

# **Supporting Materials for a Safe Use Determination for Exposure to Residents to Diisononyl Phthalate (DINP) in Vinyl Flooring Products**

**Office of Environmental Health Hazard Assessment  
June 2016**

## **Summary**

This document presents an evaluation of a request from the Resilient Floor Covering Institute (RFCI) for a Safe Use Determination (SUD) for diisononyl phthalate (DINP) in vinyl flooring 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 for residents of homes and other facilities from vinyl flooring was determined based on the available data on DINP air emissions from vinyl flooring, measured dermal exposures to DINP from related materials, indoor air quality models, and several assumptions. OEHHA compared the 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 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 vinyl flooring products corresponds to a calculated excess cancer risk of one in 100,000 for exposures to residents with these vinyl flooring products containing 18.9% DINP by weight installed in their homes. Thus OEHHA determined that exposure of residents to DINP from these vinyl flooring products is at or below the NSRL when the DINP content in the product is 18.9% by weight, or less. A warning for products meeting this DINP concentration limit would not be required for residents in buildings where these products are present.

A number of factors may tend to increase or decrease estimates of exposure relative to the approach used to develop the exposure level described above. We believe, on the whole, that the assumptions made are likely to have resulted in an overestimate of exposure from the average use of vinyl flooring products. This analysis only applies to the exposure scenarios discussed in this document.

This SUD request was limited to exposures to residents to DINP from vinyl flooring products (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 vinyl flooring products were not reviewed by OEHHA in the context of this request.

## 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<sup>1</sup>. On January 2, 2015, OEHHA announced that it had received a request from the Resilient Floor Covering Institute (RFCI) on behalf of its member companies for a Safe Use Determination (SUD) for the use of diisononyl phthalate (DINP) in vinyl flooring products. RFCI is an industry trade association representing resilient flooring manufacturers and suppliers of raw materials, additives and sundry flooring products for the North American market. The request was made by RFCI pursuant to Title 27 of the California Code of Regulations, section 25204(b)(3)<sup>2</sup>.

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 ( $\mu\text{g}/\text{day}$ )<sup>3</sup>.

A public comment period on this SUD request was held from January 2 to February 25, 2015, and a public hearing was held on February 25, 2015. No public comments were received.

The exposure scenarios considered in this document are limited to DINP exposures for residents of homes and other facilities from these vinyl flooring products.

This document first provides a brief description of the vinyl flooring products covered by the SUD request and how they are used, followed by a brief summary of the RFCI exposure analysis of resident exposures to DINP which accompanied the SUD request. OEHHA's analysis of resident exposures to DINP from these vinyl flooring products is then presented.

### 1.1 Product Description

The following information was supplied by the requestor. Vinyl flooring is defined by RFCI as a non-textile flooring material consisting of polyvinyl chloride (PVC), pigments, plasticizers (such as DINP), fillers (e.g., limestone), extenders, and stabilizers to protect against heat and light deterioration. DINP is added intentionally to vinyl flooring materials because it makes the PVC soft and flexible and imparts resiliency and comfort to the flooring products. Vinyl flooring often contains recycled materials, such as older PVC materials that commonly contain DINP or other plasticizers. The recycled content

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<sup>1</sup> 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.

<sup>2</sup> All further references are to sections of Title 27 of the Cal. Code of Regulations.

<sup>3</sup> The NSRL for DINP was adopted April 1, 2016 in Section 25705(b)(1).

of finished vinyl flooring products ranges from 12% to 50%. Vinyl flooring products often last for over 30 years.

Four categories of vinyl flooring products, containing different amounts of DINP, are included in this SUD request by RFCI. Each category of vinyl flooring products may be manufactured by different companies. RFCI describes these categories as follows:

1. Heterogeneous Vinyl Flooring (in sheets): This is typically available in 6- or 12-foot wide rolls, and consists of multiple layers (from bottom to top: backing layer, reinforcement layer, pattern layer, and wear layer/finish<sup>4</sup>). It is manufactured with PVC resin, pigments, plasticizers, fillers, extenders, stabilizers, and backing materials (felt or glass fiber). The total thickness of heterogeneous vinyl flooring ranges from 1.1 to 3.8 millimeters (mm), and the thickness of the wear layer ranges from 0.2 to 0.64 mm. RFCI reports that the DINP content in heterogeneous vinyl flooring varies from 3.5% – 22.0% by weight of the product, with an average DINP content of 21.2%.
2. Homogeneous Vinyl Flooring (in sheets): This is typically available in 6- or 12-foot wide rolls, and consists of a single layer, with a uniform structure and composition from top to bottom, with a clear top layer coating. It is manufactured with PVC resin, pigments, plasticizers, fillers, extenders and stabilizers. The thickness of these products is typically 2 mm. RFCI reports that the DINP content in homogeneous vinyl flooring varies from 14% - 19% by weight of the product, with an average plasticizer content of 15.6%.
3. Vinyl Tile: This is typically available in 1 foot by 1 foot squares and may be constructed as either a single layer (Solid Vinyl Tile) or multiple layers (Luxury Vinyl Tile). The multiple layers of Luxury Vinyl Tile are, from bottom to top: a backing layer, a pattern layer and a wear layer. Vinyl tile is manufactured primarily from limestone with a smaller amount of PVC resin, plasticizers, pigments, stabilizers, and in some cases, fiberglass. The thickness of the products ranges from 2 to 5 mm. The thickness of the wear layer of luxury vinyl tiles ranges between 0.078 to 1 mm. RFCI reports that the DINP content in vinyl tile varies from 6% - 21% by weight of the product, with an average plasticizer content of 7.3%.
4. Vinyl Composition Tile: This is typically available in 1 foot by 1 foot squares consisting of a single layer made primarily from limestone with a smaller amount of PVC, resin, plasticizers, pigments and stabilizers. The thickness of the products ranges between 2.4 to 3.2 mm. RFCI does not report the range of DINP content in vinyl composition tile, but notes that some products have as little as 0.07% DINP. RFCI reports the average plasticizer content as 3.5% by weight of the product.

