

SAFE USE DETERMINATION (SUD) REQUESTS: ESSENTIAL ELEMENTS

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Prop 65 Clearinghouse Conference
September 24, 2018



What is a SUD Request?

- Request is 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?



What is Exposure?

Article 1, 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?



What is Exposure?



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

Business or Trade
Organization

Testing Laboratory



OEHHA

Technical
Consultant



The SUD Process

1. Consider contacting OEHHA **before** submitting a SUD request

You are strongly encouraged to contact OEHHA informally- we can provide **confidential** guidance on what should be included in your SUD request.

2. Prepare and submit request for SUD

Determine the scope of your request

Complete statement of all relevant facts, data, and information

Description of each process, product, and activity in the scope of request

Exposure levels associated with the product(s) or activity

Frequency/duration of relevant product use/activity

3. **OEHHA:** Review of request

OEHHA may request additional information*

Requestor to respond within 30 days



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

4. **OEHHA:** Written acceptance / rejection of request

Requestor provided with cost estimate

5. Public comment period

A public hearing may be requested

6. **OEHHA:** Review request and public comments and conduct exposure assessment

OEHHA may request additional information

Requestor to respond within 60 days

Periodic invoices

7. **OEHHA:** Issue SUD or take other action

OEHHA can decline to issue a SUD, issue an informational letter, or issue an Interpretive Guideline

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
- Skin contact
- Transfer from hands to mouth



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>

