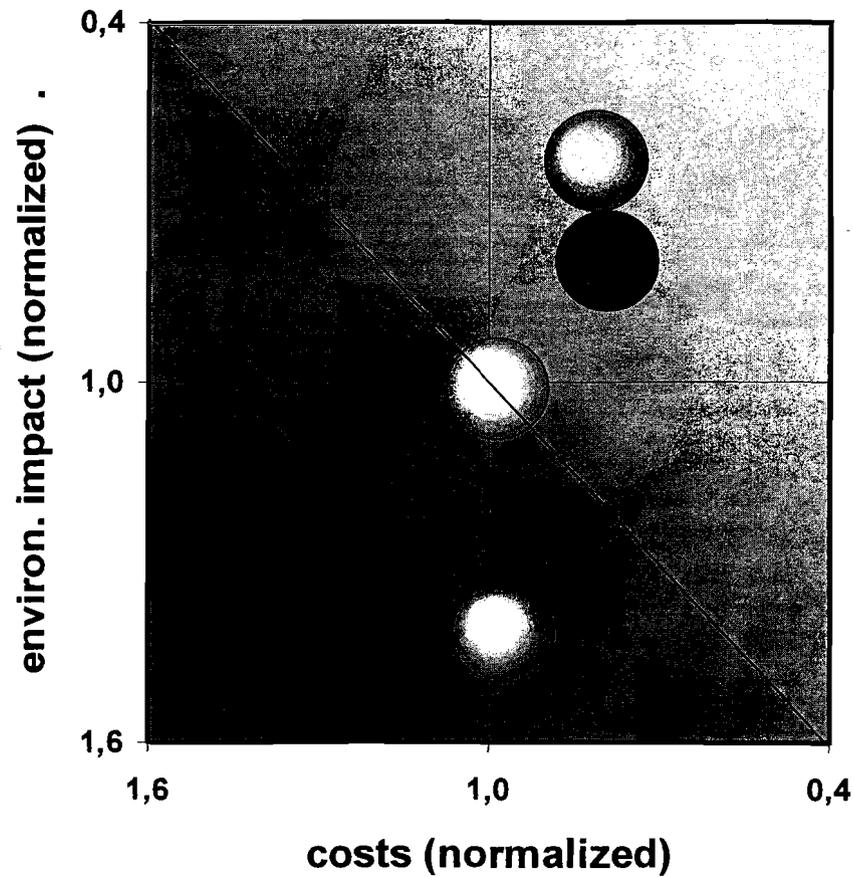
*only differences in PVC weight were considered!



Eco-Efficiency Portfolio: Base Case

user benefit:

Production and
use of 1000 toy
PVC balls

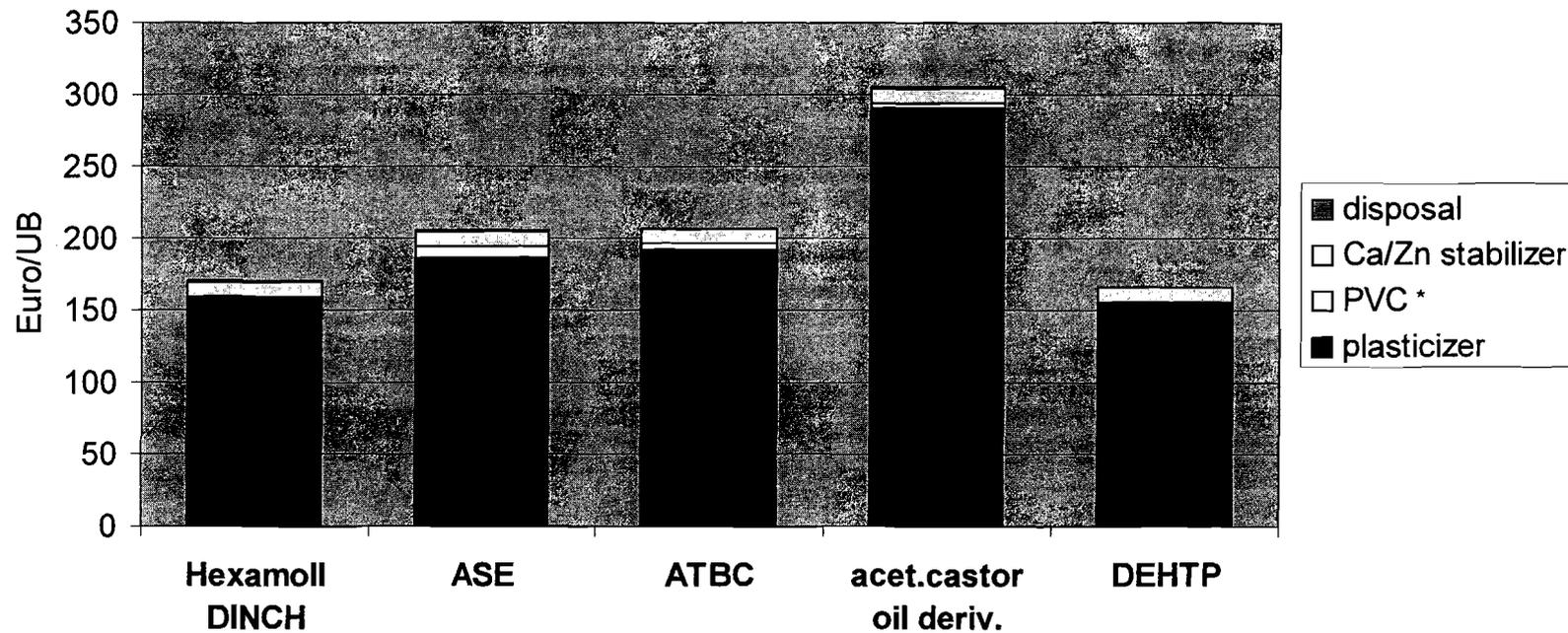


- Hexamoll DINCH
- ASE
- ATBC
- acet.castor oil deriv.
- DEHTP



Eco-Efficiency

Costs: Base Case



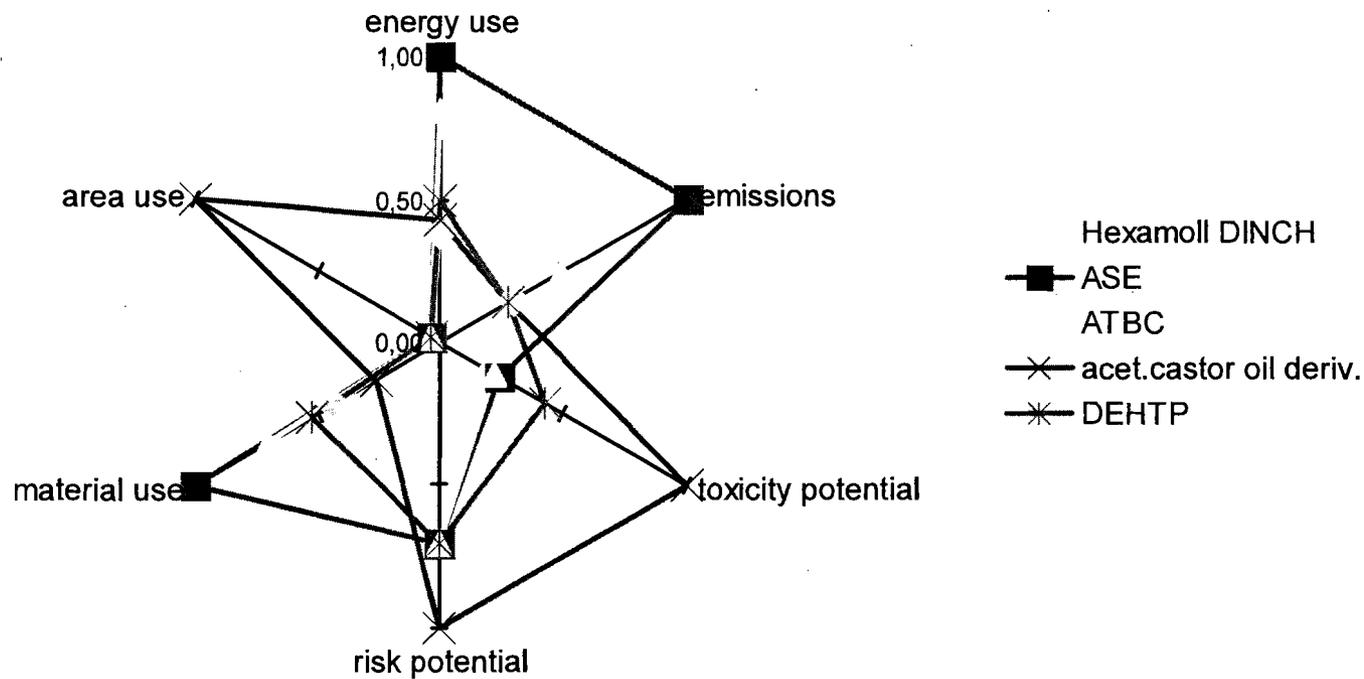
UB- user/user benefit

*differential approach



Eco-Efficiency

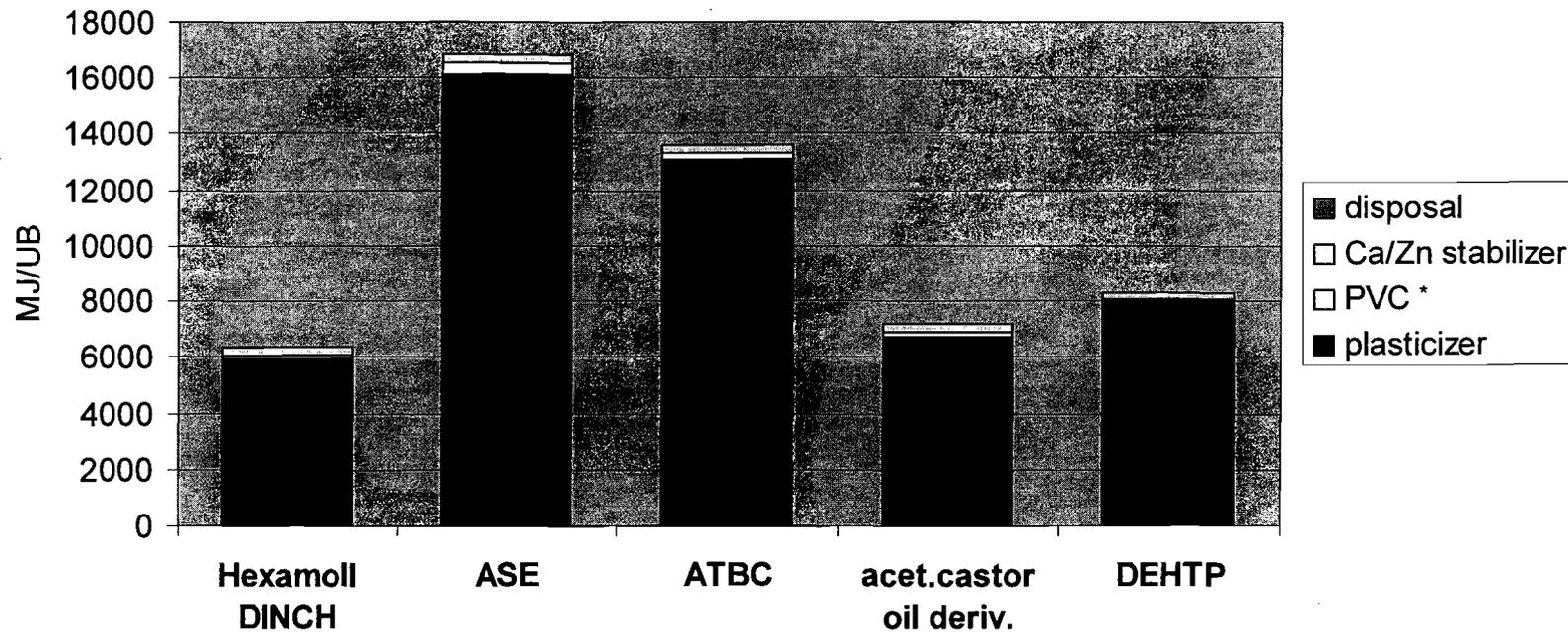
Base Case: Environmental Fingerprint



1: maximum environmental impact
0: minimum environmental impact



Base Case: Energy Consumption



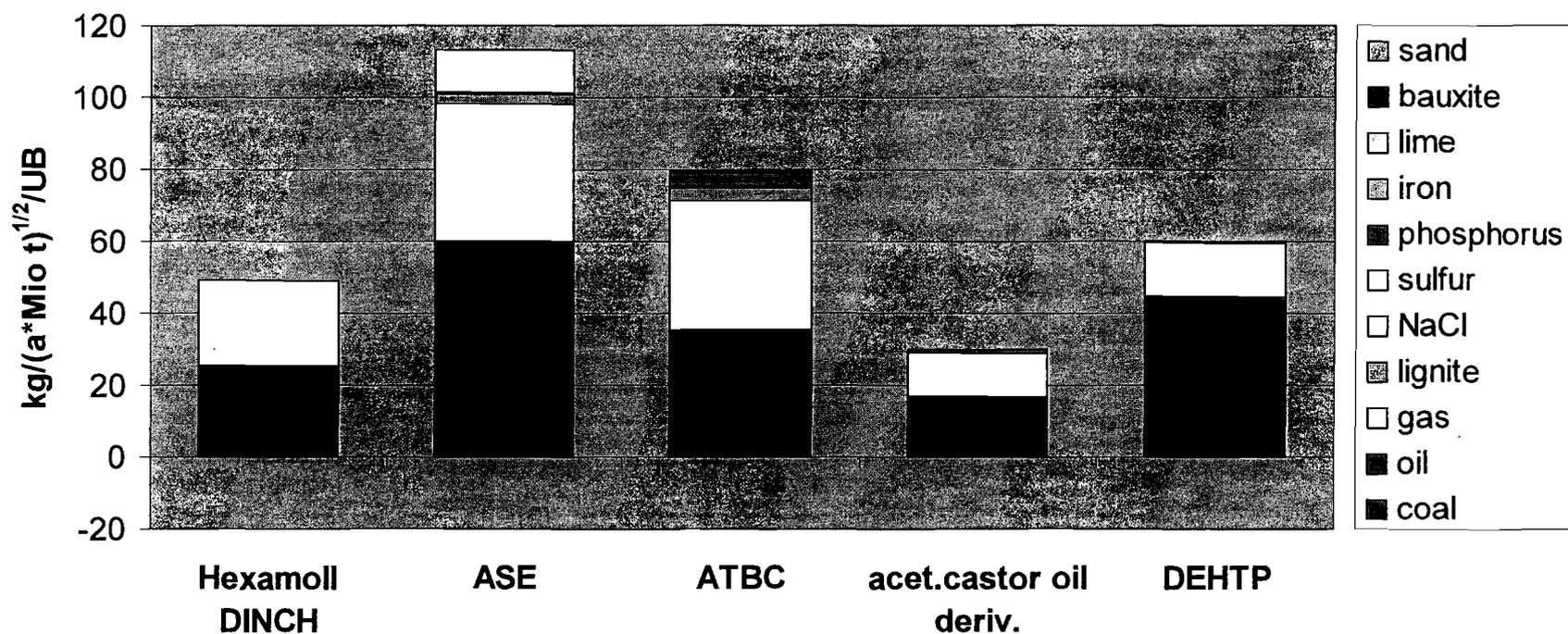
UB- user benefit

*differential approach



Eco-Efficiency

Resource Consumption: Base Case

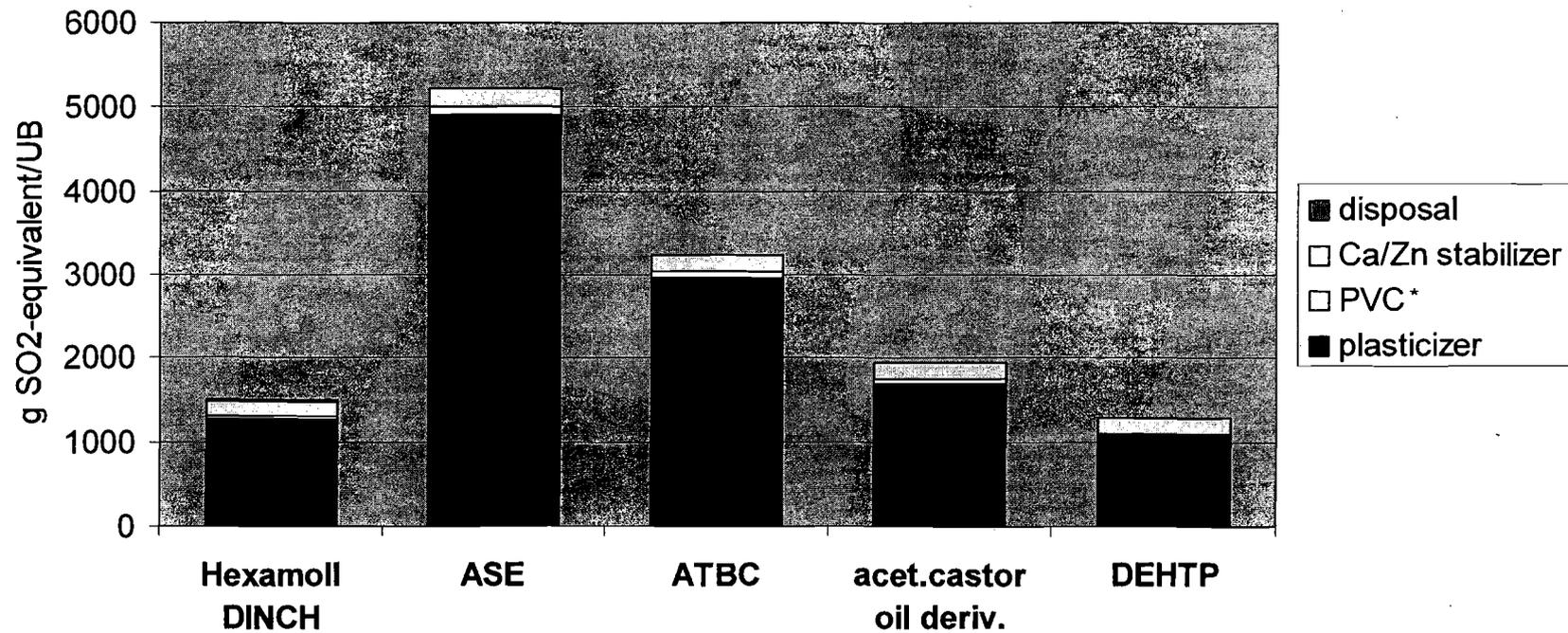


UB- user benefit



Eco-Efficiency

Air Emissions: Base Case Acidification Potential (AP)



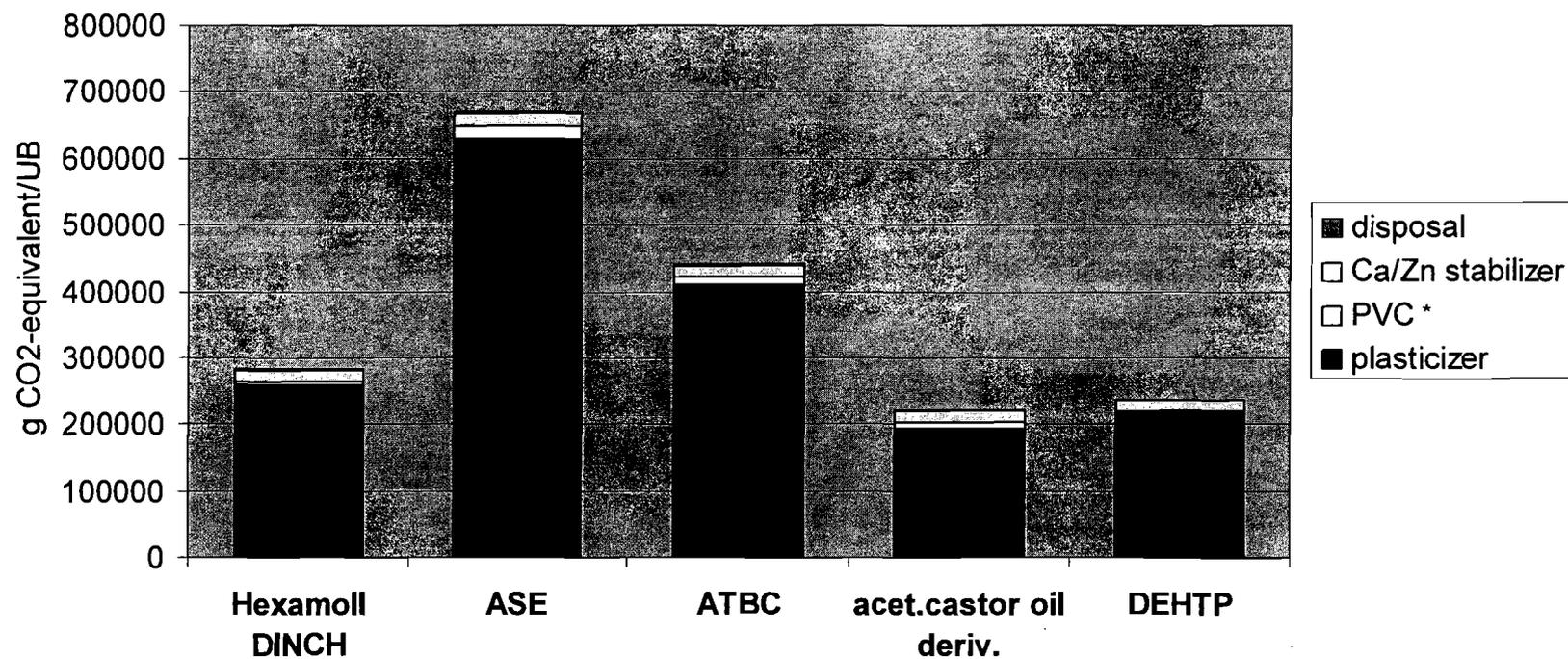
UB- user benefit

*differential approach



Eco-Efficiency

Air Emissions: Base Case Global Warming Potential (GWP)



UB- user benefit

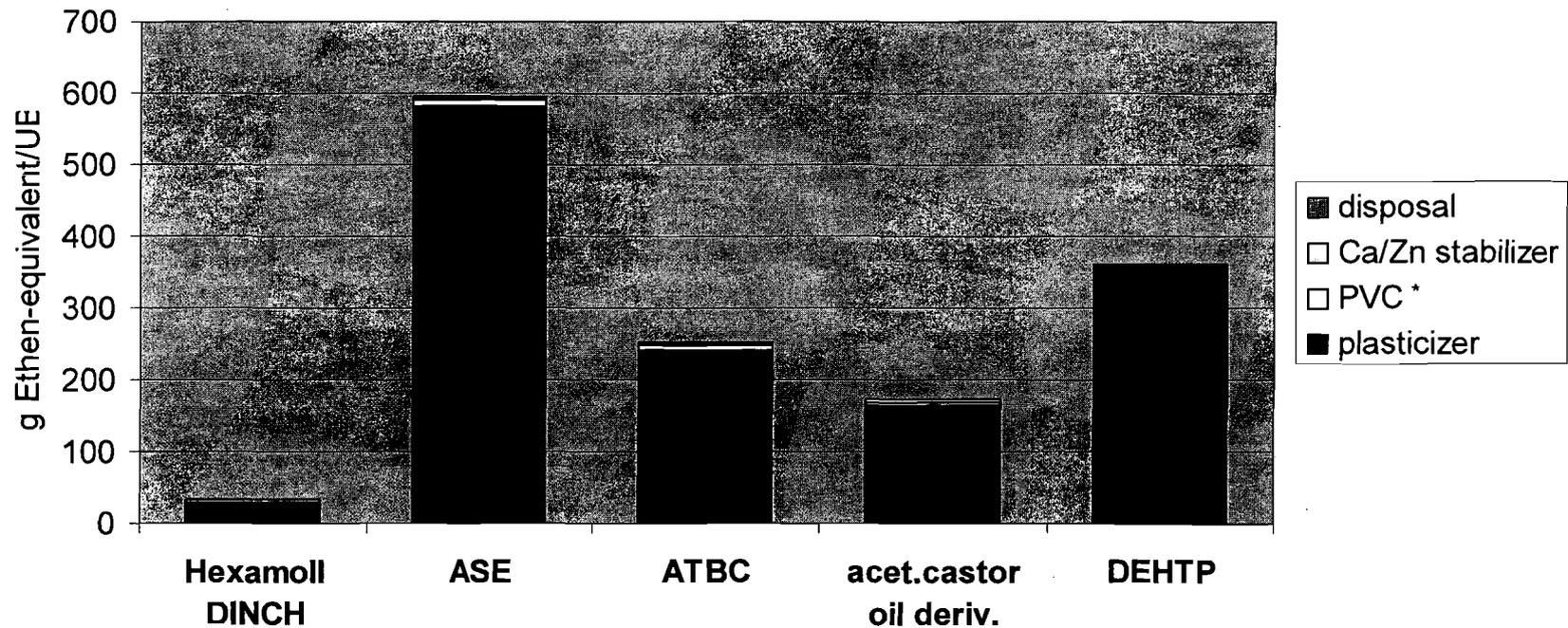
*differential approach



Eco-Efficiency

Air Emissions: Base Case

Photochemical Ozone Creating Potential (POCP) **BASF** The Chemical Company



UB- user benefit

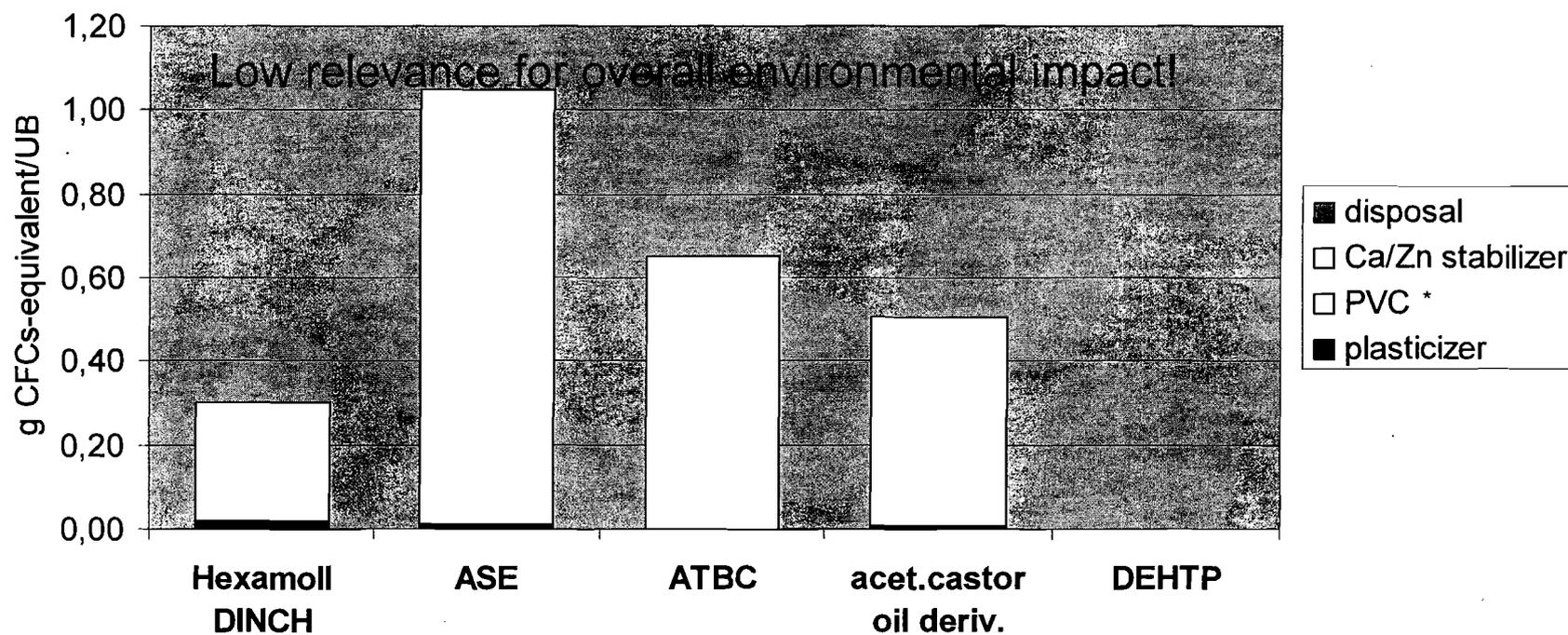
*differential approach



Eco-Efficiency

Air Emissions: Base Case

Ozone Depletion Potential (ODP)



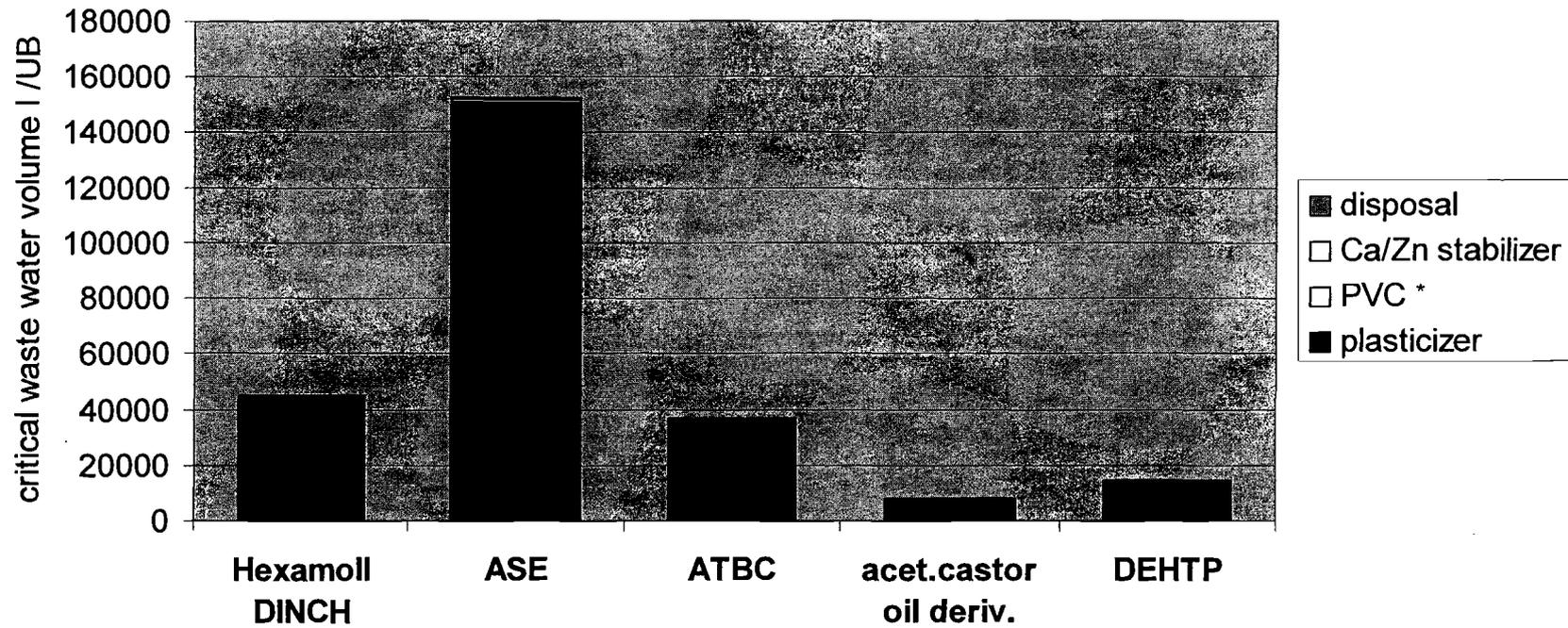
UB- user benefit

*differential approach



Eco-Efficiency

Water Emissions: Base Case



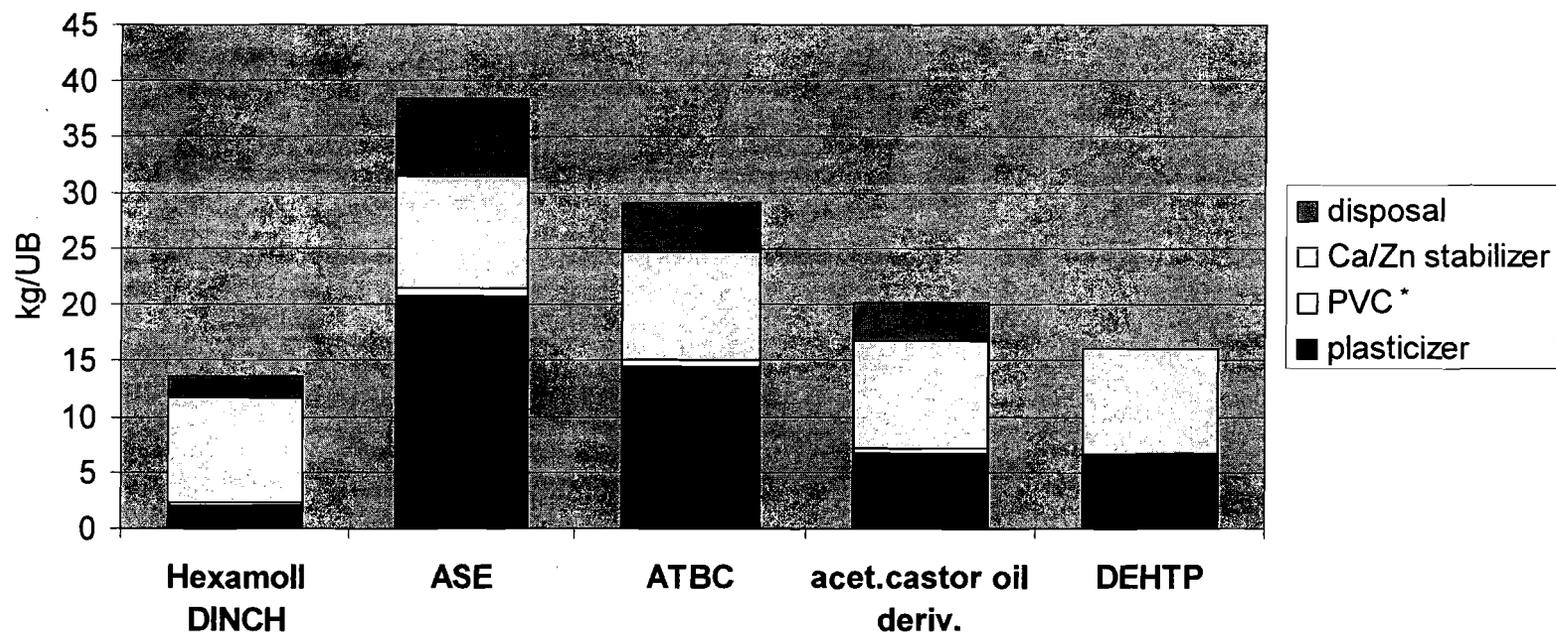
UB- user benefit

*differential approach



Eco-Efficiency

Solid Wastes: Base Case

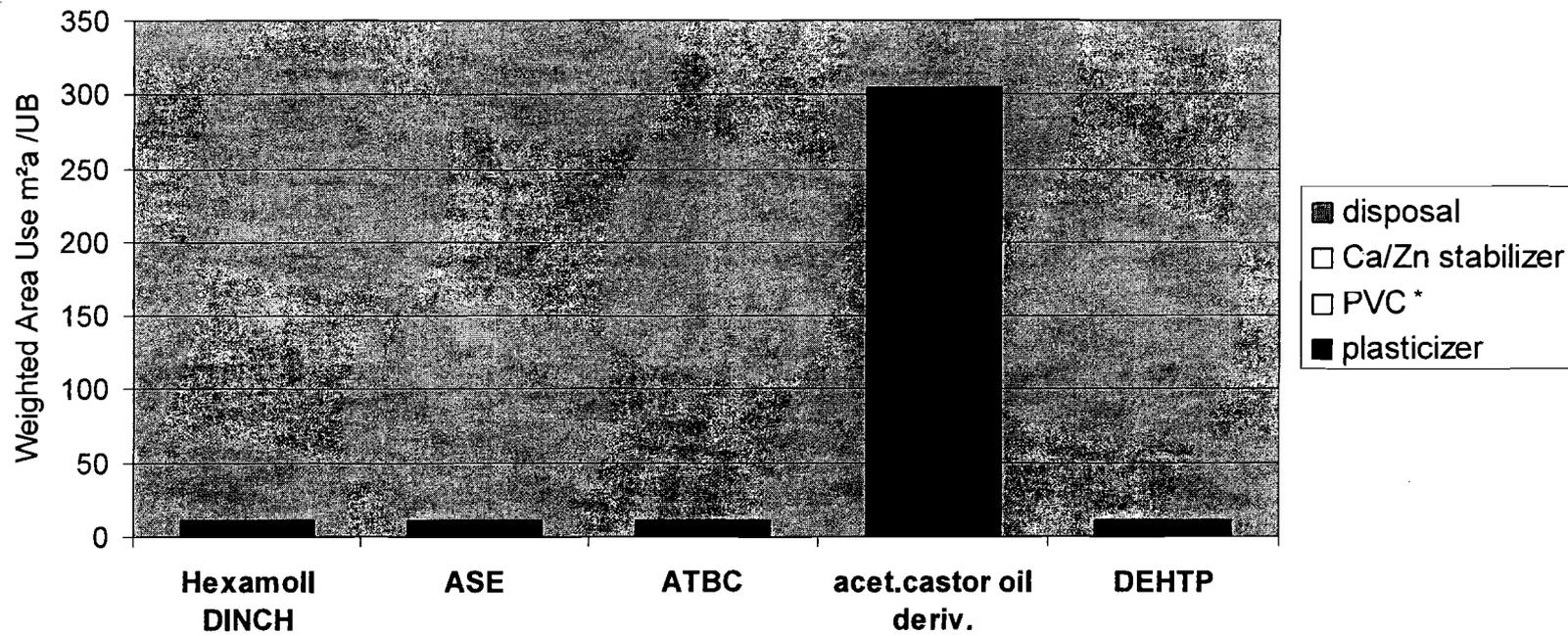


UB- user benefit
*differential approach



Eco-Efficiency

Area Use: Base Case



UB- user benefit

*differential approach

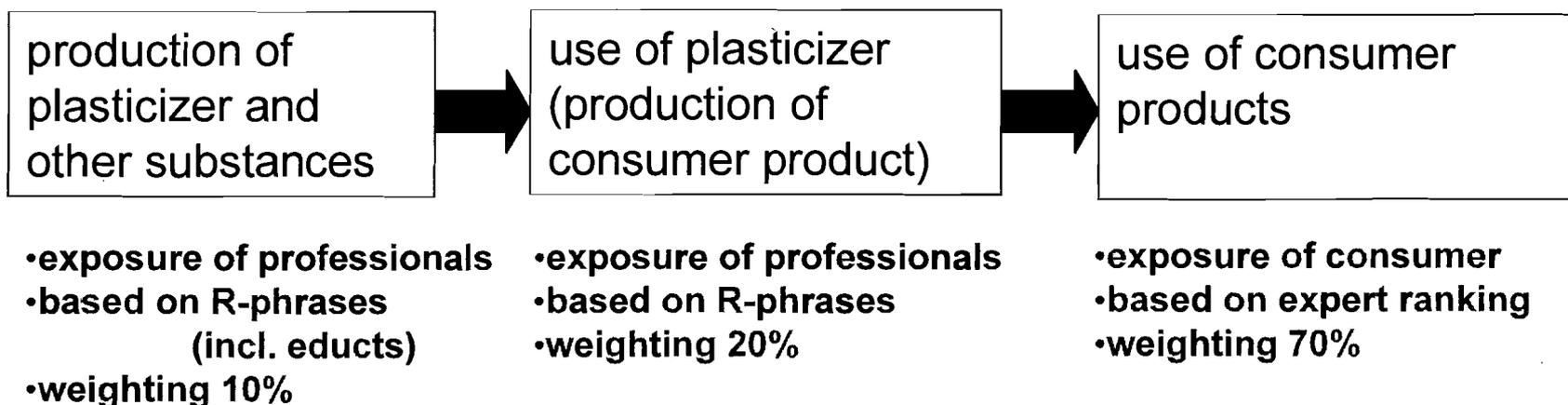


Eco-Efficiency

Toxicity Potential: Determination (1)

The toxicity potential was determined by considering all substances involved in the life cycle of the balls. Exposure of the public to a toxic substance was weighted more heavily than exposure of professionals (see scheme below) since the latter have better training and equipment to deal with critical substances.

For all production steps, the R-phrases (from EU safety data sheets) were used as a measure of toxicity potential. For the consumer use of the ball, an expert ranking of various toxicological and ecotoxicological values (see next page) was used to compare the various plasticizers.



Toxicity Potential: Determination (2)

Toxicity ranking for consumer use of product

impact	ASE	DINCH	ATBC	DEHP	acet.castor oil	DOA
1 acute toxicity	5	10	10	10	10	10
1 skin irritation	10	10	10	10	-5	10
1 eye irritation	10	10	-5	5	-5	10
5 sensitization	10	10	10	10	-5	10
2 repeated dose toxicity	5	10	10	10	10	10
2 genotoxicity in vitro	10	10	10	10	10	10
10 genotoxicity in vivo	0	10	10	0	0	10
10 carcinogenicity	0	10	10	10	0	-10
10 repro: dev.tox.	0	10	5	10	0	-5
10 repro: fertility	5	10	10	5	0	10
1 acute aquatic toxicity	10	10	-5	5	5	10
2 biodegradation	5	5	10	5	5	10
2 bioconcentration	-5	10	10	0	5	10

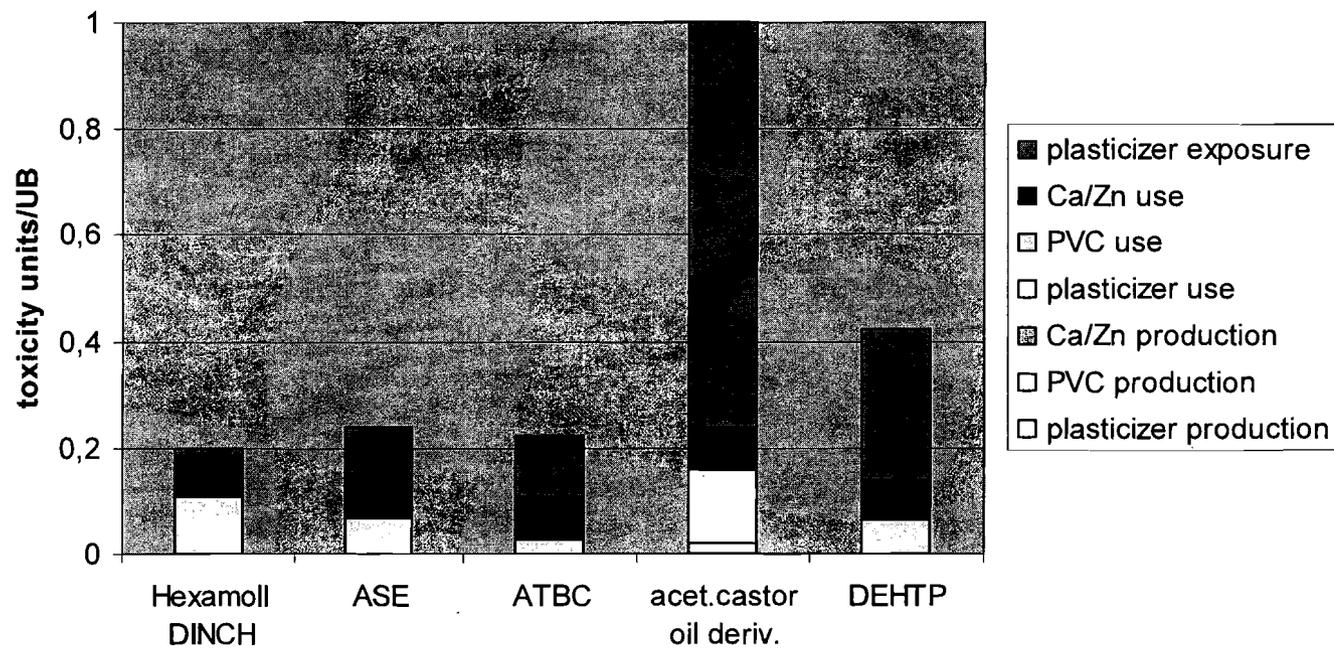
Ranking:
-10 (worst) to +10 (best)

Toxicity ranking of the five plasticizer alternatives during consumer use (i.e. of the ball). Ranking was performed by Dr. Rainer Otter based on EFSA reports and other publicly available data.



Toxicity Potential: Base Case

(a) By Life Cycle Step



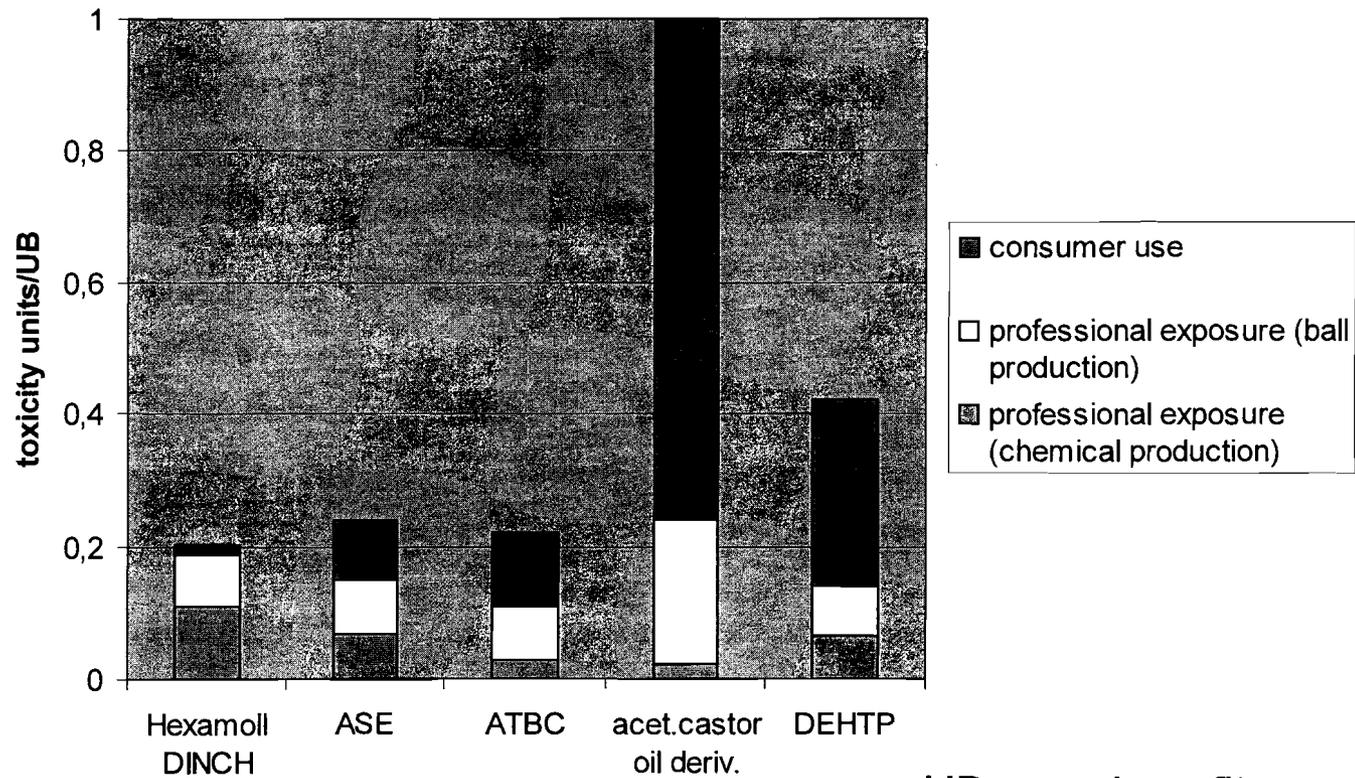
UB- user benefit



Eco-Efficiency

Toxicity Potential: Base Case

(b) By Exposure Group



UB- user benefit



Eco-Efficiency

Toxicity Potential: Comments



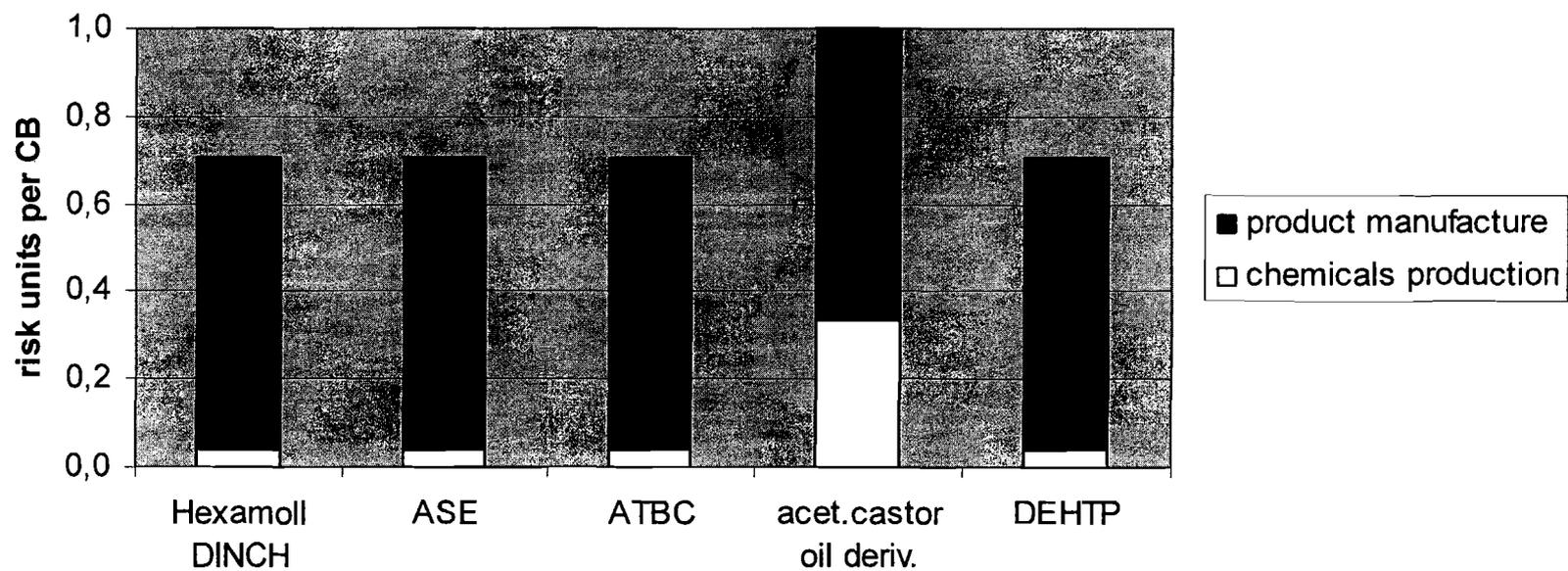
Acetylated castor oil derivative is by far the worst alternative in terms of toxicity potential. While all plasticizers have a roughly similar (from a toxicity point of view) prechain, acet. castor oil derivative is the only one denoted with a R-phrase (R43: possible skin sensitization). It also ranks worse in terms of skin and eye irritation.

DEHTP, while showing a much lower toxicity potential than acet. castor oil derivative, is significantly more critical than the DINCH, ATBC and ASE, which are all comparable.



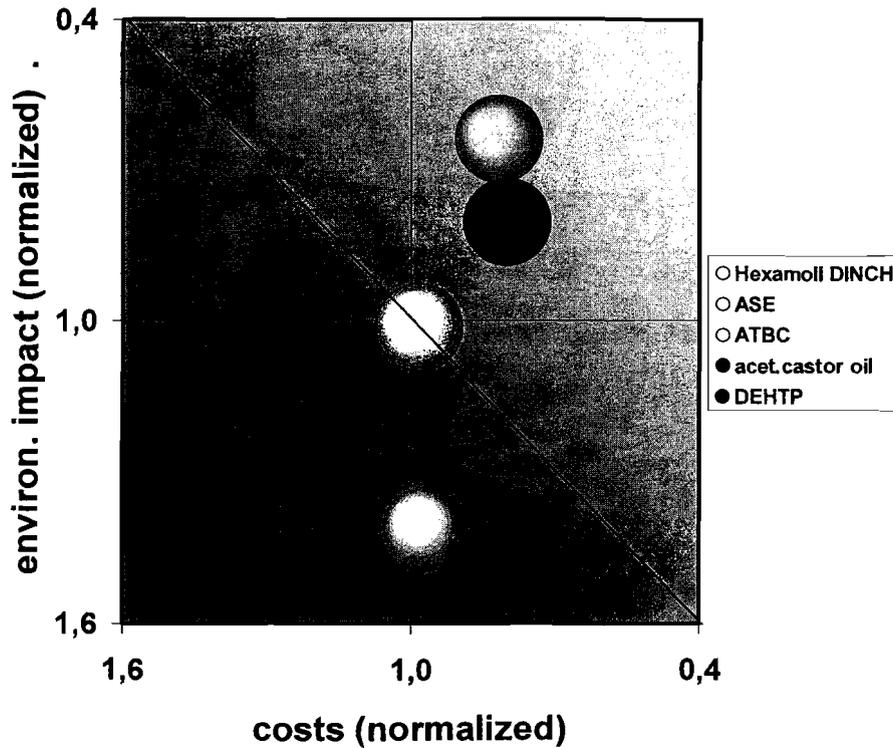
Eco-Efficiency

Risk Potential: Base Case

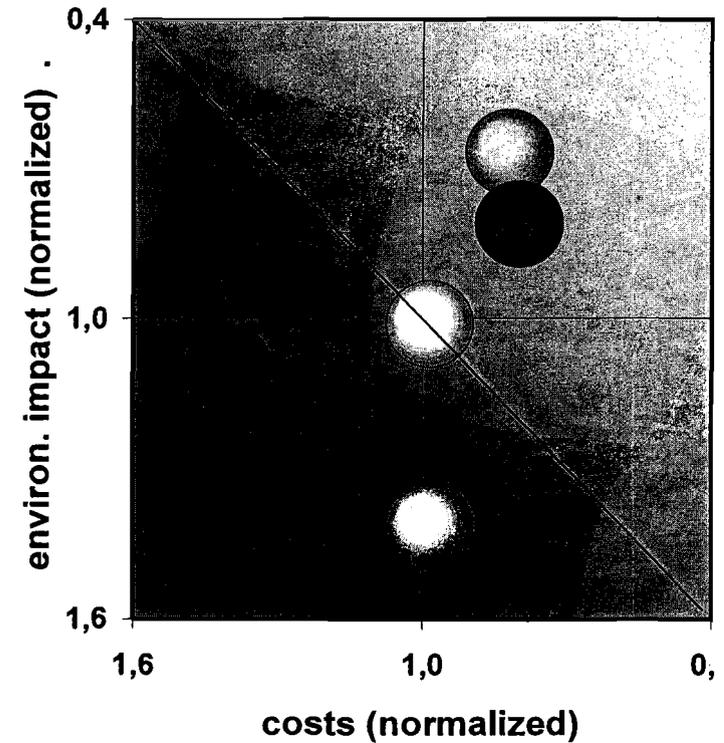


Scenario 1: Garden Hose and Medicinal Tubing

1000 m garden hose



1000 m medicinal tubing



Comments Scenario 1: Garden Hose and Medicinal Tubing



In addition to balls, 1000 m each of garden hose and medicinal tubing were considered. The compositions differed somewhat, in the latter case ESO was also used.

