

**INFORMATION FOR THE CONSUMER PRODUCT SAFETY COMMISSION  
CHRONIC HAZARD ADVISORY COMMITTEE ON PHTHALATES  
July 19, 2010**

**ATTACHMENT 9**

**Estimates of exposure of infants and toddlers to DINP (apart from toys) and DIDP**

Originally submitted to the  
National Toxicology Program Center for the Evaluation of Risks to Human Reproduction  
by the  
American Chemistry Council Phthalate Esters Panel

**Attachment A to Preliminary Technical Comments on Draft DINP Monograph, Section 5**  
**Submitted By**  
**CMA Phthalate Esters Panel**  
**December 10, 1999**

**DINP - Exposure Assessment**

I. Background

The question addressed in this paper is "how much DINP are children exposed to from sources other than toys?" The question was originally raised by the European Union's CSTE in its report of April 24, 1998 (CSTE, 1998a). The CSTE identified a number of potential sources for exposure but did not locate any specific information on DINP. A subsequent risk assessment from the Netherlands suggested that exposures from sources other than toys would not exceed 50 ug/kg/day (Konemann, September, 1998). However, this was not, at least initially, an estimate of DINP exposure exclusively. The Dutch authorities relied on a previous estimate that exposure from food sources of **all phthalates** would not exceed 23 ug/kg/day (Peijnenburg, 1991). It was then assumed that exposure from non-food sources (other than toys) would not be more than the exposure from food, i.e., 23 ug/kg/day. In round numbers this became 50 ug/kg/day. Again, it is important to emphasize that this was an estimate of "maximum daily intake" for all phthalates, rather than an estimate of DINP exposure.

In a subsequent opinion the CSTE questioned that estimate, concluding that "this estimate is quite uncertain so it does not seem appropriate to include it in a margin of safety consideration" (CSTE 1998b). They also noted that when the critical effects were similar, the phthalates could be considered additive, "[b]ut for phthalates with different critical effects, as for DINP and DEHP, the assessment should be done separately for the two compounds" (CSTE, 1998b). A Health Canada risk assessment, on the other hand, seems not to have considered either of these qualifying points. Health Canada said that "[C]onsistent with the Dutch in vivo study, Health Canada has estimated the combined dietary and other sources of DINP to be 50 ug/kg/day" (Health Canada, 1998). However, Health Canada did not provide any documentation of the underlying assumptions or any other description of their process.

We have been compiling a data base on DINP concentrations in various media. The potential sources of DINP exposure which have been identified include food, infant formula, air, water, and dust. Literature data were collected and compiled to develop the best estimates for concentrations of DINP in the various media. These estimates were then used, in the context of the relevant children's exposure factors to develop comprehensive exposure estimates.

II. Sources of Exposure

Potential sources of DINP exposure for young children, other than toys, include breast milk, infant formula, food, air, water, ingestion of dust, and exposure from dermal contact with formulated articles. Recent data exist for all of these except dermal contact. Exposure by that route was estimated thorough use of models based on experimental data primarily for di(2-ethylhexyl) phthalate (DEHP), a substance of similar physical and chemical properties.

III. Estimates of Exposure from Various Media

III.1. Exposure from Food

The best data on phthalate levels in food and infant formula come from recent studies by the U.K. Ministry of Agriculture, Fisheries and Food (MAFF). A study of phthalates including DINP in carcass meat, poultry, eggs and milk (MAFF, 1996) indicated that DINP is sometimes present at the limit of detection (0.01 mg/kg) but never at levels that could be quantified. A German study (Pfordt and Brunsweller, 1999) reported that DINP was below detection limits (0.01 mg/kg) in samples of milk and cream; and an Austrian study (Pfannhauser et al., 1997) reported DINP to be below detection levels in fish. In fact, the only report of detectable levels comes from a study of nuts (Pfordt and Brunsweller, 1999) which

reported levels ranging from 0.01 to 0.06 mg/kg. Data from the US Department of Agriculture (USDA, 1997) indicate that nuts comprise less than 0.5% of the diet of young children. As the incremental contribution from nuts is negligible, the data were not used in the exposure assessment calculations.

