

Presented by



Proposition 65 Demystified

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Agenda

- Background – What the law Says
- Enforcement – What actually happens
 - Enforcement action process
- Approaches for Addressing Proposition 65 – What do you do?
 - Test to exposure levels
 - Test to enforcement actions
 - Labeling
- Labeling
 - Content
 - Transmission
 - Proposed updates

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Proposition 65 Demystified

Background – What the law says

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Background – What the law says

- Ballot initiative adopted by California voters in 1986
- Required Governor to publish a list of chemicals that are known to cause cancer, birth defects, or other reproductive harm
- List must be updated at least once a year
- The list is updated and maintained by the California Office of Environmental Health Hazard Assessment (OEHHA)
- As of June 2021, over 890 chemicals have been listed

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Background – What the law says

- What Proposition 65 requires
 - Proposition 65 is a “right to know” law
 - Requires warnings prior to harmful exposure to Proposition 65 chemicals

“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 . . .”
- Warnings
 - Help Californians take whatever action they feel are necessary to protect themselves
 - Make it possible for Californians to make informed decision about the products they buy
- Warnings triggered by
 - Exposure to a harmful amount of a Proposition 65 chemical

Important note: The law does not require products to have a warning label just because it contains a Proposition 65 chemical.

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Background – What the law says

- Warning label is triggered based on **exposure**
 - OEHHA establishes “safe harbor” levels
 - Carcinogens - No Significant Risk Levels (NSRL)
 - Reproductive toxins - Maximum Acceptable Dose Levels (MADL)
 - Products that could result in exposure above the “safe harbor” limits must have warnings
 - “Safe harbor” levels are given in terms of micrograms of exposure per day ($\mu\text{g}/\text{day}$)

Important note: There is no “equation” that can translate micrograms of exposure per day ($\mu\text{g}/\text{day}$) into parts per million (ppm)
 - Toxicological assessment can determine potential exposure

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Enforcement – What actually happens

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Enforcement – What actually happens

- Enforcement is **NOT** carried out by regulatory bodies
 - Enforcement is by lawsuit
 - California District Attorney (DA) / Attorney General (AG) enforce (without notice) or
- **Any private individual can enforce**
 - Notify AG and defendant with enforcement notice (60 day notice)
 - Private enforcement can proceed if AG takes no action in 60 days

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Enforcement – What actually happens

Enforcers

- **Prove “contact” with one or more Proposition 65 chemical (easy)**
 - Only requires total content testing (inexpensive)
 - Reports of hand held XRFs in Stores
- **Settlements often include reimbursement for legal fees**
 - Enforcers are often lawyers

Defendants

- **Prove no significant risk (difficult)**
 - Requires content and / or extraction testing and a toxicological review (expensive)
 - Must also establish safe harbor level if none exists
- Even a successful defense results in legal fees

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Enforcement – What actually happens

- In 2019
 - Total settlement payments: ~ \$30 Million USD
 - Attorney fees: ~ \$23 Million USD (76 % of total payments)
 - total number of settlements: 898
 - Individual settlement payments range: \$5,000 USD - \$350,000 USD
 - Average Settlement cost: \$33,197 USD

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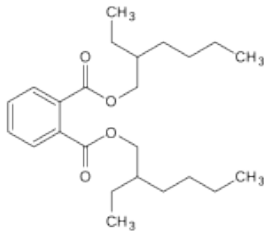


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Enforcement – What actually happens

Chemicals

- § **Lead**
- § **Phthalates**
- § Cadmium
- § Flame retardants
- § BPA
- § CrVI



Materials

- § Ceramics
- § Brass
- § PVC/Vinyl



Products

- § Children's products
- § Household Items
- § Jewelry
- § Hand tools
- § Furniture
- § Apparel



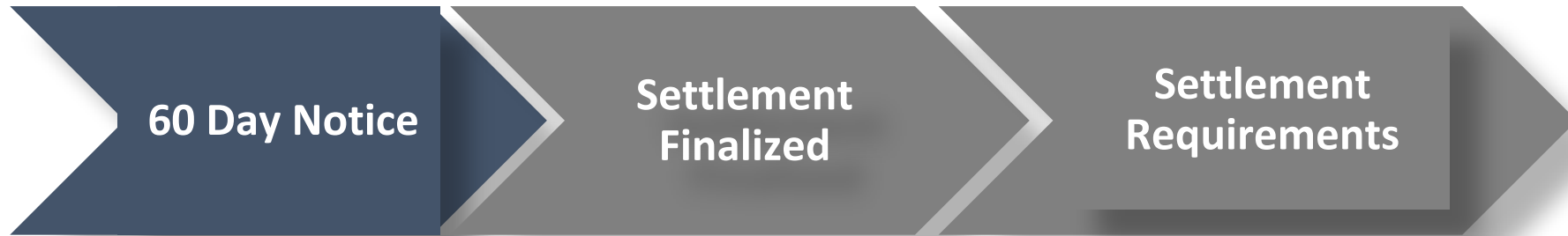
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Enforcement – What actually happens

