Supporting Materials for a Safe Use Determination for Diisononyl Phthalate (DINP) in Phifertex® Fabric Used in Outdoor Furniture Products

Office of Environmental Health Hazard Assessment

January 2017

Summary

This document presents an evaluation of a request from McKenna Long & Aldridge LLP (“MLA”) on behalf of Phifer Incorporated (“Phifer”) for a Safe Use Determination (SUD) for diisononyl phthalate (DINP) in Phifertex® fabric used in outdoor furniture products.

The Office of Environmental Health Hazard Assessment (OEHHA) utilized a screening level approach to evaluate this request. In this approach, an upper-end estimate of the level of exposure to DINP from Phifertex® fabric used in outdoor furniture products was determined for users of these products based on several assumptions. OEHHA compared this upper-end estimate of DINP exposure to the estimate of exposure associated with a one in 100,000 excess cancer risk, i.e., the No Significant Risk Level (NSRL) of 146 micrograms per day (µg/day).

Based on the screening level analysis discussed in this document, and the NSRL of 146 µg/day, the estimated exposure to DINP from Phifertex® fabric for users of these outdoor furniture products corresponds to a calculated cancer risk of less than one in 100,000. Thus OEHHA determined that exposure to DINP for users of these products is below the NSRL. No warning is required for consumer exposure to DINP from Phifertex® fabric containing up to 25% DINP when used in outdoor furniture products.

This evaluation performed in response to the SUD request was limited to exposure to DINP from Phifertex® fabric for users of outdoor furniture products made with this type of fabric (see Section 1.1 below for a description of the products covered). Exposures to other listed substances, if any, that may result from the use of these outdoor furniture products were not reviewed by OEHHA in the context of this request. Also, this evaluation does not address DINP exposures from Phifertex® fabric used in products other than outdoor furniture.

1. Introduction

The California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) is the lead agency for the implementation of Proposition 65 [1]. On February 13, 2015, OEHHA announced that it had received a request from McKenna Long & Aldridge LLP ("MLA") on behalf of Phifer Incorporated ("Phifer") for a Safe Use Determination (SUD) for diisononyl phthalate (DINP) in Phifertex® fabric used in outdoor furniture products. The SUD request was made by MLA pursuant to Title 27 of the California Code of Regulations, section 25204 [2].

DINP is on the Proposition 65 list of chemicals known to the state to cause cancer. For chemicals that are listed as causing cancer, the "No Significant Risk Level (NSRL)" is defined as the level of exposure that would result in no more than one excess case of cancer in 100,000 individuals exposed to the chemical over a 70-year lifetime. The NSRL for DINP is 146 micrograms per day (µg/day) [3].

A public comment period on this SUD request was held from February 13 to March 30, 2015, and a public hearing was held on March 30, 2015. No public comments were received.

Based on information provided in the SUD request, OEHHA has analyzed DINP exposures to users of outdoor furniture products made with Phifertex® fabric.

This document first provides a brief description of Phifertex® fabric and how this fabric is used in outdoor furniture products, followed by a brief summary of the MLA exposure analysis of consumer exposure to DINP which accompanied the SUD request. OEHHA's analysis of DINP exposure from Phifertex® fabric for users of these outdoor furniture products is then presented. This is followed by OEHHA's conclusion that Phifertex® fabric in outdoor furniture produces exposures that fall below the NSRL.

1.1 Product Description and Use

The following information was supplied by the. The SUD request covers the Phifertex® line of outdoor fabrics used in outdoor furniture products. Phifertex®

---

[1] The Safe Drinking Water and Toxic Enforcement Act of 1986, codified at Health and Safety Code section 25249.5 *et seq*, is commonly known as Proposition 65 and is hereafter referred to as Proposition 65.
[2] All further references are to sections of Title 27 of the Cal. Code of Regulations.
[3] The NSRL for DINP was adopted April 1, 2016 in section 25705(b)(1).

Standard Mesh Solids are used to manufacture a number of outdoor furniture products, such as chaises, chairs, patio umbrellas and awnings. DINP is present in Phifertex® fabrics as a component of the polyvinyl chloride (PVC) coating on the underlying polyester yarn. The DINP content of the PVC coating ranges from 20% to 25%, depending on the particular mesh of the fabric.

1.2 Exposure Analysis Provided by MLA

MLA assessed DINP exposure from Phifertex® fabric used in outdoor furniture products and concluded that users of these products may be exposed to DINP by dermal absorption and incidental ingestion via hand-to-mouth (HTM) activities. No product-specific DINP surface or hand-wipe data were submitted by MLA.