For these products, the eco-efficiencies of the plasticizers remain essentially the same as in the base case situation. Hexamoll® DINCH is most eco-efficient, followed relatively closely by DEHTP. ATBC is characterized by an intermediate eco-efficiency. ASE and castor oil derivative are significantly less eco-efficient.



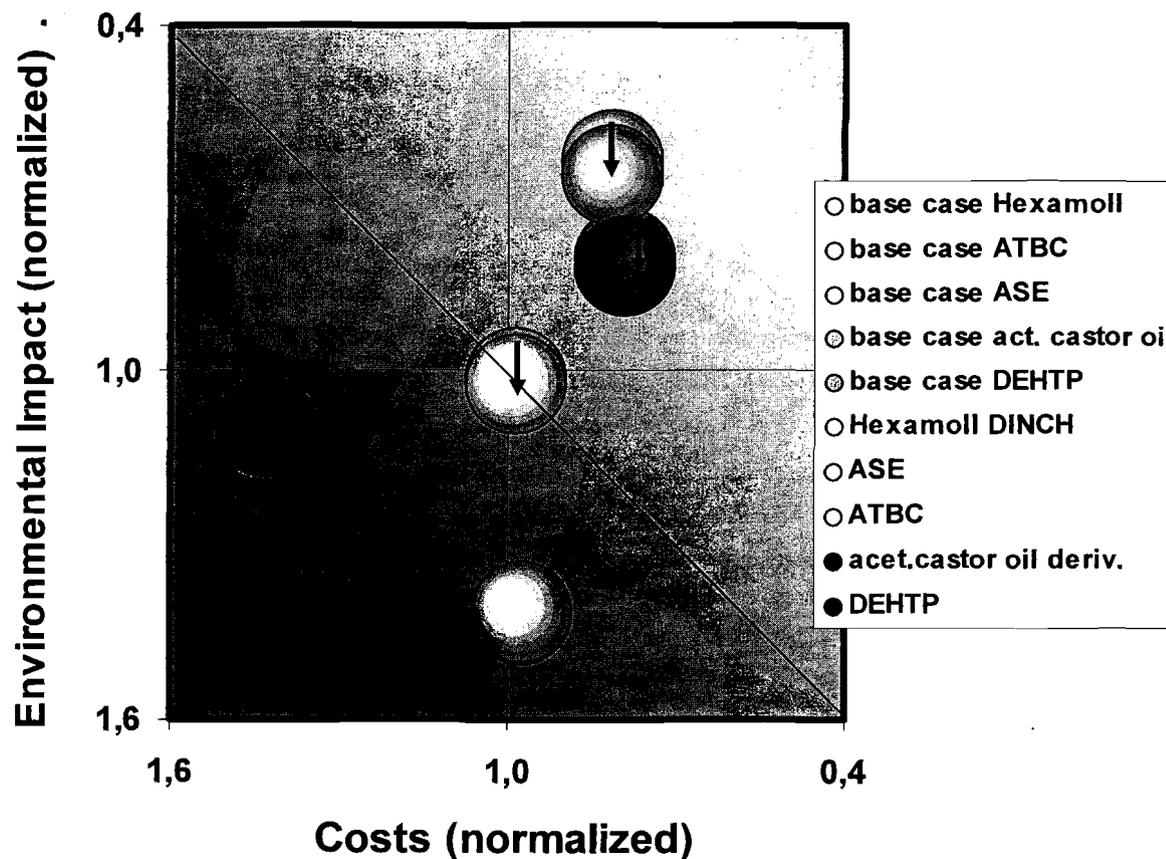
Eco-Efficiency

Scenario 2: Acetylated Castor Oil Derivative with No R-Phrase

user benefit:

Production and use of 1000 toy PVC balls

No R-phrase associated with acetylated castor oil derivative



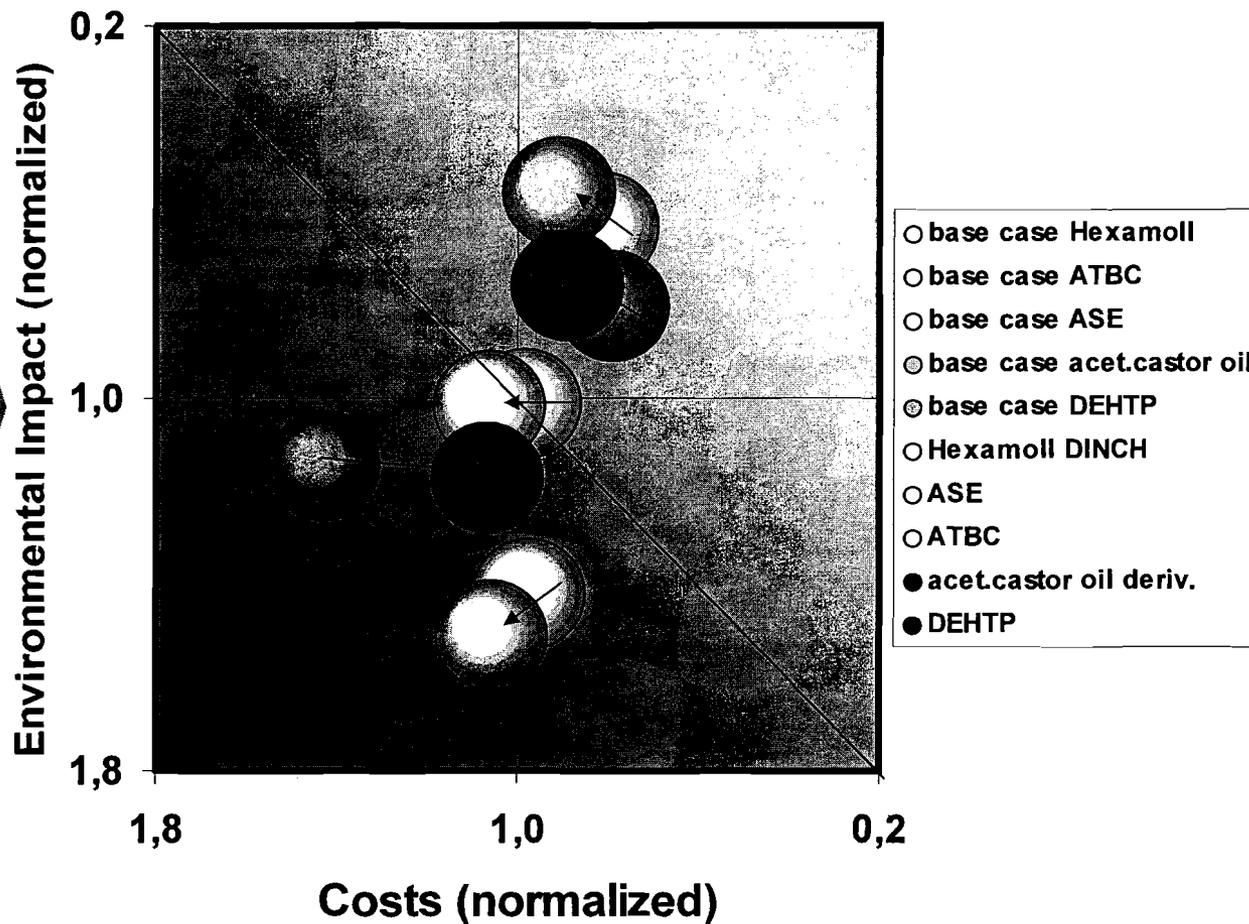
Eco-Efficiency

Scenario 3: Price Variation for Acetylated Castor Oil

user benefit:

Production and use of 1000 toy PVC balls

Price 2,00 EUR/kg
(base case 3,00 EUR/kg)

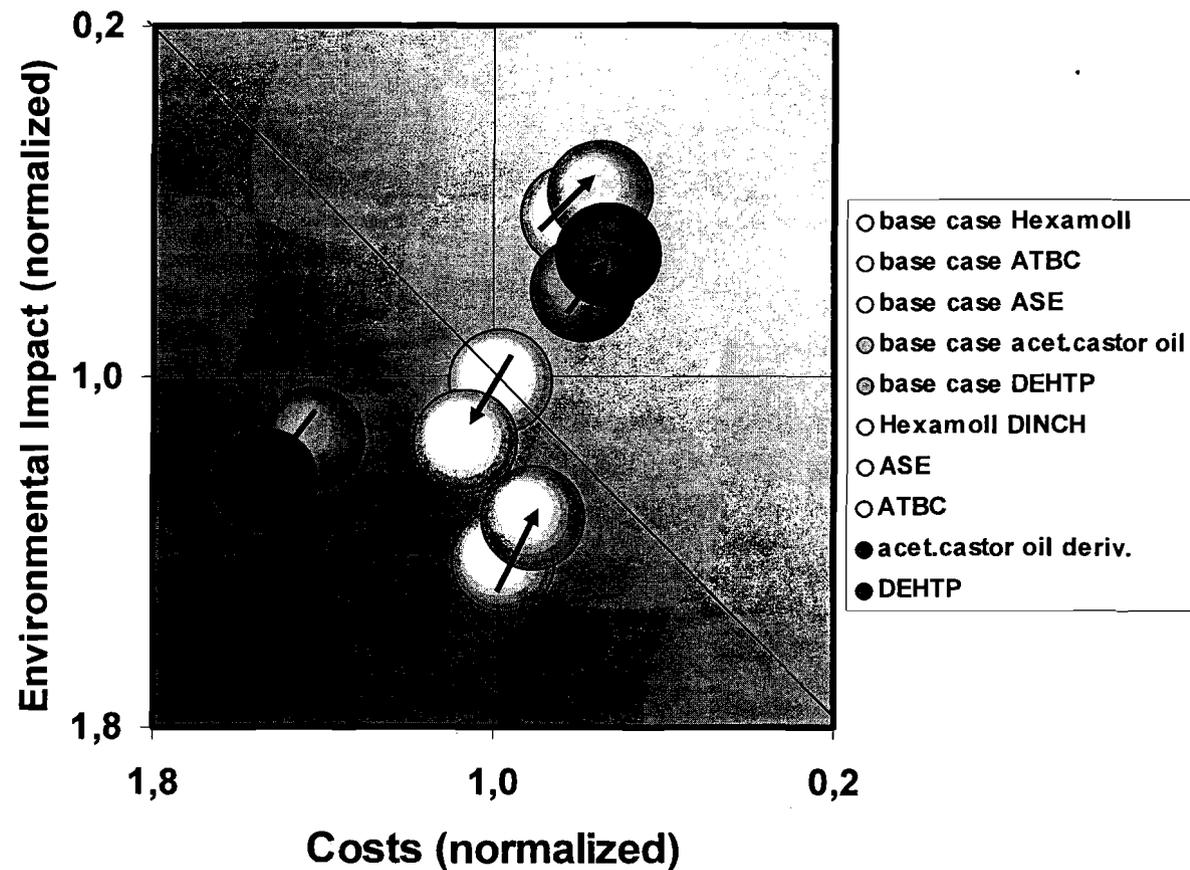


Scenario 4: Variation in Durability of PVC Products

user benefit:

Production and use of 1000 toy PVC balls

ATBC and castor derivative have 25% shorter life span (base case same durability for all plasticizers)



Eco-Efficiency

Contact



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Eco-Efficiency

Restriction: In accordance with other silver biocides these biocides will be subject to a group SML of 0.05 mg Ag/kg food

In accordance with other boron compounds the biocide Ref No 86432/40 will be subject to a group SML of 6 mg B/kg food

Ref. No.: 95020
Name of the substance: 2,2,4-Trimethyl-1,3-pentanediol diisobutyrate
CAS number: 6846-50-0
Classified in list: 3
Restriction: 5 mg/kg food

Ref. No.: 95420
Name of the substance: 1,3,5-tris(2,2-dimethylpropanamido)benzene
CAS number: 745070-61-5
Classified in list: 3
Restriction: 0.05 mg/kg food

KEY WORDS

Food Contact Materials, Plastics, Monomers, Additives, REF. No 45705, CAS No 166412-78-8, 1,2-cyclohexyldicarboxylic acid, diisononyl ester, REF. No 81500, CAS No 9003-39-8, Polyvinylpyrrolidone, REF. No 86432/20, Silver containing glass (silver-magnesium-aluminium-phosphate-silicate), silver content less than 2%, REF. No 86432/40, Silver containing glass (silver-magnesium-aluminium-sodium-phosphate-silicate-borate), silver content less than 0.5%, REF. No. 86432/60, Silver containing glass (silver-magnesium-sodium-phosphate), silver content less than 3 %, REF. No 95020, CAS No 6846-50-0, 2,2,4-Trimethyl-1,3-pentanediol diisobutyrate, REF. No 95420, CAS No. 745070-61-5, 1,3,5-tris(2,2-dimethylpropanamido)benzene.

BACKGROUND

Before a substance is authorised to be used in food contact materials and is included in a positive list EFSA's opinion on its safety is required. This procedure has been established in Articles 8 and 9 of the Regulation (EC) No. 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food¹.

¹ This Regulation replaces Directive 89/109/EEC of 21 December 1988, OJ L 40, 11.2.1989, P.38

TERMS OF REFERENCE

The EFSA is required by Article 10 of Regulation (EC) No. 1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food to carry out risk assessments on the risks originating from the migration of substances from food contact materials into food and deliver a scientific opinion on:

1. new substances intended to be used in food contact materials before their authorisation and inclusion in a positive list;
2. substances which are already authorised in the framework of Regulation (EC) No. 1935/2004 but need to be re-evaluated.

ASSESSMENT

Within this general task the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) evaluated the following substances used in food contact materials.

The substances examined are listed in ascending order of their Reference Number (REF No.), with their chemical name, Chemical Abstract Number (CAS No.) and classification according to the “SCF list”. (Since in the past the evaluation of substances used in food contact materials was undertaken by the Scientific Committee on Food (SCF), the same system of classification into a “SCF list” is retained for uniformity purposes). The definitions of the various SCF lists and the abbreviations used are given in the appendix.

The studies submitted for evaluation followed the SCF guidelines for the presentation of an application for safety assessment of a substance to be used in food contact materials prior to its authorisation (http://ec.europa.eu/food/fs/sc/scf/out82_en.pdf).

Ref. No.:	45705
Name of the substance:	1,2-cyclohexanedicarboxylic acid, diisononyl ester

CAS number: 166412-78-8

Document reference: EFSA/AFC/FCM/293-Rev.IB/45705 of June 2006

General information:

According to the petitioner 1,2-cyclohexanedicarboxylic acid, diisononyl ester is used as a plasticiser in PVC (up to 40%) and as an impact modifier in polystyrene (max 3%).
The plasticiser is used in PVC cling films for fresh meat packaging (10%), for aqueous food and fruits and vegetables (35%), artificial corks (35%), sealing gaskets for beverage containers (35%), flexible tubes for beverages, alcoholic and non-alcoholic (40%), conveyor belts for fatty foods (12%) and other foods (12%) and as polystyrene impact modifier (3%). The conditions of contact of the food with the packaging material depend on the food and its required storage conditions.

Previous evaluations (by SCF or AFC): None

Available data

used for this evaluation:

Non-toxicity data: - Data on identity, physical/chemical properties, use, authorisation
- Migration data into food simulants and various foodstuffs
- Simulation of the migration using mathematical modelling
- Data on the actual content in the test samples

Toxicity data: - Gene mutation in bacteria
- *In vitro* mammalian cell gene mutation test
- *In vitro* mammalian chromosome aberration test
- *In vivo* micronucleus test
- Subchronic (3 months) oral toxicity study in rats
- Prenatal developmental toxicity studies in rats (by gavage)
- Two-generation reproduction/developmental toxicity studies in rats and rabbits (by dietary administration)
- Chronic toxicity/carcinogenicity study in rats
- Biokinetic and metabolism studies in rats
- Studies on thyroid function, liver enzymes induction and S-phase response in rat liver, thyroid and kidney (by dietary administration).

Ref. No.:	45705
Name of the substance:	1,2-cyclohexanedicarboxylic acid, diisononyl ester

Evaluation:

The specific migration of 1,2-cyclohexanedicarboxylic acid, diisononyl ester (DINCH) from plasticized PVC cling film containing 10 - 17.8 % of DINCH into food simulants and foodstuffs was determined. by a Gas Chromatography/ Mass Spectrometry (GC/MS) method. The method was properly described and validated. The recovery data and precision data showed the reliability of the method. The following migration results were obtained:

Test sample	Food/simulant	Fat content (fresh product) %	Storage conditions	Migration mg/dm ²
Cling film ; thickness 14 µm, 17,8% 1,2-cyclohexanedicarboxylic acid, diisononyl ester	Sunflower oil	100	6 -144 h at 10 and 20°C	29 ± 2 ¹⁾
	Ethanol 10%	0	24 h at 40 °C	0.016 ± 0.002
	Turkey (escalope)	1.0 ± 0.5	5d at 5 °C	0.3 ± 0.1
	Pork (neck)	11.3 ± 2.5	5d at 5 °C	1.2 ± 0.2
	Pork (escalope)	0.7	5d at 5 °C	0.1 ± 0.01
	Pork (liver)	5.0 ± 0.1	5d at 5 °C	0.1 ± 0.02
	High fat cheese	44.3	10d at 5 °C	27.5 ± 2.2
	Low fat cheese	11.4	10d at 5 °C	2.4 ± 0.7
Cling film ; thickness 14 µm 12%	Pork (neck)	14.7 ± 2.9	5d at 5 °C	1.0 ± 0.3
	Pork (bacon)	22.1 ± 2.7	5d at 5 °C	1.4 ± 0.1
Cling film ; thickness 14 µm 10%	Pork (neck)	17.9 ± 0.5	5d at 5 °C	0.5 ± 0.1
	Pork (bacon)	25.8 ± 2.4	5d at 5 °C	0.8 ± 1.5

1) the kinetic curved showed complete migration within 6 h at both 10°C and at 20°C

DINCH migrates quantitatively into foods with high fat content and the overall migration limit of 10 mg/dm² may be exceeded. The migration in foods like fresh meat and low fat cheese is low.

Ref. No.:	45705
Name of the substance:	1,2-cyclohexanedicarboxylic acid, diisononyl ester

Migration of DINCH from bottle closures containing a PVC sealing layer with 37% DINCH was determined in carbonated mineral water, grape fruit juice and orange lemonade.

In all cases migration into the aqueous beverages was low, in the range of 10-30 microg/kg.

Also the migration into 10% ethanol, 50% ethanol and olive oil from a polystyrene sample containing 3% DINCH was determined. For this purpose a LC/MS method was used which was validated for precision and detection limit. Recovery including storage conditions was found to be 97% for 50% ethanol. The following results were obtained:

simulant	Storage conditions	Migration mg/kg
Olive oil	1, 5 and 10 d at 40°C	nd (<0.037)
10% ethanol	1, 5 and 10 d at 40°C	nd (<0.031)
50% ethanol	10 d at 40°C	0.053

The actual content of DINCH in the various polymer samples was determined and was found to be at the intended level.

DINCH was tested in three *in vitro* mutagenicity assays (reversion in bacteria, forward mutation and chromosomal aberration tests in mammalian cells) and in the micronucleus test in mouse bone marrow. Based on the negative results obtained, it is concluded that DINCH is not genotoxic.

In a subchronic (13 weeks) oral toxicity study in Wistar rats given 100, 300 and 1000 mg DINCH/kg bw/day, signs of renal toxicity (haematuria and increased occurrence of degenerated transitional epithelial cells in urine) were observed at high dose (1000 mg/kg bw/day) in males and females, and at mid dose (300 mg/kg bw/day) in males. Significantly increased liver weight, without histological alterations, was observed at high dose (both sexes) and at mid dose (females only). An increased incidence of thyroid hyperplasia was observed in males at all doses and in females at high dose. As marked species differences exist in thyroid cancer related effects (IARC, 1999), the NOAEL for thyroid hyperplasia was considered inappropriate to set a TDI. The NOAEL for kidney effects was 100 mg/kg bw/day.

No evidence of developmental or reproductive toxicity was obtained in prenatal and two-generation toxicity studies in Wistar rats and in

Ref. No.:	45705
Name of the substance:	1,2-cyclohexanedicarboxylic acid, diisononyl ester

rabbits, up to the highest administered dose of 1000 mg/kg bw/day. In rats, the following signs of general toxicity were observed in the F1 generation after 26 weeks of dietary exposure at high and mid doses (1000 and 300mg/kg bw/day): vacuolization of kidney tubular epithelia in males and thyroid hyperplasia in females. For reasons outlined above thyroid hyperplasia was not taken as the critical effect to define the TDI. The NOAEL for general toxicity from the 2 generation study in rats, based on renal toxicity findings, was 100 mg/kg bw/day. No toxic effects were observed in rabbits.

A 2-year chronic toxicity/carcinogenicity study in Wistar rats with dietary administration of DINCH at 40, 200 and 1000 mg/kg bw/day showed no treatment related mortality or increase in malignant neoplasias up to the highest dose of 1,000 mg/kg bw/day. Increased incidences of thyroid adenomas and increased thyroid weight were observed in both sexes at the high dose, and at mid dose in males. High dose females also showed significantly increased platelets counts. A transient increase in the excretion of the degenerated transitional epithelial cells, with no histopathological findings at sacrifice, was observed after 3 months in high dose males. In this study, the NOAEL for thyroid effects was 40 mg/kg bw/day. The NOAEL for other adverse effects was 200 mg/kg bw/day (based on increased platelet counts in females at 1000 mg/kg bw/day).

A biokinetic study in the rat with ¹⁴C-labelled DINCH showed rapid absorption after oral administration and extensive elimination. Tissue concentrations declined after administration, with less than 1% of radioactivity remaining after 1 week. Overall, kinetic data do not indicate a potential for accumulation in man.

The characterisation of metabolites after oral and intravenous administration of DINCH indicates two main pathways: the partial hydrolysis of DINCH to the mono-isononyl ester followed by conjugation to glucuronic acid, which is the most abundant metabolite in bile, or the hydrolysis of the remaining ester bond to yield free cyclohexane dicarboxylic acid, the predominant metabolite in urine.

Considering the absence of genotoxic properties, the induction of follicular cell hyperplasia and adenomas in rat thyroid can be attributed to a non-genotoxic, indirect mechanism. As rodents are far more sensitive than humans to chemical disturbance of thyroid function (IARC, 1999), the effects on thyroid observed in 90 days and chronic toxicity/carcinogenicity studies are not appropriate to set a TDI. To this aim the evidence of renal toxicity observed in the rat subchronic toxicity study and in the 2-generation rat study can be considered as the pivotal effect, for which a NOAEL of 100 mg/kg bw/day has been identified.

Ref. No.:	45705
Name of the substance:	1,2-cyclohexanedicarboxylic acid, diisononyl ester

In view of the absence of genotoxicity, and of the extensive toxicity database available, a Tolerable Daily Intake (TDI) for DINCH can be derived from the NOAEL for renal effects with the application of the default uncertainty factor of 100:

$$100 \text{ mg/kg bw/day (NOAEL)} : 100 = 1 \text{ mg/kg bw/day (TDI)}$$

Conclusion: Based on the above-mentioned data, the substance is classified:
SCF_List: 2
Restriction: TDI = 1 mg/kg bw/day
Remark for Commission:

- FRF is applicable
- Overall migration limit into high fat content foods may be exceeded.

Needed data or
information None

References:

- Unpublished data submitted by the petitioner in May 2004 and February 2006
- IARC (1999) International Agency for Research on Cancer. *Species Differences in Thyroid, Kidney and Urinary Bladder Carcinogenesis*. C.C. Capen *et al.*, (Eds.). IARC Scientific Publications n.147. IARC, Lyon, 1999.

Ref. No.:	81500
Name of the substance:	Polyvinylpyrrolidone

CAS number: 9003-39-8

Document reference: SDS EFSA/AFC/FCM/641-Rev.0B/81500 of June 2006

General information: According to the petitioner polyvinylpyrrolidone (PVP) is intended to be used as a polymeric additive in polyamide. Maximum percentage in formulation is 0.1%.

Previous evaluations (by SCF or AFC): The SCF evaluated polyvinylpyrrolidone in 1990 (SCF, 1992) for its use as a food additive and the monomer vinylpyrrolidone in 2001 and 2002 (SCF, 2002a and 2002b)

Available data

used for this evaluation:

- Non-toxicity data:
- Data on identity and physical and chemical properties
 - Intended application of the substance
 - Authorisation of the substance
 - Data on migration of the substance
 - Data on the residual content of the substance

Toxicity data: This aspect has been evaluated by the Joint FAO/WHO Experts Committee on Food Additives in 1986 (JECFA, 1987) and the SCF in 1990 and 2001 and 2002 (SCF, 1992 and 2002a and 2002b)

Evaluation:

In contrast to most polymers, PVP is readily soluble in both water and a large number of organic solvents, such as alcohols, amines, acids, chlorinated hydrocarbons, amides and lactames. On the other hand, the polymer is insoluble in the common esters, ethers, hydrocarbons and ketones. When cross-linked, PVP becomes insoluble in all solvents.

The PVP has a wide molecular weight range, from 25,000 – 2,500,000 D.

The substance meets the purity requirements on food additives as set in Directive 96/77/EC.

Specific migration of PVP was determined in 10% ethanol and Miglyol. A polyamide sample containing 0.1% PVP was tested by total immersion after 4 hours at 100°C and after 10 days at 40°C. Specific migration of PVP was found to be non-detectable under all test conditions applied. The detection limit of the method corresponds to 0.144 mg/kg food.

The migration of the residual monomer N-vinylpyrrolidone (NVP) is calculated to be 0.2 microg/kg into food, based on the specifications for residual monomer and assuming 100% migration.

Ref. No.:	81500
Name of the substance:	Polyvinylpyrrolidone

Polyvinylpyrrolidone (PVP) has been evaluated by the JECFA in 1986 (JECFA, 1987) and it was allocated an ADI of 0-50 mg/kg bw. The substance was also evaluated by the SCF in 1990 (SCF, 1992) and it was considered as toxicologically acceptable for its use as an excipient in vitamin and sweetener preparations.

PVP is an approved food additive included in the positive list of the Council Directive No 95/2 /EC for use in dietary food supplements in tablet and coated tablet form following the *quantum satis* principle.

The Panel endorsed the previous SCF opinions and taking into account that exposure to NVP from the use of PVP in food contact materials is in a similar range to the exposure from its use as excipient in food supplements, the Panel concluded that PVP is acceptable for use in food contact materials provided that the specifications for the food additive are met.

Conclusion: Based on the above-mentioned data the substance is classified:
SCF_List: 3
Restriction: None
Remark for Commission: The substance should meet the purity criteria established for food additives
 Needed data or information

References:

- Unpublished data submitted by petitioner on 27/01/2006
- JECFA (1987), 30th report of the Joint FAO/WHO Expert Committee on Food Additives, WHO Technical report series 751, Geneva, 1987
http://whqlibdoc.who.int/trs/WHO_TRS_751.pdf
- European Parliament and Council Directive No 95/2/EC of February 1995 on food additives other than colours and sweeteners.
http://europa.eu.int/eur-lex/en/consleg/pdf/1995/en_1995L0002_do_001.pdf
- Commission Directive 2002/82EC of 15 October 2002 amending directive 96/77/EC laying down the purity criteria on food additives other than colours or sweeteners.
http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/l_292/l_29220021028en00010028.pdf

Ref. No.:	81500
Name of the substance:	Polyvinylpyrrolidone
	<ul style="list-style-type: none"> - SCF (1992), reports, 26th series, second series of food additives of various technological functions, 19 October 1990, published in 1992 http://europa.eu.int/comm/food/fs/sc/scf/reports/scf_reports_26.pdf - SCF (2002a), opinion of the Scientific Committee on Food on the safety of N-vinyl-2-pyrrolidone residues in polyvinylpyrrolidone and polyvinylpolypyrrolidone when used as food additives, expressed on 30 May 2001, corrected on 17 April 2002. http://europa.eu.int/comm/food/fs/sc/scf/out87_en.pdf - SCF (2002b), opinion of the Scientific Committee on Food on the 18th list of monomers and additives for food contact materials. PM REF No. 26230:N-vinyl-2-pyrrolidone, expressed at 134th meeting of the SCF on 24 September 2002. http://europa.eu.int/comm/food/fs/sc/scf/out140_en.pdf

Ref. No.:	86432/20, 86432/40 and 86432/60
Name of the substance:	<ul style="list-style-type: none"> - Silver containing glass (silver-magnesium-aluminium-phosphate-silicate), silver content less than 2%. - Silver containing glass (silver-magnesium-aluminium-sodium-phosphate-silicate-borate), silver content less than 0.5% - Silver containing glass (silver-magnesium-sodium-phosphate), silver content less than 3 %

CAS number: The petitioner has indicated a CAS number, which may not be adequate (CAS for glass in general)

Document reference: SDS EFSA/AFC/FCM604-Rev.0D/86432/20/40/60 of May 2006

General information: According to the petitioner, glass matrices containing silver, magnesium, phosphorus and/or calcium and/or boron and/or aluminium and/or sodium and/or silicon oxides are glasses to be used as additives for food contact plastic materials. The three following defined mixtures were evaluated:
Ref. No. 86432/20: Silver containing glass (silver-magnesium-aluminium-phosphate-silicate), silver content less than 2%.

Ref. No.:	86432/20, 86432/40 and 86432/60
Name of the substance:	<ul style="list-style-type: none"> - Silver containing glass (silver-magnesium-aluminium-phosphate-silicate), silver content less than 2%. - Silver containing glass (silver-magnesium-aluminium-sodium-phosphate-silicate-borate), silver content less than 0.5% - Silver containing glass (silver-magnesium-sodium-phosphate), silver content less than 3 %

Ref. No. 86432/40: Silver containing glass (silver-magnesium-aluminium-sodium-phosphate-silicate-borate), silver content less than 0.5%

Ref. No. 86432/60: Silver containing glass (silver-magnesium-sodium-phosphate), silver content less than 3 %.

The maximum use levels requested were 0.6% for the first 2 and 0.3% for the last one.

When they are incorporated in a food contact material, these silver containing glasses release silver and develop an antimicrobial activity on the surface of the material. The composition of the glasses plays a major role on the silver release capacity.

The materials containing the glass are to be used in a wide range of applications, for any polymer and for any food, for single and for repeated uses.

Previous evaluations (by SCF or AFC): None

Available data used for this evaluation:

Non-toxicity data:

- Identity and composition
- Physical and chemical properties
- Mechanism of action
- Intended use and authorisation
- Migration with samples which do not represent worst case situations

Microbiological data:

- Intended microbiological function
- Spectrum of antimicrobiological activity
- Level of activity (minimum inhibitory concentrations)
- Information on consequences of use
- Efficacy
- Efficacy upon repeated use
- Lack of biocidal activity against microbes on /in food.

Ref. No.:	86432/20, 86432/40 and 86432/60
Name of the substance:	<ul style="list-style-type: none"> - Silver containing glass (silver-magnesium-aluminium-phosphate-silicate), silver content less than 2%. - Silver containing glass (silver-magnesium-aluminium-sodium-phosphate-silicate-borate), silver content less than 0.5% - Silver containing glass (silver-magnesium-sodium-phosphate), silver content less than 3 %

Toxicity data: This aspect has been evaluated for similar substances by the EFSA in 2004 and 2005 (EFSA, 2004 and EFSA, 2005)

Evaluation:

Migration of silver and other ions in glass has been tested for 10 days at 40°C, using properly described methods. Migration was tested in 3% acetic acid, 15% ethanol and in olive oil. For all samples tested, 3% acetic acid gave the highest migration of silver, and can be considered as a worst case test medium for these glasses.

Migration is shown to be proportional to the percentage of silver in the final material, for each glass.

Migration values for silver reported were between 42 and 95 microg/kg food simulant, depending on the glass and of the actual percentages of glass and of silver in the formulations.

Other elements, mainly phosphate, magnesium and boron (in the case of Ref. No. 86432/40) migrated at low levels. Overall migration has not been tested.

The applicant has demonstrated that the three substances, when incorporated into appropriate polymers, have antimicrobial activity against a wide spectrum of microorganisms including Gram positive and negative bacteria, yeasts and moulds. In tests viable counts after 24 hours incubation in their presence were usually 10⁴ to 10⁵ fold less than in their absence. This level of activity was maintained after washing the final products for 16 hours at 50°C or after many wash cycles at 40°C if the biocides were incorporated into fibres.

Virtually all microorganisms that might be expected to be present in a food environment will be sensitive to silver ions so that the problem of selecting populations that are resistant to silver ions appears unlikely. This was supported by the fact that the use of silver compounds in water treatment and medical environments has not so far resulted in the selection of silver-resistant mutants within the sensitive population of microbes.

The applicant provided data on another silver-containing glass (silver-magnesium-calcium-phosphate-borate), Ref No. 86432,

Ref. No.:	86432/20, 86432/40 and 86432/60
Name of the substance:	<ul style="list-style-type: none"> - Silver containing glass (silver-magnesium-aluminium-phosphate-silicate), silver content less than 2%. - Silver containing glass (silver-magnesium-aluminium-sodium-phosphate-silicate-borate), silver content less than 0.5% - Silver containing glass (silver-magnesium-sodium-phosphate), silver content less than 3 %

already evaluated by the EFSA (EFSA, 2004) to demonstrate that the substance incorporated into polymers would not inhibit microbes in food. Since the antimicrobial effect is based on the same principle of the action of silver ions being released from a glass matrix on the surface of a plastic material, this is plausible. No evidence is provided of efficacy under "in-use" conditions i.e. to demonstrate that the use of the substance in food contact materials improves the hygienic state of food preparation areas over and above that of general cleaning procedures although the laboratory experiments reported suggest that might be the case.

The Panel noted that due to the nature of the substances the only ions that might migrate in toxicologically relevant quantities are silver and boron (in the case of Ref. No. 86432/40).

For boron a group restriction of 6 mg B/kg food has already been allocated (Directive 2002/72/EC).

Concerning silver, the EFSA has evaluated in 2004 and in 2005 (EFSA, 2004 and EFSA, 2005) various silver releasing biocides allocating a group specific migration limit (SML) of 0.05 mg Ag/kg food.

The Panel also took note of the WHO "Guidelines for drinking-water quality" (WHO, 2004). According to these Guidelines a total lifetime oral intake of about 10 g of silver (equal to 0.39 mg/day/person) can be considered on the basis of epidemiological and pharmacokinetic knowledge as the human NOAEL.

Based on the data above, a restriction of 0.05 mg/kg of food (as silver) for the substance would limit intake to less than 13 % of the human NOAEL, under the assumption that each day a kg of food is consumed containing silver at the restriction limit.

Conclusion:

Based on the above-mentioned data the substance is classified:

SCF_List: List 3:

Restriction : In accordance with other silver biocides these biocides will be subject to a group SML of 0.05 mg Ag/kg food

In accordance with other boron compounds the biocide Ref No

Ref. No.:	86432/20, 86432/40 and 86432/60
Name of the substance:	<ul style="list-style-type: none"> - Silver containing glass (silver-magnesium-aluminium-phosphate-silicate), silver content less than 2%. - Silver containing glass (silver-magnesium-aluminium-sodium-phosphate-silicate-borate), silver content less than 0.5% - Silver containing glass (silver-magnesium-sodium-phosphate), silver content less than 3 %

86432/40 will be subject to a group SML of 6 mg B/kg food

Remark for Commission: - The substances are surface biocides
 - The migration of silver may exceed the relevant restrictions in acidic foods if substances with the maximum silver content are used at the maximum use level requested.

Needed data or information None

References:

- Unpublished data submitted by the petitioner, October 2005
- Commission Directive 2002/72/EC of August 2002, relating to plastic materials and articles intended to come into contact with foodstuffs, L39/2, 13.2.2003
http://europa.eu.int/comm/food/food/chemicalsafety/foodcontact/2002-72_en.pdf
- EFSA Opinion on a 4th list of substances for food contact materials, adopted by the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food on 26 May 2004
http://www.efsa.eu.int/science/afc/afc_opinions/468_en.html
- EFSA Opinion on a 7th list of substances for food contact materials, adopted by the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food on 29 March 2005
http://www.efsa.eu.int/science/afc/afc_opinions/890_en.html
- World Health Organization (2004). Guidelines for drinking-water quality. Third edition.
http://www.who.int/water_sanitation_health/dwq/gdwq3/en/

Ref. No.:	95020
Name of the substance:	2,2,4-Trimethyl-1,3-pentanediol diisobutyrate

Ref. No.:	95020
Name of the substance:	2,2,4-Trimethyl-1,3-pentanediol diisobutyrate

CAS number: 6846-50-0

Document reference: SDS EFSA/AFC/FCM/646-Rev.0C/95020 of September 2006

General information: According to the petitioner 2,2,4-trimethyl-1,3-pentanediol diisobutyrate is used in plasticised PVC single use gloves for contact with food. 2,2,4-trimethyl-1,3-pentanediol diisobutyrate reduces the formation of pinholes during the manufacturing process of single use gloves. The final product, gloves, will come in contact with all kinds of food for a period of not longer than 30 min and at a temperature not exceeding 40°C.

Previous evaluations (by SCF or AFC): None

Available data

used for this evaluation:

Non-toxicity data:

- data on identity, physical and chemical properties
- data on intended use and authorisation of the substance
- data on migration of the substance and its main impurity
- data on the residual content of the substance

Toxicity data

- gene mutation in bacteria
- chromosomal aberrations in cultured mammalian cells
- gene mutation in cultured mammalian cells
- subchronic (one 90-day and one 100-day) oral toxicity study in rats and a 90-day oral toxicity study in dogs; additional feeding studies in rats for 50 and 100 days
- reproductive/developmental toxicity "screening" study
- absorption, distribution, metabolism and excretion
-

Evaluation:

The specific migration of 2,2,4-trimethyl-1,3-pentanediol diisobutyrate is determined in the food simulants 3% acetic acid, 10% ethanol and olive oil using the test condition of 30 min at 40°C. The analytical gas chromatography-flame ionisation detector (GC-FID) method for the determination of the compound in food simulants is provided and properly validated.

Under the specific conditions applied the migration of 2,2,4-trimethyl-1,3-pentanediol diisobutyrate in 3% acetic acid, 10% ethanol and olive oil is 0.17, 0.14 and 41.1 mg/6 dm² respectively. For single use gloves the following indicative migration levels were calculated for different types of foodstuffs: 0.016 mg/kg for salad, 0.64 mg/kg for cheese, 1.28 mg/kg for mayonnaise-containing salad and 1.20 mg/kg for chicken meat.

Ref. No.:	95020
Name of the substance:	2,2,4-Trimethyl-1,3-pentanediol diisobutyrate

The actual content of 2,2,4-trimethyl-1,3-pentanediol diisobutyrate in the plasticised PVC single use gloves was found to be 0.76%.

2,2,4-trimethylpentanediol-1,3-diisobutyrate did not induce mutagenicity in bacteria and in mammalian cells and did not induce chromosome aberrations in mammalian cells and is thus considered as non-genotoxic. In the only adequate 90-day oral feeding study in rats in which doses of 0, 30, 150 and 750 mg/kg bw/day were given, the liver was identified as a relevant target organ. Based on statistically significant increases in relative liver weights at the higher dose (750 mg/kg bw/day), the NOAEL was 150 mg/kg bw/day. The kidney effects observed in high dose male rats were characterised as hyaline droplet nephropathy and an exacerbation of progressive nephropathy at 750 mg/kg bw/day. Hyaline droplets in the kidney of male rats were also observed at the lower doses. 2,2,4-Trimethylpentanediol-1,3-diisobutyrate is rapidly metabolized in rats, mainly by hydrolysis, and most of a single oral dose is eliminated with urine and faeces within 4 days after administration.

The data from the toxicokinetic study do not suggest a potential for accumulation in man.

From the other available studies no additional relevant information could be gained.

Conclusion: Based on the above-mentioned data the substance is classified:

SCF_List: 3

Restriction: 5 mg/kg food

Remark for Commission: For single use gloves

Needed data or information -

References: - Unpublished data submitted by the petitioner in January and June 2006

Ref. No.:	95420
Name of the substance:	1,3,5-tris(2,2-dimethylpropanamido)benzene
CAS number:	745070-61-5
Document reference:	SDS EFSA/AFC/FCM650-Rev.0A/95420 of September 2006

General information: According to the petitioner 1,3,5-tris(2,2-dimethylpropanamido)benzene is requested for use as nucleating agent only in polypropylene (PP) at a maximum level around 0.02%. The products containing the additive are for single and multiple use, for all types of foods, in conditions ranging from refrigerator

Ref. No.:	95420
Name of the substance:	1,3,5-tris(2,2-dimethylpropanamido)benzene

conditions, to prolonged contact at room temperature, up to 100°C for 1 hour.

Previous evaluations (by SCF or AFC): None

Available data used for this evaluation:

- Non-toxicity data:
- Data on identity, physical and chemical properties,
 - Hydrolysis studies,
 - Data on the intended use and authorisation,
 - Specific migration tests in 3%acetic acid, 10% ethanol, miglyol,
 - Determination of residual content
 -

- Toxicity data
- Gene mutation in bacteria
 - *In vitro* mammalian cell gene mutation test
 - *In vitro* mammalian chromosome aberration test
 - *In vivo* micronucleus test

Evaluation:

Specific migration tests of 1,3,5-tris(dimethylpropanamido)benzene were performed on PP plaques nominally containing 0.02% of the additive (1 mm thickness, d 0.9 g/cm³), in 10% ethanol, 3% acetic acid, and miglyol, substitute simulant for olive oil, for 1 hour at 100°C and for 10 days at 40°C. Analytical methods, based on High Performance Liquid Chromatography (HPLC) determination and Limit of Quantitation (LOQ) of 9.5 microg/kg food were developed. Validation of the analytical methods was performed with satisfactory results.

In the acetic simulant, no migration of 1,3,5-tris(2,2-dimethylpropanamido)benzene was undetected after 10 days at 40°C. A migration of 9.8 microg/kg was measured after 1 hour at 100°C. In the ethanolic simulant, no migration of the substance was detected after 10 days at 40°C. A migration of 13.0 microg/kg was measured after 1 hour at 100°C. In miglyol the migration of 1,3,5-tris (dimethylpropanamido) benzene was undetectable after 10 days at 40°C. A migration of 25 microg/kg was measured after 1 hour at 100°C.

In order to verify that no pH dependent hydrolysis of 1,3,5-tris(dimethylpropanamido)benzene occurred under physiological conditions, hydrolysis tests in saliva simulant (pH 8.7, 0.5h at 37°C) and in gastric juice simulant (pH 1.14, 4 h at 37 °C) were performed. No primary aromatic amines were detected.

Ref. No.:	95420
Name of the substance:	1,3,5-tris(2,2-dimethylpropanamido)benzene

1,3,5-Tris(2,2-dimethylpropanamido)benzene did not show mutagenic potential in bacteria and in mammalian cells *in vitro*. It did not induce chromosome aberrations *in vitro* or micronuclei in bone marrow cells *in vivo*. Based on the genotoxicity tests performed, there is no evidence for a genotoxic potential of 1,3,5-tris(2,2-dimethylpropanamido)benzene.

Conclusion: Based on the above-mentioned data the substance is classified:
SCF_List: 3
Restriction: 0.05 mg/kg food
 Remark for Commission:
 Needed data or information None

References: - Unpublished data submitted by the petitioner, March 2006

SCIENTIFIC PANEL MEMBERS

Fernando Aguilar, Herman Autrup, Sue Barlow, Laurence Castle, Riccardo Crebelli, Wolfgang Dekant, Karl-Heinz Engel, Nathalie Gontard, David Gott, Sandro Grilli, Rainer Gürtler, John Christian Larsen, Jean-Charles Leblanc, Catherine Leclercq, François Xavier Malcata, Wim Mennes, Maria Rosaria Milana, Iona Pratt, Ivonne Rietjens, Paul Tobback, Fidel Toldrá.

ACKNOWLEDGEMENTS

The Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food wishes to thank M.-L. Binderup, A. Feigenbaum, B.E.B. Moseley, A.K. Müller, M.A.H. Rijk, S. Rossi, T.G. Siere, A.A.M. Stolker for their contribution to the draft opinion.

List of abbreviations:

bw Body weight
 D Dalton
 MW Molecular weight
 NOAEL No observed adverse effect level
 SML Specific migration limit
 TDI Tolerable daily intake

APPENDIX

DEFINITION OF THE SCF LISTS

The classification into a SCF_List is a tool used for tackling authorisation dossiers and do not prejudice the management decisions that will be taken on the basis of the scientific opinions of the AFC Panel and in the framework of the applicable legislation.

- List 0** Substances, e.g. foods, which may be used in the production of plastic materials and articles, e.g. food ingredients and certain substances known from the intermediate metabolism in man and for which an ADI need not be established for this purpose.
- List 1** Substances, e.g. food additives, for which an ADI (=Acceptable Daily Intake), a t-ADI (=temporary ADI), a MTDI (=Maximum Tolerable Daily Intake), a PMTDI (=Provisional Maximum Tolerable Daily Intake), a PTWI (=Provisional Tolerable Weekly Intake) or the classification "acceptable" has been established by this Committee or by JECFA.
- List 2** Substances for which this Committee has established a TDI or a t-TDI.
- List 3** Substances for which an ADI or a TDI could not be established, but where the present use could be accepted.
Some of these substances are self-limiting because of their organoleptic properties or are volatile and therefore unlikely to be present in the finished product. For other substances with very low migration, a TDI has not been set but the maximum level to be used in any packaging material or a specific limit of migration is stated. This is because the available toxicological data would give a TDI, which allows that a specific limit of migration or a composition limit could be fixed at levels very much higher than the maximum likely intakes arising from present uses of the additive.
Depending on the available toxicological studies a restriction of migration into food of 0.05 mg/kg of food (3 mutagenicity studies only) or 5 mg/kg of food (3 mutagenicity studies plus 90-day oral toxicity study and data to demonstrate the absence of potential for bio-accumulation in man) may be allocated.
- List 4** (for monomers)
- 4A** Substances for which an ADI or TDI could not be established, but which could be used if the substance migrating into foods or in food simulants is not detectable by an agreed sensitive method.
- 4B** Substances for which an ADI or TDI could not be established, but which could be used if the levels of monomer residues in materials and articles intended to come into contact with foodstuffs are reduced as much as possible.
- List 4** (for additives)
- Substances for which an ADI or TDI could not be established, but which could be used if the substance migrating into foods or in food simulants is not detectable by an agreed sensitive method.
- List 5** Substances that should not be used.

- List 6** Substances for which there exist suspicions about their toxicity and for which data are lacking or are insufficient.
The allocation of substances to this list is mainly based upon similarity of structure with that of chemical substances already evaluated or known to have functional groups that indicate carcinogenic or other severe toxic properties.
- 6A** Substances suspected to have carcinogenic properties. These substances should not be detectable in foods or in food simulants by an appropriate sensitive method for each substance.
- 6B** Substances suspected to have toxic properties (other than carcinogenic). Restrictions may be indicated.
- List 7** Substances for which some toxicological data exist, but for which an ADI or a TDI could not be established. The required additional information should be furnished.
- List 8** Substances for which no or only scanty and inadequate data were available.
- List 9** Substances and groups of substances which could not be evaluated due to lack of specifications (substances) or to lack of adequate description (groups of substances).
Groups of substances should be replaced, where possible, by individual substances actually in use. Polymers for which the data on identity specified in "SCF Guidelines" are not available.
- List W** "Waiting list". Substances not yet included in the Community lists, as they should be considered "new" substances, i.e. substances never approved at national level. These substances cannot be included in the Community lists, lacking the data requested by the Committee.

Case study: Plasticisers for human contact applications

**Plasticisers 2008
29-30 January
Brussels, Belgium**

Product Safety –
safe products,
safe business

BASF

The Chemical Company

Dr. Rainer Otter

- Plasticisers – generic aspects
- Toys
- Exploring toxicity and performance
- Do alternative plasticisers require reformulation
- What do I have to consider when changing the plasticiser
- Possible effects on finished products
- Conclusions



Plasticisers – public image

Product Safety –
safe products,
safe business

 **BASF**
The Chemical Company

- „Phthalates“ in general are used as synonym for plasticisers
- Key substances with specific properties are referred to
 - DEHP, DBP and BBP
 - Only phthalates, where the longest linear chain of the alcohol is between C4 and C6 show reproductive toxicity in animal studies
- Emotional discussion, science often seems to be just ignored
- Worst case scenarios are referred to
- Precautionary principle propagated as guidance for regulatory action

Plasticisers - general aspects

Product Safety –
safe products,
safe business

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The Chemical Company

- Plasticiser content may reach 40 per cent per weight in soft PVC articles
- Plasticisers are not covalently bonded into the polymer matrix
 - Migration is a common issue for plasticisers
- Plasticisers of different structural classes are available
 - Migration tendency depends on molecular weight and structure of the plasticiser
- Plasticisers are lipophilic
 - Migration into specific media (e.g. fatty food, saliva)
- The availability of toxicological data varies
 - Risk assessment requires hazard and exposure data

Phthalates and toys

Product Safety –
safe products,
safe business

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The Chemical Company

- Issue started in 1997
- Emergency ban (1999/815/EC, Dec. 1999) based on Council directive 92/59/EEC
 - Toys and childcare articles intended to be placed in the mouth by children of less than 3 years of age
 - DINP, DEHP, DNOP, DIDP, BBP, DBP content < 0,1 %
- Permanent restriction by directive 2005/84/EC, 22nd amendment of 76/769/EEC
 - DEHP, DBP and BBP shall not be used
 - DINP, DIDP and DNOP shall not be used, if article can be mouthed by children

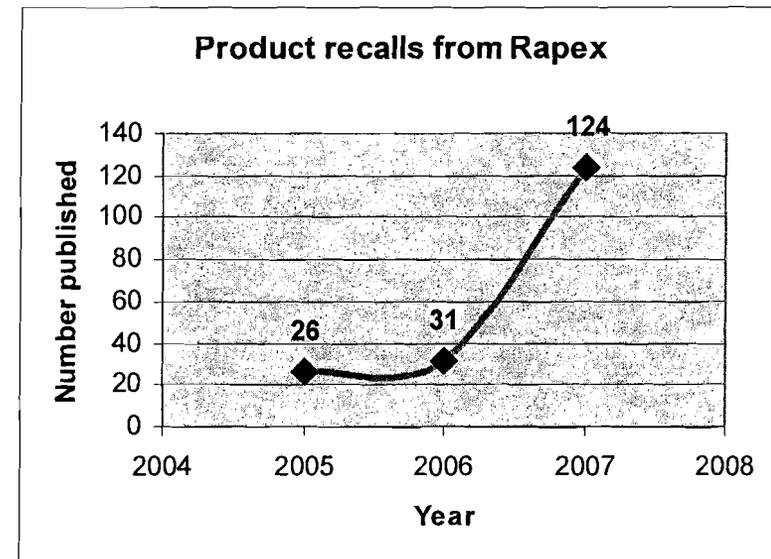
Directive 2005/84/EEC

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- By 16 July 2006 Member States shall adopt and publish the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith inform the Commission thereof.
- They shall apply these measures from **16 January 2007**.

