

Fact Sheet on Proposition 65 Safe Use Determination (SUD) Process

Q. What is the purpose of this fact sheet?

A. This fact sheet is intended to inform businesses and the public about the process that OEHHA uses to develop Safe Use Determinations (SUDs) under Proposition 65. This is often a rigorous process that can nevertheless clarify important questions as to whether a business' products are subject to Proposition 65 requirements. By providing this SUD "road map," we hope to make the SUD request process as smooth and transparent as possible.

Q. What is Proposition 65 and what does it require?

A. In 1986, California voters approved the Safe Drinking Water and Toxic Enforcement Act of 1986, often referred to as Proposition 65, to address their growing concerns about exposure to toxic chemicals. Proposition 65 requires the State to annually update and publish a list of chemicals known to cause cancer or birth defects or other reproductive harm. Proposition 65 requires businesses to notify Californians when they expose them to listed chemicals. By requiring these warnings, Proposition 65 enables Californians to make informed decisions about protecting themselves from exposure to toxic chemicals.

Proposition 65 also prohibits California businesses from knowingly discharging significant amounts of listed chemicals into sources of drinking water.

Q. What are the warning requirements?

A. Current law states that "no person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the State to cause cancer or reproductive toxicity without first giving a clear and reasonable warning. "If you do business or put products in the stream of commerce in California, you should review the Proposition 65 list to determine if your products or activities are likely to expose individuals to any of those chemicals. If you anticipate causing such an exposure, you must provide a warning. Regulations explaining how to provide a warning are found in Title 27, California Code of Regulations, section 25601.

Q. Are there exceptions to the warning requirements or discharge prohibition?

A. Yes. Small businesses with fewer than 10 employees, governmental agencies, and public water systems are exempt from the warning requirements and discharge prohibition of Proposition 65.

Also, businesses do not have to provide a warning if the exposures they cause are so low

as to create no significant risk of cancer or birth defects or other reproductive harm. It is the responsibility of the business causing the exposure to determine whether the exposure poses no significant risk.

For a chemical that causes cancer, the No Significant Risk Level (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 chemical over a 70-year lifetime. In other words, a person exposed to the chemical at the NSRL for 70 years would not have more than a one in 100,000 chance of developing cancer as a result of that exposure.

For a chemical that causes birth defects or reproductive harm, the No Observable Effect Level (NOEL) is determined by identifying the highest level of exposure that has been shown to pose no harm to humans or laboratory animals. Proposition 65 then requires this NOEL to be divided by 1,000. Businesses subject to Proposition 65 are required to provide a warning if they cause exposures to chemicals listed as causing birth defects or reproductive harm that exceed 1/1000th of the NOEL, also referred to as the Maximum Allowable Dose Level (MADL).

To assist businesses, the Office of Environmental Health Hazard Assessment (OEHHA) develops numerical guidance levels, known as “Safe Harbor numbers.” A business does not need to provide a warning for exposures below the “Safe Harbor” level and the discharge prohibition also does not apply if discharges are below the Safe Harbor level. OEHHA has established Safe Harbor numbers for over 300 chemicals and continues to develop Safe Harbor numbers for listed chemicals. If you would like more information about Safe Harbor numbers please visit: <http://www.oehha.ca.gov/prop65/getNSRLs.html>

Q. Who implements and enforces Proposition 65?

A. OEHHA implements Proposition 65, including coordinating the various processes for listing chemicals. The California Office of the Attorney General, local prosecutors and private attorneys enforce the law.

Q. What is a Safe Use Determination (SUD)?

A. A Safe Use Determination (SUD) is a written statement issued by OEHHA, which interprets and applies Proposition 65 and its implementing regulations to a specific set of facts in response to a request by a business or a trade group. Requests for SUDs seek OEHHA’s determination whether an exposure or discharge of a listed chemical resulting from specific business actions or the average use of a specific product is subject to the warning requirement or discharge prohibition. The SUD determines if the discharge or exposure is at or below the Safe Harbor number. Regulations setting out the requirements for requesting a SUD are found in Title 27, California Code of Regulations, section 25204.

