

SAFE USE DETERMINATION (SUD) REQUESTS: ESSENTIAL ELEMENTS

Reproductive and Cancer Hazard Assessment Branch
Office of Environmental Health Hazard Assessment



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?



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

Business or Trade
Organization

Testing Laboratory



Technical Consultant

OEHHA



The SUD Process

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

You are 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

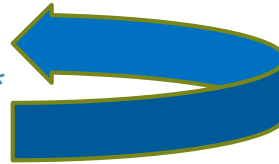
Exposure levels associated with the product(s) or activity

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 /will 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

Data should be **representative** of the product(s) within the scope of request, covering all exposure routes.

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



ESSENTIAL ELEMENTS FOR SUCCESS:

Data Submitted

Common pitfalls to avoid

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
- A request reliant on modelled 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 for submitted data

- Measures not made in replicates appropriate for the approach/method used.
 - Note: inclusion of validation data allows for evaluation of method and data quality



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 (residential and installer) 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 Process Guidance

<https://oehha.ca.gov/proposition-65/proposition-65-safe-use-determination-sud-process>

SUD Fact Sheet & Check List

https://oehha.ca.gov/media/downloads/crn/sudfactso3112016_o.pdf

