California Prop. 65:
The Statutory Basics and the Real Scoop

Karen F. Lederer
Troutman Sanders LLP

Eric L. Unis
Troutman Sanders LLP

April 17, 2013
CALIFORNIA PROP. 65:
THE STATUTORY BASICS AND THE REAL SCOOP

by
Karen F. Lederer, Esq.
Eric L. Unis, Esq.

I. WHAT PROP. 65 IS ALL ABOUT

A. What is Prop. 65?


2. Prop. 65 is codified at Health and Safety Code Section 25249.5-25249.13 and is administered by the Office of Environmental Health Hazard Assessment ("OEHHA").

3. Prop. 65 is codified at Health and Safety Code Section 25249.5-25249.13 and is administered by the Office of Environmental Health Hazard Assessment ("OEHHA").

4. There are two sets of regulations under the statute, which are amended from time to time. One set is issued by the OEHHA (the "Regulations"). The second set is issued by the Office of the Attorney General and governs private enforcement of Prop. 65 (the "Enforcement Regulations").

5. Prop. 65 requires the Governor to publish, at least annually, a list of chemicals known to the state to cause cancer or reproductive toxicity. Cal. Health & Safety Code §25249.8. The California Court of Appeals recently held that styrene and vinyl acetate, chemicals listed by the International Agency for Research on Cancer (IARC) as possibly carcinogenic, could not be automatically added to the Prop. 65 list. Chemicals may be included on the Prop. 65 list only if there is a sufficient showing that they in fact cause cancer or reproductive toxicity. Styrene Information and Research Center v. Office of Environmental Health Hazard Assessment, No. C064301 (Cal. Ct. App. Oct. 31, 2012).

6. There are currently more than 800 chemicals on the Prop. 65 list. The list contains chemicals, additives or ingredients present in many common household and office products including toys, jewelry, pesticides, rugs, appliances, luggage, over-the-counter drugs, food, etc.

7. A complete and updated list of chemicals can be found on the OEHHA website, http://www.oehha.ca.gov/prop65.html.

8. "No person in the course of doing business shall knowingly or intentionally expose an individual to a chemical known to the state to cause cancer or reproductive toxicity without
first giving a clear and reasonable warning to such individual, except as provided in

9. Note that Prop. 65 is concerned with all types of exposure: environmental, occupational or
consumer products exposure.

10. “A consumer products exposure is an exposure which results from a person’s acquisition,
purchase, storage, or other foreseeable use of a consumer good, or any exposure that
results from receiving a consumer service.” Cal. Code Regs. 22 tit. §12601(b).

11. Exposure may result from dermal absorption, inhalation, direct mouthing, direct ingestion,
and hand-to-mouth pathway.

B. What Entities are Covered?

1. The law applies to all businesses with 10 or more employees.

2. Typical Prop. 65 actions involve companies that manufacture, distribute, or sell at retail
consumer or commercial products; companies that discharge chemicals into the air or
groundwater; and companies that may be involved in occupational exposures.

3. Retailers with stores in California are affected by Prop. 65 as well as online and catalog
sellers who sell to California residents.

C. What is the Clear and Reasonable Warning Requirement?

1. §25249.6 requires a warning before exposure to any of the listed chemicals. The warning
must be clear and reasonable.

2. According to the Regulations, a warning can appear on a product's label or other
packaging or can consist of identification of the product at the retail outlet through shelf
labeling, signs or menus or a combination thereof. "The method employed to transmit the
warning must be reasonably calculated, considering alternative methods available under
the circumstances, to make the warning message available to the individual prior to

3. "The warning must clearly communicate that the chemical in question is known to the state
to cause cancer, or birth defects or other reproductive harm." Cal. Code Regs. 22 tit.
§12601(a).

4. "Warnings for consumer products exposures which include the methods of transmission
and the warning message as specified by this subsection shall be deemed clear and
5. Common real-life example: "This product contains lead, a chemical known to the state of California to cause cancer."

D. **What are the Exemptions and Safe Harbors?**

1. Exemptions are covered under §25249.10 of the Health and Safety Code. No warning is required if it can be proven that "no significant risk" is presented by a carcinogen or that chemicals causing birth defects would show "no observable effect" at 1,000 times the level of exposure.

2. For cancer, the "no significant risk" level (NSRL) is 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. *See Cal. Health & Safety Code §25249.10(c).*

3. For birth defects, the "no observable effect" level is determined by identifying the level of exposure that has been shown not to pose harm to humans or laboratory animals. This "no observable effect" level then has to be divided by 1,000 to obtain the Maximum Allowable Dose Level (MADL). *Cal. Health & Safety Code §25249.10(c).*

4. The OEHHA has provided Safe Harbor numbers for many of the chemicals on the list. For chemicals for which no Safe Harbor number exists, it is up to the business to prove that exposure falls within an exemption.

