

# **PROP 65 & DINP: USING ACC'S REVISED WORKBOOK TO ESTIMATE EXPOSURE FROM CONSUMER PRODUCTS**

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# Speakers

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# DINP

**General purpose plasticizer used in a multitude of vinyl products that demand flexibility, durability and specific functionality**

**Primary function is as a softener; also used in sealants, paints and lubricants**

**Benefits of DINP in vinyl are evident in products manufactured by the automotive, wire and cable, roofing and flooring industries**

# DINP

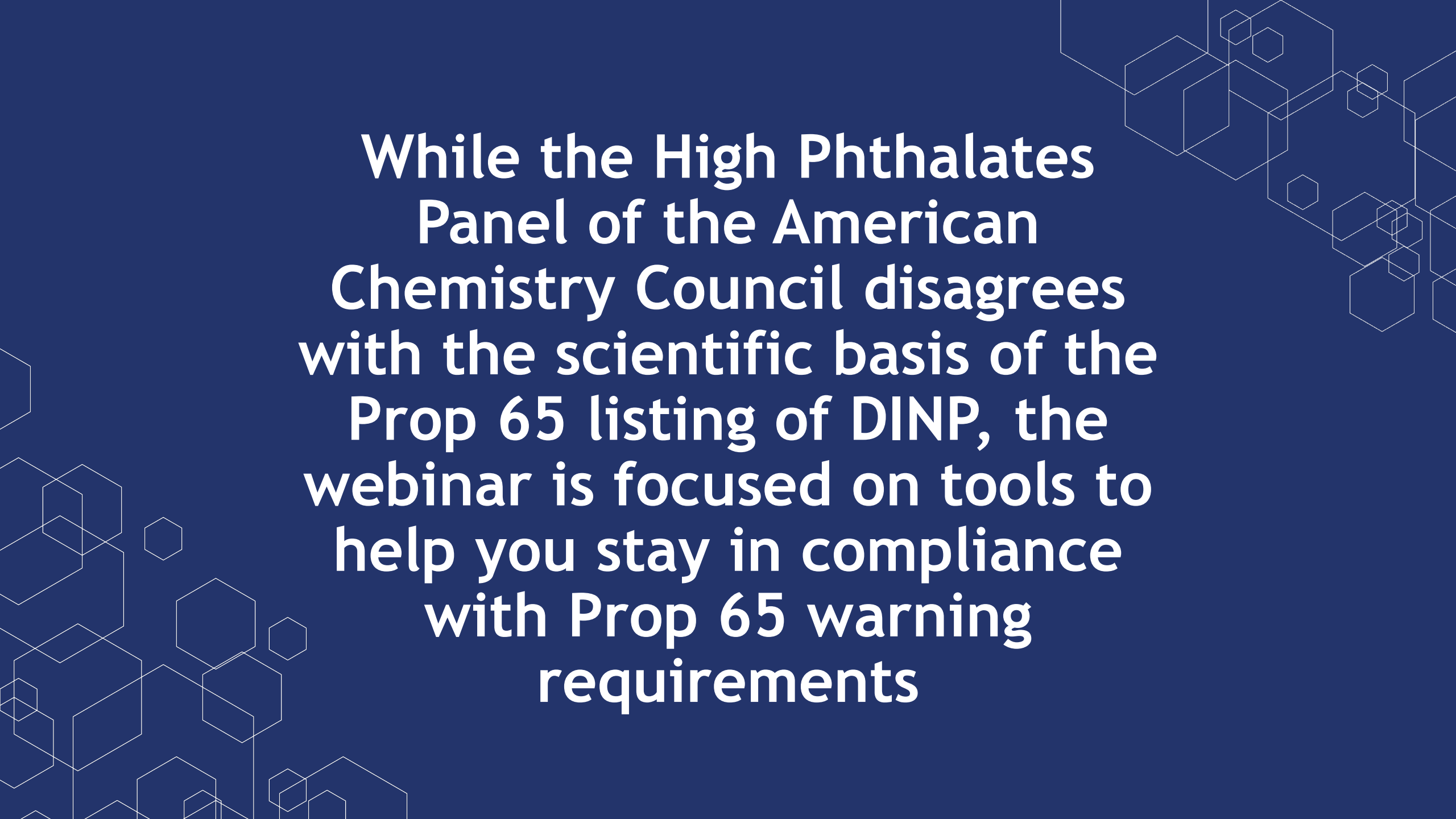


- ✓ Phthalates are among the most thoroughly studied family of compounds in the world and have been reviewed by multiple regulatory bodies in the United States, Europe, Australia and Canada
- ✓ High phthalates, including DINP, have been reviewed by numerous scientific panels

# DINP



- ✓ The conclusions are essentially the same: phthalates used in commercial and consumer products do not pose a risk to human health at typical exposure levels
- ✓ Most recently, ECHA's RAC confirmed an earlier conclusion that DINP does not warrant classification for reproductive and developmental toxicity effects under the E.U.'s Classification, Labelling and Packaging regulation



**While the High Phthalates  
Panel of the American  
Chemistry Council disagrees  
with the scientific basis of the  
Prop 65 listing of DINP, the  
webinar is focused on tools to  
help you stay in compliance  
with Prop 65 warning  
requirements**

