

Proposition 65: Compliance 101

Proposition 65 Clearinghouse Conference
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Presenters

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Compliance 101 Outline

- Proposition 65 Overview
- Assessing a product under Prop 65
- Warning under Prop 65
- Prop 65 Enforcement
- Alternatives to Warning
- Questions?

Proposition 65



Approved in 1986 by California voters by a 63-37 margin.
A reaction to 1980s perceptions that government was not doing enough to regulate toxic chemicals.



CA Governor responsible for establishing and updating a list of chemicals that cause cancer or reproductive toxicity.



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 **clear and reasonable warning** to such individual...



What Does “expose” Mean?


“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.


Title 27, Article 6, Sec. 25102(i)




Clear and Reasonable Warnings

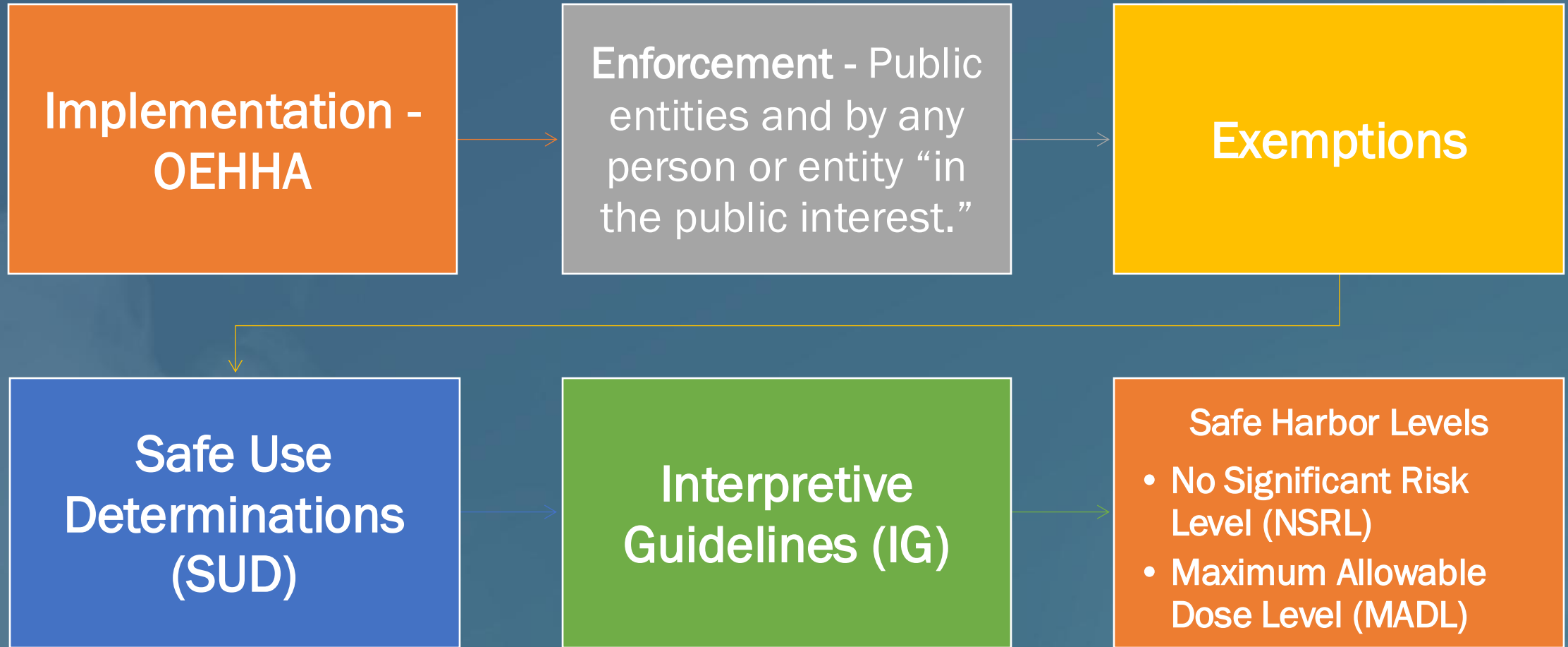
- Businesses - manufacturer, producer, packager, importer, supplier, or distributor of a product, and retail seller.
- OEHHA's regulatory warnings are presumptively clear and reasonable.
- Assists businesses by providing a “safe harbor.”
- Can use other warnings that are clear and reasonable.
- Consumer Product Warnings – Tit. 27 § 25601 -25603



 **WARNING:** Cancer and
Reproductive Harm - www.P65Warnings.ca.gov.

 **WARNING:** Can expose you to formaldehyde,
a carcinogen and toluene, a reproductive toxicant.
See www.P65Warnings.ca.gov

Overview of Concepts in Prop 65



The Proposition 65 Assessment Process

- Determine if substance is present
- Assess exposure to substance
- Compare exposure to Safe Harbor Level

If exposure is < relevant NSRL/MADL, warning is not required!

