

# **PROPOSITION 65 COMPLIANCE 101**

**Proposition 65 Clearinghouse Conference  
September 2022**

# **PROPOSITION 65 COMPLIANCE 101**

## **SESSION GOALS**

- **Provide an overview of the:**
  - **Nuts and bolts of compliance**
  - **Key technical and policy issues**
  - **Resources available to support compliance**

# PROPOSITION 65 COMPLIANCE 101

## PRESENTERS

- **Kristi Morioka** – Senior Staff Counsel  
Office of Environmental Health Hazard  
Assessment (OEHHA), Sacramento CA
- **Renee Kalmes** – Principal, Exponent  
Oakland CA
- **Kaya Sugerman** – Director of Illegal Toxic  
Threats, Center for Environmental Health  
(CEH), Oakland CA



# **PROPOSITION 65 COMPLIANCE 101**

## **OUTLINE**

- 1. Introduction**
- 2. Prop 65 Overview**
- 3. Resources for Compliance**
- 4. Prop 65 Assessment**
  - a. List of chemicals**
  - b. Warning Exemption Levels – MADLs, NSRLs, and Safe Harbor Levels**
  - c. Exposure Assessment**
- 5. Risk Management**
- 6. CEH Case Studies**



# **THE SAFE DRINKING WATER & TOXIC ENFORCEMENT ACT OF 1986**

## **PROPOSITION 65**

- **Voter approved initiative passed in November 1986**
- **Requires State to develop list of carcinogens and reproductive toxicants**
- **Warning requirement**
- **Discharge prohibitions**
- **OEHHA is Lead Agency – Administers (no enforcement authority)**
- **Enforced by State Attorney General, local prosecutors and private individuals acting in the public interest**
- **Burden of proof and burden shift**
- **Penalties**

# PROPOSITION 65 LIST

- **Types of chemicals listed:**
  - **Carcinogens** – chemicals that are known to cause cancer in animals or humans
  - **Reproductive Toxins** – chemicals that are known to cause reproductive toxicity (developmental, male reproductive, female reproductive)(Cal. Health & Safety Code § 25249.8)
- **The Prop 65 List:**
  - <https://oehha.ca.gov/proposition-65/proposition-65-list/>

# **PROP 65 LISTING MECHANISMS**

**How do chemicals get listed under Prop 65?**

- 1. Labor Code (LC)**
- 2. State's Qualified Experts (SQE) – CIC and DARTIC**
- 3. Authoritative Bodies (AB)**
- 4. Formally Required to be Labeled (FR)**

# COMPLIANCE ASSISTANCE FROM OEHHA

- **Warnings and Other Regulatory Improvements**
- **Two webpages**
  - **Main OEHHA website, Prop 65 specific page:**  
<https://oehha.ca.gov/proposition-65>
  - **Prop 65 Warnings website:** <https://www.p65warnings.ca.gov/>
- **Safe Harbor Levels**
  - **Maximum Allowable Dose Levels (MADLs)**
  - **No Significant Risk Levels (NSRLs)**
- **Safe Use Determinations (SUD) / Interpretive Guidelines (IG)**
- **Stakeholder Involvement**

# USEFUL RESOURCES FOR PROP 65 COMPLIANCE SUPPORT

- **Main OEHHA website, Prop 65 specific page:**
  - <https://oehha.ca.gov/proposition-65>
- **Prop 65 Warnings website:**
  - <https://www.p65warnings.ca.gov/>
- **Laws and Regulations**
  - <https://oehha.ca.gov/proposition-65/law/proposition-65-law-and-regulations>
- **Cases Interpreting Prop 65**
  - <https://oehha.ca.gov/proposition-65/background/cases-interpreting-proposition-65>

# USEFUL RESOURCES FOR PROP 65 COMPLIANCE SUPPORT

- **California Attorney General – Prop 65 Enforcement Reporting**
  - <https://oag.ca.gov/prop65>
  - 60-day notices
  - AG letters
  - Searchable 60-Notice database
- **Enforcement questions to AG**
  - <https://oag.ca.gov/prop65/contact-us>