### Examples of Safe Harbor Numbers:

<table>
<thead>
<tr>
<th>Chemical</th>
<th>NSRL</th>
<th>MADL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acrylamide</td>
<td>0.2pg/day</td>
<td>140pg/day</td>
</tr>
<tr>
<td>Asbestos</td>
<td>100 fibers/day (inhalation)</td>
<td></td>
</tr>
<tr>
<td>Benzene</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• 6.4 pg/day (oral)</td>
<td></td>
<td>• 24 pg/day (oral)</td>
</tr>
<tr>
<td>• 13pg/day (inhalation)</td>
<td></td>
<td>• 49pg/day (inhalation)</td>
</tr>
<tr>
<td>Cadmium</td>
<td>0.05 pg/day (inhalation)</td>
<td>4.1 pg/day (oral)</td>
</tr>
<tr>
<td>Di(2-ethylhexyl)phthalate</td>
<td>310 pg/day</td>
<td></td>
</tr>
<tr>
<td>Lead</td>
<td>15 pg/day (oral)</td>
<td>0.5 pg/day</td>
</tr>
<tr>
<td>Lead acetate</td>
<td>23 pg/day (oral)</td>
<td></td>
</tr>
<tr>
<td>Lead phosphate</td>
<td>58 pg/day (oral)</td>
<td></td>
</tr>
<tr>
<td>Lead subacetate</td>
<td>41 pg/day (oral)</td>
<td></td>
</tr>
</tbody>
</table>

*Note: The numbers may vary if product exposure is via more than one route of exposure.*
5. Retailers can seek a Safe Use Determinations (SUD) from the OEHHA. A SUD is “a written statement issued by the 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 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.” OEHHA, Fact Sheet on Proposition 65 Safe Use Determination (SUD) Process.

6. As a practical matter, limits can also be established by court-approved settlements (consent judgments).

Example: In the 2010 Aldo case, the Superior Court of the State of California, County of San Francisco entered a consent judgment regarding the content of di(2-ethylhexyl) phthalate (DEHP) in fashion accessories. The court-approved settlement called for a “maximum concentration of DEHP by weight of 1,000 parts per million (ppm) or less in each accessible component.” Held v. Aldo US, Inc, Case No. CGC-10-497729 (Cal. Super. Ct. Oct. 29, 2010).

E. What is the "Naturally Occurring" Exception for Food?

1. Section 25501 of the Regulations governs the application of the "naturally occurring" exception for food.

2. "Human Consumption of food shall not constitute an 'exposure' for purposes of Section 25249.6 of the Act to a listed chemical in the food to the extent that the person responsible for the exposure can show that the chemical is naturally occurring in the food."

3. The exception only applies to the exposure to listed chemicals in foods, or to the exposure to listed chemicals in consumer products, other than foods, to the extent that the defendant can show that the chemical was a naturally occurring chemical in food, and the food was used in the manufacture, production, or processing of the consumer product.

4. A chemical is naturally occurring only to the extent that the chemical did not result from any known human activity.

5. A chemical is naturally occurring in food to the extent that it was not avoidable by good agricultural or good manufacturing practices. The producer, manufacturer, distributor, or holder of the food shall at all times utilize quality control measures that reduce natural chemical contaminants to the "lowest level currently feasible," as this term is used in Title 21 Code of Federal Regulations, Section 110.110, subdivision (c) (2001).
II. THE MECHANICS OF A PROP. 65 ACTION

A. Who can Bring an Action?

1. "Actions pursuant to this section may be brought by the Attorney General in the name of the people of the State of California, by any district attorney, by any city attorney of a city having a population in excess of 750,000, or with the consent of the district attorney, by a city prosecutor in any city or county having a full-time city prosecutor, or as provided by subdivision (d)." Cal. Health & Safety Code §25249.7(c).

2. "Actions pursuant to this section may be brought by any person in the public interest." Cal. Health & Safety Code §25249.7(d).

3. §25249.7(d) creates private attorneys general. This provision led to the creation of a cottage industry consisting of organizations and lawyers who routinely bring Prop. 65 actions. They collaborate with scientists, laboratories and other "investigators" to substantiate their claims.