■ Rapex – EU's rapid alert system



Source: http://ec.europa.eu/consumers/dyna/rapex/create_rapex_search.cfm
Product recalls or voluntary withdrawals from market based on phthalate content

Market demand for a substitute

Product Safety –
safe products,
safe business

 **BASF**
The Chemical Company

- The market needs alternatives to meet the regulatory requirements
- What are the key parameters a putative substitute has to meet?
 - Technical requirements
 - Percieved market opportunities by singularity
 - Security of supply

 - Risk assessment should be provided
 - Third party/regulatory opinions are helpful
 - Regulatory requirements

Hexamoll®DINCH – technical properties

Product Safety –
safe products,
safe business

 **BASF**
The Chemical Company

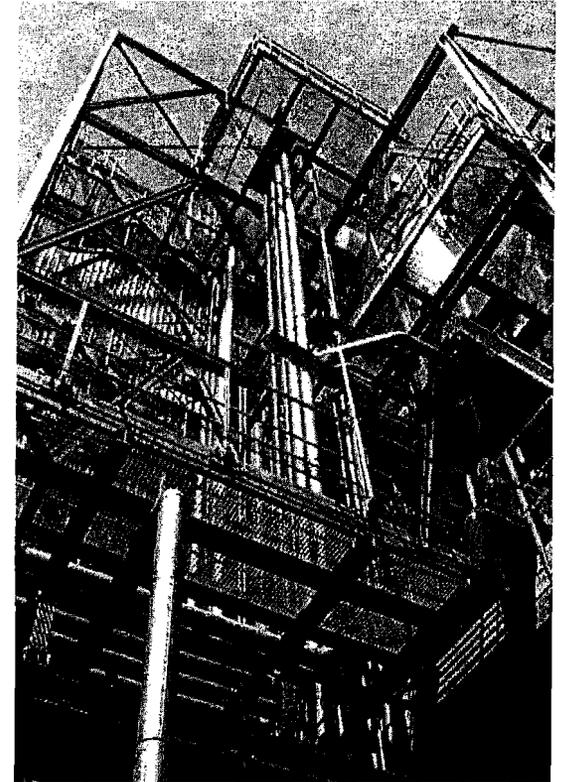
- Specific gravity lower than DEHP
- Plasticiser efficiency slightly lower than DEHP
- Plastisol viscosity lower
- Gelation temperature slightly higher than DEHP
 - Customers report that this is not relevant
- Improved cold flexibility
- Lower migration as compared to other plasticisers
- Meeting requirements of 76/769/EEC
- Customer feedback → Overall an acceptable monomeric plasticiser which is miscible and compatible with other plasticisers

Hexamoll®DINCH – availability

Product Safety –
safe products,
safe business

 **BASF**
The Chemical Company

- Production in Ludwigshafen/Germany
- Starting materials and full production process under own quality control
- Production plant annual capacity expanded from 25 kt to 100 kt/year since 2007
- Worldwide availability based on BASF logistics support concept



■ Technical applications

- Human exposure is assumed to be low by intended use, e.g.
 - Wire and cable
 - Flooring
 - Car undercoating

■ Sensitive applications

- Human exposure is related to the intended use, e.g.
 - Food contact
 - Medical applications
 - Toys

Hexamoll® DINCH – database

Product Safety –
safe products,
safe business

 **BASF**
The Chemical Company

■ Environmental hazards	NO
■ Peroxisome proliferation	NO
■ Reproductive hazard	NO
● Testicular toxicity	NO
● Impairment of fertility	NO
● Developmental toxicity	NO
● Teratogenicity	NO
● Endocrine action	NO
■ Accumulation within the body	NO
■ Carcinogenicity	NO

Hexamoll®DINCH especially qualified for sensitive applications

Product Safety –
safe products,
safe business



- Complete set of regulatory studies regarding physico-chemical, ecotoxicological and toxicological studies available
- All studies have been conducted with the last years according to the most recent versions of the OECD/EU testing guidelines
- Hexamoll®DINCH is the only plasticiser successfully tested regarding developmental toxicity in a rodent and a non-rodent species, i.e. absence of any adverse substance related effect
- External study reviews during the notification processes and by EU's EFSA and SCENIHR
- Specific regulatory requirements can be met

■ EU

- DINCH notified according to new chemicals legislation and listed in ELINCS

– Therefore according to article 24 of REACH:

„A notification in accordance with Directive 67/548/EEC shall be regarded as a registration for the purposes of this Title and the Agency shall assign a registration number by 1 December 2008.“

➔ ready for REACH

■ Worldwide availability

- DINCH listed in all national chemical inventories

Food contact requirements

Product Safety –
safe products,
safe business

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The Chemical Company

- Migration studies regarding food contact applications (85/572/EEC) and toys (head-over heels, TNO, JRC) have been undertaken
- Listed in 4th amendment of 2002/72/EC (2007/19/EC) Annexes III (no specific migration limit) and IVa(full fat reduction factor)
- **EFSA has set the TDI to:**
 - **1 mg/kg bw/day**
[http://www.efsa.europa.eu/en/science/afc/afc_opinions/ej395-401_12FCM_list.html]
- Listed in German BfR plastics recommendations

Published migration data

[http://www.efsa.europa.eu/en/science/afc/afc_opinions/ej395-401_12FCM_list.html]

Product Safety –
safe products,
safe business

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- Migration test method available
- PVC-Cling films containing different amounts of DINCH
 - Migration into different foods:
 - Very low solubility in water and acetic acid: <<< 0,1 mg/l
 - Low migration into non-alcoholic and alcoholic beverages
e.g. solubility in 15 % ethanol: ca. 0,1 mg/l
also recommended for artificial wine corks
- Fresh meat packaging
- Very low migration from polystyrene matrix

Hexamoll®DINCH – toys

Product Safety –
safe products,
safe business



- Technical suitability proven
- Compliant with directive 76/769/EEC and EN 71-3, 71-5, 71-9
- Low migration confirmed by customer products

Comparison of migration according to CSTE model: Child with a body weight of 8 kg, mouthing for 180 minutes						
Plasticiser	Migration [µg/min/10 cm ²]	Time [min.]	Total [µg]	Dose [µg/kg bw.]	NOAEL [mg/kg bw.]	Margin of Safety (MOS)
ATBC ¹⁾	10,1	180	1818	227,3	100	440
DINCH ²⁾	0,35	180	63	7,9	107	13587

¹⁾ data taken from CSTE opinion (CSTE-OP/08.01.2004)
²⁾ data taken from LGA Nuernberg, Germany, migration study contracted by a customer of BASF

NOAEL's taken from published EFSA Opinions

- Hexamoll®DINCH - the first choice for toy producers

Migration into enteral nutrition fluids

Product Safety –
safe products,
safe business

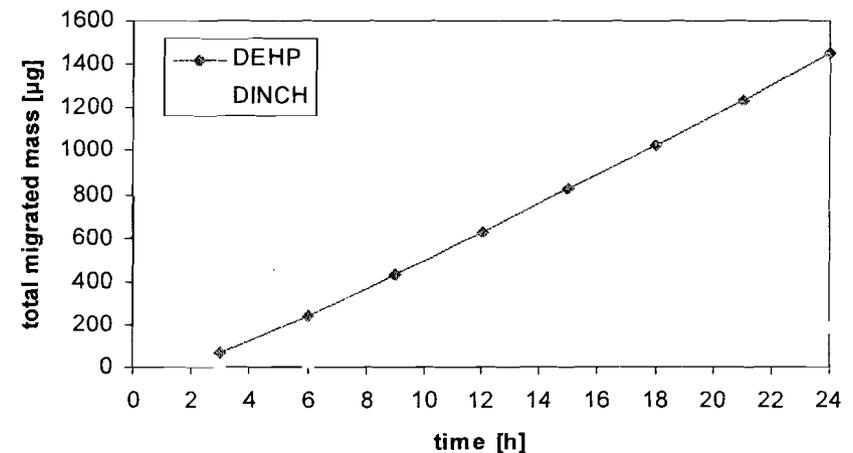
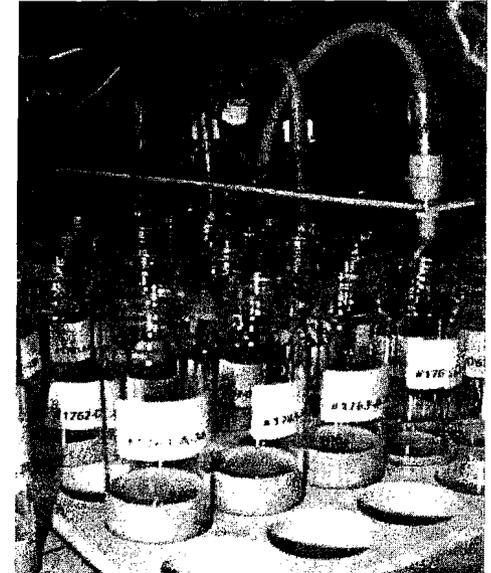
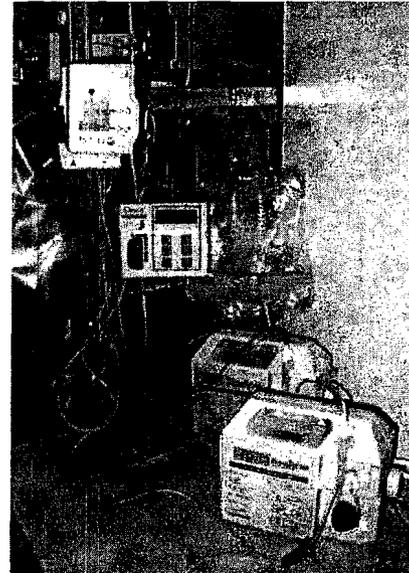
 **BASF**
The Chemical Company

■ Nutrition fluids

- Nutrison Energy, 5,8 % fat
- Nutrison Nenatal, 4,4 % fat
- Nutrison Concen., 10,0 % fat

■ Different commercial application systems

■ 8fold lower migration of DINCH as compared to DEHP

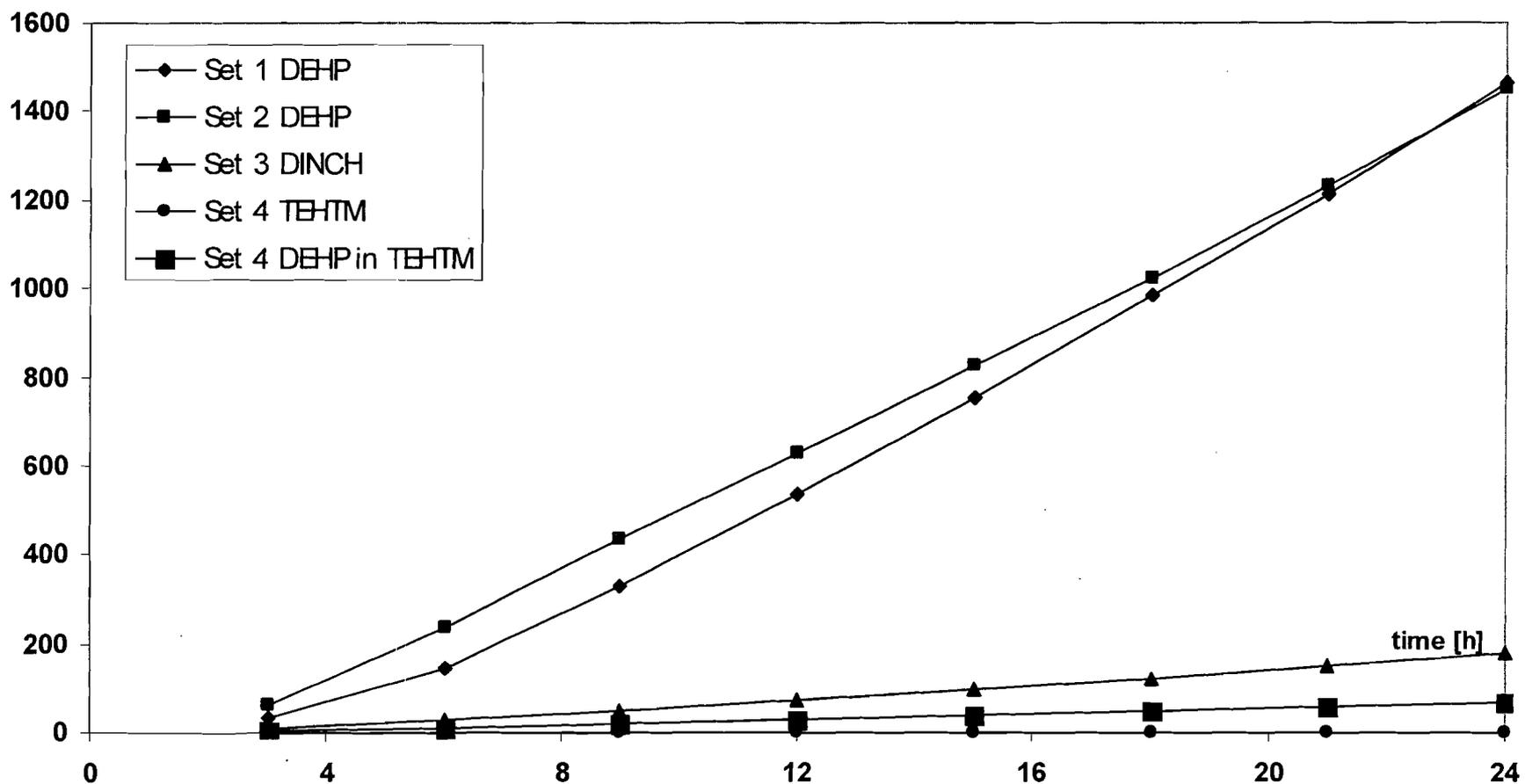


Plasticiser migration into enteral nutrition

Product Safety –
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cumulated amount plasticiser in solution [μg]



Cumulative migration of plasticizers into feeding solution B (4.4% fat) under real application conditions (total duration of the experiments

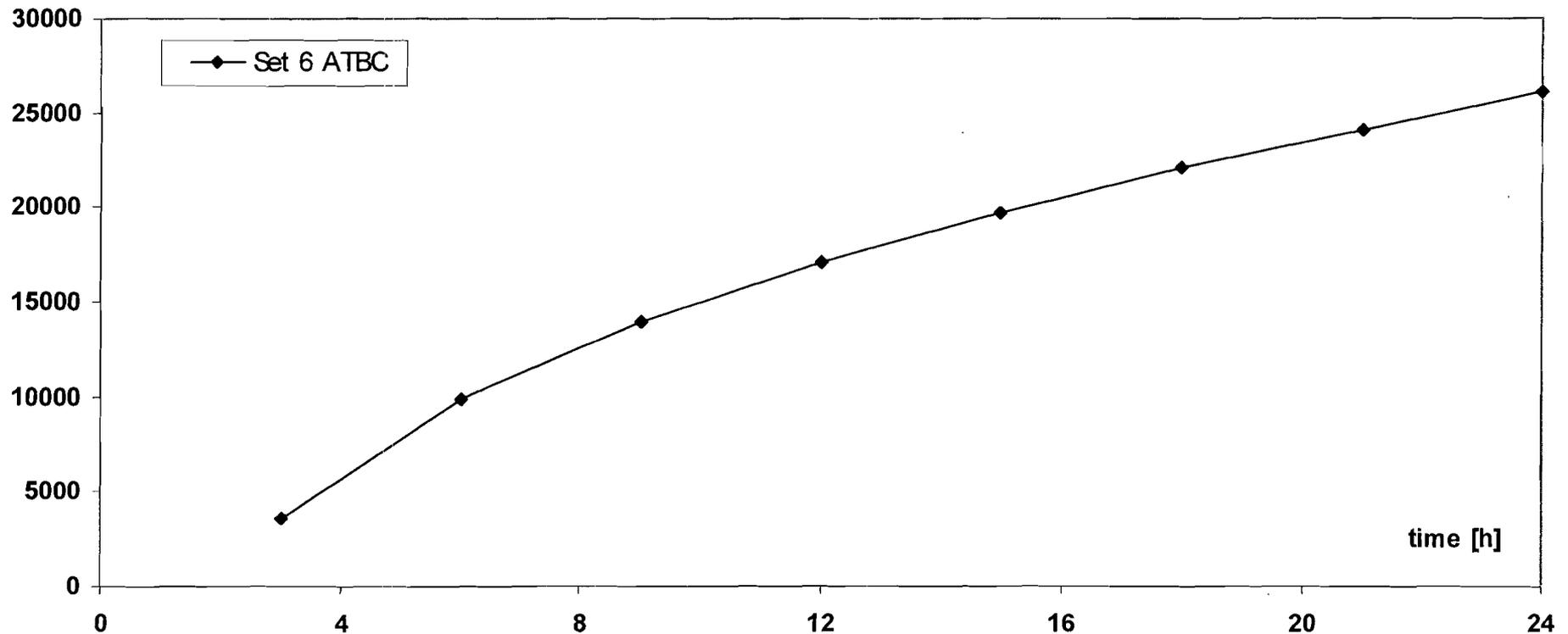
24 h, room temperature, feed rate 5 ml h^{-1})

Plasticiser migration into enteral nutrition

Product Safety –
safe products,
safe business

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The Chemical Company

cumulated amount plasticiser in solution [μg]



Cumulative migration of ATBC into feeding solution B (4.4% fat) from set 6 under real application conditions (total duration of the experiment 24 h, room temperature, flow rate 5 ml h^{-1}) (please note other scaling of y-axis!)

Patient exposure for a neonate

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The Chemical Company

Plasticizer used for device	24 h Migration [µg]	Dose ³⁾ [mg/kg bw./day]	TDI (EFSA) [mg/kg bw./day]	Dose/TDI
DEHP ¹⁾	1400	0,93	0,025	37,3
TEHTM	< 5	n.a.	n.a.	
DEHP 2)	70	0,05	0,025	1,9
DINCH	180	0,12	1	0,1
ATBC	25000	16,67	1	16,7

1) 2002/72/EC, 4th Amendment

2) Impurity in TEHTM

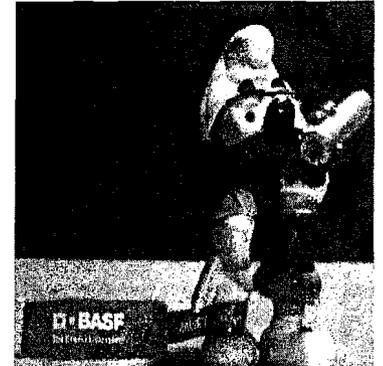
3) 24 h Migration, 1,5 kg body weight

Changing over to a new plasticiser

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safe business

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- In most cases there were no problems at all
 - Careful preparation of changeover by customer with the support of our application technologists
 - Cleaning of storage tanks and production hardware before changing to new product
 - Avoid cross contamination in your production
 - Plastisol producer
 - Raw material suppliers (stabilizer, PVC, pigments or colours and dyes)
- In some specific cases our application specialists adapted the production parameters together with the customer

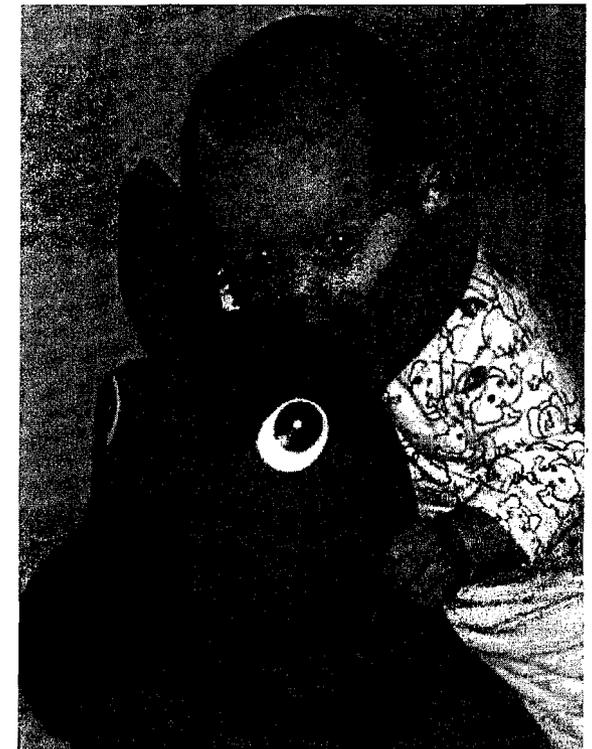


Effects on end products

Product Safety –
safe products,
safe business

 **BASF**
The Chemical Company

- Hexamoll®DINCH results in an **improved cold flexibility**
- UV-stability of films has been shown in a specific setup where yellowing/darkening of the films was found to be reduced
 - relevance of this advantage not yet comprehensively studied
- **Pleasant surface feeling/haptics**
- **Cling films are perceived to cling better**
- **Printability**
 - Some customers reported problems that could be solved, for others this wasn't an issue



Hexamoll® DINCH - success factors

Product Safety –
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safe business

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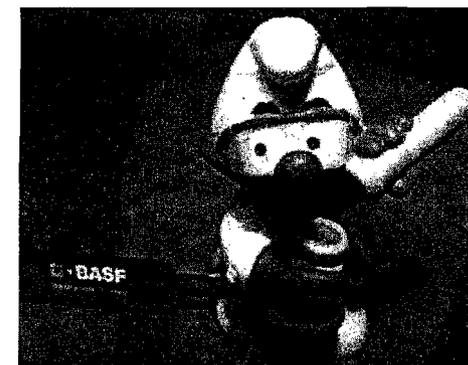
- Broad database with regard to toxicological and ecological data
- Joint projects with customers and their customers
 - Toys
 - Food contact
 - Medical applications
- Safeguarding of investment
 - Customers are enabled to further use existing equipment
 - Customers benefit from their know-how in the PVC polymer

Hexamoll®DINCH – summary

Product Safety –
safe products,
safe business

 **BASF**
The Chemical Company

- With Hexamoll®DINCH, we provide the market with a viable alternative plasticiser
- For this plasticiser the whole toxicological and ecological profile is available and is downloadable from e.g. the EFSA website
- Applications are developed in cooperation with our customers
 - Safety of the applications can be demonstrated
- With Hexamoll®DINCH – our customers are well prepared for the future





31

UNION INK COMPANY, INC.

453 BROAD AVENUE • RIDGEFIELD, NJ 07657 • 201-945-5766 • TOLL FREE • 800-526-0455 FAX 201-945-4111

January 9, 2009

To Whom It May Concern:

Phthalates:

Union Ink Company states that our Screen Print Plastisols do not contain Di-2-Ethyhexyl Phthalate (DEHP), CAS Reg. No. 117-81-7.

Union Ink Screen Print Plastisols contain phthalates at levels >1%, with the exception of the Phthalate Free line of plastisols.

Heavy Metals:

The Union Ink Company discontinued purchasing raw materials which contained heavy metals (lead, mercury, cadmium and hexavalent chromium) before the end of 1990. We have requested that our suppliers of metal containers ship us only containers which use no lead solder.

This is to certify that the Union Ink Company does not intentionally nor willingly use any raw materials nor add any materials to its packaging or labels or to the inks it supplies for packaging or labels which contain heavy metals (lead, mercury, cadmium and hexavalent chromium). We have requested that all of our suppliers certify to us that all materials they are furnishing us conform to these standards. Nor is there any latex products in any of our non-water based inks.

Based on representation to us by the suppliers of the materials we use to manufacture inks we ship to you, the inks should contain either no lead compounds or should contain lead compounds in such a quantity that the dried coating film of our product will have a lead content (calculated as the metal) not in excess of 0.06 percent of the total weight of the dried coated film.

Therefore, all of our inks should comply with the Consumer Product Safety Act, Title 16 of the United States Code of Federal Regulations Section 1303.1 (a) (1).



UNION INK COMPANY, INC.

453 BROAD AVENUE•RIDGEFIELD, NJ 07657•201-945-5766•TOLL FREE•800-526-0455 FAX 201-945-4111

Moreover, we are only using in our "Lead-Free" Inks those materials which our suppliers state to us have less than .06% of the following heavy metals and therefore should comply with the requirements of ASTM F963 regarding the following heavy metals:

Mercury	Selenium
Cadmium	Arsenic
Antimony	Barium (water-soluble)-1%.
Chromium (hexavalent)	

Our suppliers certify to us only on representative batches and do not guarantee each individual shipment.

Therefore, we recommend that your laboratory test the individual batches shipped if an absolute determination is required.

Sincerely yours,
UNION INK COMPANY, INC.

A handwritten signature in black ink, appearing to read "Richard Labov". The signature is written in a cursive, flowing style.

Richard Labov
Chairman

Stevenson, Todd

From: Jim Cronin [jcronin@emt.com]
Sent: Friday, January 09, 2009 5:42 PM
To: Phthalates Project
Subject: Suitable testing methods

Categories: Technical comment

Hello,

I work for an accredited CPSC laboratory which has been providing environmental analyses to our Clients since 1984. I would like to comment on allowing labs the ability to have several testing option to determine the analytes of concern.

With regard to phthalates, EPA SW-846 8270 is a credible, repeatable and well know method that can determine individual phthalates by GC/MS.

Most methods, whether ASTM, EPA, ISO or EN, are very similar. For instance, determining total lead (Pb) content can be achieved by ASTM 1645/1613, EPA SW-846 3050/6010 and IEC 62321 chapter 8 by hotblock digestion and analysis by ICP-AES.

I believe that allowing different methods that provide the same type of analytical testing should be allowed with every analyte the CPSC determines as a substance of concern.

Lastly, EMT is available to participate in round robin testing and is interested in assisting the CPSC in any capacity.

Thank you,

Jim Cronin
Product Ecology Manager
Direct: 847-324-3307 | Cell: 630-816-1126 | Fax: 847-967-6735
jcronin@emt.com

EMT, Inc | www.emt.com
ISO/IEC 17025:2005



Please consider the environment before printing this e-mail. Thank you!

Stevenson, Todd

From: Christine Richard [canefarm@charter.net]
Sent: Saturday, January 10, 2009 2:48 PM
To: Phthalates Project
Subject: Section 108: Phthalates in Children's Products

I am writing this email because I believe that H.R. 4040, also known as CPSIA (Consumer Product Safety Information Act) will be a detriment to the public at large if not amended to exclude children's books. It will affectively make unavailable to the masses all of the wonderful, collectable children's stories and picture books that were printed before the date of February 10, 2009. It will also force out of business all of those small businesses that produce items marketed to children 12 and under unless each item is tested for and proven to be free of phthalates.

Particularly of concern to me is the area of used booksellers, as this is my profession. The cost of testing is prohibitive and will be impossible for me to afford for each book intended for resale. Also important to note is that the testing actually destroys the product, an obvious problem for those of us who will likely only have one of each title in the first place.

Please lend your support to the amending of this law.

Christine D. Richard
Books From the Bayou



Polymer Diagnostics Inc.

33587 Walker Road
Avon Lake, OH 44012
Phone: 800-438-2335
FAX: 440-930-1644

34

Fax

To: ^{CPSC} Office of Secretary From: James Isner

Phone: Phone: 440 930-1605

Fax: 301 504-0127 Date: 1/12/09

cc: Number Pages including cover sheet: 3

Urgent For Review Please Comment Please Reply Please Recycle

RE:

Office of the Secretary
Consumer Product Safety Commission
Room 502, 4330 East-West Highway
Bethesda, MD 20814.

Dear CPSC Secretary,

Polymer Diagnostics Inc., (PDI) would like to submit the attached comments for your review, concerning the "Measurement of Phthalates in Children's Products", as outlined in the recent CPSC document,

**Section 108 of the Consumer Product Safety Improvement Act (CPSIA),
"PROHIBITION ON
SALE OF CERTAIN PRODUCTS CONTAINING SPECIFIED PHTHALATES"**

In the attachment, PDI analytical chemist, Dr. David Ernes, comments on issues involved in making such measurements and also offers a *Suggested Analytical Approach*.

Finally, I support Dr. Ernes's offer for Polymer Diagnostics Inc. to participate in any round robin evaluation of the final protocol, and to be considered in any certification program that is developed as a third-party laboratory.

Thank you for your consideration and please contact me if you have any questions concerning these comments.

Sincerely,

James D. Isner
Vice President
Polymer Diagnostics Inc.
(440) 930-1605
isnerj@polymerdiagnostics.com

January 10, 2009

Prohibition of the Sale of Certain Products Containing Specified Phthalates
Section 108 of Consumer Product Safety Improvement Act
Request for Comments and Information

The above titled document requested comments concerning several aspects of the pending requirements. I am currently working on refinements to a method to be used to determine the level of the six phthalates in products intended for children's articles. Although this effort is not yet finalized, my work in this area has revealed several issues that should be addressed in any final protocol adopted for the analysis.

Historical method: Most of the documents that I have seen reference ASTM D3421-75 "Extraction and Determination of Plasticizer Mixtures from Vinyl Chloride Plastics". This method was discontinued by the ASTM about 20 years ago. It specifies technologies that are no longer practiced in most modern analytical labs (e.g. packed column gas chromatography [GC]). Therefore, it is apparent that a new method is required. It appears that most labs are utilizing soxhlet extraction followed by gas chromatography - mass spectrometry [GC-MS] for analysis.

Round Robin Testing: Although I have not participated in any round robin testing, we have on occasion had the same sample analyzed by several labs. One such data set is shown below. These were done by labs already accredited.

Lab #	DINP	DEHP	DnOP	DIDP	BBP	DBP
#1	516	n/d	140	n/d	300	n/d
#2	n/d	n/d	130	n/d	290	n/d
#3	n/d	n/d	160	n/d	370	n/d

The data clearly shows that there is an issue with the analysis for DINP. It is not clear which lab accurately reflects the level of DINP, but it does point out the need for standardization.

Sample Form: As I stated, many labs utilize soxhlet extraction. In addition to the final product (i.e. toy / article / etc), there is often a need to analyze the raw materials (e.g. non-phthalate plasticizers), compound pellets, as well as liquid colorants and semi-liquid inks. Soxhlet extraction would not be the optimum method for sample preparation with liquid samples. Provisions should be made to allow for modification to the method based on these sample forms.

Plasticizer Identification: Four of the six banned phthalates (DBP, BBP, DEHP, and DnOP) are single components with a single defined structure. In the case of DINP and DIDP, these are blends of several isomers resulting in a complex chromatogram. No single structure represents these commercial products. In addition, there exist several commercial products which are designated as "DINP", but which have structural and characterizable differences when analyzed by appropriate techniques (e.g. nuclear magnetic resonance). They also have slightly different elution profiles when examined using chromatographic techniques. Each, however, yields a mass spectrum consistent with a di-nonyl phthalate. They would also elute in the same window as DINP. It would be helpful to have the regulation specifically describe what is considered to be DINP. This could also hold true for DIDP as well

Interferences: There are many instances for interferences especially at low detection limits where low level impurities begin to appear. Some of these can be corrected for by the use of GC-MS. However, I have encountered some instances where a component in the product will prevent the determination of one or more of the phthalates of interest even with the use of GC-MS. Most labs use fast run times to improve

throughput (and thus cost-effectiveness). The potential for false positives can exist when resolution is collapsed. Some provision needs to be made to resolve these situations. There are other cases where an additive in the formulation masks the detection of one or more of the phthalates, even with the use of conventional GC-MS. How this is addressed must be within the scope of the analytical protocol eventually adopted.

Screening test method: There was an interest in a screening method. Most, but not all phthalates, are in poly(vinyl chloride) based products. As such, poly(vinyl chloride)'s solubility parameters would suggest a fast method for screening. The sample would first be dissolved in tetrahydrofuran [THF]. To the solution would be added a poor solvent to precipitate the polymer – such as acetonitrile or methanol. The resulting solution could then be analyzed by GC-MS.

Suggested Analytical approach: Based on the work that I have been conducting, I believe that the analysis of children's toys, articles, and products intended for those markets should be analyzed in a series of steps.

1. First, the screening method (dissolve / reprecipitate followed by GC-MS) should be conducted. It is likely that for most cases, this approach would yield acceptable results without significant issues. GC-MS parameters should be done to utilize multiple ions and verify that the relative ratios are in line with the standard.
2. If the screen reveals any positive results for phthalates, but the ion ratios do not match, a potential interference would be suspected. This could be addressed in multiple ways. First, the full spectral data should be examined to insure that the peak is the component of interest. Next, the chromatographic conditions should be altered to resolve the interfering component from the expected retention time for the phthalate of interest. Thirdly, an alternative technique (e.g. liquid chromatography [LC]) could be evaluated.
3. Soxhlet extraction is time consuming, and requires close attention to the cleanliness of the glassware. I would suggest that soxhlet be evaluated with the dissolve / reprecipitate approach before one defaults to the more time consuming soxhlet.

Finally, I would like to offer Polymer Diagnostics Inc. to participate in any round robin evaluation of the final protocol. We would also like to be considered in any certification program that is developed as a third-party laboratory. PDI is currently accredited by A2LA and an analysis for plasticizer determination in poly(vinyl chloride) compounds is included on our scope of accreditation.

David A. Ernes, Ph.D.
Polymer Diagnostics Inc.
ernesd@polymerdiagnostics.com



Toy Industry Association, Inc.

January 12, 2009

Cheryl Falvey, General Counsel
Office of the General Counsel
U.S. Consumer Product Safety Commission
4330 East West Highway
Bethesda, MD 20814

Gib Mullan, Assistant Executive Director
Office of Compliance and Field Operations

Comments on Section 108's Phthalate Requirements for Certain Toys and Child Care Articles

In response to the request of the Commission's staff, the Toy Industry Association Inc. ("TIA") submits the following initial comments on Section 108 of the Consumer Product Safety Improvement Act of 2008 ("CPSIA"), which prohibits the sale of certain products containing specified phthalates. TIA hopes that these comments will assist the Commission in implementing, efficiently and effectively, regulations that will for the first time govern the use of phthalates in certain children's products in the United States. Because these issues are important to the TIA's 500 members and of first impression, and comments are being requested before the Commission holds its first public information session concerning phthalates, TIA reserves the right to supplement or amend its comments as appropriate.

These comments first identify materials used by TIA members that may contain phthalates and those that do not. We then explain why and how the Commission should interpret, apply, or clarify subsection 108(b)'s requirements, consistent with that subsection's focus on eliminating any reasonable possibility that a child will be exposed to any measurable amount of the specified phthalates by mouthing, the overwhelmingly predominant exposure pathway. We conclude by providing two additional categories of information that the staff requested: available testing protocols and newer publications regarding phthalates.

I. PHTHALATES IN MATERIALS

A. Materials That May Include Phthalate Plasticizers, and Thus Merit Testing.

As the Commission is aware, phthalates are a group of widely used chemicals most known for being added to polyvinyl chloride (PVC) to soften it and make it flexible.¹ Part of the staff's request seeks information concerning materials currently used in children's toys and child care articles that may contain phthalate plasticizers subject to the requirements of Section 108. In the experience of the members of TIA, those materials are the following: PVC (polyvinyl

¹ E.g., Dr. Marilyn Wind, Deputy Assoc. Exec. Dir. for Health Sciences, U.S. Consumer Product Safety Comm'n, *Testimony before the Subcomm. on Consumer Affairs, Ins. and Auto. Safety 1* (May 14, 2008); Congressional Research Service, "Phthalates in Plastics and Possible Human Health Effects" 2 (July 29, 2008).

chloride), PVDC (polyvinylidene chloride), synthetic rubber, cellulose, adhesives and glues, polyurethane, surface coatings applied to flexible substrates, and foamed plastics.

B. Materials That Do Not Inherently Contain Plasticizers, and Thus Do Not Merit Testing.

On the other hand, materials such as natural fabrics, wood, metals, and ceramics have no potential to include phthalate plasticizers. Additionally, a variety of plastic materials other than those enumerated above do not generally contain phthalates. As opposed to lead “contaminants,” phthalates are intentionally added as part of the formulation and function of specific plastics to provide softness and flexibility. They are not added as part of the formulation of the following materials, and if added they would reduce the integrity of such materials: styrene, ABS, polypropylene, polyethylene, and polyoxymethylene.

To avoid unnecessary, burdensome expensive material testing, it is essential for the CPSC staff to specify materials that do not contain phthalate additives and exclude them from testing and certification requirements under Section 102. This is a consistent approach to that taken with other substances. For example, the CPSC staff has reasonably determined that if paint is not used there is no requirement to perform lead in paint testing.

II. THE COMMISSION SHOULD CLARIFY THE SCOPE AND APPLICABILITY OF SECTION 108’S REQUIREMENTS, PARTICULARLY REGARDING THE PHTHALATES SUBJECT TO SECTION 108(B)’S INTERIM PROHIBITION.

Section 108 regulates the use in certain children’s products of six specified phthalates, which the statute treats in two groups of three phthalates each. The first group consists of the phthalates known as DEHP, DBP, and BBP. Section 108(a) makes it unlawful for a children’s toy or child care article to “contain[] concentrations of more than 0.1 percent” of any of these three. This restriction is permanent. A “children’s toy” is defined as “a consumer product designed or intended by the manufacturer for a child 12 years of age or younger *for use by the child when the child plays.*” § 108(e)(1)(B) (emphasis added). This definition amounts to the definition of “children’s product” in Section 235(a) plus the italicized phrase. A “child care article” is defined as “a consumer product designed or intended by the manufacturer to *facilitate* sleep or the feeding of children age 3 and younger, or to help such children with sucking and teething.” § 108(e)(1)(C) (emphasis added).

The second group of regulated phthalates consists of those known as DINP, DIDP, and DnOP. DINP has been widely used in recent years as a substitute for DEHP. It is unlawful under Section 108(b)(1) for a “children’s toy that can be placed in a child’s mouth or child care article” to “contain[] concentrations of more than 0.1 percent” of each of these. This restriction is interim, pending the creation and report of a Chronic Hazard Advisory Panel and the Commission’s promulgation of a rule in response to the Panel’s report. § 108(b)(2)&(3). The applicable definitions of “children’s toy” and “child care article” are the same as for the first group, but the restriction regarding a children’s toy is expressly limited to a toy “that can be placed in a child’s mouth.” Section 108(e)(2)(B) defines this quoted phrase.

A. Section 108, Particularly 108(b), is Generally Concerned With Risks of Children’s Exposure to the Specified Phthalates, Not Mere Use of a Product that Contains Such Phthalates.

There are several reasons that the Commission, at least in applying Section 108(b)’s interim prohibitions on DINP, DIDP, and DnOP, may and should, consistent with the statutory text and its authority under *Chevron*, consider the potential for exposure of a child to phthalates from a toy or article. First, this is the overarching concern of Section 108(b) itself. The Chronic Hazard Advisory Panel mandated by Section 108(b)(2), whose report will play a large role in determining the future of these interim prohibitions, must consider “the likely level of . . . exposure to phthalates, based on a reasonable estimation of normal and foreseeable use and abuse of” products for children. § 108(b)(2)(B). It also must consider “the cumulative effect of total exposure to phthalates.” *Id.* And it specifically must consider “ingestion,” “dermal,” and “hand-to-mouth” exposure, as well as any “other exposure.” *Id.* Finally, the Panel is to take into account “uncertainties regarding exposure.” *Id.*

Second, the statutory definitions of “children’s toy” and “child care article” reinforce this overarching concern of Section 108 with exposure. A “children’s toy” is a product designed or intended for “*use by the child*” when the child plays. “Use” indicates contact, which is a potential source of exposure. The definition of “child care article” is even narrower. It does not extend to all use of the product by a child three years or younger; rather, such use must directly facilitate sleep, feeding, sucking, or teething. A product to “help” a child “with sucking or teething” will be one on which a child sucks or teethes—creating a particular risk of exposure. A plain reading indicates that the activities referenced involve mouthing behavior as a pre-requisite. That is why the Commission’s prior efforts regarding phthalates, as far back as the 1980s, have focused on teethers, rattles, and pacifiers—all items that a child puts in his mouth.² Similarly, the statutory reference to a product designed or intended “to facilitate sleep or the feeding of” a young child (including a pacifier) is most reasonably understood as one that the child will use for that purpose, meaning that he will come into contact with it.

As an example, nothing in the text or in reason requires applying the phthalate restriction to a plasticized anti-skid floor protector on the bottom of a high chair, or the seating material, even though a child uses the high chair when eating. The requirement that the product actually “facilitate” the activity indicates a narrower requirement than “use” of the product. Obviously a plain reading of the language indicates that Congress intended a causal relationship between the product and the activity that results in sleep, feeding, or aid in sucking and teething. This requirement requires more than mere “use” of the product. This is why use alone should be an insufficient basis for subjecting a child care product to these requirements.

In addition, when product accessories or incidental packaging do not even involve use in the primary regulated activity, such materials should be excluded from the scope of the standard. That is presumably why the staff’s FAQs for § 108 give the following explanation for why the phthalates restrictions generally do not apply to packaging: “Packing is generally not intended for use by children when they play, given that most packaging is discarded, and *is not used or played with as a children’s toy or child care article.*” Parents who discard the packaging of a child care article will no doubt contact it. The sensible point of the FAQ is that their children will not.

² See, e.g., Dr. Wind’s testimony and attachments.

Third, Section 108(e)'s definition of mouthability, and Section 108(b)(1)'s express limitation of the regulation of three phthalates in children's toys to those that are mouthable, reinforce this point. The definition contrasts a toy that "can be sucked and chewed" with one that only can "be licked." Both common sense and (as explained below) the legislative and scientific evidence indicate that the former is a much greater potential source of exposure than the latter, even though licking also may cause exposure. With the three interim-banned phthalates, Congress (consistent with the European Union and California) sought to focus on this primary risk of exposure—in ways we explain further below in Part II.B—whereas with the permanently prohibited phthalates it cast a wider net. That Congress has cast a wider net in some cases than in others does not mean that exposure fails to remain the touchstone. Rather, it merely means that in some cases Congress used mouthability as a bright line and in others it did not. The underlying policy concern remains exposure of children to phthalates.

The European Union's phthalate regulations reinforce this point. Among the findings in the preamble of the relevant Directive is that "the exposure of children to all practically avoidable sources of emissions of [phthalates], *especially from articles which are put into the mouth by children*, should be reduced as far as possible." Directive 2005/84/EC, preamble ¶ 9 (emphasis added).

A final textual indicator is that the phrase "contains concentrations" in Section 108 is undefined. It is ambiguous, and allows for interpretation in light of Section 108's overall concern with children's exposure to phthalates. For example, given that the grammatical subject of this phrase is "toy" or "article" in Section 108(b)(1), as well as Section 108(a), rather than "part" or "component part" (terms not directly mentioned), one might contend that whether a product has an impermissible concentration of any of the six specified phthalates is determined on the basis of the whole product. The Senate amendment of H.R. 4040 that introduced the phthalates restriction into what became the CPSIA highlights the ambiguity: As to DEHP, DBP, and BBP, its restriction applied to a product "any part of which contains" any combination of those three exceeding 0.1 percent. Yet as to DINP, DIDP, and DnOP (or a combination of all six), the restriction used "contains" without referring to component parts. *See* Senate-amended H.R. 4040, § 40(b)(3) (Mar. 6, 2008). Reading Section 108 to require a whole-product assessment would favor manufacturers. But we recognize that, practically, this would be a difficult, perhaps even impossible, approach to testing based on the likelihood of mouthing and exposure to a part of children's product that can be "sucked and chewed, but not licked." And, one might oppose it by noting that children's toys and child care articles are defined as kinds of consumer products, and that the Consumer Product Safety Act defines "consumer product" as an "article, or component part thereof." 15 U.S.C. § 2052(a)(1). Thus, the Commission's own test method suggests that one only samples component parts that have PVC. (*See* Commission FAQ on § 108, posted 12/18/2008, citing www.cpsc.gov/about/cpsia/phthalate_test_method.pdf.) The point is simply that the Commission has some discretion in interpreting the phrase "contains concentrations of," and should do so in light of other provisions of Section 108 emphasizing the importance of exposure.

The ambiguity of Section 108 regarding how to factor in questions of exposure is highlighted by the legislative history, which leaves Congress's precise intent un-illuminated. No phthalates regulation appeared in H.R. 4040 as the House passed it. The House committee simply noted in the concluding paragraph of its report that it was made aware of "possible dangers" from phthalates "late in the process" and would address this issue "in subsequent hearings and legislation." H. Rep. 110-501, at 47 (2007). Thus, the details of phthalates

exposure and restrictions on them received no airing in the House. The same was true in the Senate. The initial phthalate regulation was added on the floor as an amendment approved by voice vote without debate. Cong. Rec. S1669, S1693 (Mar. 6, 2008). And the Conference Committee gave Section 108 one sentence in its report, simply noting that it had “agreed to a modified version of” the Senate’s provision. H. Rep. 110-787, at 68 (2008).

Policy considerations reinforce the need for the Commission to avail itself of the opportunity to clarify Section 108’s focus on exposure. Among other things, both the statute and the legislative history leave open the question of how a manufacturer might substitute for a phthalate that is prohibited under Section 108. The Senate amendment regulated this subject (in § 40(b)), but the Conference Committee removed it. Section 108 merely directs the Panel to consider the effects of phthalate alternatives. § 108(b)(1). It does not even directly authorize the Commission to declare products containing phthalate alternatives to be banned hazardous products in response to the report. *See* § 108(b)(3)(B). As a result, if a manufacturer substitutes a different additive chemical, that substitute may well have health risks or other issues of its own (known or unknown). Alternatively, if no suitable substitute exists, the manufacturer may become unable to produce the product (and parents may then substitute another product), or it may alter the design in ways that leave the product more rather than less risky for a child. This is a particular issue, for example, with high-current (120V AC, 230V AC, or 8+ amps DC) power cables, adaptors, and transformers, which may be mouthable or otherwise accessible. The members of TIA have been unable to obtain UL-approved substitute material for these applications that is phthalate compliant; in such case, eliminating phthalates may increase other risks such as fire and electrocution. There is no reason for the Commission to run such risks by reading Section 108 to require more than it actually does. To that end, we next explain particular ways of concern to the TIA’s members by which the Commission may clarify Section 108’s focus on exposure to avoid rather than run such risks.

B. In Particular, Section 108(b)’s Interim Prohibition of Three Phthalates Focuses on Mouthability and Applies Only to Mouthable Products or Component Parts.

There are two primary and interrelated ways by which the Commission can and should implement Section 108’s overarching policy concern with exposure in the context of Section 108(b). In doing so, the Commission also will helpfully clarify Section 108 for manufacturers and others seeking to comply with it but uncertain of its specific requirements and concerned about possible disruptions, not compelled by the statute, that would lack any policy justification.

First, the Commission should clarify that Section 108(b)(1)’s interim prohibition of DINP, DIDP, and DnOP applies only to product components that can be mouthed, whether the components are in children’s toys or child care articles. We of course recognize that Congress in that subsection expressly limited the interim ban regarding children’s toys to those that can be mouthed but did not include a similarly explicit qualification regarding child care articles. But that is because Congress defined the term “child care article” so as implicitly to require mouthability or at least be consistent with such a qualification. By contrast with the definition of “children’s toy” (quoted above), there is a close textual parallel between Section 108’s definition of mouthability (“so that it can be sucked and chewed”) and its definition of “child care article” (“sucking,” “teething,” and facilitation of “feeding,” and “sleep[ing]”). This parallel readily allows the Commission, in an appropriate context, to read “child care article” as an article that can be placed in the mouth. In Section 108(b)(1), that context is the adjoining express

mouthability limitation for children's toys, which does not appear in the context of section 108(a).

Several other considerations reinforce what the text indicates, and provide compelling grounds for the Commission not to read Section 108(b)(1) to impose different requirements on child care articles than on children's toys. One is the danger of absurdity. It would make no sense for only one of two similar non-mouthable products, both designed for children of the same age, to be subject to the interim prohibition simply because one is a children's toy and the other is a child care article.

Another is the example of other major jurisdictions—the European Union and California—together with the legislative history of Section 108. The EU's Directive, like Section 108, draws a distinction between DEHP, DBP, and BBP, on the one hand, and DINP, DIDP, and DNoP, on the other. *See* Directive 2005/84/EC, Annex. Also like Section 108, the Directive imposes a 0.1% limitation on the presence of the former category of phthalates in plasticized material in any toys and child care articles without regard to mouthability, but includes a mouthability qualification in regulating the latter category of phthalates. Specifically, the EU provides that the three phthalates at issue in Section 108(b)'s interim prohibition “[s]hall not be used as substances or as constituents of preparations at concentrations greater than 0.1% by mass of the plasticized material, in toys and childcare articles which can be placed in the mouth by children.” *Id.* California too distinguishes between the two categories of phthalates and, likewise, for the second category has a mouthability qualification for both toys and child care articles. Cal. Health & Safety Code § 108935 *et seq.*; *see* CRS Report at 16 (summarizing). The question then is whether Congress in Section 108 had, or has indicated, some intention to break with this established approach to DINP, DIDP, and DNoP. As explained above, we do not think that the text requires such a break, and in fact suggests the contrary. Moreover, one would expect to see in the legislative history some reference to—not to mention justification for—an intention to depart from this approach, but there is none. In the face of such silence, it would be particularly strange to conclude that Congress in a merely *interim* regulation sought to be *stricter* than these well known precedents.

Finally, there is good policy and scientific reason for limiting prohibitions of DINP, DIDP, and DNoP to mouthable product components of both children's toys and child care articles. Potential risks to humans from such phthalates are less clear and significant than are the risks of the permanently prohibited phthalates.³ This reality makes appropriate (for the time being, as the Panel conducts its work) a narrower prohibition that focuses on what is, as legislative materials and the scientific literature make plain, far and away the primary means by which children are exposed to phthalates by toys or child care articles. That is why, as noted, the Commission has, since the 1980s, focused on use of phthalates in teething rings, rattles, and pacifiers. That also is why, as noted, the EU is “especially” concerned with “articles that are put into the mouth by children.” A Commission study in 2004 emphasized that, “[b]ecause plasticizers are not tightly bound to PVC, they may be released *when children place PVC products in their mouths*,” and only mentioned offhand that “[s]ome dermal exposure from soft plastic toys is likely to occur.”⁴ The European Union's committee for considering such questions similarly has

³ See, for example, Dr. Wind's testimony, including discussion of substitution of DINP for DEHP, and the materials relating to the Commission's denial in February 2003 of a petition to ban PVC in children's products that focused on DINP.

⁴ Michael A. Babich *et al.*, *Risk Assessment of oral exposure to diisononyl phthalate from children's products*, 40 *Regulatory Toxicology and Pharmacology* 151, 151-52, 164 (2004).

recognized that “[t]he plasticiser can be transferred to the skin via direct physical contact,” but that “[f]or small children, however, the oral exposure is probably the most effective route as they suck and ‘chew’ the toys.”⁵ Thus, text, legislative precedent, and policy all indicate that “child care article” should, in the context of its usage in Section 108(b)(2), be read as implicitly requiring a product’s mouthability.

Second, the Commission further should clarify that Section 108(b)’s interim prohibition applies *only to the mouthable parts* of children’s toys and child care articles. That is, a children’s toy or child care article may well have some “part” that “can actually be brought to the mouth and kept in the mouth by a child,” § 108(e)(2)(B), and thus, as a general matter the product may be subject to Section 108(b). But it would be unreasonable to end the inquiry there. As discussed above, the overarching question under Section 108(b) is whether a child will be exposed to phthalates by the indisputably primary mouthing pathway. It accordingly would make little sense to apply the interim ban to product components that are not mouthable and pose no such risk. Clarification is especially required because some testing laboratories currently are interpreting the incomplete FAQ responses prepared by the Commission staff to require that products be disassembled (even using tools to do so) in order to test plastic insulation on nonmouthable parts (such as wires and diodes on electronic circuit boards) at costs exceeding \$300 per test, even though there is no risk of access, let alone mouthing.

Applying the interim phthalate prohibition only to mouthable components of toys and child care articles indirectly incorporates some consideration of the accessibility of the phthalates in a product, given that mouthability of a part is just a subset of whether it is accessible. The European Commission’s Guidance Document on mouthability makes this explicit.⁶ But that is only a by-product of Section 108(b)’s own focus on mouthability, not the consideration of accessibility for its own sake, whatever may be the case with regard to such considerations under Section 108(a).

III. AVAILABLE TESTING PROTOCOLS.

The request invited comments concerning possible testing protocols. In addition to CPSC test protocols, testing procedures and equivalent alternative procedures already exist to determine the concentration of individual phthalates in materials used in children’s products that may contain phthalates. The listed test methods mainly address PVC materials, but all are also suitable (after test method validation) for testing for phthalates in other materials. Differences may be associated with test sample preparation base on the material tested, not the analytical test method itself.

⁵ EU Scientific Committee on Toxicity, Ecotoxicity and the Environment, *Phthalate migration from soft PVC toys and child-care articles: Opinion expressed at the CSTE third plenary meeting* § 3.2.1 (Brussels, April 24, 1998).

⁶ European Commission, Enterprise and Industry Directorate-General, *Guidance Document on the interpretation of the concept “which can be placed in the mouth” as laid down in the Annex to the 22nd amendment of Council Directive 76/769/EEC*, at 2 (undated) (“Inaccessible parts of articles can also not be taken into the mouth. Articles or parts of articles should be considered inaccessible if, during proper use or reasonable foreseeable improper use by children, they cannot be reached. . . . Inaccessible plastic material, such as cables in toys, can not be taken into the mouth under normal, foreseeable conditions.”).

- EN 14372, Annex A, “Suitable Gas - Chromatography — Mass - Spectrometry (GC-MS) Apparatus, Method and Precision Data for Determination of Phthalate Plasticizers.”
- Method C-34, “Determination of Phthalates in Polyvinyl Chloride Consumer Products,” Canada Product Safety Laboratory, Book 5 - Laboratory Policies and Procedures Part B: Test Methods Section.
- Chinese ICS 97.200.50; GB/T DRAFT, Toys and Children Products,” Determination of Phthalate Plasticizers in Poly Vinyl Chloride Plastics.”⁷

There is a need for guidance because some independent laboratories are not using one of these recognized, standard testing procedures. However, the CPSC should consider the need to specify a practical, cost effective approach to sampling and testing protocols. At a minimum, any such protocols should take into consideration, as noted earlier, that certain materials do not contain phthalates and need not be tested. Additionally, as to materials that potentially could contain phthalates, the use of phthalate alternatives in the re-formulation of those materials or verification by material suppliers that the materials do not contain phthalates should be permitted as evidence of compliance.

IV. NEW PUBLICATIONS RELATING TO THE POTENTIAL TOXICITY OF OR EXPOSURE TO PHTHALATES.

Finally, the request sought information on data that became available after 2002 on the toxicity of phthalates and on exposure to phthalates. TIA has identified a number of publications that appear to be responsive to Commission’s request. We list those, grouped by category, in the accompanying appendix.