Q. What are some of the reasons a business or trade group might request a SUD from OEHHA?

A. A SUD is a tool that can provide verification to businesses that their product or operating practices comply with the requirements of Proposition 65. A SUD can also provide important assurance to the public that a given product or activity is in compliance with Proposition 65. Businesses that request a SUD are usually fairly certain that their product or activities do not require a warning or do not violate the discharge prohibition, and would like a best judgment made by OEHHA to reinforce their claim. Based upon the specific set of facts presented in your request, OEHHA can issue a decision representing our best judgment on whether the discharge or exposure in question complies with the law and regulations, or whether the exposure in question requires a warning.

Q. Who can request a SUD?

A. Any business that meets all of the following conditions can request a SUD:

- The business (or businesses represented by a trade organization) is subject to the requirements of Proposition 65 (it has 10 or more employees);
- The chemical of concern is listed under Proposition 65 as known to cause cancer, or reproductive or developmental harm;
- The subject matter of the request is **not**:
 - 1) at issue in a civil or criminal case pending in any court,
 - 2) the subject of a notice of violation to the Attorney General, or a district attorney; or
 - 3) at issue in any administrative proceeding pending before a federal, state or local agency; and
- The business process or subject matter to be considered for the SUD involves a current or planned activity (e.g., it is not hypothetical or a request for a determination on several alternative plans).

Q. How broadly may a SUD be applied?

A. A SUD applies only to the business or trade group that requested it and the specific chemical(s), product(s), uses or processes specified in the determination.

For example, a business may request a SUD for a specific chemical listed under Proposition 65 which is present in a topical lotion, when the lotion is used under a specific set of conditions. In response to this request, a SUD may be issued for the specified chemical in the specified topical lotion, when used under a specific set of conditions, and when present in the lotion at a specified concentration. The SUD will not apply if the concentrations of the specified chemical in the lotion are greater than specified amount, or to other uses of the lotion, or to other lotions not specified in the SUD. In addition, if the lotion contains another chemical listed under Proposition 65 which was not specifically

identified and included in the request, the SUD will not apply to that other listed chemical. If, in this example, the requester wishes the SUD to apply to both listed chemicals present in the topical lotion, then the requester must clearly specify this in the request for the SUD. Thus, a SUD is specific to a particular chemical(s) in a particular product, or range of products, used in a specified manner.

If during the course of the initial evaluation of a SUD request (prior to acceptance), the available data indicate the scope of the SUD should be narrower than that in the original request, we will consult with the requester to determine if the requester wishes us to continue with the evaluation. After acceptance of a SUD request we may also find it necessary to narrow the scope of the SUD depending on the availability of data to support the request.

Below are examples of SUDs issued by OEHHA in the past:

- A SUD issued to Sorptive Mineral Institute, for crystalline silica in packaged sorptive mineral-based pet litters that are purchased and poured by the consumer, used by the pet, disposed of by the consumer, and replenished by the consumer.
- A SUD issued to the National Paint and Coatings Association, for crystalline silica in interior flat latex paints containing 6% crystalline silica, or less, with diatomaceous earth as the sole source of crystalline silica.
- Information on current activities is available at: http://www.oehha.ca.gov/prop65/CRNR_notices/safe_use/index.html.

Q. What is the Requester's role in the SUD process?

A. The requester is required to provide all relevant facts and information, such as:

- A complete description of and all relevant information on the processes, product or activity in question.
- Data concerning anticipated consumer or public exposure to the chemical through the product or activity in question.
- Data concerning the frequency and duration of use of the product or activity.

The requester is responsible for paying any costs we will incur in evaluating the request.

Q. What is OEHHA's role in the SUD process?

A. OEHHA will:

- Review the information and data submitted.
- Evaluate the adequacy of information and data submitted.
- Request additional information, data and/or published literature and other supporting documents, if needed.

