

# Supporting Materials for a Safe Use Determination for Diisononyl Phthalate (DINP) in Certain Single-ply Polyvinyl Chloride Roofing Membrane Products

Office of Environmental Health Hazard Assessment  
CORRECTED<sup>1</sup> ON JULY 1, 2016

## 1. Introduction

The Office of Environmental Health Hazard Assessment (OEHHA) is the lead agency for the implementation of Proposition 65<sup>2</sup>. On April 17, 2015, OEHHA announced that it had received a request from the Chemical Fabrics & Film Association, Inc. (CFFA) for a Safe Use Determination (SUD) for the use of diisononyl phthalate (DINP) in certain polyvinyl chloride (PVC) roofing membrane products. CFFA is an international trade association representing manufacturers of polymer-based fabric and film products used in the building and construction, automotive, fashion and other industries. The request was made by CFFA pursuant to Title 27 of the California Code of Regulations, section 25204(b)(3)<sup>3</sup>.

Based on the analysis discussed in this document, the estimated exposure to DINP as a result of installation by roofing professionals of single-ply (SP) PVC roofing membrane products with a nominal finished thickness of between 1.016

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<sup>1</sup> OEHHA has recently become aware of the need to correct some of the information used in OEHHA's analysis supporting the Safe Use Determination (SUD) published on December 4, 2015. This correction to OEHHA's analysis supporting the SUD does not change OEHHA's determination regarding the issuance of the SUD. The information that OEHHA is correcting is the content of DINP in the secondary backing layer of carpet tiles used to generate data on hand and fingertip loading of DINP after handling these materials. Specifically, the correct DINP content in the secondary backing layer of the carpet tiles is 9 percent. This information is used in OEHHA's analysis for this SUD to estimate DINP exposures via the dermal absorption and incidental ingestion pathways. Use of the corrected information results in an increase in the upper-end estimate of estimate of DINP exposures to professional roof installers during the installation of the specified SP PVC roofing membrane products from 83 to 109 micrograms ( $\mu\text{g}$ ) per day. This corrected estimate of exposure is approximately 75 percent of the No Significant Risk Level (NSRL) for DINP of 146  $\mu\text{g}/\text{day}$ , and corresponds to an excess cancer risk of less than one in 100,000.

<sup>2</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>3</sup> All further references are to sections of Title 27 of the Cal. Code of Regulations.

to 2.438 mm, containing no more than 15 percent DINP and heated to surface temperatures up to and including 210°C during installation, corresponds to an excess cancer risk of less than one in 100,000. Therefore, no warning is required under Proposition 65 for these specific exposures. OEHHA made this determination by conducting a screening level exposure analysis to derive an upper-end estimate of DINP exposures to professional roof installers, and comparing it to estimates of exposure associated with a one in 100,000 excess cancer risk. As discussed in detail below, this analysis only applies to the exposure scenarios discussed in this document.

This SUD request was limited to exposures to DINP in SP PVC roofing membrane products with a nominal finished thickness of between 1.016 to 2.438 millimeters (mm) (40 to 96 mils). OEHHA determined the SUD request complete for these SP PVC roofing membrane products that are heated to surface temperatures up to and including 210°C during installation. Exposures to other listed substances, if any, that may result from such installation and use of these SP PVC roofing membrane products were not reviewed by OEHHA in the context of this request.

A public comment period on this SUD request was held from April 17 to May 19, 2015, and a public hearing was held on May 19, 2015. No public comments were received.

Based on information provided in the SUD request, OEHHA has identified the DINP exposures for analysis to be those to individuals participating in the installation of these PVC roofing products. According to the information provided in the SUD request, these PVC roofing products are installed only by roofing professionals. The exposure potential for building occupants is considered negligible. Thus, OEHHA's analysis is specific to exposures to professional installers of these roofing materials, and is based on information provided in the SUD request and additional information identified in the scientific literature.

This document first provides a brief description of SP PVC roofing membrane products and how they are used and installed, followed by a brief summary of the CFFA exposure analysis of professional installer exposures to DINP which accompanied the SUD request. OEHHA's analysis of professional roofing installer exposures to DINP from these SP PVC roofing membrane products is then presented.

## 1.1 Product Description

The requester described the roofing membrane products as:

“Single-ply (SP) thermoplastic or thermoset membranes of compounded synthetic materials manufactured in a factory for use in roofing. A SP PVC roofing membrane consists of two layers of PVC materials with a reinforcement material such as polyester between the layers. The top layer has special additives to make the membrane UV stable, plasticizers to make it flexible, and pigments for color. The bottom layer is typically darker, containing less pigment by weight, but otherwise containing a similar mix of plasticizers, stabilizers, fillers, and fire retardant additives. DINP is intentionally added to the top and bottom layers at a maximum concentration of 15% of the total product by weight.”