MLA estimated DINP exposure to users of these products as 9.8 µg/day (Table 1). The potential exposure pathways identified in the MLA's analysis for users of these products are:

- Dermal absorption of DINP through direct contact with the Phifertex® outdoor furniture product, e.g., chaise.
- Incidental ingestion of DINP via indirect hand-to-mouth (HTM) activities.

MLA considered inhalation exposure to DINP to be negligible, given the low vapor pressure of DINP (5.4×10^{-7} mmHg at 25°C) and the intended outdoor use of these products, where the limited amount of DINP emissions from these products would be expected to dissipate quickly in the ambient air.

In estimating user exposure to DINP, MLA assumed the outdoor furniture product was the chaise lounge, stating that this has the highest DINP exposure potential of all the other possible outdoor furniture products made with Phifertex® fabric.

In estimating exposure by the dermal absorption pathway, MLA assumed the Phifertex® fabric used for the chaise lounge had the maximum DINP content in the PVC coating, i.e., 25%. Information from Deisinger *et al.* (1998), an *in vivo* study of di-(2-ethylhexyl) phthalate (DEHP) absorption in rats, was used to estimate the loading and absorption of DINP on the skin of users from contact with the Phifertex® fabric. MLA indicates that the DEHP skin absorption rate in rat skin (Line F, Table 1) from Deisinger *et al.* (1998) was adjusted by the DEHP/DINP and rat/human absorption ratio (Line G, Table 1) and concentration differences (Line C, Table 1) to obtain the DINP skin absorption rate from Phifertex® fabric (Line I, Table 1). In estimating skin surface area in contact with the fabric, MLA assumed the chaise is used without cushions or towels, that direct skin contact with the fabric occurs, and that the user is wearing a short-sleeved shirt and short pants, yielding an estimated skin contact surface area of 1700 cm^2 (Line J, Table 1). MLA assumed the duration of use of the chaise is half of the median time spent outdoors, i.e., 0.75 hours per day (Line K, Table 1). Dermal exposure was further adjusted by assumed seasonal use of the chaise (i.e., the chaise is assumed to be used only six months per year; 50%) (Line L, Table 1).

In estimating exposure by the incidental HTM ingestion pathway, MLA assumed for chaise users that exposure to DINP was due solely to "indirect hand-to-mouth and hand-to-object contact"[4], and assumed 25% transfer efficiency of DINP from such contacts (Line Q, Table 1). MLA assumed the part of the hands coming in contact with the mouth are the tips of the thumb and the first two fingers of the dominant hand (19 cm^2, Line P, Table 1); that the average loading period of DINP on the tips of the thumb and first two fingers of the dominant hand prior to each HTM contact is one minute (Line N, Table 1), and that the amount of DINP loaded on the tips of the thumb and first two fingers of the dominant hand is 0.014 $\mu g/cm^2$ (Line O, Table 1). MLA assumed the number of HTM contacts per hour was 5.5 (Line R, Table 1), based on summing data for the average frequency of contacts with the face (3.9 events/hour) and the average frequency of mouthing an object (1.6 events/hour) reported in observation studies of university students (Cherrie *et al*., 2006).

[4] In its exposure calculations, MLA summed values reported by Cherrie *et al*. (2006) on the frequency of hand-to-face contacts and the frequency that objects are mouthed as "indirect hand-to-mouth" contact frequency. OEHHA notes that the mouthing of an object is generally considered a type of direct oral ingestion to chemical components of the object. The mouthing of objects is not considered an indirect hand-to-mouth contact, unless the contaminant loaded on the hand (from the source of interest) is transferred to the object, and the object is subsequently mouthed, such as can occur when eating finger foods.

Table 1. Summary of MLA evaluation of DINP exposure from use of Phifertex® outdoor furniture products