# USEFUL LINKS FOR PROPOSITION 65 COMPLIANCE SUPPORT

- **“The Hidden Success of a Conspicuous Law: Proposition 65 and the Reduction of Toxic Chemical Exposures” - Polsky, Claudia and Schwarzman, Megan, (December 1, 2020). Ecology Law Quarterly, Vol. 47, No. 3, 2021.**
  - Qualitative evidence of the law’s indirect roles in influencing legislation, regulation, and business activity to reduce exposure to toxic chemicals.
  - <https://doi.org/10.15779/Z38959C833>
- **“State Law, National Change: How a California Law makes air, water, and products safer for children and families nationwide”**
  - Success stories from 30 years of Proposition 65 – report authored by CEH.
  - <https://ceh.org/wp-content/uploads/2019/07/P65-Successes-2018-National-Version.pdf>
- **Center for Environmental Health v. Lulu NYC, LLC**
  - pages 4-5: injunctive relief & lead limits in fashion accessories.
  - <https://www.oag.ca.gov/system/files/prop65/judgments/2009-00410J1053.pdf>
- **Center for Environmental Health v. Lamb Weston Holdings, Inc.**
  - Pages 3-4: injunctive relief & acrylamide reformulation levels.
  - <https://oag.ca.gov/system/files/prop65/judgments/2016-01412J3851.pdf>
- **Center for Environmental Health v. Trend Textile, Inc.**
  - Page 3: injunctive relief & cadmium reformulation levels.
  - <https://oag.ca.gov/system/files/prop65/judgments/2018-00731J4146.pdf>

STATE OF CALIFORNIA  
ENVIRONMENTAL PROTECTION AGENCY  
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT  
SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986

CHEMICALS KNOWN TO THE STATE TO CAUSE CANCER OR REPRODUCTIVE TOXICITY  
February 25, 2022

The Safe Drinking Water and Toxic Enforcement Act of 1986 requires that the Governor revise and republish at least once per year the list of chemicals known to the State to cause cancer or reproductive toxicity. The identification number indicated in the following list is the Chemical Abstracts Service (CAS) Registry Number. No CAS number is given when several substances are presented as a single listing. The date refers to the initial appearance of the chemical on the list. For easy reference, chemicals which are shown underlined are newly added. Chemicals or endpoints shown in strikeout were placed on the Proposition 65 list on the date noted, and have subsequently been removed.

<u>Chemical</u>	<u>Type of Toxicity</u>	<u>CAS No.</u>	<u>Date Listed</u>
A-alpha-C (2-Amino-9H-pyrido [2,3-b]indole)	Cancer	26148-68-5	January 1, 1990
Abiraterone acetate	developmental, female, male	154229-18-2	April 8, 2016
Acetaldehyde	cancer	75-07-0	April 1, 1988
Acetamide	cancer	60-35-5	January 1, 1990
Acetazolamide	developmental	59-66-5	August 20, 1999
Acetochlor	cancer	34256-82-1	January 1, 1989
Acetohydroxamic acid	developmental	546-88-3	April 1, 1990
2-Acetylaminofluorene	cancer	53-96-3	July 1, 1987
Acifluorfen sodium	cancer	62476-59-9	January 1, 1990
Acrylamide	cancer	79-06-1	January 1, 1990
Acrylamide	developmental, male	79-06-1	February 25, 2011
Acrylonitrile	cancer	107-13-1	July 1, 1987
Actinomycin D	cancer	50-76-0	October 1, 1989
Actinomycin D	developmental	50-76-0	October 1, 1992
AF-2;[2-(2-furyl)-3-(5-nitro-2-furyl)] acrylamide	cancer	3688-53-7	July 1, 1987
Aflatoxins	cancer	---	January 1, 1988
Alachlor	cancer	15972-60-8	January 1, 1989
Alcoholic beverages	cancer	---	April 29, 2011
Alcoholic beverages, when associated with alcohol abuse	cancer	---	July 1, 1988
Aldrin	cancer	309-00-2	July 1, 1988
All-trans retinoic acid	developmental	302-79-4	January 1, 1989
<u>Allyl chloride, Delisted October 29, 1999</u>	<u>cancer</u>	<u>107-05-1</u>	<u>January 1, 1990</u>
Aloe vera, non-decolorized whole leaf extract	cancer	---	December 4, 2015

