

SAFE USE DETERMINATION (SUD) REQUESTS: ESSENTIAL ELEMENTS

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What is a SUD Request?

- A request made by a business or trade group to OEHHA
- A request is **specific** to **exposure** or discharge of a listed chemical(s) resulting from specific business actions or average use of a specific product
- A request seeks a determination by OEHHA:
Is the **exposure** or discharge at or below the Safe Harbor Level?



A Safe Use Determination
is based on an
exposure assessment



What is Exposure?

Section 25102, Title 27 of the California Code of Regulations

(i) 'Expose' means to cause to ingest, inhale, contact via body surfaces or otherwise come into contact with a listed chemical. An individual may come into contact with a listed chemical through water, air, food, consumer products and any other environmental exposure as well as occupational exposures.



What is Exposure?



Does my product cause exposures to a Proposition 65 listed chemical?



Exposure Assessment for Chemicals Listed under Proposition 65

- Exposure to a listed chemical is estimated from a **given product or source**.
 - An **entity causing an exposure is only responsible for the exposure it causes, *not for other sources of exposure to the chemical***.
 - For example, a business that makes vinyl flooring containing DINP need only assess exposure to DINP from vinyl flooring. It is not responsible for exposures to DINP that may occur from other sources (such as from other home furnishings or consumer products).
- Exposure assessment may be performed by:
 - Entities causing exposures (businesses).
 - Entities that enforce Proposition 65 warning and discharge requirements.
 - OEHHA (i.e., when evaluating a SUD request).



What to consider when conducting an exposure assessment for a product

Chemical-specific factors

- Is the chemical volatile? Semi-volatile?
- Can it be absorbed through the skin or in the gastrointestinal tract?

Product-specific factors

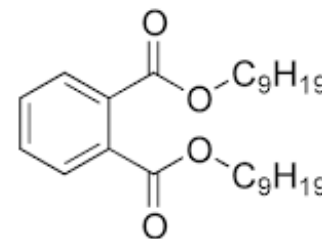
- How is the product used?
- Can use of the product result in release or formation of airborne particles or aerosols?

Ways that exposure can result from product use

- Inhalation
- Ingestion
- Skin contact
- Transfer from hands to mouth



Example Exposure Assessment: DINP in vinyl flooring products



The following exposure assessment was conducted in the context of a request for a Safe Use Determination under Proposition 65

From the Request:

- Products are non-textile flooring materials consisting of polyvinyl chloride (PVC, vinyl), pigments, plasticizers (such as DINP), fillers (e.g., limestone), extenders, and stabilizers to protect against heat and light deterioration.
- Four product categories: heterogeneous sheets, homogeneous sheets, vinyl tile, vinyl composition tile.
- DINP content in the four product categories included in the request ranges from <1% to 22% by weight.

Safe Harbor Level:

- The No Significant Risk Level (NSRL) for DINP is 146 µg/day.

<https://oehha.ca.gov/media/downloads/proposition-65/chemicals/121914isora25903.pdf>



Example Exposure Assessment: DINP in vinyl flooring products

Factors

- **Chemical specific factors**
 - Semi-volatile
 - Absorption through the skin, GI tract, respiratory tract
- **Product specific factors**
 - Used in homes, offices, and other settings

Ways that exposure can result from product use

- **Professional Installers**
 - Dermal absorption via direct contact with vinyl flooring products
 - Incidental ingestion via hand-to-mouth contact

[Inhalation is considered negligible, due to the slow rate of volatilization during the installation period]
- **Residents**
 - Dermal absorption via direct contact with vinyl flooring products
 - Incidental ingestion via hand-to-mouth contact
 - Inhalation



Example Exposure Assessment: DINP in vinyl flooring products

OEHHA conducted screening-level exposure analyses to derive upper-end estimates of DINP exposure.

Professional Installers:
151 µg/day

Residents:
154.5 µg/day

Estimated
for flooring
containing
9% DINP
by weight

Estimated
for flooring
containing
20% DINP
by weight

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.

oeeha.ca.gov/media/downloads/crnrr/vinylflooringinstallersud123016.pdf

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
Inhalation			
A. Airborne gas-phase concentration	µg/m ³	0.207	See Table 3, Line M
B. Particle-air partition coefficient	m ³ /µg	0.023	Weschler and Nazaroff (2010); Liang and Xu (2014)
C. Total suspended particles concentration	µg/m ³	20	Little <i>et al.</i> (2012)
D. Airborne particle-phase concentration	µg/m ³	0.095	= A x B x C
E. Total DINP air concentration	µg/m ³	0.302	= A + D
F. Breathing rate	m ³ /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	µg/day	4.7	= E x F x G
Dermal absorption			
I. Dermal contact surface	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	g/m ² -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	µg/m ² -hr/(µg/m ³)	1.12	Weschler and Nazaroff (2012); Liang and Xu (2014)
M. Dermal intake from dust	µg/day	16	= I x J x K x Q
N. Dermal intake from gas	µg/day	2	= A x G x I x L x 24 h/d
O. Dermal absorption dose	µg/day	18	= M + N
Incidental ingestion			
P. Dust-air partition coefficient	m ³ /µg	0.0165	Liang and Xu (2014); Weschler and Nazaroff (2010)
Q. DINP in dust	µg/g	3415.5	= A x P x 10 ⁶ µg/g
R. Dust ingestion rate	g/day	0.03857	Age-weighted value calculated based on US EPA (2011; Table 5-1)
S. DINP ingestion dose	µg/day	131.7	= Q x R
Total exposure by all pathways			
T. Lifetime daily dose	µg/day	154.5	= H + O + S