Exposure factor	Unit	Value	Basis
Dermal absorption			
A. Maximum DINP content in Phifertex® fabric	unitless	25%	MLA
B. DEHP content in material tested by Deisinger *et al.* (1998)	unitless	40%	Deisinger *et al.* (1998)
C. Adjustment factor	unitless	0.625	= A / B
D. Surrogate DEHP migration to skin	$\mu g/cm^2$-hr	1.34	Deisinger *et al.* (1998)
E. Migration to skin adjusted for content difference	$\mu g/cm^2$-hr	0.84	= C × D
F. Absorption rate in rats at 40% DEHP	$\mu g/cm^2$-hr	0.242	Deisinger *et al.* (1998)
G. DEHP/DINP & rat/human absorption ratio	unitless	10[a]	EU (2003)
H. Absorption rate @ 40% [DINP]	$\mu g/cm^2$-hr	0.024	= F / G
I. Absorption rate @ 25% [DINP]	$\mu g/cm^2$-hr	0.0151	= H × C
J. Surface area in contact	cm^2	1700	CPSC (2006)
K. Contact duration	hr/d	0.75	Assumed to be half of "median" time spent outdoors (1.5 hr/d; US EPA, 2011, Table 16-20)
L. Seasonal adjustment of chaise use	unitless	50%	Assumed
M. Daily dermal uptake dose	µg/d	9.7	= I × J × K × L
Hand-to-Mouth (HTM) ingestion			
N. Fingertip contact time with Phifertex® fabric prior to each HTM contact	hr	0.017	Assumed to be 1 min (= 1/60 hr)
O. Fingertip DINP loading	$\mu g/cm^2$	0.014	= E × N
P. HTM contact surface area	cm^2	19	OEHHA (2011)
Q. Transfer efficiency	unitless	25%	Indirect transfer efficiency in OEHHA (2011)
R. HTM activity frequency	events/hr	5.5	Sum of touching face (3.9/hr) and mouthing objects (1.6/hr); Cherrie *et al.* (2006)
S. Daily ingestion dose	µg/d	0.1	= K × L × O × P × Q × R
Total intake by all pathways			
T. Daily dose from all pathways	µg/d	9.8	= M + S

[a] In an alternative analysis submitted by MLA as Attachment B, an additional four-fold adjustment factor was used to account for differences between rat and human dermal absorption. Application of this additional adjustment factor results in a daily dermal uptake dose of 2.4 µg/d (Attachment B).

2. OEHHA Analysis of DINP Exposure to Users from Phifertex® Fabric Used in Outdoor Furniture Products

According to MLA, the DINP content in the PVC coatings used in the Phifertex® fabrics covered by this SUD request ranges from 20% to 25%.

OEHHA conducted a screening level exposure analysis to derive an upper-end estimate of DINP exposure from Phifertex® fabric for users of these outdoor furniture products. OEHHA's upper-end estimate of DINP exposure is 52.1 µg/day (Table 2), assuming a DINP content of 25% in the PVC coating of the fabric.

The potential exposure pathways included in the analysis are:

- Dermal absorption of DINP through direct contact with the Phifertex® fabric.
- Incidental ingestion of DINP via direct and indirect HTM activities.

Inhalation exposure to DINP, a semi-volatile organic compound, from the outdoor furniture products covered by this SUD request is considered to be negligible, as these products are assumed to be used exclusively outdoors under conditions with ample air exchange.

Consistent with MLA, OEHHA chose the chaise lounge as the outdoor furniture product to use in estimating user exposure to DINP. The assumptions made and exposure parameter values applied by OEHHA in this screening level exposure analysis are discussed below. In addition, differences between OEHHA's analysis and that of MLA are noted.

Table 2 summarizes the exposure parameters OEHHA used to estimate DINP exposure from Phifertex® fabric for users of these outdoor furniture products by the dermal absorption and HTM incidental ingestion pathways, and the results of this analysis.

Table 2. Parameters used in and results of the OEHHA analysis of DINP exposures to users from Phifertex® fabric in outdoor furniture products

Parameter	Unit	Value	Basis
Dermal absorption			
A. Absorption rate in rats at 40% DEHP	$\mu g/cm^2$-hr	0.242	Deisinger *et al.* (1998)
B. DEHP/DINP & rat/human absorption adjustment	unitless	40	10X adjustment for DEHP/DINP (EU, 2003) and 4X for human/rat skin (Scott *et al.*, 1987)
C. Absorption rate in humans at 40% [DINP]	$\mu g/cm^2$-hr	0.006	= A / B
D. Adjustment for concentration difference	unitless	0.625	= 25% / 40%
E. Absorption rate in humans at 25% [DINP]	$\mu g/cm^2$-hr	0.00378	= C × D
F. Time spent using chaise lounge	hr/day	2	Assumed to be 50% of time spent outdoor (US EPA, 2011; Table 16-1)
G. Percent of skin surface area in contact with Phifertex® fabric of a chaise lounge	unitless	28%	Age-weighted average, based on OEHHA (2012; warm weather data in Table 6.8)
H. Total body surface area	cm^2	18500	US EPA (2011)
I. Dermal dose	µg/day	39.2	= E × F × G × H
Hand-to-Mouth (HTM) ingestion			
Direct HTM activity			
J. DINP migration over a 4-hour period from a product containing 14.4% DINP	$\mu g/cm^2$	0.028	Tonning *et al*. (2008)[a]
K. Concentration adjustment factor	unitless	1.74	= 25% / 14.4%
L. DINP migration from Phifertex® fabric containing 25% DINP	$\mu g/cm^2$	0.0487	= J × K
M. Direct HTM contact frequency	events/hr	9	OEHHA (2008)
N. Direct HTM contact surface area	cm^2	19	OEHHA (2008)
O. Direct HTM transfer efficiency	unitless	50%	OEHHA (2008, 2011)
P. Direct HTM ingestion dose	µg/day	8.3	= F × L × M × N × O
Indirect HTM activity			
Q. Indirect HTM contact frequency	events/hr	10	OEHHA (2008)
R. Indirect HTM contact surface area	cm^2	19	OEHHA (2008)
S. Indirect HTM transfer efficiency	unitless	25%	OEHHA (2008, 2011)
T. Indirect HTM ingestion dose	µg/day	4.6	= F × L × Q × R × S
U. Total HTM ingestion dose	µg/day	12.9	= P + T
Total exposure by all pathways			
V. Lifetime daily dose	µg/day	52.1	= I + U