Some vinyl flooring products may also have a top coating of either urethane or acrylate. RFCI characterizes the urethane and acrylate coatings as impervious to DINP. RFCI

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<sup>4</sup> Some heterogeneous vinyl flooring consists of three layers: backing layer, reinforcement layer, and a combined pattern/wear layer.

suggests these coatings can prevent or greatly reduce DINP migration out of the top surface of vinyl flooring products.

## 1.2 Product Use

Based on information submitted by RFCI, these vinyl flooring products are used in residential (e.g., homes, apartments), commercial (e.g., offices, retail stores, hotels) and institutional (e.g., schools, hospitals) buildings. These products can be installed by both flooring professionals and do-it-yourself consumers.

Vinyl flooring products (in sheets or tiles) account for 12.1% market share of US floor covering sales (Catalina Research, 2013). The reported distribution of end-use applications of resilient flooring sales in the US in 2013 are as follows: residential replacement (48%), educational and institutional (17%), new residential (11%), retail (8%), health care (7%), and offices (6%).

## 1.3 Exposure Analysis for Residents Provided by RFCI

RFCI assessed DINP exposure to residents from these vinyl flooring products and concluded that residents may be exposed to DINP by inhalation, incidental ingestion via hand-to-mouth (HTM) activities, and dermal absorption. RFCI noted that although some vinyl flooring products have a top coating of urethane or acrylate that they characterize as preventing or reducing the release of DINP from the product's top surface, the RFCI exposure assessment assumed that no top coatings were present. No product-specific DINP emission data, surface or hand-wipe data were submitted by RFCI.

RFCI estimated the residents' DINP exposure as 1.1 µg/day. The potential exposure pathways identified in the RFCI analysis for residents are:

- Inhalation of DINP.
- Dermal absorption of DINP through direct contact with vinyl flooring products.
- Incidental ingestion of DINP via hand-to-mouth (HTM) activities.

In estimating residents' inhalation exposure to DINP, RFCI used the emission parameter ( $Y_0$ ) from Liang and Xu (2014) and a box model to estimate the indoor gas-phase DINP concentration. However, RFCI used an incorrect  $Y_0$  value (0.52 µg/cubic meter [ $m^3$ ]), instead of the correct value of 0.42 µg/ $m^3$  from the Liang and Xu (2014) publication.

The age-weighted breathing rate was calculated using values specified in Section 25721(d)(2)(A). The breathing rate was weighted by the time spent indoors at home (US Environmental Protection Agency [US EPA], 2008).

In estimating exposure by the dermal absorption pathway, RFCI assumed that vinyl flooring products are only installed in the bathroom, kitchen and dining room in the residence. RFCI assumed that dermal exposure of residents to DINP from these vinyl flooring materials was limited to time spent in these three room types. For the duration

of dermal absorption, RFCI used US EPA (2008) estimates of time spent in these room types, which are available for subjects younger than 21 years old. For subjects older than 21 years old, RFCI assumed a total of 30 minutes per day is spent in these three room types.

To estimate residents' exposed skin area, RFCI used age-specific skin surface areas for the trunk, arms, hands, legs and feet based on US EPA (2008). However, the RFCI submission, including the spreadsheets used in the analysis, does not clearly describe how these age-specific estimates of exposed skin area were made (e.g., the fractions of particular body parts assumed to contact the vinyl flooring for a given age group). The age-weighted dermal contact surface area was adjusted by the age-specific estimates of time spent in the three room types assumed to have vinyl flooring.

In estimating exposure by the HTM incidental ingestion pathway, the age-specific estimates of time spent in the three room types described above were used as estimates of age-specific HTM activity duration. RFCI used HTM contact frequency values for subjects younger than 11 years old from US EPA (2011). For subjects older than 11 years old, RFCI assumed the HTM contact frequency is 2 contacts per hour. The age-weighted HTM contact frequency was adjusted by the age-specific estimates of time spent in the three room types assumed to have vinyl flooring.

Table 1 lists the exposure factors used in the RFCI analysis for estimating DINP exposure to residents by each of these pathways, and the adjustment factor RFCI used to account for absences from the residence (e.g., vacation) (92% = 48/52 weeks; Line K, Table 1) to derive the adjusted lifetime average daily dose to residents of 1.1  $\mu\text{g}$  DINP.