There are two studies by MAFF on phthalate levels in infant formula (MAFF 1996b, 1998). In the first of these studies DINP was detected in 4 of 12 samples but at levels too low to be quantified. The detection limit was approximately 0.01 mg/kg. In the second study DINP was not specifically targeted for analysis but there was no evidence of significant concentrations at the expected retention time, i.e., DINP was below detection limits in all samples. DINP was assessed but not found in a series of baby food samples (Pford and Bruns-Weller, 1999). Phthalate levels were also measured in infant formula in the US (Department of Health and Human Services, 1996). DINP was not among the phthalates measured, but the potential for phthalate exposure by this route was low as the measured substances were only found at low ppb levels.

Another potential source of children's exposure is breast milk. The CSTEE report (CSTEE, 1998a) stated that they were not able to find any measured data on phthalate levels in breast milk. There are a few reports of phthalates in breast milk, but only one (Pford and Bruns-Weller) included DINP in the analysis. DINP was not found at a detection limit of 0.01 mg/kg.

When all of these data are considered, a reasonable assessment of children's exposure to DINP from food sources could be developed conservatively assuming DINP to be present at the level of detection (0.01 mg/kg) in all ingested material. As the data indicated that DINP concentrations were either at or below this level, this could be considered a worst case assessment.

### III.II. Levels in Air

At 20 °C DINP has a vapor pressure of  $6.1 \times 10^{-5}$  Pa (best estimated value) and a calculated saturated vapor concentration of  $10 \text{ ug/m}^3$ . It is unlikely, however, that saturated vapor concentrations would be achieved, and certainly not under non-occupational conditions since consumers are only exposed to plasticized articles and not to the plasticizers themselves. The measured data are consistent with this. DINP is not detected in outdoor air (Wechsler, 1984). In indoor air, DINP has been reported at levels in the range of 15-20  $\text{ng/m}^3$  (Wechsler, 1984; RIC, 1999). As 20  $\text{ng/m}^3$  is the highest measured value, it seems reasonable for use in a worst case exposure assessment.

### III.III. Levels in Water

The water solubility limit for DINP is below 1  $\text{ug/l}$  (Staples et al., 1997). No reports of DINP in water were identified. It seems reasonable to assume, as a worst case, that levels of DINP in water would not exceed 1  $\text{ug/l}$ .

### III.IV. Levels in Dust

Pfordt and Bruns-Weller (1999) reported that levels in dust were at or below 10  $\text{ug/gm}$ . RIC reported levels of 44 and 80  $\text{ug/kg}$ . Oie et al. (1997) reported levels of 100  $\text{ug/kg}$ . Based on these data, it seems reasonable to assume that levels of DINP in dust do not exceed 0.1  $\text{mg/kg}$ .

### III.V. Dose from Dermal Exposure

There is some potential for dermal exposure as a consequence of the use of vinyl products for gloves and other articles which may be worn. To assess the potential for exposure from contact with plasticized articles, Deisinger et al. (1998) measured the DEHP dose to rats from dermal contact with vinyl films. The maximal dermal absorption rate was reported to be  $0.24 \text{ ug/cm}^2/\text{hr}$ . Another study compared skin penetration of DIDP, a phthalate which is very similar to DINP with a slightly higher molecular weight (447 v. 421) and found it was 10 times less than DEHP (Elsisi et al., 1989).

Barber et al., (1992) compared percutaneous absorption of a number of chemicals including DEHP in human and rat skin. The measured absorption rate in rat skin was 4.2 times that for an in vitro preparation of stratum corneum. Thus, human skin is at least 4 times less penetrable by phthalates than rat skin. In fact, this may be a minimal estimate. According to Melnick et al. (1987) "The dermal absorption of DEHP was slightly greater than DIDP and much less than DMP, DEP, DBP [for which the rat/human absorption ratio was 22.7], DIBP, BBP or DNHP." Thus it seems reasonable to assume that rat skin is 25 times more permeable to DINP than is human skin.

Assuming DINP to be 5 times less well absorbed than DEHP (i.e., half way between the DEHP and DIDP), the estimated dermal absorption rate of DINP in rat skin is approximately  $0.05 \text{ ug/cm}^2/\text{hr}$ . If human skin is assumed to be 4 times less penetrable than rat skin, the estimated dermal absorption rate in humans becomes  $0.0125 \text{ ug/cm}^2/\text{hr}$ .

#### IV. Estimated Exposure Factors

##### IV.I Food Intake

The most current data available for US children were taken from the 1994-1995 USDA Continuing Survey of Food Intake by Individuals (CSFII). The US data covered the periods 0-1, 1-2, and 2-5 years of age (USDA, 1997).