V. CONCLUSION.

Thank you for the opportunity to continue our participation in your deliberations concerning the implementation of the CPSIA. Should you have any questions, please do not hesitate to contact Rob Herriott at rherriott@toyassociation.org or (646) 520-4843.

Sincerely,



Carter Keithley,
President
Toy Industry Association

⁷ The withdrawn ASTM D 3421, “Practices for Extraction and Determination of Plasticizer Mixtures from Vinyl Chloride Plastics” would also be suitable.



Toy Industry Association, Inc.

PUBLICATION APPENDIX

A. The EU published risk assessments for BBP, DEHP, DBP.

“European Union Risk Assessment Report, benzyl butyl phthalate (BBP),” CAS No: 85-68-7, EINECS No: 201-622-7 (2007).

“European Union Risk Assessment Report, dibutyl phthalate (DBP), Addendum to the Environmental Section – 2004,” CAS No: 84-74-2, EINECS No: 201-557-4 (2004).

“European Union Risk Assessment Consolidated Report, bis(2-ethylhexyl) phthalate (DEHP),” CAS-No.: 117-81-7, EINECS-No.: 204-211-0 (2003).

B. U.S. Department of Health and Human Services, National Toxicology Program, Center for the Evaluation of Risks to Human Reproduction, published a monograph on the potential human reproductive and developmental effects of DEHP in 2006.

“NTP-CERHR Monograph on the Potential Human Reproductive and Developmental Effects of Di(2-ethylhexyl) Phthalate (DEHP),” NIH Pub. No. 06-4476 (2006).

C. Alphabetical list, by first author, of publications appearing in the literature since 2002 concerning the reproductive effects of BBP, DBP, and their monomers that was compiled based on a PubMed literature search using the CAS RNs 85-68-7, 84-74-2, 131-70-4, and 2528-16-7.

Aso S, Ehara H, Miyata K, Hosyuyama S, Shiraishi K, Umamo T, Minobe Y. A two-generation reproductive toxicity study of butyl benzyl phthalate in rats. *J Toxicol Sci.* 2005 Dec;30 Spec No.:39-58.

Carruthers CM, Foster PM. Critical window of male reproductive tract development in rats following gestational exposure to di-n-butyl phthalate. *Birth Defects Res B Dev Reprod Toxicol.* 2005 Jun;74(3):277-85.

Duty SM, Calafat AM, Silva MJ, Ryan L, Hauser R. Phthalate exposure and reproductive hormones in adult men. *Hum Reprod.* 2005 Mar;20(3):604-10. Epub 2004 Dec 9.

Ferrara D, Hallmark N, Scott H, Brown R, McKinnell C, Mahood IK, Sharpe RM. Acute and long-term effects of in utero exposure of rats to di(n-butyl) phthalate on testicular germ cell development and proliferation. *Endocrinology.* 2006 Nov;147(11):5352-62. Epub 2006 Aug 17.

Hallmark N, Walker M, McKinnell C, Mahood IK, Scott H, Bayne R, Coutts S, Anderson RA, Greig I, Morris K, Sharpe RM. Effects of monobutyl and di(n-butyl) phthalate in vitro on steroidogenesis and Leydig cell aggregation in fetal testis explants from the rat: comparison with effects in vivo in the fetal rat and neonatal marmoset and in vitro in the human. *Environ Health Perspect.* 2007 Mar;115(3):390-6. Epub 2006 Dec 19.

Hauser R, Meeker JD, Duty S, Silva MJ, Calafat AM. Altered semen quality in relation to urinary concentrations of phthalate monoester and oxidative metabolites. *Epidemiology.* 2006 Nov;17(6):682-91.

Higuchi TT, Palmer JS, Gray LE Jr, Veeramachaneni DN. Effects of dibutyl phthalate in male rabbits following in utero, adolescent, or postpubertal exposure. *Toxicol Sci.* 2003 Apr;72(2):301-13. Epub 2003 Mar 7.

Howdeshell KL, Furr J, Lambright CR, Rider CV, Wilson VS, Gray LE Jr. Cumulative effects of dibutyl phthalate and diethylhexyl phthalate on male rat reproductive tract development: altered fetal steroid hormones and genes. *Toxicol Sci.* 2007 Sep;99(1):190-202. Epub 2007 Mar 30.

Howdeshell KL, Wilson VS, Furr J, Lambright CR, Rider CV, Blystone CR, Hotchkiss AK, Gray LE Jr. A mixture of five phthalate esters inhibits fetal testicular testosterone production in the Sprague-Dawley rat in a cumulative, dose-additive manner. *Toxicol Sci.* 2008 Sep;105(1):153-65. Epub 2008 Apr 14.

Johnson KJ, McCahan SM, Si X, Campion L, Herrmann R, Barthold JS. The orl rat with inherited cryptorchidism has increased susceptibility to the testicular effects of in utero dibutyl phthalate exposure. *Toxicol Sci.* 2008 Oct;105(2):360-7. Epub 2008 Jul 10.

Lee KY, Shibutani M, Takagi H, Kato N, Takigami S, Uneyama C, Hirose M. Diverse developmental toxicity of di-n-butyl phthalate in both sexes of rat offspring after maternal exposure during the period from late gestation through lactation. *Toxicology.* 2004 Oct 15;203(1-3):221-38.

Lehmann KP, Phillips S, Sar M, Foster PM, Gaido KW. Dose-dependent alterations in gene expression and testosterone synthesis in the fetal testes of male rats exposed to di (n-butyl) phthalate. *Toxicol Sci.* 2004 Sep;81(1):60-8. Epub 2004 May 12.

Mahood IK, Scott HM, Brown R, Hallmark N, Walker M, Sharpe RM. In utero exposure to di(n-butyl) phthalate and testicular dysgenesis: comparison of fetal and adult end points and their dose sensitivity. *Environ Health Perspect.* 2007 Dec;115 Suppl 1:55-61.

Ryu JY, Lee BM, Kacew S, Kim HS. Identification of differentially expressed genes in the testis of Sprague-Dawley rats treated with di(n-butyl) phthalate. *Toxicology.* 2007 May 5;234(1-2):103-12. Epub 2007 Feb 17.

Salazar V, Castillo C, Ariznavarreta C, Campón R, Tresguerres JA. Effect of oral intake of dibutyl phthalate on reproductive parameters of Long Evans rats and pre-pubertal development of their offspring. *Toxicology.* 2004 Dec 1;205(1-2):131-7.

Shono T, Shima Y, Kondo T, Suita S. In utero exposure to mono-n-butyl phthalate impairs insulin-like factor 3 gene expression and the transabdominal phase of testicular descent in fetal rats. *J Pediatr Surg.* 2005 Dec;40(12):1861-4.

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Tyrkiel EJ, Dobrzyńska MM, Derezińska E, Ludwicki JK. Effects of subchronic exposure of laboratory mice to benzylbutyl phthalate (BBP) on the quantity and quality of male germ cells. *Rocz Panstw Zakl Hig.* 2007;58(4):677-86. Polish.

Veeramachaneni DN. Impact of environmental pollutants on the male: effects on germ cell differentiation. *Anim Reprod Sci.* 2008 Apr;105(1-2):144-57. Epub 2007 Nov 26.

Zhang Y, Jiang X, Chen B. Reproductive and developmental toxicity in F1 Sprague-Dawley male rats exposed to di-n-butyl phthalate in utero and during lactation and determination of its NOAEL. *Reprod Toxicol.* 2004 Jul;18(5):669-76.

Zhang YH, Lin L, Liu ZW, Jiang XZ, Chen BH. Disruption effects of monophthalate exposures on inter-Sertoli tight junction in a two-compartment culture model. *Environ Toxicol.* 2008 Jun;23(3):302-8.

D. Alphabetical list, by first author, of papers that have appeared in the literature since September 2005, the approximate date of preparation of item B above, the NTP-CERHR Monograph, concerning the reproductive effects of DEHP that was compiled based on a PubMed literature search using the CAS RNs 117-81-7 and 4376-20-9.

Andrade AJ, Grande SW, Talsness CE, Gericke C, Grote K, Golombiewski A, Sterner-Kock A, Chahoud I. A dose response study following in utero and lactational exposure to di-(2-ethylhexyl) phthalate (DEHP): reproductive effects on adult male offspring rats. *Toxicology.* 2006 Nov 10;228(1):85-97. Epub 2006 Aug 22.

Andrade AJ, Grande SW, Talsness CE, Grote K, Chahoud I. A dose-response study following in utero and lactational exposure to di-(2-ethylhexyl)-phthalate (DEHP): non-monotonic dose-response and low dose effects on rat brain aromatase activity. *Toxicology.* 2006 Oct 29;227(3):185-92. Epub 2006 Aug 1.

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Borch J, Metzdorff SB, Vinggaard AM, Brokken L, Dalgaard M. Mechanisms underlying the anti-androgenic effects of diethylhexyl phthalate in fetal rat testis. *Toxicology.* 2006 Jun 1;223(1-2):144-55. Epub 2006 Apr 3.

- Culty M, Thuillier R, Li W, Wang Y, Martinez-Arguelles DB, Benjamin CG, Triantafilou KM, Zirkin BR, Papadopoulos V. In utero exposure to di-(2-ethylhexyl) phthalate exerts both short-term and long-lasting suppressive effects on testosterone production in the rat. *Biol Reprod*. 2008 Jun;78(6):1018-28. Epub 2008 Mar 5.
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- Ge RS, Chen GR, Dong Q, Akingbemi B, Sottas CM, Santos M, Sealfon SC, Bernard DJ, Hardy MP. Biphasic effects of postnatal exposure to diethylhexylphthalate on the timing of puberty in male rats. *J Androl*. 2007 Jul-Aug;28(4):513-20. Epub 2007 Feb 7.
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- Gunnarsson D, Leffler P, Ekwurtzel E, Martinsson G, Liu K, Selstam G. Mono-(2-ethylhexyl) phthalate stimulates basal steroidogenesis by a cAMP-independent mechanism in mouse gonadal cells of both sexes. *Reproduction*. 2008 May;135(5):693-703. Epub 2008 Feb 27.
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- Hokanson R, Hanneman W, Hennessey M, Donnelly KC, McDonald T, Chowdhary R, Busbee DL. DEHP, bis(2)-ethylhexyl phthalate, alters gene expression in human cells: possible correlation with initiation of fetal developmental abnormalities. *Hum Exp Toxicol*. 2006 Dec;25(12):687-95.
- Howdeshell KL, Furr J, Lambright CR, Rider CV, Wilson VS, Gray LE Jr. Cumulative effects of dibutyl phthalate and diethylhexyl phthalate on male rat reproductive tract development: altered fetal steroid hormones and genes. *Toxicol Sci*. 2007 Sep;99(1):190-202. Epub 2007 Mar 30.
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- Nabae K, Doi Y, Takahashi S, Ichihara T, Toda C, Ueda K, Okamoto Y, Kojima N, Tamano S, Shirai T. Toxicity of di(2-ethylhexyl)phthalate (DEHP) and di(2-ethylhexyl)adipate (DEHA) under conditions of renal dysfunction induced with folic acid in rats: enhancement of male reproductive toxicity of DEHP is associated with an increase of the mono-derivative. *Reprod Toxicol*. 2006 Oct;22(3):411-7. Epub 2006 Jul 21.
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Stroheker T, Regnier JF, Lassurguere J, Chagnon MC. Effect of in utero exposure to di-(2-ethylhexyl)phthalate: distribution in the rat fetus and testosterone production by rat fetal testis in culture. *Food Chem Toxicol*. 2006 Dec;44(12):2064-9. Epub 2006 Aug 8.

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Tay TW, Andriana BB, Ishii M, Choi EK, Zhu XB, Alam MS, Tsunekawa N, Kanai Y, Kurohmaru M. An ultrastructural study on the effects of mono(2-ethylhexyl) phthalate on mice testes: cell death and sloughing of spermatogenic cells. *Okajimas Folia Anat Jpn*. 2007 Feb;83(4):123-30.

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Wirth JJ, Rossano MG, Potter R, Puscheck E, Daly DC, Paneth N, Krawetz SA, Protas BM, Diamond MP. A pilot study associating urinary concentrations of phthalate metabolites and semen quality. *Syst Biol Reprod Med.* 2008 May-Jun;54(3):143-54.

Yanagisawa R, Takano H, Inoue K, Koike E, Sadakane K, Ichinose T. Effects of maternal exposure to di-(2-ethylhexyl) phthalate during fetal and/or neonatal periods on atopic dermatitis in male offspring. *Environ Health Perspect.* 2008 Sep;116(9):1136-41.

Zhang YH, Lin L, Liu ZW, Jiang XZ, Chen BH. Disruption effects of monophthalate exposures on inter-Sertoli tight junction in a two-compartment culture model. *Environ Toxicol.* 2008 Jun;23(3):302-8.

Stevenson, Todd

From: Herriott, Rob [rherriott@toyassociation.org]
Sent: Monday, January 12, 2009 4:42 PM
To: CPSC-OS; Wolfson, Scott; Falvey, Cheryl; Parisi, Barbara; Smith, Timothy; Mullan, John
Cc: Lawrence, Joan; Keithley, Carter; Desmond, Edward
Subject: TIA Comments on Phthalates
Attachments: WAI_2906524_5_Phthalate Comments for TIA (final).pdf; WAI_2906843_1_Publication Appendix.pdf

Attached please find the comments (including appendix) by the Toy Industry Association regarding the new phthalate standards. We appreciate your consideration of our views and are happy to add further clarification if you deem it necessary.

If any questions arise, please do not hesitate to contact me.

Rob Herriott
Director of International Relations
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Stevenson, Todd

From: Carlson, Richard [Richard.Carlson@dionex.com]
Sent: Monday, January 12, 2009 2:56 PM
To: Phthalates Project
Cc: Richter, Bruce; Henderson, Sheldon; Francis, Eric; Dominick, Paul
Subject: Comments on Section 108: Phthalates in Children's Products
Attachments: CPSC Phthalates.doc

Categories: Technical comment

Dear CPSC Office of the Secretary,

We desire to comment on Section 108: Phthalates in Children's Products, specifically on the measurement of phthalates in children's products.

- What analytical method(s) may be suitable for the routine identification and measurement of total phthalate concentration for each of the covered phthalate chemicals in children's products?

The analytical method must be separated into at least two techniques; sample preparation and sample analysis. Regarding sample preparation, solvent extraction using Pressurized Fluid Extraction (PFE) or Soxhlet extraction are the most efficient. The advantage of PFE over Soxhlet extraction is speed and economy. Using PFE phthalates have been extracted in 15 minutes from plastics whereas Soxhlet requires several hours (6 hours as specified in ASTM D 2124). PFE requires minimal extraction solvent (20mL or less) and Soxhlet requires a few hundred milliliters of solvent. Regarding sample analysis, chromatographic techniques are best suited to provide the information requested in Section 108; phthalate identity and concentration. Both gas and liquid chromatography are well suited for the separation of phthalates from a solvent extract. Gas Chromatography coupled with flame ionization or mass spectrometric detection and high performance liquid chromatography coupled with ultra violet or mass spectrometric detection are both practical and highly feasible solutions.

- Include information on repeatability and reproducibility, such as interlaboratory ("round-robin") studies.

Round-robin data to support ASTM D 2124 is available from ASTM Headquarters as RR: D20-22. Data supporting the use of PFE is supplied with this document.

- Are there any standard reference materials available for phthalates or phthalate substitutes in PVC?

NIST has some standard reference materials for phthalates, but not in a plastic or PVC matrix. I am not aware of any phthalate substitutes in PVC.

- Are there any screening methods or technologies that may be suitable for the rapid identification of plasticizers in children's products?

No. Not sufficient to meet the requirements of Section 108

Current ASTM Test Methods

D 494 (Test Method for Acetone Extraction of Phenolic Molded or Laminated Products).

This method is not intended for phthalate determination, but some researches have reported using this test method for phthalates. D 494 is a “degree of cure” test using Soxhlet extraction with acetone followed by gravimetric determination. As such, the extractable components are not identified using D 494.

D 2124 (Test Method for Analysis of Components in PVC Compounds Using an Infrared Spectrophotometric Technique). This test method includes sections on sample preparation and plasticizer extraction using Soxhlet (sections 8 and 8.2)

D 7083 (Standard Practice for Determination of Monomeric Plasticizers in PVC by GC).

This practice recommends following ASTM D 2124 for extraction. Some plasticizers are not single components requiring the use of plasticizer standards and/or GC/ or LC/MS determination.

Extraction of Plasticizers from PVC Using Pressurized Fluid Extraction
PFE and Soxhlet Results expressed as weight percent plasticizer in PVC

Plasticizer	PFE Results n=3	Soxhlet Results (ASTM D2124) (% Plasticizer) n=2	Recovery (%)*
Bis(2-ethylhexyl) adipate	9.81 %	9.56 %	102.6 %
Tris(2-ethylhexyl) phosphate	9.50 %	9.28 %	102.4 %
Di-(2-ethylhexyl) phthalate	9.42 %	9.35 %	100.7 %
Trioctyl trimellitate	9.17 %	9.05 %	101.3 %
Extraction time	12 minutes	360 minutes	
Extraction solvent volume	20 mL	120 mL	

*() % recovery vs. Soxhlet

Sincerely,

Bruce E. Richter, Ph.D.
Manager

Richard Carlson, Ph.D
Staff Chemist
ASTM D20.70 Subcommittee Chairman
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Kind regards,
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January 12, 2009

Office of the Secretary
Consumer Product Safety Commission
Room 502
4330 East-West Highway
Bethesda, MD 20814

To whom it may concern,

The Specialty Graphic Imaging Association (SGIA), representing the interests of the facilities engaged in the production of certain child care articles, submits the following to the Commission's Request for Information on "Prohibition on the Sale of Certain Products Containing Specified Phthalates, Section 108 of the Consumer Product Safety Information Act.

SGIA members produce child care articles as defined in the CPSIA. Specifically, the industry sector, through screen printing, produces sleepwear, bibs and other decorated garment items that are used to facilitate sleep or feeding of children under 3 years of age.

Currently, the ink manufacturers that supply this market segment are working to remove all phthalates listed in Subsection 108(a) and Section 108(b)(1) of the CPSIA. The reformulations do not contain any of the chemicals listed in the CPSIA.

The issue we wish to raise, and one that is not addressed in the request for information, concerns the testing of products that no longer contain the phthalates listed in the CPSIA. Products that no longer contain the phthalates in the amounts listed in the legislation should not be required to undergo the rigorous testing for measurement purposes. The goal of the legislation is to remove these chemicals from children's products, and if the manufacturer can document, based on incoming supplier information, that their products do not contain the phthalates listed in Section 108(a) or Section 108(b) (1), then testing should not be necessary.

Thank you for the opportunity to comment and provide information on this important industry initiative. If you have any questions, please do not hesitate to contact me directly at 703-359-1313 or by email at marcik@sgia.org.

Sincerely,

A handwritten signature in black ink that reads "Marcia Y. Kinter". The signature is written in a cursive style.

Marcia Y. Kinter
Vice President – Government & Business Information

Stevenson, Todd

From: Marci Kinter [marcik@sgia.org]
Sent: Monday, January 12, 2009 3:31 PM
To: Phthalates Project
Subject: Comments on Request for Comments for Section 108 of the CPSIA
Attachments: Request for Comment -- Section 108 of the CPSIA.doc

Categories: Technical comment

Please find attached comments on the above referenced document. Thank you.
Marci Kinter
SGIA

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CHAMBER OF COMMERCE
OF THE
UNITED STATES OF AMERICA

WILLIAM L. KOVACS
VICE PRESIDENT
ENVIRONMENT, TECHNOLOGY &
REGULATORY AFFAIRS

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WASHINGTON, D.C. 20062
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January 12, 2009

VIA ELECTRONIC FILING

Office of the Secretary
U.S. Consumer Product Safety Commission
4330 East West Highway, Room 502
Bethesda, MD 20814

Re: Section 108: Phthalates in Children's Products

The U.S. Chamber of Commerce, the world's largest business federation representing more than three million businesses and organizations of every size, sector, and region, is pleased to submit these comments on the "Prohibition on the Sale of Certain Products Containing Specified Phthalates." The Chamber believes it is critically important for the Consumer Product Safety Commission to remain informed on the most recent scientific data and analyses of phthalates and phthalate alternatives, and commends CPSC staff for soliciting information from the private sector on these matters in advance of any proposed rulemaking.

In its request for comments, CPSC states that it is seeking information on phthalates and alternative plasticizers in children's toys. The Chamber urges CPSC, as part of any safety assessment, to consider not just the chemical toxicity of a product, but also other potential health and safety hazards that could ensue should a product be manufactured with alternative materials that could alter the physical properties of the product.

The Chamber notes that while some alternative plasticizing materials do exist, the body of science surrounding the safety of these materials is not anywhere near as extensive as that supporting phthalates safety, and therefore we caution CPSC against the unknown risks associated with the use of these substances. With the passage of the Consumer Product Safety Improvement Act (CPSIA), manufacturers that have been using phthalates for decades in a wide variety of consumer products are now turning to less-tested materials. As such, the Chamber is concerned about the

potential for “unintended consequences” that could result from the use of these less-tested alternatives.

A recent and widely publicized example of such an “unintended consequence” occurred in the case of Aqua Dots. This children’s bead toy was the subject of a multi-nation product recall after the production factory in China substituted a cheaper chemical for the one specified in some shipments. The non-toxic chemical 1,5-pentanediol, a viscous oily liquid used as a solvent, was replaced with 1,4-butanediol that, when ingested, is metabolized into the drug gamma-hydroxybutyric acid (GHB), an anesthetic which is misused as a recreational drug more commonly known as the “date rape drug.” The chemically changed product resulted in the illness and hospitalization of children who ingested the beads.

An incomplete safety determination can result in unintended consequences if all hazards haven’t been fully considered and contemplated. The benchmark for the safety of consumer products should be comprehensive to include not only chemical safety issues, but also whether or not the introduction of alternative materials or altered components might make the product less safe. A children’s product that is currently made soft, flexible and lightweight through the use of Polyvinyl Chloride (PVC) plasticized with a phthalate or alternative plasticizer might become less safe if that toy is manufactured without using plasticized PVC in the future. This could possibly result in a toy that is brittle and easily shatters, causing a choking hazard or other harm to children. If the lightweight PVC plastic is replaced with a heavier material such as metal or wood, this could likewise cause harm if dropped.

The Chamber strongly believes that Congress passed this legislation not only to determine the safety of phthalates used in different types of toys, but also to require a similar assessment of alternatives to phthalates that have not been subjected previously to the same level of scientific scrutiny and evaluation. While the legislation specifically mandates the assessment of phthalates and alternatives to phthalates, we believe that assessment should not be conducted solely on the basis of chemical toxicity, but must also address additional health and safety hazards that could result from the production of toys with the use of any alternative materials.

U.S. Chamber of Commerce
January 12, 2009
Page 3 of 3

Again, the Chamber thanks CPSC staff for actively soliciting information and providing interested parties the opportunity to comment.

Sincerely,

A handwritten signature in cursive script, appearing to read "William L. Kovacs".

William L. Kovacs

Stevenson, Todd

From: Myers, Thomas [tmyers@USChamber.com]
Sent: Monday, January 12, 2009 4:11 PM
To: Phthalates Project
Subject: Section 108: Phthalates in Children's Products
Attachments: US Chamber of Commerce - Comments re Phthalates in Children Products.doc

Categories: Legal comment

The U.S. Chamber of Commerce is pleased to submit the attached comments on the "Prohibition on the Sale of Certain Products Containing Specified Phthalates." The Chamber commends the staff of the Consumer Product Safety Commission for soliciting information from the private sector in advance of any proposed rulemaking.

If you have any questions or need additional information, please contact me.

Thank you.

THOMAS MYERS

Counsel
Environment, Technology & Regulatory Affairs
U.S. Chamber of Commerce
1615 H Street, N.W.
Washington, D.C. 20062-2000
(202) 463-5804
tmyers@uschamber.com



Jan. 12, 2009

Office of the Secretary
Consumer Product Safety Commission
Room 502
4330 East-West Highway
Bethesda, MD 20814

Re: Request for Comment on safety of PVC plasticized with phthalates

The Vinyl Institute, Inc. ("VI")¹ appreciates the opportunity to submit these comments to the Consumer Product Safety Commission (CPSC) on the Commission's request for information relating to "the toxicity of PVC or other materials that may contain phthalates or phthalate alternatives." This information is requested pursuant to Section 108 of the Consumer Product Safety Improvement Act.

VI is not aware of any new or unpublished information that would alter the long-standing acceptance of PVC as a safe and effective material used in myriad products. The homopolymer PVC is an essentially inert material, and PVC products -- fabricated with additives according to desired end-product characteristics -- are widely accepted as safe and effective by government agencies and private organizations. As examples:

- PVC is widely used in blood bags, medical tubing and other products regulated by the U.S. Food and Drug Administration (FDA) for safety.
- PVC is one of the most widely used piping materials for delivery of safe drinking water and is certified for safety by NSF International.

¹ VI is a U.S. trade association representing the leading manufacturers of vinyl, vinyl chloride monomer, vinyl additives and modifiers, and vinyl packaging materials. VI's mission is to advocate the responsible manufacture of vinyl resins, lifecycle management of vinyl products, and promotion of the value of vinyl to society. VI member companies include CertainTeed Corporation, Formosa Plastics Corporation, U.S.A., Oxyvinyls, LP, PolyOne Corporation, Shintech, Inc., and Westlake Chemical Corporation.

- PVC is the material of choice for insulating wire and cable, able to comply with codes set by the National Fire Protection Association even in challenging plenum locations.

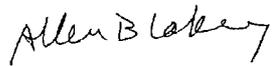
Regulatory authorities as well other scientific panels worldwide have reviewed the safety of phthalates commonly used in flexible vinyl (rigid vinyl products do not require use of plasticizers), finding no actual harm and little cause for concern in most applications. These reviews, of course, included a lengthy evaluation by CPSC that ended in rejection of a petition to ban vinyl toys softened with phthalates. To supplement CPSC's information, following are highlights of significant reviews of DEHP, the main phthalate used in medical products:

- June 1999. A blue-ribbon panel of 17 distinguished scientists and physicians led by former U.S. Surgeon General C. Everett Koop concluded that the scientific literature shows that "DEHP, as used in medical devices, is not harmful to humans even under chronic or higher-than-average conditions of exposure."
- February 2000. The International Agency for Research on Cancer (IARC), part of the World Health Organization, lowered the risk estimate on DEHP to the category, "not classifiable as a human carcinogen."
- February 2002. Health Canada issued a safety review of DEHP, finding "very little concern that exposure to DEHP from medical procedures will cause reproductive toxicity in human adults." While the report expressed concern over the reproductive tract development of critically ill male infants on intensive medical therapy, it added that "the benefits of [these] medical procedures may outweigh these risks."
- July 2002. U.S. FDA issued a notice recommending reducing exposure to DEHP in medical products for certain populations, particularly male newborns, pregnant women carrying male babies and adolescent males. FDA also found that most patients have minimal risk from exposure to DEHP and added that, "The risk of not doing a needed procedure is far greater than the risk associated with exposure to DEHP."
- September 2002. U.S. EPA removed DEHP from its draft list of persistent, bioaccumulative and toxic (PBT) substances.
- October 2002. The European Commission's Scientific Committee on Medicinal Products and Medical Devices stated, "there are no reports concerning any adverse effects in humans following exposure to DEHP-PVC" and concludes that "at this moment no specific recommendations can be made to limit the use of DEHP in any particular patient group."

Although we do not know of any large, long-term, follow-up studies of infants who were exposed to phthalates in invasive medical therapies at an early age, according to news reports at least one study found no problems related to reproductive development into the former patients' teen years ("Male fertility not harmed by phthalates-study," Reuters Health, Jul 13, 2005). While the numbers in this study are small, the preliminary conclusions are important.

Finally, vinyl is a valuable material for use in toys and childcare products. Vinyl does not form sharp edges, splinter or break. Vinyl's unique softness, color-fastness, durability and other performance characteristics explain why it is so widely used in these products.

Respectfully submitted,

A handwritten signature in cursive script that reads "Allen B. Blakey".

Allen Blakey
Vice President, Industry and Government Affairs

Stevenson, Todd

From: Blakey, Allen [Allen_Blakey@plastics.org]
Sent: Monday, January 12, 2009 5:40 PM
To: Phthalates Project
Subject: Vinyl Inst. comments on safety of PVC plasticized with phthalates
Attachments: VI to CPSC on PVC Safety 2009-01-12.doc

Categories: Technical comment

Please accept these comments on the request for information under Section 108 of the Consumer Product Safety Improvement Act.

Allen Blakey
VP-Industry & Govt. Affairs
The Vinyl Institute
Arlington, VA 22209
703-741-5666

Stevenson, Todd

From: sandy.j.henry@exxonmobil.com
Sent: Monday, January 12, 2009 5:58 PM
To: Phthalates Project
Subject: ExxonMobil submission to CPSC regarding Section 108: Phthalates in Children's Products
Attachments: ExxonMobil Information submitted to CPSC Jan 12 2009.pdf

Categories: Test method, Technical comment

Sent via email to: phthalates-info@cpsc.gov

Office of the Secretary
U.S. Consumer Product Safety Commission
4330 East West Highway
Bethesda, MD 20814

To Whom It May Concern,

ExxonMobil Chemical submits the following information to the U.S. Consumer Product Safety Commission's (CPSC) request for information on Section 108 of the Consumer Product Safety Improvement Act (CPSIA), "PROHIBITION ON THE SALE OF CERTAIN PRODUCTS CONTAINING SPECIFIED PHTHALATES."

ExxonMobil Chemical is a producer of two of the phthalates, DINP and DIDP, that will be subject to the CPSIA interim prohibition. DINP and DIDP are subsequently used to plasticize PVC. We take product safety very seriously and are committed to ensuring that our products meet the most stringent regulatory requirements. Our Biomedical Sciences staff of more than 100 full-time scientists perform health and toxicology studies in support of product safety. ExxonMobil believes that our testing has demonstrated that DINP and DIDP are safe for their intended use and welcomes further study.

For more information regarding this submission please contact:

Worth Jennings
Global Oxo Marketing Manager
Business Phone: 281-870-6049
Email: Worth.a.Jennings@exxonMobil.com

(See attached file: ExxonMobil Information submitted to CPSC Jan 12 2009.pdf)

Tel: 281-870-6049
Mobile: 281-948-7006
e-mail: sandy.j.henry@exxonmobil.com

**EXXONMOBIL's RESPONSE TO CPSC's REQUEST FOR INFORMATION
Regarding Section 108 of the Consumer Product Safety Improvement Act (CPSIA):
Phthalates in Children's Products**

Sent via email to: phthalates-info@cpsc.gov

Office of the Secretary
U.S. Consumer Product Safety Commission
4330 East West Highway
Bethesda, MD 20814

To Whom It May Concern,

ExxonMobil Chemical submits the following information to the U.S. Consumer Product Safety Commission's (CPSC) request for information on Section 108 of the Consumer Product Safety Improvement Act (CPSIA), "PROHIBITION ON THE SALE OF CERTAIN PRODUCTS CONTAINING SPECIFIED PHTHALATES."

ExxonMobil Chemical is a producer of two of the phthalates, DINP and DIDP, that will be subject to the CPSIA interim prohibition. DINP and DIDP are subsequently used to plasticize PVC. We take product safety very seriously and are committed to ensuring that our products meet the most stringent regulatory requirements. Our Biomedical Sciences staff of more than 100 full-time scientists perform health and toxicology studies in support of product safety. ExxonMobil believes that our testing has demonstrated that DINP and DIDP are safe for their intended use and welcomes further study.

For more information regarding this submission please contact:

Worth Jennings
Global Oxo Marketing Manager
Business Phone: 281-870-6049
Email: Worth.a.Jennings@exxonMobil.com

**EXXONMOBIL's RESPONSE TO CPSC's REQUEST FOR INFORMATION
Regarding Section 108 of the Consumer Product Safety Improvement Act (CPSIA):
Phthalates in Children's Products**

1. Use of Polyvinyl Chloride (PVC) in Children's Products

What types of toys for children up to age 12, as defined in the CPSIA, may contain PVC or vinyl plastic, and why?

ExxonMobil Chemical produces phthalates that are subsequently used to make PVC or vinyl plastic soft and flexible. While we do not manufacture PVC or children's toys, we can offer the following information.

PVC or vinyl plastic can be used in a variety of toys including, for example, dolls, inflatable balls, play balls, children's books, play figures, bath toys, pool toys, and flexible stickers. In addition, there may be rather complex toys which are mostly other plastics or other materials, but have some flexible PVC parts such as grips or handles.

Flexible PVC is chosen by toy manufacturers because no other flexible plastic offers the same combination of cost and performance. Soft, flexible plastic toys are typically produced using roto-molding or calendared sheet process technologies, and no other plastic used with these technologies results in the same high quality product as does flexible PVC. PVC resin (the hard plastic to which plasticizer is added to make it soft and flexible) is cost effective and can easily be reformulated to a broad range of new products that meet performance standards. PVC can be brightly colored, is soft and flexible, and is durable and long-lasting--all critical performance parameters for toys. PVC is lightweight and toys made from PVC will not injure a child if dropped, whereas heavy objects made with metal or wood could result in injury. More brittle plastics could break and create a choking hazard.

It is important to also consider what is not a toy. For example:

- Sporting Goods
- Clothing
- Shoes
- School equipment: backpacks, pencil cases, erasers, notebooks, folders, rulers

What types of toys that can be mouthed or child care articles, for children up to age 3, as defined in the CPSIA, may contain PVC or vinyl plastic, and why?

ExxonMobil Chemical produces phthalates that are subsequently used to make PVC or vinyl plastic soft and flexible. While we do not manufacture PVC or children's toys that can be mouthed or child care articles that facilitate sleeping or feeding, we can offer the following information.

It is our understanding that mouthing toys and child care articles that facilitate feeding such as pacifiers and baby bottle nipples are typically made from silicone, rubber, or latex because these materials provide a more natural feel and texture than other flexible plastics. Teethers can use flexible PVC but it is our understanding that this is less common today than in the past.

**EXXONMOBIL's RESPONSE TO CPSC's REQUEST FOR INFORMATION
Regarding Section 108 of the Consumer Product Safety Improvement Act (CPSIA):
Phthalates in Children's Products**

The CPSIA restricts phthalates from use in child care articles which facilitate sleep or the feeding of children age 3 and younger, or to help such children with sucking or teething. However, many children's products do not serve any of these purposes and therefore should remain outside the scope of the CPSIA phthalate restrictions. For example, given that soft PVC plastic is preferred because it is hypoallergenic, easy to clean and sanitize, provides protection from water damage, and is long-lasting and durable, it is typically used to make mattress covers for cribs. In this example, the PVC mattress cover is not facilitating sleep, it is merely keeping the mattress clean and dry. Another example is PVC bibs which do not facilitate feeding, but they do protect infants' clothing from stains and make for easier clean-up after feeding. And still another example is pajama non-slip foot pads which do not facilitate sleep, but they do provide traction and prevent slipping and falling.

What children's products other than toys, toys that can be mouthed, or child care articles contain PVC or vinyl plastic, and why?

ExxonMobil Chemical produces phthalates that are subsequently used to make PVC or vinyl plastic soft and flexible. While we do not manufacture PVC or children's products, we can offer the following information.

PVC plastic is used in a variety of products that are used by children that are not toys or child care articles. While this is not an exhaustive list, PVC is used in rain coats, rain ponchos, rain hats, rain boots, umbrellas, shoes, sandals, printing inks on t-shirts, seat covers, bibs, lunch boxes, backpacks, pencil cases, erasers, notebooks, folders, rulers, PVC-coated metal playground equipment, air mattresses, sporting goods, swimming pools and swimming pool liners.

Flexible PVC is chosen by manufacturers of children's products because no other flexible plastic offers the same combination of cost and performance. PVC resin (the hard plastic to which plasticizer is added to make it soft and flexible) is cost effective and easily reformulated to a broad range of new products that meet performance standards. PVC can be brightly colored, is soft and flexible, and is durable and long-lasting--all critical performance parameters for children's products. PVC is lightweight and products made from PVC will not injure a child if dropped, whereas heavy objects made with metal or wood could result in injury. More brittle plastics could break and create a choking hazard.

Considering that phthalates may have uses other than as plasticizers for PVC, are there any other types of children's toys, toys that can be mouthed, or child care articles that may contain phthalates or phthalate alternatives?

We have assumed that the CPSC is interested in information regarding the use of phthalates and phthalate alternatives in children's toys and child care articles for purposes other than plasticizing PVC. ExxonMobil Chemical produces phthalates and some phthalate alternatives that are subsequently used to make PVC or vinyl plastic soft and flexible. ExxonMobil also produces some, but not all plastics, polymers, rubbers and elastomers. While we do not manufacture children's products, we can offer the following information.

**EXXONMOBIL's RESPONSE TO CPSC's REQUEST FOR INFORMATION
Regarding Section 108 of the Consumer Product Safety Improvement Act (CPSIA):
Phthalates in Children's Products**

PVC has unique properties and requires use of a plasticizer to make it soft and flexible. We do not use phthalate plasticizers in the manufacture of the other plastics, polymers, rubbers, or elastomers that we produce. We are not aware of any products for children that are made with plastics other than PVC that also contain phthalates.

However, phthalates are used to a much lesser extent in other polymers for non-plasticizing applications including polyurethane sealants or coatings, and acrylic caulks. These products are used in construction applications rather than toys.

One phthalate, DBP, can be used in fingernail polish to make it more resilient and resistant to chipping. Generally fingernail polish would not be considered to be a toy or child care article.

Another phthalate, DEP, can be used in perfumes or fragrances as a fixative agent or carrier. Generally perfumes and fragrances would not be considered to be toys or child care articles.

Phthalate alternatives can be used to plasticize PVC. However, we do not have sufficient knowledge to provide further information on their possible use in children's products for purposes other than plasticizing PVC.

2. Use of Non-PVC Plastics in Children's Products

What non-PVC types of plastics, polymers, rubbers, and elastomers are currently used in children's toys, toys that can be mouthed, or child care articles?

ExxonMobil produces some but not all types of plastics, polymers, rubbers and elastomers. We do not manufacture finished children's products made with these materials, and we do not have sufficient knowledge to provide detailed information on their possible use in children's products.

In which types of products are they commonly used?

It is our understanding that silicone, rubber and latex are typically used for pacifiers and baby bottle nipples.

We do not have sufficient knowledge regarding use of other plastics, polymers, rubbers, and elastomers to indicate which are preferred in various types of children's toys and child care articles. Manufacturers of these children's products are best able to provide this information.

Are they used in other types of children's products other than toys or child care articles?

Other types of plastics, polymers, rubbers, and elastomers are used in a variety of products that are not considered toys or child care articles.

**EXXONMOBIL's RESPONSE TO CPSC's REQUEST FOR INFORMATION
Regarding Section 108 of the Consumer Product Safety Improvement Act (CPSIA):
Phthalates in Children's Products**

What plastics, polymers, rubbers, and elastomers will be used after the effective date of section 108 of the CPSIA, February 10, 2009?

ExxonMobil produces some but not all types of plastics, polymers, rubbers and elastomers. We do not manufacture finished plastic products for children; however, we can offer the following information.

Typically flexible PVC is chosen for toys because it provides the best overall balance of cost and performance. In many types of toys, there are no other acceptable polymeric solutions other than flexible PVC. For many of the PVC-based products, we would expect that either the manufacturer will continue using PVC, but with an alternative plasticizer that is not a phthalate, or that particular toy will disappear from the market, or it will be replaced with a different, more brittle plastic product that is of a lower quality.

Are phthalates used as plasticizers, solvents, or for any other purpose in any of the plastics, polymers, rubbers, or elastomers that may be used in children's products?

ExxonMobil produces some but not all types of plastics, polymers, rubbers and elastomers. We do not manufacture finished products for children; however, we can offer the following information.

PVC has unique properties and requires use of a plasticizer to make it soft and flexible. We do not use phthalate plasticizers in the manufacture of any of the other plastics, polymers, rubbers, or elastomers that we produce. We are not aware of any products for children that are made with plastics other than PVC that also contain phthalates.

Manufacturers of children's products are best able to provide this information.

3. Use of Phthalates and Phthalate Alternatives in Children's Products

What phthalates or phthalate alternatives are currently used in children's toys, toys that can be mouthed, or child care articles, and why?

ExxonMobil Chemical produces phthalates and some phthalate alternatives that are subsequently used to make PVC or vinyl plastic soft and flexible. While we do not manufacture PVC or children's products, we can offer the following information.

Two phthalates are typically used in PVC toys or child care articles, DEHP and DINP. DEHP was voluntarily removed from all mouthing toys (ASTM Toy Standard F963) but is still used to some extent in toys that cannot be placed in the mouth and in child care articles. As a result of this voluntary action on the part of the toy industry, DINP became the primary phthalate used in toys.

**EXXONMOBIL's RESPONSE TO CPSC's REQUEST FOR INFORMATION
Regarding Section 108 of the Consumer Product Safety Improvement Act (CPSIA):
Phthalates in Children's Products**

In 1998, DINP was also voluntarily removed from pacifiers, teethingers and rattles as a precautionary step prior to the CPSC's initial Chronic Hazard Advisory Panel completed their study of DINP and PVC toys in 2001, and the Commission staff completed their mouthing and migration studies in 2002. Once these studies were complete, in early 2003 the Commission rejected a petition to ban PVC toys and concluded there was no demonstrated health risk from use of DINP in children's toys, including toys that can be placed in the mouth.

Today, DINP is still the primary phthalate used in children's toys because it provides the best balance of cost, performance, and availability. Furthermore, and equally important, DINP is different from other phthalates. DINP has been thoroughly assessed and found to be safe for use in children's toys, including mouthing toys, by multiple regulatory bodies around the world. DINP has been thoroughly studied by the U.S. Consumer Product Safety Commission and found to be acceptable for use in PVC toys, including mouthing toys. DINP has been thoroughly studied by the European Union's risk assessment organization and found to be acceptable for use in PVC toys, including mouthing toys. The Israeli government reversed a proposed ban on DINP in children's toys after reviewing all the scientific data. The U.S. National Toxicology Program has concluded there is minimal concern from use of DINP. The U.S. CDC biomonitoring data shows that the vast majority of people tested do not have measurable levels of a DINP metabolite in their urine. The CDC biomonitoring data indicates that exposures to the general population are very low and well within established safe limits.

With the new CPSIA restrictions we expect manufacturer's of toys that can be mouthed and child care articles will convert away from DINP to phthalate alternatives for PVC toys and child care articles, and in some cases to plastics other than PVC depending on their formulation needs.

We would expect that toys that cannot be placed in the mouth would continue to use PVC and DINP plasticizer. For example, a doll head is not something that can be easily placed in the mouth (has no dimensions smaller than 5 cm and can only be licked) so even though it is a toy for children age 12 and under it will not be required to convert to a phthalate alternative. PVC and DINP will continue to be used because they offer the best overall balance of cost and performance.

Our understanding is that DnOP, DBP, BBP, and DIDP are not typically used in children's toys or child care articles. DnOP is not a commercial product.

We do not have sufficient knowledge to ascertain which phthalate alternatives are in use in toys and child care articles in the U.S. today.

What phthalates or phthalate alternatives will be used after February 10, 2009, and why?

ExxonMobil Chemical produces phthalates and some phthalate alternatives that are subsequently used to make PVC or vinyl plastic soft and flexible. We do not market the phthalate alternatives we produce into toys or child care articles. As we do not manufacture PVC or children's products and toys, it is difficult to predict what alternatives will be utilized by manufacturers of these products in the future.

**EXXONMOBIL's RESPONSE TO CPSC's REQUEST FOR INFORMATION
Regarding Section 108 of the Consumer Product Safety Improvement Act (CPSIA):
Phthalates in Children's Products**

However, we expect that DINP will continue to be used in toys that cannot be placed in the mouth. DIDP could possibly be used in toys that cannot be placed in the mouth. As mentioned above, DnOP is not a commercial product. DPHP could be used in toys and child care articles. DPHP has been produced in relatively higher volumes only after the European Union phthalate restrictions were implemented in 2005. Another class of closely related plasticizers are terephthalates. The highest production volume terephthalate is DOTP, and this could be used in toys and child care articles.

Are phthalates or phthalate alternatives used in plastics other than PVC, and why?

Phthalates are not used as plasticizers in other plastic resins used to make toys, as previously mentioned above.

Are phthalates or phthalate alternatives used in children's products for purposes other than as PVC plasticizers? Which products?

We are not aware of any products for children that are made with plastics other than PVC that also contain phthalates, as previously mentioned above.

One phthalate, DBP, can be used in fingernail polish to make it more resilient and resistant to chipping. Generally fingernail polish would not be considered to be a toy or child care article.

Another phthalate, DEP, can be used in perfumes or fragrances as a fixative agent or carrier. Generally perfumes and fragrances would not be considered to be toys or child care articles.

We do not have sufficient knowledge to provide further information on the possible use of phthalate alternatives in children's products for purposes other than plasticizing PVC.

Are there any additional phthalates or phthalate alternatives that may be used or are likely to be used in children's products in the future?

Since plasticized PVC is likely to be among the preferred flexible plastics for manufacture of children's toys and child care articles, it is likely that over time the industry will develop new phthalate alternatives that are suitable for use in children's products, but this will take many years and will require major capital investment and R&D expenditures, as well as significant reformulation costs.

**EXXONMOBIL's RESPONSE TO CPSC's REQUEST FOR INFORMATION
Regarding Section 108 of the Consumer Product Safety Improvement Act (CPSIA):
Phthalates in Children's Products**

4. Measurement of Phthalates in Children's Products

What analytical method(s) may be suitable for the routine identification and measurement of total phthalate concentration for each of the covered phthalate chemicals in children's products?

The available methods of measurement include Gas Chromatography (GC), High Performance Liquid Chromatography (HPLC), and Gas Chromatography-Mass Spectrometry (GC-MS). The latter, GC-MS, is the preferred method.

To measure the amount of plasticizer in a PVC article, the plasticizers are first removed from the article using solvent extraction, and then the extract is analyzed using one of the three above-mentioned analytical methods. There are a variety of suitable extraction solvents and extraction techniques available.

Typically plasticizers are present in PVC articles at levels greater than about 10 wt%. If the total amount of plasticizer present is at a level much below this, the plasticizer will not have the desired functional impact on softness and flexibility. Therefore, measurement of plasticizers at levels much below 10 wt% may not represent intentional addition but rather contamination from laboratory equipment or misidentification of another phthalate or alternative plasticizer.

Migration of phthalates can be measured by the ASTM method D1203 "Volatile loss from Plastics using activated carbon methods". This method records losses either by direct migration or by volatile losses.

Include information on repeatability and reproducibility, such as inter-laboratory ("round-robin") studies.

ExxonMobil is unaware of any studies on the reproducibility or repeatability of the measurement of phthalates in children's products. However, the European Commission's Joint Research Centre coordinated the validation of methodologies to test the migration of DINP, the phthalate most commonly used in toys. The validation exercise included 15 laboratories in the EU and US. The data showed that DINP release rates are lower and can be reproducibly measured by one of the methods examined. The results are published in the report entitled, "Validation of methodologies for the release of diisononyl phthalate (DINP) in saliva stimulant from toys" available at the following address:

http://cpf.jrc.it/toys/downloads/validation%20toys%20report_FINAL.pdf

Are there any standard reference materials available for phthalates or phthalate substitutes in PVC?

Standard reference materials exist for five of the phthalates restricted by the CPSIA: DBP, BBP, DEHP, DINP, and DIDP. As DnOP is not a commercial product, a standard for that plasticizer may prove to be difficult to obtain. Standard reference materials for the phthalate alternatives would likely be available from their manufacturers.

**EXXONMOBIL's RESPONSE TO CPSC's REQUEST FOR INFORMATION
Regarding Section 108 of the Consumer Product Safety Improvement Act (CPSIA):
Phthalates in Children's Products**

Are there any screening methods or technologies that may be suitable for the rapid identification of plasticizers in children's products?

ExxonMobil is not aware of any technology for rapid identification of low levels of phthalates or phthalate alternatives. Furthermore, it is very difficult to rapidly detect the type of phthalate or phthalate alternative used without the GC-MS technique.

Attenuated Total Reflectance Fourier Transform Infrared Spectroscopy (ATR FTIR) can be used to detect the presence of phthalates in a flexible PVC article but only at levels greater than about 10 wt%. This technique would not allow one to distinguish between the different types of phthalates in a PVC article.

X-Ray Fluorescence (XRF) is not suitable for detection of phthalates. This technique can only detect the presence of halogenated compounds like PVC resin, and metals like lead and cadmium.

Until new technology is developed, GC-MS will continue to be used as the standard method for identification of plasticizers.

**5. Toxicity of Phthalates and Phthalate Alternatives. The staff is interested in any new (since 2002) or unpublished data relating to:
The toxicity of phthalates or phthalate alternatives.**

ExxonMobil is aware of the following toxicity studies that have been conducted since 2002. The studies listed below are based upon information believed to be reliable on the date compiled, but we do not represent that these are complete lists. The inclusion of a study in these lists does not imply endorsement by ExxonMobil of the study quality and/or study findings.

In our view, the most robust, scientific studies are those that are conducted according to Good Laboratory Practices (GLP) and published in peer-reviewed scientific journals.

The results of the toxicity studies that are new since 2002 do not change ExxonMobil's assertion that DINP and DIDP are safe for use in all current applications, including toys that can be placed in the mouth in the case of DINP.

See Attachment 1 for a list of Toxicity studies on High Molecular Weight (HMW) phthalates.
See Attachment 2 for a list of Toxicity studies on Low Molecular Weight (LMW) phthalates.
See Attachment 3 for a list of Toxicity studies on phthalate alternatives.

The OECD Screening Information Data Sets (SIDS) defines High Molecular Weight (HMW) phthalates as those esters with an alkyl carbon backbone with 7 carbon (C) atoms or greater. This category was formed on the principle that substances of similar structure have similar environmental and toxicological properties. They include DINP (CAS RN 68515-48-0) and DIDP (CAS RN 68515-49-1) in this category.

**EXXONMOBIL's RESPONSE TO CPSC's REQUEST FOR INFORMATION
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Low Molecular Weight (LMW) phthalate esters have an alkyl carbon backbone of 4-6 carbon (C) atoms. DEHP, also known as DOP, as well as DBP and BBP have alkyl carbon backbones in the 4-6 carbon range and therefore are LMW phthalates.

In 2004, as the result of a review of the toxicity, ecotoxicity, and exposure studies for the high molecular weight category of phthalate esters, the OECD concluded that this category was "low priority for further work because of their low hazard profile."

See: "OECD SIDS CATEGORY: HIGH MOLECULAR WEIGHT PHTHALATE ESTERS" (2004)

In addition to the above-mentioned phthalate study lists, we refer you to the monographs prepared by the National Toxicology Program's Center for the Evaluation of Risks to Human Reproduction on certain phthalates.

- Butyl Benzyl Phthalate, available at the following address:
http://cerhr.niehs.nih.gov/chemicals/phthalates/bb-phthalate/BBP_Monograph_Final.pdf
- Di-n-Butyl Phthalate, available at the following address:
http://cerhr.niehs.nih.gov/chemicals/phthalates/dbp/DBP_Monograph_Final.pdf
- Di-(2-EthylHexyl) Phthalate, available at the following address:
<http://cerhr.niehs.nih.gov/chemicals/dehp/DEHP-Monograph.pdf>
- Diisodecyl Phthalate, available at the following address:
http://cerhr.niehs.nih.gov/chemicals/phthalates/didp/DIDP_Monograph_Final.pdf
- Diisononyl Phthalate (DINP), available at the following address:
http://cerhr.niehs.nih.gov/chemicals/phthalates/dinp/DINP_Monograph_Final.pdf
- Di-n-Hexyl Phthalate, available at the following address:
http://cerhr.niehs.nih.gov/chemicals/phthalates/dnhp/DnHP_Monograph_Final.pdf
- Di-n-Octyl Phthalate, available at the following address:
http://cerhr.niehs.nih.gov/chemicals/phthalates/dnop/DnOP_Monograph_Final.pdf

The NTP's CERHR has not evaluated all of the commercially available phthalates and has evaluated none of the phthalate alternatives.

In 2006, the Oslo-Paris Convention for the Protection of the Marine Environment of the North-East Atlantic (OSPAR) removed DINP and DIDP from their List of Chemicals for Priority Action, and removed DINP from their List of Substances of Possible Concern (DIDP was not on the list). This removal was based on the conclusion that "DINP and DIDP are not PBT substances and there is no indication of potential for endocrine disruption". The list of substances removed from these lists is available at the following address:

http://www.ospar.org/documents/DBASE/DECRECS/Agreements/04-13e_List%20of%20deselected%20Substances.doc

The toxicity of PVC or other materials that may contain phthalates or phthalate alternatives.

Please contact the Vinyl Institute for information on PVC.

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6. Exposure to Phthalates and Phthalate Alternatives. The staff is interested in any new (since 2002) or unpublished data or analyses relating to:

Migration of phthalates or phthalate alternatives from PVC or children's products.

Information on how migration studies relate to human exposure from mouthing, handling, or inhaling phthalates or phthalate alternatives, or products containing these chemicals.

Migration of phthalates can be measured by the ASTM method D1203 "Volatile loss from Plastics using activated carbon methods". This method records losses either by direct migration or by volatile losses.

The European Commission Joint Research Centre published a report entitled, "Validation of methodologies for the release of diisononyl phthalate (DINP) in saliva stimulant from toys." The report and proposed method was critiqued by the European Commission's Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) and found to be adequate.

ExxonMobil is aware of the following exposure studies that have been conducted since 2002. The studies listed below are based upon information believed to be reliable on the date compiled, but we do not represent that these are complete lists. The inclusion of a study in these lists does not imply endorsement by ExxonMobil of the study quality and/or study findings.