**Table 1. Summary of RFCI evaluation of resident exposure to DINP from vinyl flooring products**

Exposure Factor	Unit	Value	Basis
<b>Inhalation</b>			
A. DINP concentration in the air	µg/m <sup>3</sup>	0.085	Estimated by a box model using Y <sub>0</sub> from Liang and Xu (2014) <sup>a</sup>
B. Breathing rate	m <sup>3</sup> /day	11.9	Age-weighted inhalation rate from Section 25721(d)(2)(A) weighted by time spent indoors at home (US EPA, 2008)
C. Inhalation dose	µg/day	1.01	= A × B
<b>Dermal absorption</b>			
D. DINP product-to-hand transfer rate	µg/cm <sup>2</sup> -hr	0.007	Tonning <i>et al.</i> (2008)
E. Dermal absorption coefficient	unitless	1.72%	Deisinger <i>et al.</i> (1998); Elsisi <i>et al.</i> (1989)
F. Dermal absorption dose	µg/day	0.15	= D × E × (age-weighted contact surface and duration in three room types) (US EPA, 2008)
<b>Hand-to-Mouth (HTM) ingestion</b>			
G. HTM contact surface area	cm <sup>2</sup>	19	OEHHA (2008)
H. Transfer efficiency	unitless	6.5%	Gorman Ng <i>et al.</i> (2014)
I. DINP ingestion dose	µg/day	0.025	= D × G × H × (age-weighted HTM frequency and contact surface in three room types) (US EPA, 2008 & 2011)
<b>Total uptake by all pathways</b>			
J. Daily dose from all exposure pathways	µg/day	1.19	= C + F + I
K. Lifetime averaging adjustment factor	unitless	92%	= 48 wk/ 52 wk (RFCI assumption)
L. Lifetime average daily dose	µg/day	1.1	= J × K

<sup>a</sup> RFCI used an incorrect Y<sub>0</sub> value of 0.52 µg/m<sup>3</sup>. Using the correct Y<sub>0</sub> value (0.42 µg/m<sup>3</sup>, Liang and Xu, 2014) would raise the DINP air concentration to 0.101 and the lifetime average daily dose to 1.27 µg/day.

## 2. OEHHA Analysis of DINP Exposure to Residents from Vinyl Flooring Products

According to RFCI, the DINP content in the four vinyl flooring product categories covered by this request ranges from less than 1% to 22% by weight, while the average DINP content in one category, heterogeneous vinyl flooring, is 21.2%.

OEHHA conducted a screening-level exposure analysis to derive an upper-end estimate of DINP exposure to residents of homes, and occupants of offices, and other facilities that have vinyl flooring products. For purposes of this SUD, OEHHA is using the term “residents” to also cover occupants of offices and other facilities that may be exposed to

these products. OEHHA's upper-end estimate of DINP exposure to residents is 154.5 µg/day (Table 2), assuming a DINP content of 20% by weight in vinyl flooring products.

The potential exposure pathways for residents included in the analysis are:

- Inhalation of DINP in the air.
- Dermal absorption of DINP via dust-to-dermal and air-to-dermal absorption (direct contact with vinyl flooring products is considered negligible relative to dust-to-dermal absorption).
- Incidental ingestion of DINP via incidental ingestion of dust.

The models used, 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 RFCI are noted.

OEHHA evaluated the lifetime daily DINP exposure for residents in homes with vinyl flooring products. DINP, an SVOC, is commonly found in gas and condensed phases, redistributing from the emission source to indoor air and interior surfaces, including airborne particles, dust and skin. DINP will release from the vinyl flooring products over time. Over the typical use duration of these vinyl flooring products, DINP is released from the product and sorbed onto airborne-particles and dust, and onto other indoor surfaces. Thus residents' exposure to DINP occurs following emission from the source into air and subsequent migration into different media and re-emission/desorption from these media as indoor conditions (e.g., temperature) change (Xu and Zhang, 2011).

Residents' exposure to DINP was estimated using the screening model proposed by Little *et al.* (2012), which includes inhalation of DINP in the gas phase, inhalation of DINP sorbed to airborne particles, dermal sorption of DINP from the air and dust, and ingestion of DINP sorbed to dust. Table 2 summarizes the exposure parameters OEHHA used to estimate DINP exposures by the inhalation, dermal absorption, and incidental ingestion pathways and the results of OEHHA's exposure assessment for residents. Age-adjusted exposure parameters were calculated based on age-specific values specified in Section 25721(d)(2)(A) (inhalation rate), the OEHHA Air Toxics Exposure Assessment Guidelines (2012) (body surface area), and the US EPA Exposure Factors Handbook (2011) (time spent indoors, dust adherence to skin, dust ingestion rate). Table 3 shows the calculation of indoor air gas-phase DINP concentration that is used to calculate the inhalation, dermal, and incidental ingestion doses (Table 2).