REMEMBER -

- Prop. 65 warning based on exposure, not mere presence in product
- Consider each Prop. 65 substance individually
- Exposure to substance from other sources not considered

When Considering a New Product:

Is the substance reasonably expected to be present?

Do analytical data show it is present? At what level?

What is the potential exposure? Is it less than safe harbor?

Is the Substance Reasonably Expected to be Present?

- Knowledge of product composition:
 - Manufacturing process and raw materials;
 - Information from suppliers (Safety Data Sheets, Prop 65 statements, supplier test results);
 - Historical test results; and
 - Specifications set on product or raw material.
- Common environmental contaminants (from soil, air, or water)
- Other information (e.g., publications or test results)

Do Analytical Data Show it is Present? At What Level?

- Testing data is often developed to determine the concentration of the listed substance in the product.
- When developing testing data or reviewing testing data, consider:
 - Are the data reliable? Consider: Lab competency, method specificity, data validation
 - Are the samples representative of product?
 - How were samples handled before analysis?

What is the Potential Exposure? Is it Less Than Safe Harbor?

- Concentration in product = mass substance ÷ mass product
- Exposure = mass substance (μg) per day
- **Concentration in Product \neq Exposure**
- How is exposure calculated?
- Remember, there may be multiple routes of exposure (inhalation, dermal, and/or ingestion)
- How does the exposure compare to the safe harbor?

Estimating Exposure to Carcinogens

- Assume lifetime exposure = 70 years
- Lifetime exposure = **level in question** x **reasonably anticipated rate of exposure** for an individual to the given medium of exposure.
 - **Level in question** = concentration in medium of exposure (e.g., water or air)
- Assumptions used to calculate **reasonably anticipated rate of exposure** for general population:
 - Exposed individual ingests 2 L drinking water per day.
 - Exposed individual inhales 20 m³ air per day.

“Reasonably Anticipated Rate of Exposure”

For consumer products, lifetime exposure to a carcinogen shall be calculated using the average rate of intake or exposure for average users of the consumer product

- *Not on per capita basis for general population*

Average rate of intake or exposure

- Based on data for use of a general category or categories of consumer products
- *E.g., USDA Report, Foods Commonly Eaten by Individuals: Amount Per Day and Per Eating Occasion*

Estimating Exposure to Reproductive Toxicants

- Level of exposure = level in question x reasonably anticipated rate of exposure for an individual to a given medium
 - For substance with effect on fetus, level of exposure based on reasonably anticipated rate of maternal exposure during nine-month gestation period
-
- Based on pattern and duration of exposure relevant to the reproductive effect
 - *E.g.*, an exposure of short duration for a teratogenic chemical, vs. protracted exposure for substance that retards fetal growth

Prop. 65 Listings vs. Safe Harbor Levels

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
August 11, 2023

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.

Chemical	Type of Toxicity	CAS No.	Date Listed
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

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In the Listing Mechanism column, "AB" denotes authoritative bodies, "SQE" denotes State's Qualified Experts, "FR" denotes formally required to be labeled or identified, and "LC" denotes Labor Code. For those chemicals for which the basis for listing documentation is available electronically, a hyperlink to the documentation is provided. 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 those chemicals for which a no significant risk level (NSRL) for carcinogens or maximum allowable dose level (MADL) for reproductive toxicants has been adopted, it is denoted in the column, "NSRL or MADL." For those NSRLs or MADLs for which the risk assessment documentation is available electronically, a hyperlink to the documentation is provided.