# Prop 65 Overview

- Prop 65 is the original name for the initiative that became California's Safe Drinking Water and Toxic Enforcement Act of 1986
- Administered by California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA)
- Under Prop 65, the California Governor must issue an annual list of substances "known to the State" to cause cancer, birth defects or reproductive harm
  - It is not a ban of Prop 65 listed substances
  - It is not a restriction or requirement to discontinue a listed substance's use
  - It is not a labelling requirement for other states or countries
- There are over 800 substances on this list, including: food ingredients, common household products, naturally occurring substances, ethyl alcohol in alcoholic beverages, aspirin and many prescription drugs
- Prop 65 requires anyone doing business in California to label a product if human exposure to a listed substance in the product is expected to be above a level expected to cause a carcinogenic or reproductive effect, such as an OEHHA established "safe harbor" level for that substance

# Prop 65 Safe Harbor Levels

**OEHHA can develop a Safe Harbor Level for a listed chemical**

- For chemicals listed as “known to cause cancer” the Safe Harbor Level is called a No Significant Risk Level (NSRL)
- For chemicals listed as “known to cause birth defects or reproductive harm” the Safe Harbor Level is called a Maximum Allowable Dose Level (MADL)

**NSRL is defined as the level of exposure that would result in not more than one excess case of cancer in 100,000 individuals exposed to the substance over a 70-year lifetime**

- A person exposed to the substance at the “no significant risk level” for 70 years would not have more than a “one in 100,000” chance of developing cancer as a result of that exposure

**A product does not require a Prop 65 warning if exposure to a listed substance occurs at or below the NSRL, i.e. it has ‘Safe Harbor’ from the requirements of Proposition 65**

**OEHHA has adopted an NSRL for DINP of 146 micrograms per day effective April 1, 2016**



# Prop 65 Enforcement

Prop 65 warning label requirements can be enforced through civil lawsuits brought by the California Attorney General, certain district and city attorneys, or private parties acting in the public interest

Before filing a lawsuit, private enforcers must provide at least 60-days notice of the alleged violation to the business, as well as to the Attorney General and the appropriate district and city attorney

If a business is found to be in violation of Prop 65, a court may order the business to stop committing the violation

The business is also subject to civil penalties of up to \$2,500 per day for each violation

Practical threshold for a private party to file a suit is relatively low

# Prop 65 Summary



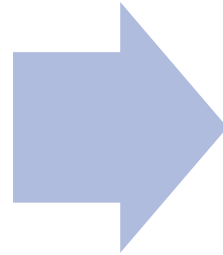
It is not a safety  
determination

It does not  
mean that a  
product is in  
“violation of  
any product-  
safety  
standards”

DINP was added to  
the list on  
December 20,  
2013; warning  
requirement  
became effective  
on December 20,  
2014

# DINP and Prop 65

To reiterate, CIC's decision was based on cancer effects in rodents without any consideration of human relevance



Other regulatory bodies worldwide, including from the E.U., Canada, Australia and the U.S. CPSC, have all dismissed the human relevance of the cancer endpoints that formed the basis of the DINP listing

# Applying the NSRL



- ✓ ACC High Phthalates Panel has revised its exposure workbook for DINP that includes guidance and examples on how to estimate potential product exposures to DINP
- ✓ Using this tool, you can compare the exposure estimate with OEHHA's safe harbor level
- ✓ If the exposure is lower, no warning label should be needed
- ✓ If the exposure is higher, then a warning label is likely needed

# Prop 65: 3 Requirements

**Employer labeling obligations when you operate in California**

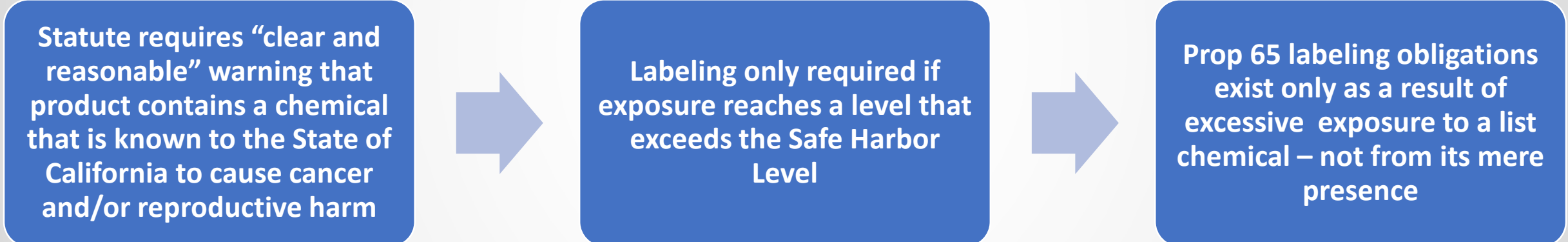
**Employer obligations regarding environmental releases of Prop 65-listed chemicals when you operate in California**

**Product warning labels for products containing Prop 65-listed chemicals available to the consumer in California regardless of any other federally-mandated labels**



# Prop 65 Labels

Statute requires “clear and reasonable” warning that product contains a chemical that is known to the State of California to cause cancer and/or reproductive harm



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graph LR; A[Statute requires “clear and reasonable” warning that product contains a chemical that is known to the State of California to cause cancer and/or reproductive harm] --> B[Labeling only required if exposure reaches a level that exceeds the Safe Harbor Level]; B --> C[Prop 65 labeling obligations exist only as a result of excessive exposure to a list chemical – not from its mere presence];
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Labeling only required if exposure reaches a level that exceeds the Safe Harbor Level

Prop 65 labeling obligations exist only as a result of excessive exposure to a list chemical – not from its mere presence

# Assessing the Need to Label

## OEHHA has adopted an NSRL for DINP of 146 $\mu$ g/day

- It's an overly conservative estimate
- Does not change regardless of the use of DINP