**Table 2. Parameters used in and results of the OEHHA analysis of DINP exposures for residents of homes with vinyl flooring products containing 20% DINP**

Parameter	Units	Value	Basis
<b>Inhalation</b>			
A. Airborne gas-phase concentration	$\mu\text{g}/\text{m}^3$	0.207	See Table 3, Line M
B. Particle-air partition coefficient	$\text{m}^3/\mu\text{g}$	0.023	Weschler and Nazaroff (2010); Liang and Xu (2014)
C. Total suspended particles	$\mu\text{g}/\text{m}^3$	20	Little <i>et al.</i> (2012)
D. Airborne particle-phase concentration	$\mu\text{g}/\text{m}^3$	0.095	= A x B x C
E. Total DINP air concentration	$\mu\text{g}/\text{m}^3$	0.302	= A + D
F. Breathing rate	$\text{m}^3/\text{day}$	19	Age-weighted value calculated based on age-specific values in Section 25721(d)(2)(A)
G. Time spent indoors	unitless	82.4%	US EPA (2011; Table 16-1)
H. DINP inhalation dose	$\mu\text{g}/\text{day}$	4.7	= E x F x G
<b>Dermal absorption</b>			
I. Dermal contact surface	$\text{m}^2$	0.44	= 25% of total body surface (age-weighted value calculated based on OEHHA, 2012; Table 6.4)
J. Mass of dust adhered to skin	$\text{g}/\text{m}^2\text{-day}$	7.1	US EPA (2011, Table 7-23)
K. Human dermal absorption coefficient	unitless	0.15%	McKee <i>et al.</i> (2002); Scott <i>et al.</i> (1987)
L. Skin permeability coefficient	$\mu\text{g}/\text{m}^2\text{-hr}/(\mu\text{g}/\text{m}^3)$	1.12	Weschler and Nazaroff (2012); Liang and Xu (2014)
M. Dermal intake from dust	$\mu\text{g}/\text{day}$	16	= I x J x K x Q
N. Dermal intake from gas	$\mu\text{g}/\text{day}$	2	= A x G x I x L x 24 h/d
O. Dermal absorption dose	$\mu\text{g}/\text{day}$	18	= M + N
<b>Incidental ingestion</b>			
P. Dust-air partition coefficient	$\text{m}^3/\mu\text{g}$	0.0165	Liang and Xu (2014); Weschler and Nazaroff (2010)
Q. DINP in dust	$\mu\text{g}/\text{g}$	3415.5	= A x P x $10^6$ $\mu\text{g}/\text{g}$
R. Dust ingestion rate	$\text{g}/\text{day}$	0.03857	Age-weighted value calculated based on US EPA (2011; Table 5-1)
S. DINP ingestion dose	$\mu\text{g}/\text{day}$	131.7	= Q x R
<b>Total exposure by all pathways</b>			
T. Lifetime daily dose	$\mu\text{g}/\text{day}$	154.5	= H + O + S



## 2.1 Inhalation Pathway

The inhalation dose for residents with vinyl flooring products containing 20% DINP installed in their home is estimated to be 4.7 µg/day (Line H, Table 2). This inhalation dose is higher than that estimated by RFCI (1.01 µg/day) due to the higher DINP air concentration modeled by OEHHA. OEHHA's inhalation dose estimate for residents is based on the following assumptions:

1. OEHHA assumed that 50% of the indoor floor area is covered with vinyl flooring materials (Table 3, Line I).
2. OEHHA used the Liang and Xu (2014) chamber study to estimate the gas-phase DINP concentration emitted from vinyl flooring materials (details in Table 3 and Appendix A). The authors reported a DINP emission parameter ( $Y_0$ ) of 0.42 µg/m<sup>3</sup>, based on emissions from a single PVC tile containing 20% DINP. The gas-phase DINP concentration, 0.207 µg/m<sup>3</sup> (Table 2, Line A; Table 3, Line M) is calculated from the parameters listed in Table 3 (see Appendix A for details of the indoor air quality models and calculations).
3. The concentration of DINP in airborne-particles (Table 2, Line D) was calculated from the gas-phase DINP concentration by multiplying the total suspended particle concentration (TSP; Table 2, Line C) and the particle-air partition coefficient (Table 2, Line B). This partition coefficient (0.023 m<sup>3</sup>/µg) is estimated from the octanol-air partition coefficient ( $K_{oa}$ , Weschler and Nazaroff, 2010) and adjusted by particle size distribution (Liang and Xu, 2014) (See Appendix A).
4. The age-weighted breathing rate, 19 m<sup>3</sup>/d (Line F, Table 2), is calculated based on the age-specific values listed in Section 25721(d)(2)(A).
5. Time activity data were obtained from US EPA (2011; Table 16-1) for total time spent indoors. An age-weighted average of time spent indoors of 82.4% (Line G, Table 2) is used for the inhalation dose calculation.

**Table 3. OEHHA's calculation of indoor gas-phase DINP concentration**

Parameter	Unit	Value	Basis
A. Emission parameter	µg/m <sup>3</sup>	0.42	Liang and Xu (2014)
B. Convective mass-transfer coefficient	m/s	0.00047	= 1.7 m/h conversion; Liang and Xu (2014)
C. Convective mass-transfer coefficient near sorption surface	m/s	0.000096	Liang and Xu (2014)
D. Sorption surface partition coefficient	m	2100	Liang and Xu (2014)
E Particle-air partition coefficient	m <sup>3</sup> /µg	0.023	Weschler and Nazaroff (2010); Liang and Xu (2014) (See text)
F. Floor surface area	m <sup>2</sup>	279	3000 ft <sup>2</sup> , assumed
G. Room height	m	2.59	8.5 ft, standard ceiling height
H. Room volume	m <sup>3</sup>	723	= F × G
I. Fraction covered with vinyl flooring materials	unitless	50%	Assumed
J. Air changes per hour	/hr	0.23	CDPH EHLB (2010) default
K. Ventilation rate	m <sup>3</sup> /s	0.046	= H × J × (1/3600 h/s)
L. Total suspended particles	µg/m <sup>3</sup>	20	Little <i>et al.</i> (2012)
M. Gas-phase DINP concentration	µg/m <sup>3</sup>	0.207	= (A × B × F × I) / [B × F × I + (1 + E × L) × K]