PVC resin and plasticizers together account for 77% of the total mass of the roofing membrane. The PVC roofing products are configured in long rolls up to 10-feet wide.

## 1.2 Product Use and Installation

These SP PVC roofing membrane products are installed on top of vapor barriers or insulation materials, and are often installed with fasteners or adhesives. In the case of green roofs, these PVC roofing products can be loosely laid beneath vegetated covers and pavers. The PVC roofing products subject to this SUD request are designed for both low-slope and steep-slope residential and commercial roofing applications.

During installation, these SP PVC roofing membrane products are welded together with hot air. Based on information provided in the SUD request, the welded seams are 1 to 1.5 inches wide, and the surface temperature of the membranes is 210°C or less during installation (Van de Ven and Erdman, 2007). DINP in the SP PVC roofing membrane vaporizes and escapes during this welding process.

## 1.3 Exposure Analysis Provided by CFFA

CFFA assessed DINP exposure from these SP PVC roofing membrane products and concluded that the expected exposure of a professional installer to DINP is 0.11 – 0.83 µg/day. The potential exposure pathways identified in the CFFA analysis for professional installers are:

- Inhalation of DINP in outdoor air
- Dermal absorption of DINP through direct contact with the PVC roofing materials
- Incidental ingestion of DINP via hand-to-mouth (HTM) activities.

CFFA used a plume model to estimate the air concentration of DINP that the professional installer is exposed to during roof membrane welding. Their initial and final estimates are summarized in Table 1. In their initial submission, CFFA assumed the membrane welding seams were 3.5 cm wide, and the heated area was 22.6814 cm<sup>2</sup>. The heated area generated a DINP plume that was assumed to be 1 meter (m) high by 1 m wide. The plume's other dimension was defined by the wind speed (2.125 m/sec). The estimated concentration of DINP in the plume was 42.7 µg/m<sup>3</sup>. CFFA assumed that the worker's location relative to the plume was random, so the fraction of time the worker would be in the plume was estimated as the width of the plume divided by the circumference of a circle of diameter 3 m surrounding the welding point (i.e., 0.106). This model and set of assumptions results in a time-weighted average DINP air concentration for workers of 4.53 µg/m<sup>3</sup>. A later submission assumed a higher wind speed (use of the average of harmonic means instead of the minimum harmonic mean of wind speed) and a lower emission factor to arrive at a time-weighted average DINP air concentration of 0.61 µg/m<sup>3</sup>.

**Table 1. CFFA air concentration estimate using a plume model**

Parameter	Value	Unit	Basis
A. Wind speed	2.125 <sup>a</sup> (3.22)	m/s	Minimum 8AM -5PM wind
B. Emission factor	4 <sup>a</sup> (0.815)	µg/s/cm <sup>2</sup>	CFFA Excel file
C. Heated area	22.6814	cm <sup>2</sup>	CFFA Excel file
D. Emission rate	90.7256 <sup>a</sup> (18.5)	µg/s	= B × C
E. Plume x-sectional area	1	m <sup>2</sup>	Plume is 1 m x 1 m
F. Dilution volume	2.125 <sup>a</sup> (3.22)	m <sup>3</sup> /s	= A × E
G. Concentration in plume	42.69 <sup>a</sup> (5.75)	µg/m <sup>3</sup>	= D/F
H. Fraction in plume	0.106	unitless	see text
I. Average air concentration	4.53 <sup>a</sup> (0.61)	µg/m <sup>3</sup>	= G × H

<sup>a</sup> The first value is from the initial CFFA submission; the second value in the parenthesis is from the final CFFA submission.

In estimating the dermal loading of DINP on the hands of the professional installer as a result of handling the SP PVC roofing membrane product during installation, CFFA applied a product-to-hand transfer rate of  $0.007 \mu\text{g}/\text{cm}^2/\text{hr}$ , citing Topping *et al.* (2008) (Table 2). These authors reported an average of  $0.028 \mu\text{g}/\text{cm}^2$  as the amount of DINP that leached from a nursing pillow (containing 14.4% DINP by weight) during a four-hour incubation in an artificial sweat solution. It appears that CFFA assumed that DINP migrated from the nursing pillow at a constant rate of  $0.007 \mu\text{g}/\text{cm}^2/\text{hr}$  for the four-hour period in the Topping *et al.* (2008) studies, and applied the same migration rate for DINP in SP PVC roofing membrane products. This DINP migration rate was used as a surrogate for the product-to-hand transfer rate, and was used in the CFFA analysis to estimate both the dermal absorption and the incidental ingestion of DINP (Table 2).

