

Supporting Materials for a Safe Use Determination for Exposure to Professional Installers to Diisononyl Phthalate (DINP) in Vinyl Flooring Products

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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. This SUD pertains specifically to DINP exposures to professional vinyl flooring installers¹.

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 professional installers of vinyl flooring was determined based on measured dermal exposures to DINP from related materials, and several assumptions. OEHHA compared the upper-end estimate of DINP exposure for professional installers 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 professional installers as a result of installing vinyl flooring products, when these products contain 8.7% DINP by weight. Thus OEHHA determined that exposure of professional installers to DINP is at or below the NSRL where DINP content in the vinyl flooring product is 8.7% by weight, or less. A warning would not be required for workers (i.e., professional installers) for products meeting this DINP concentration limit.

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 installation of vinyl flooring products. This analysis only applies to the exposure scenarios discussed in this document.

This SUD request was limited to exposures to professional installers 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 installation or use of these vinyl flooring products were not reviewed by OEHHA in the context of this request.

¹ The results of a separate evaluation of a SUD request for DINP exposure from vinyl flooring products to residents of homes and other facilities was published earlier this year, on June 24, 2016 (OEHHA, 2016).

1. Introduction

The California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) is the lead agency for the implementation of Proposition 65². 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)³.

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 ($\mu\text{g}/\text{day}$)⁴.

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 to professional installers from these vinyl flooring products. Earlier this year OEHHA evaluated DINP exposure scenarios specific to residents of homes and other facilities from the use of vinyl flooring products (see OEHHA, 2016⁵).

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 professional installer exposures to DINP which accompanied the SUD request. OEHHA's analysis of professional installer 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

² 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.

³ All further references are to sections of Title 27 of the Cal. Code of Regulations.

⁴ The NSRL for DINP was adopted April 1, 2016 in Section 25705(b)(1).

⁵ <http://oehha.ca.gov/proposition-65/crn/issuance-safe-use-determination-exposure-residents-diisononyl-phthalate-vinyl>

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 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/finish⁶). 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.

⁶ Some heterogeneous vinyl flooring consists of three layers: backing layer, reinforcement layer, and a combined pattern/wear layer.

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

1.2 Product Use

According to 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 Professional Installers Provided by RFCI

RFCI assessed DINP exposure to professional installers from these vinyl flooring products and concluded that professional installers 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 DINP exposure during installation of vinyl flooring products and concluded that the expected exposure of a professional installer to DINP is 0.03 µg/day. The potential exposure pathways identified in the RFCI analysis for professional installers 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 installers' 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.

For estimation of exposure via the dermal and HTM incidental ingestion pathways, RFCI applied a product-to-hand transfer rate of 0.007 µg/ cm^2 -hr (Line D, Table 1), citing a study by Topping *et al.* (2008). Topping *et al.* (2008) reported that an average of 0.028 µg DINP/square centimeter [cm^2] leached from a nursing pillow containing 14.4% DINP

by weight during a four-hour incubation in an artificial sweat solution. RFCI assumed that DINP migrated from the nursing pillow at a constant rate of 0.007 $\mu\text{g}/\text{cm}^2\text{-hr}$ and used this rate as an estimate of the product-to-hand transfer rate for both the dermal absorption and the HTM incidental ingestion pathways.

Table 1 lists the exposure factors used in the RFCI analysis for estimating DINP exposure to professional installers by each of these pathways, and the adjustment factors RFCI used to derive the adjusted lifetime average daily dose of 0.03 μg DINP.

Table 1. Summary of RFCI evaluation of professional installer exposure to DINP during installation of vinyl flooring products