## Three ways exposure typically occurs from consumer products

- Direct contact with DINP – skin/dermal absorption
- Breathing air containing DINP – inhalation
- Hand-to-mouth ingestion – oral exposure

## Examples to demonstrate use of the ACC HPP exposure estimation tool

- Walking barefoot on vinyl flooring
- Wearing PVC gloves
- Home installation of PVC coated electrical wire
- Home installation of vinyl floor covering

# Table 1

**Table 1.** Representative Mean Surface Areas of the Human Body <sup>1</sup>

	<b>Adult Female <sup>2</sup></b>	<b>Adult Male <sup>3</sup></b>
<b>Body part</b>	<b>Surface area (cm<sup>2</sup>)</b>	<b>Surface area (cm<sup>2</sup>)</b>
Total	18,500	20,600
Head	1,140	1,360
Trunk (including neck)	6,540	8,270
Upper extremities	3,040	3,930
Arms	2,370	3,140
Hands	890	1,070
Lower extremities	7,070	8,020
Legs	5,980	6,820
Thighs	3,640	4,120
Lower legs	2,330	2,680
Feet	1,220	1,370
Soles of Feet <sup>4</sup>	610	685



# Example 1: Vinyl Flooring

## 4.2.1. Dermal

1. Will the DINP-containing portion of the product be in direct contact with skin during normal use?  
 NO. You do not need to estimate dermal exposure.  
 YES. Go to Line 2 of this worksheet.
2. How many hours per day is the average consumer in direct contact with the product?  
8 hours per day
3. How much surface area of the body ordinarily comes in direct contact with the DINP-containing portion of the product during normal use?  
610 cm<sup>2</sup> (Total of all relevant body parts – Use Table 1)  

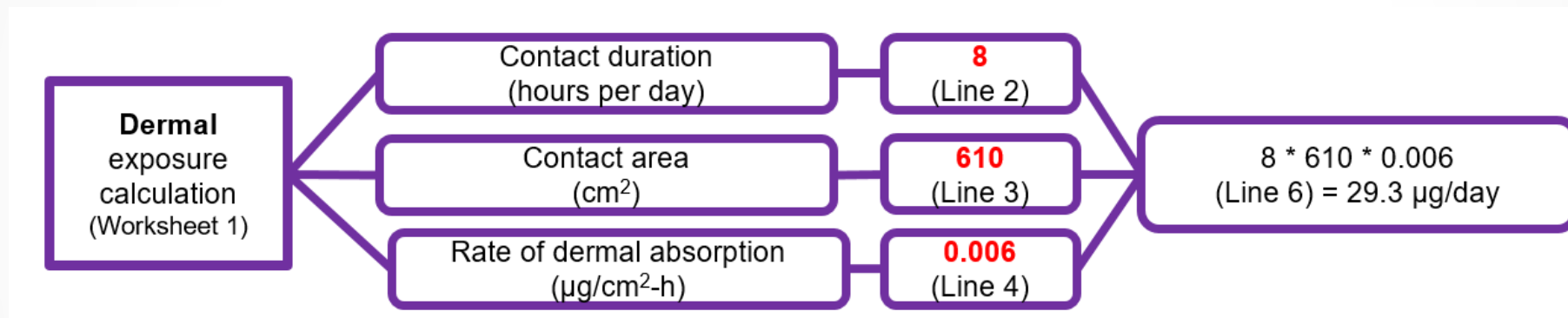
This is equal to the soles of both feet for an adult female as given by Table 1.
4. Enter the dermal absorption rate for the product.  
0.006 (µg/cm<sup>2</sup>)/hour
5. Using the following formula, estimate the Dermal Exposure to DINP from the product:  
$$\frac{8}{\text{(Line 2)}} \text{ hours/day} \times \frac{610}{\text{(Line 3)}} \text{ cm}^2 \times \frac{0.006}{\text{(Line 4)}} \text{ µg/cm}^2/\text{hour} = \underline{29.3} \text{ µg/day}$$

For the most current information please see the DINP exposure workbook

# Vinyl Flooring



- Scenario: the product is used in a vinyl floor in a kitchen where an adult female might walk bare-footed on the surface for 8 hours a day and inhale any DINP emitted by the flooring. No oral exposure occurs in this scenario.



Note: Numbers in **red** will likely vary per product.