Table 2 below lists the exposure factors used in the CFFA analysis for estimating exposures by each of these pathways, and the adjustment factors initially employed in the CFFA analysis to derive the adjusted lifetime average daily dose of  $0.83 \mu\text{g}$  DINP per day. As noted above, the DINP air concentration was later changed from  $4.53$  to  $0.61 \mu\text{g}/\text{m}^3$ , lowering the estimated daily dose from  $0.83$  to  $0.11 \mu\text{g}/\text{day}$ .

**Table 2. Summary of CFFA evaluation of professional installer exposure to DINP during installation of SP PVC roofing membrane products**

Exposure Factor	Unit	Value	Basis
Inhalation			
A. DINP air concentration	µg/m <sup>3</sup>	4.53 <sup>a</sup> (0.61)	see Table 1 above
B. Breathing rate	m <sup>3</sup> /day	5	4 hours/day x 1.25 m <sup>3</sup> /hour
C. Daily inhalation dose	µg/day	22.65 <sup>a</sup> (3.1)	= A x B
Dermal absorption			
D. Product-to-hand transfer rate	µg/cm <sup>2</sup> /hr	0.007	Tonning <i>et al.</i> (2008)
E. Surface area (palmar surface of two hands)	cm <sup>2</sup>	420	US EPA (2011)
F. Contact duration	hr/day	0.67	CFFA's assumed contact duration of roofing material
G. Dermal absorption coefficient	Unitless	1.72%	Table 2 in Deisinger <i>et al.</i> (1998); Elsisi <i>et al.</i> (1989)
H. Daily Dermal uptake dose	µg/day	0.03	= D x E x F x G
Hand-to-Mouth (HTM) ingestion			
I. Transfer efficiency	Unitless	6.5%	Gorman Ng <i>et al.</i> (2014a)
J. Surface area (three finger tips)	cm <sup>2</sup>	19	OEHHA (2008)
K. HTM activity frequency	events/hr	6.3	Gorman Ng <i>et al.</i> (2014b)
L. HTM activity duration	hr/day	1	Gorman Ng <i>et al.</i> (2014b)
M. Daily ingestion dose	µg/day	0.05	= D x I x J x K x L
Total uptake by all pathways			
N. Daily dose from all exposure pathways	µg/day	22.7 <sup>a</sup> (3.18)	= C + H + M
O. Lifetime averaging adjustment factor	Unitless	0.19	4 day/7 day x 48 wk/52 wk x 25 yr/70 yr
P. Lifetime average daily dose	µg/day	4.3	= N x O
Q. Market share	Unitless	19.3%	SPRI (2013-2014) <sup>b</sup>
R. Adjusted lifetime average daily dose	µg/day	0.83 <sup>a</sup> (0.11)	= P x Q

<sup>a</sup> The first value is from the initial CFFA submission; the second value in the parenthesis is from the final CFFA submission.

<sup>b</sup> Data from Single Ply Roofing Industry (SPRI, 2013-2014)

## **2. OEHHA analysis of DINP exposures from SP PVC roofing membrane products**

OEHHA conducted a screening level exposure analysis to derive an upper-end estimate of DINP exposures to professional roof installers during the installation of SP PVC roofing membrane products of 109 µg/day. The potential exposure pathways for professional roof installers included in the analysis are:

- Inhalation of DINP in outdoor air
- Dermal absorption of DINP through direct contact with the PVC roofing materials
- Incidental ingestion of DINP via hand-to-mouth (HTM) activities.

Table 3 summarizes the exposure factors OEHHA used to estimate DINP exposures by the inhalation, dermal and incidental ingestion pathways, and the adjustment factors used to derive the lifetime average daily dose of DINP.

**Table 3. Parameters used in the OEHHA analysis of DINP exposures during installation of SP PVC roofing membrane products**

Parameter	Unit	Value	Basis
Inhalation			
A. DINP concentration in the air	µg/m <sup>3</sup>	33.5	See Table 4
B. Breathing rate	m <sup>3</sup> /day	5	1.25 m <sup>3</sup> /hr x 4 hours welding daily
C. Inhalation dose	µg/day	167.5	= A x B
Dermal absorption			
D. Hand DINP loading	µg/day	463	Calculated by OEHHA, see below
E. Human dermal absorption coefficient	Unitless	0.15%	Scott <i>et al.</i> (1987), McKee <i>et al.</i> (2002), see below
F. Dermal dose	µg/day	0.7	= D x E
Hand-to-Mouth (HTM) ingestion			
G. HTM fingertip DINP loading	µg/event	26	Calculated by OEHHA see below
H. HTM transfer efficiency	Unitless	50%	OEHHA (2008)
I. HTM contact frequency	events/hr	2.28	Calculated by OEHHA based on Gorman Ng <i>et al.</i> (2014b), see below
J. HTM activity duration	hr/day	4	Assumes 4 welding hours/day
K. HTM Ingestion dose	µg/day	119	= G x H x I x J
Total exposure by all pathways			
L. Total daily dose (all pathways)	µg/day	287	= C + F + K
M. Lifetime averaging factor	Unitless	0.38	= 5/7 day x 48/52 wk x 40/70 yr <sup>a</sup>
N. Lifetime average daily dose	µg/day	109	= M x N

<sup>a</sup> 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 m<sup>3</sup> of air per 8 hour work day, and that the exposure duration for a worker is 50 weeks per year for 40 years. For the professional roof installer scenario, OEHHA adjusted the exposure duration to 48 weeks per year to account for sick days and rainy days.