Exposure Factor	Unit	Value	Basis
Inhalation			
A. DINP air concentration	$\mu\text{g}/\text{m}^3$	0.085	Box model using an emission parameter (Y_0) from Liang and Xu (2014) ^a
B. Breathing rate	m^3/day	5	= 4 hours/day \times 1.25 m^3/hr
C. Daily inhalation dose	$\mu\text{g}/\text{day}$	0.425	= A \times B
Dermal absorption			
D. Product-to-hand transfer rate	$\mu\text{g}/\text{cm}^2\text{-hr}$	0.007	Tonning <i>et al.</i> (2008)
E. Contact surface area	cm^2	420	Palmar surface of the hands; OEHHA (2008)
F. Dermal absorption coefficient	Unitless	1.72%	Deisinger <i>et al.</i> (1998); Elsisi <i>et al.</i> (1989)
G. Contact duration	hr/d	4	Assumed by RFCI
H. Daily dermal uptake dose	$\mu\text{g}/\text{day}$	0.2	= D \times E \times F \times G
Hand-to-Mouth (HTM) ingestion			
I. HTM contact surface area	cm^2	19	Three fingertips; OEHHA (2008)
J. Transfer efficiency	Unitless	6.5%	Gorman Ng <i>et al.</i> (2014)
K. HTM activity frequency	event/hr	6.3	Gorman Ng <i>et al.</i> (2016), average for all workers
L. HTM activity duration	hr/d	4	Assumed by RFCI
M. Daily Ingestion dose	$\mu\text{g}/\text{day}$	0.2	= D \times I \times J \times K \times L \times (100% - 1.72%) ^b
Total uptake by all pathways			
N. Daily dose from all exposure pathways	$\mu\text{g}/\text{day}$	0.845	= C + H + M
O. Lifetime averaging adjustment factor	unitless	23.5%	= 5 day/7 day \times 48 wk/52 wk \times 25 yr/70 yr
P. Lifetime average daily dose	$\mu\text{g}/\text{day}$	0.2	= N \times O
Q. Market share	unitless	15%	Catalina Research (2013)
R. Adjusted lifetime average daily dose	$\mu\text{g}/\text{day}$	0.03	= P \times Q

^a RFCI used an incorrect Y_0 value of 0.52 $\mu\text{g}/\text{m}^3$. Using the correct Y_0 value of 0.42 $\mu\text{g}/\text{m}^3$ (Liang and Xu, 2014) would raise the DINP air concentration to 0.101 $\mu\text{g}/\text{m}^3$ and the adjusted lifetime average daily dose to 0.033 $\mu\text{g}/\text{day}$.

^b The ingestion dose is adjusted by deducting 1.72% of dose via dermal absorption (Line F)

2. OEHHA Analysis of DINP Exposure to Professional Installers 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 professional installers. OEHHA's upper-end estimate of DINP exposure to professional installers is 151 µg/day (Table 2), assuming a DINP content of 9% by weight in vinyl flooring products.

The potential exposure pathways for professional installers included in the analysis are:

- Dermal absorption of DINP via direct contact with vinyl flooring products.
- Incidental ingestion of DINP via HTM activities.

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.

Inhalation of DINP by professional installers during floor installation is considered to be negligible because the degree to which DINP, a semi-volatile organic compound, will volatilize from vinyl flooring products over the course of a few days is expected to be minimal. The slow rate of DINP volatilization from the new flooring products is not expected to result in significant air concentrations of DINP during the installation period.

Table 2 summarizes the exposure parameters OEHHA used to estimate DINP exposures to professional vinyl flooring installers by the dermal absorption and HTM incidental ingestion pathways, the adjustment factor used to derive the lifetime average daily dose of DINP, and the results of this analysis.

Table 2. Parameters used in and results of the OEHHA analysis of DINP exposures during installation of vinyl flooring products containing 9% DINP

Parameter	Unit	Value	Basis
Dermal absorption			
A. Hand (palmar surface) DINP loading	µg/day	278	= (139 µg/hand) x (two hands), maximum, measured @ 45 tiles, NRF (2014)
B. Human dermal absorption coefficient	unitless	0.15%	McKee <i>et al.</i> (2002); Scott <i>et al.</i> (1987) (see below)
C. Dermal dose	µg/day	0.4	= A x B
Hand-to-Mouth (HTM) ingestion			
D. HTM fingertip DINP loading	µg/event	51.9	Calculated by OEHHA based on wipe data from NRF, see text
E. HTM transfer efficiency	unitless	50%	OEHHA (2008)
F. HTM contact frequency	events/hr	2.28	Calculated by OEHHA based on Gorman Ng <i>et al.</i> (2016), see text
G. HTM activity duration	hr/day	6.5	Assumed by OEHHA
H. HTM ingestion dose	µg/day	384.6	= D x E x F x G
Total exposure by all pathways			
I. Total daily dose (all pathways)	µg/day	385	= C + H
J. Lifetime averaging factor	unitless	39.2%	= 5 day/7 day x 50 wk/52 wk x 40 yr/70 yr ^a
K. Lifetime average daily dose	µg/day	151	= I x J

^a Section 25721(d)(3) provides a number of assumptions to be used in calculating the reasonably anticipated rate of exposure to carcinogens in the workplace, unless more specific and scientifically appropriate data are available. These include assumptions that workers breathe 10 m³ of air per 8-hour work day, and that the exposure duration for a worker is 50 weeks per year for 40 years.