   Examples: In 2011, Russell Brimer, a California resident working with the law firm the Chanler Group, participated in a total of 62 reported settlements. He was also involved in 30 reported settlements in 2010, and 13 in 2009. Similarly, the Center for Environmental Health was the citizen enforcer in 64 settlements reached in 2009. The same organization reported 37 settlements in 2010 and 107 in 2011.

4. Other top citizen enforcers include Mateel Environmental Justice Foundation, Consumer Advocacy Group, Inc., and Anthony E. Held, Ph.D., P.E.

5. Most Prop. 65 actions are brought by citizen enforcers. In 2011, there were 338 settlements, only 11 of which were brought by the Attorney General. The other 327 settlements were reached in actions brought by citizen enforcers.

B. The 60- day Notice Requirement

1. §25249.7(d)(1) requires 60-days prior notice for citizen enforcers to bring an action in the public interest. The notice must be distributed to the Attorney General, the district attorney, city attorney, or prosecutor in whose jurisdiction the violation is alleged to have occurred, and to the alleged violator.
2. "The notice shall include a certificate of merit executed by the attorney for the noticing party, or by the noticing party, if the noticing party is not represented by an attorney." Cal. Health & Safety Code §25249.7(d)(1).

3. "The certificate of merit shall state that the person executing the certificate has consulted with one or more persons with relevant and appropriate experience or expertise who has reviewed the facts, studies or data regarding the exposure to the listed chemical that is the subject of the action, and that based on that information, the person executing the certificate believes there is a reasonable and meritorious case for the private action." Cal. Health & Safety Code §25249.7(d)(1).

4. The Enforcement Regulations specify in §3101 that proving the existence of a reasonable and meritorious case "requires not only documentation of exposure to a listed chemical, but a reasonable basis for concluding that the entire action has merit. The certifier must have a basis to conclude that there is merit to each element of the action on which the plaintiff will have the burden of proof. The certifier does not need to have a basis to conclude that it will be able to negate all affirmative defenses, but must certify that the information relied upon does not prove that any affirmative defense has merit." Cal. Code Regs. 11 tit. §3101.

C. Recent Development:

1. On February 4, 2013, Assembly Member Mike Gatto (D-Los Angeles) introduced legislation AB 227 to provide a mechanism whereby companies could attempt to avoid Prop. 65 liability.

2. Under the proposal, an entity receiving a 60-day notice would have 14 days to correct the alleged violation and demonstrate to the Attorney General, city attorney or district attorney in whose jurisdiction the notice is filed that the violation has been corrected.

3. If the Attorney General, city attorney or district attorney concurs that the violation has been corrected, the bill would prohibit the commencement of an enforcement action.

4. Legislation AB 227 would thus impose new duties on local agencies with regard to concurring in the correction of a violation.

5. The bill requires a two-thirds vote of the Legislature to be approved.
III. LITIGATING A PROP. 65 ACTION

- To prevail, the defendant must show the absence of the chemical; or that the level falls within an exemption or Safe Harbor; or that its current warning is adequate. See §25249.10(c); see also below "Defenses" in "Litigating a Prop. 65 Action."

- Only a handful of Prop. 65 cases have gone to trial. Settling is almost always the only cost effective way of dealing with a Prop. 65 action.


A. What is at Stake?

1. The Civil Penalty
   
   i. “Any person who has violated 25249.6 shall be liable for a civil penalty not to exceed $2,500 per day for each violation in addition to any other penalty established by law.” *Cal. Health & Safety Code* §25249.7(b)(1).

   ii. The appropriate method for calculating the penalty remains unclear. The most aggressive Prop. 65 plaintiffs argue that each product constitutes an individual violation. It is generally accepted that civil penalties should not exceed $912,500.00 ($2,500 per day for 365 days, based on the statute of limitations). See below discussion of statute of limitations in "Defenses."

   iii. Unlike in class actions, the Enforcement Regulations indicate in §3203(a) that a settlement with little or no penalty may be entirely appropriate.

   iv. The civil penalty may be reduced by payments to funds for environmental activity, public education programs, and funds to the plaintiff for additional enforcement of Prop. 65 or other laws. Certain requirements must be met. See *Cal. Code Regs.* 11 tit. §3203(b). In 2011, out of settlements totaling $16,286,728.32, attorneys fees and costs comprised $11,941,918.82. In 2010, out of total settlements totaling $13,629,981.00, attorneys fees and costs comprised $7,806,539.00. That means that in 2011, 73% of settlement amounts went to attorneys fees and costs, 14% went to civil penalties and 13% went elsewhere.

   v. The plaintiff is entitled to 25% of any civil penalty recovered while 75% of the penalty must be provided to the Department of Toxic Substances Control. See *Cal. Code Regs.* 11 tit. §3201(f) and §3203(a).