- Estimate exposure to the listed chemical through use of the product or activity and compare it with the Safe Harbor number.
- Develop a Safe Harbor number or some other estimate of an intake level if no Safe Harbor number has been adopted.
- Issue the SUD, decline to issue the SUD or issue its opinion in an alternative form (information letter or an interpretive guidance).

Q. What is the usual process for requesting a SUD?

A. Individuals or businesses interested in a SUD are encouraged to contact OEHHA informally to discuss the request. By doing this, we can provide guidance on the types of data and information that should be included in the SUD request. For any questions or assistance, please contact OEHHA Proposition 65 Implementation staff at 916-445-6900.

The SUD request and the required application fee of \$1,000 are submitted to the OEHHA Deputy Director for Scientific Affairs. A SUD request is considered confidential until it is formally accepted in writing by OEHHA.

During the initial review of the request, we may request additional information, such as exposure data. If the information is not received within 30 days, the request will be closed. If the requested information is submitted after 30 days, the request may be reopened and a new application fee will be required.

After we have determined that the request is complete, a written notice of acceptance will be sent to the requester. The acceptance will include an estimate of the anticipated costs associated with evaluation of the SUD.

A public notice of the acceptance will simultaneously be submitted for publication in the California Regulatory Notice Register (CRNR) and a public hearing date will be announced. At this point, the SUD request is no longer considered confidential, though certain information provided by the requester (such as trade secrets) may be protected.

Q. What happens after the SUD request is accepted?

A. We will examine all of the information and data provided by the requester and any additional information available concerning the chemical in question. (See OEHHA's role in the SUD process, above).

At any time after a request has been accepted, we may request additional information or data from the requester. The requester has 60 days to provide the additional information or data unless we agree in writing to an extension of the 60-day period.

We will evaluate the request after careful consideration of the information and materials submitted or otherwise identified, including oral and written comments received during the public comment period and at the public hearing, and comments received from other public agencies.

Following the evaluation, OEHHA can respond by:

1. Issuing a SUD.
2. Declining to issue a SUD.
3. Issuing an information letter.
4. Issuing an interpretive guideline.

A description of the information letter and interpretive guideline can be found in Title 27, California Code of Regulations, section 25102, subsections (l) and (m).

Our response will be sent to the requester and a summary of the response will be sent to interested parties and published in the CRNR.

Q. What information should a request contain?

A. The request should contain:

1. A complete statement of all relevant facts, data and information related to the activity for which the SUD is requested.
2. A description of the business reason for the activity.
3. A detailed description of the product or activity.
4. Copies of contracts, agreements, instruments, reports, data or analyses or other documents that may be relevant to the request.
5. A non-refundable processing fee of \$1,000. This fee should be submitted in the form of a check made payable to OEHHA. This fee does not cover the entire cost of OEHHA's evaluation of the request. Unless OEHHA grants a waiver, the requester will be periodically charged for all costs that are incurred by OEHHA in considering the request, including compensation for staff time.
6. If the activity for which the SUD is sought is only one step in a larger integrated process (e. g. one step in an entire manufacturing process), the description of the activity must include a description of the entire process. This description is vital in a situation where a certain procedure that occurs during a manufacturing process, for example, could potentially increase or decrease the chemical level in the final product.
7. If the applicant believes the SUD needs to contain a specific finding (e.g., a product does not require a Proposition 65 warning), the applicant must provide data to support the finding.
8. If a waiver of fees or other charges for the SUD is requested, due to financial hardship, the request must include an explanation of the basis for granting such a waiver.
9. A statement demonstrating, to the best of the requester's knowledge, the subject matter of the request is not:
 - (A) At issue in a civil or criminal case pending in any court.
 - (B) At issue in any administrative proceeding pending before a federal, state or local agency.
 - (C) The subject of a 60-day notice of violation. For more information

regarding 60-day notices, please see of the Safe Drinking Water and Toxic Enforcement Act of 1986, Health and Safety Code section 25249. 7(d) and Title 27 of the California Code of Regulations, section 25903.