# Vinyl Flooring

## 4.2.2. Dermal absorption of indoor dust

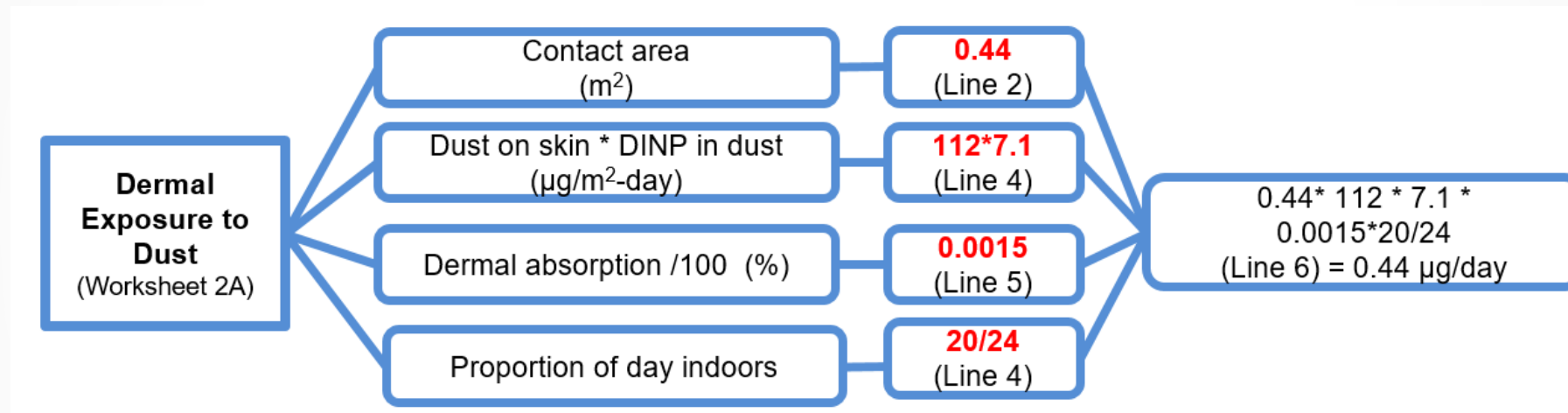
1. Is the DINP-containing product used in building materials?  
       NO. You do not need to estimate dermal exposure to indoor dust.  
✓ YES. Go to Line 2 of this worksheet.
2. Enter the average mass of dust adhered to skin  
7.1 g/m<sup>2</sup>-day
3. Enter surface area of the body that ordinarily comes in direct contact with the DINP-containing portion of the product?  
0.44 m<sup>2</sup>
4. Enter average concentration of DINP in dust.  
112 µg/g dust
5. Enter the dermal absorption rate of DINP.  
0.0015 (dimensionless)
6. What is the number of hours in a day spent indoors?  
20 out of 24 hours      Proportion = 0.833 (dimensionless)
7. Using the following formula, estimate the dermal exposure to DINP from contact with dust.  
$$\frac{7.1 \text{ g/m}^2\text{-day}}{\text{(Line 2)}} \times \frac{0.44 \text{ m}^2}{\text{(Line 3)}} \times \frac{112 \text{ µg/g dust}}{\text{(Line 4)}} \times \frac{0.0015}{\text{(Line 5)}} \times \frac{0.833}{\text{(Line 5)}} = \underline{0.44} \text{ µg/day}$$

For the most current information please see the DINP exposure workbook

# Vinyl Flooring



- Scenario: the product is used in a vinyl floor in a kitchen where an adult female might walk bare-footed on the surface for 8 hours a day and inhale any DINP emitted by the flooring. No oral exposure occurs in this scenario.



Note: Numbers in **red** will likely vary per product.

# Vinyl Flooring

## 4.2.3. Inhalation

1. Is the DINP-containing product used in building materials?  
 NO. You do not need to estimate exposure to indoor air.  
 **YES. Go to Line 2 of this worksheet.**
2. How many hours per day is the average consumer potentially exposed to the product?  
20 **hours per day**
3. What is the hourly exposure rate for DINP?  
0.009 **µg/hour**
4. Estimate the inhalation exposure to DINP from the product:  
$$\frac{\underline{20}}{\text{(Line 1)}} \text{ hours/day} \times \frac{\underline{0.009}}{\text{(Line 2)}} \text{ µg/hour} = \underline{0.18} \text{ µg/day}$$

## 4.2.4. Oral (from hand-to-mouth activity)

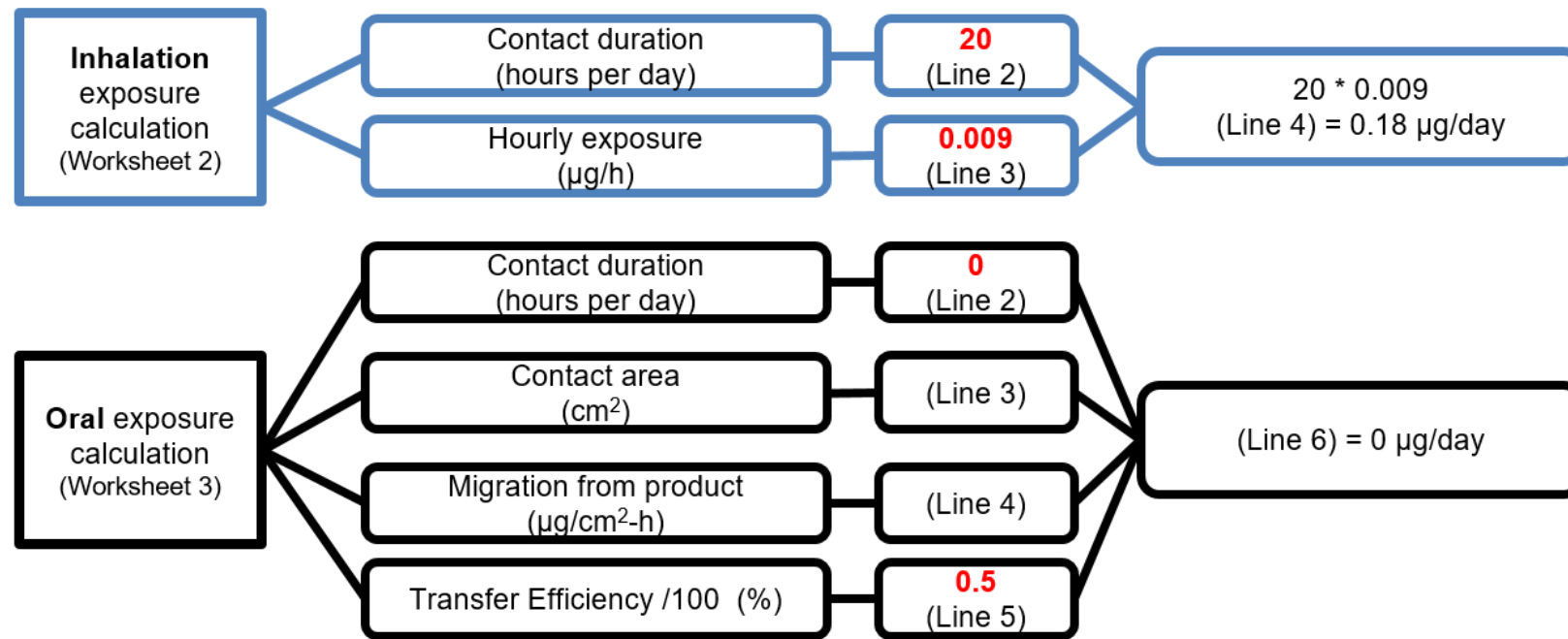
1. Will the DINP-containing portion of the product be in direct contact with skin that subsequently will come into contact with the mouth during normal use?  
 **NO. You do not need to estimate oral exposure.**  
 YES. Go to Line 2 of this worksheet.