Chemical	Type of Toxicity	Listing Mechanism	CAS No.	Date Listed	NSRL or MADL
A-alpha-C (2-Amino-9H-pyrido[2,3-b]indole)	cancer	AB	26148-68-5	1-Jan-90	2
Abiraterone acetate	developmental, female, male	FR	154229-18-2	8-Apr-16	
Acetaldehyde	cancer	SQE	75-07-0	1-Apr-88	90 (inhalation)
Acetamide	cancer	AB	60-35-5	1-Jan-90	10
Acetazolamide	developmental	FR	59-66-5	20-Aug-99	
Acetochlor	cancer	SQE	34256-82-1	1-Jan-89	
Acetohydroxamic acid	developmental	FR	546-88-3	1-Apr-90	
2-Acetylaminofluorene	cancer	SQE	53-96-3	1-Jul-87	0.2
Acifluorfen sodium	cancer	AB	62476-59-9	1-Jan-90	
Acrylamide	cancer	AB	79-06-1	1-Jan-90	0.2
Acrylamide	developmental, male	AB	79-06-1	25-Feb-11	140
Acrylonitrile	cancer	FR	107-13-1	1-Jul-87	0.7
Actinomycin D [Basis for listing changed effective February 22, 2013]	cancer	FR	50-76-0	1-Oct-89	0.00008
Actinomycin D	developmental	FR	50-76-0	1-Oct-92	

Approximately **1000** listings for cancer or developmental/reproductive toxicity

Approximately **315** NSRLs + MADLs

Determining Safe Harbor Levels

- Businesses are free to develop and use their own safe harbor levels, even if OEHHA has developed a safe harbor level for a chemical.
- OEHHA regulations (Sections 25703 and 25803) provide guidance for conducting a quantitative assessment needed to develop a safe harbor level from the available data on a substance.
- Business would need to defend its safe harbor level if challenged by an enforcer.

Determining Safe Harbor Levels

- **No Significant Risk Level (NSRL)** – Not more than one excess case of cancer in 100,000 individuals exposed to this chemical over a 70-year lifetime.
- **Maximum Allowable Dose Levels (MADL)** – 1/1000 of the No Effect Level for reproductive/developmental effects.

When To Warn

- Determine “level of exposure” for each route of exposure
- Determine MADL/NSRL
- Compare “level of exposure” to MADL/NSRL
- If exposure > MADL or NSRL, warning may be needed

Case Study: Is a Prop 65 Warning Required?

- **Product:** polystyrene (PS) cottage cheese container
- **Is a substance reasonably expected to be present?**
 - PS is made from styrene monomer;
 - Styrene monomer is listed as a carcinogen on Prop 65; and
 - Styrene has an NSRL of 27 $\mu\text{g}/\text{person}/\text{day}$.

What Do I Need to Know to Assess Exposure?

- Concentration of styrene monomer in container;
- Predicted or measured level of migration into food (concentration of styrene in food); and
- Rate of consumption of cottage cheese.



Styrene Migration Assessment

- Styrene Concentration = 100 $\mu\text{g/g}$ (ppm) in container
- Styrene Migration = 55 ppb ($\mu\text{g/kg}$) in food
 - Based on principles of diffusion
 - Published information on diffusivity of styrene through PS
- Styrene Concentration in Food = “Level in medium”

Rate of Exposure: Cottage Cheese

USDA, *Foods Commonly Eaten by Individuals: Amount Per Day and Per Eating Occasion*

Table 2.048. Total Cottage Cheese: Percentage of persons using food in 2 days and quantities consumed in a day.

Statistic	All individuals age 2 and over	Age (years) and sex											
		2-5		6-11		12-19		20-39		40-59		60 and older	
		Males and females	Males and females	Males	Females	Males	Females	Males	Females	Males	Females	Males	Females
Number in sample	14,262	2,109	1,432	696	702	1,543	1,449	1,663	1,694	1,545	1,429		
Percent of persons using		%											
at least once in 2 days	9.0	7.8	7.5	6.9	8.0	8.5	8.0	8.9	11.0	10.1	12.2		
on 1 of 2 days	8.3	7.4	7.2	6.8	7.5	8.2	7.2	8.5	10.4	8.6	10.3		
on both days	0.7	0.4 *	0.3 *	0.1 *	0.6 *	0.3 *	0.8 *	0.4 *	0.6 *	1.5	1.9		
Quantity consumed in a day (1/2 cup = 105 g)		g											
Mean	75	44	51	89	81	76	66	91	73	95	83		
SEM	4	5	7	17	20	10	7	7	7	9	4		
5th percentile	5	#	3 *	1 *	10 *	1 *	3 *	7 *	6 *	13 *	7 *		
10th percentile	12	1	6 *	13 *	14 *	10	8 *	19	11	19	14		
25th percentile	26	9	20	34 *	31	26	23	32	26	27	30		
50th percentile	50	26	32	51	45	49	38	61	51	70	66		
75th percentile	105	59	61	116 *	93	90	90	112	104	111	108		
90th percentile	206	106	108 *	213 *	151 *	153	120 *	210	209	208	170		
95th percentile	225	122 *	177 *	226 *	280 *	218 *	209 *	222 *	214 *	226 *	217 *		