oeeha.ca.gov/media/downloads/crnrr/sud1supportingmaterials06212016.pdf



OEHHA issued the following Safe Use Determinations as a result of these screening level exposure assessments:

A Safe Use Determination for DINP exposures to professional vinyl flooring installers from **vinyl flooring products containing 8.7% DINP by weight, or less.**

<https://oehha.ca.gov/proposition-65/cnr/issuance-safe-use-determination-exposure-professional-installers-diisononyl>

A Safe Use Determination for DINP exposures to residents of homes and other facilities from **vinyl flooring products containing 18.9% DINP by weight, or less.**

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

OEHHA has issued additional Safe Use Determinations for DINP exposures from other products:

- Fabric used in outdoor furniture products
- Modular carpet tiles
- Single-ply polyvinyl chloride roofing membrane products

<https://oehha.ca.gov/proposition-65/proposition-65-safe-use-determinations-suds>



The SUD Process: Rigorous, DATA-DRIVEN, and Collaborative

Business or Trade
Organization

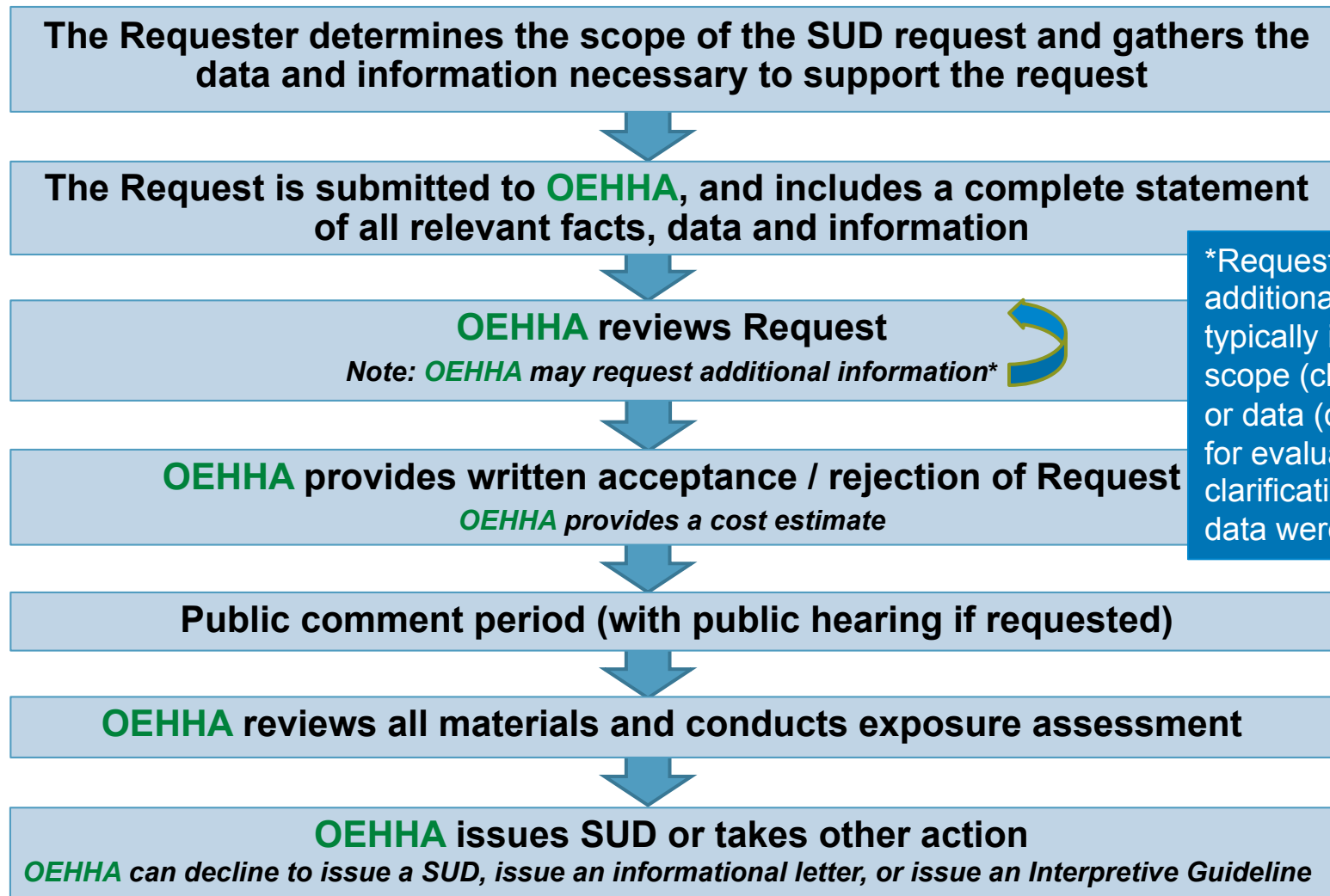
Testing Laboratory

Consultant(s)-
Legal
& Technical

OEHHA



The SUD Process:



*Requests for additional information typically involve scope (clarification) or data (data needed for evaluation and/or clarification as to how data were obtained).