##### IV. II. Drinking Water

US values were based on the tap water ingestion rates of Roseberry and Burmaster (USEPA, 1997).

##### IV. III Soil and Dust

The soil/dust ingestion rates utilized, 35 mg/day infants and 50 mg/day toddlers were taken from the Canadian Environmental Protection Act (CEPA, 1994). These were chosen because a distinction was made between infants and toddlers which seemed appropriate for this purpose. An evaluation of phthalate levels in soil and dust indicated that levels in soil were so much lower than those in dust that the incremental effect of soil ingestion was negligible. Thus, as a worst case, it was assumed that all material was ingested as dust.

##### IV. IV. Inhalation Rates

Values of 4.5 and  $8.3 \text{ m}^3/\text{day}$  for infants and toddlers were used, based on the study by Layton (1993) described in the US EPA Exposure Factors Handbook.

##### IV. V. Body Weights

A value of 7.2 kg for infants was based on the data of Hamill et al. (1979) as presented in the US EPA Exposure Factors Handbook (USEPA, 1997). A time-weighted average of the median body weight values for children up through 12 months of age was estimated for males and females and then the average of the gender estimates was used. For toddlers, 14.3 kg was the arithmetic mean of the weights of male and female children (1-4) years of age (USEPA, 1997).

#### V. Estimation of Exposure from Different Sources

##### V.I. Estimation of Exposure from Food

Estimates taken from the United States Department of Agriculture's 1994-1006 CFSII indicate that infants ingest approximately 700 g of formula and 350 g of food per day. Estimates for older children are 1309 g/day for 1-2 year olds and 1348 g/day for 2-5 year old. The United States Environmental Protection Agency (EPA, 1997) estimates ingestion of breast milk by infants as 700 g/day. As a reasonable worst

case, we can assume that infants ingest 1050 g of which approximately 700 g would be either breast milk or formula and the remainder all other sources of food. Toddlers are assumed to ingest 1350 g food but no breast milk or formula. Assuming DINP to be present in all food sources at a level of 0.01 mg/kg (the detection limit and the highest level reported), intake is 10 ug/day (1.5 ug/kg/day) for infants and 13.5 ug/day (0.9 ug/kg/day) for toddlers.

#### V. II. Exposure from Air

Assuming a concentration of 20 ng/m<sup>3</sup> in air and a daily inhalation volume of 4.5 m<sup>3</sup> by infants and 8.3 by toddlers, the total amount inhaled is 90 ng/day by infants and 166 ng/day by toddlers. When expressed on a body weight basis, this becomes 0.012 ug/kg/day by infants and 0.012 ug/kg/day by toddlers.

#### V. III. Exposure from Water

Taking 1 ug/l as a worst case estimate and assuming that infants drink 0.3 l/day and toddlers 0.35 l/day, the daily doses are 0.3 ug/day for infants and 0.35 ug/day for toddlers. On a body weight basis this becomes 0.04 ug/kg/day (infants) and 0.02 ug/kg/day (toddlers).

#### V. IV. Exposure from Dust

Assuming infants ingest 35 mg dust/day and toddlers ingest 50 and that the concentration of DINP in the dust is 100 ug/gm, the amount of DINP ingested would be 3.5 g by infants and 5 by toddlers. On a body weight basis this becomes 0.49 ug/kg/day by infants and 0.35 ug/kg/day by toddlers.

#### V. V. Exposure from Plasticized Articles

In theory there could be some absorption of phthalate as a consequence of dermal contact with plasticized flooring. The estimated total skin surface areas are 220 cm<sup>2</sup> for infants and 600 cm<sup>2</sup> for toddlers (Plunkett et al., 1992). This equates to approximately 2.75 ug/hr for infants and 7.5 ug/hr for toddlers. Assuming children spend 3 hours/day in contact with flooring or other PVC articles, the total becomes 8.25 ug/day for infants and 22.5 ug/day for toddlers. Expressed on a body weight basis, this is 1.15 ug/kg/day for infants and 1.6 ug/kg/day for toddlers.

It should be noted, however, that there is substantial uncertainty associated with the estimate. As a result further research is needed before any firm conclusions can be drawn.