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 CFFA are noted.

## 2.1 Inhalation Pathway

OEHHA estimated the dose of DINP to the professional roof installer by the inhalation pathway to be 167.5 µg per working day (Table 3). This inhalation dose is higher than that estimated by CFFA (initial estimate: 22.65 µg/day), and



is due to the higher DINP emission rate and concentration in the air estimated by OEHHA.

**Use of a box model**

In estimating the air concentration of DINP that the professional installer is exposed to as a result of roof membrane welding activity, OEHHA used a simple box model to estimate the DINP concentration in the air as 33.5 µg/m<sup>3</sup> (Table 4). This is higher than the air concentration estimated by CFFA, using a plume model with a smaller emission factor. CFFA’s plume model assumes that workers breathe uncontaminated air outside the plume 89% of the time, thereby decreasing the time-weighted average exposure concentration.

**Table 4. OEHHA’s estimation of DINP concentration in the air using a box model**

Parameter	Units	Value	Basis
A. Seam welding speed	m/min	3.66	Product-specific data
B. Seam width	M	0.038	1.5 inches x 0.025 m/inch
C. Area welded in one minute	m <sup>2</sup>	0.28	= A x B x 2 (seams are double)
D. PVC membrane density	µg/m <sup>2</sup>	1.8x10 <sup>9</sup>	CFFA online document (2014) <sup>a</sup>
E. DINP content	unitless	15%	CFFA data
F. Total DINP in 1-min welded area	µg	7.56x10 <sup>7</sup>	= C x D x E
G. DINP emission constant at 210°C	(min) <sup>-1</sup>	0.047%	Extrapolated, based on data in Kovacic and Mrklic (2002) (see text and Appendix A)
H. DINP emission rate at 210°C	µg/min	3.55x10 <sup>4</sup>	= F x G
I. Wind speed	m/min	193.2	CFFA data <sup>b</sup> : 3.22 m/s x 60 s/min
J. Height of the box	M	1.5	Adult breathing zone height
K. Width of the box	M	3.66	Welding distance traveled in one minute = A x 1 min
L. Dilution (box) volume	m <sup>3</sup> /min	1061	= I x J x K
M. DINP air concentration	µg/m <sup>3</sup>	33.5	DINP concentration in the modeled box = H / L

<sup>a</sup> CFFA (2014). Declaration for CFFA [Chemical Fabrics and Film Association] Environmental Product Single-ply polyester reinforced PVC roofing membrane. Available at:

[http://www.astm.org/CERTIFICATION/DOCS/195.EPD\\_for\\_CFFA\\_PVC\\_Roofing\\_Membrane.pdf](http://www.astm.org/CERTIFICATION/DOCS/195.EPD_for_CFFA_PVC_Roofing_Membrane.pdf)

<sup>b</sup> The wind speed data were collected in eight locations (e.g., San Francisco, Fresno, Long Beach; page 24 of the submission) throughout the state. The average of the harmonic means was used.

### **Assumptions used in estimating inhalation exposure**

OEHHA estimated the DINP emission from the heated membrane seams by assuming the following:

1. A double thickness welding seam 0.038 m (1.5 inch) wide and a welding speed of 3.66 m/min (12 feet/min) based on product-specific information provided in the SUD application, and hence;

$$\begin{aligned}\text{Area welded in one minute} &= 2 \times \text{width of seam} \times \text{welding speed} \times 1 \text{ min} \\ &= 2 \times 0.038 \text{ m} \times 3.66 \text{ m/min} \times 1 \text{ min} \\ &= 0.28 \text{ m}^2 \text{ (Line C in Table 4)}\end{aligned}$$

2. A PVC membrane density of  $1.8 \times 10^9 \mu\text{g}/\text{m}^2$  (CFFA, 2014) and a DINP content of 15 percent (product-specific data), and therefore;

$$\begin{aligned}\text{Total DINP in the 1-minute welded area} \\ &= \text{PVC density} \times \text{welded area} \times 15\% \\ &= 1.8 \times 10^9 \mu\text{g}/\text{m}^2 \times 0.28 \text{ m}^2 \times 0.15 \\ &= 7.56 \times 10^7 \mu\text{g} \text{ (Line F in Table 4)}\end{aligned}$$