2. Attorneys Fees
   
   i. Plaintiffs are entitled to the cost of bringing a Prop. 65 suit, including their reasonable attorneys fees.
ii. §3201 of the Enforcement Regulations governs the award of attorneys fees. It adopts the test found in the Code of Civil Procedure and "permits an award of attorney's fees to a successful party in any action which has resulted in the enforcement of an important right affecting the public interest if (a) a significant benefit has been conferred on the general public or a large class of persons, (b) the necessity and financial burden of private enforcement are such as to make the award appropriate, and (c) such fees should not in the interest of justice be paid out of the recovery, if any." Cal. Code Regs. 11 tit. §3201.

iii. Under §3201(a), a plaintiff can be found successful even if the defendant changed its conduct prior to the entry of a court order or judgment, "if the plaintiff was the cause or 'catalyst' of the change in conduct." Cal. Code Regs. 11 tit. §3201(a).

iv. However, if a defendant is successful in defending a Prop. 65 action, it will generally not be awarded attorneys fees. DiPirro v. Bondo, 153 Cal. App. 4th, at 199-200 (finding that a manufacturer of paint containing toluene demonstrated that its product was exempt from the warning requirement and that the plaintiff's case was frivolous. The court determined nonetheless that attorneys fees for the defendant were inappropriate because the principal objective and consequence of the defense was to advance the defendant's economic interest, not to enforce an important right affecting the public interest.). But see § 25 249.7(h)(2)

v. There has been increased criticism over plaintiffs' requests for attorneys fees. The Office of the Attorney General has been more aggressive in looking at settlements and asking the court to reject settlements when attorneys fees seem excessive.

Example: In Held v. Aldo U.S. Inc, Case No. CGC-10-497729 (S.F. Super. Ct., filed March 11, 2010), plaintiffs alleged that numerous fashion accessories contained unsafe levels of phthalates. A first group of defendants agreed to settle the case and pay $2,274,076.68 in attorneys fees. When the parties sought to add additional companies to the settlement, the plaintiff's attorneys requested an additional $3,424,674.05 in attorneys fees. The Attorney General intervened to ask the court to reject the new agreement, arguing that the plaintiffs' attorneys, the Chanler Group, had completed little additional work to justify the additional fees. After substantial motion practice and oral arguments, the Attorney General and the plaintiffs came to an agreement of $2,338,869.79 in additional attorneys fees.

3. Injunctive Relief

i. §25249.7(a) provides that "any person that violates or threatens to violate 25249.5 or 25249.6 may be enjoined in any court of competent jurisdiction." Cal. Health & Safety Code §25249.7(a).
B. Defenses

1. Statute of Limitations
   i. Under the California Code of Civil Procedure, the statute of limitations for statutory penalties is 1 year and the one for injunctive relief is 3 years. It is generally accepted that the statute of limitations for Prop. 65 actions is 1 year.
   ii. However, plaintiffs have argued that a 4 year statute of limitations should apply, based on the Business and Professions Code. Indeed, with Prop. 65 claims, plaintiffs often bring a second cause of action under the Unfair Competition Law, which is codified under §17208 of the Business and Professions Code. They essentially allege that the Prop. 65 violation constituted an unfair business practice. The statute of limitations under the Business and Professions Code is 4 years. See Consumer Defense Group v. Shell Oil, 2006 Cal. App. Unpub. LEXIS 7885, n. 10 (Aug. 31, 2006); see also Consumer Advocacy Group v. Exxon Mobil Corporation, 104 Cal. App. 4th 438 (Cal. 2nd App. Dist., Dec. 17, 2002).

2. Defective Notices
   i. If a court determines that the 60-day notice is defective, it may require a plaintiff to begin the entire process anew.
   ii. Tip: A Prop. 65 defendant should always ask to see the citizen enforcer's testing which is alleged to support the Prop. 65 notice.

3. Exposure is not excessive
   i. Defendants may be able to demonstrate that no warning is required because the exposure level does not violate Prop. 65.
   ii. In some cases there is an accepted Prop. 65 test that can be administered by a lab.
   iii. An exposure defense may require expert opinion on human behaviors that can lead to exposure as well as on rates of absorption resulting from dermal exposures, inhalation, ingestion or other routes.
   iv. Plaintiffs often try to establish an unreasonable standard for determining exposure. They usually seek to analyze the most extreme usage or the most vulnerable user in calculating exposure.