## 2.2 Dermal Absorption Pathway

The dose of DINP to residents by the dermal absorption pathway is estimated to be 18 µg/day (Table 2, Line O) via dermal contact with DINP-containing dust and direct air-to-dermal absorption (Weschler and Nazaroff, 2012). Dermal exposure from direct dermal contact with vinyl flooring (approximately 0.04 µg/day) is considered negligible relative to dust-to-dermal absorption (16 µg/day). The estimated dermal absorption dose of 18 µg/day is higher than that estimated by RFCI (0.15 µg/day; Line F, Table 1) due to the use of different information to estimate the amount of DINP dermal loading. RFCI did not include direct air-to-dermal exposure or dermal exposure via dust, which is considerably higher than dermal exposure by direct contact with the vinyl flooring product.

The dermal dose from dust (Table 2, Line M) is estimated as the product of dermal dust loading, contact surface area, the DINP concentration in the dust, and the human dermal absorption coefficient. The dermal dose from gas-phase DINP (Table 2, Line N) is the product of the exposed skin surface area, gas-phase concentration, and the dermal permeability coefficient, adjusted by time spent indoors.

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

1. Skin contact surface area is  $0.44 \text{ m}^2$ , about one-fourth of the age-weighted body surface area calculated from age-specific values presented in OEHHA (2012) (Table 2, Line I).
2. Dermal dust loading is  $7.1 \text{ g/m}^2\text{-day}$  (Table 2, Line J; US EPA, 2011).
3. Since there are no DINP-specific absorption data for human skin, OEHHA's absorption estimate is based on dermal DINP absorption in rats, adjusted by the ratio of human to rat dermal absorption from studies of di-(2-ethylhexyl) phthalate (DEHP), as summarized below.
  - i. 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%).
  - ii. 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.
  - iii. 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
    - =  $0.6\% \times 0.25$
    - =  $0.15\%$  (Table 2, Line K)
  - iv. The requester used a higher dermal absorption coefficient of  $1.72\%$  (Table 1, Line E).
4. The skin permeability coefficient for direct air-to-dermal absorption is  $1.12 \text{ } \mu\text{g/m}^2\text{-hr}/(\text{ } \mu\text{g/m}^3)$  (Table 2, Line L), based on the model proposed by Weschler and Nazaroff (2012), as calculated by Liang and Xu (2014).
5. The DINP concentration in dust is calculated as the product of the dust-air partition coefficient and the gas-phase concentration (Table 2, Line Q; see Section 2.3 for details).

### 2.3 Incidental Ingestion Pathway

Residents' DINP intake from incidental ingestion is estimated to be  $131.7 \text{ } \mu\text{g}$  per day (Table 2, Line S). This ingestion dose is higher than that estimated by RFCI ( $0.025 \text{ } \mu\text{g/day}$ ), and is due to the use of different assumptions and models. While RFCI used assumptions regarding HTM activity to estimate residents' intake via the ingestion pathway, OEHHA estimated intake as the product of the gas-phase DINP concentration, the dust-air partition coefficient, and the daily dust ingestion rate.

In estimating the DINP dose by the incidental ingestion pathway for residents, the following assumptions were made:

1. The gas-phase concentration (Line A, Table 2) calculation is the same as presented in Section 2.1 above for the inhalation calculations.
2. Calculation of the concentration of DINP in airborne particles (Line D, Table 2) is the same as presented in Section 2.1 above for the inhalation calculations.
3. The concentration of DINP in dust (Table 2, Line Q) is calculated from the gas-phase DINP concentration using the dust-air partition coefficient (Table 2, Line P). The dust-air partition coefficient is estimated as  $0.0165 \text{ m}^3/\mu\text{g}$ , using the octanol-air partition coefficient (Weschler and Nazaroff, 2010) adjusted by the particle size distribution (Liang and Xu, 2014) (See Appendix A).
4. OEHHA calculated an age-weighted dust ingestion rate of  $0.03857 \text{ g/d}$  (Table 2, Line R) based on age-specific values reported in the US EPA Exposure Factors Handbook (US EPA, 2011; Table 5-1). According to US EPA (2011), this rate accounts for ingestion of indoor settled dust only.

## **2.4 Total Exposure by All Pathways to Residents**

The total lifetime exposure to DINP via all pathways for residents of homes with vinyl flooring products containing 20% DINP by weight was  $154.5 \mu\text{g/day}$  (Line T in Table 2), and was calculated as the sum of the inhalation, dermal absorption (via direct air-to-dermal and dust absorption), and incidental ingestion pathways. This estimate exceeds the NSRL for DINP of  $146 \mu\text{g/day}$ . Assuming that the relationship between total DINP exposure for residents and DINP content in the vinyl flooring products is linear, the maximum allowable DINP concentration in the vinyl flooring products to reach a daily intake of  $146 \mu\text{g/day}$  for residents is 18.9% ( $146/154.5 \times 20\% = 18.9\%$ ).

## **2.5 Uncertainties Associated with Residents' Exposure Estimate**

There are many uncertainties associated with the indoor air quality (IAQ) models and parameter inputs used in the exposure assessment for residents. DINP is an SVOC that is difficult to measure, which makes it a challenge to develop and validate IAQ models for this chemical. For the same reason, many of the IAQ model parameters, such as the partition coefficients, are not well characterized for DINP.