3. A DINP emission constant at 210 °C of 0.047%/min was estimated based on linear extrapolation of emission data from Kovacic and Mrklic (2002). These researchers measured the weight loss of DINP-containing PVC discs (0.1 mm thick and 5 mm in diameter), upon heating to temperatures ranging from 120 to 150°C. Weight loss was assumed to be attributed solely to the emission of DINP from the PVC disc upon heating (See text below and Appendix A).
4. The welded area continued to emit DINP at a constant emission rate for one minute, as estimated for 210°C. The emission rate for DINP from the PVC membrane was derived as:

DINP emission rate at 210°C = DINP emission constant at 210°C x Total DINP in 1-min welded area

$$\begin{aligned}&= 0.047\%/min \times 7.56 \times 10^7 \mu\text{g} \\ &= 3.55 \times 10^4 \mu\text{g}/min \text{ (Line H in Table 4)}\end{aligned}$$

OEHHA then used a box model to derive an upper-bound estimate of the DINP air concentration to which a worker could be exposed during installation of SP PVC roofing membranes. OEHHA chose to use a box model because it is a simple and conservative tool to estimate the air concentration based on the assumption that the amount of DINP emitted from the welding seam in one minute is dispersed uniformly within a hypothetical box. The height of the box is 1.5 m, the height of the breathing zone for adults (Line J in Table 4). The width of the box is the length of seam

welded in one minute and the length of the box is the distance the wind travels in one minute. The dilution volume was calculated as the volume of the hypothetical box:

$$\begin{aligned}\text{Dilution volume} &= \text{Height of the box} \times \text{width of the box (welding distance} \\ &\quad \text{traveled in one minute)} \times \text{wind speed} \\ &= 1.5 \text{ m} \times 3.66 \text{ m} \times 3.22 \text{ m/s} \times 60 \text{ s/min} \\ &= 1061 \text{ m}^3/\text{min (Line L in Table 4)}\end{aligned}$$

5. DINP air concentration = DINP emission rate at 210°C / dilution volume

$$\begin{aligned}&= 3.55 \times 10^4 \text{ } \mu\text{g/min} / 1061 \text{ m}^3/\text{min} \\ &= 33.5 \text{ } \mu\text{g/m}^3 \text{ (Line A in Table 3 \& Line M in Table 4)}\end{aligned}$$

The box model may overestimate the air concentration because it assumes that all emitted DINP is contained within the hypothetical enclosed box, and does not account for diffusion or other possible loss of DINP out of the box.

The following additional assumptions were used in estimating DINP inhalation exposure to professional roof installers:

1. Installers spend 4 hours of the working day laying and attaching SP PVC membrane materials to the roof and another 4 hours welding seams.
2. During the 4 hours of the workday that is spent welding seams, installers breathe 5 m<sup>3</sup> of air that contains the DINP air concentration that was estimated using the box model.
3. The installers have no other sources of DINP air emissions from SP PVC membrane materials, other than those associated with welding seams during the work day.

### ***Estimation of DINP Emission Rate at 210°C***

Kovacic and Mrklic (2002) measured the weight loss in DINP-containing PVC discs upon heating at temperatures ranging between 120 and 150°C. PVC discs with various DINP content, 0.1 mm thick and 5 mm in diameter, weighing 3 mg, were subjected to isothermal thermogravimetric measurement at four temperatures. Table 5 summarizes the fractional weight loss rate of the discs at the 130-150°C temperatures that were examined. The weight loss was assumed by the authors to be due solely to DINP emission upon heating of these discs.