[a] The value of 0.028 $\mu g/cm^2$ is derived from the average of two measurements (4.8 µg; 6.6 µg) of the amount of DINP that leached from a 200 cm^2 section of the outer cover of a nursing pillow during a 4-hour incubation in artificial sweat (see page 37 of Tonning *et al*., 2008).

2.1 Dermal Absorption Pathway

The dose of DINP by the dermal absorption pathway is estimated to be 39.2 µg per day (Line I, Table 2). This estimated dermal absorption dose is higher than that estimated by MLA (9.7 µg/day, Line L, Table 1) due to the use of different information and assumptions.

In estimating the DINP dose by the dermal absorption pathway, the following assumptions were made:

1. Dermal exposure to DINP occurs during use of the chaise lounge, when skin comes in direct contact with the Phifertex® fabric.
2. The duration of chaise lounge use is assumed to be equivalent to 50% of the time spent outdoors. The estimated age-weighted average of time spent outdoors is 237 min/day (= 3.95 hr/d) (US EPA, 2011). A value of 2 hours per day is used as a conservative assumption for chaise lounge use to approximate 50% of the total time spent outdoors (Line F, Table 2). It is further assumed that the chaise lounge is used every day.
3. The percent of the total skin surface area in direct contact with Phifertex® fabric when using a chaise lounge was estimated to be 28% (Line G, Table 2). The user is assumed to be wearing shorts and a short-sleeved shirt. Thus, the parts of the body assumed to be in direct contact with Phifertex® fabric when using a chaise lounge are the hands, forearms, lower legs and feet. Age-specific values (i.e., < 2 years old, 2 - 16 years old, and adults) for exposed skin surface areas of these parts of the body under 'warm weather' conditions were obtained from OEHHA (2012) and used to calculate an age-weighted average percent (28%).
4. Total body surface area is from US EPA (2011), 18500 cm^2 (Line H, Table 2).
5. No Phifertex® fabric-specific data were available on the amount of DINP that is transferred from the fabric to the skin as a result of direct contact, or the amount of DINP that is absorbed by human skin. In lieu of such data, OEHHA identified two separate approaches for estimating the amount of DINP that is transferred from Phifertex® fabric to the skin and absorbed by users of these outdoor furniture products. The first approach utilizes data from an *in vivo* DEHP absorption study in rats (Deisinger *et al.*, 1998). The second approach utilizes data from a DINP migration study conducted on a different product (i.e., a nursing pillow) (Tonning *et al.*, 2008). Because of different study designs and methodologies (e.g., *in vivo* absorption vs. migration concentration) employed by Deisinger *et al.* (1998) and Tonning *et al.* (2008), each approach required different assumptions and adjustments in deriving an

estimate of the dermal DINP dose from Phifertex® fabric. To be conservative, we chose to use the approach based on data from Deisinger *et al.* (1998), which resulted in a higher dermal DINP dose estimate.

Assumptions used in estimating the dermal DINP dose from the data of Deisinger *et al.* (1998) are as follows:

Deisinger *et al.* (1998)

i. The *in vivo* absorption of DEHP was assessed in rats. Rats were exposed dermally for 24 hours to PVC film containing 40% DEHP. The average dermal absorption rate of DEHP in rats (from PVC containing 40% DEHP) was reported as 0.242 µg/cm^2-hr (Line A, Table 2). This value is an internal absorption rate for DEHP in rats exposed via the dermal route.