# PROP 65 LIST

- There are over 900 chemicals on the Prop 65 list.



# WARNING EXEMPTION LEVELS UNDER PROP 65

- Expressed as daily dose (micrograms/day)
- Warning Exemption Levels
  - No Significant Risk Level (NSRL) – one in a hundred thousand lifetime incremental cancer risk
  - MADL – 1/1000 of the No Effect Level for reproductive/developmental effects
- Where to find MADLs and NSRLs
  - Values are described as micrograms per day ( $\mu\text{g}$  /day)
  - <https://oehha.ca.gov/media/downloads/proposition-65//safeharborlist032519.pdf>
- Safe Harbor Levels
  - Intended to provide “safe harbor” for businesses
  - Do not preclude use of alternative levels that can be demonstrated by their users as being scientifically valid.

# DOSE RESPONSE ASSESSMENT UNDER PROP 65

- **What to do if no published NSRL or MADL?**
  - Still responsible for evaluating need to warn
  - Warn?
  - Develop warning exemption level for chemical



# THE PROPOSITION 65 ASSESSMENT PROCESS:

- **Is chemical present?**
- **Does exposure require a warning?**
  - Mere presence of a chemical does not indicate need for warning
  - Warning Exemption levels (e.g., Safe Harbor Levels)
  - Compare estimated exposure to warning exemption levels
- **Consider one chemical at a time under Prop 65**
  - Cumulative risk not addressed

# EXPOSURE ASSESSMENT: GUIDANCE

- **Prop 65 regulations have limited guidance on assumptions to be used to calculate exposure**
  - Exposure Frequency
  - Exposure Duration
  - Averaging time
- **OEHHA Interpretive Guidelines**
  - Behaviors (hand to mouth)
- **OEHHA Safe Use Determinations**
- **Attorney General Letters**
- **EPA Exposure Assessment Guidance**
- **Other – CPSC, ECHA, etc.**



# EXPOSURE ASSESSMENT: TYPES

- **Types**
  - environmental
  - occupational
  - consumer products \*\*\*\*\*
  - food products \*\*\*
- **Assess the “reasonably anticipated rate of exposure”**

# EXPOSURE ASSESSMENT: AVERAGE EXPOSURE LEVEL

- **Proposition 65 warning exemptions based the average level of exposure**
  - Differs from other regulatory programs
  - Some default exposure assumptions provided in regulations
  - What is “average”
  - Naturally occurring chemicals in food exempt
    - Plus “lowest level currently feasible”

# EXPOSURE ASSESSMENT: EXPOSURE AVERAGING TIME

- **Depends on health effect and mechanism of action:**
  - **Carcinogens: compare NSRL to Lifetime Average Daily Dose (LADD) (i.e., over 70 years)**
  - **Reproductive toxicants:**
    - **“The reasonably anticipated rate of exposure shall be based on the pattern and duration of exposure that is relevant to the reproductive effect which provided the basis for the determination that a chemical is known to the State to cause reproductive toxicity.**