See Attachment 4 for a list of Exposure studies on High Molecular Weight (HMW) phthalates
See Attachment 5 for a list of Exposure studies on Low Molecular Weight (LMW) phthalates
See Attachment 6 for a list of Exposure studies on phthalate alternatives

The results of the exposure studies that are new since 2002 do not change ExxonMobil's assertion that DINP and DIDP are safe for use in all current applications, including toys that can be placed in the mouth in the case of DINP.

Human (including children's and pregnant women's) exposure to phthalates or phthalate alternatives from all sources, including building materials, consumer products, personal care products, and food.

In addition to the above-mentioned lists of exposure studies, the European Union Risk Assessments conducted on several phthalates include information on human exposures (both occupational and consumer) to these phthalates from all sources. The EU has not conducted comprehensive Risk Assessments on any of the phthalate alternatives. Regarding phthalates, we refer you to the following:

EU Risk Assessment Report for DINP, pages 118 - 141; available at the following address:
http://ecb.jrc.ec.europa.eu/DOCUMENTS/Existing-Chemicals/RISK_ASSESSMENT/REPORT/dinpreport046.pdf

EU Risk Assessment Report for DIDP, pages 107 - 129; available at the following address:
http://ecb.jrc.ec.europa.eu/DOCUMENTS/Existing-Chemicals/RISK_ASSESSMENT/REPORT/didpreport041.pdf

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EU Risk Assessment Report for DEHP, pages 231 - 282; available at the following address:
http://ecb.jrc.ec.europa.eu/DOCUMENTS/Existing-Chemicals/RISK_ASSESSMENT/REPORT/dehpreport042.pdf

EU Risk Assessment Report for DBP, pages 41 - 64; available at the following address:
http://ecb.jrc.ec.europa.eu/DOCUMENTS/Existing-Chemicals/RISK_ASSESSMENT/REPORT/dibutylphthalatereport003.pdf

EU Risk Assessment Report for BBP, pages 91 - 124; available at the following address:
http://ecb.jrc.ec.europa.eu/DOCUMENTS/Existing-Chemicals/RISK_ASSESSMENT/REPORT/benzylbutylphthalatereport318.pdf

In addition, the European Commission's Scientific Committee on Health and Environmental Risks (SCHER) published an opinion on the risk of exposure to phthalates, including DINP, from school supplies. This is available at the following address:
http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_106.pdf

Levels of phthalates or phthalate alternatives in human tissues, milk, or body fluids, including those of children.

In addition to the above-mentioned lists of exposures studies, the U.S. Centers for Disease Control has an extensive biomonitoring database tracking levels of phthalate metabolites in human urine. Their most recent report published in 2005 summarizes data collected in 2001 and 2002 and is available on the internet at the following address (see pages 251 - 284):
<http://www.cdc.gov/exposurereport/pdf/thirdreport.pdf>

The CDC has also measured levels of phthalate metabolites in human urine for samples collected in 2003 and 2004. This data is available from the National Health and Nutrition Examination Survey (NHANES) database, but requires special software to interpret the dataset. A summary is available on the internet at the following address:
http://www.cdc.gov/nchs/data/nhanes/nhanes_03_04/124ph_c.pdf

The CDC has not conducted any biomonitoring data collection that we are aware of for the phthalate alternatives.

The European Union Risk Assessments conducted on several phthalates specifically considered levels of phthalates and phthalate metabolites in human tissues, milk, or body fluids. In particular, we refer you to the following:

EU Risk Assessment Report for DINP, pages 138 - 140; available at the following address:
http://ecb.jrc.ec.europa.eu/DOCUMENTS/Existing-Chemicals/RISK_ASSESSMENT/REPORT/dinpreport046.pdf

EU Risk Assessment Report for DIDP, pages 126 - 129; available at the following address:
http://ecb.jrc.ec.europa.eu/DOCUMENTS/Existing-Chemicals/RISK_ASSESSMENT/REPORT/didpreport041.pdf

EU Risk Assessment Report for DEHP, pages 261 - 282; available at the following address:
http://ecb.jrc.ec.europa.eu/DOCUMENTS/Existing-Chemicals/RISK_ASSESSMENT/REPORT/dehpreport042.pdf

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EU Risk Assessment Report for DBP, page 64; available at the following address:

http://ecb.jrc.ec.europa.eu/DOCUMENTS/Existing-Chemicals/RISK_ASSESSMENT/REPORT/dibutylphthalatereport003.pdf

EU Risk Assessment Report for BBP, pages 117 - 123; available at the following address:

http://ecb.jrc.ec.europa.eu/DOCUMENTS/Existing-Chemicals/RISK_ASSESSMENT/REPORT/benzylbutylphthalatereport318.pdf

The presence of phthalates or phthalate alternatives in indoor air or household dust.

In addition to the above-mentioned lists of exposure studies, the European Union Risk Assessments conducted on several phthalates specifically considered human exposures to these phthalates from their presence in indoor air. In particular, we refer you to the following:

EU Risk Assessment Report for DINP, pages 134 - 137; available at the following address:

http://ecb.jrc.ec.europa.eu/DOCUMENTS/Existing-Chemicals/RISK_ASSESSMENT/REPORT/dinpreport046.pdf

EU Risk Assessment Report for DIDP, pages 123 - 125; available at the following address:

http://ecb.jrc.ec.europa.eu/DOCUMENTS/Existing-Chemicals/RISK_ASSESSMENT/REPORT/didpreport041.pdf

EU Risk Assessment Report for DEHP, pages 251 - 254 and 255 - 257; available at the following address:

http://ecb.jrc.ec.europa.eu/DOCUMENTS/Existing-Chemicals/RISK_ASSESSMENT/REPORT/dehpreport042.pdf

EU Risk Assessment Report for DBP, pages 60 - 62; available at the following address:

http://ecb.jrc.ec.europa.eu/DOCUMENTS/Existing-Chemicals/RISK_ASSESSMENT/REPORT/dibutylphthalatereport003.pdf

EU Risk Assessment Report for BBP, pages 114 - 115; available at the following address:

http://ecb.jrc.ec.europa.eu/DOCUMENTS/Existing-Chemicals/RISK_ASSESSMENT/REPORT/benzylbutylphthalatereport318.pdf

† The CPSIA directs the staff to evaluate all available data as part of a “de novo review.” The staff has copies of many studies on phthalates prior to 2002 and is not requesting duplicate copies of studies it already has in its files or are readily available in peer-reviewed publications.

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**ATTACHMENT 1
TOXICITY STUDIES ON HMW PHTHALATES SINCE 2002**

ExxonMobil is aware of the following toxicity studies on HMW phthalates that have been conducted since 2002. The studies listed below are based upon information believed to be reliable on the date compiled, but we do not represent this as a complete list. The inclusion of a study in this list does not imply endorsement by ExxonMobil of the study quality and/or study findings.

Reproductive Toxicity – Mechanistic Studies

DINP

1. Borch et al. (2003). The effect of combined exposure to di(2-ethylhexyl) phthalate and diisononyl phthalate on testosterone levels in foetal rat testis. *Reprod Toxicol.* 17, 487-488.
2. Borch et al. (2004). Steroidogenesis in fetal male rats is reduced by DEHP and DINP, but endocrine effects of DEHP are not modulated by DEHA in fetal, prepubertal and adult male rats. *Reprod Toxicol.* 18, 53-61.
3. European Chemicals Bureau - Institute for Health and Consumer Protection (2003). European Union Risk Assessment Report for DINP.
4. European Commission Recommendation regarding the EU Risk Assessment for DINP as published in the Official Journal of the European Union (2006). Available at: http://ecb.jrc.ec.europa.eu/DOCUMENTS/Existing-Chemicals/RISK_ASSESSMENT/OJ_RECOMMENDATION/ojrec68515491.pdf (p. 12-13)
5. Lee, HC et al. (2006). Effects of perinatal exposure to phthalate/adipate esters on hypothalamic gene expression and sexual behavior in rats. *J Reprod Dev* 52:343-352.
6. Masutomi et al. (2003). Impact of dietary exposure to methoxychlor, genistein, or diisononyl phthalate during the perinatal period on the development of the rat endocrine/reproductive systems in later life. *Toxicology* 192, 149-170.
7. McKee RH, Butala JH, David RM and Gans G. 2004. NTP center for the evaluation of risks to human reproduction reports on phthalates: addressing the data gaps. *Reproductive Toxicology* 18: 1-22.
8. Tagaki H et al. (2005). Impact of maternal dietary exposure to endocrine-acting chemicals on progesterone receptor expression in microdissected hypothalamic medial preoptic areas of rat offspring. *Toxicol & App Pharmacol.* 208, 127-136.

DIDP

9. European Chemicals Bureau - Institute for Health and Consumer Protection (2003). European Union Risk Assessment Report for DIDP.
10. European Commission Recommendation regarding the EU Risk Assessment for DIDP as published in the Official Journal of the European Union (2006). Available at: http://ecb.jrc.ec.europa.eu/DOCUMENTS/Existing-Chemicals/RISK_ASSESSMENT/OJ_RECOMMENDATION/ojrec68515491.pdf (p. 9-10)

DINP/DIDP

11. Akahori Y, Nakai M, Yamasaki K, Takatsuki M, Shimohigashi Y, Ohtaki M. (2008). Relationship between the results of in vitro receptor binding assay to human estrogen receptor α and in vivo uterotrophic assay: Comparative study with 65 selected chemicals. *Toxicology in Vitro* 22, 225-231.
12. Kruger T, Manhai L, Bonefeld-Jorgensen EC. (2008). Plastic components affect the activation of the aryl hydrocarbon and the androgen receptor. *Toxicology (Ireland)* 246, 112-123.
13. Lee BM and Koo HJ. (2007). Hershberger assay for antiandrogenic effects of phthalates. *J Toxicol & Environ Health Part A.* 70, 1365-1370.
14. Takeuchi et al. (2005). Differential effects of phthalate esters on transcriptional activities via human estrogen receptors α and β , and androgen receptor. *Toxicology* 210, 223-233.

DPHP

15. BASF (2002) Palatinol 10-P, Acute dermal irritation/corrosion in rabbits, BASF Germany (unpublished report, provided by the notifier)

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16. BASF (2002) Palatinol 10-P, Acute eye irritation in rabbits, BASF Germany (unpublished report, provided by the notifier)
17. BASF AG (2003). Product Safety, 30R0183/02046, Volume I of III, 24.11.2003. Unpublished report.
18. Identified from the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) Full Public Report and the OECD HPV Dossier
 1. Developmental Screening Study - Rat - GD6-15, gavage
 2. Developmental Toxicity - Rat, GD 6-19, gavage

Immunology

DINP

19. Butala et al. (2004). Phthalate treatment does not influence levels of IgE or Th2 cytokines in B6C3F1 mice Toxicology 201, 77-85.
20. Lee MH et al. (2004). Enhancement of interleukin-4 production in activated CD4+ T cells by diphthalate plasticizers via increased NF-AT binding activity. Int Arch Allergy & Immunol. 134, 213-222.

DINP/DIDP

21. Jepsen KF, Abildtrup A, Larsen ST. (2004). Monophthalates promote IL-6 and IL-8 production in the human epithelial cell line A549. Toxicology in vitro – an international journal published in association with BIBRA. 18, 265-269.

DPHP

22. Biosearch Inc. (1979) Guinea pig contact dermal irritation/sensitization, Biosearch Inc. USA (unpublished report, provided by the notifier)
23. Identified from the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) Full Public Report and the OECD HPV Dossier
 1. Skin Sensitization - Guinea pig - non-adjuvant test

Repeat Dose/Carcinogenesis – Mechanistic Studies

DINP

24. Bility MT et al. (2004). Activation of mouse and human peroxisome proliferator-activated receptors (PPARs) by phthalate monoesters. Toxicol Sci. 82, 170-082.
25. Kaufmann et al. (2002). Tumor induction in mouse liver: di-isononyl phthalate acts via peroxisome proliferation. Regul Toxicol Pharmacol. 36, 175-183.
26. Shaw D, Lee R, Roberts RA. (2002). Species differences in response to the phthalate plasticizer monoisononyl phthalate (MINP) in vitro: a comparison of rat and human hepatocytes. Ach Toxicol. 76, 344-350.
27. Valles et al. (2003). Role of the peroxisome proliferators-activated receptor alpha in responses to diisononyl phthalate. Toxicology 191, 211-225.

DIDP

28. Cho W-S et al. (2008). Peroxisome proliferator di-isodecyl phthalate has no carcinogenic potential in Fischer 344 rats. Toxicol Lett. 178, 110-116.
29. Turan N, Cartwright LS, Waring RH, Ramsden DB. (2008). Wide ranging genomic effects of plasticizers and related compounds. Current Drug Metab. 9, 285-303.

DINP/DIDP

30. Kamendulis L, et al. (2002). Comparative effects of phthalate monoesters on gap junctional intercellular communication and peroxisome proliferation in rodent and primate hepatocytes. J Toxicol & Environ Health. Part A. 65, 569-588.

DPHP

31. Identified from the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) Full Public Report and the OECD HPV Dossier
 1. Repeat Dose - Rat - 90 day diet
 2. Mutagenicity - Ames assay

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**ATTACHMENT 2
TOXICITY STUDIES ON LMW PHTHALATES SINCE 2002**

ExxonMobil is aware of the following toxicity studies on LMW phthalates that have been conducted since 2002. The studies listed below are based upon information believed to be reliable on the date compiled, but we do not represent this as a complete list. The inclusion of a study in this list does not imply endorsement by ExxonMobil of the study quality and/or study findings.

Reproductive Toxicity – Mechanistic Studies

DEHP

1. Akahori Y, Nakai M, Yamasaki K, Takatsuki M, Shimohigashi Y, Ohtaki M. (2008). Relationship between the results of in vitro receptor binding assay to human estrogen receptor and in vivo uterotrophic assay: Comparative study with 65 selected chemicals. *Toxicology in Vitro* 22, 225-231.
2. Akingbemi BT, Ge R, Klinefelter GR, Zirkin BR, Hardy MP. (2004). Phthalate-induced Leydig cell hyperplasia is associated with multiple endocrine disturbances. *PNAS - National Academy of Sciences* 10, 775-780
3. Andrade AJM, Grande SW, Talsness CE, Grote K, Golombiewski A, Sterner-Kock A, Chahoud I.
4. (2006). A dose response study following in utero and lactational exposure to Di-(2-ethylhexyl) phthalate (DEHP): Effects on androgenic status, developmental landmarks and testicular histology in male offspring rats. *Toxicology* 225, 64-74.
5. Bhattacharya N, Dufour JM, Vo M-N, Okita J, Okita R, Kim KH. (2005). Differential effects of phthalates on the testis and the liver. *Biology of Reproduction* 72, 745-754.
6. Banerjee S. (2002). In utero exposure to di(2-ethylhexyl) phthalate alters growth, tissue organization, and the expression of androgen receptor protein of rat prostate. *Biol Reprod* 66(Suppl 1):200.
7. Borch et al. (2002). The effect of combined prenatal exposure to di(2-ethylhexyl)phthalate and di(2-ethylhexyl)adipate on testosterone production in rats. *Reprod Toxicol.* 16, 406
8. Borch et al. (2004). Steroidogenesis in fetal male rats is reduced by DEHP and DINP, but endocrine effects of DEHP are not modulated by DEHA in fetal, prepubertal and adult male rats. *Reprod Toxicol.* 18, 53-61.
9. Borch et al. (2005). Early testicular effects in rats perinatally exposed to DEHP in combinations with DEHA — apoptosis assessment and immunohistochemical studies. *Reprod Toxicol.* 19, 515-525.
10. Borch J, Metzendorff SB, Vinggaard AM, Brokken L, Dalgaard M. (2006). Mechanisms underlying the antiandrogenic effects of diethylhexyl phthalate in fetal rat testis. *Toxicology* 223, 144-155.
11. Borch J, Vinggaard AM, and Ladefoged O. (2003). The effect of combined exposure to di(2-ethylhexyl) phthalate and diisononyl phthalate on testosterone levels in foetal rat testis. *Reprod Toxicol.* 17, 487-488.
12. Culty M, Thuillier R, Li W, Wang Y, Martinez-Arguelles DB, Benjamin CG, Triantafyllou KM, Zirkin BR, Papadopoulos V. (2008). In Utero Exposure to Di-(2-ethylhexyl) Phthalate Exerts Both Short-Term and Long-Lasting Suppressive Effects on Testosterone Production in the Rat. *Biology of Reproduction* 78, 1018-1028
13. Dalgaard M. (2002). Di(2-ethylhexyl) adipate (DEHA) is foetotoxic but not anti-androgenic as di(2-ethylhexyl) phthalate (DEHP). *Reprod Toxicol* 16, 408-409.
14. Dobrzynska MM, Mikulska U, Tyrkiel E. (2005). The effects of subchronic exposure to phthalates on the reproductive ability of male mice. *Mutagenesis* 20, 480-481.
15. Duty S M; N P Singh; M J Silva; D B Barr; J W Brock; L Ryan; R F Herrick; D C Christiani; R Hauser. (2002). The relationship between environmental exposures to phthalates and DNA damage in human sperm using the neutral comet assay. *Journal of Toxicology and Environmental Health. Journal of the National institute of environmental sciences* 1-3.
16. European Chemicals Bureau - Institute for Health and Consumer Protection (2008). European Union Risk Assessment Report for DEHP.
17. European Commission Recommendation regarding the EU Risk Assessment for DEHP as published in the Official Journal of the European Union (2008). Available at: http://ecb.jrc.ec.europa.eu/DOCUMENTS/Existing-Chemicals/RISK_ASSESSMENT/OJ_RECOMMENDATION/ojrec117817.pdf (p. 26-29)

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18. EU Scientific Committee on Emerging and Newly-Identified Health Risks (SCENIHR). (2007). Preliminary report on the safety of medical devices containing DEHP-plasticized PVC or other plasticizers on neonates and other groups possibly at risk.
 1. Reproductive Toxicity; Prenatal Development; Rats; GD14 - Postnatal Day 3; Gavage
19. Gaido K et al. (2007). Fetal mouse phthalate exposure shows that gonocyte multinucleation is not associated with decreased testicular testosterone. *Toxicol Sci.* 97, 491-503.
20. Ge R-S, Chen G-R, Dong Q, Akingbemi B, Sottas CM, Santos M, Sealfon SC, Bernard D J, Hardy MP. (2007). Biphasic Effects of Postnatal Exposures to Diethylhexyl phthalate on the Timing of Puberty in Male Rats. *Journal of Andrology* 28, 513-520.
21. Grande SW, Andrade AJM, Talsness CE, Grote K, Golombiewski A, Sterner-Kock A, Chahoud I. A dose response study following in utero and lactational exposure to Di-(2-ethylhexyl) phthalate (DEHP): Reproductive effects on adult female offspring rats. *Toxicology* 229, 114-122.
22. Gray LE. (2004). Chronic exposure to diethyl hexyl phthalate (DEHP) delays puberty and reduces androgen-dependent tissue weights in the male rat. *Biol Reprod* 113.
23. Gray LE. (2005). Exposure to diethyl hexyl phthalate (DEHP) delays puberty and reduces androgen-dependent tissue weights in long Evans Hooded and Sprague-Dawley male rats. *Biol Reprod. (Special Issue)*, 134-5.
24. Hass U. (2004). Effects of finasteride and DEHP on anogenital distance and nipple retention after perinatal exposure in rats.; *Reprod Toxicol* 2004 July;18(5):731.
25. Howdeshell KL. (2005). Combination dose of two phthalates additively depresses testosterone production and *insl3* gene expression in male rat fetuses. 87.
26. Howdeshell KL, Furr J, Lambright CR, Rider CV, Wilson VS, Gray, Jr LE. (2007). Cumulative Effects of dibutyl phthalate and diethylhexyl phthalate on Male Rat Reproductive Tract Development: Altered Fetal Steroid Hormones and Genes. *Toxicol Sci* 99, 190-202.
27. Howdeshell et al. (2008). A mixture of five phthalate esters inhibits fetal testicular testosterone production in the Sprague Dawley rat in a cumulative dose, additive manner. *Toxicol Sci.* 105, 153-165.
28. Jarfelt K, Dalgaard M, Hass U, Borch J, Jacobsen H, Ladefoged O. (2005). Antiandrogenic effects in male rats perinatally exposed to a mixture of di(2-ethylhexyl) phthalate and di(2-ethylhexyl) adipate. *Reprod Toxicol* 19, 505-515.
29. Kang SC. (2004). Comparative evaluation of phthalates for sperm motility and male fertility in Sprague-Dawley rats.; *Birth Defects Res Part A Clin Mol Teratol* 70, 310.
30. Kang IH (2005). Anti-androgenic activity of phthalate esters (di(2-ethylhexyl) phthalate, di(n-butyl) phthalate, and butylbenzyl phthalate) in the rodent 10-day Hershberger assay using immature castrated male rats. *J Toxicol & Public Health : an Official Journal of the Korean Society of Toxicology* 21, 187-93.
31. Karbe E and Kerlin RL (2002). Cystic degeneration/spongiosis hepatitis in rats. *Toxicology Pathology* vol. 30, no.2: 216-227.
32. Kessler et al. (2004). Blood burden of di(2-ethyl hexyl) phthalate and its primary metabolite mono(2-ethylhexyl) phthalate in pregnant and non-pregnant rats and marmosets. *Toxicol & App Pharmacol.* 195, 142-153.
33. Kim H-S, Saito K, Ishizuka M, Kazusaka A, Fujita S. (2003). Molecular Toxicology: Short period exposure to di-(2-ethylhexyl) phthalate regulates testosterone metabolism in testis of prepubertal rats. *Archives of Toxicology.* 1-15
34. Kobayashi K. (2004). Effects of *in utero* and lactational exposure to di(2-ethylhexyl) phthalate (DEHP) on postnatal development and thyroid status in rat offspring. *J Toxicol Sci* 29, 465.
35. Kobayashi K. (2005). Postnatal development in rat offspring following in utero and lactational exposure to di (2-ethylhexyl) phthalate.; *Toxicol Lett* 158(Suppl 1), S130.
36. Kruger T, Manhai L, Bonefeld-Jorgensen EC. (2008). Plastic components affect the activation of the aryl hydrocarbon and the androgen receptor. *Toxicology (Ireland)* 246, 112-123.
37. Kurata Y, Makinodan F, Okada M, Kawasuso T, David RM, Gans G, Regnier F, and Katoh M. 2003. Blood concentration and tissue distribution of ¹⁴C-di(2-ethylhexyl)phthalate (DEHP) in juvenile and adult common marmoset. *Toxicologist* 72:1865.
38. Lague E and Tremblay JJ. (2008). Antagonistic effects of testosterone and the endocrine disruptor mono-(2-ethylhexyl) phthalate on *Ins13* transcription in leydig cells. *Endocrinology* 149, 4688-4694
39. Lambrot R, Muczynski V, Lecureuil C, Angenard G, Coffigny H, Pairault C, Moison D, Frydman R, Habert R, Rouiller-Fabre V. (2009). Phthalates impair germ cell development in the human fetal testis *in vitro* without change in testosterone production. *Environmental Health Perspectives* 117, 32-37.

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40. Lampen A. (2002). Teratogenic phthalates and metabolites activate the nuclear receptors PPARs and induce differentiation of F9 cells. *Reprod Toxicol* 16, 430
41. Latini G. (2003). Health hazards for prenatal exposure to di-(2-ethylhexyl)-phthalate. *Pediatr Res* 54, 561
42. Latini G. (2002). Human prenatal exposure to di-(2-ethylhexyl)-phthalate. *Pediatr Res* 52, 780.
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Immunology

DEHP

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170. Dearman RJ, Beresford L, Bailey L, Caddick HT, Betts CJ, Kimber I. (2008). Di-(2-ethylhexyl) phthalate is without adjuvant effect in mice on ovalbumin. *Toxicology* 244, 231-241.
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173. Kolarik B, Naydenov K, Larsson M, Bornehag C-G, Sundell J. (2008). The association between phthalates in dust and allergic diseases among Bulgarian children. *Environ Health Perspect.* 116, 98-103.
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175. Larsen ST and Nielsen GD. (2007). The adjuvant effect of di-(2-ethylhexyl) phthalate is mediated through a PPAR α -independent mechanism. *Toxicology Letters* 170, 223-228.
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177. Lee MH et al. (2004). Enhancement of interleukin-4 production in activated CD4+ T cells by diphthalate plasticizers via increased NF-AT binding activity. *Int Arch Allergy & Immunol.* 134, 213-222.
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182. *Acta Scientiae Circumstantiae (Huanjing Kexue Xuebao)* 28, 995-1000.
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DBP

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BBP

190. Butala et al. (2004). Phthalate treatment does not influence levels of IgE or Th2 cytokines in B6C3F1 mice *Toxicology* 201, 77-85.
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193. Larsen ST and Nielsen GD. (2008). Structure-activity relationship of immunostimulatory effects of phthalates. *BMC Immunology* 9, 61.

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Repeat Dose/Carcinogenesis – Mechanistic Studies

DEHP

196. Barr et al. (2003). Assessing human exposure to phthalates using monoester and their oxidized metabolites as biomarkers. 111, 1148-1151.
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198. Ito Y and Nakajima T. (2008). PPAR α - and DEHP-Induced Cancers. *PPAR Research* 2008,1-12
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201. Kamendulis L, et al. (2002). Comparative effects of phthalate monoesters on gap junctional intercellular communication and peroxisome proliferation in rodent and primate hepatocytes. *J Toxicol & Environ Health*. Part A. 65, 569-588.
202. Kim I Y; S Y Han; A Moon. (2004). Phthalates inhibit tamoxifen-induced apoptosis in mcf7 human breast cancer cells. *Journal of Toxicology and Environmental Health* 67 Part A, 2025-2035
203. Nakagawa T et al (2008). Molecular mechanics and molecular orbital simulations on specific interactions between peroxisome proliferator-activated receptor PPAR α and plasticizer. *J Mol Graphics & Mod*. 27, 45-58.
204. Numtip W; Naunyn Schmiedebergs. (2003). Kinetics of di(2-ethylhexyl) phthalate and mono(2-ethylhexyl) phthalate in non-pregnant and pregnant marmosets. *Arch Pharmacol* 367(Suppl 1):R129.
205. Pogribny IP, Tryndyak VP, Boureiko A, Melnyk S, Bagnyukova TV, Montgomery B, Rusyn I. (2008). Mechanisms of peroxisome proliferator-induced DNA hypomethylation in rat liver. *Mutation Research* 644, 17-23.
206. Takashima K, Ito Y, Gonzalez F J, Nakajima T. (2008). Different mechanisms of DEHP-induced hepatocellular adenoma tumorigenesis in wild-type and Ppara-null mice. *Journal of Occupational Health* 50, 169-180.
207. Turan N, Cartwright LS, Waring RH, Ramsden DB. (2008). Wide ranging genomic effects of plasticizers and related compounds. *Current Drug Metab*. 9, 285-303.
208. Voss C, Zerban H, Bannasch P, Berger MR. (2005). Lifelong exposure to di-(2-ethylhexyl)-phthalate induces tumors in liver and testes of Sprague-Dawley rats. *Toxicology* 206, 359-371

DBP

209. Bility MT et al. (2004). Activation of mouse and human peroxisome proliferator-activated receptors (PPARs) by phthalate monoesters. *Toxicol Sci*. 82, 170-182.
210. Dearman RJ, Betts, CJ, Beresford L, Bailey L, Caddick HT, Kimber I. 2008. Butyl benzyl phthalate: effects on immune responses to ovalbumin in mice, *J.Appl. Toxicol*
211. Dearman RJ, Beresford L, Bailey L, Caddick HT, Betts CJ and Kimber I. 2008. Di-(2-ethylhexyl) phthalate is without adjuvant effect in mice on ovalbumin. *Toxicology* 244: 231-241.
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213. Kim I Y; S Y Han; A Moon. (2004). Phthalates inhibit tamoxifen-induced apoptosis in mcf7 human breast cancer cells. *Journal of Toxicology and Environmental Health* 67 Part A, 2025-2035
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216. Nakagawa T et al (2008). Molecular mechanics and molecular orbital simulations on specific interactions between peroxisome proliferator-activated receptor PPAR α and plasticizer. *J Mol Graphics & Mod.* 27, 45-58.
217. Wellejus A; et al (2002). Oxidative DNA damage in male Wistar rats exposed to di-n-butyl phthalate. *Journal of Toxicology and Environmental Health* 65.

BBP

219. Bility MT et al. (2004). Activation of mouse and human peroxisome proliferator-activated receptors (PPARs) by phthalate monoesters. *Toxicol Sci.* 82, 170-082.
220. Kang SC, Lee BM. (2005). DNA methylation of estrogen receptor alpha gene by phthalates. *J Toxicol Environ Health A.* 68, 1995-2003.
221. Kim I Y; S Y Han; A Moon. (2004). Phthalates inhibit tamoxifen-induced apoptosis in mcf7 human breast cancer cells. *Journal of Toxicology and Environmental Health* 67 Part A, 2025-2035
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223. Zhuang M-Z; Y F Li; T Li; X W Huang; N Shi (2008). Effects of butyl benzyl phthalate on neurobehavioral development of rats [in Chinese]. *Zhonghua Lao Dong Wei Sheng Zhi Ye Bing Za Zhi (J Ind Hygiene and Occupational Diseases - China)* 26, 285-288.

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**ATTACHMENT 3
TOXICITY STUDIES ON PHTHALATE ALTERNATIVES**

ExxonMobil is aware of the following toxicity studies on phthalate alternatives. The studies listed below are based upon information believed to be reliable on the date compiled, but we do not represent this as a complete list. The inclusion of a study in this list does not imply endorsement by ExxonMobil of the study quality and/or study findings.

ATBC (Acetyltri-n-butyl citrate; marketed as Citroflex® A-4) (CAS No. 77-90-7)

Reproductive Toxicity Studies

1. Chase KR and Willoughby CR. 2002. Citroflex A-4 toxicity study by dietary administration to Han Wistar rats for 13 weeks with an in utero exposure phase followed by a 4-week recovery period. Project No. MOX 002/013180. Huntingdon Life Sciences Ltd. UK.
2. Robbins MC 1994. A two-generation reproduction study with acetyl tributyl citrate in rats. Report No. 1298/1/2/94. BIBRA Toxicology International, Surrey, UK.

Immunology

3. Hill Top Research, Inc. 1978. Repeated insult patch test on Citroflex 2 liquid, Citroflex A-2 liquid, and Citroflex A-4 liquid. Unpublished data submitted by CTFA, December 4, 1998.
4. Uniliver Limited. 1976. Sensitization potential of Citroflex A2 (Acetyl triethyl citrate), Citroflex A4 (acetyl tributyl citrate), and Citroflex 2 (triethyl citrate). Unpublished data submitted by CTFA, May 12, 1999.

Repeat Dose/Carcinogenesis – Mechanistic Studies

5. Ames, BNJ, McCann J and Yamasaki E. 1975. Methods for detecting carcinogens and mutagens with the salmonella/mammalian-microsome mutagenicity test. *Mutat. Res.* 31, 347-364.
6. Bigger CAH and Harbell JW. 1991. Mouse lymphoma assay (L5178Y TK +/-). Study No. C316.703. Microbiological Associates Inc. Bethesda, MD.
7. CTFA. 1982b. Genetic toxicology report. CP-61,838 (Citroflex A-6). Citrate ester plasticizer. Unpublished data submitted by CTFA, December 4, 1998.
8. DOW Chemical Company. 1991. Evaluation of acetyl tributyl citrate in the Chinese hamster ovary cell/hypoxanthine-guanine-phosphoribosyl transferase (CHO/HGPRT) forward mutation assay. Sanitized Laboratory Report. [Name of Testing Facility not Stated].
9. DOW Chemical Company. 1988. Evaluation of acetyl tributyl citrate in an in vitro chromosomal aberration assay utilizing rat lymphocytes. Sanitized Laboratory Report. [Name of Testing Facility not stated].
10. Ekwall B. 1990. Toxicity of HeLa cells of 205 drugs as determined by the metabolic inhibition test supplemented by microscopy. *Toxicology* 17, 279-295.
11. Ekwall B, Nordenstein C and Albanus L. 1982. Toxicity of 29 plasticizers to HeLa cells in the MIT-24 system. *Toxicology* 24, 199-210.
12. Fellows, M. 1999. Acetyl tributyl citrate (ATBC): Measurement of unscheduled DNA synthesis in rat liver using an in vivo/in vitro procedure. Report No. 1734/1-DE140. Covance Laboratories Limited, North Yorkshire, England.
13. Finkelstein M and Gold H. 1959. Toxicology of the citric acid esters: tributyl citrate, acetyl tributyl citrate, triethyl citrate, and acetyl triethyl citrate. *Toxicology and Applied Pharmacology* 1, 283-298.
14. Fouda HG. 1982. Safety assessment of Citroflex plasticizers – In vitro hydrolysis by serum, liver, and intestinal enzymes. Unpublished data submitted by CTFA, December 4, 1998.
15. Gold H, Modell W and Finkelstein M. 1959. On the pharmacology of triethyl, acetyl triethyl, tributyl, and acetyl tributyl citrates by oral administration in rats and cats. Cornell University Medical College.
16. Gollapudi BB and Linscombe VA. 1988. Evaluation of acetyl tributyl citrate in the Ames salmonella/mammalian-microsome bacterial mutagenicity assay. Health and Environmental Services, Texas.
17. Heath, JL and Reilly M. 1982. Mutagenesis Testing of acetyl-tributylcitrate and epoxidized soybean oil. *Poultry Science.* 61, 2517-2519.
18. Jonker ID, Hollanders VMH. 1991. Subchronic (90day) dietary toxicity study with acetyl tributyl citrate (ATBC) in rats. Report No. V 91.255. TNO Nutrition and Food Research, The Netherlands.
19. Jonker ID, Hollanders VMH. 1990. Range-finding study (14-day, dietary) with acetyl tributyl citrate (ATBC) in rats. Report No. V 90.3355. TNO Nutrition and Food Research, The Netherlands.

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20. Larionov AG and Cherkasova TE. 1977. Toxicological evaluation of acetyltributylcitrate. *Gig. Sanit.*, 4, 102-103.
21. Meyers DB, Autian J and Guess WL. 1964. Toxicity of plastics used in medical practice II. Toxicity of citric acid esters used as plasticizers. *Journal of Pharmaceutical Sciences.* 53, 774-777.
22. Mochida K, Gomyoda KM, and Fujita T. 1996. Acetyl tributyl citrate and dibutyl sebacate inhibits the growth of cultured mammalian cells. *Bull. Environ. Contam. Toxicol.* 56, 635-637.
23. San RHC and Wagner VO. 1991. Salmonella/Mammalian-microsome plate incorporation mutagenicity assay (Ames Test). Laboratory Study Number C316.501017. Microbiological Associates, Inc. Rockville, MD.
24. Soeler, AO, Slinton M, Boggs J and Drinker P. 1950. Experiments on the chronic toxicity of acetyl tributyl citrate. Department of Industrial Hygiene, Harvard Medical School, Boston, MA.

DOTP (Di-octyl terephthalate; also called DEHT or di(2-ethylhexyl) terephthalate) (CAS No. 6422-86-2)

Reproductive Toxicity Studies

25. Faber WD, Deyo JA, Stump DG, and Ruble K. (2007). Two-generation reproduction study of di-2-ethylhexyl terephthalate in Crl: CD Rats. *Birth Defects Res (Part B)* 80, 69-81.
26. Faber WD, Deyo JA, Stump DG, Navarro L, Ruble K, Knapp J. (2007). Developmental toxicity and uterotrophic studies with di-2-ethylhexyl terephthalate. *Birth Defects Res B Dev Reprod Toxicol.* 80, 396-405.
27. Gray E Jr., Ostby J, Furr J, Prince M, Rao Veeramachaneni DN, Paiks L (2000). Perinatal exposure to the phthalates DEHP, BBP, and DINP, but not DEP, DMP or DOTP, alters sexual differentiation of the male rat. *Toxicol Sci.* 58, 350-365.
28. EU Scientific Committee on Emerging and Newly-Identified Health Risks (SCENIHR). (2007). Preliminary report on the safety of medical devices containing DEHP-plasticized PVC or other plasticizers on neonates and other groups possibly at risk.
 2. Reproductive Toxicity; Prenatal Development; Rats; GD14 - Postnatal Day 3; Gavage

Immunology

29. David RM, Lockhart LK, and Ruble KM. (2003). Lack of sensitization for trimellitate, phthalate, terephthalate and isobutyrate plasticizers in a human repeated insult patch test. *Food Chem Toxicol.* 41, 589-593.

Repeat Dose/Carcinogenesis – Mechanistic Studies

30. Barber ED. (2006). Genetic toxicology testing of di(2-ethylhexyl) terephthalate. *Environ Mol Mut.* 23, 228-233.
31. Barber ED, Fox JA, and Giodano CJ. (1994). Hydrolysis, absorption and metabolism of di(2ethylhexyl) terephthalate in the rat. *Xenobiotica.* 24, 441-450.
32. Barber ED and Topping DC. (1995). Subchronic 90 Day oral toxicology of di(2-ethylhexyl) terephthalate in the rat. *Food Chem Toxicol.* 33, 971-978.
33. Deyo JA. (2008). Carcinogenicity and chronic toxicity of di-2-ethylhexyl terephthalate (DEHT) following a 2-year dietary exposure in Fischer 344 rats. *Food Chem Toxicol.* 46, 990-1005.
34. EU Scientific Committee on Emerging and Newly-Identified Health Risks (SCENIHR). (2007). Preliminary report on the safety of medical devices containing DEHP-plasticized PVC or other plasticizers on neonates and other groups possibly at risk.
 1. Repeat Dose Toxicity; Rat; 10 day; oral
 2. Repeat Dose Toxicity; Rat; 10 day; inhalation
 3. Mutagenicity; Ames Test
 4. Mutagenicity; in vitro Chinese Hamster Ovary Test
 5. Mutagenicity; In vitro Chromosome Aberration test

DINCH (Di-isononyl cyclohexanoate; marketed as Hexamoll® DINCH) (CAS No. 166412-78-8 or 474919-59-0)

Reproductive Toxicity Studies

35. EU Scientific Committee on Emerging and Newly-Identified Health Risks (SCENIHR). (2007). Preliminary report on the safety of medical devices containing DEHP-plasticized PVC or other plasticizers on neonates and other groups possibly at risk.
 1. Reproductive Toxicity; Prenatal Development; Rabbits; GD 6-29; Diet

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2. Reproductive Toxicity; Prenatal Development; Rats; Day 6-19 Post coitum; Diet
3. Reproductive Toxicity; Pre and Post-Natal Development; Rats; Day 3 post coitum – Day 20 post partum; Oral
4. Two Generation Reproductive/Developmental Study; Rats; Continuous Dietary Administration

Repeat Dose/Carcinogenesis – Mechanistic Studies

36. EU Scientific Committee on Emerging and Newly-Identified Health Risks (SCENIHR). (2007). Preliminary report on the safety of medical devices containing DEHP-plasticized PVC or other plasticizers on neonates and other groups possibly at risk.
 1. Repeat Dose Toxicity; Species Unknown; 28 day; diet
 2. Repeat Dose Toxicity; Species Unknown; 90 day; diet
 3. Mutagenicity; Ames Test
 4. Mutagenicity; in vitro Chinese Hamster Ovary Test
 5. Mutagenicity; In vitro Chromosome Aberration test
 6. Mutagenicity; In vivo mouse micronucleus test (bone marrow)
 7. 2 yr Carcinogenicity Test: Diet; Rat

TOTM (Tris (2-ethylhexyl) trimellitate) (CAS No. 3319-31-1)

Reproductive Toxicity Studies

37. Ministry of Health & Welfare, Japan (1998). Toxicity Testing Reports of Environmental Chemicals, Vol. 6
 1. Reproductive Toxicity Test; Rat; gavage

Immunology

38. David R, Lockhart L, Ruble K. (2003). Lack of sensitization for trimellitate, phthalate, terephthalate and isobutyrate plasticizers in a human repeated insult patch test. Food Chem Toxicol. 4, 589-593.

Repeat Dose/Carcinogenesis – Mechanistic Studies

39. Chemical Manufacturers Association (1985). A 28-day toxicity study with tris (2-ethylhexyl) trimellitate in the rat. Performed at the British Industrial Biological Research Association, unpublished report. Project No. 3.0496. Report No. 0496/1/85.
40. Chemical Manufacturers Association (1987). A 21-day gavage study of 2-ethylhexanol and tris (2-ethylhexyl) trimellitate to rats: effects on the liver and liver lipids. Performed at the British Industrial Biological Research Association, unpublished report.
41. Cifone MA et al. (1986). Genetic toxicity of tris (2-ethylhexyl) trimellitate (TOTM) in the USD and CHO/HGPRT assays. The Toxicologist 6:A#905.
42. Hodgson JR. (1987). Results of peroxisome induction studies on tri(2-ethylhexyl) trimellitate and 2-ethylhexanol. Toxicol and Ind Health 3, 49-60.
43. Kambia N et al. (2008). Molecular modeling of phthalates – PPARs interactions. J Enzyme Inhibition and Med Chem. 23, 611-616.
44. Martis L, Freid E, Woods E. (1987). Tissue distribution and excretion of tri-(2-ethylhexyl)trimellitate in rats. J Toxicol Environ Health 20, 357-366.
45. Ministry of Health & Welfare, Japan (1996). Toxicity Testing Reports of Environmental Chemicals, Vol. 4
 1. Genetic Toxicity; Ames Test (GLP compliant)
 2. Genetic Toxicity; Ames Test (at least 4 non-GLP compliant)
 3. Genetic Toxicity; Chromosomal Aberrations
 4. Genetic Toxicity; Reverse Gene Mutation Assay
46. Rathinam K Srivastava S Seth P. (1990). Hepatic studies of intraperitoneally administered tris(2-ethylhexyl)trimellitate (TOTM) and di(2ethylhexyl) phthalate in rats. J App Toxicology 10, 39-41.
47. Zeiger E, Andersen B, Haworth S, Lawlor T, and Mortelmans K (1988). Salmonella mutagenicity test. IV. Results from the testing of 300 chemicals. Environ Molec Muta. 11, 1-158.

Alkyl sulfonic acid ester of phenol (marketed as Mesamoll® II) (CAS No. 91082-17-6)

Reproductive Toxicity Studies

48. Bormmann, G et al., (1956) Z. Lebensmittel-Untersuch. Forsch. 103, 413-424.
 1. Reproductive Toxicity; Repeat Dose; 6 wk; gavage; Rat

Repeat Dose/Carcinogenesis – Mechanistic Studies

49. Bayer AG data (1986) Report No. 14540: Repeat Dose; 28 day; oral feed; Rat

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50. Bayer AG data (1987) Report No. 16244: Repeat Dose; 90 Day; oral feed; Rat
51. Bayer AG data (1975) Report No. 5760: Repeat Dose; 43 Day; oral feed; Rat
52. Bayer AG data (1981) Report No. 10414: Genetic Toxicity: Ames Test
53. Bayer AG data (1996) Report No. 25209: Genetic Toxicity: HGPRT Assay
54. Bornmann, G et al., (1956) Z. Lebensmittel-Untersuch. Forsch. 103, 413-424.
 1. Repeat Dose; 1 yr; gavage; Rat
55. May C. (1996). BAU data. Report No. F1250 p. 131-154.
 1. Genetic Toxicity: Cytogenetic Assay
 2. Repeat Dose; 49 Day; oral feed; Rat

Epoxidized soybean oil (ESO, ESBO) (CAS No. 8013-07-8)

Reproductive Toxicity Studies

56. Hans Y et al. (2000). Embryotoxicity and teratogenicity studies of epoxidized soy bean oil (ESBO) using in vitro battery test system. Teratology 61, 485
57. Centre International de Toxicologie. (1993). One generation study by oral route (gavage) in rats. Project No. 8707 RSR
58. Centre International de Toxicologie. (1993). Embryotoxicity/Teratogenicity study of epoxidized soybean oil by oral route in rats. Project No. 8709 RSR

Repeat Dose/Carcinogenesis – Mechanistic Studies

59. Ames BN, McCann J, Yamasaki E. (1975). Mutation Res. 31, 347-364.
60. Hazelton Microtest. (1992). Study to determine the ability of epoxidized soybean oil to induce mutations as the thymidine kinase (tk) locus in mouse lymphoma L5178Y cells using a fluctuation assay. Project No. CGG 1/TK.
61. Hazelton Microtest. (1992). Study to evaluate the chromosome damaging potential of epoxidized soybean oil by its effects on cultured human peripheral blood lymphocytes using an in vitro cytogenetics assay. Project No. CGG 1/HLC
62. Kirckebusch W, Jahr K, Czok G, Degkwitz E, and Lang K. (1963). Pette-Seifen-Anstrichmittel 65, 919-924.
63. Maron DM and Ames BN (1983). Mutation Res 113, 173-215.
64. McLaughlin J Jr., Marliac JP, Verrett MJ, Fitzjugh OG. (1965). Toxicity of some food additive chemicals as measured by the chick embryo technique. Toxicol Appl Pharmacol. 7, 491.

COMGHA (Acetylated monoglycerides of fully hydrogenated castor oil; marketed as Grindsted® Soft'n'Safe) (CAS No. 736150-63-3)

Repeat Dose/Carcinogenesis – Mechanistic Studies

65. EU Scientific Committee on Emerging and Newly-Identified Health Risks (SCENIHR). (2007). Preliminary report on the safety of medical devices containing DEHP-plasticized PVC or other plasticizers on neonates and other groups possibly at risk.
 1. Metabolism Study – Absorption, Distribution, Metabolism, Excretion
 2. Repeat Dose Toxicity Study – Rats; 90 Day; gavage
 3. Repeat Dose Toxicity Study – Rats; 90 Day; Rats; diet
 4. Repeat Dose Toxicity Study – Rats; unknown duration; 8.5 ml/kg bw; Test of liver enzymes and peroxisome proliferation
 5. Mutagenicity – Ames Test; in vitro
 6. Mutagenicity – Chromosome Aberration Test; in vitro

Polyol ester benzoate made from pentaerythriol, 2-EH acid and benzoic acid (marketed as LGflex EBN) (CAS No. 610787-77-4)

Repeat Dose/Carcinogenesis – Mechanistic Studies

66. Estimated from LG Chem MSDS: LGflex EBN
 1. Genotoxicity: Ames test
 2. Genotoxicity: Mouse micronucleus test in vivo
 3. Repeat Dose Toxicity: 28 day; oral



OFFICE OF THE SECRETARY
FREEDOM OF INFORMATION

2009 JAN 16 A 10:18

4/2

January 12, 2009

VIA ELECTRONIC MAIL

Office of the Secretary
Consumer Product Safety Commission
Room 502
4330 East-West Highway
Bethesda, MD 20814

Re: Section 108 of the Consumer Product Safety Improvement Act: Phthalates in Children's Products; Request for Comments and Information

To the Office of the Secretary:

The Phthalate Esters Panel (Panel)¹ of the American Chemistry Council submits these comments on the U.S. Consumer Product Safety Commission's (CPSC) request for information pursuant to Section 108 of the Consumer Product Safety Improvement Act (CPSIA), "PROHIBITION ON SALE OF CERTAIN PRODUCTS CONTAINING SPECIFIED PHTHALATES." The Panel is composed of all major manufacturers and some users of the primary phthalate esters in commerce in the United States. As set forth below, the Panel addresses several of the questions contained in the information request posted on the CPSC website.² In particular, the Panel discusses the use and measurement of phthalates in children's products, and highlights recent scientific information sponsored by the Panel as well as recent risk assessments conducted by governmental entities. The Panel looks forward to additional opportunities to provide information to the CPSC, particularly as it begins the process of establishing the Chronic Hazard Advisory Panel pursuant to Section 108(b)(2) of the CPSIA.

Use of Phthalates in Children's Products

The fourteen phthalates³ commonly in domestic use today have thousands of applications.⁴ However, the CPSC requests information specific to the use of phthalates in toys and child care articles.

¹ Panel members are: BASF Corporation, Eastman Chemical Company, ExxonMobil Chemical Company, and Ferro Corporation. Teknor Apex Company, a major user of the materials, is an associate member.

² <http://www.cpsc.gov/about/cpsia/108rfc.pdf>

³ These include dimethyl phthalate (DMP), diethyl phthalate (DEP), dibutyl phthalate (DBP), diisobutyl phthalate (DIBP), butylbenzyl phthalate (BBP), diisooheptyl phthalate (DIHP), di(2-ethylhexyl) phthalate (DEHP), diisooctyl phthalate (DIOP), diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), diundecyl phthalate (DUP) and diisoundecyl phthalate (DIUP), ditridecyl phthalate (DTDP), dipropyl heptyl phthalate (DPHP) and various linear phthalates (C6-



Therefore, the panel has focused its comments on the use of phthalates in those two product categories. If the CPSC is interested in applications beyond those used in toys and child care articles, the Panel would be pleased to provide information on those applications. Of those fourteen phthalates, all except DMP, DEP, and DBP are primarily used to plasticize. (*i.e.*, soften) polyvinyl chloride (PVC or vinyl) without sacrificing its durability. Importantly, phthalate esters or an alternative plasticizer must be added to vinyl to achieve its flexibility. Phthalates provide good performance characteristics for flexible vinyl applications.

Phthalates are the major vinyl plasticizers, making up nearly 70% of the U.S. plasticizer market. The fourteen phthalates listed in footnote 3 account for 98% of the phthalates used domestically today.⁵ About 70% of that phthalate market is comprised of DINP, DIDP, DPHP and DEHP.⁶

Use of DINP in Toys and Child Care Articles

DINP is the most commonly used phthalate in flexible vinyl toys. DINP has been extensively studied and has a strong safety profile. (See Appendix A for references for toxicological information on DINP). Consistent with Section 108(b)(1) of the CPSIA, DINP may continue to be used as a plasticizer in PVC children's toys that cannot be placed in the mouth.

Although DINP is the most commonly used phthalate in flexible vinyl toys, DINP would not be expected to be used as a vinyl softener in child care articles intended to be mouthed, including teething rings, rattles, and pacifiers. This is the result of a 1998 voluntary agreement between the CPSC and toy manufacturers where DINP was voluntarily removed from flexible vinyl toys pending completion of the Chronic Hazard Advisory Panel's (CHAP) risk assessment on DINP. The CHAP was convened by the CPSC in 1998 and subsequently issued its report in 2001. Among its conclusions, the CHAP determined "For the majority of children, the exposure to DINP from DINP-containing toys would be expected to pose a minimal to non-existent risk of injury."⁷

C11). Throughout these comments, the terms "phthalates" and "phthalate esters" are used interchangeably.

⁴ The use and production volume information provided here is based on the Panel's knowledge of the domestic market and it may not reflect the total market for phthalates used in toys or child care articles when imported products are included for analysis.

⁵ Bizzari *et al.* 2007. "Plasticizers" CEH Marketing Research Report. Chemical Economics Handbook – SRI Consulting.

⁶ *Id.* There are potential alternative plasticizers which can be used in toys and child care articles. For information, see Biedermann *et al.* (2008). Plasticizers in PVS Toys and Child Care Products: What succeeds the Phthalates? Market Survey 2007. *Chromatographia* 68, August (No. 3/4): 227-234.

⁷ Report to the U.S. Consumer Product Safety Commission by the Chronic Hazard Advisory Panel on Diisononyl Phthalate (DINP), U.S. Consumer Product Safety Commission, Bethesda, MD, June 2001, at 7.

Use of DEHP in Toys and Child Care Articles

As noted above, DINP is the primary phthalate used in toys. Di(2-ethylhexyl) phthalate (DEHP), however, also is used in some toys or child care articles. DEHP, as with DINP, would not be expected to be used as a vinyl softener in child care articles intended to be mouthed including teething rings, rattles, and pacifiers. In a voluntary agreement with the toy industry, DEHP's use was restricted as a vinyl softener.⁸ Additionally, ASTM F 963-07 consumer safety specification - nationally recognized safety requirements for toys - precludes the use of DEHP in these applications as a vinyl softener (only de minimis amounts of DEHP may be in these products under the specification).

Use of Other Phthalates in Toys and Child Care Articles

No phthalate ester would be expected to be used as a plasticizer in toys and child care articles intended to be mouthed (*i.e.*, teething rings, rattles, and pacifiers) for the reasons mentioned above. Additionally, the specific CPSIA phthalates DIDP, DnOP, DBP and BBP, would not be expected to be used in toys or childcare articles. DnOP is not produced or used in the United States or the European Union as a separate commercial product. It may be used as a component of linear phthalates which have very special applications such as vinyl sheet roofing.

Measurement of Phthalates in Children's Products

There are several methods suitable for the routine identification and measurement of total phthalate concentration for consumer products under Section 108 of the CPSIA.

- ASTM D7083-04 Standard Practice for Determination of Monomeric Plasticizers in Poly Vinyl Chloride (PVC) by Gas Chromatography is a test method to determine monomeric plasticizers including phthalate esters. This test method is available at <http://www.astm.org/Standards/D7083.htm>
- The Canada Product Safety Bureau has a test method for total phthalate content in PVC products. This method describes a general procedure for the determination of phthalate esters in consumer products made of PVC by solvent extraction and precipitation of the polymer. More information on this method is available at http://www.hc-sc.gc.ca/cps-spc/alt_formats/hecs-sesc/pdf/prod-test-essai/_method-chem-chim/c-34-eng.pdf
- The European Toy Safety Directive (EN 71 0 Parts 9, 10, 11) specifies analytical methods for the identification and determination of several organic chemicals including DEHP and DINP, but not total phthalate content.