For the most current information please see the DINP exposure workbook

# Vinyl Flooring



- Scenario: the product is used in a vinyl floor in a kitchen where an adult female might walk bare-footed on the surface for 8 hours a day and inhale any DINP emitted by the flooring. No oral exposure occurs in this scenario.



For the most current information please see the DINP exposure workbook

Note: Numbers in **red** will likely vary per product.

# Vinyl Flooring

## 4.2.5. Oral (from ingestion of indoor dust)

1. Is the DINP-containing product a building material used indoors?

     NO. You do not need to estimate contact with dust.

✓ YES. Go to Line 2 of this worksheet.

2. What is the rate of ingestion of indoor dust?

0.039 g/ day

3. What is the concentration of DINP in indoor dust?

112 µg/g dust

4. What is the number of hours in a day spent indoors?

20 out of 24 hours      Proportion = 0.833 (dimensionless)

5. Estimate the oral exposure to DINP from ingestion to indoor dust

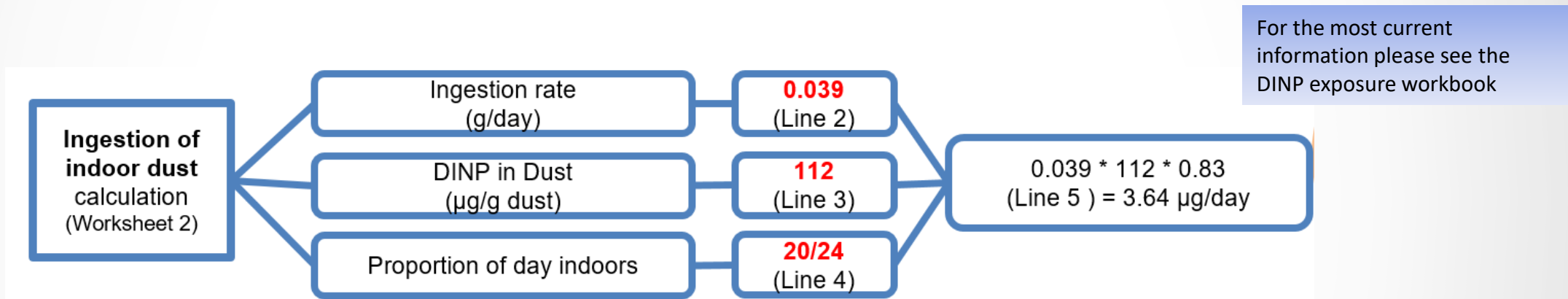
$$\frac{0.039}{\text{(Line 2)}} \text{ g/day} \times \frac{112}{\text{(Line 3)}} \text{ µg/g dust} \times \frac{0.833}{\text{(Line 4)}} = \underline{3.64} \text{ µg/day}$$

For the most current information please see the DINP exposure workbook

# Vinyl Flooring



- Scenario: the product is used in a vinyl floor in a kitchen where an adult might walk bare-footed on the surface for 8 hours a day and inhale any DINP emitted by the flooring. No oral exposure occurs in this scenario.



Note: Numbers in **red** will likely vary per product.



# Vinyl Flooring Total

## 4.2.6. Calculating Total Exposure – Single Day

1. Add the dermal, indoor inhalation, and oral components:

a. Dermal exposure:	<u>29.3</u>	µg/day
b. Dermal contact to indoor dust:	<u>0.44</u>	µg/day
c. Inhalation exposure:	<u>0.18</u>	µg/day
d. Oral exposure:	<u>0</u>	µg/day
e. Oral exposure to indoor dust:	<u>3.64</u>	µg/day
f. <b>TOTAL:</b>	<b><u>33.6</u></b>	<b>µg/day</b>