Because SVOCs are released from sources at a slow rate and because of their propensity to sorb onto materials, SVOCs can persist indoors for years after they are introduced. Parallels can be drawn between indoor persistent SVOCs and outdoor persistent organic pollutants (Weschler and Nazaroff, 2008). Even if the SVOC source is removed, SVOC will persist indoors for weeks or years because all indoor surfaces have become coated with SVOC (LBNL IAQ Resources Bank). Though we do not have good quantification of the DINP emission from vinyl flooring materials, we do know from studies on other SVOCs that over time DINP is likely to slowly release from the floor materials which, more often than not, will be present in residents' homes for decades.

Once DINP is released from the vinyl flooring material, it will be sorbed onto indoor surfaces, airborne particles, and dust.

There are only two published studies reporting the emission parameter  $Y_0$  for DINP, Liang and Xu (2014) and Liang *et al.* (2015). OEHHA used the  $Y_0$  for DINP reported by Liang and Xu (2014) which is based on data from PVC tile containing 20% DINP. Liang *et al.* (2015) used the same chamber design as Liang and Xu (2014), and reported  $Y_0$  for DINP at different temperatures.  $Y_0$  for DINP was found to increase 10-fold (0.42 to 4.31  $\mu\text{g}/\text{m}^3$ ) when the chamber temperature increased from 25°C to 36°C. 36°C is not a comfortable indoor temperature; however, 30°C (= 86°F) is likely in California, especially in homes without air conditioning during the summer months. The study by Liang *et al.* (2015) indicates that  $Y_0$  for DINP will increase with higher temperature, but the degree of increase with temperature is unknown. A change in  $Y_0$  will result in a similar change in all DINP dose estimates for residents. The absence of product-specific emission factors ( $Y_0$ ) for DINP under common usage conditions adds to the uncertainty in the exposure assessment for residents.

Other parameters used in the IAQ models are estimated using chemical properties of DINP, such as the octanol-air partition coefficient, but validation of these estimated parameter values can be difficult. For example, the vapor pressure of DINP reported in the literature from empirical experiments varies two orders of magnitude ( $10^{-5}$  to  $10^{-7}$  pascal) (Liang and Xu, 2014). This demonstrates a challenge in SVOC research, namely that more robust data on basic parameters used in IAQ models are needed to better quantify SVOC emissions and human exposure.

The IAQ model proposed by Little *et al.* (2012) was originally developed to obtain screening-level estimates of potential indoor exposure to prioritize different SVOCs using chemical-specific properties and common IAQ parameters. We do not know whether the model overestimates or underestimates actual human exposure to DINP. The modelled DINP air and dust concentrations we predicted in homes with vinyl flooring products are within the range of the limited published DINP data (Table 4), although those published levels were from all emission sources, and not limited to a particular flooring source.

**Table 4. Comparison of predicted DINP concentrations by OEHHA and published data**

Airborne concentration ( $\mu\text{g}/\text{m}^3$ )	Dust concentration (ppm; reported as $\mu\text{g}/\text{g}$ or $\text{mg}/\text{kg}$ )	Source
0.207	3415.5	Predicted (see Table 2)
0.025 - 0.763	30 - 7091	Fromme <i>et al.</i> (2013)
<MDL - 0.192	10 - 1200	Kanazawa <i>et al.</i> (2010)
0.0005 - 1.293	11.3 - 674	Wormuth <i>et al.</i> (2006)

\*MDL: method detection limit

Among the different exposure pathways for residents, intake from the incidental ingestion of dust is highest (131.7 µg; about 85% of total intake), followed by dermal absorption (18 µg) and inhalation (4.7 µg). This is due, in part, to the higher predicted concentration of DINP in dust, as compared to the airborne gas-phase. Findings of published studies on DINP (Wormuth *et al.*, 2006) and other phthalates (Tran and Kannan, 2015; Guo and Kannan, 2011) also indicate that DINP/phthalate concentrations in dust are higher than airborne concentrations. High molecular weight phthalates such as DEHP and DINP are used in floor and wall coverings and are found in house dust at high concentrations (Wormuth *et al.*, 2006; Fromme *et al.*, 2013). For example, measured DINP concentrations in indoor air in German daycare centers were in the range of 25 to 763 ng/m<sup>3</sup>, and the DINP dust levels range from 30 to 7091 ppm (Fromme *et al.*, 2013). Dust may serve as a reservoir for DINP exposure, similar to the results found for other SVOCs such as flame retardants. Incidental ingestion of DINP from dust is not included in the RFCI exposure assessment for residents.

### **3. Conclusions**

This screening level analysis for residents, which relied on relatively conservative assumptions, only applies to the exposure scenarios discussed in this document. OEHHA is not drawing conclusions for other exposure scenarios.

Based on this screening level exposure analysis for residents with vinyl flooring products containing 20% DINP by weight installed in their homes, an upper-end estimate of DINP exposures is 154.5 µg/day, exceeding the NSRL for DINP of 146 µg/day. Limiting the DINP content of the vinyl flooring products to 18.9% by weight would reduce the residents' daily dose to 146 µg/day, assuming a linear relationship between the DINP content in the vinyl flooring products and residents' total DINP intake.