2.1 Dermal Absorption Pathway

Installers are exposed to DINP via direct dermal contact with the vinyl flooring products. Dermal dose is the product of dermal loading and dermal absorption. Dermal dose for professional installers is estimated to be 0.4 µg per working day (Line C, Table 2). This dermal absorption dose is more than that estimated by RFCI (0.2 µg/day), due primarily to the use of different information to estimate the amount of DINP that is loaded on the installer's hands.

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

1. Dermal exposure of the professional installer to DINP occurs only during the time spent handling the vinyl flooring materials.
2. Dermal exposure is limited to the palmar surface of both hands (data on DINP loading on other parts of the body during vinyl flooring installation are not available).

3. Due to lack of product-specific data, hand wipe data generated from handling a different product, namely Tandus Centiva ER3® modular vinyl carpet tiles (NRF, 2014), were used to estimate the amount of DINP that is loaded onto the hands of vinyl flooring installers. These data consist of wipe samples of the palmar surface of the hand collected from two volunteers after simulated installation of the vinyl carpet tiles. The maximum amount of DINP reported from the palmar surface of a single hand (139 µg/hand) was used to estimate the vinyl flooring installer's dermal dose from two DINP-loaded hands (278 µg; Table 2, Line A).
 - i. OEHHA assumed that for a given DINP content in the flooring material (percent of DINP by weight), the amount of DINP loaded on the hands during simulated installation of vinyl carpet tiles containing DINP in the secondary backing layer is the same as the amount of DINP that will be loaded on the hands of professional vinyl flooring installers. We also assumed that the relationship between the amount transferred to the hands and fingers of an installer and the DINP content of the flooring material is linear across a fairly broad range of DINP concentrations in the flooring material. The vinyl carpet tiles contained 9% DINP in the secondary backing layer; the DINP content of vinyl flooring products, which are the subject of this SUD, ranges from <1% to 22% by weight.
4. Since there are no data regarding DINP absorption by 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:
$$\begin{aligned} &\text{DINP dermal absorption coefficient for humans} \\ &= \text{DINP dermal absorption coefficient for rats} \times \text{dermal permeability} \\ &\quad \text{coefficient ratio for humans to rats} \\ &= 0.6\% \times 0.25 \\ &= 0.15\% \text{ (Table 2, Line B)} \end{aligned}$$
 - iv. RFCI used a higher dermal absorption coefficient, 1.72% (Table 1, Line F).

2.2 HTM Ingestion Pathway

OEHHA estimated the dose of DINP to the professional installer by the HTM ingestion pathway as 384.6 µg per working day (Line H, Table 2), higher than that estimated by RFCI (0.2 µg/d; Line M, Table 1), due to selection of different exposure parameters.

In estimating the DINP dose by the HTM ingestion pathway, the following assumptions were made:

1. All direct HTM contact for professional installers is assumed to occur during the portion of the workday when the installer is handling the new vinyl flooring products, and involves contact of the fingertips with the perioral area. Each contact with the perioral area is assumed to involve three fingertips. It is judged unlikely for professional installers to have direct contact of the fingertips in the mouth (i.e., hand-to-oral contact) when working.
2. Indirect HTM exposure (e.g., via food consumption) is not estimated due to data limitations. We assume implicitly that professional installers wash their hands before eating and at the end of the work day, completely removing DINP from the hands/fingertips.
3. Due to the lack of product-specific data, five-fingertip wipe data generated from handling a different product, Tandus Centiva ER3® modular vinyl carpet tiles (NRF, 2014), were used to estimate the amount of DINP that is loaded onto the fingertips of vinyl flooring installers⁷. These data consist of five-fingertip wipe samples collected from two volunteers after simulated installation of the vinyl carpet tiles. The maximum amount of DINP reported from a five-fingertip wipe sample (86.5 µg) was adjusted by assuming that DINP loading on three fingertips is related to HTM exposure. The fingertip loading used for HTM exposure for professional installers is 51.9 µg (= 86.5 µg × 3/5; Table 2, Line D).
 - i. The carpet tiles used in the simulated installation scenario from which the five-fingertip wipe data was generated contained 9% DINP by weight in the secondary backing layer.
4. In the absence of data on the HTM transfer efficiency of DINP, OEHHA applied the same direct HTM transfer efficiency of 50% (Table 2, Line E) used in OEHHA (2008), based on empirical data of transfer efficiencies of three pesticides (technical mixtures of chlorpyrifos, pyrethrin I, and piperonyl butoxide) in three volunteers (Camann *et al.*, 2000). RFCI based the hand-to-perioral transfer efficiency estimate on Gorman Ng *et al.* (2014), which reported a hand-to-perioral transfer efficiency of 6.5% for acetic acid. DINP is a sticky substance and may not behave exactly like the three pesticides studied by Camann *et al.* (2000) or acetic acid. In the absence of DINP-specific transfer efficiency data, OEHHA chose a more conservative estimate of 50% for HTM transfer efficiency.