In addition to the methods listed above, there are commercially available methods and commercial laboratories that can test toys to determine phthalate content. Agilent Technologies, Intertek and NSF International, for example, all have capabilities to determine phthalate content for products that

⁸ Consumer Product Safety Review, Summer 2003 at 4. "Although other toys were not included in the agreement, manufacturers in general switched to another phthalate. The phthalate substituted for DEHP was diisononyl phthalate (DINP)." *Id.*

contain phthalates that are covered under the CPSIA. Additionally, X-ray fluorescence has been used to attempt to rapidly determine phthalate content in toys and child care articles, however, to the Panel's knowledge, there are no accurate screening methods or technologies available for the rapid detection of phthalate esters.

Toxicity and Risk Assessment Information on Phthalates

There is a wealth of recent and scientifically credible information on the toxicity profile of individual phthalates. Since its inception in 1973, Panel members have demonstrated their commitment to the safe use of their products by sponsoring health, safety and environmental research on phthalate esters. The Panel has funded more than \$15 million of research, excluding research conducted by individual companies.

Results of Panel-sponsored research are routinely shared with government agencies around the globe in order to support a comprehensive and thorough assessment of the safety of their products. Panel research and conclusions are peer-reviewed and published in respected scientific journals. Phthalate esters research produced by Panel members has been subjected to extensive health and environmental scrutiny by both independent scientists and national and international government bodies.

For more information on Panel sponsored research since 2002, please refer to Appendix A – References.

Risk assessments have been conducted on a number of phthalates by the European Chemicals Bureau (ECB)⁹ and the U.S. National Toxicology Program's Center for the Evaluation of Risk to Human Reproduction (NTP).¹⁰ Given the available scientific information available on phthalates, these risk assessments are necessarily lengthy and provide a wealth of toxicity and exposure information that the CPSC should review thoroughly.

⁹ DINP, http://ecb.jrc.it/DOCUMENTS/Existing-Chemicals/RISK_ASSESSMENT/REPORT/dinpreport046.pdf

DEHP, http://ecb.jrc.ec.europa.eu/documents/Existing-Chemicals/RISK_ASSESSMENT/REPORT/dehpreport042.pdf

DIDP,
http://ecb.jrc.ec.europa.eu/DOCUMENTS/ExistingChemicals/RISK_ASSESSMENT/REPORT/didpreport041.pdf

DBP,
http://ecb.jrc.ec.europa.eu/DOCUMENTS/ExistingChemicals/RISK_ASSESSMENT/REPORT/dibutylphthalatereport003.pdf

BBP, http://ecb.jrc.ec.europa.eu/DOCUMENTS/Existing-Chemicals/RISK_ASSESSMENT/REPORT/benzylbutylphthalatereport318.pdf

¹⁰ For reports on DINP, DIDP, DEHP, BBP, DBP, DnOP and DnHP, see <http://cerhr.niehs.nih.gov/reports/index>.

Human Exposure to Phthalates

Vinyl is widely used in consumer products, thus phthalate-plasticized vinyl is also in wide use. However, the general population's exposures to phthalates from all sources are quite low based on U.S. Centers for Disease Control and Prevention (CDC) biomonitoring data. Indeed, the general population's exposure for each phthalate measured is below its EPA reference dose (see Table below).¹¹

Some have incorrectly concluded that the presence of phthalate metabolites in human tissues, milk or body fluids mean that phthalates will bioaccumulate in the body. Studies have shown (Rowland *et al.*, 1974; Rowland *et al.*, 1977; White *et al.*, 1980; Wittassek and Angerer, 2008) that phthalates are readily broken down by biological organisms such as fish and mammals. In humans, this occurs within 12 to 24 hours of entry into the body. Thus, phthalates do not pose a concern for bioaccumulation. Additionally, higher molecular weight phthalates do not biomagnify in food chains (Mackintosh *et al.*, 2004); further evidence that these compounds are readily metabolized.

Phthalate Exposures Based on Third CDC National Exposure Report^a Expressed as Micrograms per Kilogram of Body Weight per Day^b

Geometric Mean		By Age Group			By Gender		By Race/Ethnicity			
Phthalate	Overall	6-11	12-19	20+	Men	Women	Mexican-American	Black	White	RfD ^c
DINP	LOD ^d	LOD	LOD	LOD	LOD	LOD	LOD	LOD	LOD	120 ^e
DEHP	0.80	0.55	0.39	0.79	0.70	0.91	0.81	0.93	0.76	20
f	2.05	2.29	1.15	1.87	1.95	2.15	1.91	2.29	2.07	20
f	2.29	2.66	1.35	2.07	2.14	2.45	2.25	2.51	2.31	20
BBP	0.51	0.80	0.35	0.43	0.46	0.56	0.46	0.54	0.51	200
DBP	0.88	0.91	0.53	0.80	0.68	1.12	0.83	0.94	0.84	100
DEP	5.83	1.82	2.79	6.40	5.04	6.69	5.86	7.44	5.33	800

^a Third National Report on Human Exposure to Environmental Chemicals, U.S. Centers for Disease Control and Prevention, January 2003. The Panel encourages the CPSC to review the most recent exposure information available from the CDC.

^b The urinary concentrations of phthalate monoesters reported by CDC were converted to daily intake of the parent phthalate using the methodology described in David, R. (2000). Exposure to phthalate esters. Environmental Health Perspectives 108(10):A440. The values given by this methodology are very similar to values derived by a separate methodology used by the CDC and the National Institute for Environmental Health Sciences. Kohn, M., et al. (2000). Human exposure estimates for phthalates. Environmental Health Perspectives 108(10):A440-442.

^c RfD = reference dose. From the Integrated Risk Information System (IRIS) database maintained by the US Environmental Protection Agency (www.epa.gov/ngispgm3/iris). A reference dose is an exposure level defined by the Environmental Protection Agency as "a numerical estimate of a daily oral exposure to the human population, including sensitive subgroups such as children, that is not likely to cause harmful effects during a lifetime."

^d Below Level of Detection

^e EPA has not developed an RfD for DINP. The value given is the Acceptable Daily Intake from Report to the U.S. Consumer Product Safety Commission by the Chronic Hazard Advisory Panel on Diisononyl Phthalate (DINP), June 2001 (available at <http://www.cpsc.gov/LIBRARY/FOIA/Foia01/os/dinp.pdf>).

^f CDC tested for three different metabolites of DEHP

¹¹ A reference dose is an exposure level defined by the U.S. Environmental Protection Agency as "a numerical estimate of a daily oral exposure to the human population, including sensitive subgroups such as children, that is not likely to cause harmful effects during a lifetime."

Conclusion

Given the wealth of scientific information on phthalates, including those references listed in Appendix A, the risk assessments conducted by governmental entities, and the CPSC's own conclusions based on the CHAP on DINP, the Panel believes that phthalates can continue to be used in toys and child care articles. The Panel welcomes other opportunities to provide additional information on phthalates for CPSC's consideration. If you have any questions, please contact me at (703) 741-5614 or at Kristy_Morrison@americanchemistry.com

Sincerely,

A handwritten signature in cursive script that reads "Kristy Morrison".

Kristy Morrison

Manager, Phthalate Esters Panel

APPENDIX A – REFERENCES ¹²

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¹²

These studies include Panel sponsored studies since 2002 as well as other information available on phthalates. Inclusion of any studies listed in this Appendix is for informational purposes. Any claims or statements made in these references, however, are not necessarily agreed upon or endorsed by the Phthalate Esters Panel.

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Stevenson, Todd

From: Morrison, Kristy [Kristy_Morrison@americanchemistry.com]
Sent: Monday, January 12, 2009 6:47 PM
To: Phthalates Project
Subject: Non Phthalate Ester Plasticizer Panel Comments Section 108
Attachments: FINAL Non-PE Panel CPSC comments Section 108.pdf

Importance: High

Categories: Technical comment

To the Office of the Secretary:

The Non-Phthalate Esters Panel (Panel) of the American Chemistry Council submits the attached comments on the U.S. Consumer Product Safety Commission's (CPSC) request for information pursuant to Section 108 of the Consumer Product Safety Improvement Act (CPSIA), "PROHIBITION ON SALE OF CERTAIN PRODUCTS CONTAINING SPECIFIED PHTHALATES." The Panel was formed in December 2008, to address product stewardship and regulatory issues on non-phthalate plasticizers, including benzoates, citric acid esters, terephthalates, phosphate esters and polymeric plasticizers and other ester chemistries not specified.

If you have any questions, please contact me at (703) 741-5614 or at Kristy_Morrison@americanchemistry.com

Sincerely yours,
Kristy L. Morrison
Manager, Chemical Products & Technology Division
American Chemistry Council
1300 Wilson Boulevard
Arlington, VA 22209
Office: (703) 741-5614
Mobile: (703) 328-7037

416



OFFICE OF THE SECRETARY
FREEDOM OF INFORMATION

2009 JAN 21 A 11: 01

January 12, 2009

Via Electronic Mail

Office of the Secretary
Consumer Product Safety Commission
Room 502
4330 East-West Highway
Bethesda, MD 20814

Re: Section 108 of the Consumer Product Safety Improvement Act: Phthalates in Children's Products; Request for Comments and Information

To the Office of the Secretary:

The Non-Phthalate Ester Plasticizers Panel (Panel)¹ of the American Chemistry Council appreciates the U.S. Consumer Product Safety Commission's (CPSC) request for information pursuant to Section 108 of the Consumer Product Safety Improvement Act (CPSIA), "PROHIBITION ON SALE OF CERTAIN PRODUCTS CONTAINING SPECIFIED PHTHALATES." This request for information pertains to phthalates as well as phthalate alternatives that may be used in children's products. The Panel was formed in December 2008, to address product stewardship and regulatory issues on non-phthalate plasticizers, including benzoates, citric acid esters, terephthalates, phosphate esters and polymeric plasticizers and other ester chemistries not specified. In this regard, the Panel is pleased to offer the following comments on the CPSC's information request and looks forward to additional opportunities to provide information to the CPSC, particularly as it begins the process of establishing the Chronic Hazard Advisory Panel (CHAP) pursuant to Section 108(b)(2) of the CPSIA. Importantly, the Panel strongly believes that before the CHAP conducts a risk assessment on a subset of the many possible alternative plasticizers, a basic set of toxicological and exposure information is essential.

Based on analytical research conducted on toys in Europe and Japan², non-phthalate plasticizers/additives are used in toys and childcare products. For example, in a recent article by Biedermann-Brem, *et al.*, the authors identified numerous non-phthalate plasticizers/additives, including acetyl-tributyl-citrate (Citroflex® A-4), 2,2,4-trimethyl-1,3-pentanediol-diisobutyrate (Eastman TXIB), and dioctyl terephthalate (Eastman 168)³, among others.⁴ The European Union banned the use of certain

¹ Panel Members are: Eastman Chemical Company, Ferro Corporation, HallStar, ICL-IP America Products and Vertellus Performance Materials, Inc.

² T. Niino, *et al.*, Analysis of Phthalate Ester Plasticizers in Polyvinyl Chloride Children's Toys, after 1998, *Jpn. J. Food Chem*, vo. 8(3), 2001.

³ This alternative is referred to as di-(2-ethylhexyl)-terephthalate in the article.



phthalates as plasticizers in toys and childcare products nearly 10 years ago, thus it is not surprising that Biedermann-Brem, *et al.*, identified numerous non-phthalate alternatives.

The Panel is aware that alternative plasticizers are used in PVC toys in North America. Moreover, the Panel believes that the potential use of alternative plasticizers for PVC toys and child care articles, as well as other consumer products, could be significant based on the most recent Chem Service General Catalog, in which hundreds of non-phthalate plasticizer kits are available for use as analytical standards and reference materials, and for other laboratory purposes.⁵ The toy and childcare article manufacturers, however, may have more detailed use information.

The Panel welcomes other opportunities to provide additional information on non-phthalate alternatives for CPSC's consideration. If you have any questions, please contact me at (703) 741-5614 or at Kristy_morrison@americanchemistry.com

Sincerely,



Kristy Morrison
Manager, Non Phthalate Ester Plasticizers Panel

⁴ S. Biedermann-Brem, *et al.*, Plasticizers in PVC Toys and Childcare Products: What Succeeds the Phthalates? Market Survey 2007, Chromatographia, 2008, 68, August (No. 3/4). Panel members include manufacturers of several of the plasticizers identified in this article.

⁵ Available at <http://www.chemservice.biz/catalog-info.htm>.

Stevenson, Todd

From: Morrison, Kristy [Kristy_Morrison@americanchemistry.com]
Sent: Monday, January 12, 2009 6:17 PM
To: Phthalates Project
Cc: Morrison, Kristy
Attachments: FINAL Phthalate Esters Panel Comments - Section 108_Phthalates in Children's Products January 12 2009.pdf

Importance: High

Categories: Test method, Technical comment

To the Office of the Secretary:

The Phthalate Esters Panel (Panel) of the American Chemistry Council submits the attached comments on the U.S. Consumer Product Safety Commission's (CPSC) request for information pursuant to Section 108 of the Consumer Product Safety Improvement Act (CPSIA), "PROHIBITION ON SALE OF CERTAIN PRODUCTS CONTAINING SPECIFIED PHTHALATES."

If you have any questions, please contact me at (703) 741-5614 or at Kristy_Morrison@americanchemistry.com

Sincerely yours,
Kristy L. Morrison
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January 12, 2009

Office of the Secretary
Consumer Product Safety Commission, Room 502
4330 East-West Highway
Bethesda, MD 20814

Comments of the Breast Cancer Fund, Consumers Union, Consumer Federation of America, Kids in Danger, National Research Center for Women & Families, Public Citizen, and U.S. Public Interest Research Group
On
“Section 108: Phthalates in Children’s Products”

Introduction

Our groups, representing consumer, scientific, and public health interests, submit the following comments in response to the U.S. Consumer Product Safety Commission (CPSC) staff request for information regarding:

- Toxicity of Phthalates and Phthalate Alternatives;
- Exposure to Phthalates and Phthalate Alternatives;
- Use of Polyvinyl Chloride (PVC) in Children’s Products;
- Use of Non-PVC Plastics in Children’s Products;
- Use of Phthalates and Phthalate Alternatives in Children’s Products;
- Measurement of Phthalates in Children’s Products.

We are commenting first on the broader topics of toxicity and exposure to phthalates and phthalate alternatives, and then commenting on the four remaining topics, which are narrower in scope.

Toxicity of Phthalates and Phthalate Alternatives

The studies we submit for your review in these sections have all been replicated in controlled laboratory settings and were conducted by government agencies, government researchers, and independent scientists who have no financial stake in the use of phthalates or phthalate alternatives in consumer products. We highlight human studies whenever available but wish to note that animal studies are widely recognized to have direct relevance to the health risks posed to humans, based on the similarities in the endocrine system and other physiology of the studied animals and humans. The hormonal signals that guide development of the reproductive tract are the same in rodents as they are in humans. Therefore, animal studies showing reproductive harm, particularly in male animals, have important implications for humans.

Human studies are less likely to be conducted because it requires decades of research and millions of dollars to follow thousands of subjects from exposure in the womb until reproductive age at current exposure levels. Furthermore, it is unethical to deliberately expose humans to high

levels of phthalates to observe effects. Therefore, the human studies that have found effects are especially concerning because they have been able to find statistically significant changes at current levels of exposure and these changes are consistent to those found in the animal studies.

Summary of major studies pertaining to toxicity of phthalates:

CDC scientists have found phthalates in the urine and blood of Americans of all ages.¹ There are hundreds of *independent, peer-reviewed* scientific studies that have been generated since the 1970s that have linked phthalate exposure to serious health hazards. Since 2002, several studies have found: reduced testosterone levels,^{2 3} lowered sperm counts in boys and adult males^{4 5 6 7} and genital defects in baby boys.^{8 9 10} An additional remaining hazard is also reflected in a 2000 human study linking phthalates exposure to early puberty in girls.¹¹

Moreover, several studies in humans have indicated the incidence of some of these toxic effects at levels similar to what the average American is currently exposed to.^{12 13} Additionally, a review of the literature further links phthalate exposure to other serious health effects including:

- Endometriosis, or growth of uterine tissue outside the uterus, which can cause pain, infertility and other health complications^{14 15}
- Increased waist size and insulin resistance^{16 17 18}
- Respiratory disorders^{19 20}

Lastly, male genital abnormalities^{21 22 23 24} and female sexual abnormalities^{25 26 27} resulting from phthalate exposure have been demonstrated in several additional animal studies since 2002.

Toxicity of PVC or other materials that may contain phthalates or phthalate alternatives

It is essential to study the impact of phthalates from multiple sources, and to try to quantify the contribution of phthalates in the products regulated by the CPSC. Individual phthalates can have cumulative effects or interactive effects on fetal testosterone and pregnancy, regardless of whether one of these phthalates has relatively small effects.²⁸ Studies in rats show that combining phthalates with other phthalates or with pesticides can produce cumulative, additive, adverse effects.^{29 30 31}

Polyethylene and Polypropylene (non PVC plastic). When hard plastic, such as PVC is used to make soft plastic toys, phthalates are needed to soften the material. Three types of plastics are potential replacements for soft PVC in toys: Thermoplastic elastomers (TPEs), ethylene vinyl acetate (EVA) and polyolefins (polyethylene/polypropylene), including the new metallocenes.

Biobased plastics, thermoplastic elastomers, and ethylene vinyl acetate (EVA) do not use toxic additives.³²

Citrates. The EU Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) cleared citrates in 2004 as an alternative to phthalates. The industry submitted a risk assessment on citrates (acetyl tributyl citrate (ATBC) in 2003, and the CSTEE concluded they were safe in January 2004.³³ Research on rats and mice

found that ATBC was *not* a developmental or reproductive toxicant.³⁴ The EU ban became permanent in 2005.

DINCH. The German chemical company BASF, shut down its European DEHP production after the EU ban became permanent in 2005 and now produces an alternative plasticizer line called DINCH, which is used in toys, food-contact materials and medical applications. DINCH is a safer alternative. However, independent, peer-reviewed scientific studies are needed to confirm the company's safety claims.³⁵

Grindsted Soft-n-Safe. Danisco is a Danish company that is one of the largest manufacturers of food additives in the world. They introduced a phthalate alternative for toys and other products that is made from vegetable oil and does not disrupt hormones; it was approved for use in the EU in 2005. Danisco received The Danish Society of Engineers' Product Award for developing GRINDSTED® SOFT-N-SAFE to soften products made with PVC.

However, independent, peer-reviewed scientific research on Grindsted Soft-n-Safe is needed to confirm the safety of Danisco:^{36 37}

Exposure of Phthalates and Phthalates Alternatives

A growing body of evidence supports the conclusion that the timing of phthalate exposure may be just as significant as the dose of exposure.^{38 39} Infants and children are not just smaller adults. They are still developing and are changing almost every day. A small dose of chemical can have a devastating impact one day whereas a few days or weeks later, the chemical would not have the same effect. This is because their endocrine systems are incredibly sensitive and are sending signals to the brain and back to the endocrine system to direct growth and development. Phthalates interrupt these critical signals and, although the effects may not show up for many years, this interruption may cause infertility, prostate cancer, or breast cancer in later life.^{40 41}

The scientific evidence shows that humans are chronically exposed to many phthalates from multiple sources and that these various phthalates interact with each other and with other chemicals in our environment to produce cumulative, additive and adverse effects. However, removing even one route of exposure can make a significant difference in terms of reducing human's cumulative impact and preventing disease or abnormalities.

Summary of Studies Pertaining to Migration of Phthalates and Phthalates Alternatives from PVC or children's products:

Phthalates are dialkyl or alkyl/aryl esters of 1,2-benzenedicarboxylic acid.^{42 43} They are widely used as plasticizers for poly vinyl chloride (PVC) products because they add softness and flexibility to the normally rigid material.⁴⁴ Since phthalate esters (PEs) are not chemically bound to the PVC⁴⁵ they leach into the environment and are now found "ubiquitously" in air, water, dust and food.^{46 47} Many different products such as upholstery, floor tiles, children's toys and teething rings,⁴⁸ food containers and jar seals⁴⁹ contain PEs – some, such as children's toys, can contain as high as 40-50% PE by weight.⁵⁰ It is estimated that over 900 tons of phthalates are produced globally each year,⁵¹ maybe even as much as 4 million tons.⁵²

Summary of Studies Pertaining to Human (including children's and pregnant women's) Exposure to Phthalates and Phthalates Alternatives from *All Sources*, including building materials, consumer products, personal care products and food:

Phthalate plasticizers are not chemically bound to PVC, therefore they can leach, migrate or evaporate into indoor air and atmosphere, foodstuff, other materials, etc. Consumer products containing phthalates can result in human exposure through direct contact and use, indirectly through leaching into other products, or general environmental contamination.⁵³ Humans are exposed through ingestion, inhalation, and dermal exposure during their whole lifetime, including intrauterine development. Exposure assessment via modeling ambient data give hints that the exposure of children to phthalates exceeds that in adults.⁵⁴ Current human biomonitoring data prove that the tolerable intake of children is exceeded to a considerable degree, in some instances up to 20-fold. Very high exposures to phthalates can occur via medical treatment, i.e. via use of medical devices containing DEHP or medicaments containing DBP phthalate in their coating.⁵⁵

One study assessed the risk of exposure of the population to chemicals with estrogen-like activity through mineral water consumption by monitoring the presence of estrogenic compounds in Italian mineral water bottled in polyethylene terephthalate (PET). This study showed that more than 90% of the water samples did not exhibit any appreciable estrogenic activity.⁵⁶ Another study which measured the migration of PET into soft drinks and fruit juices found that PET migration is generally controlled by the very low diffusion of the polymer and, as a consequence, the partitioning coefficients of migrants between the polymer material and the foodstuff do not influence the migration levels significantly.⁵⁷

Acetyl tributyl citrate (ATBC) has been shown to inhibit the growth of different human, monkey and dog cells⁵⁸ and migrates into food from plastic food-wrap.⁵⁹ Approximately 99% of orally administered ATBC is excreted - intermediate metabolites include acetyl citrate, monobutyl citrate, acetyl monobutyl citrate, dibutyl citrate, and acetyl dibutyl citrate. In acute, short-term, subchronic, and chronic feeding studies, these ingredients were relatively nontoxic. ATBC is also considered safe as used in cosmetics.⁶⁰

Summary of Studies Pertaining to the Presence of Phthalates or Phthalates Alternatives in Indoor Air or Household Dust:

In a review of relevant studies on the respiratory and allergic effects of exposure to phthalates from PVC products, epidemiologic studies in children showed associations of phthalates from PVC plastics in the home and risk of asthma and allergies.⁶¹

Use of Polyvinyl Chloride (PVC) in Children's Products

Comments on polyvinyl chloride

PVC (polyvinyl chloride) plastic cannot be used to make soft plastic products without the addition of a plethora of toxic additives, which can make the PVC product itself harmful to consumers. These chemicals can evaporate or leach out of PVC, posing risks to children and consumers. One of the most common toxic additives is DEHP, a phthalate that is a suspected

carcinogen and reproductive toxicant readily found in numerous PVC products. Children can be exposed to phthalates by chewing on vinyl toys. The European Parliament voted in July, 2005 to permanently ban the use of certain toxic phthalates in toys.

Note: On the following page is a chart of the use of PVC and non-PVC plastics in children's products.

Use of PVC in Children's Products	Use of Non-PVC Plastics in Children's Products (Available alternatives)
Mattresses - Those with a waterproof coating of PVC are common, as are waterproof sheets to protect mattresses.	Cotton mattresses and futons, and uncovered foam mattresses. Waterproof covers made of polypropylene are available.
Baby changing mats	Polyester
Diaper covers	Polyester, nylon and polyurethane
Bibs	Textiles and polyethylene/polypropylene.
Strollers - Clear PVC is used in transparent hoods to keep out the rain on pushchairs or strollers.	
Toys - Teethers, squeeze toys, inflatable toys, dolls..	Natural materials are suitable alternatives for most types of toys, as well as some alternative plastics, which don't require the addition of plasticizers or other hazardous additives.
Shoes - Soft PVC is used in shoes and parts of shoes, such as soles, labels for logo imprints, upper parts made from PVC imitation leather coatings.	Products such as leather, rubber and polyurethane.
Boots and galoshes - Rubber boots are sometimes made from PVC containing phthalate softeners.	Boots made from other materials are available.
Bags - Sports bags and school bags are often made from nylon with a PVC coating to make them waterproof.	Cotton canvas, textiles with polyurethane coatings, nylon or polyester.
Clothes – Screen printed T-shirts; raincoats. <i>Phthalate plasticizers in textiles will be washed out in normal washing - almost the entire phthalate contents are washed out during the service life of products such as printed T shirts. People can also be exposed to phthalates through contact with the skin, although the extent of this exposure is not known.</i>	

Use of Non-PVC Plastics in Children's Products

Alternatives to soft PVC

Given that soft plastic is desirable for certain children's products, it is necessary to identify plastics which are preferable to soft PVC. In the long term, bio-based polymers, made from renewable sources, are preferable to any of petrochemical plastics for products which have relatively short lifecycles such as toys. In the interim, until bio-based plastics are widely available, there are some petroleum-based plastics which are less harmful to the environment and which do not pose such a direct threat to children's health as soft PVC. Many of these plastics are already being used by toy manufacturers for certain products, such as teething rings and soft blocks.

Three potential replacements for soft PVC in toys fulfill safety requirements: Thermoplastic elastomers (TPEs), ethylene vinyl acetate (EVA) and polyolefins (polyethylene/polypropylene), including the new metallocenes (see page 2). All three materials are easy to process (possibly on the same equipment as PVC); have aesthetic appeal, lessen environmental and health impacts; and are cost competitive. The use of these materials to replace soft PVC is a significant improvement and represents progress toward sustainable materials. In addition, none of these alternatives requires phthalate plasticizers to be soft and flexible (although they could be used and care should be taken to prevent this) and all require less overall additives than PVC. When they do contain additives, these additives make up a much smaller percentage (0-2% of the polymer mixture), in comparison to up to 50% phthalate content in PVC toys. Furthermore, it appears that the alternatives are also less likely to leach than PVC as the additives are bound tighter to the polymer.

Use of Phthalates and Phthalate Alternatives in Children's Products

Comments on phthalates or phthalate alternatives currently used in children's toys

According to scientists, diisononyl phthalate (DINP) has been the principal phthalate in soft plastic toys, and because it is not tightly bound to PVC it may be released when children mouth PVC products.⁶² DINP is an endocrine disruptor.

Substitutes for phthalates plasticizers are acetyl tributyl citrate (see page 4), tributyl citrate and diisononyladipate.⁶³ As we mention earlier, the EU ban on phthalates would not have happened, if the EU Scientific Committee on Toxicity, Ecotoxicity and Environment (CSTEE) had not cleared citrates in 2004 as alternative to banned phthalates.

Other phthalate alternatives include polyethylene and polypropylene, and bio-based alternatives thermoplastic elastomer, and ethylene vinyl acetate.⁶⁴

Possible phthalates or phthalate alternatives to use after February 10, 2009

We listed several potential alternatives earlier in this letter. Whatever phthalate alternatives are used must not be listed as possible human carcinogens by the International Agency for Research on Cancer or listed in a National Toxicology Report, or identified as a carcinogen by the EPA or OSHA. In addition, alternatives should not be a substance identified as having evidence of adverse developmental, male reproductive or female reproductive toxicity

effects by the National Toxicology Program's Center for the Evaluation of Risks to Human Reproduction.

Phthalates or phthalate alternatives used in children's products for purposes other than as PVC plasticizers

Phthalates are used in shampoos, scents, soap, lotion, cosmetics, medications, and medical devices that are used by children.⁶⁵

Measurement of Phthalates in Children's Products

Our organizations support scientific evidence that is built through replicated research relying on a process that welcomes criticism from other scientists, and is reviewed by unbiased peers in scientific and medical journals.

In addition to the analysis of concentration of phthalates in children's products, it is essential to study the extent to which the phthalates migrate, leach, or evaporate into water and air.

For example, a recent study conducted by scientists at the University of California at Davis measured endocrine-disruption chemicals in indoor air, from phthalates and other sources.⁶⁶ The study found that the levels of Di-(2-ethylhexyl) phthalate was much higher than other chemicals.

Conclusion

Our organizations support Section 108 of the Consumer Product Safety Improvement Act (CPSIA), which prohibits the sale of certain children's toys and products containing six specified phthalates (BBP, DBP and DEHP permanently, and DIDP, DINP and DnOP on an interim basis). Scientific evidence suggests that phthalates may be harmful to humans, and increase the risk of serious diseases such as cancer and reproductive problems.

We are pleased that the Chronic Hazard Advisory Panel (CHAP), which will decide whether to continue the interim ban on DIDP, DINP and DnOP "will consider the cumulative effects of exposure to multiple phthalates from all sources, including personal care products."⁶⁷ A recent report, "Phthalates and Cumulative Risk Assessment: The Task Ahead," by the National Research Council stated, "The U.S. Environmental Protection Agency should examine whether combined exposures to chemicals known as phthalates could cause adverse health effects in humans."⁶⁸ The report stated, "Recent data have shown widespread human exposure to multiple phthalates from a multitude of sources."⁶⁹ The report also noted that "A focus solely on phthalates to the exclusion of other chemicals would be artificial and could seriously underestimate risk."⁷⁰

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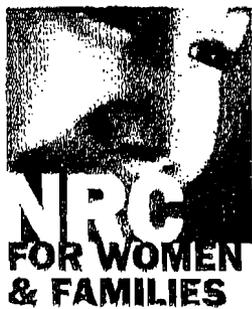
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FASCIMILE TRANSMITTAL SHEET

TO: Office of the Secretary,
Consumer Product Safety Commission, Room 502

FROM: Paul Brown

COMPANY: CPSC

DATE: January 12, 2009

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Attached: Comments on "Section 108: Phthalates in Children's Products"

URGENT FOR REVIEW PLEASE COMMENT PLEASE REPLY

January 12, 2009

Office of the Secretary
Consumer Product Safety Commission, Room 502
4330 East-West Highway
Bethesda, MD 20814

**Comments of the Breast Cancer Fund, Consumers Union, Consumer Federation of
America, Kids in Danger, National Research Center for Women & Families,
Public Citizen, and U.S. Public Interest Research Group
On
“Section 108: Phthalates in Children’s Products”**

Introduction

Our groups, representing consumer, scientific, and public health interests, submit the following comments in response to the U.S. Consumer Product Safety Commission (CPSC) staff request for information regarding:

- Toxicity of Phthalates and Phthalate Alternatives;
- Exposure to Phthalates and Phthalate Alternatives;
- Use of Polyvinyl Chloride (PVC) in Children’s Products;
- Use of Non-PVC Plastics in Children’s Products;
- Use of Phthalates and Phthalate Alternatives in Children’s Products;
- Measurement of Phthalates in Children’s Products.

We are commenting first on the broader topics of toxicity and exposure to phthalates and phthalate alternatives, and then commenting on the four remaining topics, which are narrower in scope.

Toxicity of Phthalates and Phthalate Alternatives

The studies we submit for your review in these sections have all been replicated in controlled laboratory settings and were conducted by government agencies, government researchers, and independent scientists who have no financial stake in the use of phthalates or phthalate alternatives in consumer products. We highlight human studies whenever available but wish to note that animal studies are widely recognized to have direct relevance to the health risks posed to humans, based on the similarities in the endocrine system and other physiology of the studied animals and humans. The hormonal signals that guide development of the reproductive tract are the same in rodents as they are in humans. Therefore, animal studies showing reproductive harm, particularly in male animals, have important implications for humans.

Human studies are less likely to be conducted because it requires decades of research and millions of dollars to follow thousands of subjects from exposure in the womb until reproductive age at current exposure levels. Furthermore, it is unethical to deliberately expose humans to high

levels of phthalates to observe effects. Therefore, the human studies that have found effects are especially concerning because they have been able to find statistically significant changes at current levels of exposure and these changes are consistent to those found in the animal studies.

Summary of major studies pertaining to toxicity of phthalates:

CDC scientists have found phthalates in the urine and blood of Americans of all ages.¹ There are hundreds of *independent, peer-reviewed* scientific studies that have been generated since the 1970s that have linked phthalate exposure to serious health hazards. Since 2002, several studies have found: reduced testosterone levels,^{2 3} lowered sperm counts in boys and adult males^{4 5 6 7} and genital defects in baby boys.^{8 9 10} An additional remaining hazard is also reflected in a 2000 human study linking phthalates exposure to early puberty in girls.¹¹

Moreover, several studies in humans have indicated the incidence of some of these toxic effects at levels similar to what the average American is currently exposed to.^{12 13} Additionally, a review of the literature further links phthalate exposure to other serious health effects including:

- Endometriosis, or growth of uterine tissue outside the uterus, which can cause pain, infertility and other health complications^{14 15}
- Increased waist size and insulin resistance^{16 17 18}
- Respiratory disorders^{19 20}

Lastly, male genital abnormalities^{21 22 23 24} and female sexual abnormalities^{25 26 27} resulting from phthalate exposure have been demonstrated in several additional animal studies since 2002.

Toxicity of PVC or other materials that may contain phthalates or phthalate alternatives

It is essential to study the impact of phthalates from multiple sources, and to try to quantify the contribution of phthalates in the products regulated by the CPSC. Individual phthalates can have cumulative effects or interactive effects on fetal testosterone and pregnancy, regardless of whether one of these phthalates has relatively small effects.²⁸ Studies in rats show that combining phthalates with other phthalates or with pesticides can produce cumulative, additive, adverse effects.^{29 30 31}

Polyethylene and Polypropylene (non PVC plastic). When hard plastic, such as PVC is used to make soft plastic toys, phthalates are needed to soften the material. Three types of plastics are potential replacements for soft PVC in toys: Thermoplastic elastomers (TPEs), ethylene vinyl acetate (EVA) and polyolefins (polyethylene/polypropylene), including the new metallocenes.

Biobased plastics, thermoplastic elastomers, and ethylene vinyl acetate (EVA) do not use toxic additives.³²

Citrates. The EU Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) cleared citrates in 2004 as an alternative to phthalates. The industry submitted a risk assessment on citrates (acetyl tributyl citrate (ATBC) in 2003, and the CSTEE concluded they were safe in January 2004.³³ Research on rats and mice

found that ATBC was *not* a developmental or reproductive toxicant.³⁴ The EU ban became permanent in 2005.

DINCH. The German chemical company BASF, shut down its European DEHP production after the EU ban became permanent in 2005 and now produces an alternative plasticizer line called DINCH, which is used in toys, food-contact materials and medical applications. DINCH is a safer alternative. However, independent, peer-reviewed scientific studies are needed to confirm the company's safety claims.³⁵

Grindsted Soft-n-Safe. Danisco is a Danish company that is one of the largest manufacturers of food additives in the world. They introduced a phthalate alternative for toys and other products that is made from vegetable oil and does not disrupt hormones; it was approved for use in the EU in 2005. Danisco received The Danish Society of Engineers' Product Award for developing GRINDSTED® SOFT-N-SAFE to soften products made with PVC.

However, independent, peer-reviewed scientific research on Grindsted Soft-n-Safe is needed to confirm the safety of Danisco.^{36 37}

Exposure of Phthalates and Phthalates Alternatives

A growing body of evidence supports the conclusion that the timing of phthalate exposure may be just as significant as the dose of exposure.^{38 39} Infants and children are not just smaller adults. They are still developing and are changing almost every day. A small dose of chemical can have a devastating impact one day whereas a few days or weeks later, the chemical would not have the same effect. This is because their endocrine systems are incredibly sensitive and are sending signals to the brain and back to the endocrine system to direct growth and development. Phthalates interrupt these critical signals and, although the effects may not show up for many years, this interruption may cause infertility, prostate cancer, or breast cancer in later life.^{40 41}

The scientific evidence shows that humans are chronically exposed to many phthalates from multiple sources and that these various phthalates interact with each other and with other chemicals in our environment to produce cumulative, additive and adverse effects. However, removing even one route of exposure can make a significant difference in terms of reducing human's cumulative impact and preventing disease or abnormalities.

Summary of Studies Pertaining to Migration of Phthalates and Phthalates Alternatives from PVC or children's products:

Phthalates are dialkyl or alkyl/aryl esters of 1,2-benzenedicarboxylic acid.^{42 43} They are widely used as plasticizers for poly vinyl chloride (PVC) products because they add softness and flexibility to the normally rigid material.⁴⁴ Since phthalate esters (PEs) are not chemically bound to the PVC⁴⁵ they leach into the environment and are now found "ubiquitously" in air, water, dust and food.^{46 47} Many different products such as upholstery, floor tiles, children's toys and teething rings,⁴⁸ food containers and jar seals⁴⁹ contain PEs – some, such as children's toys, can contain as high as 40-50% PE by weight.⁵⁰ It is estimated that over 900 tons of phthalates are produced globally each year,⁵¹ maybe even as much as 4 million tons.⁵²

Summary of Studies Pertaining to Human (including children's and pregnant women's) Exposure to Phthalates and Phthalates Alternatives from *All Sources*, including building materials, consumer products, personal care products and food:

Phthalate plasticizers are not chemically bound to PVC, therefore they can leach, migrate or evaporate into indoor air and atmosphere, foodstuff, other materials, etc. Consumer products containing phthalates can result in human exposure through direct contact and use, indirectly through leaching into other products, or general environmental contamination.⁵³ Humans are exposed through ingestion, inhalation, and dermal exposure during their whole lifetime, including intrauterine development. Exposure assessment via modeling ambient data give hints that the exposure of children to phthalates exceeds that in adults.⁵⁴ Current human biomonitoring data prove that the tolerable intake of children is exceeded to a considerable degree, in some instances up to 20-fold. Very high exposures to phthalates can occur via medical treatment, i.e. via use of medical devices containing DEHP or medicaments containing DBP phthalate in their coating.⁵⁵

One study assessed the risk of exposure of the population to chemicals with estrogen-like activity through mineral water consumption by monitoring the presence of estrogenic compounds in Italian mineral water bottled in polyethylene terephthalate (PET). This study showed that more than 90% of the water samples did not exhibit any appreciable estrogenic activity.⁵⁶ Another study which measured the migration of PET into soft drinks and fruit juices found that PET migration is generally controlled by the very low diffusion of the polymer and, as a consequence, the partitioning coefficients of migrants between the polymer material and the foodstuff do not influence the migration levels significantly.⁵⁷

Acetyl tributyl citrate (ATBC) has been shown to inhibit the growth of different human, monkey and dog cells⁵⁸ and migrates into food from plastic food-wrap.⁵⁹ Approximately 99% of orally administered ATBC is excreted - intermediate metabolites include acetyl citrate, monobutyl citrate, acetyl monobutyl citrate, dibutyl citrate, and acetyl dibutyl citrate. In acute, short-term, subchronic, and chronic feeding studies, these ingredients were relatively nontoxic. ATBC is also considered safe as used in cosmetics.⁶⁰

Summary of Studies Pertaining to the Presence of Phthalates or Phthalates Alternatives in Indoor Air or Household Dust:

In a review of relevant studies on the respiratory and allergic effects of exposure to phthalates from PVC products, epidemiologic studies in children showed associations of phthalates from PVC plastics in the home and risk of asthma and allergies.⁶¹

Use of Polyvinyl Chloride (PVC) in Children's Products

Comments on polyvinyl chloride

PVC (polyvinyl chloride) plastic cannot be used to make soft plastic products without the addition of a plethora of toxic additives, which can make the PVC product itself harmful to consumers. These chemicals can evaporate or leach out of PVC, posing risks to children and consumers. One of the most common toxic additives is DEHP, a phthalate that is a suspected

carcinogen and reproductive toxicant readily found in numerous PVC products. Children can be exposed to phthalates by chewing on vinyl toys. The European Parliament voted in July, 2005 to permanently ban the use of certain toxic phthalates in toys.

Note: On the following page is a chart of the use of PVC and non-PVC plastics in children's products.

Use of PVC in Children's Products	Use of Non-PVC Plastics in Children's Products (Available alternatives)
Mattresses - Those with a waterproof coating of PVC are common, as are waterproof sheets to protect mattresses.	Cotton mattresses and futons, and uncovered foam mattresses. Waterproof covers made of polypropylene are available.
Baby changing mats	Polyester
Diaper covers	Polyester, nylon and polyurethane
Bibs	Textiles and polyethylene/polypropylene.
Strollers - Clear PVC is used in transparent hoods to keep out the rain on pushchairs or strollers.	
Toys - Teethers, squeeze toys, inflatable toys, dolls..	Natural materials are suitable alternatives for most types of toys, as well as some alternative plastics, which don't require the addition of plasticizers or other hazardous additives.
Shoes - Soft PVC is used in shoes and parts of shoes, such as soles, labels for logo imprints, upper parts made from PVC imitation leather coatings.	Products such as leather, rubber and polyurethane.
Boots and galoshes - Rubber boots are sometimes made from PVC containing phthalate softeners.	Boots made from other materials are available.
Bags - Sports bags and school bags are often made from nylon with a PVC coating to make them waterproof.	Cotton canvas, textiles with polyurethane coatings, nylon or polyester.
Clothes - Screen printed T-shirts; raincoats. <i>Phthalate plasticizers in textiles will be washed out in normal washing - almost the entire phthalate contents are washed out during the service life of products such as printed T shirts. People can also be exposed to phthalates through contact with the skin, although the extent of this exposure is not known.</i>	

Use of Non-PVC Plastics in Children's Products

Alternatives to soft PVC

Given that soft plastic is desirable for certain children's products, it is necessary to identify plastics which are preferable to soft PVC. In the long term, bio-based polymers, made from renewable sources, are preferable to any of petrochemical plastics for products which have relatively short lifecycles such as toys. In the interim, until bio-based plastics are widely available, there are some petroleum-based plastics which are less harmful to the environment and which do not pose such a direct threat to children's health as soft PVC. Many of these plastics are already being used by toy manufacturers for certain products, such as teething rings and soft blocks.

Three potential replacements for soft PVC in toys fulfill safety requirements: Thermoplastic elastomers (TPEs), ethylene vinyl acetate (EVA) and polyolefins (polyethylene/polypropylene), including the new metallocenes (see page 2). All three materials are easy to process (possibly on the same equipment as PVC); have aesthetic appeal, lessen environmental and health impacts; and are cost competitive. The use of these materials to replace soft PVC is a significant improvement and represents progress toward sustainable materials. In addition, none of these alternatives requires phthalate plasticizers to be soft and flexible (although they could be used and care should be taken to prevent this) and all require less overall additives than PVC. When they do contain additives, these additives make up a much smaller percentage (0-2% of the polymer mixture), in comparison to up to 50% phthalate content in PVC toys. Furthermore, it appears that the alternatives are also less likely to leach than PVC as the additives are bound tighter to the polymer.

Use of Phthalates and Phthalate Alternatives in Children's Products

Comments on phthalates or phthalate alternatives currently used in children's toys

According to scientists, diisononyl phthalate (DINP) has been the principal phthalate in soft plastic toys, and because it is not tightly bound to PVC it may be released when children mouth PVC products.⁶² DINP is an endocrine disruptor.

Substitutes for phthalates plasticizers are acetyl tributyl citrate (see page 4), tributyl citrate and diisononyladipate.⁶³ As we mention earlier, the EU ban on phthalates would not have happened, if the EU Scientific Committee on Toxicity, Ecotoxicity and Environment (CSTEE) had not cleared citrates in 2004 as alternative to banned phthalates.

Other phthalate alternatives include polyethylene and polypropylene, and bio-based alternatives thermoplastic elastomer, and ethylene vinyl acetate.⁶⁴

Possible phthalates or phthalate alternatives to use after February 10, 2009

We listed several potential alternatives earlier in this letter. Whatever phthalate alternatives are used must not be listed as possible human carcinogens by the International Agency for Research on Cancer or listed in a National Toxicology Report, or identified as a carcinogen by the EPA or OSHA. In addition, alternatives should not be a substance identified as having evidence of adverse developmental, male reproductive or female reproductive toxicity

effects by the National Toxicology Program's Center for the Evaluation of Risks to Human Reproduction.

Phthalates or phthalate alternatives used in children's products for purposes other than as PVC plasticizers

Phthalates are used in shampoos, soents, soap, lotion, cosmetics, medications, and medical devices that are used by children.⁶⁵

Measurement of Phthalates in Children's Products

Our organizations support scientific evidence that is built through replicated research relying on a process that welcomes criticism from other scientists, and is reviewed by unbiased peers in scientific and medical journals.

In addition to the analysis of concentration of phthalates in children's products, it is essential to study the extent to which the phthalates migrate, leach, or evaporate into water and air.

For example, a recent study conducted by scientists at the University of California at Davis measured endocrine-disruption chemicals in indoor air, from phthalates and other sources.⁶⁶ The study found that the levels of Di-(2-ethylhexyl) phthalate was much higher than other chemicals.

Conclusion

Our organizations support Section 108 of the Consumer Product Safety Improvement Act (CPSIA), which prohibits the sale of certain children's toys and products containing six specified phthalates (BBP, DBP and DEHP permanently, and DIDP, DINP and DnOP on an interim basis). Scientific evidence suggests that phthalates may be harmful to humans, and increase the risk of serious diseases such as cancer and reproductive problems.

We are pleased that the Chronic Hazard Advisory Panel (CHAP), which will decide whether to continue the interim ban on DIDP, DINP and DnOP "will consider the cumulative effects of exposure to multiple phthalates from all sources, including personal care products."⁶⁷ A recent report, "Phthalates and Cumulative Risk Assessment: The Task Ahead," by the National Research Council stated, "The U.S. Environmental Protection Agency should examine whether combined exposures to chemicals known as phthalates could cause adverse health effects in humans."⁶⁸ The report stated, "Recent data have shown widespread human exposure to multiple phthalates from a multitude of sources."⁶⁹ The report also noted that "A focus solely on phthalates to the exclusion of other chemicals would be artificial and could seriously underestimate risk."⁷⁰

Respectfully submitted,

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Stevenson, Todd

From: Paul Brown [pb@center4research.org]
Sent: Monday, January 12, 2009 6:46 PM
To: Phthalates Project
Subject: Comments on "Section 108: Phthalates in Children's Products"
Attachments: Sign-onLtrCPSCPhthalatesFinal.doc

Categories: Technical comment

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From: Bill Sells [BSells@sgma.com]
Sent: Monday, January 12, 2009 6:55 PM
To: Phthalates Project
Subject: SGMA Comments to CPSC on Phthalates Ban

Below please find the Sporting Goods Manufacturers Association's comments regarding the pending ban on Phthalates in Toys
(and application of ban to Sporting Goods and Fitness Equipment)



January 12, 2009

Contact: Bill Sells

Vice President

Government Relations

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Comment of the Sporting Goods Manufacturers Association On Phthalates ban and limits

On behalf of the members of the Sporting Goods Manufacturers Association we respectfully urge the Consumer Product Safety Commission (CPSC or the Commission) to grant an exemption to performance sporting goods and fitness equipment used in legitimate sports and fitness activities with respect to §108 of the CPSIA. Action by the Commission is urgently needed in light of the upcoming February 10, 2009 deadline for phthalate bans and limits. Issuance of a final rule is particularly critical since the statute's deadlines do not mesh with other deadlines and requirements. An example of this confusion and inconsistency is represented by ASTM F963, the Children's Toy Standard, which also becomes mandatory on February 10, 2009. In other words, the CPSIA specifies that a pending rulemaking will not delay implementation of the effective dates for such limits, but does not adequately provide for an orderly implementation of a comprehensive rule that clarifies definitions to a sufficient degree so that manufacturers can deal with inventory as well as the distribution of new products in commerce.

As a result the Sporting Goods Manufacturers Association (SGMA) submits this comment in response to the CPSC's request for comments regarding CPSIA section 108. The SGMA, the trade association of leading industry sports and fitness brands, enhances industry vitality and fosters sports and fitness participation through research, thought leadership, product promotion and public policy. SGMA produces the industry leading National Health-through-Fitness Day on Capitol Hill as well as representing the industry on trade and consumer issues.

The membership of the Association is extremely concerned about the classification of performance sporting goods used for legitimate sports activities under §108 of the Act. Subsection 108(e) defines "children's toy" as "a consumer product designed or intended by the manufacturer for a child 12 years of age or younger for use by the child when the child plays." A "child care article" is defined as "a consumer product designed or intended by the manufacturer to facilitate sleep or the feeding of children age 3 and younger, or to help such children with sucking or teething." A toy is considered a "toy that can be placed in a child's mouth"... "if any part

of the toy can actually be brought to the mouth and kept in the mouth by a child so that it can be sucked and chewed. If the children's product can only be licked, it is not regarded as able to be placed in the mouth. If a toy or part of a toy in one dimension is smaller than 5 centimeters, it can be placed in the mouth."

The SGMA takes the position that legitimate performance sporting goods are not "children's toys" as defined in §108. Whether the product is made for pee-wee sports, youth sports, or adult sports should not be the determining factor. As long as the sporting good is intended to develop a child's interest and ability in a legitimate sports activity, and is not merely a toy replica of a sporting good, then that product should not be defined as a "toy" for purposes of §108. For instance, the mere fact that a sporting good is used by children under the age of 13 does not make it a toy. That is true of footballs, basketballs, soccer balls, helmets, lacrosse sticks, bats, swim goggles, fins, and so on. These products and many others are made with the intent of promoting youth to engage in a truly legitimate sports and fitness activity.

Indeed the Commission recognizes this analysis to be valid in answering the question, "does the prohibition on phthalates apply to sporting goods?" Your analysis begins by recognizing that under ASTM F963, which becomes a mandatory standard on February 10, 2009, sporting goods equipment are not defined as toys unless the product is a toy version of a sporting good. However, the SGMA respectfully disagrees with your interpretation that the definition of "children's toy" somehow broadens the definition of "toy". In fact §108 merely adds a step in the analysis that all sporting goods manufacturers have made before the CPSIA existed. Manufacturers have always made the analysis of whether the product was a true "sporting good" intended for a legitimate sports activity, whether for youth or adult usage. Replicas of sporting goods equipment have always been viewed as "toys" by manufacturers. To now indicate that there is somehow a new and different analysis without giving specific guidance as to how that analysis should be made is to cast an enormous shadow of doubt on all youth sporting goods equipment manufactured. Stating that there needs to be a case-by-case analysis under the 4 factors you identify is not very helpful to a sporting goods manufacturer as there is little guidance offered other than the repeated listing of these factors and statements by the Commission that you will not provide advice on a case-by-case basis. SGMA members are making every effort to comply with all aspects of the CPSIA. However, they are confused and concerned because of a belief that somehow the Commission is changing the definitional analysis of what is a traditional performance sporting good. The SGMA believes that in fact there is no change in how manufacturers have traditionally and fairly analyzed and defined their products either as "sporting goods" or "toy" replicas of sporting goods.

Moreover, the United States Customs and Border Patrol recognize the clear distinction between "sporting goods" and "toys". The Harmonized Tariff Schedule of the United States 2008, supplement 1, classifies toys separately from different types of sporting goods. In chapter 95 of the Schedule toys, games, and sporting goods are classified for tariff purposes. However, they are classified under different subchapters. Toys are classified under subchapter 9504 while sporting goods equipment is classified primarily under subchapter 9506. This demonstrates that toys and sporting goods are treated differently for tariff purposes and there is a specific delineation between "toys" and "sporting goods" so there is very little confusion in the world of imports.

In conclusion, the SGMA and its membership firmly believes that performance sporting goods that are used in legitimate sports activities should be granted an exemption from §108 of the Act. The SGMA has asked for a meeting at the CPSC on numerous occasions. The Association realizes that everyone at the Commission is extremely busy trying to implement and provide guidance to the consumer products industry. However, sporting goods manufacturers must have clarity as to its products as there are tens of millions of dollars at stake regarding product already in inventory as well as future product development. The SGMA is willing to meet at a moment's notice. We thank you for your consideration of this truly crucial issue to sporting goods manufacturers.

Thank you.

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NATURAL RESOURCES DEFENSE COUNCIL

January 12, 2009

To: Consumer Product Safety Commission
Office of the Secretary
Submitted by email: phthalates-info@cpsc.gov

Re: Section 108: Phthalates in Children's Products, Request for Information.

These comments are submitted by Natural Resources Defense Council (NRDC), who on behalf of our 1.2 million members and online activists, uses law and science to ensure a safe and healthy environment for all living things. NRDC has no financial interest in phthalates, PVC, or children's toys or childcare articles.

The CPSC has requested information and comments on Section 108 of the Consumer Product Safety Improvement Act (CPSIA), "PROHIBITION ON SALE OF CERTAIN PRODUCTS CONTAINING SPECIFIED PHTHALATES".

Since CPSC last analyzed the toxicity of phthalates in toys, there have been over 500 studies published on phthalates and their toxicity. While we are pleased that the CHPA has been asked to consider cumulative effects when considering the toxicity of the Tier 2 phthalates in toys, we recognize the CHAP will have to consider a voluminous amount of information in a relatively short period of time. We have summarized and appended here the studies we think are most relevant to CPSC and the CHAP in evaluating the cumulative effects of phthalates. Most of these studies were conducted by independent scientists and published in peer-reviewed journals.

NRDC's comments pertain to the last two sections of CPSC's request for information: a. Toxicity of Phthalates and Phthalate Alternatives and b. Exposure to Phthalates and Phthalate Alternatives. A summary of the main points of our comments is followed by a brief description of each.

Toxicity of Phthalates and Phthalate Alternatives.

1. DiNP is a male reproductive toxin which acts through a mode of action similar to other phthalates such as DEHP, DBP or BBP.
2. There is evidence in humans that phthalates cause male reproductive harm similar to that observed in animal studies.
3. Reproductive outcomes in females are also impacted by phthalate exposure.
4. Phthalates have additive effects with one another and with other anti-androgenic chemicals. Therefore cumulative exposures to all anti-androgenic chemicals should be considered when evaluating toxicity.
5. Exposure to phthalates has been associated the neurobehavioral changes.
6. Exposure to phthalates in dust has been associated with the development of allergic symptoms and worsening asthma.
7. Exposure to phthalate has been associated with the alterations in the development of endocrine tissues and may cause reproductive cancers.
8. Phthalates have been associated with disturbances in metabolism and thyroid dysfunction.
9. Di-iso butyl phthalate, an alternative to DBP, has a toxicity profile similar to DBP.