Therefore, OEHHA must restrict the safe use determination for residents living in homes with vinyl flooring products installed to vinyl flooring products containing 18.9% DINP by weight, or less.

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## Appendix A. Details of Indoor Air Quality Models

We provide the detailed calculations for values presented in Tables 2 and 3, namely DINP concentrations in the airborne gas-phase, the airborne particle-phase, and dust. These values are derived from the chamber study data by Liang and Xu (2014). The DINP emission parameter  $Y_0$  obtained from this chamber study is the basis for the estimate of the DINP airborne gaseous concentration ( $Y_{\text{gas}}$ ), airborne particle concentration ( $Y_{\text{part}}$ ), and dust concentration ( $Y_{\text{dust}}$ ) in indoor settings.

Parameters used to estimate the  $Y_{\text{gas}}$  and  $Y_{\text{part}} / Y_{\text{dust}}$  are discussed below in three sections. Section 1 describes how to estimate  $Y_0$  from the chamber results (Liang and Xu, 2014). Section 2 details the estimation of  $Y_{\text{gas}}$  in the residence using the  $Y_0$  data from Liang and Xu (2014). Section 3 shows how  $Y_{\text{gas}}$  is used to obtain the specific values for  $Y_{\text{part}}$  and  $Y_{\text{dust}}$ . The OEHHA DINP exposure analysis for residents that have the specific vinyl flooring materials installed in their indoor environments is estimated using all three modeled values ( $Y_{\text{gas}}$ ,  $Y_{\text{part}}$ , and  $Y_{\text{dust}}$ ).

### 1. Chamber data by Liang and Xu (2014): $Y_0$ (the thin-film gas phase concentration of DINP in equilibrium with the material phase)

A novel chamber study design was reported by Liang and Xu (2014) to shorten the time needed to reach equilibrium from months to a few days by maximizing the emission area and minimizing the sorption area in the specially designed stainless steel chamber. One tested polyvinyl chloride (PVC) flooring sample included in this study contained 20% DINP.  $Y_0$  (the thin-film gas phase concentration of DINP in equilibrium with the material phase) was calculated for this sample using Eq. A-1 based on the chamber settings ( $Q$  and  $A$ ), the measured  $Y_{\text{ss}}$  (steady-state DINP concentration in the chamber;  $0.255 \mu\text{g}/\text{m}^3$ ) and the calculated  $h_m$  (the convective mass transfer coefficient, estimated from diffusivity and molecular weight using dimethyl phthalate as the reference chemical).  $Y_0$  was calculated from this chamber study for the PVC flooring sample containing 20% DINP as  $0.42 \mu\text{g}/\text{m}^3$  at  $25^\circ\text{C}$ .

$$Y_0 = (Y_{\text{ss}} \times Q) / (h_m \times A) + Y_{\text{ss}} \quad (\text{Eq. A-1})$$

$Y_0$ : The thin-layer gas-phase concentration of DINP in equilibrium with the material phase in the chamber ( $\mu\text{g}/\text{m}^3$ )

$Q$ : Volume of the chamber ( $\text{m}^3$ )

$A$ : Surface area of emission ( $\text{m}^2$ )

$Y_{\text{ss}}$ : Steady-state concentration in the chamber (measured, in  $\mu\text{g}/\text{m}^3$ )

$h_m$ : The convective mass transfer coefficient in the chamber (unit:  $\text{m}/\text{s}$  are converted to  $\text{m}/\text{h}$  for calculation), estimated from air diffusivity that is approximated by the chemical molecular weight using dimethyl phthalate as the reference chemical

The theory behind Eq. A-1 is a mechanistic mass-transfer model developed by Xu and Little (2006) for semi-volatile organic compounds (SVOCs). Due to the low vapor pressure of SVOCs, emission from the product is primarily subject to “external control,” including equilibrium between the product surface and gas-phase SVOC concentration immediately adjacent to the product surface, convective mass transfer through the boundary layer into the bulk air, and sorption to interior surfaces.  $Y_0$  can only be estimated in a chamber that reaches steady-state.  $Y_0$  remains constant for a given product at the same temperature, and is the basis to estimate the corresponding airborne- and dust-concentrations of the SVOC from a specific product.

## 2. Estimation of indoor airborne gaseous concentration ( $Y_{\text{gas}}$ ) using $Y_0$

A screening IAQ model was proposed by Little *et al.* (2012) to estimate the indoor gaseous concentration of SVOCs (and further estimate potential occupants' SVOC exposures) from the emissions of SVOCs that are present in materials and products as additives, based on  $Y_0$  and other indoor parameters. The exposure estimates depend strongly on the steady state gas-phase concentration of the SVOC that can be predicted from  $Y_0$  by Eq. A-2.

$$Y_{\text{gas}} = (h_m \times Y_0 \times A) / [h_m \times A + (1 + K_{\text{part}} \times \text{TSP}) \times V] \quad (\text{Eq. A-2})$$

$Y_{\text{gas}}$ : Airborne gas-phase DINP concentration ( $\mu\text{g}/\text{m}^3$ )

$h_m$ : Convective mass transfer coefficient indoors (m/s); this indoor  $h_m$  is different from the  $h_m$  in the chamber setting

$Y_0$ : The thin-film gas phase concentration of DINP in equilibrium with the material phase ( $\mu\text{g}/\text{m}^3$ ); calculated from the chamber result at steady state

A: Surface area of flooring containing DINP ( $\text{m}^2$ )

$K_{\text{part}}$ : Particle-air partition coefficient ( $\text{m}^3/\mu\text{g}$ )

TSP: Total suspended particles ( $\mu\text{g}/\text{m}^3$ )

V: Ventilation rate ( $\text{m}^3/\text{hr}$ ; conversion to  $\text{m}^3/\text{s}$  by multiplying 3600 (hr/s))

The most reasonable value of the key parameters that affect DINP intake was used to estimate the corresponding DINP concentration by Eq. A-2 as indoor conditions vary from home to home. Each of these key parameters is discussed briefly below.