2. Compare the total on Line 1f to the No Significant Risk Level (NSRL):

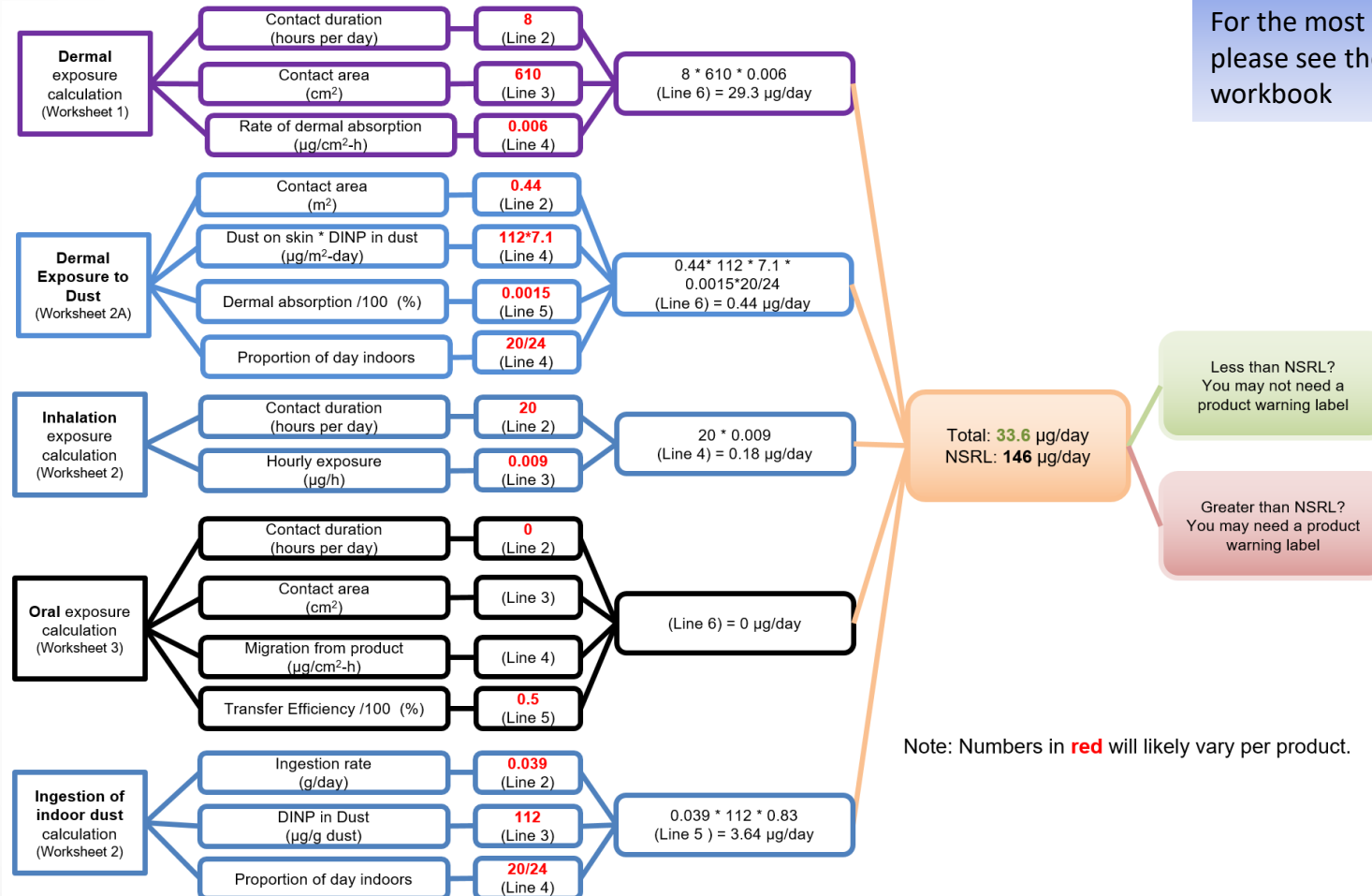
Exposure Estimate µg/day	NSRL µg/day
<b>33.6</b>	146

For the most current information please see the DINP exposure workbook

# 1: Vinyl Flooring



- Scenario: the product is used in a vinyl floor in a kitchen where an adult female might walk bare-footed on the surface for 8 hours a day and inhale any DINP emitted by the flooring. No oral exposure occurs in this scenario.