ii. A 10-fold adjustment factor is applied to account for differences in skin absorption between DEHP and DINP in rats (EU, 2003). An additional four-fold adjustment factor is applied to account for differences in phthalate skin permeability between rats and humans (Scott *et al*., 1994). This results in an adjustment factor of 40 (Line B, Table 2) to extrapolate from a DEHP dermal absorption rate in rats based on Deisinger *et al.* (1998) to an estimated DINP dermal absorption rate in humans of 0.006 µg/cm^2-hr (Line C, Table 2).

iii. An adjustment factor of 0.625 (Line D, Table 2) is applied to account for the difference in the percentage of phthalate present in the product, calculated as 25% (DINP in Phifertex® fabric) divided by 40% (DEHP in the PVC film used in the Deisinger *et al.,* 1998 study).

iv. The estimated DINP absorption rate in humans exposed to 25% DINP from Phifertex is 0.00378 µg/cm^2-hr (Line E, Table 2).

For purposes of comparison, an alternative approach to estimating the dermal DINP dose, using the DINP migration data of Tonning *et al*. (2008), is presented below. This alternative approach results in an estimated dermal DINP dose of 0.4 µg/day, which is lower than the dermal dose of 39.2 µg/day estimated using data from the *in vivo* DEHP dermal absorption study in rats by Deisinger *et al*. (1998).

Tonning *et al.* (2008)

Tonning *et al.* (2008) reported data on the amount of DINP that leached from a nursing pillow containing 14.4% DINP by weight during a four-hour incubation at 37ºC into an artificial sweat solution.

Table 2.30 (p. 37) of Tonning *et al.* (2008) reports two measured values for the amount of DINP that migrated from a 200 cm^2 section of the outer cover of a nursing pillow during the 4-hour incubation (e.g., 4.8 and 6.6 µg). In the absence of data on the rate of migration of DINP over multiple time points, OEHHA did not calculate a migration rate based on the data from Tonning *et al.* (2008). Rather, OEHHA took the average of the two measured values, expressed as the amount of DINP that migrated per square centimeter of the nursing pillow (0.028 $\mu g/cm^2$, see for example Line J, Table 2), and assumed this represents the amount of DINP that migrates from an object's surface, when that object contains 14.4% DINP, to the skin.

This DINP migration value was then adjusted to account for the difference in DINP content between the nursing pillow studied by Tonning *et al.* (2008) and that in Phifertex® fabric (= 25% /14.4%= 1.74, see for example Line K, Table 2), assuming linearity between DINP migration and DINP content in the object. The adjusted value is the estimated DINP migration from Phifertex® fabric (0.0487 µg DINP/cm^2, see for example Line L, Table 2).

OEHHA further assumed the daily DINP product-to-skin transfer rate is equivalent to the DINP migration level specified above, i.e., 0.0487 µg DINP/cm^2-day. More specifically, OEHHA conservatively assumed that the amount of DINP that leaches out of Phifertex® fabric from the chaise lounge during the assumed daily 2-hour use period is equivalent to the concentration-adjusted migration level derived from the 4-hour incubation data from Tonning *et al.* (2008).

Since there are no data on the extent to which DINP loaded on human skin is absorbed, we derived a human dermal absorption coefficient based on a study of dermal DINP absorption in rats, adjusted by the ratio of human to rat dermal absorption from studies of DEHP, as summarized below.

- McKee *et al.* (2002) reported that 0.3% to 0.6% of the applied dose of DINP was absorbed over a 24-hour period in dermal absorption studies in male and female F344 rats. We used the upper end of this range (0.6%).

- A study by Scott *et al*. (1987) suggests that human skin is less permeable to phthalates than rat skin. In this study, the authors measured the *in vitro* permeability coefficient of DEHP in abdominal skin from human cadavers and dorsal skin removed from Wistar-derived AL/pk rats. The study reported a four-fold higher dermal permeability coefficient for DEHP in rat skin as compared to human skin. Since the molecular weight of DEHP (390.6 g/mol) is reasonably similar to that of DINP (418.6 g/mol), the DEHP dermal permeability coefficient ratio for humans to rats (0.25) was applied as a surrogate value for the DINP permeability coefficient ratio.
- The human dermal absorption coefficient for DINP is estimated as follows:

  DINP dermal absorption coefficient for humans
  = DINP dermal absorption coefficient for rats x dermal permeability coefficient ratio for humans to rats
  = 0.6% x 0.25
  = 0.15%

Using the DINP migration data of Tonning *et al*. (2008), this alternative approach results in an estimated daily dermal DINP dose of 0.4 µg/day (rounded to the nearest tenth decimal place). This estimate is calculated as the product of the DINP product-to-skin transfer rate (0.0487 µg DINP/cm^2-day), the human dermal absorption coefficient (0.15%), the percent of skin surface area in contact with Phifertex® fabric (28%), and the total body surface area (18500 cm^2).