#### VI. Summary of Exposure

	Infants	Toddlers
Food (all sources)	1.5 ug/kg/day	0.9 ug/kg/day
Air	0.01 ug/kg/day	0.01 ug/kg/day
Water	0.04 ug/kg/day	0.02 ug/kg/day
Dust	0.49 ug/kg/day	0.35 ug/kg/day
Dermal Contact	1.15 ug/kg/day	1.6 ug/kg/day
Total	3.19 ug/kg/day	2.88 ug/kg/day

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**Table 1. Summary of Exposure Factors**

Units	Infants	Toddlers	Contact Rate	Exposure Medium
Baby formula (liquid) <sup>a</sup>	g/day	686	6.7	
Powdered Baby Formula <sup>b</sup>	g/day	98	0.96	
Breast Milk	g/day	709	0	
Fish	g/day	0.5	4	
Meat <sup>c</sup>	g/day	30.5	116	
Milk <sup>d</sup>	g/day	57	346	
Other dairy	g/day	6	46	
Other Beverages	g/day	15	247	
Snacks <sup>e</sup>	g/day	5	72	
Grains	g/day	52	215	
Vegetables	g/day	52	89	
Fruits <sup>f</sup>	g/day	131	213	
Tap Water <sup>g</sup>	l/day	0.3	0.35	
Dust <sup>h</sup>	g/day	0.035	0.05	
Soil	g/day	0.035	0.05	
Inhalation rate of air <sup>i</sup>	m <sup>3</sup> /day	4.5	8.3	
Body Weight <sup>j</sup>	kg	7.2	14.3	

a: Infants: assumed baby formula ingestion was the portion of total milk, milk drinks and yogurt that had fluid milk and yogurt excluded.

b: Total formula intake divided by an estimated dilution factor of 7 (indicated by package directions).

c: Ingestion is the sum of total meat, poultry and eggs

d: Includes yogurt, milk deserts, cheese and butter.

e: Cakes, cookies, pastries, pies, crackers, popcorn, pretzels, corn chips, sweets

f: Includes fruit juice and fruit

g: Infant tap water ingestion based on Roseberry and Burmaster (EPA, 1997); for toddlers total is the sum of water, coffee and tea

h: Dust ingestion assumed same as soil, use time indoors for exposure; values taken from CEPA 1993 risk assessment with EHD (1994) cited as the original source.

i: Layton, 1993 (EPA, 1997).

J: Hamill in EPA (1997)

**Supplement to Preliminary Technical Comments on Draft DIDP Monograph, Section 5**

**Submitted By**

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**December 10, 1999**

**(Supplement submitted December 13, 1999)**

**DIDP - Exposure Assessment**

This document provides a summary of the potential for exposure of children to DIDP. It relies on the same data sources and assumptions as were used for the exposure assessment which has previously been provided for DINP (Attachment A to Preliminary Technical Comments on Draft DIDP Monograph), and should be read in conjunction with that document. A table at the end of this document provides a summary of the exposure estimates for both DINP and DIDP.

The total exposure estimate given below is 2.6 ug DIDP/kg bw/day for infants and 2.1 ug/kg bw/day for toddlers. Other estimates of exposure in the draft CERHR monographs include: 2.4 and 5.0 ug/kg/day for infants and toddlers (DBP); approximately 8 ug/kg/day (DEHP); and 2-6 ug/kg/day (BBP). Thus the estimates that exposures to DINP and DIDP from all sources other than toys would be in the range of 2-3 ug/kg/day are quite consistent with the data on other phthalates already incorporated in the monographs.

(1) Food - Assuming (as shown in the DINP example) that infants consume approximately 1050 g/day of food from all sources, that toddlers consume 1350, and that the concentration of DIDP does not exceed the detection limit (0.01 mg/kg), the calculations would be:

infants -  $1.05 \text{ kg} \times 0.01 \text{ mg/kg} = 0.01 \text{ mg/day}$ . Assuming body weight to be 7.2 kg = 0.0015 mg/kg bw/day or 1.5 ug/kg bw/day

toddlers -  $1.350 \text{ kg} \times 0.01 \text{ mg/kg} = 0.014 \text{ mg/day}$ . Assuming body weight to be 14.3 kg = 0.0009 mg/kg bw/day or 0.9 ug/kg bw/day.