ESSENTIAL ELEMENTS FOR SUCCESS: **Scope of the Request**

The request must be specific to a particular chemical or group of chemicals, and to a particular process/activity or to a particular product or group of products and specified uses of those products.

In reviewing the SUD request for **completeness***, OEHHA looks to see whether the **Scope of the Request** is supported by the description of the relevant facts, and the data and information in the request.

*Note that when issuing a SUD, OEHHA may further limit the scope of the SUD.

Key considerations in developing the Scope of the Request

What do you absolutely need the SUD to cover?

Do you have all the relevant facts, data and information needed for the SUD request? If not, can you obtain the needed data and information?



ESSENTIAL ELEMENTS FOR SUCCESS: **Scope of the Request**

Key considerations in developing the Scope of the Request (continued)

Keep in mind that...

A scope can be fairly narrow.

One chemical in one type of product (crystalline silica, interior flat latex paint) and its uses (covering interior building walls and ceilings)

A scope can be broader, covering multiple products/product lines or for multiple uses.

One chemical in multiple (but related) product lines (DINP, vinyl sheet and tile flooring) and their uses (covering residential, commercial, office, and other floors)

A scope can take into consideration exposures to different users, such as residential and occupational users.

DINP exposures to professional installers of vinyl flooring and DINP exposures to residents / occupants of buildings with vinyl flooring



ESSENTIAL ELEMENTS FOR SUCCESS: Data Submitted

Key considerations

Chemical-specific factors

- Is the chemical volatile? Semi-volatile?
- Can it be absorbed through the skin or in the gastrointestinal tract?

Product-specific factors

- How is the product used?
- Can use of the product result in release or formation of airborne particles or aerosols?

Ways that exposure can result from product use

- Inhalation
- Ingestion
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Data should be **representative** of the product(s) within the scope of the request, covering all relevant exposure routes. For example:

- For products containing a volatile or semi-volatile Proposition 65-listed chemical, air emissions data may be warranted
- For products with food contact applications, data on migration of the listed chemical into food may be warranted

Methods should be scientifically appropriate for the chemical, product, and exposure(s) of concern:

- If migration testing is warranted, it should be performed under testing conditions (e.g., migration matrices, temperature, time) appropriate to the product's use scenario(s).



ESSENTIAL ELEMENTS FOR SUCCESS: Data Submitted

Common pitfalls to avoid (1 of 2)

Submission of data that is not specific to the chemical as listed.

- Example 1. Submitting data on the level of a polymer (made with a listed chemical) that is present in a product, when the polymer is not on the Proposition 65 list.
- Example 2. Submitting data on the amount of crystalline silica **of any size** that released from use of a product, when the substance on the list is “crystalline silica (airborne particles of **respirable size**)”.

Submission of data that is not sufficient to estimate exposure

- Providing only chemical concentration data for a product, without results of tests that would inform release of the chemical from the product, such as migration studies, chamber studies, or product- or hand-wipe data.



ESSENTIAL ELEMENTS FOR SUCCESS: Data Submitted

Common pitfalls to avoid (2 of 2)

Insufficient product-specific data provided / no product-specific data provided

- Submitting data for a single sample not sufficiently representative of product(s) within the scope of a request.
 - Note: if data from one product is intended to cover multiple products/ product lines, additional data and information may be required to support this.
- Submitting measured data from other products or publications.
- Submitting a request reliant on modeled data that have large uncertainties associated with the models or parameters.
 - Note: some empirical data on critical exposure routes are preferred for exposure assessment.

Insufficient QA/QC documentation for evaluation of method/data quality

- Measures not made in replicates appropriate for approach / method used.



ESSENTIAL ELEMENTS FOR SUCCESS: Data Submitted

Examples from granted SUDs of data provided to OEHHA

Data including a chamber study for air emissions, modular vinyl carpet tile wipes, and hand-wipes from simulated users were submitted for use of DINP in modular vinyl carpet tiles.

Data including a series of pour tests, with measurements of respirable dust every 10 seconds over 3 minutes following the initial pour, were submitted for crystalline silica in packaged sorptive mineral-based pet litters.



Safe Use Determination Resources

Regulations

Title 27, Cal. Code of Regs., section 25204 Safe Use Determination

SUD Home Page

Includes notices of Accepted SUD Requests and Granted SUDs as well as the SUD Fact Sheet with Check List

<https://oehha.ca.gov/proposition-65/proposition-65-safe-use-determinations-suds>