2.2 HTM Ingestion Pathway

OEHHA estimated the dose of DINP to the users of outdoor Phifertex® products by the HTM ingestion pathway as 12.9 µg per day (Line U, Table 2), higher than that estimated by MLA (0.1 µg/day), due to the use of different exposure parameters. In estimating the DINP dose by the HTM ingestion pathway, the following assumptions were made:

1. Exposure to DINP via HTM contact occurs during use of the chaise lounge.
2. The duration of chaise lounge use is assumed to be equivalent to 50% of the time spent outdoors. The estimated age-weighted average of time spent outdoors is 237 min/day (= 3.95 hr/d) (US EPA, 2011). A value of

2 hours per day is used as a conservative assumption for chaise lounge use to approximate 50% of the total time spent outdoors (Line F, Table 2). It is further assumed that the chaise lounge is used every day.

3. No Phifertex® fabric-specific data were available on the amount of DINP that is transferred from the fabric to the skin as a result of direct contact. Migration data from a study by Tonning *et al.* (2008), which measured the amount of DINP that leached from a nursing pillow containing 14.4% DINP by weight during a four-hour incubation into an artificial sweat solution, were identified as the most relevant data available in the scientific literature for use in estimating DINP HTM exposure from Phifertex® fabric. This measured value, 0.028 µg DINP/cm^2 (Line J, Table 2), was then adjusted to account for the difference in DINP content between the nursing pillow studied by Tonning *et al.* (2008) and Phifertex® fabric (= 25% / 14.4%, Line K, Table 2), assuming linearity between the DINP migration and DINP content in the object. The adjusted value is the estimated DINP migration from Phifertex® fabric (0.0487 µg DINP/cm^2, Line L, Table 2).
4. The amount of DINP loaded on the hands for HTM exposure is assumed to be the same as the migration level derived from Tonning *et al.* (2008), 0.0487 µg/cm^2 (Line L, Table 2). This implicitly assumes that DINP will be re-loaded onto the hands after each HTM contact.
5. HTM activities for consumers in recreational settings may include both direct and indirect (e.g., eating snacks) HTM activities. In the absence of data on HTM activity when using outdoor furniture products such as a chaise lounge, default values of direct and indirect HTM contact frequency and contact surface area from OEHHA (2008) were used.
   i. Direct HTM activities are assumed to involve contact of the fingertips, and the frequency of such contacts is assumed to be 9 contacts per hour (Line M, Table 2). Each direct HTM contact is assumed to involve three fingertips, corresponding to 19 cm^2 of contact surface area (Line N, Table 2).
   ii. Indirect HTM activities (e.g., via food consumption) are assumed to occur with a frequency of 10 contacts per hour (Line Q, Table 2), and involve a contact surface area of the hand of 19 cm^2 (Line R, Table 2). In OEHHA (2008), two scenarios were proposed for indirect HTM contact frequency and surface area: eating small bite-sized foods (e.g., chips) with more frequent contact frequency and smaller hand contact surface area (Scenario 1), and eating large-sized food (e.g., hamburgers) with less contact frequency and larger hand contact surface area (Scenario 2). As shown in

Table 3 below, the calculated indirect HTM exposure (i.e., contact surface area multiplied by contact frequency) is the same for each of these two scenarios. Thus, Table 2 only presents the values from Scenario 1 with a contact frequency of 10/hr and a contact surface area of 19 cm^2 for indirect HTM activities.

Table 3. Comparison of parameters used for men in two scenarios of indirect HTM activities, from OEHHA (2008)

Parameter (unit)	Scenario 1: Bite-sized food	Scenario 2: Large-sized food
Contact surface area of the hand (cm^2)	19	190
Contact frequency (/hr)	10	1

6. In the absence of data on the HTM transfer efficiency of DINP, OEHHA applied the same transfer efficiencies for direct and indirect HTM activities as used in OEHHA (2008; 2011).
   i. For direct HTM activity: OEHHA used a transfer efficiency of 50% (Line O, Table 2). The direct HTM transfer efficiency of 50% was based on empirical data of transfer efficiencies of three pesticides in three volunteers (Camann *et al*., 2000). A recent study (Gorman Ng *et al.*, 2014) reported a hand-to-perioral transfer efficiency of 6.5% for acetic acid. DINP is sticky and may not behave exactly like pesticides or acetic acid. In the absence of DINP-specific transfer efficiency data, OEHHA chose a more conservative estimate of 50% for HTM transfer efficiency.
   ii. For indirect HTM activity: OEHHA used a transfer efficiency of 25% (Line S, Table 2).