Exposure to Phthalates.

1. Children are highly exposed to phthalates.
2. There is widespread exposure to the phthalate, DiNP.
3. Air fresheners are one source of exposure to phthalates.
4. Toys contain multiple phthalates, including DiNP.
5. Dust and Food are also likely to be sources of exposure to phthalates.
6. Phthalates can be absorbed across the skin.

Toxicity of Phthalates and Phthalate Alternatives.

In animal studies, there is clear and solid scientific evidence that certain phthalates are capable of disrupting testis function in prenatal and peri-pubertal rats. Exposures to phthalates such as BBP, DBP and DEHP have been shown to cause changes in hormone levels, birth defects of the penis (hypospadias) and testicles (cryptorchidism), alter the onset of puberty, and later in life result in poor semen quality and infertility.¹ It is generally accepted that exposures during critical periods of development are most harmful and that these effects are irreversible and permanent.

Numerous government agencies have reviewed the scientific data on phthalates, including the state of California which recognizes four of the phthalates listed in Section 108 as being reproductive and developmental toxins.² Those phthalates are DEHP, BBP, DBP and DiDP which were listed after review by the National Toxicology Program's Committee on the Evaluation of Risks to Human Reproduction (NTP CERHR).

Since the NTP CERHR evaluations of seven phthalates were completed in 2000³, there have been many important new studies published on the toxicity of phthalates, including the importance of considering cumulative effects and the reproductive toxicity of DiNP. New research has also shown cause for concern beyond reproductive outcomes to include neurobehavioral outcomes, allergic and respiratory disease, cancer and metabolic disturbances. In addition, there are new human epidemiological studies which have found similar toxicological outcomes to those seen in laboratory animals. Select studies published after 2002 on phthalate toxicity are listed below according to outcomes.

¹ Foster, P. M. D. (2006). Disruption of reproductive development in male rat offspring following in utero exposure to phthalate esters. *International Journal of Andrology* **29**, 140-147.

And

Gray, L. E., Jr, et al. (1999). Administration of potentially antiandrogenic pesticides (procymidone, linuron, iprodione, chlozolate, p,p'-DDE, and ketoconazole) and toxic substances (dibutyl- and diethylhexyl phthalate, PCB169, and ethane dimethane sulphonate) during sexual differentiation produces diverse profiles of reproductive malformations in the male rat. *Toxicol. Ind. Health* **15**, 94-118.

² California EPA, Safe Drinking Water and Toxic Enforcement Act, List of chemicals known to the State of California to cause cancer or reproductive toxicity.

http://www.oehha.org/Prop65/prop65_list/Newlist.html

³ Federal Register Notice, October 10, 2000 (Vol. 65, No. 196). "CERHR Phthalates -- Availability of Reports". <http://ntp.niehs.nih.gov/index.cfm?objectid=06F3BF5F-D13F-7A42-7E3DF3C0E61AD1F0>

1. DiNP is a male reproductive toxin which acts through a mode of action similar to other phthalates such as DEHP, DBP or BBP.

In 2000, Earl Gray and colleagues published a study showing DiNP caused male reproductive toxicity in a manner similar to the toxicity of other phthalates such as DEHP, DBP or BBP.⁴ Recent research has replicated this work and demonstrates the DiNP acts through a similar mode of action by reducing the production of testosterone.⁵ The anti-androgenic effects of DiNP and other phthalates, including DIDP, in pre-pubertal males have also been demonstrated in the Hershberger assay.⁶

2. There is evidence in humans that phthalates cause male reproductive harm similar to that observed in animal studies.

In the past 4 years, human studies have found phthalates are associated with many of the same effects that have been observed in laboratory studies, including alterations in sex hormone levels, feminization of male genitalia and alterations in semen quality.

In utero exposure to phthalates including DBP and BBP has been associated with a feminization of male genitalia with a shortening of the ano-genital distance.⁷ Post-natal exposure to the phthalate metabolites of DiNP and DBP in breast milk has been associated with alterations in male hormone profiles in baby boys.⁸ In adult men, phthalate exposures have been associated with poor sperm quality⁹ and DNA damage¹⁰. Finally, occupational exposures to DBP and DEHP have been associated with alterations in testosterone levels.¹¹

⁴ Gray, L. E., Jr., et al. (2000). Perinatal Exposure to the Phthalates DEHP, BBP, and DINP, but Not DEP, DMP, or DOTP, Alters Sexual Differentiation of the Male Rat. *Toxicol. Sci.* **58**, 350-365.

⁵ Borch, J., et al. (2004). Steroidogenesis in fetal male rats is reduced by DEHP and DINP, but endocrine effects of DEHP are not modulated by DEHA in fetal, prepubertal and adult male rats. *Reproductive Toxicology* **18**, 53-6.

⁶ Lee, B. M., and Koo, H. J. (2007). Hershberger Assay for Antiandrogenic Effects of Phthalates. *Journal of Toxicology and Environmental Health, Part A* **70**, 1365 – 1370.

⁷ Swan, S., et al. (2005). Decrease in Anogenital Distance Among Male Infants with Prenatal Phthalate Exposure. *Environ Health Perspect* **113**, 1056-1061.

⁸ Main KM, et al. (2006) "Human breast milk contamination with phthalates and alterations of endogenous reproductive hormones in three months old infants." *Environmental Health Perspectives*, 114(2):270-6.

⁹ Hauser R, et al. (2006). "Altered semen quality in relation to urinary concentrations of phthalate monoester and oxidative metabolites." *Epidemiology*, 17:682-691

¹⁰ Hauser R, et al. "DNA damage in human sperm is related to urinary levels of phthalate monoester and oxidative metabolites." *Human Reproduction*, 22:688-695 (2007).

¹¹ Pan G, et al. (2006) "Decreased serum free testosterone in workers exposed to high levels of di-n-butyl phthalate (DBP) and di-2-ethylhexyl phthalate (DEHP): a cross-sectional study in China." *Environmental Health Perspectives*, 114:1643-1648.

3. Reproductive outcomes in females are also impacted by phthalate exposure.

Pregnant female rats exposed to DBP had fetal loss and altered ovarian hormone production.¹² The authors of this study suggest these changes were caused by alterations in females sex hormones through a similar mode of action as has been described in males.

Female rats who inhaled DEHP were found to undergo puberty early and have irregular estrous cycles¹³.

In humans, DEHP exposure has been associated with shorter pregnancy duration¹⁴ and exposures to BBP, DBP, DEHP and DnOP have been strongly correlated with the occurrence of endometriosis in women¹⁵.

4. Phthalates have additive effects with one another and with other anti-androgenic chemicals. Therefore cumulative exposures should be considered when evaluating toxicity.

Recent research has demonstrated that exposures to low dose mixtures of phthalates can cause the same reproductive harm as exposure to high dose exposure to one phthalate. A mixture of five phthalates including DBP, BBP and DEHP was recently shown to cause a reduction in fetal testosterone levels in a cumulative and dose-additive manner¹⁶. Other studies have shown that other anti-androgenic chemicals, such as some pesticides, are able to act in an additive manner with phthalates to cause harm to male reproductive development¹⁷. In humans, an interaction between PCBs and DBP that is

¹² Gray LE Jr, Laskey J, Ostby J. "Chronic di-n-butyl phthalate exposure in rats reduces fertility and alters ovarian function during pregnancy in female Long Evans hooded rats." *Toxicological Sciences*. 93(1):189-95 (2006).

¹³ Ma M, et al. (2006). "Exposure of prepubertal female rats to inhaled di(2-ethylhexyl)phthalate affects the onset of puberty and postpubertal reproductive functions." *Toxicological Sciences*. 93(1):164-71.

¹⁴ Latini G, et al. "In-Utero Exposure to Di-(2-ethylhexyl)-phthalate and Duration of Human Pregnancy." *Environmental Health Perspectives*, 111(14):1783-1785 (2003).

¹⁵ Reddy BS, et al. "Association of phthalate esters with endometriosis in Indian women." *British Journal of Obstetrics and Gynaecology*, 113(5):515-20 (2006).

¹⁶ Howdeshell, K. L., et al. (2008). A Mixture of Five Phthalate Esters Inhibits Fetal Testicular Testosterone Production in the Sprague-Dawley Rat in a Cumulative, Dose-Additive Manner. *Toxicol. Sci.* **105**, 153-165.

¹⁷ Rider, C. V., et al. (2008). A mixture of seven antiandrogens induces reproductive malformations in rats. *International Journal of Andrology* **31**, 249-262.

greater than additive has been shown to cause alterations in semen quality¹⁸. To date, none of these mixture studies have included DiNP, DIDP or DnOP.

The National Academy of Sciences recently reviewed the evidence for cumulative toxicity of phthalates and issued guidance to EPA regarding how to conduct a cumulative risk assessment on phthalates. The NAS states in their report¹⁹:

“Phthalates and other agents that cause androgen insufficiency or block androgen receptor signaling, and are thus capable of inducing effects that characterize components of phthalate syndrome, should be considered in a cumulative risk assessment.”

And

“A focus solely on phthalates to the exclusion of other antiandrogens would be artificial and could seriously underestimate cumulative risk.”

The NAS committee concluded by stating that there is sufficient data now to proceed with a cumulative risk assessment of phthalates and other anti-androgens.

The CHAP also should follow this guidance and consider cumulative exposures to anti-androgenic chemicals including phthalates when conducting their safety assessment.

5. Exposure to phthalates has been associated the neurobehavioral changes.

There are a number of studies which have been published in the past 5 years which indicate exposure to many different phthalates interferes with sexual differentiation of the brain.

Perinatal exposure to DBP and DiNP has been associated with alterations in gene involved in sexual differentiation of the rat hypothalamus resulting in alterations in male sexual behavior²⁰. Perinatal DBP exposure has also been associated with alterations in the development of the pituitary gland²¹ in both male and female rats. In

¹⁸ Hauser R, et al. (2005). “Evidence of interaction between polychlorinated biphenyls and phthalates in relation to human sperm motility.” *Environmental Health Perspectives*, 113:425-30.

¹⁹ *Phthalates and Cumulative Risk Assessment: The Tasks Ahead*. (2008). National Research Council of the National Academies, Washington, D.C. Available on-line: http://www.nap.edu/catalog.php?record_id=12528&utm_source=dels&utm_medium=gateway&utm_campaign=delsref

²⁰ Lee HC, Yamanouchi K, Nishihara M. (2006). “Effects of perinatal exposure to phthalate/adipate esters on hypothalamic gene expression and sexual behavior in rats.” *Journal Reproduction and Development*, 52(3):343-52.

²¹ Lee, K. Y., et al. (2004). Diverse developmental toxicity of di-n-butyl phthalate in both sexes of rat offspring after maternal exposure during the period from late gestation through lactation. *Toxicology* **203**, 221-238.

utero and lactational exposure to DEHP in rats altered levels of brain aromatase²², the enzyme necessary for conversion of androgens to estrogens, and has also been shown to alter male sexual behavior²³.

6. Exposure to phthalates in dust has been associated with the development of allergic symptoms and worsening asthma.

Both laboratory animal and human epidemiological studies have found that exposure to phthalates, presumably through inhalation, is associated with allergic symptoms and worsening of pulmonary function.

In mice, atopic dermatitis has been shown to develop after exposure to DEHP and then challenge with a mite allergen²⁴. A similar response was seen in male rat pups exposed to DEHP during lactation²⁵.

In children, DEHP has been associated with wheezing²⁶ and worsening of asthma symptoms²⁷ in those exposed through house dust. BBP in house dust has been associated with the allergic responses of rhinitis and eczema²⁸ in children. In study of U.S. adult men, exposure to DBP, but not DEHP, (as measured by urinary metabolites) was associated with decrements in pulmonary function testing²⁹.

²² Andrade AJ, et al. (2006). "A dose-response study following in utero and lactational exposure to di-(2-ethylhexyl)-phthalate (DEHP): non-monotonic dose-response and low dose effects on rat brain aromatase activity." *Toxicology*, 227: 185-192.

²³ Moore RW, et al. (2001). "Abnormalities of sexual development in male rats with in utero and lactational exposure to the antiandrogenic plasticizer Di(2-ethylhexyl) phthalate." *Environmental Health Perspectives*, 109(3):229-37.

²⁴ Takano, H., et al. (2006). Di-(2-ethylhexyl) phthalate enhances atopic dermatitis-like skin lesions in mice. *Environ Health Perspect* **114**, 1266-1269.

²⁵ Yanagisawa, R., et al. (2008). Effects of maternal exposure to di-(2-ethylhexyl) phthalate during fetal and/or neonatal periods on atopic dermatitis in male offspring. *Environ Health Perspect* **116**, 1136-1141.

²⁶ Kolarik B, et al. (2008). "The Association between Phthalates in Dust and Allergic Diseases among Bulgarian Children." *Environmental Health Perspectives*, 116: 98-103.

²⁷ Bornehag CG, et al. (2004). "The Association between Asthma and Allergic Symptoms in Children and Phthalates in House Dust: A Nested Case-Control Study." *Environmental Health Perspectives*, 112(14):1393-7.

²⁸ Ibid.

²⁹ Hoppin JA, Ulmer R, London SJ. (2004). "Phthalate exposure and pulmonary function." *Environmental Health Perspectives*, 112(5):571-574.

7. Exposure to phthalate has been associated with the alterations in the development of endocrine tissues and may cause reproductive cancers.

In laboratory animal studies, exposure to the phthalates DBP and BBP has been associated with changes in the mammary gland that could precede the development of cancer. Exposure to BBP has been found to increase the proliferative index in terminal end-buds and change the gene expression profile of mammary tissue³⁰. Peri-natal exposure to DBP has been associated with alterations in mammary gland development that appeared irreversible but the study was not carried out long enough to assess cancer development³¹. In vitro studies have shown DBP, BBP and DEHP interfere with tamoxifen induced apoptosis in MCF-7 cells³², suggesting that phthalates could promote the progression of mammary tumors.

Testicular cancer has also been associated with phthalate exposure. Male rats exposed to DBP in utero develop Leydig cell tumors³³. The formation of these tumors may result from abnormal clusters of Leydig cells that form inside seminiferous tubules³⁴. Furthermore, a large study of rats exposed to DEHP chronically demonstrated these animals developed testicular tumors earlier than they developed hepatocellular tumors and the number of testicular tumors increased with time³⁵.

8. Phthalates have been associated with disturbances in metabolism and thyroid dysfunction.

In addition to their well recognized ability to interfere with the steroidogenesis and the production of sex hormones, certain phthalates have also been associated with alterations in thyroid hormone, which is important for development of the brain and nervous system as well as for maintaining metabolic rates in adults.

³⁰ Moral R, et al. (2007). "The plasticizer butyl benzyl phthalate induces genomic changes in rat mammary gland after neonatal/prepubertal exposure." *BioMed Central, Genomics*, 8: 453.

³¹ Lee, K. Y., et al. (2004). Diverse developmental toxicity of di-n-butyl phthalate in both sexes of rat offspring after maternal exposure during the period from late gestation through lactation. *Toxicology* **203**, 221-238.

³² Kim IY, Han SY, Moon A (2004). "Phthalates inhibit tamoxifen-induced apoptosis in MCF-7 human breast cancer cells." *Journal of Toxicology and Environmental Health*, 67:2025-2035.

³³ Barlow, N. J., McIntyre, B. S., and Foster, P. M. (2004). Male reproductive tract lesions at 6, 12, and 18 months of age following in utero exposure to di(n-butyl) phthalate. *Toxicologic pathology* 32, 79-90.

³⁴ Mahood, I. K., et al. (2006). Cellular origins of testicular dysgenesis in rats exposed in utero to di(n-butyl) phthalate. *International Journal of Andrology* **29**, 148-154.

³⁵ Voss, C., et al. (2005). Lifelong exposure to di-(2-ethylhexyl)-phthalate induces tumors in liver and testes of Sprague-Dawley rats. *Toxicology* **206**, 359-371.

Exposure to DEHP has been associated with alterations in free T4 and total T3 in adult men³⁶. In pregnant women, DBP has been associated with decrements in T4 levels³⁷.

Using NHANES data in a U.S. national cross-sectional study of adult men, increased waist circumference and insulin resistance was associated with exposure to three different phthalates³⁸. Another study of US men found BBP exposure was associated with obesity³⁹. One animal study in rats found exposure to DEHP was associated with an increase in serum glucose and decrease in insulin, as well as thyroid and adrenocortical dysfunction⁴⁰.

9. Di-iso butyl phthalate, an alternative to DBP, has a toxicity profile similar to DBP.

Di-isobutyl phthalate (DiBP) has a similar structural profile to di-butyl phthalate and reportedly can serve as a replacement for DBP in all applications including as a softener of PVC, printing inks and adhesives⁴¹.

In laboratory studies, DiBP has been shown to have anti-androgenic properties⁴² and causes a male reproductive harm at the same doses as BBP, DBP or DEHP⁴³.

³⁶ Meeker JD, Calafat AM, Hauser R. (2007). "Di(2-ethylhexyl) phthalate metabolites may alter thyroid hormone levels in men." *Environmental Health Perspectives*, 115(7):1029-34.

³⁷ Huang PC, et al. (2007). "Associations between urinary phthalate monoesters and thyroid hormones in pregnant women." *Human Reproduction*, 22:2715-2722.

³⁸ Stahlhut RW, et al. (2007). "Concentrations of urinary phthalate metabolites are associated with increased waist circumference and insulin resistance in adult U.S. males." *Environmental Health Perspectives*, 115: 876-882.

³⁹ Hatch, E. E., et al. (2008). Association of urinary phthalate metabolite concentrations with body mass index and waist circumference: a cross-sectional study of NHANES data, 1999-2002. *Environ Health* 7, 27.

⁴⁰ Gayathri NS, et al. (2004). "Changes in some hormones by low doses of di (2-ethyl hexyl) phthalate (DEHP), a commonly used plasticizer in PVC blood storage bags & medical tubing." *Indian Journal of Medical Research*. 119:139-44.

⁴¹ Draft DiBP Hazard Assessment, Australian Government, Department of Health and Ageing, NICNAS. April 2007. http://www.nicnas.gov.au/industry/existing_chemicals/phthalate_hazard_assessments/dibp_hazard_assessment_30-4-07.pdf

⁴² Borch, J., et al. (2006). Diisobutyl phthalate has comparable anti-androgenic effects to di-n-butyl phthalate in fetal rat testis. *Toxicol Lett* 163, 183-190.

And

Saillenfait, A. M., Sabate, J. P., and Gallissot, F. (2008). Diisobutyl phthalate impairs the androgen-dependent reproductive development of the male rat. *Reprod Toxicol* 26, 107-115.

⁴³ Howdeshell, K. L., et al. (2008). A Mixture of Five Phthalate Esters Inhibits Fetal Testicular Testosterone Production in the Sprague-Dawley Rat in a Cumulative, Dose-Additive Manner. *Toxicol. Sci.* 105, 153-165.

Furthermore, DiBP has been shown to cause reproductive harm when combined with other phthalates capable of causing male reproductive developmental toxicity⁴⁴.

Because of its toxicity profile and evidence for causing harm when combined with other phthalates, DiBP should not be permitted for use as an alternative in children's toys.

Exposure to Phthalates.

Biomonitoring from the CDC has indicated there is widespread exposure in the general population to phthalates.⁴⁵ Biomonitoring from other countries⁴⁶ and from non-governmental organizations in the U.S.⁴⁷ also have found evidence of widespread exposure. However, there is relatively little information available on how people are being exposed, what the major sources of exposure are and where individual phthalates are used.

We do know that in general, phthalates are found in a wide array of places including automobiles, food, pesticides, in building materials, personal care products, medical devices and pharmaceuticals, and consumer products such as toys, air fresheners, and furniture.

Select studies published after 2002 on phthalate exposure are listed below and the relevant studies are attached.

1. Children are highly exposed to phthalates.

Although the CDC data does not collect biological samples from children younger than six years old, in their 2004 study⁴⁸ children ages 6-11 were found to have the highest levels of these three phthalates.

It is certain that exposures to phthalate are occurring in children less than six years of age. A pilot study of 19 U.S. toddlers found when compared to the 6-11 year old

⁴⁴ Ibid.

⁴⁵ Silva, M. J., et al. (2004). 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.

⁴⁶ Wittassek, M., et al. (2007). Daily intake of di(2-ethylhexyl)phthalate (DEHP) by German children -- A comparison of two estimation models based on urinary DEHP metabolite levels. *International journal of hygiene and environmental health* **210**, 35-42.

⁴⁷ Environmental Working Group, Human Toxome Project. Data on phthalates available at: http://www.ewg.org/sites/humantoxome/chemicals/chemical_classes.php?class=Phthalates

⁴⁸ Silva, M. J., et al. (2004). 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.

children, levels of the DBP monoester metabolite, MBP, were three times higher than the geometric mean while levels of the monoester metabolites of BBP and DEHP were similar⁴⁹. A study of preschool children found urine levels of DBP and BBP metabolites were higher than adult levels⁵⁰.

Phthalates have also been found in breast milk⁵¹, cord blood⁵², and amniotic fluid⁵³. This indicates there is on-going and widespread exposure in the population and that children are highly exposed during critical periods of development.

2. There is widespread exposure to the phthalate DiNP.

When the US CDC analyzed a cross section of the U.S. population for the DiNP monoester metabolite, MiNP in human urine, less than 16% of the samples were positive. However, as has been demonstrated for other phthalates such as DEHP, the monoester metabolite may not be the best indicator of exposure and the oxidative metabolites may be better because the urinary levels are higher and less subject to contamination⁵⁴.

When the CDC analyzed a pilot group of urine samples they found none of the 129 samples contained the detectable levels of the DiNP monoester metabolite MiNP but three oxidative metabolites, MCIOP, MHINP, and MOINP were detected in 97, 100, and 87% of the urine samples, respectively⁵⁵. Therefore, the prevalence of human exposure to DINP has previously been underestimated by using MINP as the sole DINP urinary biomarker and future biomonitoring studies should use the oxidative metabolites for a more accurate assessment.

⁴⁹ Brock, J. W., et al. (2002). Phthalate monoesters levels in the urine of young children. *Bulletin of environmental contamination and toxicology* **68**, 309-314.

⁵⁰ Koch HM, et al.. (2005). "Exposure of nursery school children and their parents and teachers to di-n-butylphthalate and butylbenzylphthalate." *International Archives of Occupational and Environmental Health*, 78(3):223-229.

⁵¹ Frederiksen H, Skakkebaek NE, Andersson AM. (2007). "Metabolism of phthalates in humans." *Molecular Nutrition & Food Research*, 51: 899-911.

⁵² Latini, G., et al. (2003). Exposure to Di(2-ethylhexyl)phthalate in humans during pregnancy. A preliminary report. *Biology of the neonate* **83**, 22-24.

⁵³ Silva MJ, et al. (2004). "Detection of phthalate metabolites in human amniotic fluid." *Bulletin of Environmental Contamination and Toxicology*, 72: 1226-1231.

⁵⁴ Silva, M. J., et al. (2006). Measurement of eight urinary metabolites of di(2-ethylhexyl) phthalate as biomarkers for human exposure assessment. *Biomarkers* **11**, 1-13.

⁵⁵ Silva, M. J., et al. (2006). Oxidative metabolites of diisononyl phthalate as biomarkers for human exposure assessment. *Environ Health Perspect* **114**, 1158-1161.

3. Air fresheners are one source of exposure to phthalates.

In 2007, NRDC did a pilot study of phthalates in air fresheners. We purchased 14 different air fresheners, including aerosols, plug-ins and stand-alone specimens and sent the unopened containers to a commercial laboratory for testing of 15 different phthalates by GC/MS.

At least one phthalate was found in 12 of 14 products and over half of the air fresheners contained more than one phthalate. Phthalates found included DBP, DiBP, DiHP, DEP and DMP and levels ranged from below the level of detection to one specimen that contained 7,300 ppm DEP. A full description of the methodology and results can be found at: <http://www.nrdc.org/health/home/airfresheners.asp>

4. Toys contain multiple phthalates, not only DiNP.

Independent laboratory analyses have found that DiNP is not the only phthalate in children's toys. The San Francisco Chronicle in an investigative story published November 19, 2006⁵⁶, results of their own toy testing. DEHP was found in one product at level 13 times higher than is allowed under the new legislation. Other phthalates were also found to exceed the proposed legal limit. Additional testing done by Environment California found four phthalates - DEHP, DBP, BBP, and DnOP - in several different children's toys at levels far above what will be allowed in this legislation.⁵⁷ Some toys that were labeled "phthalate-free" were found to contain phthalates. The San Francisco Department of the Environment continues to conduct toy testing and publishes the results of their findings on their website⁵⁸.

5. Dust and Food are also likely to be sources of exposure to phthalates.

Recently published studies have found phthalates in house dust⁵⁹. A study of 11 homes in Northern California found DEHP and BBP were the most abundant analytes found amongst a group of environmental chemicals which included flame retardants, PCBs,

⁵⁶ <http://www.sfgate.com/cgi-bin/article.cgi?f=/c/a/2006/11/19/TOXICTOYS.TMP>

⁵⁷ Environment California, "The Right Start" report on chemical contaminants in children's toys. Available at: <http://www.environmentcalifornia.org/reports/environmental-health/environmental-health-reports/the-right-start-the-need-to-eliminate-toxic-chemicals-from-baby-products>

⁵⁸ sfenvironment.org/downloads/library/sfe_phthalate_testing_in_toys_results.pdf

⁵⁹ Hwang, H. M., et al. (2008). Occurrence of endocrine-disrupting chemicals in indoor dust. *The Science of the total environment* **404**, 26-35.

And

Rudel, R. A., et al. (2003). Phthalates, alkylphenols, pesticides, polybrominated diphenyl ethers, and other endocrine-disrupting compounds in indoor air and dust. *Environ science & tech* **37**, 4543-4553.

pesticides and other persistent chemicals⁶⁰. Inhalation is likely to be one route of exposure to phthalates and phthalate have been measured in personal air monitors⁶¹.

Market surveys of food, mostly in European countries have found widespread contamination of food with phthalates⁶². DBP, DiBP, DEHP and BBP were all found in foods ranging from spices to grains to dairy products. Of note, the U.S. FDA has approved several phthalates as food additives but there is no current information on phthalate contamination in the U.S. food supply.

6. Phthalates can be absorbed across the skin.

Numerous human studies have correlate phthalate exposure with the use of personal care products such as shampoos, lotions and soaps⁶³. In a controlled laboratory experiment, volunteers applied lotion containing known amounts of DEP and DBP to their skin⁶⁴. Within a few hours, levels of these phthalate metabolites peaked in the urine indicating there was rapid absorption across the skin.

The mode of exposure may be relevant for personal care products and items of clothing made from vinyl or containing phthalates.

NRDC looks forward to an open and transparent process as CPSC continues their evaluation of toxicity of phthalates in children's toys. We welcome any opportunity to participate in or comment on selection of the Chronic Hazard Advisory Panel (CHAP) members, give comments at public meetings of the CHAP or respond to any questions or concerns CPSC has on the materials submitted herein.

Respectfully submitted,

Sarah Janssen, MD, PhD, MPH
Natural Resources Defense Council

⁶⁰ Hwang, H. M., et al. (2008). Occurrence of endocrine-disrupting chemicals in indoor dust. *The Science of the total environment* **404**, 26-35.

⁶¹ Adibi, J. J., et al. (2008). Characterization of Phthalate Exposure among Pregnant Women Assessed by Repeat Air and Urine Samples. *Environ Health Perspect* **116**, 467-473.

⁶² Wormuth, M., et al. (2006). What Are the Sources of Exposure to Eight Frequently Used Phthalic Acid Esters in Europeans? *Risk Analysis* **26**, 803-824.

⁶³ Sathyanarayana, S., et al.. (2008). Baby Care Products: Possible Sources of Infant Phthalate Exposure. *Pediatrics* **121**, e260-268.

And

Duty, S. M., et al. (2005). Personal care product use predicts urinary concentrations of some phthalate monoesters. *Environ Health Perspect* **113**, 1530-1535.

⁶⁴ Janjua, N. R., et al. (2007). Systemic uptake of diethyl phthalate, dibutyl phthalate, and butyl paraben following whole-body topical application and reproductive and thyroid hormone levels in humans. *Environmental science & technology* **41**, 5564-5570.

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Clearing the Air

Hidden Hazards of Air Fresheners

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Executive Summary

Of all the products in the home, clean-smelling air fresheners seem to pose little risk. But the fresh scent of air fresheners may mask a health threat—chemicals called phthalates (pronounced *thal-ates*) that can cause hormonal abnormalities, birth defects, and reproductive problems. NRDC’s independent testing discovered phthalates in 86 percent (12 of 14) of air freshener products tested, including those marketed as “all-natural” or “unscented”—and none of the products we tested listed phthalates on their labels. To protect consumers, government regulators should follow up by doing more thorough tests on these products and enacting basic measures to limit exposure to these chemicals. Meanwhile, consumers may wish to avoid using air fresheners—especially in places where there are children or pregnant women.

Phthalates are versatile chemicals, used as solvents in perfumes and fragrances, as softeners in plastics, as anti-foam agents in aerosols, and as sealants and adhesives. Given their many uses, phthalates are found in a wide array of consumer products, including cosmetics and fragrances, pesticides, pharmaceuticals, vinyl children’s toys, automobiles, paints, and interior finishes.¹ Phthalates are used in air fresheners to dissolve and carry the smell of fragrances.

When people use air fresheners, the phthalates are released into the air. They may then be inhaled, or the aerosol particles may land on the skin and be absorbed.² Once these chemicals enter the bloodstream, they can alter hormone levels and cause other health problems.

There has been a boom in air freshener use in recent years, driven by advertising that promotes a scented environment as a clean and healthy environment. Air fresheners are now a \$1.72 billion industry in the United States—a 50 percent increase from 2003—and are used in an estimated 75 percent of households. Air fresheners are also being used in a greater number of rooms throughout the home, further increasing exposure.³ Moreover, air freshener advertising is targeting the younger generation of tweens and teenagers, making the potential health impacts associated with the products that much more worrisome.

CHEMICALS IN AIR FRESHENERS COULD CAUSE HEALTH PROBLEMS

Unfortunately, the rise in popularity of air fresheners has outpaced awareness of the potential health threats from exposure to the chemicals they may contain. Most phthalates are well known to interfere with production of the male hormone, testosterone, and have been associated with reproductive abnormalities. Numerous animal studies have linked prenatal exposure to certain phthalates with decreases in testosterone, malformations of the genitalia, and reduced sperm production.⁴ In humans, phthalates have been associated with changes in hormone levels, poor semen quality, and changes in genital development.⁵ Five phthalates—including one that we found in air freshener products—are listed by the State of California as chemicals “known to cause birth defects or reproductive harm.”⁶ Phthalate exposure in indoor environments has also been associated with allergic symptoms and asthma.⁷

Because there are no labeling requirements and even “natural” products can contain toxic chemicals, it is virtually impossible for the average consumer to know which products may pose a risk.

RECOMMENDATIONS FOR SAFER HOME AIR QUALITY

Air fresheners are rarely necessary. Because they cannot substitute for good ventilation, the best solution is to open windows to bring in fresh air or to use fans to maintain air circulation. Air fresheners also are not a solution to poor air quality; they mask bad odors but they do not eliminate the chemicals that cause them.

If you decide you do want to use an air freshener, careful selection may reduce phthalate exposures to you and your family. Of the 14 products tested by NRDC, there was wide variation in the level of phthalates contained. The three products with the highest level of phthalates—Ozium Glycol-ized Air Sanitizer, Walgreens Air Freshener, and Walgreens Scented Bouquet—all contained greater than 100 parts per million (ppm) of phthalates, with one containing 7,300 ppm (see Table 1). Two products—Febreze Air Effects and Renuzit Subtle Effects—contained no detectable levels of phthalates. However, we only tested one sample of each product, and more thorough testing is necessary to confirm the levels we detected.

There is a clear need for closer monitoring of the types of chemicals manufacturers are allowed to put into air fresheners—and for consumers to be provided with better information about what is in the products they do purchase. In the near term, government agencies need to more thoroughly test air fresheners and inform consumers about what they contain. NRDC recommends the following:

- Consumers should avoid using air fresheners, but when necessary should use products with the lowest levels of phthalates to limit exposures to toxic chemicals.
- The Environmental Protection Agency should require manufacturers to test and submit data on phthalates found in air fresheners, the extent of human exposure to phthalates in air fresheners, the health effects of the exposure, and the toxicity, persistence, sensitization, and other health effects of inhaling chemicals in air fresheners.
- The Consumer Product Safety Commission should ban hazardous phthalates in consumer products and should require that manufacturers provide ingredient information on the label.

“Although our study is far from comprehensive, it does suggest that there’s a problem with many air freshener products. Our work raises concerns that should be followed up immediately by thorough government testing of these products. Meanwhile, consumers should be aware that the pretty label and sweet scent may mask something much less pleasant.”

Gina Solomon, M.D., M.P.H., Senior Scientist, NRDC

Table 1: Phthalate Level in Air Fresheners Tested

Brand	Level of Toxic Phthalates Found	Phthalates Found
Air Wick Scented Oil	●	0.75 ppm DBP; 6.3 ppm DEP; 1.6 ppm DIBP; 2.1 ppm DIHP
Citrus Magic	○	0.25 ppm DBT
Febreze Air Effects Air Refresher	⊗	0
Febreze NOTICEables Scented Oil	●	0.19 ppm DBP; 1.5 ppm DIBP
Glade Air Infusions	●	1.5 ppm DEP
Glade PlugIn Scented Oil	●	4.5 ppm DBP
Lysol Brand II Disinfectant	○	0.12 ppm DBP; 0.49 ppm DEP
Oust Air Sanitizer Spray	●	5.7 ppm DEP
Oust Fan Liquid Refills	○	0.78 ppm DEP; 0.24 ppm DIBP
Ozium Glycol-ized Air Sanitizer	●	360 ppm DEP; 0.15 ppm DMP
Renuzit Subtle Effects	⊗	0
Walgreens Air Freshener Spray	●	1,100 ppm of DEP
Walgreens Scented Bouquet Air Freshener	●	7,300 ppm of DEP; 0.47 ppm of DBP; 6.5 ppm DMP
Walgreens Solid Air Freshener	●	23 ppm DEP

Legend:

- = Contained highest level of phthalates (more than 10 ppm of total phthalates)
- = Contained moderate level of phthalates (between 1 and 10 ppm of total phthalates)
- = Contained trace level of phthalates (less than 1 ppm of total phthalates)
- ⊗ = Contained no phthalates

BEYOND PHTHALATES: OTHER RISKY CHEMICALS HIDDEN IN AIR FRESHENERS

While the focus of this issue paper is the presence of phthalates in air fresheners, it is worth noting that researchers have detected other chemicals of concern to human health in these products as well. A 2005 European Consumers Union study, for example, found volatile organic compounds (VOCs) in these products at high levels and concluded that VOCs substantially contributed to indoor air pollution. In particular, the European study detected cancer-causing chemicals such as benzene and formaldehyde in some air fresheners. Benzene is known to cause leukemia in humans, and formaldehyde has been linked to cancers of the upper airways. The majority of products also contained allergens (such as limonene).⁸ People with allergies to these chemicals could have adverse reactions, including rashes or even asthma attacks, from exposures to air freshener products.

Exposure to phthalates can come from many sources. And, according to studies done by the U.S. Centers for Disease Control, the majority of the U.S. population is routinely exposed to at least five different phthalates.⁹ Although the measured levels in the human blood stream are small, they are significant because a mixture of phthalates at low doses can act in an additive manner to cause the same health hazards as just one phthalate at a higher dose.¹⁰ Human exposure to phthalates via inhalation from the ambient environment is also a cause of concern. Studies in New York City and Krakow, Poland have demonstrated that levels of phthalates in the air are correlated with levels of phthalate metabolites in the body.¹¹

The difficulty of avoiding general exposure is all the more reason to eliminate further exposure in an environment over which you have much more control—your home.

From Berry Burst to Cleansing Rain: 14 Air Fresheners Tested

NRDC purchased one sample each of 14 different air freshener products at a major San Francisco Bay Area retail chain, including eight aerosol sprays, five continuously emitting liquids, and one solid. Products included all the brands available for sale at that store, and represented a variety of methods of scent dispersal and a variety of scents (see Table 2). The products were sent to a commercial lab for testing for 15 different phthalates. (See Appendix A for a detailed methodology of laboratory procedure and Appendix B for a list of the phthalates tested.) This sampling is not comprehensive; however, it is the first such testing that we are aware of in the United States. More thorough testing should be done to follow up on these findings.

Table 2: Air Freshener Products Tested

Product name	Scent name	Type of product	Ingredients	Distributor
Citrus Magic	Tropical Citrus Blend	Spray	100% PURE & NATURAL premium concentrate citrus fragrance oils from oranges, lemons, limes, tangerines, and grapefruits.	Beaumont Products, Inc.
Febreze Air Effects Air Refresher	Spring & Renewal	Spray	None listed	Procter and Gamble
Glade Air Infusions	Refreshing Springs	Spray	None listed	S. C. Johnson and Son, Inc.
Lysol Brand II Disinfectant	Summer Breeze	Spray	Active ingredients: alkyl dimethyl benzyl ammonium saccharinate (.106%), ethanol (79.646%) and inert ingredients (20.248%)	Reckitt Benckiser Inc.
Oust Air Sanitizer	Floral Scent	Spray	Triethylene glycol (6%, active ingredient). Inert ingredients (94%).	S.C. Johnson and Son, Inc.
Ozium Glycol-ized Air Sanitizer	Original	Spray	Active ingredients: triethylene glycol (4.4%), propylene glycol (4.4%). Inert ingredients: 91.2%.	SOPUS Products
Renzit Subtle Effects	Cool Morning Air	Spray	None listed	Dial Corporation
Walgreens Air Freshener	Fresh Country	Spray	None listed	Walgreen Co.
Walgreens Solid Air Freshener	Potpourri Scented	Solid	None listed	Walgreen Co.
Air Wick Scented Oil Refill (for Air Wick warmer)	Relaxation Lavender & Chamomile	Liquid (oil)	None listed	Reckitt Benckiser Inc.
Febreze NOTICEables	Morning Walk & Cleansing Rain	Liquid (oil)	None listed	Procter and Gamble
Glade PlugIns Scented Oil	Berry Burst	Liquid (oil)	None listed	S. C. Johnson and Son, Inc.
Oust Fan Refill (for use in Oust Fan)	Citrus Scent	Liquid	None listed	S.C. Johnson and Son, Inc.
Walgreens Scented Bouquet Air Freshener	Rose	Liquid	None listed	East West Distributing Co.

Masking the Risk: Phthalates Found in Majority of Fresheners

Eighty-six percent (12 of 14) of the products tested had detectable levels of phthalates, including an “all-natural” product and an “unscented” air sanitizer (see Figure 1).

There was a wide range of concentrations of phthalates in our samples (see Figure 2). Nearly one-quarter of the products (three of 14) had very high levels—more than 100 parts per million (ppm)—including products that ranged from 360 ppm to 7,307 ppm. Seventy percent (10 of 14) of all products had more than 1 part per million of total phthalates. The reporting limit from the testing laboratory ranged from 0.1 to 1.0 ppm, depending on the specific phthalate chemical (see Appendix A for the laboratory methodology).

The major phthalates found were di-butyl phthalate (DBP), di-ethyl phthalate (DEP), di-isobutyl phthalate (DIBP), and di-methyl phthalate (DMP) (see Figure 3). Di-isohexyl phthalate (DIHP) was also found in a single sample.

Figure 1: Proportion of Air Fresheners Tested that Contain Phthalates

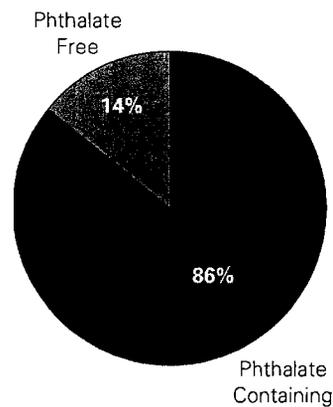
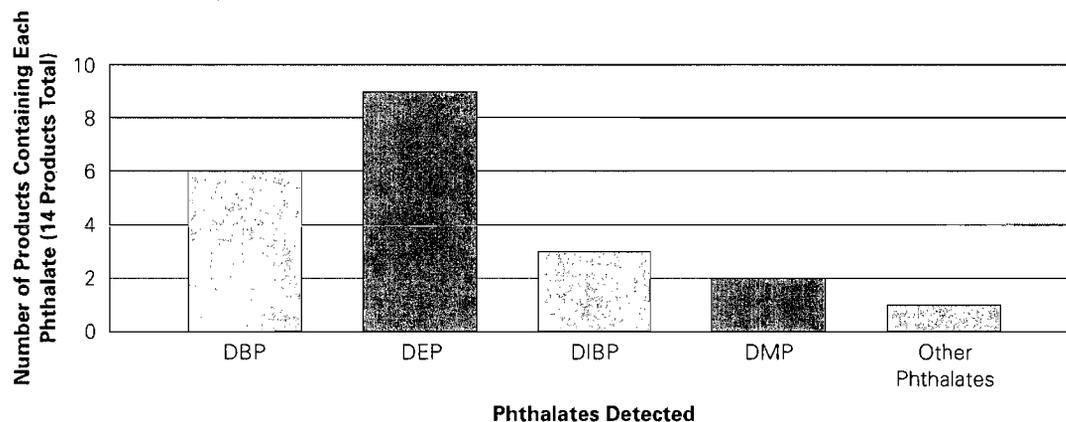


Figure 2: Phthalates Present in Air Fresheners



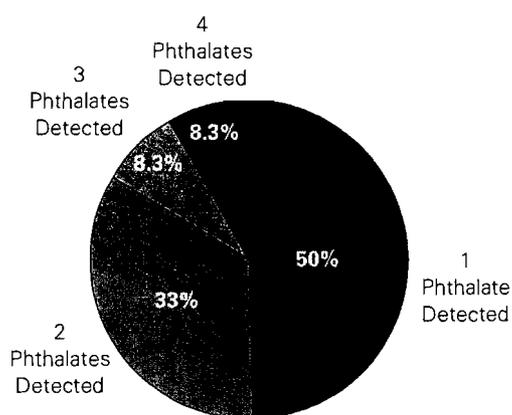
Many of the products we tested contained more than one phthalate chemical. One-half of the phthalate-containing air fresheners (six of 12) had two or more phthalates, including one product that contained four different phthalates (see Figure 4). Mixtures of phthalates in consumer products are of particular concern because phthalates may act in combination to have a more toxic effect than they would alone.

How Much of the Phthalates Get Into People from Air Fresheners?

When phthalates or other toxic chemicals are used in air fresheners, some but not all of it gets into our bodies. There's no simple answer to the question of whether enough of the phthalates get into people to pose a health hazard. The answer depends on many factors, including the amount of phthalates in the product that's being used, the size of the room it's used in, the frequency of use, and how much time people spend in that room. It also depends on whether the person is an adult or a child, how much of their skin is bare, and even on how hard and fast the person breathes. To make matters more complicated, health risks from skin or inhalation exposure are tricky to predict because most of the studies done on phthalate toxicity focus on oral exposure rather than inhalation, and susceptibility varies widely.

Common sense suggests that products that contain higher levels of phthalates would be more risky than those that contain none. It is also NRDC's opinion that these exposures are unnecessary and should thus be avoided.

Figure 3: Frequency of Phthalate Mixtures



Di-ethyl Phthalate (DEP)

NRDC detected DEP in three-quarters (nine of 12) of phthalate-containing samples. Five of these samples contained DEP only; four contained other phthalates as well. DEP levels in these products ranged from 0.8 ppm to a shocking 7,300 ppm. The average level among DEP-containing products was 977 ppm.

DEP is used in personal care products, food packaging, pesticides, and molded plastics.¹² DEP has been shown in animal studies to affect growth and food consumption, but has not been shown to affect male reproductive development in animal studies.¹³ However, human studies have repeatedly associated exposure to DEP in a mixture of phthalates with adverse reproductive outcomes, including changes in hormone levels, poor semen quality, and changes in genital development.¹⁴ Until we have more evidence, it would be prudent to avoid exposure to this chemical.

Prior Study on Phthalates in Air Fresheners

We are aware of only one previous study on phthalates in air fresheners. This study, done by the European Bureau of Consumers Unions (BEUC), tested a variety of air fragrance products for di-ethyl phthalate (DEP). Results were consistent with NRDC findings. DEP was detected in 13 out of 21 European aerosol products, in three of the 10 liquid diffusers, and in three out of nine gels. Concentrations ranged from 0.2 to 82 ppm. These levels are similar to levels we found in five of the products we tested, although they are lower than what we found in three products.

Di-n-butyl Phthalate (DBP)

NRDC detected DBP in one-half (six of 12) of the phthalate-containing air freshener products tested. Two of these products contained DBP only; the other four had DBP as part of a phthalate mixture. DBP levels in these products ranged from 0.1 ppm to 4.5 ppm. The average level among DBP-containing products was 1.1 ppm.

DBP is recognized as a reproductive toxicant by both the National Toxicology Program and the state of California.¹⁵ In animal studies, exposure to DBP has been associated with a syndrome of reproductive abnormalities that includes malformations of male reproductive organs, low sperm counts, and infertility. In humans, exposure to DBP with a mixture of phthalates has been associated with changes in hormone levels, poor semen quality, and changes in genital development.¹⁶

Di-isobutyl Phthalate (DIBP)

NRDC detected DIBP in one-quarter (three of 12) of phthalate-containing air freshener products. DIBP levels in these products ranged from 0.2 ppm to 1.6 ppm. The average level was 1.1 ppm.

DIBP has properties similar to DBP and is used as a substitute for DBP in many applications. Although DIBP testing has been limited, this phthalate appears similar to DBP, acting as a male reproductive toxicant that causes decreases in testis weight and lower testosterone levels in rats exposed prenatally.¹⁷ DIBP metabolites have been detected in human urine samples and have been associated with changes in male genital development.¹⁸

Di-methyl Phthalate (DMP)

NRDC detected DMP in 17 percent (two of 12) of phthalate-containing products, with levels ranging from 0.2 ppm to 6.5 ppm and an average of 3.3 ppm.

DMP is used a wide variety of products, including cosmetics, printing inks, insecticides, adhesives, and paper coatings. There is inconclusive evidence on the reproductive toxicity of DMP in animal studies, and it has not been associated with any adverse effects in any human study to date.

Di-isohexyl Phthalate (DIHP)

One product contained DIHP at a level of 2.1 ppm.

There is limited information on the commercial uses of DIHP. It is known to be used in automotive lubricants.¹⁹ DIHP has similar structural properties to other phthalates that are known to be male reproductive toxicants. Limited toxicity testing has suggested that DIHP is indeed a developmental and reproductive toxicant.²⁰

Detailed Individual Product Test Results

Air fresheners with the highest levels of phthalates:

- **Walgreens Scented Bouquet Air Freshener** contained off-the-charts DEP levels of 7,300 ppm, as well as 0.47 ppm DBP and 6.5 ppm DMP.
- **Walgreens Air Freshener Spray** contained 1,100 ppm DEP.
- **Ozium Glycol-ized Air Sanitizer**, an unscented product commonly used in hospitals and similar settings, also contained very high levels of phthalates: 360 ppm DEP and 0.15 ppm DMP.
- **Walgreens Solid Air Freshener** contained 23 ppm DEP.

Air fresheners with moderate levels of phthalates:

- **Air Wick Scented Oil** contained a variety of phthalates: 0.75 ppm DBP, 6.3 ppm DEP, 1.6 ppm DIBP, and 2.1 ppm DIHP.
- **Oust Air Sanitizer** spray contained 5.7 ppm DEP.
- **Glade PlugIn Scented Oil** contained the highest level of DBP—a reproductive toxicant according to the State of California—with a level of 4.5 ppm DBP.
- **Febreze NOTICEables Scented Oil** contained 0.19 ppm DBP and 1.5 ppm DIBP.
- **Glade Air Infusions** contained 1.5 ppm DEP.

Air fresheners with trace levels of phthalates:

- **Oust Fan Liquid Refills** contained 0.78 ppm DEP and 0.24 ppm DIBP.
- **Lysol Brand II Disinfectant**, which is sometimes used as an air freshener, contained 0.12 ppm DBP and 0.49 ppm DEP.
- **Citrus Magic**, an all-natural product, still contained a trace level of DBP of 0.25 ppm.

Air fresheners with no phthalates detected:

- **Febreze Air Effects Air Refresher**
- **Renuzit Subtle Effects**

Appendix A: Methodology of Laboratory Procedure, Provided by Analytical Sciences Laboratories

Samples were analyzed by GC/MS according to a modified version of EPA method 8270 for semi-volatile organic compounds. One to two milliliters (ml) of liquid was obtained directly from a liquid product or by spraying an aerosol product into a new 40 ml volatile organics analysis (VOA) vial. All spraying was conducted inside of an operating fume hood to prevent sample cross-contamination. Only one sample was present in the fume hood at any one time and VOA vials were sealed immediately after spraying. One sample was a gel. A weighed amount of the gel was soaked in 1 ml of acetone in a sealed vial. The acetone extract of the gel was then analyzed. The liquid products exhibited varying degrees of polarity of the primary ingredients as observed by their variable solubility in hexane. The phthalates to be determined would be expected to dissolve completely in the hexane solvent even if some of the freshener chemical constituents would not.

After a liquid sample was obtained from all products, a volumetric dilution was made directly into hexane to accomplish the two GC/MS analyses conducted. The first GC/MS analysis utilized six microliters of product in 300 microliters of hexane (50X dilution). A full scan GC/MS analysis (similar to EPA method 8270) was conducted with an instrument calibrated using a fresh 16 component mixed phthalate standard purchased from Absolute Standards (part# 80601). The initial analysis allowed an evaluation of the magnitude of the phthalate presence in the product and permitted the important assessment of the magnitude of other non-target hydrocarbons.

The second GC/MS analysis was identical in all respects to the first except the instrument was operated in "Selective Ion Monitoring Scan" (SIMS) mode using ions 163 and 149. Ion 163 was used solely to observe dimethyl phthalate. Ion 149 is the primary and common ion to most phthalates and was used to observe the other 15 phthalates. The instrument was calibrated for both phthalate retention time and quantity prior to the SIMS analysis. The SIMS GC/MS technique is well recognized as a means to lower detection limits by focusing all the mass spectrometers time resources on the specific target ion of the contaminants of concern. This technique makes compounds containing other ions, of which there are many, completely unobserved thereby simplifying the chromatogram obtained. It is estimated that the sensitivity of the instrument was increased by approximately 100-fold using this SIMS technique. QA/QC was performed according to standard practices. Blanks were negative, and a quality assurance report was provided with the sample results.

Appendix B:

Phthalates Tested in Each Sample and Lab Reporting Detection Limit

Phthalate	CAS Number	Detection Limit (ppm)
Dimethyl Phthalate (DMP)	00131-11-3	0.10
Diethyl Phthalate (DEP)	00084-66-2	0.10
Diisobutyl Phthalate (DIBP)	00084-69-5	0.10
Di-n-butyl Phthalate (DBP)	00084-74-2	0.10
Bis(2-methoxyethyl) Phthalate	00117-82-8	1.00
Diisohexyl phthalate (DIHP)	00146-50-9	0.10
Bis(2-ethoxyethyl) Phthalate	00605-54-9	1.00
Diamyl Phthalate (DAP)	00131-18-0	0.10
Dihexyl Phthalate (DHP)	00084-75-3	0.10
Butyl benzyl Phthalate (BBP)	00085-68-7	0.50
Bis(2-n-butoxyethyl)Phthalate	00117-83-9	1.00
Bis(2-ethylhexyl) Phthalate (DEHP)	00117-81-7	0.50
Dicyclohexyl Phthalate (DCP)	00084-61-7	0.10
Di-n-octyl Phthalate (DOP)	00117-84-0	0.50
Dinonyl Phthalate	00084-76-0	0.50

Endnotes

1. Detailed information regarding the chemical properties, production, use, and health effects of certain phthalates can be found on the web: Agency for Toxic Substances and Disease Registry, US Dept. of Health and Human Services, Public Health Service, Toxicological Profiles for Diethyl Phthalate (DEP); Di-n-butyl phthalate (DBP), <http://www.atsdr.cdc.gov/toxpro2.html0> (September 5, 2007); Australian National Industrial Chemicals Notification and Assessment Scheme, 2007. Draft Human Health Hazard Assessment of diisobutyl phthalate (DIBP), http://www.nicnas.gov.au/Industry/Existing_Chemicals/Phthalate_Hazard_Assessments/DiBP%20hazard%20assessment%2030-4-07.pdf (July 25, 2007).
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10. C. Wolf et al., "Administration of potentially antiandrogenic pesticides (procymidone, linuron, iprodione, chlozolinate, pp'-DDE, and ketoconazole) and toxic substances (dibutyl- and diethylhexyl phthalate, PCB 169, and ethane dimethane sulphonate) during sexual differentiation produces diverse profiles of reproductive malformations in the male rat," *Toxicology and Industrial Health* 15, nos. 1-2 (1999), pp. 94-118; K. L. Howdeshell et al., "Cumulative Effects of dibutyl phthalate and diethylhexyl phthalate on Male Rat Reproductive Tract Development: Altered Fetal Steroid Hormones and Genes," *Toxicological Sciences*, (March 2007).
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20. *Ibid.*

Stevenson, Todd

From: Janssen, Sarah [sjanssen@nrdc.org]
Sent: Tuesday, January 13, 2009 3:50 AM
To: Phthalates Project
Subject: Section 108: Phthalates in Children's Products
Attachments: NRDC.airfresheners.pdf; NRDC comments on Section 108.doc

Please accept the attached comments and supporting materials from NRDC. I attempted to send an email early with more attachments but your mail server would not accept it due to the large size. I am now resending with just NRDC's comments and our report on phthalates in air fresheners.