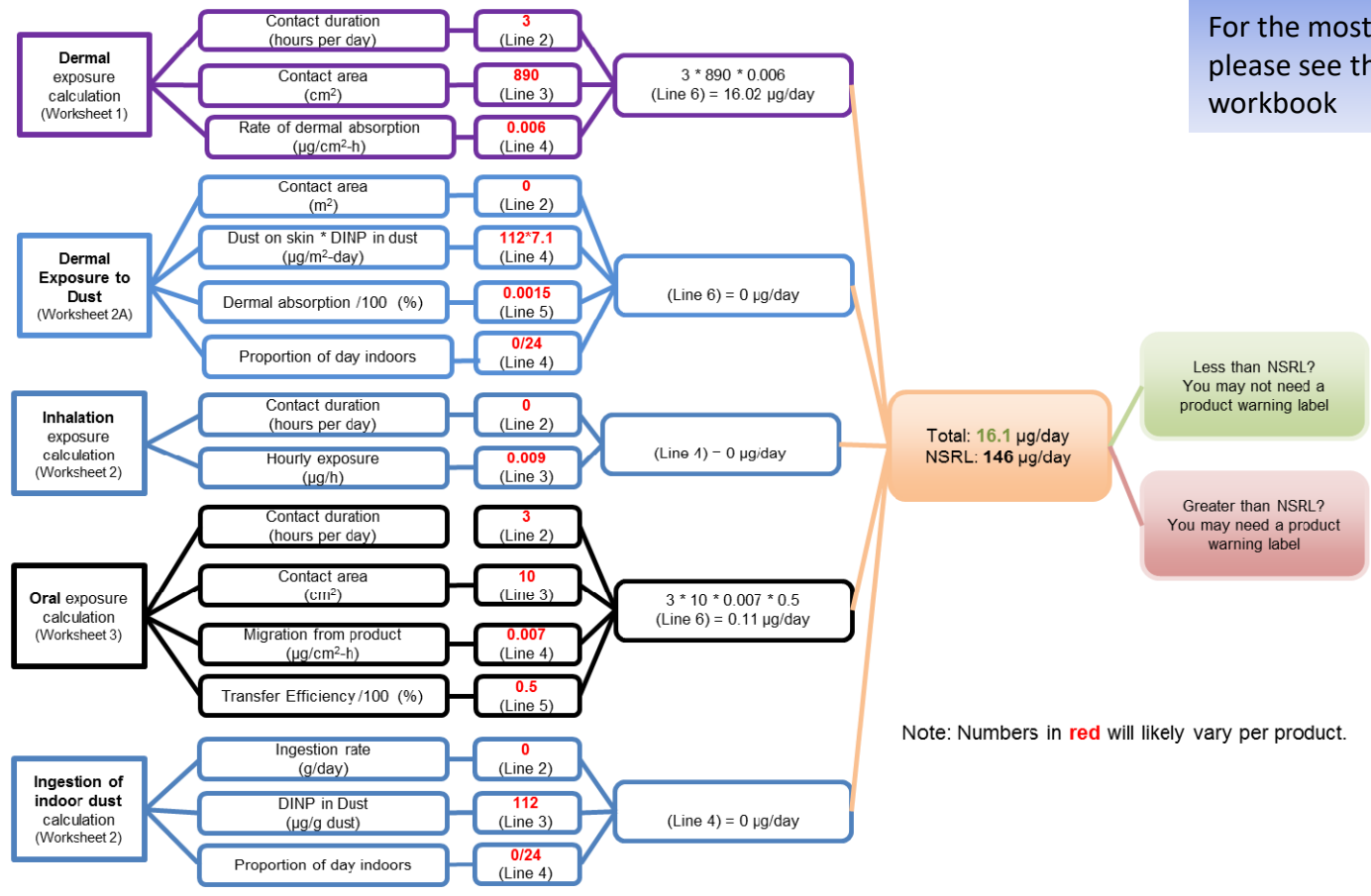


For the most current information please see the DINP exposure workbook

# 2: PVC Gloves

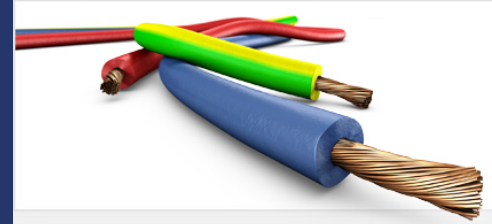


- Scenario: The product is used in a domestic situation where a person is exposed only during times when dishes are washed, i.e., after breakfast, lunch, dinner.

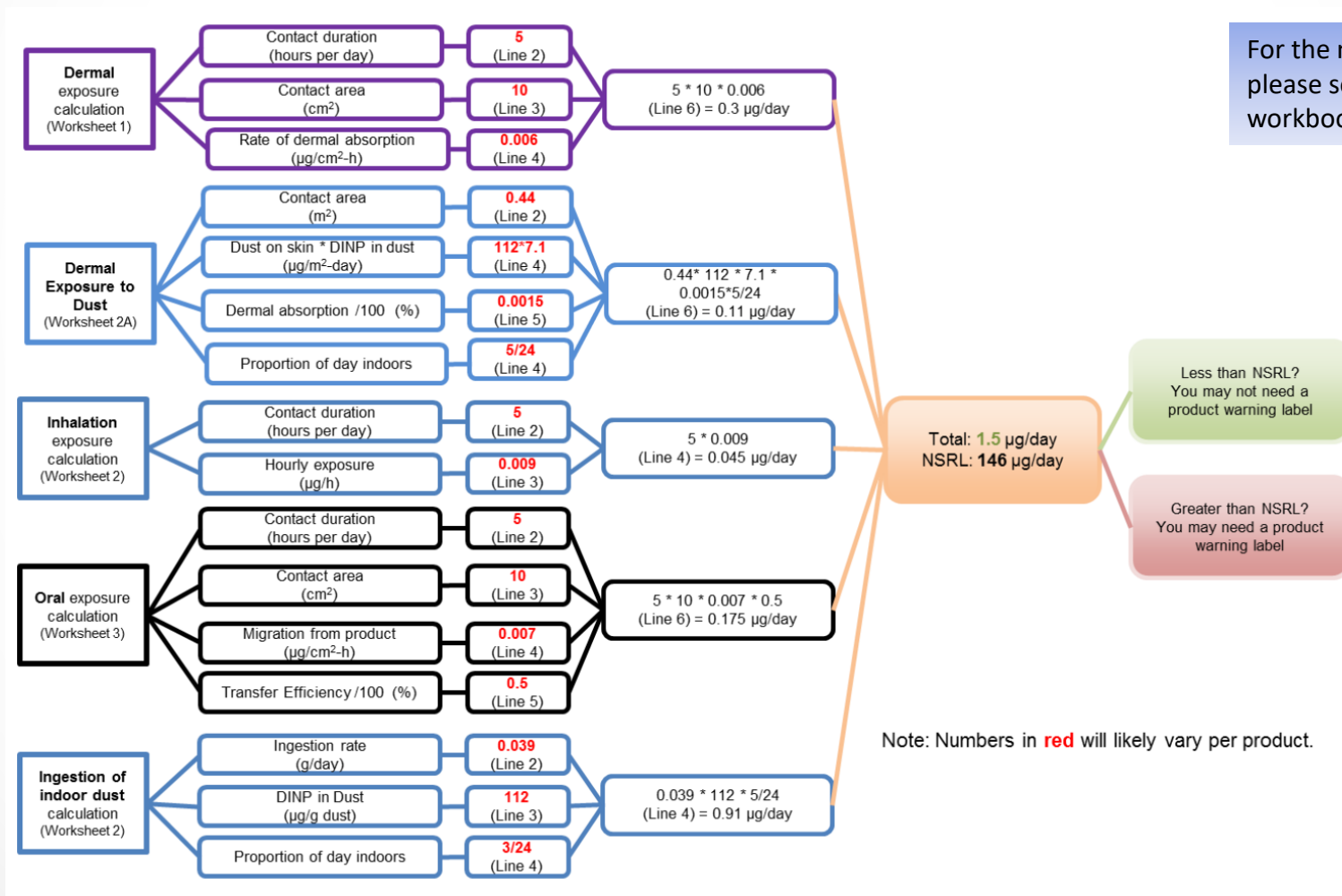


For the most current information please see the DINP exposure workbook

# 3: Home Wire Installation



- Scenario: the product is used in as a coating on electrical wire that is being installed by a do-it-yourself homeowner.