**Table 5. The rate constants of DINP evaporation from PVC discs (from Table 2 in Kovacic and Mrklic, 2002)**

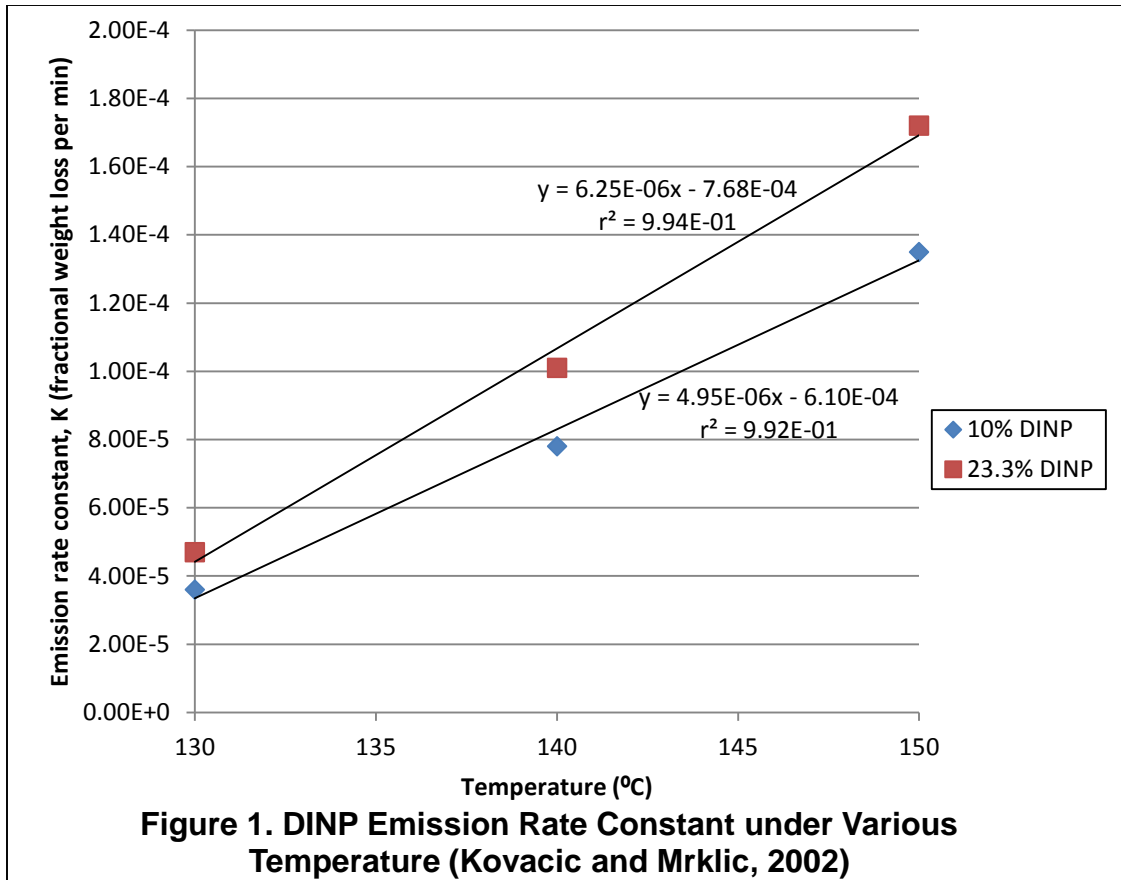
DINP content in the PVC discs	DINP evaporation rate constant (K) (fractional weight loss per min)		
	130°C	140°C	150°C
10%	$3.60 \times 10^{-5}$	$7.80 \times 10^{-5}$	$1.35 \times 10^{-4}$
23.3%	$4.70 \times 10^{-5}$	$1.01 \times 10^{-4}$	$1.72 \times 10^{-4}$
29.9%	$7.20 \times 10^{-5}$	$1.64 \times 10^{-4}$	$2.47 \times 10^{-4}$

The emission of DINP from SP PVC roofing membranes containing 15% DINP during welding (at 210°C) was estimated from the DINP evaporation rate constants reported by Kovacic and Mrklic (2002), and presented in Table 5, above. Plots of the emission constants (K) at various heating temperatures yielded near-linear relationships at temperatures between 130 and 150°C, with regression coefficients,  $r^2$ , of 0.994 and 0.992 for the PVC discs containing 10% and 23.3% DINP, respectively (Figure 1). These regression equations were used to estimate K values at 210°C for PVC containing 10% and 23.3% DINP (0.043%/min and 0.0545%/min, respectively). Interpolating between 10% and 23.3%, OEHHA estimated the DINP emission rate constant for a PVC membrane containing 15% DINP as 0.047%/min at 210°C. DINP loss during 1 minute of heating at 210°C was estimated as 0.047% (Line G in Table 4) using the expression

$$\text{DINP loss} = [1 - \text{Exp}^{-Kt}]$$

K = temperature-specific emission constant (/min);

t = welding time (min).



OEHHA also estimated the DINP emission rate constant at 210°C by extrapolating data from another published study (Gil *et al.*, 2006). These investigators estimated DINP emissions from PVC using a continuous heating protocol where the temperature was increased at a rate of 5°C/min, up to 200°C. Using the data of Gil *et al.* (2006) and extrapolating from 200 to 210°C, the emission of DINP at 210°C for a one minute period was estimated to be 0.057% (See Appendix A). If this value were used in place of the value from Kovacic and Mrklic (2002), the modeled DINP concentration in the air would increase to 40.5 µg/m<sup>3</sup>, the inhalation exposure dose to 202 µg/day, and the lifetime average daily dose to 96 µg/day.