Appendix Table B. Mean quantities consumed per person per day -- continued

Food (corresponding table)	All individuals age 2 and over	Age (years) and sex											
		2-5		6-11		12-19		20-39		40-59		60 and older	
		Males and females	Males and females	Males	Females	Males	Females	Males	Females	Males	Females	Males	Females
Number in sample	14,262	2,109	1,432	696	702	1,543	1,449	1,663	1,694	1,545	1,429		
Milk and Milk products		g											
Fluid Milk (1.049)	182	313	303	299	178	162	131	164	112	174	140		
Fluid Milk Consumed with Cereal (1.050, 2.046)	57	80	100	90	63	49	43	46	34	65	49		
Whole Milk (1.051)	57	147	104	97	58	53	40	42	25	45	29		
Whole Milk Consumed with Cereal (1.052)	17	41	40	27	22	13	12	8	6	13	10		
Lowfat Milk (1.053)	88	142	160	158	83	80	56	80	47	88	68		
Lowfat Milk Consumed with Cereal (1.054)	28	33	49	49	31	26	18	25	14	34	24		
Skim Milk (1.055)	34	18	32	41	35	27	34	41	39	40	41		
Skim Milk Consumed with Cereal (1.056)	12	5	10	12	10	10	13	12	14	17	14		
Cheese, Other Than Cream or Cottage (1.057)	13	10	11	19	11	21	12	13	10	9	6		
Ice Cream and Ice Milk (1.068, 2.049)	15	10	17	18	17	17	10	19	12	21	13		
Total Milk (2.045)	271	386	413	425	262	256	206	257	191	269	216		
Total Cheese Other than Cream or Cottage (2.047)	21	15	19	35	22	34	20	21	15	14	9		
Total Cottage Cheese (2.048)	4	2	2	3	4 *	3	3	5	4	6	6		

Mean cottage cheese consumption = 75 g/day for consumers of the product

Styrene Exposure Assessment

- Styrene in cottage cheese = $55 \mu\text{g}/\text{kg} = 0.055 \mu\text{g}/\text{g}$
- Mean rate of consumption of cottage cheese = $75 \text{ g}/\text{p}/\text{d}$
- Styrene exposure = $0.055 \mu\text{g}/\text{g} \times 75 \text{ g}/\text{p}/\text{d} = \underline{4.1 \mu\text{g}/\text{day}}$
- Exposure < NSRL
- Warning for styrene is not required


When a Warning is Needed – Methods of Warning

- Sign, shelf tag, shelf sign at each point of display of the product
- Electronic device that automatically provides warning prior to or during purchase
- On the Label
- Internet
- Catalog
- As per the specific regulation





Content of Safe Harbor Warnings

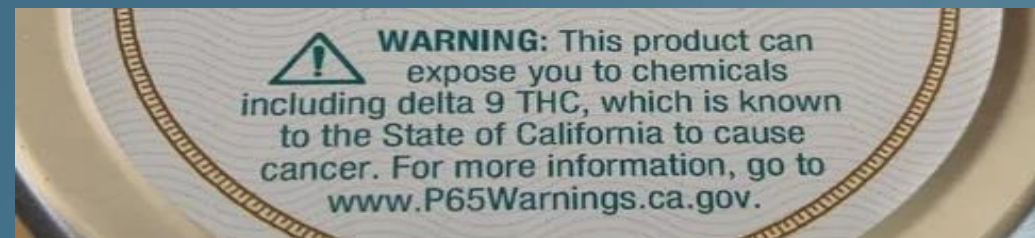
- Full-length warning
- Short-form warning (proposed)
- Tailored warning

 **WARNING:** This product can expose you to chemicals including formaldehyde, which is known to the State of California to cause cancer, and toluene, which is known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

 **WARNING:** Cancer -- www.P65Warnings.ca.gov.

 **WARNING:** Can expose you to formaldehyde, a carcinogen. See www.P65Warnings.ca.gov.

 **CA WARNING:** Cancer risk from exposure to formaldehyde. See www.P65Warnings.ca.gov.



Enforcement of Proposition 65

- **Public Enforcers**
 - Attorney General
 - District Attorneys
 - City Attorneys for cities with a population > 750,000
- **Private Enforcers**
 - “Any person in the public interest”