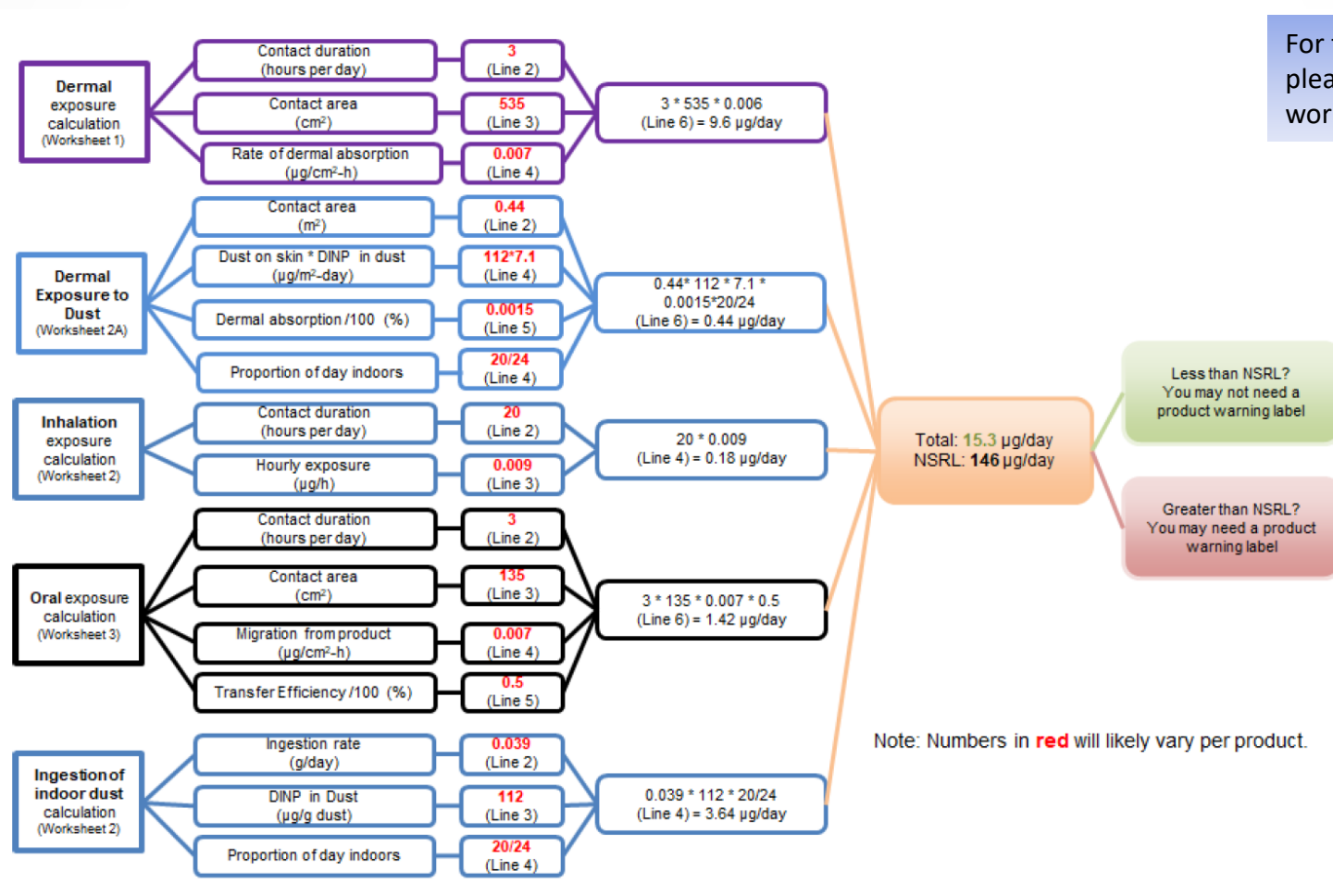


For the most current information please see the DINP exposure workbook

# 4: Vinyl Wall Covering



- Scenario: the product is used as part of a wall covering, being installed by a homeowner.



For the most current information please see the DINP exposure workbook

# Summary

Phthalates are among the most thoroughly studied family of compounds in the world and have been determined by numerous scientific panels not to pose a risk to human health at normal exposure levels

Regardless of a lack of scientific basis, DINP has been listed by California as a product known to cause cancer

Prop 65 requires that companies label products containing listed ingredients if exposure levels are above a level expected to cause a carcinogenic or reproductive effect

A product does not require a warning label if exposure to the substance occurs at or below the NSRL

The DINP Workbook is designed to help you estimate potential exposures to DINP in your products and compare potential exposure to the proposed NSRL so that you can make an informed labeling judgment



**Questions?**

# High Phthalates Panel

For more information please visit [www.phthalates.org](http://www.phthalates.org)

To obtain a copy of the workbook contact:

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