- Ventilation rate (V) = air changes per hour (ACH/hr)  $\times$  home volume ( $\text{m}^3$ )

Air changes per hour (ACH) data for homes were compiled from various sources (Table A-1). To be conservative, OEHHA chose the default ACH of 0.23/hr used by the California Department of Public Health (CDPH) Environmental Health Laboratory Branch (EHLB) to calculate  $Y_{\text{gas}}$ .

**Table A-1. Air change rates per hour (ACH) in homes**

Data source	Mean	Minimum	Median	10 <sup>th</sup> percentile
ARB (2009) 24-hr data	0.48	0.09	0.26	
ARB (2009) 2-wk data	0.45	0.11	0.24	
US EPA (2011)	0.45			0.18
CDPH EHLB (2010) default	<b>0.23</b>			

- TSP (total suspended particles)

The concentration of indoor particles depends on the indoor sources and conditions (e.g., cleaning practices, floor types - carpet versus vinyl flooring) in the home. Lower concentrations of TSP will result in higher DINP  $Y_{\text{gas}}$  and  $Y_{\text{dust}}$  concentrations (but lower  $Y_{\text{part}}$ ), and subsequently a higher total DINP intake. OEHHA chose the TSP value of 20  $\mu\text{g}/\text{m}^3$ , which is the average TSP used by Little *et al.* (2012), to calculate  $Y_{\text{gas}}$ .

### 3. Estimation of DINP concentration in airborne-particles ( $Y_{\text{part}}$ ) and dust ( $Y_{\text{dust}}$ )

Concentrations of DINP in airborne-particles and dust can be calculated from  $Y_{\text{gas}}$  and the partition coefficients between particle-air ( $K_{\text{part}}$ ) and dust-air ( $K_{\text{dust}}$ ) (Eq. A-3; Eq. A-5).  $K_{\text{part}}$  (particle-air partition coefficient) and  $K_{\text{dust}}$  (dust-air partition coefficient) are estimated from  $K_{\text{oa}}$  (octanol-air partition coefficient) using equations A-4 and A-6 below (Weschler and Nazaroff, 2010).

$$Y_{\text{part}} \text{ (in } \mu\text{g/g)} = K_{\text{part}} \times Y_{\text{gas}} \times 10^6 \text{ (}\mu\text{g/g)} \quad \text{(Eq. A-3)}$$

$$K_{\text{part}} = f_{\text{om part}} \times K_{\text{oa}} / D_{\text{part}} \quad \text{(Eq. A-4)}$$

$$Y_{\text{dust}} \text{ (in } \mu\text{g/g)} = K_{\text{dust}} \times Y_{\text{gas}} \times 10^6 \text{ (}\mu\text{g/g)} \quad \text{(Eq. A-5)}$$

$$K_{\text{dust}} = f_{\text{om dust}} \times K_{\text{oa}} / D_{\text{dust}} \quad \text{(Eq. A-6)}$$

$f_{\text{om part}}$ : volume fraction of organic matter associated with airborne particles; 0.4; unitless

$D_{\text{part}}$ : density of airborne particles ( $10^6 \text{ g}/\text{m}^3 = 1 \text{ g}/\text{cm}^3$ )

$f_{\text{om dust}}$ : volume fraction of organic matter associated with settled dust; 0.2; unitless

$D_{\text{dust}}$ : density of settled dust ( $2 \times 10^6 \text{ g}/\text{m}^3$ )

$K_{\text{oa}}$ : octanol-air partition coefficient ( $1.07 \times 10^{11}$ ; unitless; estimated as no authoritative experimental value is available; Liang and Xu, 2014)

$K_{\text{part}}$  and  $K_{\text{dust}}$  can be adjusted by an assumed particle size distribution (Xu, personal communication, 2015). Unadjusted and adjusted  $K_{\text{part}}/K_{\text{dust}}$  values are listed in Table A-2. OEHHA selected the latter, since particle size is an important factor determining human exposure. In theory, these partition coefficients could also be estimated using the vapor pressure of DINP, but the empirical data of the extremely low vapor pressure for DINP is very limited.

**Table A-2.  $K_{\text{part}}$  and  $K_{\text{dust}}$  estimated by different approaches (Liang and Xu, 2014)**

<b>Partition coefficients (in <math>\text{m}^3/\mu\text{g}</math>)</b>	<b>Estimated by <math>K_{\text{oa}}</math></b>	<b>Estimated by <math>K_{\text{oa}}</math> and particle size distribution</b>
$K_{\text{part}}$	0.0429	<b>0.023</b>
$K_{\text{dust}}$	0.0107	<b>0.0165</b>