10. The signature of the person making the request for determination. Where the request is made by an authorized representative for an individual or organization, the request must indicate the source of the authority to make the request. (Please also see the attached check list.)

Q. What is meant by “all relevant facts”?

A. The relevant facts are specific to each SUD request. In general, all SUD requests should include a list of products/procedures the requester wishes to include in the request. All data, product/process descriptions, explanations, and relevant peer-reviewed literature that may be necessary to evaluate exposure to the chemical(s) in question or the discharge at issue should also be included. This may include, but is not limited to, information on the product development processes or business procedures from start to finish, frequency and duration of product use, amount of product per use, empirically measured levels of the chemical of interest throughout the process, and any other information necessary to assess likely consumer exposures and risks encountered while using the specified product or process. Proposition 65 does not regulate the amount of a chemical that may be present in a product. The warning requirement applies to exposures to chemicals on the Proposition 65 list. Therefore we will need exposure data, not just chemical concentration levels.

In evaluating a discharge to drinking water, relevant facts may include but are not limited to: the amount of the listed chemical in the discharge, the volume and frequency of discharge and the type and size of the body of water the discharge is or may be entering.

Q. What types of data make OEHHA’s acceptance of the request and issuance of the SUD more likely?

A. Proposition 65 regulations require that the request for a SUD must contain “a complete statement of all relevant facts and information related to the activity for which the SUD is requested.” (Title 27 of California Code Regulations, section 25204(c)(1)). Data generated by scientifically valid testing according to generally accepted principles are needed to support scientific conclusions regarding potential safe uses of products containing listed chemicals. Successful past applicants have provided information such as product analysis data (concentrations or levels of the listed chemical in products, for example), exposure data, and product use data (this can include frequency of use, duration of use, amount of the product used per application). Our confidence in analytic data is generally enhanced by increasing the number of samples tested or the number of trial runs in an experimental setting. Data that help to establish that the information provided is representative of the average users of the product are also helpful.

Q. What constitutes acceptable quality for exposure data?

A. All data should be generated using scientifically valid methodology with good quality control. Data may include chemical concentrations in products, consumer or occupational use patterns, and chemical concentrations released into the environment. Scientifically valid test results include representative and randomized sampling, adequate sample size and precision in measurement data. By providing sufficient and scientifically sound data, the requester enables OEHHA to evaluate the request efficiently and avoid multiple requests for clarification or additional data from the requester.

Q. What if I don't have data or information on exposure to a listed chemical in my product or business activity?

A. If you lack data on exposure to the listed chemical, consider hiring a qualified consultant to help you identify and collect appropriate data prior to making the SUD request. OEHHA does not generate data for SUDs, although we may advise or inform you of the types of data that are needed. When such data are unavailable, our evaluation of the request will rely on conservative assumptions (worst-case scenarios) to estimate exposure and risks if such an evaluation is possible. Furthermore, relying on worst case assumptions will make it less likely that a SUD can be issued.

Q. Does confidential business information on products or activities have to be provided for the SUD?

A. Complete data and information are required to evaluate a SUD request in a timely fashion. To the extent allowed by law, trade secrets or other sensitive data will be kept confidential. However, the health and exposure information that the SUD is based on will have to be disclosable. If you have concerns in this regard, it is best to work with legal counsel to make certain the information can be protected. In the event a SUD request is rejected by OEHHA as incomplete or is withdrawn by the requester prior to issuance of a written acceptance by OEHHA, all data will be returned. Data will not be returned after we have accepted **AND** completed a SUD request. It is recommended that you retain copies of material submitted to us for the SUD request.

Q. Why might a SUD request be rejected as incomplete?

A. It is not possible for us to evaluate a request for a SUD without sufficient data to assess exposure to a listed chemical through the use of the particular product, or specific activity.

Q. Where can I get help in putting together a request for a SUD and the appropriate supporting materials?

A. If you need assistance in putting together the SUD request, we can provide limited

advice. We also recommend that you consider working with a consultant with expertise in exposure assessment. In addition, you may also want to consider consulting an accredited analytical laboratory.