Sincerely,

Sarah Janssen, MD, PhD, MPH
Staff Scientist,
Natural Resources Defense Council

111 Sutter St., 20th floor
San Francisco, CA 94104
(415) 875-6100 (office)
(415) 875-6161 (fax)

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45

January 12, 2008

Office of the Secretary
Consumer Product Safety Commission
Room 502
4330 East West Highway
Bethesda, Maryland, 20814
Dear Mr. Todd Stevenson:

RE: Comments to Consumer Product Safety Commission in response related to Phthalates and CPSIA

On behalf of the American Apparel & Footwear Association (AAFA) – the national trade association of the apparel and footwear industries and their suppliers – I am writing in response to the Consumer Product Safety Commission's (CPSC) request for comments on Section 108 of the Consumer Product Safety Improvement Act (CPSIA), "Prohibition on Sale of Certain Products Containing Specified Phthalates."

We are in receipt of the letter dated October 17, 2008 which states that footwear is not covered by the definition of "children's toy" or "child care articles," and therefore not covered by the CPSIA phthalate ban. We agree wholeheartedly with this opinion and would encourage the CPSC to enshrine the letter further in regulations it issues governing application of the phthalate ban.

We are also in receipt of the CPSC letter dated November 25, 2008, which exempts most apparel items from the definitions of "children's toy" or "child care articles" and therefore from the phthalate ban. While we agree with much of what is stated in the letter, we feel it incorrectly characterizes children's sleepwear and bibs as childcare articles. The letter states, "children's sleepwear or bibs, while not considered to be toys, would be considered childcare articles as defined under Section 108, and, therefore, subject to the ban on phthalates." As we will explain further, we find no information to support such a conclusion and, in fact, believe there is substantial information to the contrary. Accordingly, we believe that children's pajamas and bibs do not fall under the definition of "child care articles" and should therefore be exempt from the phthalate ban as well.

The definition of "child care article" in the CPSIA is a "consumer product designed or intended by the manufacturer to facilitate sleep or the feeding of children age 3 and younger, or to help such children with sucking or teething." Merriam-Webster defines pajamas as, "a loose usually two-piece lightweight suit designed especially for sleeping or lounging."¹ Pajamas are **not** designed to "facilitate" sleep (facilitate being defined as "to make easier: help bring about"²), they are simply worn when sleeping. Including pajamas under this definition applies the term "child care article" too broadly.

Many sources recommend ways for parents to facilitate sleep for babies. These techniques include dimming the lights, creating a bedtime routine, avoiding stimulation, rocking and cuddling, but no mention of putting a baby in pajamas. Furthermore, newborn babies may sleep up to 16 hours a day often for only 3-4 hour stretches at a time and cannot distinguish between night and day.³ It is therefore just as likely that a baby will fall asleep wearing pajamas as wearing normal day time clothing.

It is also important to consider the origins of the CPSIA phthalate ban. Section 108 was copied from California's phthalate law which comes directly from the European Union's Directive on phthalates in toys and child care articles. Like the CPSIA, the European Union's phthalate Directive applies to "child care articles" defined as, "any product intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of children."⁴ Immediately after its passage, the European Commission issued a guidance defining child care articles

¹ <http://www.merriam-webster.com/dictionary/pajamas>

² <http://www.merriam-webster.com/dictionary/facilitate>

³ <http://kidshealth.org/parent/growth/sleep/sleepnewborn.html>

⁴ http://ec.europa.eu/enterprise/chemicals/legislation/markrest/guidance_document_final.pdf

and children's toys. This guidance states: "The main purpose of pyjamas is to dress children when sleeping and not to facilitate sleep. Pyjamas should therefore be regarded as textiles and, like other textiles, do not fall under the scope of the Directive."⁵

A similar argument to bibs can be made. The definition of bib in Merriam-Webster is, "a cloth or plastic shield tied under the chin to protect the clothes."⁶ That a child happens to wear a bib while eating does not mean the bib plays a part in facilitating the feeding process. The bib may facilitate laundry by keeping the clothes clean, but not facilitate eating.

The apparel and footwear industry has historically never had a problem with phthalates in children's products as these products are not designed to be mouthed and therefore do not present a risk of phthalate ingestion. Further, the language in other phthalate initiatives has never applied bans to children's clothing and shoes. Thus, the CPSC's opinion is tantamount to informing the industry on November 25 that phthalate rules will begin to apply to certain kinds of apparel two months later – a regulation the apparel industry has never operated under prior to your opinion.

Thank you for your time and consideration in this matter. If you have any questions, please contact Rebecca Mond with my staff at 703-797-9038 or at rmond@apparelandfootwear.org.

Sincerely,



Kevin M. Burke
President and CEO

⁵ http://ec.europa.eu/enterprise/chemicals/legislation/markrestr/guidance_document_final.pdf

⁶ <http://www.merriam-webster.com/dictionary/bib%5B2%5D>

Stevenson, Todd

From: Rebecca Mond [rmond@apparelandfootwear.org]
Sent: Friday, January 16, 2009 10:58 AM
To: Phthalates Project
Cc: Falvey, Cheryl; Steve Lamar
Subject: AAFA Phthalate Comments
Attachments: phthalate comments January.doc

Please see the attached comments on phthalates submitted by the American Apparel & Footwear Association.

Regards,

Rebecca Mond
Government Relations Representative
American Apparel & Footwear Association
1601 North Kent Street
Suite 1200
Arlington, VA 22209
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703-797-9038

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If you have received this information and do not work for an AAFA member company, please contact Maureen Storch at AAFA (mstorch@apparelandfootwear.org, 703-797-9047) for information on how you can join AAFA.

If you would like to be removed from this distribution list, or if you know other AAFA members who would like to receive this information, please email Rebecca Mond at rmond@apparelandfootwear.org.



January 13, 2009

Office of the Secretary
Consumer Product Safety Commission
Room 502
4330 East-West Highway
Bethesda, MD 20814

RE: JPMA Comments on Section 108 Phthalates in Certain Toys and Child Care Articles

The U.S. Consumer Product Safety Commission (CPSC) staff has requested comments on Section 108 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), which prohibits the sale of certain defined toys and childcare products containing six specified phthalates.

The Juvenile Products Manufacturers Association (JPMA) is a not-for-profit trade association representing the producers, importers, or distributors of a broad range of childcare articles that provide protection to infants and assistance to their caregivers. These comments are provided to assist the CPSC staff in developing rationale regulations related to the use of the six Section 108 identified phthalates in certain children’s products in the United States. These issues have a significant impact on several hundred of the Association’s members. These comments discuss materials that may contain phthalates and those that do not.

Furthermore, we comment on the need for the Commission to use common sense and a plain reading of the statutory language in interpreting and applying Section 108 consistent with the need to address likely risk of significant demonstrable (as opposed to hypothetical) exposure by ingestion of the restricted phthalates to children under 3 years of age. We are also commenting on potential testing protocols and available data regarding the restricted phthalates.

1. Materials That May Require Testing

As the Commission is aware, phthalates are a group of widely used chemicals added to polyvinyl chloride (PVC) to soften it and make it flexible.¹ Part of the staff’s request seeks information concerning materials currently used in children’s toys and child care articles that may contain phthalate plasticizers subject to the requirements of Section 108. In the experience of the members of the Association their materials are primarily the following: PVC (polyvinyl chloride), PVDC (polyvinylidene chloride), synthetic rubber, certain vinyl based adhesives, polyurethane and vinyl surface coatings applied to foamed plastics. However, if such materials are demonstrated in their formulation to contain phthalate alternatives as additives, testing should not be required. In addition regulations need to recognize that materials used for childcare products intended for children over the age of 3 years of age may not present a health hazard since mouthing behavior substantially diminishes by the time the child reaches such age. The Commission should also be clear that testing for phthalates in materials that have no potential to

¹ Congressional Research Service, “Phthalates in Plastics and Possible Human Health Effects” 2 (July 29, 2008).

include phthalate plasticizers should not be required in order to certify compliance pursuant to Section 102 of the CPSIA.

DINP is the most commonly used phthalate in flexible vinyl children's products; however it has not generally been used as a vinyl softener in child care articles intended to be mouthed, including teethingers, rattles, feeding utensils, and pacifiers. This is the result of action more than a decade ago in 1998 when the industry voluntarily removed DINP from flexible vinyl mouthing products pending completion of the Chronic Hazard Advisory Panel's (CHAP) risk assessment on DINP. The CHAP was convened by the CPSC in 1998 and subsequently issued its report in 2001. The CHAP determined "For the majority of children, the exposure to DINP from DINP-containing toys would be expected to pose a minimal to non-existent risk of injury." Similarly, to a lesser extent Di(2-ethylhexyl) phthalate (DEHP), may be used in some child care articles or vinyl covered furniture. However, DEHP, as with DINP, is generally not used as a vinyl softener in child care articles intended to be mouthed including teethingers, rattles, feeding utensils, and pacifiers. DEHP's use was restricted as a vinyl softener in the ASTM F 963 Consumer Safety Specification for Toys for more than a decade.

2. Materials Without Phthalate Plasticizers Shouldn't Be Tested

A variety of other plastic materials simply do not contain phthalates, which are substances that are intentionally added in high quantities to the formulation of specific plastics enumerated above in order to provide softness and flexibility. These substances are not generally added as part of the formulation of the following materials and if added they would reduce the integrity of such materials: Styrene, ABS, Polypropylene, and Polyethylene. In order to avoid unnecessary, burdensome expensive material testing, it is essential for the CPSC staff to specify materials, unlikely to contain phthalate additives that are excluded from testing and certification requirements. This is consistent with the approach taken with other substances. For example, the CPSC staff has reasonably determined that if paint is not used there is no requirement to perform lead in paint testing. A similar approach should be specified for materials that do not inherently contain added phthalates.

3. Section 108's Requirements Are Limited in Scope

Section 108 regulates the use in certain children's products of six specified phthalates, which the statute treats in two groups of three phthalates each. The first group consists of the phthalates known as DEHP, DBP, and BBP. Section 108(a) makes it unlawful for a children's toy or child care article to "contain concentrations of more than 0.1 percent" of any of these three. This restriction is permanent. A "children's toy" is defined as "a consumer product designed or intended by the manufacturer for a child 12 years of age or younger *for use by the child when the child plays.*" § 108(e)(1)(B) (emphasis added). This definition amounts to the definition of "children's product" in section 235(a) plus the italicized phrase. A "child care article" is defined as "a consumer product designed or intended by the manufacturer to *facilitate* (emphasis supplied) sleep or the feeding of children age 3 and younger, or to help such children with sucking and teething." § 108(e)(1)(C).

The second group of regulated phthalates consists of those known as DINP, DIDP, and DnOP. It is unlawful under section 108(b)(1) for a “children’s toy that can be placed in a child’s mouth or child care article” to “contain concentrations of more than 0.1 percent” of these. This restriction is interim, pending the creation and report of a Chronic Hazard Advisory Panel and the Commission’s promulgation of a rule in response to the Panel’s report. § 108(b)(2)&(3). The applicable definitions of “children’s toy” and “child care article” are the same as for the first group, but the restriction regarding a children’s toy is expressly limited to a toy “that can be placed in a child’s mouth.” Section 108(e)(2)(B) defines this quoted phrase.

A. Risk of Exposure to the Specified Phthalates from the Regulated Activity; Needs to Be Essential Regulatory Criteria

In Section 108(b)(2) the required CHAP must consider “the likely level of . . . exposure to phthalates, based on a reasonable estimation of normal and foreseeable use and abuse of such products [that is, ‘products for children’]” and “the cumulative effect of total exposure to phthalates.” *Id.* And it specifically must consider “ingestion,” “dermal,” and “hand-to-mouth” exposure, as well as any “other exposure.” *Id.* These listed methods are of course the primary ways in which a child might be exposed to phthalates from a children’s product. Finally, the Panel is to take into account “uncertainties regarding exposure.” *Id.* Given that statutory language used here and the historical scientifically acceptable process for assessing risk (as used in the DINP Assessment previously conducted by the CPSC staff) it is and should continue to be a precondition that exposure to phthalates at hazardous levels be considered an essential prerequisite.

In addition, the definitions of “children’s toy” and “child care article” reinforce the need to con exposure. A “children’s toy” is a product designed or intended for “*use by the child*” when the child plays. “Use” suggests contact, which is a potential source of exposure. The definition of “child care article” is even narrower in that use of a product in and of itself does not necessarily render such products childcare products for children under 3 years of age; such use must directly facilitate sleep, feeding or teething. In effect the prerequisite that such product “help” a child “with sleep, feeding, sucking or teething” indicates that more than mere use of the product is required. There must be a direct relationship between the use of the product and activity cited. Similarly, a product “to facilitate sleep or the feeding of” a young child (including a pacifier) is most reasonably understood as one that the child will use for that purpose, meaning that he will come into contact with it and use it solely to facilitate sleep, feeding or to help with teething. Nothing in the text requires applying the phthalate restriction to plasticized portions of products not directly involving the regulated activity. Therefore anti-skid floor protector on the bottom of a high chair, or the seating material, even though a child uses the high chair when eating should not be considered as directly “facilitating” feeding. The requirement that the product actually “facilitate” the activity indicates a narrower requirement than “use” of the product. Obviously a plain reading of the language employed indicates that Congress intended a causal relationship between the product and the activity that results in sleep, feeding or aid in sucking and teething. This requirement requires more than mere “use” of the product. This is why use alone should be an insufficient basis for subjecting a childcare product to these requirements.

In addition Section 108(e)'s definition of mouthability, and section 108(b)(1)'s limitation of the regulation of three phthalates in children's toys to those that are mouthable, reinforces exposure as the essential criteria. Congress recognized this when it regulated toys that "can be sucked and chewed" but not "licked." Congress (consistent with the European Union and California) sought only to focus on regulating products that presented the greatest risk of exposure. With "child care articles," Congress defined the term so that mouthability ("sucking," "teething," and facilitation of "feeding," and "sleep[ing]") is directly related to the activity. A plain reading indicates that the activities referenced involved mouthing behavior as a pre-requisite to the activity engaged in. The underlying requirement is direct exposure. This rationale is also reflected current CPSC health risk assessment protocols. In effect without adverse exposure, there is no health hazard.

B. Substitutes Permitted

Policy considerations reinforce the need for the Commission to avail itself of the opportunity to clarify Section 108's inherent focus on exposure. Among other things, both the statute and the legislative history leave open the question of how a manufacturer might substitute for a phthalate that is prohibited under Section 108. Although the Senate amendment regulated this subject, § 40(b), the Conference Committee removed it. All that Section 108 does on the question is direct the Panel to consider the effects of phthalate substitutes. § 108(b)(1). It does not even directly authorize the Commission to declare products containing phthalate substitutes to be banned hazardous products. *See* § 108(b)(3)(B). As a result, if a manufacturer simply substitutes a different additive chemical, that substitute may well have health risks or other issues of its own (known or unknown). Alternatively, if no suitable substitute exists, the manufacturer may be unable to produce the product any longer (and parents may then substitute another product), or it may alter the design in ways that on the whole make it more rather than less risky for a child. There is no reason for the Commission to run such risks by reading Section 108 to require more than it actually does.

C. Ban Should Not Apply to Inaccessible Parts to Which a Child Will Not be Exposed

The Commission should clarify that child-care article restrictions under Section 108 should only apply to parts that can be mouthed. Congress's definition of "child care article" so as implicitly to extend only to mouthable parts (as explained above), as well as its express adding of such a restriction regarding children's toys containing the interim-banned phthalates, is justifiable. Mouthing is the primary means by which children are exposed to phthalates from toys or child-care articles. That is why, as noted above, the Commission has since the 1980s focused on reviewing the use of phthalates in teething rings, rattles, and pacifiers and the EU regulatory scheme is concerned with "articles what are put into the mouth by children." Clearly, some parts of a children's toy or child care article will not produce any exposure of a child to phthalates because the child will not, in normal and reasonably foreseeable use of the product, come into any contact with parts by ingesting, sucking, chewing t sufficient levels so as to create health concerns. *See* § 108(b)(2); *cf.* § 101(b)(1)&(2) (referring to swallowing, mouthing, and breaking, among other things). Absent exposure, the part should not subject to Section 108's restrictions for the reasons given above. The Commission should clarify this point. As the Commission's FAQs point out, Section 108 of course does not directly make "accessibility" a determining factor, unlike Section 101's lead limits, but it does not follow that any consideration of accessibility is prohibited. As

part of an overall assessment of possible exposure to a specified phthalate from a component part, it is reasonable to consider accessibility a precondition to health risk. Mouthability is just a subset of whether a part is accessible, as the European Commission's Guidance Document on the question makes explicit². All hazardous exposures depend on accessibility. As far as we are aware, there is nothing in the literature indicating any verifiable risk of exposure, much less harm, to any child from a children's toy or child care article with an inaccessible part that has phthalates. Congress did not expressly require the Commission, to regulate such parts absent exposure risk, and the Commission should not do so. This is especially a concern since many testing laboratories are currently interpreting incomplete FAQ responses, such as this, as providing an unrealistic basis to require products to be disassembled (even using tools to do so) for the purposes of doing testing on plastic insulation on inaccessible parts (such as wire and diodes on electronic bards) at cost exceeding \$300.00 per test even though there is no exposure risk.

4. Available Testing Protocols

The request sought comments concerning possible testing protocols and JPMA notes that in addition to CPSC test protocols the following are often cited: ASTM D7083-04 Standard Practice for Determination of Monomeric Plasticizers in Poly Vinyl Chloride (PVC) by Gas Chromatography; EN 14372, Annex A, "Suitable Gas - Chromatography - Mass - Spectrometry (GC-MS) Apparatus, Method and Precision Data for Determination of Phthalate Plasticizers;" Method C-34, "Determination of Phthalates in Polyvinyl Chloride Consumer Products," Canada Product Safety Laboratory, Book 5 - Laboratory Policies and Procedures Part B: Test Methods Section; Chinese ICS 97.200.50; GB/T DRAFT, Toys and Children Products," Determination of Phthalate Plasticizers in Poly Vinyl Chloride Plastics."

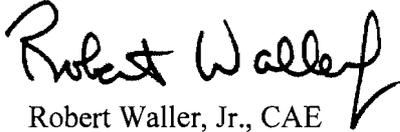
In evaluating suitable test procedures, CPSC should consider the need for practical cost effective approaches to sampling and testing protocols. Also as referenced above the staff needs to exclude from testing and certification requirements, certain materials that do not inherently contain phthalates. In addition certification of use of phthalate alternatives in the re-formulation of such materials and verification of use by the material suppliers should be permitted as evidence of non-phthalate based PVC material use.

Finally, we defer to updated research data as may be provided by the Phthalate Esters Panel, Academic Research and other experts providing updated exposure data and toxicological assessments.

² European Commission, Enterprise and Industry Directorate-General, *Guidance Document on the interpretation of the concept "which can be placed in the mouth" as laid down in the Annex to the 22nd amendment of Council Directive 76/769/EEC*, at 2 (undated) ("Inaccessible parts of articles can also not be taken into the mouth. Articles or parts of articles should be considered inaccessible if, during proper use or reasonable foreseeable improper use by children, they cannot be reached. . . . Inaccessible plastic material, such as cables in toys, can not be taken into the mouth under normal, foreseeable conditions").

Thank you for providing us with the opportunity to comment on these important issues. JPMA respectfully reserves the right to file additional comments and we urge the CPSC to provide additional guidance and clarity by publishing a rule on the provisions in question contained herein.

Respectfully submitted,

A handwritten signature in black ink that reads "Robert Waller, Jr." with a stylized flourish at the end.

Robert Waller, Jr., CAE
President
(856) 642-4402

Stevenson, Todd

From: Mike Dwyer [mdwyer@ahint.com]
Sent: Tuesday, January 13, 2009 5:44 PM
To: Phthalates Project
Subject: JPMA Comments on Section 108 (Phthalates) of CPSIA
Attachments: CPSIA Section 108 Comments-Phthlates.pdf

To: The Office of the Secretary, Consumer Product Safety Commission

Attached you will find comments on Section 108 of the CPSIA as filed by the Juvenile Products Manufacturers Association.

Thank you for your consideration.

Mike Dwyer, CAE
Executive Director

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January 14, 2009

Dear Chairperson Nord,

I am writing to you today regarding a House subcommittee hearing that may be held in the coming weeks on the Consumer Product Safety Commission's ("CPSC") efforts to implement the new lead and phthalate requirements (effective February 10, 2009) under the recently enacted Consumer Product Safety Improvement Act of 2008 (CPSIA).

I own a specialty toy store in McMinnville Oregon. I have four employees. I currently have on my shelves \$150,000 worth of inventory that I can not sell after February 10th 2008, because the CPSC is interpreting the CPSIA RETROACTIVELY. These are toys that passed testing to either the EN-71 and/or ASTM standards in effect when they were manufactured. However, they have not been tested to the total lead content standard going into effect next month, because that was a test created by the new statute, and did not exist when the toys were put on the market. Applying the new testing requirements retroactively means I can not sell products that passed all safety laws in effect when I bought them. This is not fair. I am a law abiding citizen and will obey the law, even if it puts me out of business, but it does not make sense to me that I can not sell toys that were legal and safe when purchased last year. I am proud of the toys I sell. I've spent years gathering the safest toys in the world, and have always been committed to providing the best toys to our children, who are the leaders of tomorrow. However, if you do not pass an amendment specifying that the toys I have on hand can be sold, I, and many other independent stores across the country will be out of business. In this time of economic recession, small businesses are hanging on by a thread. We can not absorb such losses.

There are other problems with the way CPSA is interpreting this law. One is that they are telling us that we can not even donate the toys to charity, but must dump them. THIS DOES NOT MAKE SENSE. There are millions of toys across the country on toystore shelves - just the logistics of finding somewhere to dump them all is mindboggling.

Another is that the law is being applied to thrift stores. A children's consignment store in our area is closing because it can not provide test results for the used children's clothes and other products it recycles to new homes. The poor will be hit the hardest as Goodwill and others will shut down the children's sections. Poor families can not afford to buy newly made clothes for their kids and our environment can not afford to take on the unnecessary waste caused by perfectly safe and reusable children's products being dumped and abandoned.

PLEASE HELP US BEFORE IT IS TOO LATE! Hold hearing on how the CPSA is implementing the CSPIA. Amend the law as necessary to bring some common sense back into the enforcement. Share my concerns, which are those of thousands of other small children's toy stores, book stores, clothing stores and more across the country, with the chairman and members of the House Energy & Commerce Subcommittee on Commerce, Trade and Consumer Protection so they can be prepared for their upcoming hearings on the retroactive application of the law.

I want to be clear that I support the intent of the CPSIA to increase the safety of toys, especially those low cost mass produced toys imported from China that have caused the problem with recalls over the past two years. However, the CPSA is interpreting the law so broadly that it will have the opposite effect - reducing the number of well made safe products available to children in America as small manufacturers find they can not afford to do the testing and paperwork required. Already one of the best toy companies in Europe, Selecta, has stopped shipping it's handmade wooden toys to the US citing the high cost of compliance to the CPSIA. This company has never had

a recall, makes its toys in small batches in Germany, and tests all its toys to both the EN-71 and ASTM F963 standards. These are not the type of toys you intended to get rid of - but you did.

WE NEED ANSWERS FAST. This is buying season in the toy market. Huge toy fairs will be held in NYC and Europe in February. Millions of dollars worth of sales usually take place. Right now, no toy store that I've talked to across the country is planning on buying anything until we know whether we will be in business. I want to do my part to stimulate the economy - but I can't until I know that the CPSIA will not be applied retroactively and that I can sell through last year's inventory to provide the cash flow to buy this year's toys.

I don't believe Congress intended these consequences of this law. I respectfully request that you immediately contact Chairman Rush, members of his Subcommittee on Consumer Protection, and to also have your staff contact Subcommittee staff to stress these concerns and urge the subcommittee to act with these concerns in mind. Thank you for your attention to this urgent matter.

Sincere Regards,



Linda Hays

Hopscotchtoys

McMinnville OR

503-472-8702

503-474-2899



48

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2009 JAN 21 A 11:01

I am writing to you today regarding the Consumer Product Safety Commission's ("CPSC") efforts to implement the new lead and phthalate requirements (effective February 10, 2009) under the recently enacted Consumer Product Safety Improvement Act of 2008 (CPSIA).

If inventory manufactured before Feb 10 2008 is subject to this ban, we will go out of business.

We employ 30 employees in Michigan and are one of the 500 fastest-growing Internet retailers in the country. We've been in business for nearly 60 years and selling via the web for the last 10. We've enjoyed growth rates of over 100% the last few years. In fact, we went from only 5 employees 5 years ago to 30 this year. But if the phthalate ban is applied retroactively, Century Novelty (and our future employees) will be done.

We found out about this potential ban on December 17... only 2 months before the law goes into effect. You can't simply ban a chemical and expect retailers to be compliant within 2 months. It takes at least 3 months to get a new product designed and manufactured. And it can take over a year to sell through an existing inventory. That means any ban without a window of at least 1 and half years will be detrimental to our business. An immediate ban will be the end of our business.

We're simply asking that merchandise already in the country be permitted to sell.

There are significant negative economic concerns associated with these new requirements being implemented. As a company doing business in your state or district, I am writing to tell you how my company will be impacted and to ask that you share my concerns with the CPSC Commissioners as soon as possible.

My company is a member of the Toy Industry Association, which supported the passage of the CPSIA, and we continue to be supportive by making the necessary changes to meet the various implementation requirements to date. The February 10, 2009 deadline for lead, however, will impose significant hardships on my company, on other toy companies and other industries. Moreover, if applied retroactively to existing inventory the new requirements could have grave consequences on my business.

As you are aware, the CPSIA imposed additional new requirements restricting lead and phthalate levels in various children's products. As an industry, we support such restrictions if they are necessary to protect the health and safety of children. The CPSC General Counsel recently issued an opinion that the new requirements for phthalates levels will apply only prospectively to products manufactured after February 10, we applaud this decision. At the same time, the CPSC General Counsel opined that the lead requirements will apply to existing inventory, thus impacting products produced prior to the CPSIA's enactment date. We believe any new law should apply prospectively. Any other interpretation would punish those of us who in good faith met the strict requirements of the law when we were manufacturing product that is still the safest in the world.

I am specifically contacting you to stress the importance that the lead restrictions not be applied retroactively to products produced in good faith before the law existed. These implementing opinions directly impact and threaten the viability of thousands of businesses and their employees. For example:

(Continued on Page 2)

38239 Plymouth Road
Livonia, Michigan 48150
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Fx 734.464.6860
Info@CenturyNovelty.com

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(Continued from Page 1)

*Small and medium sized-companies will be most negatively impacted, with many of these companies pushed to the point of possible bankruptcy. The retroactive application would require existing products be removed from store shelves on February 10. This would mean that product on store shelves, in warehouses or anywhere in the supply chain must be removed for costly testing to demonstrate compliance with the new requirements and could result in possible destruction. Retroactive enforcement will impose huge costs for removal, testing and certification, lost sales and other logistical costs on these companies -- destroying untold millions of dollars worth of inventory, even though those very products were compliant with arguably the strictest safety standards in the world when put into the marketplace.

*The CPSC General Counsel's opinion applying the phthalates standards prospectively should stand and be endorsed by Congress. Congress specifically set out a path for some of these products to return to the market place in the future so a retroactive application does not make sense and is not warranted.

*The economy today is in far worse condition than it was when Congress debated and enacted the CP-SIA and I believe the CPSC and Congress should factor the current economic crisis into it's analysis of the implementation timelines and requirements.

Currently, the lack of clarity has left the marketplace in a state of confusion. The result has been efforts by some to declare previously sold legal goods "illegal" and to promote testing at great expense, when none is actually required. Unchecked misapplication of yet-to-be-established requirements for lead content to current inventories at retail potentially threatens to obsolete billions of dollars of safe products introduced into interstate commerce well prior to the effective date of the CPSIA. The expense of forced returns from retailers of previously sold products or unnecessary testing could put smaller companies out of business and result in job losses during this perilous economic time. Congress could not have reasonably intended such consequences from a chaotic implementation of the CPSIA and, in light of the economic crisis we currently operate in, Congress must not act in a manner that does not add to safety but rather cripples the ability of companies like mine from continuing to exist.

I respectfully request that you immediately contact CPSC Commissioners and request that the lead restrictions not be applied retroactively to products produced before February 10, 2009 and that they uphold their decision to apply the phthalates requirements prospectively. On behalf of my company and the toy industry, who shares your interest in the safety of consumer products, thank you for your attention to this urgent matter.

Sincerely,

Kevin Madigan
President

Phone: (734)464-0590 Ext. 14

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Sincerely,

Ian MacDonald
Vice President & General Manager
Direct: (734)437-3113

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Info: CenturyNovelty.com



RE: Consumer Product Safety Improvement Act (CPSIA)

January 15, 2009

Nancy Nord,

As a local manufacturer who has been producing children's products for 20 years, I am writing to express my concerns regarding the enforcement of the Consumer Product Safety Improvement Act (CPSIA), effective Feb. 10, 2009. I support this new law and feel that children's safety should be of utmost importance to our government and to the juvenile products industry. However, the ambiguity and broad-reaching scope of this particular legislation holds potentially devastating economic ramifications, impacting large and small manufacturers, retailers and consumers alike.

My company, Rein Designs Inc., prides itself on offering my retailers and consumers unique, high-quality products made from the best materials available. We have produced over one million items and have never had a safety issue. I have read the CPSIA and under its new regulations, manufacturers of all sizes will be required to submit a sample of each SKU to cost-prohibitive third-party testing labs. Due to the nature of my business, batches are relatively small and are "run" well over 24 times per year. The cost to test my products on an annual basis and according to the law, as it currently stands, is over \$1 million dollars. The testing alone would effectively eliminate the ability of small manufacturers to do business legally in the U.S.

February 10, 2009 is being dubbed "National Bankruptcy Day" by many experts within the juvenile, toy and handmade industries. I suspect that if this legislation is allowed, without thoughtful considerations and proper exemptions, it will negatively affect everyone from individual handcrafters and big-box manufacturers, to parents looking for safe and affordable products for their children. Due to the law's retroactivity, millions of pieces of merchandise on store shelves and in warehouses will become illegal to sell until the appropriate testing is applied. This will greatly impact retailers including consignment/thrift stores and charities that will no longer be able to accept donations. The possible negative impact on the environment is also a consideration. Manufacturers may choose to dispose of perfectly safe products because it makes more sense financially.

We also publish children's books that are subject to the regulations. As the law is written, not only will our company be impacted, but libraries and schools will bear a tremendous hardship. I have heard that libraries will either have to shut their doors to children or dispose of all their children's books to comply.

I join hundreds of large and small juvenile product manufacturers (both locally and nationally) when I say that the CPSIA is much needed and well intentioned, yet deeply flawed. I believe that careful interpretation of the law by the CPSC (along with assistance from a subset of manufacturers that accurately represent the industries at hand) can both keep our children safe and simultaneously allow our industries and the economy as a whole to prevail.

Please allow my voice to be heard and help give my company the opportunity to comply and survive.
Thank you in advance for your assistance!

Sincerely,

Ric Diltz, President



香港玩具協會
Hong Kong Toys Council

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30 September, 2008

Mr. Richard W. O'Brien,
Director, Office of International Programs and Intergovernmental Affairs,
U.S. Consumer Product Safety Commission,
4330 East West Highway,
Bethesda, MD 20814,
U.S.A.
Email: robrien@cpsc.gov

Re: H.R. 4040 Consumer Product Safety Improvement Act of 2008, Section 108 Prohibition on sale of certain products containing specified phthalates

Dear Mr. O'Brien,

Further to our discussions in Guangzhou and your meeting with Vincent Tam at Jetta facility in Panyu, we seek your understanding and assistance in addressing an issue which is causing considerable concern among Chinese toy manufacturers which will no doubt also be being experienced in other manufacturing countries.

With reference to H.R. 4040 Consumer Product Safety Improvement Act of 2008, Section 108 - Prohibition on sale of certain products containing specified phthalates, beginning 180 days after enactment of H.R. 4040 it will be illegal to import, sell, offer for sale or distribute in commerce any children's toy or child-care article that contains concentrations of more than 0.1 percent of di-(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP) or benzyl butyl phthalate (BBP). In addition, beginning on this date and until a final rule is promulgated, it will be illegal to import, sell, offer for sale or distribute in commerce any children's toy that can be placed in a child's mouth or child-care article that contains concentrations of more than 0.1 percent of diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), or di-n-octyl phthalate (DnOP).

This section of the Act does not specifically indicate whether the prohibition is for accessible parts or inaccessible parts or both as was indicated with the heavy element section. Thus, in order to fully comply with the wording of the Act, we are subjected to third party laboratories and toy brands interpretation of this requirement to the exact letter of the Act as published.





香港玩具協會
Hong Kong Toys Council

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We have been advised that due to the urgency with which H.R.4040 needed to be brought to completion there might be an omission in the final version in regards to the testing of Phthalates in that the requirements (which were to mirror the testing for lead) in relation to accessibility were not included. Therefore, the Act of 2008 Section 108 makes no reference to the accessibility or otherwise of phthalates in products to be tested.

As toy manufacturers, we are being instructed by many toy brands to test all accessible as well as inaccessible components of a toy to make sure these components do not contain phthalates that exceed H.R. 4040 requirements. There can be dozens or even at times up to more than a hundred components inside a toy. If phthalates are found at any component(s) to be present during testing we would need to have the supplier of this component to source an alternative. This could be very difficult as the same component(s) may be generic and is perfectly acceptable in many other industries such as the electrical appliance industry. In some cases, alternative choice may not be possible as such may not be available at reasonable costs.

The following four examples are an indication of the extremes to which toys are being subjected to tests which we consider excessive. It was performed in order to ensure that all components are tested rather than what is accessible to a child as is the situation with lead which is a well documented hazard.

As phthalates have not been proven to have as significant an effect on health as lead, the existing requirement which asks for more restrictive testing to be conducted does not appear to be reasonable or necessary. We sincerely request your help in addressing this situation by providing further clarification of the exact requirement for testing accessible components.

The following are few specific examples of tests which would consider unreasonable.

1. Plastic magnet inside the motor of a toy

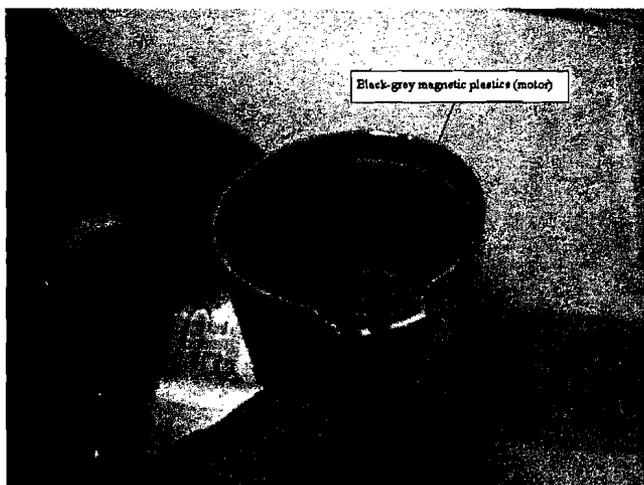
The laboratory technician broke open the toy to remove the motor from the toy. After cracking open the motor, a hammer was used to chip off pieces of the plastic magnet for testing.



香港玩具協會
Hong Kong Toys Council

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It was reported that the plastic magnet contain phthalates exceeding H.R. 4040 requirement. This is greatly in excess of testing methods used to check compliance to standards and totally unnecessary to ensure the safety of the toy.



2. Electrolytic capacitor and wiring inside a toy

The laboratory technician broke open a toy to access the components on the printed circuit board to test the electrolytic capacitor and wiring inside the toy. The wrapping of the capacitor failed to meet H.R. 4040 requirement. The electronic component industry does not manufacture capacitor specifically for the toy industry.





香港玩具協會
Hong Kong Toys Council

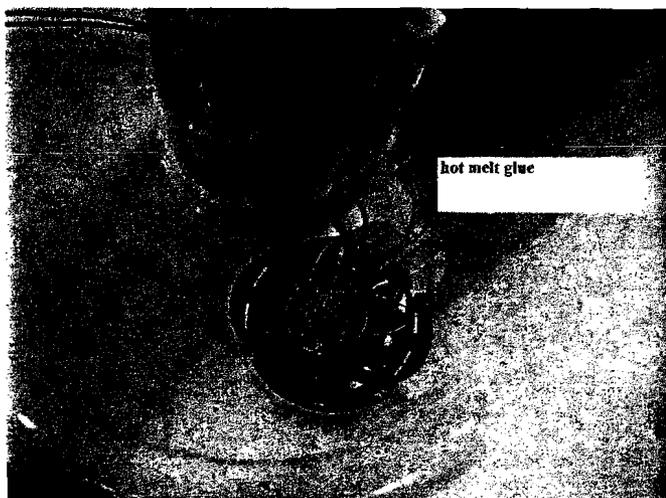
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3. Plastic belt on motor sealed inside a toy

The laboratory technician broke open a toy cassette recorder to test components which are inaccessible under any reasonable criteria and stated that the plastic belt on the motor failed to meet H.R. 4040 requirement.



The yellow hot melt glue on the speaker inside a toy and cement glue securing screws on the steel casing inside the recorder were tested which resulted failure to meet H.R. 4040 requirement.





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Summary

We believe inaccessible components containing phthalates do not pose a safety risk to children because of their inaccessibility.

We would sincerely urged CPSC to clarify that the phthalates requirement of H.R. 4040 is meant for accessible parts only which will allow the toy industry to focus its efforts to producing safe toys for our children.

Again, we would like to express our most sincere appreciation for your assistance and consideration.

Yours sincerely,

Lawrence Chan
Chairman
Hong Kong Toys Council

c.c.: Ms. Nancy Nord – Acting Chairman, CPSC email: nnord@cpsc.gov

Mr. Joseph Martyak – Legal Counsel CPSC email: jmartyak@cpsc.gov



U.S. CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

OFFICE OF THE GENERAL COUNSEL

Cheryl A. Falvey
General Counsel
Tel: 301-504-7642
E-Mail: cfalvey@cpsc.gov

January 13, 2009

Mr. Lawrence Chan
Chairman
Hong Kong Toy Council
4/F Hankow Centre
5-15 Hankow Road
Tsimshatsui, Kowloon, Hong Kong

Re: Section 108 Phthalates Ban

Dear Mr. Chan:

We have received your September 20, 2008 letter to Richard W. O'Brien, Director of the International Programs and Intergovernmental Affairs Office at the CPSC regarding the Consumer Product Safety Improvement Act of 2008 (CPSIA) section 108 ban on certain phthalates. Thank you for your insightful comments. I am responding to your letter on behalf of Mr. O'Brien. Your letter will be included as a comment under the section 108 docket for the CPSIA. Information regarding the CPSIA and current rulemakings that are underway is available on the CPSC website at: <http://www.cpsc.gov/about/cpsia/cpsia.html>.

Sincerely,

A handwritten signature in black ink, appearing to read "Cheryl A. Falvey".

Cheryl A. Falvey

51 -108
Silverstein



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Chief Executive Officer
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January 19, 2009

Dear Commissioner:

I am writing to you today on behalf of my company, Nina Footwear Corp., which is headquartered in New York, regarding the Consumer Product Safety Commission's (CPSC) efforts to implement the new lead and phthalate requirements (effective February 10, 2009) under the recently enacted Consumer Product Safety Improvement Act of 2008 (CPSIA). Our company recognizes that the CPSC was given an ambitious task of implementing CPSIA requirements in a short timeframe and we commend the agency for working diligently thus far.

However, there are significant negative economic concerns associated with these new requirements being implemented. It is necessary that you understand how my company will be impacted and to ask that you consider these issues during the rulemaking process.

Nina Footwear Corp. has become one of the most widely recognized footwear brands in the United States, enjoying its place as the number one shoe resource for accessible luxury and special occasion footwear. Nina still carries on its proud tradition of being designed in New York. Nina shoes are available in fine department stores and specialty stores across the United States, as well as in more than 20 countries worldwide. Nina Footwear Corp. is also the parent company for other footwear brands, including Delman, our high-end salon brand, Nina Dolls and Nina Kids. Nina Footwear Corp. today employs over a hundred employees domestically.

While we are supportive of CPSIA implementation and are making the necessary changes to meet the various implementation requirements to date, the February 10, 2009 deadline for lead will impose significant hardships on my company and others selling footwear to children.

Moreover, if applied retroactively to existing inventory, the new requirements could have grave consequences on my business.

As you are aware, the CPSIA imposed additional new requirements restricting lead and phthalate levels in various children's products. We support such restrictions if they are necessary to protect the health and safety of children. We support the recently issued opinion by the CPSC General Counsel that the new requirements for phthalates levels will apply only prospectively to products manufactured after February 10, 2009. At the same time, the CPSC General Counsel opined that the lead requirements will apply retroactively to existing inventory, thus impacting products produced prior to the CPSIA's enactment date.

I am contacting you to stress the importance that the lead restrictions not be applied retroactively to products produced in good faith before the law existed. We believe any new law should apply prospectively. Any other interpretation would punish those of us who in good faith met the requirements of the laws that were in place when we were manufacturing product, as well as our own strict quality control requirements

The Commission's implementing opinions directly impact and threaten the viability of thousands of businesses and their employees. For example:

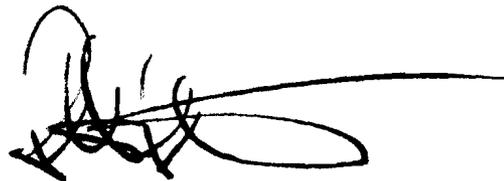
- Small and medium sized-companies will be most negatively impacted, with many of these companies pushed to the point of possible bankruptcy. The retroactive application would require existing products be removed from store shelves on February 10. This would mean that product on store shelves, in warehouses or anywhere in the supply chain must be removed for costly testing to demonstrate compliance with the new requirements. Retroactive enforcement will impose huge costs for removal, testing and certification, lost sales and other logistical costs on these companies. **Further, billions of dollars worth of inventory that does not meet the new requirements could be destroyed even though those products – when put into the marketplace – were compliant with arguably the strictest safety standards in the world.**
- The CPSC General Counsel's opinion applying the phthalates standards prospectively should stand.
- The economy today is in far worse condition than it was when Congress debated and enacted the CPSIA. We believe the CPSC and Congress should factor the current economic crisis into its analysis of the implementation timelines.

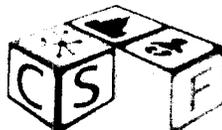
However, the need for additional clarity has left the marketplace in a state of confusion. The result has been efforts by some to declare previously sold legal goods "illegal" and to promote testing at great expense, when none is actually required. Unchecked misapplication of yet-to-be-established requirements for lead content to current inventories at retail potentially threatens to obsolete billions of dollars of safe products introduced into interstate commerce well prior to the effective date of the CPSIA. The expense of forced returns from retailers of previously sold products or unnecessary testing could put smaller companies out of business and result in job losses during this perilous economic time. Congress could not have reasonably intended such consequences from a chaotic implementation of the CPSIA and, in light of the economic crisis we currently operate in, CPSC should act in a manner that does not cripple the ability of companies like mine from continuing to exist – yet still maintaining our common mission of consumer safety.

We respectfully request the lead restrictions not be applied retroactively to products produced before February 10, 2009 and that the agency uphold the position to apply the phthalates requirements prospectively.

On behalf of my company and my colleagues in the footwear industry who share your interest in the safety of consumer products, I thank you for your attention to this urgent matter.

Very truly yours,

A handwritten signature in black ink, appearing to be 'A. J. ...', with a long horizontal line extending to the right.



Child Safety Task Force
Promoting Child Safety through Sound Science and Government Testing

January 12, 2009

Office of the Secretary
Consumer Product Safety Commission, Room 502
4330 East-West Highway
Bethesda, MD 20814

Dear Acting Chairman Nancy Nord and Commissioner Thomas Moore,

The Consumer Product Safety Commission has requested comments on Section 108 of the Consumer Product Safety Improvement Act (CPSIA) "Prohibition on sale of certain products containing specified phthalates." While the questions stated in the invitation to comment should certainly be addressed by the Chronic Hazard Advisory Panel (CHAP), there are several key points which need to be addressed by the CHAP as well.

Safety concerns that will inevitably result from replacing phthalates in children's products should be considered by the panel as well as the status of research available on phthalates alternatives. It is imperative that the CHAP have a well rounded approach in considering the effects of high molecular weight phthalates and whether to continue the interim ban.

Attached with this letter you will find four questions and answers which we believe need to be addressed by the CHAP. Thank you for your time and consideration.

Sincerely,

Robert Johnson
President
Child Safety Task Force

**Proposed Questions and Answers the Chronic Advisory Hazard Panel (CHAP)
should address**

Q: What are the safety concerns that result from replacing phthalates?

A: There are approximately a dozen known alternatives to DINP, the phthalate most commonly used to make PVC toys soft and flexible. These alternatives will have to be used to make mouthing toys and child care articles as of February 1, 2009 due to the temporary restrictions on DINP. No US government agency has approved or even tested any of these alternatives for use in children's products or toys. Forcing manufacturers to replace a proven-safe product with an untested one can lead to unintended consequences. Equally dangerous are hard plastic toys which contain none of these softeners and are brittle and breakable, thus increasing the risk of injuries, cuts, and choking hazards to children. In 2004, the CPSC staff warned "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."

Q: What is the status of research on the toxicity of phthalate alternatives? What about research on human exposures to phthalate alternatives?

A: There is far less research and regulatory review of phthalate alternatives than there is on phthalates. Several alternative plasticizers that could be used in children's toys are listed below. None of these have been studied by the U.S. Consumer Product Safety Commission, the European Union Risk Assessment organization, the U.S. National Toxicology Program, or the U.S. Centers for Disease Control and Prevention. Substituting a thoroughly tested and evaluated substance that has been found safe for use with something that has not been well-studied could introduce unknown risks and unintended consequences.

- Di 2-ethylhexyl adipate (DEHA)
- Diisononyl adipate (DINA)
- Acetyl tributyl citrate (ATBC; Citroflex® A-4)
- Tributyl citrate (TBC)
- Di-octyl terephthalate (DOTP; also known as DEHT or di(2-ethylhexyl) terephthalate)
- Di-isononyl cyclohexanoate (Hexamoll® DINCH)
- Tris (2-ethylhexyl) trimellitate (TOTM)
- Alkyl sulfonic acid ester of phenol (Mesamoll® II)
- Epoxidized soybean oil (ESO)
- Acetylated monoglycerides of fully hydrogenated castor oil (COMGHA;
- Grindsted® Soft'n'Safe)
- Polyol ester benzoate made from pentaerythritol, 2-EH acid and
- benzoic acid (LGflex EBN)

- Polyol ester benzoate made from trimethylol propane, 2-EH acid, and
- benzoic acid (LGflex BET)
- 2,2,4-trimethyl-1,3-pentanediol diisobutyrate (TXIB)

Q: If phthalates are banned, what will happen next?

A: It will take many, many years for the US plasticizer industry to build new facilities to produce the alternative plasticizers. In the meantime, most of the alternatives are produced overseas where there isn't the same level of quality control and oversight as in the U.S. As production costs for new facilities could be several hundred million dollars, it is very likely that new facilities for production would be built overseas due to lower construction and labor costs. In any event, the U.S. will likely import toys produced overseas. This means there could be significant loss of U.S. manufacturing jobs and tax revenue.

Q: How does Europe ensure products made with phthalates are off store shelves? What are the oversight mechanisms in place?

A: Europe is still devising oversight mechanisms to ensure products with the banned substances do not make it to store shelves. The Marketing & Use Directive placed the onus on industry to stop using six phthalates in children's products, and left enforcement of this legislation up to the individual EU Member States. The Commission has established a Rapid Alert System, called RAPEX, that Member States can use to report safety concerns related to consumer products. In 2008, over 140 violations of the EU restrictions on phthalates in toys were reported, despite the fact that these restrictions have been in place on at least a temporary basis for years. Most of these offending toys originated in China, other Asian countries, or Eastern Europe. This indicates that there are significant challenges associated with the enforcement of the phthalates restrictions, and that the enforcement mechanisms in the EU are still very much in the infancy stages.

Sent
10/8
PHK 53



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20 January 2009

Nancy A. Nord
Acting Chairman
Consumer Product Safety Commission
4330 East West Highway
Bethesda, MD 20814

Dear Chairman Nord:

On Thursday, January 8, I learned for the first time about the Consumer Product Safety Improvement Act (CPSIA), through a story in the *Denver Post*, a copy of which is enclosed. When I investigated the Act more fully, my blood ran cold, because I found that as of February 10, 2009, we will not be able to sell the products that comprise fully half of our annual revenue, putting our ten employees' jobs in serious jeopardy.

We are a small manufacturer of sewn products for use by children, specifically baby bibs, burping pads, and changing pads. Our products are custom screen printed and sold to hundreds of hospital maternity units, obstetricians, pediatricians, banks, and credit unions across the country. They are given out by our customers as Birth Gifts to new Moms. We've been in business since 1979.

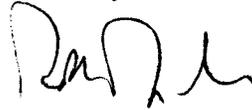
The issue is not the lead requirement of the Act. Our products have been lead-free since the mid-80's, when I first learned about the adverse effect of concentrations of lead on babies and children. The issue is phthalates. Our supplier of the vinyl-backed cotton terry cloth used in our products has informed us that a trace amount of a phthalate on the prohibited list, Di-isonyl phthalate (DINP), is present in the vinyl. I anticipate that further testing will show the "trace amount" to be over the 0.1% limit.

I urge you to delay the implementation of the phthalate ban in CPSIA so that we and other small companies like us will not be forced out of business.

We are committed to supplying child-safe products. The terry fabric we use is knitted in the U.S. and laminated in the U.S. Our baby bibs and similar products are not ingested by babies; in fact, babies are seldom in contact with the vinyl backing on the products. Yet the Act specifically mentions baby bibs as being subject to the phthalate prohibition, probably because some other bibs are made exclusively of vinyl.

All we want is some time to find a supplier of phthalate-free fabric. We're sitting on six months' worth of fabric inventory that we can't afford to replace. Please give us some time to work through this and to come into compliance with CPSIA.

Sincerely,

A handwritten signature in black ink, appearing to read "Robb Ruyle". The signature is fluid and cursive, with a prominent initial "R" and a long, sweeping tail.

Robb Ruyle
President

BUSINESS

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Hoping not to fold

"I can't even fathom the cost and just won't make any more clothes (and will) sell off what I have and move on."
Verity Freebern, owner of Denver-based children's retailer Grow, on new lead-testing requirements



Verity Freebern, owner of Grow, packs up clothes at her store in anticipation of closing because of a law going into effect Feb. 10 that will require nearly all sellers of children's products to verify that their wares have been tested for high levels of lead. *CRAG F. WALLER, The Denver Post*

By David Migoya *The Denver Post*

Local businesses that make and sell children's products — from baby-blanket makers to thrift shops — are wailing that a new federal law devised to target toys laden with lead might unintentionally force them to close.

The Consumer Product Safety Improvement Act, signed in August and effective Feb. 10, requires any maker or retailer of an item designed for children younger than 12 to conform with strict limits on lead and other harmful substances.

The law was Congress' way of slamming the door on the runaway recalls of more than 45 million products — 8 million of them toys — in the past several years, most of them from China, that contained unsafe levels of lead and other hazards. Ambiguities in the law have small-business owners worried that the costly tests will force them out of business.

"If the law isn't interpreted differently, I'm going to have to close, and I already don't make a lot, and for this to be added to my costs is unbearable," said Olivia Omega Logan, 29, whose home-based business, Baby Candy Store, makes a line of organic T-shirts.

Though her products are made from undyed, unbleached cotton and use a screening process that's lead-free, "I still will have to test them all," she said.

The Consumer Product Safety Commission, which enforces the law, voted Tuesday to exclude from the requirements all clothing, toys and other goods made of unaltered natural materials such as cotton and wood. But printing or embellishing the items would make tests necessary.

Logan is leading an effort to pool area businesses into a voice that can be heard in Washington, D.C. They plan their first meeting today at Anahaim Children's Clothing in Denver.

All items marketed for use by children must be tested and certified as meeting strict lead limits. And if a retailer doesn't have the manufacturer's certification, it's required to test and certify the item itself. So thrift stores, in theory, must test

every child-specific item on their shelves.

The law's effective date has been dubbed by some small businesses as National Bankruptcy Day because of the high costs they face in meeting the CPSIA requirements.

Though independent lab testing of items isn't required until August, alternative tests that can be used until then can still cost hundreds or thousands of dollars, affected business owners say.

It's tough having a manufacturing business since we're competing with those who are making such giant quantities overseas," said Verity Freebern, whose Denver-based business, Grow, makes and sells, among other things, children's clothing.

"I can't even fathom the cost and just won't make any more clothes (and will) sell off what I have and move on," she said.

For now, any children's item not certified by Feb. 10 — no matter how long ago it was made — cannot be sold legally. However, John Moss, a Chicago lawyer who counsels clients on CPSC issues, said it's unlikely that small retailers such as thrift shops will be targeted for enforcement.

Without clarity, though, no one can know for sure.

David Migoya, 202-954-1506 or dmigoya@denverpost.com

"Vacuum of information" » Clarify the new law, advocacy groups ask of the Consumer Product Safety Commission. »108