2.3 Total Exposure by All Pathways

The total exposure to DINP in Phifertex® fabric for users of outdoor furniture products via all pathways (52.1 µg/day, Table 2, Line V) was calculated as the sum of the daily doses for the dermal absorption (39.2 µg/day) and incidental ingestion (12.9 µg/day) pathways.

2.4 Uncertainties Associated with the Exposure Estimate

There are many uncertainties associated with the exposure estimate for users of these outdoor furniture products due to lack of product-specific information on use patterns and DINP transfer to the skin.

1. There are no direct data providing information on the use patterns (e.g., frequency and duration of use) for outdoor furniture products. OEHHA assumed conservatively that the chaise lounge is used every day and for a duration of two hours per day, as an upper-end estimate. These assumptions could over-estimate DINP exposure for the average user of outdoor furniture.
2. Skin surface area in contact with these outdoor furniture products has not been measured and reported in the literature. OEHHA derived an age-weighted average value of 28% of total body surface area as the assumed skin surface area in contact with Phifertex® fabric. This assumption could under- or over-estimate DINP exposure.
3. One key issue is the lack of product-specific DINP transfer data from Phifertex® fabric to users' skin and subsequent human absorption under specific use scenarios.
    a. The use of data on the internal absorption of another phthalate compound, DEHP, from a 24-hour PVC dermal application study in rats (Deisinger *et al*., 1998) as the basis for the estimate of DINP dermal absorption for the average user of these outdoor furniture products requires a number of assumptions that contribute to uncertainty in the estimate of dermal exposure. In using the internal DEHP absorption rate reported by Deisinger *et al*. (1998), expressed in $\mu g/cm^2$-hr, it is implicitly assumed that the rate of dermal absorption is constant over the 24-hour period. This assumption cannot be validated; however, as absorption was not measured at intermediate time points in this study. It is possible, for example, that more DEHP migrated out of the PVC and onto the skin during the first few hours of the study. Thus, the greater the degree of extrapolation in time from the experimental 24-hour average exposure period of Deisinger *et al*. (1998) to a shorter exposure period (e.g., the 2-hour exposure period assumed for users of outdoor furniture), the greater the uncertainty in the dermal absorption estimate. In addition, a number of adjustment factors to the internal DEHP absorption rate reported by Deisinger *et al*. (1998) were made in order to account for chemical, concentration, and species differences, and

application of each add to the uncertainties in the exposure estimate. These assumptions could result in over- or under-estimates of DINP exposure.

b. The use of DINP migration data from a study that incubated a nursing pillow in artificial sweat for four hours (Tonning *et al.*, 2008) requires a number of assumptions that contribute to uncertainty in the estimate of DINP that is loaded onto the hands and available for transfer to the mouth for the average user of these outdoor furniture products. In the absence of data collected at multiple time points on the rate of migration of DINP from the nursing pillow, OEHHA used the amount of DINP measured after the 4-hour incubation (expressed as micrograms per square centimeter) to represent the amount of DINP that migrates from an object's surface to the skin. This amount was then adjusted in order to account for the difference in DINP content between the object tested in the study and that of Phifertex® fabric. The amount of DINP loaded on the hand is assumed to be equivalent to this adjusted DINP migration value. It was conservatively assumed that this amount of DINP will be re-loaded onto the hand after each HTM contact. These assumptions could result in over- or under-estimates of DINP exposure.

c. There are additional uncertainties in OEHHA's estimates of DINP migration from Phifertex® fabric and DINP dermal absorption for users of outdoor furniture products, since a number of factors can affect the migration of DINP from the PVC-coated fabric, including temperature and the presence of oils, creams, and lotions on the user's skin.

As noted by the European Chemicals Agency (ECHA, 2013), phthalate plasticizers such as DINP can be released from PVC by "volatilisation, extraction to a liquid, or by migration to a solid or semi-solid. The conditions of migration depend on the type of contact, contact duration, temperature, concentration difference, concentration level, simulant properties, molecular weight and structure...Phthalates are highly lipophilic, and therefore fatty simulants, such as olive oil, can produce significant migration in contrast with non-lipophilic media." Tonning *et al.* (2008) notes that the migration of the related phthalate "DEHP was increased [by] a factor of 8 in water based cream and a factor of 1,000 in oil based cream." In the absence of data on the use of skin creams, lotions and oils by users of these outdoor furniture products, OEHHA made no adjustments to the migration data of Tonning *et al*. (2008) to account for the possible use of such creams, lotions, and oils. This contributes to the uncertainty, and may result in an under-estimate of DINP.