Prerequisites to Private Enforcement

- 60-Day Notice of Violation
- Certificate of Merit
- No public prosecutor has commenced and is diligently prosecuting an action against the violation
- 60 days has elapsed since service of Notice

Requirements for 60 Day Notices

- Basic Contents of a 60-Day Notice of Violation
 - Description of violation
 - Warning Notices must include route of exposure to listed chemical
 - OEHHA Proposition 65 Summary must be included!
- Additional specific requirements for Notices vary by type
 - Discharge Notice
 - Consumer Product Exposure Notice
 - Occupational Exposure Notice
 - Environmental Exposure Notice

60-Day Notices – What's Not Required?

- UPC, SKU model or design number or stock number or other more specific identification of products.
- Specific retail outlet, time or date where product was purchased
- Level of exposure to listed chemical
- Evidence to prove violation
- Legal description of location of violation

Certificate of Merit Requirement

- What is a Certificate of Merit?
 - Requirement added to statute in 2003
 - Certificate is form set forth in statute and regulations and must be signed by counsel for noticing party
 - Certifier must state that he or she has
 - “consulted with one or more persons with relevant and appropriate experience or expertise who has reviewed facts, studies, or other 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.**”
 - Certificate of Merit is not required for discharge notices.

How to Support Your Certificate of Merit

- Confidential factual support for certificate of merit is served on the Attorney General
 - Must include identity of persons with relevant and appropriate experience that were consulted;
 - Facts, studies or other data regarding exposure to listed chemical that is subject of Notice;
 - Support that there is merit to each element of claim where Plaintiff has the burden of proof.
- Confidential support is not discoverable

Alternative to Warning: Reformulation

- Businesses can comply with Proposition 65 in two ways:
 - (1) Clear and reasonable warnings
 - (2) Reformulating the products so that no warning is required.
- The health-protective way to comply with Proposition 65 is to remove toxic chemicals from the products that Californians buy and use every day.
 - Reformulation can occur via “quiet compliance” without the threat of litigation or through Proposition 65 enforcement settlements.

Tips for Complying with Proposition 65

- Know your suppliers and control your supply chain
- Keep up to date on the science that is coming out surrounding the products you sell
- Test your products
- Maintain a restricted substances list and send specifications to your suppliers for Proposition 65 chemicals commonly found in those products

Questions?

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Useful Resources

- Main OEHHA website, Prop 65 specific page
 - <https://oehha.ca.gov/proposition-65>
- Prop 65 Warnings website
 - www.P65warnings.ca.gov/
- The Prop 65 List
 - <https://oehha.ca.gov/proposition-65/proposition-65-list/>
- Laws and Regulations
 - <https://oehha.ca.gov/proposition-65/law/proposition-65-law-and-regulations>
- Fact Sheets home page
 - <https://www.p65warnings.ca.gov/fact-sheets>



Useful Resources

- Prop 65 Business compliance assistance webpage
 - <https://www.p65warnings.ca.gov/businesses>
- Cases Interpreting Prop 65
 - <https://oehha.ca.gov/proposition-65/background/cases-interpreting-proposition-65>
- Where to find MADLs and NSRLs
 - <https://oehha.ca.gov/proposition-65/general-info/current-proposition-65-no-significant-risk-levels-nsrls-maximum>
- California Attorney General – Prop 65 Enforcement Reporting
 - <https://oag.ca.gov/prop65>



60 Day Notices – Checklist of Requirements

- Contents of a 60-Day Notice of Violation
 - Description of violation
 - Noticing entity information
 - Violator identity
 - Time period during which violation occurred
 - Listed chemical(s) at issue
 - Warning Notices must include route of exposure to listed chemical
 - Ingestion
 - Inhalation
 - Dermal
 - OEHHA Proposition 65 Summary must be included
 - Additional specific requirements for Notices vary by type
- Discharge Notice
 - General identification of discharge or release
 - Identification of source of drinking water where discharge took place
- Consumer Product Exposure Notice
 - Name of specific type of consumer product
 - Description must be specific enough to allow recipients to distinguish those products or services from others sold or offered by the alleged violator for which no violation is alleged
- Occupational Exposure Notice
 - Geographic location where exposures occurred, or
 - Description of occupation or type of task performed by those exposed
- Environmental Exposure Notice
 - Identity, location and source of exposure