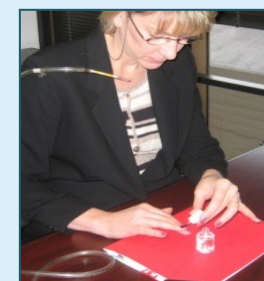
# EXPOSURE ASSESSMENT: SAMPLING

- **Common sources of information about chemicals in your product**
  - Supplier information and testing
  - Your own testing \*\*\*
  - Other relevant information (e.g., publications, plaintiff test results)
  - Specifications – Restricted Substance Lists
  - Raw material controls
  - Test Certificates
- **Do you need to sample?**
  - **OEHHA's regulations do not require a business to perform any testing**
    - If test and find ND within a year, no “knowing discharge or release” and no “intentional exposure” (27 CCR 25900(a))



# EXPOSURE TESTING: CONTENT VERSUS EXPOSURE

- **Typical Product Compliance sampling**
  - “Content” or “concentration” (ppm or mg/kg)
- **Exposure based sampling and risk assessment**
  - Provides more refined data to address what is released or dislodged during product use ( $\mu\text{g}/\text{day}$ )
  - Usually fairly simple but depends on product
  - Addresses exposures such as:
    - Oral: are chemicals released from product when mouthed?
    - Inhalation: are chemicals emitted from product (e.g., adhesives, plastics)
    - Dermal: are chemicals dislodged from product onto skin when handled (e.g., tools, office supplies)
    - Incidental hand-to-mouth: are chemicals ingested after touching product



# RISK MANAGEMENT

- **Warnings**
  - Detailed regulations available - Article 6 Clear and Reasonable Warnings – August 2018
  - Over-warning
- **Consent Judgments, Mediated Settlements, and Court Decisions**
  - e.g., Concentration agreements often in consent judgments
- **Safe Use Determination**
- **Discharge modification**
- **Product Reformulation**



**60 DAY NOTICE OF VIOLATION**

*SENT IN COMPLIANCE WITH CALIFORNIA HEALTH & SAFETY CODE §25249.7(d)*

DATE: May 26, 2017

To: President or CEO – R.C. Bigelow, Inc.  
President or CEO – Bigelow Tea  
President or CEO – Amazon.com, Inc.  
California Attorney General's Office;  
District Attorney's Office for 58 counties;  
City Attorney's for San Francisco, San Diego, San Jose, and Los Angeles.

From: Mr. Floyd Sherrod

I. My name is Floyd Sherrod. I am a citizen of the State of California acting in the interest of the general public. I seek to promote awareness of exposures to toxic chemicals in products sold in California and, if possible, to improve human health by reducing hazardous substances contained in such items. This Notice is provided to the parties listed above pursuant to California Health & Safety Code §12549.6 et seq. ("Proposition 65"). The violations covered by this Notice consist of the product exposures, routes of exposures, and types of harm potentially resulting from exposure to the toxic chemical ("listed chemical") identified below as follows:

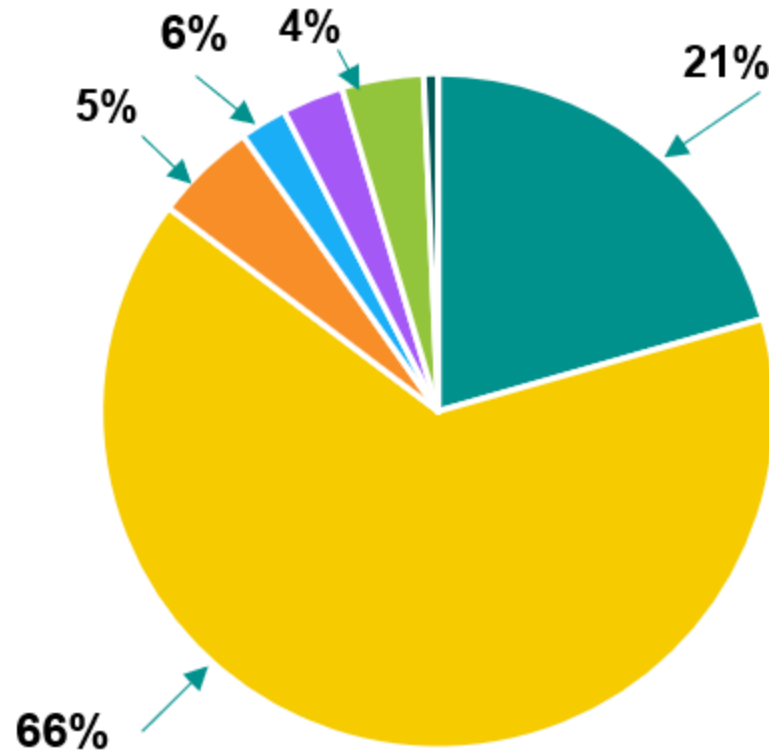
Product Exposure:	See Section VII, Exhibit A
Listed Chemical:	Lead
Routes of Exposure:	Ingestion
Types of Harm:	Birth Defects and Other Reproductive Harm