4. There are limited data on direct and indirect HTM activity patterns during the use of these outdoor furniture products. OEHHA applied the same direct and indirect HTM frequency and contact surface area values as provided in OEHHA (2008). These assumptions could over- or under-estimate DINP exposure.
5. We used 50% as the direct HTM transfer efficiency for DINP, based on pesticide data, and we used 25% as the indirect HTM transfer efficiency for DINP, based on OEHHA (2008, 2011). These assumptions could under- or over-estimate DINP exposure.

3. Conclusions

OEHHA's screening level analysis, which relied on relatively conservative assumptions, only applies to the exposure scenarios discussed in this document. OEHHA is not drawing a conclusion for other exposure scenarios.

Based on this screening level exposure analysis, an upper-end estimate of DINP exposure from Phifertex® fabric containing up to 25% DINP for users of outdoor furniture products made with this fabric is 52.1 µg/day, which is approximately 36% of the NSRL for DINP of 146 µg/day. The estimated exposure to DINP from Phifertex® fabric for users of these outdoor furniture products corresponds to an excess cancer risk of less than one in 100,000.

Therefore, DINP exposures from Phifertex® fabric for users of outdoor furniture products made with this fabric falls below the level posing significant risk.

References

Camann DE, Majumdar TK, Geno PW (2000). Evaluation of saliva and artificial salivary fluids for removal of pesticide residues from human skin. Southwest Research Institute, San Antonio TX and ManTech Environmental Technology, Inc., Research Triangle Park, NC, for US EPA. National Exposure Research Laboratory, Research Triangle Park, NC. EPA/600/R00/041.

Cherrie JW, Semple S, Christopher Y, Saleem A, Hughson GW, Philips A (2006). How important is inadvertent ingestion of hazardous substances at work? *Ann Occup Hyg* 50(7): 693-704.

Consumer Product Safety Commission (CPSC, 2006). CPSC staff preliminary risk assessment of flame retardant (FR) chemicals in upholstered foam furniture. Washington, DC. December 21, 2006.

Deisinger PJ, Perry LG, Guest D (1998). *In vivo* percutaneous absorption of [14C]DEHP from [14C]DEHP-plasticized polyvinyl chloride film in male Fischer 344 rats. *Food and Chemical Toxicology* 36: 521-527.

ECHA (2013). Evaluation of new scientific evidence concerning DINP and DIDP in relation to entry 52 of Annex XVII to REACH Regulation (EC) No 1907/2006. Final review report. European Chemicals Agency (ECHA) Available at https://echa.europa.eu/documents/10162/31b4067e-de40-4044-93e8-9c9ff1960715.

EU (2003). European Union (EU) Risk Assessment Report (RAR). 1,2-benzenedicarboxylic acid, di-C8-10-branched alkyl esters, C9-rich and di-isononyl phthalate (DINP). 2nd Priority List, Volume 35. France. Final Report, 2003.

Gorman Ng M, van Tongeren M, Semple S (2014). Simulated transfer of liquids and powders from hands and clothing to the mouth. *J of Occupational and Environmental Hygiene* 11: 633-644.

McKee RH, El-Hawari M, Stoltz M, Pallas F, Lington AW (2002). Absorption, disposition and metabolism of DINP in F-344 rats. *J Applied Tox* 22: 293-302.

OEHHA (2008). Office of Environmental Health Hazard Assessment. Proposition 65 Interpretive Guideline No. 2008-001. Guideline for hand-to-mouth transfer of lead through exposure to fishing tackle products. March 2008.

OEHHA (2011). Office of Environmental Health Hazard Assessment. Proposition 65 Interpretive Guideline No. 2011-001. Guideline for Hand-to-Mouth Transfer of Lead through Exposure to Consumer Products. Interpretive Guideline 2011-001. May 2011.

OEHHA (2012). Office of Environmental Health Hazard Assessment. *Air Toxics Hot Spots Program Risk Assessment Guidelines: Technical Support Document for Exposure Assessment and Stochastic Analysis.* August, 2012. Available at http://oehha.ca.gov/media/downloads/crnr/chapter62012.pdf

Scott RC, Dugard PH, Ramsey JD, Rhodes C (1987). *In vitro* absorption of some *o*-phthalate diesters through human and rat skin. *Environmental Health Perspectives* 74: 223-227.

Tonning K, Pedersen E, Lomholt AD, Malmgren-Hansen B, Woin P, Moller L, Bernth N (2008). *Survey, emission and health assessment of chemical substances in baby products.* Danish Technological Institute. Danish Ministry of the Environment.

US EPA (2011). Exposure Factors Handbook. Available at http://www.epa.gov/ncea/efh/pdfs/efh-complete.pdf