(2) Exposure from air - Assuming the concentration in air to be 20 ng/m<sup>3</sup> and a daily inhalation volume of 4.5 m<sup>3</sup> by infants and 8.3 m<sup>3</sup> by toddlers, the total amount inhaled is 90 ng/day (0.09 ug/day) by infants and 166 ng/day (0.166 ug/day) by toddlers. When expressed on a body weight basis, this becomes:

infants -  $(0.09 \text{ ug/day})/7.2 \text{ kg} = 0.01 \text{ ug/kg bw/day}$

toddlers -  $(0.166 \text{ ug/day})/14.3 \text{ kg} = 0.01 \text{ ug/kg bw/day}$

(3) Exposure from water - Assuming the concentration to be less than 1 ug/l (Staples et al., 1997) and assuming that infants drink 0.3 l/day and toddlers 0.35 l/day, the daily doses are 0.3 ug/day for infants and 0.35 ug/day for toddlers. When expressed on a body weight basis, this becomes:

infants -  $(0.3 \text{ ug/day})/7.2 \text{ kg} = 0.04 \text{ ug/kg bw/day}$

toddlers -  $(0.35 \text{ ug/day})/14.3 = 0.02 \text{ ug/kg bw/day}$

(4) Exposure from dust - Assuming infants ingest 35 mg dust/day and toddlers ingest 50, and that the dust concentration does not exceed 100 ug/gm (the highest reported value is 60 ug/gm), the daily doses would be 3.5 ug by infants and 5.0 ug by toddlers. When expressed on a body weight basis, this becomes:

infants -  $(3.5 \text{ ug/day})/7.2 \text{ kg} = 0.49 \text{ ug/kg bw/day}$

toddlers -  $(5.0 \text{ ug/day})/14.3 \text{ kg} = 0.35 \text{ ug/kg/day}$

(5) Exposure from plasticized articles - The DINP analysis estimates that exposure from plasticized articles would be 1.15 ug/kg bw/day for infants and 1.6 ug/kg bw/day for toddlers. That calculation assumed that absorption of DINP would be about 5 times less than DEHP, based on data showing that DIDP was about 10 times less well absorbed than DEHP. In other words, DINP would be about twice as well absorbed as DIDP. Thus, all other things being equal, the estimated exposures from DIDP would be approximately 0.58 ug/kg bw/day for infants and 0.8 ug/kg bw/day for toddlers.

Summarizing:

	Infants	Toddlers
Food (all sources)	1.5 ug/kg bw/day	0.9 ug/kg bw/day
Air	0.01 ug/kg bw/day	0.01 ug/kg bw/day
Water	0.04 ug/kg bw/day	0.02 ug/kg bw/day
Dust	0.49 ug/kg bw/day	0.35 ug/kg bw/day
Dermal Contact	0.58 ug/kg bw/day	0.8 ug/kg bw/day
Totals	2.6 ug/kg bw/day	2.1 ug/kg bw/day

As for exposures from toys, the CPSC estimates for DINP are reasonable but, as indicated in the specific comments, the estimates of mean exposure (5.7 ug/kg/day for infants and 0.7 ug/kg/day for toddlers) should be included along with the ranges. DIDP is much less commonly used in toys than DINP. Therefore, if DIDP exposure from toys is going to be included in the monograph, the basis should be the CPSC estimates for DINP, but these estimates should be qualified as noted in the specific comments for DIDP.

### Summary of Exposure Information for DINP and DIDP

Medium	DINP	DIDP	Reference
<b>Air (ng/m<sup>3</sup>)</b>			
Indoor air	< 20	< 20	RIC
Indoor air	15	20	Wechsler
Indoor air	not detected	not detected	Oie
Outdoor air	not detected	not measured	RIC
Outdoor air	not detected	not detected	Wechsler
<b>Dust (ug/g)</b>			
Indoor	44-80	38-60	RIC
Indoor	100	not reported	Oie
Indoor	0-10	not measured	Pfordt and Bruns-Weller
<b>Food (mg/kg)</b>			
Infant Formula (powder)	detected, not quantified not detected (b)	not detected (a) not detected (b)	MAFF (1996a) MAFF (1998)
Infant Formula (liquid)	not detected (a)	not detected (a)	MAFF (1998)
Baby Food	not detected (a)	not measured	Pfordt and Bruns-Weller
Milk	not detected (a) not detected (a)	not measured not detected (a)	Pfordt and Bruns-Weller MAFF (1996b)
Breast Milk	not detected (a)	not measured	Pfordt and Bruns-Weller
Carcass meat	not detected (a)	not detected (a)	MAFF (1996b)
Poultry	not detected (a)	not detected (a)	MAFF (1996b)
Eggs	not detected (a)	not detected (a)	MAFF (1996b)

(a) Level of detection was approximately 0.01 mg/kg  
(b) Not specifically evaluated but no trace on chromatogram.

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