Q. Can a SUD request still be considered if no Safe Harbor number exists for a chemical listed under Proposition 65?

A. Yes, the application will still be considered. Depending on the availability of relevant data and the complexity of the analysis required, we may consider calculating an interim guidance value or some other means to identify an intake level that can be used in the absence of a Safe Harbor number. For example, a Safe Harbor number has not been adopted for “crystalline silica (airborne particles of respirable size),” a chemical listed as known to the State to cause cancer, yet SUDs have been issued for crystalline silica (e.g., in packaged sorptive mineral-based pet litters, and in interior flat latex paints containing 6% crystalline silica, or less, with diatomaceous earth as the sole source of crystalline silica). In the absence of an adopted Safe Harbor number for crystalline silica, we used cancer potency estimates that were readily available from the scientific literature to estimate a range of concentrations of crystalline silica dust associated with one excess case of cancer in 100,000 exposed individuals (i.e., the Proposition 65 Safe Harbor risk level). These concentrations were compared to the estimated exposure levels from use of the product in question to determine the “safe use” of the products.

Q. How much will a SUD request cost?

A. The cost of the SUD includes the following:

1. Processing fee: \$1,000. This initial non-refundable fee must be paid by check to OEHHA.
2. Initial review costs prior to acceptance: OEHHA will provide an estimate of the costs to review the SUD request for completeness and bill the requester periodically for these costs.
3. Evaluation costs: Once a request has been accepted, OEHHA will provide an estimate of the additional costs to evaluate the SUD. These costs will be periodically billed to the SUD requester.

Q. How long is the process from the time an application is accepted before a Safe Use Determination is issued?

A. SUD evaluation times vary considerably based on the complexity of the issues presented. We are not able to guarantee that the evaluation of the SUD materials can be completed within a specific time frame. However, once the request is accepted, we will provide an estimate of the time that will be required to complete the process. We have found that most of the delay in issuing a SUD stems from the time required in providing follow up information. A more thorough submission can accelerate review time. By using the attached checklist, you can help ensure that your request is complete and

eliminate any unneeded delays.

Q. Where can I find regulatory information about SUDs?

A. The regulations regarding SUDs can be found in Title 27 of the California Code of Regulations, sections 25201, 25203, & 25204 and on OEHHA's website at http://www.oehha.ca.gov/prop65/law/pdf_zip/RegsArt2.pdf. In addition to the information attached, the complete set of regulations for the implementation of Proposition 65, including all listed chemicals and adopted Safe Harbor numbers, can be found in Title 27 of the California Code of Regulations, sections 25102-27001. The staff of the Proposition 65 Implementation Unit is another valuable resource for regulatory information on SUDs. Please feel free to contact them at 916-445-9600. They will be happy to answer any questions you may have.



SAFE USE DETERMINATION REQUEST CHECKLIST

PLEASE INCLUDE:

- A complete statement of ALL relevant facts, data, and information related to the activity for which the SUD is requested, including:
 - A complete description of, and all relevant information on, the processes, product or activity.
 - Consumer/public exposure levels via product/activity in question.
 - Frequency/duration of product/activity use by the public.

- A description of the business reason for the activity.
- Any copies of contracts, agreements, instruments, reports, data, analyses and other documents that may be relevant to the request.
- A description of the entire process if the activity for which the SUD is sought is part of a larger integrated process.
- If seeking a specific finding (e. g. , a product does not require a Proposition 65 warning), include data to support the finding.
- A non-refundable processing fee of \$ 1,000, in the form of a check made payable to OEHHA. If a waiver is being sought, due to financial hardship, an explanation of the basis for granting the waiver must be included.

- A statement concerning whether to the best of the requester's knowledge the subject matter of the request is:
 - At issue in a civil or criminal case pending in any court.
 - At issue in any administrative proceeding pending before a federal, state or local agency.
 - The subject of a 60-day notice of violation.

- The signature of the person making the request for determination. In the case of an applicant representing an individual or organization, proof of authority must also be provided.