## 2.2 Dermal Absorption Pathway

The dose of DINP to the professional roof installer by the dermal absorption pathway is estimated to be 0.7 µg per working day (Table 3). This dermal absorption dose is higher than that estimated by CFFA (0.03 µg/day), and is 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 roof installer to DINP occurs only during the time spent laying and attaching the SP PVC roofing membrane materials to the roof.
2. Dermal exposure is limited to the palmar surface of both hands.
3. Installers spend half of the working day (i.e., 4 hours) laying and attaching SP PVC membrane materials to the roof and another half-day welding seams.
4. Installers do not wear gloves while laying and attaching SP PVC membrane materials to the roof.

### ***DINP loading on the hands***

No data were available on the amount of DINP that is transferred to the hands as a result of the handling of SP PVC roofing membrane materials containing 15 percent DINP.

Information is available, however, on the amount of DINP that is transferred to the hands as a result of handling another type of material containing DINP, namely carpet tiles containing 9% DINP in the backing layer<sup>4</sup>. Hand wipes were taken of the palmar surface of two volunteers after handling (i.e., installing) varying numbers of carpet tiles (15, 30, or 45). The carpet tiles were supplied as stacks of tiles, so that the bottom of one tile was in contact with the top of another. DINP wipes of the tiles confirmed the presence of DINP on the top, as well as the bottom of the tiles. Large variation is shown among these limited hand wipe samples of two individuals. The hand wipe data indicated that workers' hands contained a maximum of 139 µg DINP per palmar surface, as a result of handling carpet tiles.

In the absence of data on DINP hand loading from SP PVC roofing membrane materials, these data on DINP hand loading from carpet tiles are used as follows: The 139 µg value was multiplied by 2 to account for both hands, and adjusted by the DINP concentration differences between roofing materials (15%) and carpet tiles (9%), resulting a ratio of 1.67 (= 15%/9%), 463 µg (Line D in Table 3).

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<sup>4</sup> Letter dated April 18, 2016, from Norton Rose Fulbright US LLP to OEHHA.

### ***DINP dermal absorption***

No dermal absorption data are available for DINP from studies in humans. Dermal absorption studies conducted in male and female F344 rats by McKee *et al.* (2002) reported that 0.3 to 0.6 percent of the applied dose of DINP was absorbed over a 24-hour period. OEHHA adopted 0.6 percent as a conservative estimate.

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 di-(2-ethylhexyl) phthalate (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:

$$\begin{aligned} & \text{DINP dermal absorption coefficient for humans} \\ &= \text{DINP dermal absorption coefficient for rats} \times \text{dermal} \\ & \quad \text{permeability coefficient ratio for humans to rats} \\ &= 0.6\% \times 0.25 \\ &= 0.15\% \text{ (Line E in Table 3)} \end{aligned}$$

### **2.3 HTM Ingestion Pathway**

The dose of DINP to the professional roof installer by the HTM ingestion pathway is estimated to be 119 µg per working day (Line K in Table 3). This HTM ingestion dose is higher than that estimated by CFFA (0.05 µg/day), and is 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 HTM ingestion pathway, the following assumptions were made:

1. Installers spend 4 hours of the working day laying and attaching SP PVC membrane materials to the roof, and the other 4 hours welding seams.
2. HTM activity is negligible during the 4 hours/day when the installer is welding seams and busy handling the welding machine.
3. Hand-to-mouth transfer of DINP occurs only during the time spent laying and attaching the SP PVC roofing membrane materials to the roof (Line J in Table 3).

4. HTM activity during the portion of the workday when the installer is laying and attaching the materials to the roof involves contact of the fingertips with the perioral area.
5. Installers do not wear gloves while laying and attaching SP PVC membrane materials to the roof.
6. Installers wash their hands before eating and at the end of their work day, completely removing DINP from the hands/fingertips.
7. No roofing-material-specific data were submitted for DINP loading on fingertips. Information is available, however, on the amount of DINP that is transferred to the fingertips as a result of handling carpet tiles containing 9% DINP in the backing layer. Wipe samples of two volunteers' fingertips, taken after handling 15 carpet tiles contained a maximum of 26.1 µg DINP per wipe (five fingertips). Fingertip loading for roofers was adjusted to reflect the higher DINP content (15%) of the roofing membrane. The adjustment was:  
 Fingertip loading for roofers =  $(15/9) \times 26.1 \mu\text{g} = 43.5 \mu\text{g}$ .  
 This was further adjusted downward by a factor of 0.6, reflecting OEHHA's assumption that only 3 fingertips contact the mouth or perioral area ( $43.5 \mu\text{g} \times 0.6 = 26 \mu\text{g}$ ; Table 3, Line G).
8. In the absence of data on the HTM transfer efficiency of DINP, OEHHA applied the same direct hand-to mouth transfer efficiency of 50% used in OEHHA (2008) based on empirical data of transfer efficiencies of three pesticides in three volunteers (Camann *et al.*, 2000) (Table 3, Line H). A new study (Gorman Ng *et al.*, 2014a) 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.
9. In the absence of data on the frequency of HTM activity by professional installers of SP PVC roofing membranes, data on HTM activity frequency from a study in workers by Gorman Ng *et al.* (2014b) were used. The average HTM activity frequency reported for all industrial workers, 7.6 events per hour, was selected (Gorman Ng *et al.*, 2014b). The authors 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 3, Line I).