II. NATURE OF ALLEGED VIOLATION (PRODUCT EXPOSURE)

The specific type of product that is causing consumer exposures in violation of Proposition 65, and that is covered by this Notice, is listed under "Product Category/Type" in Exhibit A in Section VII below. All products within the type covered by this Notice shall be referred to hereinafter as the "products."

The sale of these products in the state of California dating at least as far back as March 20, 2017 are subject to this notice. As a result, exposures to the listed chemical from the use of the products have been occurring without clear and reasonable warnings as required by Proposition 65. Without proper warnings regarding the toxic effects of

# CONSISTENT 60 DAY NOTICE TRENDS CONTINUE



■ Lead                      ■ Phthalates                      ■ Cadmium                      ■ BPA  
■ Carbon Monoxide   ■ Acrylamide                      ■ Marijuana Smoke   ■ Cr+6

# OUR SHARED GOAL: PUBLIC HEALTH



What is the health-protective way to comply with Prop 65?

Remove toxic chemicals from the products that Californians buy and use every day.



# HAZARDOUS LEAD REMOVED FROM TOYS

Lead contaminated toys made headlines in 2007.

Prop 65 litigation followed by a bipartisan federal law successfully ended this hazard.



# LEAD REMOVED FROM FASHION ACCESSORIES



Lead pigments were commonly used in the early 2000s.

The fashion industry worked with CEH to set strict lead limits, as part of Prop 65 litigation.



# ELIMINATION OF CHLORINATED TRIS FROM BABY PRODUCTS



Tris did not provide fire safety benefits.

Following Prop 65 litigation and a change in state regulations, manufacturers eliminated use of this chemical and other flame retardants.

# REDUCTION OF ACRYLAMIDE IN SNACK FOODS



Often found in products marketed as healthier snacks.

Following Prop 65 litigation, companies changed production practices to successfully reduce acrylamide contamination.



# LEAD & CADMIUM REMOVED FROM JEWELRY

Prior to the Prop 65 cases, one study showed that as much as 50% of jewelry purchased in California contained high levels of lead.

Following Prop 65 agreements, fewer than 5% of more than 1,500 pieces of jewelry tested had lead problems.

In 2020, cadmium was found (levels over 90%) in metallic jewelry sold at Ross Dress for Less. Suppliers agreed to reformulate to  $<0.01\%$  Cd.



# REFORMULATION OF BRASS INSTRUMENT MOUTHPIECES



Brass mouthpieces used for brass instruments were found to expose the user to lead.

Legal agreements required manufacturers to reformulate brass products to contain no more than 100 ppm lead.



# FENCE LINE AIR MONITORING FOR HEX CHROME

Southeast LA residents and environmental justice advocates raised alarm about toxic levels of hex chrome in ambient air due to metal processing facility emissions.

Legal enforcement requires emitters to pay for third party hex chrome air monitoring at their fence line when exceedances are detected.

ASP funds purchased over 50 top-of-the-line air filtration systems for homes closest to emitters.



# PRODUCT REFORMULATION



The public health approach to complying with Proposition 65 has effectively reduced Californians' exposure to toxic chemicals.

# QUESTIONS?

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