Example 1: In DiPirro, the court adopted the defendant's method for calculating the level of exposure. It found that 75 to 85 percent of the population that may use the defendant's paint did not reach levels of exposure to toluene above the statutory limit. The court rejected the plaintiff's argument that it should apply a "no consumer" standard. The "no consumer" standard dictates that the defendant would have to conduct a bounding study to show that no portion of the population that uses the

Example 2: In *Mateel Environmental Justice Foundation v. Taprite-Fassco MFG, Inc.*, Case No. CGC-11-512718 (Super. Ct. Cal, 2012), the plaintiff alleged that the defendants' kegerators (refrigeration and dispensing units for kegs of beer) contained lead. One of the issues during settlement negotiations was who were the ordinary purchasers of this "party product" and how often the product really got used.

4. Adequate Warnings
   i. Defendants may be able to prove that the warnings they have in place are clear and reasonable.

C. Settling a Prop. 65 Case

1. Settlement guidelines are included in Chapter 3 of the Enforcement Regulations.

2. Under §25249.7(f), a settlement, judgment or any final disposition must be reported to the Attorney General. *Cal. Health & Safety Code §25249.7(f)*.

3. Plaintiffs typically seek injunctive relief to prevent future offending conduct.

4. Injunctive relief includes reformulation and arrangements to post appropriate warnings.

5. Opt-in settlements
   i. A company opting into a court-approved settlement obtains the benefits of its terms and release even if that business has not been sued and has only received a 60-day notice.
   
   ii. Note: there is usually a limited time for opting in.

   iii. Opt-in settlements often provide for various settlement categories with monetary amounts predetermined based on several factors including the defendant's position in the chain of commerce, the number of products at issue and how quickly a defendant is willing to reformulate its product.

   Example: In 2010, the required payment for the opt-in settling defendants in the *Aldo* case varied from $28,000 to $54,000 based on the following factors: (1) the number of types of fashion accessories to which the Consent Judgment would apply (one, two, or three categories); (2) whether the company seeking to opt-in was named in a pre-suit Notice of Violation from the Center for Environmental Health on or before August 11, 2010, that alleged the presence of lead in any type of fashion accessory; and (3) by which of three deadlines the defendant promised to reformulate its products.
IV. THE BEECH-NUT CASE: PROP 65 ON TRIAL

1. An ongoing case, Environmental Law Foundation v. Beech-Nut Nutrition Corp. et al, Case No. RG11597384 in the Superior Court of California, County of Alameda, is likely to profoundly affect the interpretation of the statute.

2. The case involves 28 food manufacturers and retailers. The Environmental Law Foundation alleges that the defendants have sold over 100 food products containing lead, including baby food. These products were sold in California without Prop. 65 warnings.

3. The complaint was filed on September 28, 2011, and trial began on April 08, 2013. The trial involves only the manufacturer defendants.

4. The case is set to address 3 major issues:
   i. Whether Prop. 65, as applied to these products, is preempted by federal law;
   ii. Whether the lead in the products is exempted from Prop. 65 because it is naturally occurring; and
   iii. Whether the lead exposure in the products is high enough to require a warning, which will warrant a discussion on the appropriate way to measure lead levels in products.

V. COMPLIANCE: TIPS FOR RETAILERS

1. Conduct a thorough audit of your operations and products. This process requires expert assistance.

2. Monitor the list of hazardous chemicals published by the OEHHA. Remember that the list of chemicals is updated quarterly.

3. Once a chemical is listed, businesses have 12 months to comply with the warning requirement.

4. Pay attention to the Safe Harbor and consent judgment limits. The difficulty in understanding Safe Harbor numbers is that they are expressed as exposure limits. However, most consent judgments speak in terms of chemical content and therefore are very useful.

5. Note that issues can arise as to the appropriate manner of calculating exposure. (See above “Defenses” in “Litigating a Prop. 65 Action”).

6. Request a Safe Use Determination (SUD) from the OEHHA. The subject matter of the SUD can involve a current or planned activity.

7. Make sure that shelf labeling and signs are appropriately placed. Signs need to be in close proximity to the identified products, applying a reasonableness standard. The sign
has to be close enough that it would be reasonable for a consumer to see it when making a decision whether to purchase the product.

8. Implement a reasonable testing program to ensure ongoing compliance. Most prominent labs have Prop. 65 expertise.

9. To the extent possible, agreements with suppliers should provide for indemnification in the event of a Prop. 65 action.

10. If your supplier is also a target or a defendant, try to ride that supplier's coattails.