### ***Total Exposure by All Pathways***

The total exposure to DINP via all pathways (109 µg/day, Table 3, line N) was derived as the product of the sum of the daily doses for the three exposure routes (287 µg/day, Table 3, Line L) and the lifetime adjustment factor appropriate for the worker scenario (0.38, Table 3, Line M).

The lifetime average adjustment factor was calculated as:

$$5/7 \text{ days} \times 48/52 \text{ weeks} \times 40/70 \text{ years} = 0.38$$

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. For the professional roof installer scenario OEHHA adjusted the exposure duration to 48 weeks per year to account for sick days and rainy days.

### **3. Conclusions**

Based on this screening-level exposure analysis, an upper-end estimate of DINP exposures to professional roof installers during the installation of SP PVC roofing membrane products containing 15 percent DINP is 109 µg /day, which is approximately 75 percent of the proposed No Significant Risk Level (NSRL) for DINP of 146 µg/day.

Thus, based on the foregoing analysis, the estimated exposure to DINP as a result of installation by roofing professionals of SP PVC roofing membrane products with a nominal finished thickness of between 1.016 to 2.438 mm, containing no more than 15 percent DINP and heated to surface temperatures up to and including 210°C during installation, corresponds to an excess cancer risk of less than one in 100,000. Therefore, a Proposition 65 warning would not be required for these specific types of roofing products. This analysis, which relied on conservative upper-bound assumptions, only applies to the exposure scenarios discussed in this document. OEHHA is not drawing a conclusion for other exposure scenarios.

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## Appendix A. Comparison of Kovacic and Mrklic (2002) and Gil *et al.* (2006) as the basis for the Estimation of DINP Emission Rate at 210°C

Gil *et al.* (2006) reported DINP weight loss from PVC film as the temperature of the material was continuously increased, at a rate of 5°C/min, using a thermogravimetric measurement method. Samples of approximately 10 mg of PVC films, cut in strips, were analyzed over a temperature range of 25 to 600°C. However, the published report presents relative weight loss data only for temperatures ranging from 100 to 200°C (Table A-1).

**Table A-1. Weight loss of DINP-containing PVC membranes at three temperatures (Gil *et al.*, 2006)**

DINP content	DINP weight loss of PVC membrane (%)		
	100°C	150°C	200°C
13%	0.03	0.08	0.38
23%	0.01	0.08	0.51
29%	0.05	0.23	0.97

The fractional weight loss data from PVC membranes containing 13 percent DINP were used in extrapolation to estimate the DINP emission rate at 210°C, and this estimated emission rate was assumed to be applicable to the materials specified in this SUD request (i.e., PVC membranes containing 15 percent DINP).

The exponential curve fitted equation obtained from these data is shown below:

Fractional weight loss of the PVC membrane (i.e., fractional DINP loss)

$$= e^{(-10.1+0.127 \times t)}$$

where t represents the heating time in minutes

Using the exponential curve-fitted equation, OEHHA calculated the predicted weight loss data shown in Table A-2. The one-minute fractional weight loss of the PVC membrane, or the fractional DINP emission rate at 210°C was derived as 0.057%, from the difference of DINP loss between 207.5°C and 212.5°C (Table A-2). This estimate of the DINP emission derived from the data in Gil *et al.* (2006) is fairly close to the emission estimated based on the data of Kovacic and Mrklic (2002), 0.057% versus 0.047%, and hence supports the use of an emission rate constant of 0.047%/min in the inhalation exposure analysis.

**Table A-2. Predicted DINP loss at various temperatures from PVC film containing 15% DINP (model predictions based on Gil *et al.* 2002 data from PVC film containing 13% DINP, and extrapolation above 200°C)**

Temperature (°C)	Corresponding heating time, t (min)	Predicted DINP loss <sup>a</sup> (%)	Fractional DINP loss in one minute at 210°C <sup>b</sup> (%)
25	0	0.004	
100	15	0.028	
150	25	0.098	
200	35	0.350	
207.5	36.5	0.423	
210	37	0.451	0.057
212.5	37.5	0.481	

<sup>a</sup> Predicted DINP loss from PVC film containing 15% DINP, derived through regression analysis of DINP loss data measured in PVC film containing 13% DINP and heated from 100-200°C (Gil *et al.*, 2002).

<sup>b</sup> Estimated as the loss difference between 212.5°C and 207.5°C using the heating scheme reported by Gil *et al.* (2002): Temperature (in °C) = 25 + heating time (in min) × 5.