⁷ See Section 2.1.1 for additional assumptions made in using data from subjects handling vinyl carpet tiles to estimate exposure to the specific vinyl flooring materials that are the subject of this exposure analysis.

5. In the absence of data on the frequency of HTM activity by professional installers of vinyl flooring, data on HTM activity frequency from a study in workers by Gorman Ng *et al.* (2016) were used. OEHHA selected the average HTM activity frequency (which included hand-to-oral and hand-to-perioral contacts) reported for all industrial workers, 7.6 events per hour. RFCI used 6.3/hr, the mean number of direct HTM contacts for all workers in the study, including all 59 observations from both the industrial and research sectors (Gorman Ng *et al.*, 2016). We chose the higher value reported for all industrial workers, to be conservative. Gorman Ng *et al.* (2016) defined the perioral area as “the lips and the area within 2 cm of the lips.” In the absence of information on the fraction of hand-to-perioral contacts that involve the lips, OEHHA applied a factor of 0.3 (based on the estimated ratio of the surface area of the lips to the entire perioral region) to estimate the "hand-to-lip" frequency. This frequency was used in the calculation of HTM intake. The adjusted hand-to-lip contact frequency is 2.28 events per hour ($= 7.6 \times 0.3$; Table 2, Line F).
6. OEHHA used 6.5 hours per work day as the HTM activity duration (Table 2, Line G), which is longer than the 4 hours assumed by RFCI. Six and a half hours is a more reasonable and conservative estimate of the time spent working with flooring materials per 8-hr workday for full-time installers, after deducting for preparation time and breaks.

2.3 Total Exposure by All Pathways to Professional Installers

The total exposure to DINP via all pathways for installers of vinyl flooring products containing 9% DINP by weight ($151 \mu\text{g}/\text{day}$; Table 2, Line K) was calculated as the product of the sum of the daily doses for the two exposure routes ($385 \mu\text{g}/\text{day}$, Table 2, Line I) and the lifetime adjustment factor appropriate for the worker scenario (39.2%, Table 2, Line J). The lifetime average adjustment factor was calculated as: $5/7 \text{ days} \times 50/52 \text{ weeks} \times 40/70 \text{ years} = 39.2\%$.

The lifetime average adjustment factor is consistent with Section 25721(d)(3), which provides a number of assumptions to be used in calculating the reasonably anticipated rate of exposure to carcinogens in the workplace, unless more specific and scientifically appropriate data are available. These include assumptions that the exposure duration for a worker is 50 weeks per year for 40 years.

As discussed above, the estimated DINP intake for professional installers of vinyl flooring products was calculated using hand (palmar surface) and fingertip wipe data collected from volunteers handling a different product, namely vinyl carpet tiles containing 9% DINP in the backing layer. The estimated total intake of DINP via all pathways for vinyl flooring installers is $151 \mu\text{g}/\text{day}$, exceeding the NSRL for DINP of $146 \mu\text{g}/\text{day}$. Assuming that the relationship between total DINP exposure for vinyl flooring installers 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 $146 \mu\text{g}/\text{day}$ for professional installers is 8.7% ($= 146/151 \times 9\%$).

2.4 Uncertainties Associated with Professional Installers' Exposure Estimate

1. The HTM pathway dominates installers' exposure. A number of factors contribute to uncertainty in the estimate of exposure via the HTM pathway.
 - i. The HTM intake estimate is only for direct hand-to-mouth contact, i.e., not including indirect hand-to-mouth contact (e.g., via food consumption or smoking with contaminated hands) due to data limitations. This could underestimate DINP exposure.
 - ii. Five-fingertip wipe data:
 - Because we did not have fingertip wipe data for vinyl flooring products, we used data generated from handling a different product, vinyl carpet tiles.
 - Five-fingertip wipe samples were collected in a limited number of subjects (n = 2) handling vinyl carpet tiles.
 - Intra- and inter-individual variability was apparent from the wipe sample data.
 - Actual installers' contact with vinyl flooring products (in sheets or tiles; homogeneous and heterogeneous compositions) may differ from that of the two volunteer subjects handling vinyl carpet tiles.Thus, use of the vinyl carpet tile wipe sample data could under- or over-estimate DINP exposure from vinyl flooring products.
 - iii. We used 50% as the HTM transfer efficiency for DINP, based on pesticide data and assumed that only three fingertips were in contact with the mouth or perioral area, based on the best scientific judgement as no empirical data are available for professional installers. This could under- or over-estimate DINP exposure.
 - iv. We did not adjust for higher HTM contact frequency evident in the data from Gorman Ng *et al.* (2016) for smokers and for between-task periods because to do so would require additional assumptions. This could underestimate DINP exposure.
2. Regarding the dermal exposure pathway:
 - i. Dermal dose estimates include only the palmar surface of the hands, ignoring other body parts due to data limitations. This could underestimate DINP exposure.
 - ii. Because we did not have hand wipe data for vinyl flooring products we used data generated from handling a different product, vinyl carpet tiles, in a limited number of subjects (n = 2). Intra- and inter-individual variability was apparent from the wipe sample data, and actual installers' contact with vinyl flooring products (in sheets or tiles; homogeneous and heterogeneous compositions) may differ from that of the two volunteer subjects handling vinyl carpet tiles. This could under- or over-estimate DINP exposure.
3. Additional potential exposure pathways not evaluated in this analysis include worker exposure to contaminated clothing after work and exposure during removal of the old flooring materials if it contains DINP. This could underestimate DINP exposure.

4. RFCI adjusted workers' DINP exposure according to their 15% market share of vinyl flooring products. OEHHA conservatively assumed that professional installers work full-time installing the vinyl flooring materials. This could overestimate DINP exposure if workers also install vinyl flooring materials that do not contain DINP.
5. OEHHA conservatively assumed that professional installers work for 40 years⁸; workers may install vinyl flooring products for less than 40 years. This could overestimate DINP exposure for workers with less than 40 working years.

3. Conclusions

This screening level analysis for professional installers, 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 professional flooring installers, an upper-end estimate of DINP exposures during the installation of vinyl flooring products containing 9% DINP is 151 µg/day, exceeding the No Significant Risk Level (NSRL) for DINP of 146 µg/day. Limiting the DINP content of the vinyl flooring products to 8.7% by weight would reduce the installer's daily dose to 146 µg/day, assuming a linear relationship between the DINP content in vinyl flooring products and installers' total DINP intake.

Therefore, OEHHA must restrict the safe use determination for professional vinyl flooring installers to vinyl flooring products containing 8.7% DINP by weight, or less.

⁸ Section 25721(d)(3)

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 U.S. EPA. National Exposure Research Laboratory, Research Triangle Park, NC. EPA/600/R00/041.
- 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 Chem Toxicol* 36: 521-527.
- Elsisi A, Carter DE, Sipes IG (1989). Dermal Absorption of Phthalate Diesters in Rats. *Fundam Appl Toxicol* 12: 70-77.
- Gorman Ng M, van Tongeren M, Semple S (2014). Simulated transfer of liquids and powders from hands and clothing to the mouth. *J Occup Environ Hyg* 11: 633-644.
- Gorman Ng M, Davis A, van Tongeren M, Cowie H, Semple S (2016). Inadvertent ingestion exposure: hand- and object-to-mouth behavior among workers. *J Expo Sci Environ Epidemiol* 26: 9-16.
- Liang Y and Xu Y (2014). Improved method for measuring and characterizing phthalate emissions from building materials and its application to exposure assessment. *Environ Sci Technol* 48: 4475–4484.
- McKee RH, El-Hawari M, Stoltz M, Pallas F, Lington AW (2002). Absorption, disposition and metabolism of DINP in F-344 rats. *J Appl Toxicol* 22: 293-302.
- NRF (2014). Safe use determination application for DINP in Tandus Centiva ER3® modular vinyl carpet tiles, submitted by Fulbright and Jaworski LLP, Norton Rose Fulbright (NRF) US LLP.
- 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 (2016). Office of Environmental Health Hazard Assessment. Supporting Materials for a Safe Use Determination for Exposure to Residents to Diisononyl Phthalate (DINP) in Vinyl Flooring Products. Available at <http://oehha.ca.gov/media/downloads/cnr/sud1supportingmaterials06212016.pdf>
- Scott RC, Dugard PH, Ramsey JD, Rhodes C (1987). *In vitro* absorption of some *o*-phthalate diesters through human and rat skin. *Environ Health Perspect* 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.