- The Settlement Process



- § Private enforcers must file
- § Issued prior to legal action
- § Identifies chemicals
- § Identifies Product

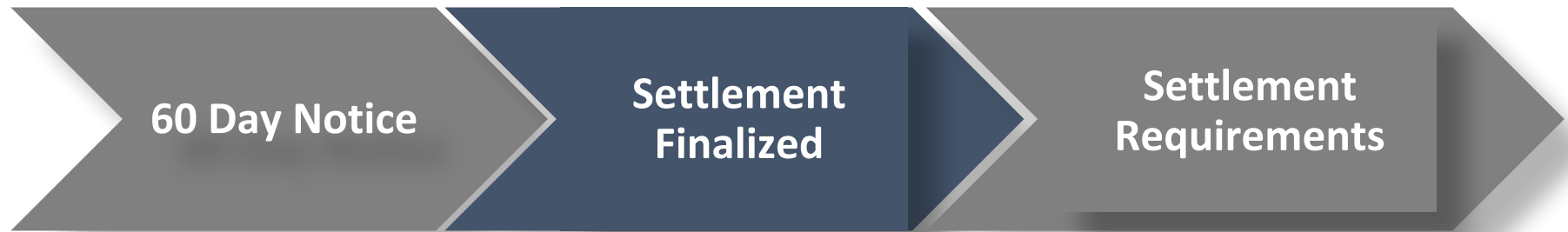
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Enforcement – What actually happens

- The Settlement Process



- § Filed at court
- § Names defendants
- § States chemical(s) and product(s) covered
- § Lists requirements and penalties

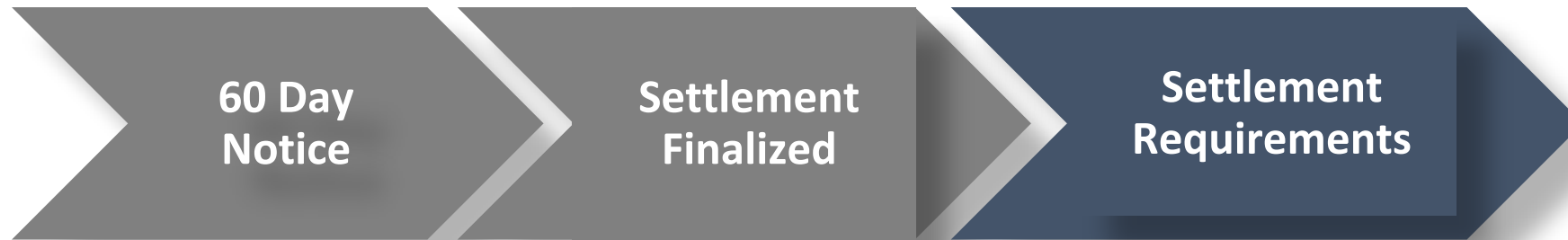
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Enforcement – What actually happens

- The Settlement Process



§ Warnings

- Visible
- “Warning”
- Known to the state of California
- Chemical name
- Harm (Cancer/Reproductive)

§ Reformulation

- Typically given as ppm requirement
- Sometimes prohibits labeling
- May have deadlines

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Approaches for Addressing Proposition 65 – What do you do?

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Approaches for Addressing Proposition 65 – What do you do?

- Test to exposure levels
 - Conduct testing and toxicological assessment to determine potential exposure
 - Conduct risk based testing of Proposition 65 chemicals
 - Perform toxicological assessment of the product and additional testing as needed
 - Determine safe harbor limit if none available
 - Reformulate or label product if exposure exceeds safe harbor limit
- Upsides
 - Comprehensive
 - Provides best assurance that the requirements of Proposition 65 are met
- Downsides
 - Not targeted according to enforcement trends / risk
 - Extremely costly
 - Enforcement is still a risk

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Approaches for Addressing Proposition 65 – What do you do?

- Test to enforcement actions
 - Conduct testing according to finalized Proposition 65 settlements
 - Determine if product was targeted by a finalized Proposition 65 settlement.
 - Conduct testing for chemicals to limits established by applicable finalized Proposition 65 settlement
 - Reformulate or label product if product exceeds limits established by existing settlements
 - Upsides
 - Targets enforcement risk
 - By far the most common industry approach
 - Does not require costly toxicological review
 - Provides best protection against enforcement actions
 - Downsides
 - Does not address all chemical risks
 - Does not guarantee compliance
 - Enforcement is still a risk

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Approaches for Addressing Proposition 65 – What do you do?

- Automatically Labeling based on potential risk
 - Label products without conducting testing based on the risk that it could potentially contain a Proposition 65 Chemical
 - Assess risk based on factors such as material type and previous enforcement of either they same products / product categories or similar ones
 - Label products based on that risk
- The good
 - Ensures no enforcement actions
 - Inexpensive
- The bad
 - OEHHA disapproves
 - Retailers don't like the labels
 - Can affect sales of products

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Labeling Details

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Labeling

- **Warning label contents**



- The warning symbol, consisting of a black exclamation point in a white or yellow equilateral triangle. Symbols should be to the left of the warning text and in a size no smaller than the height of the word “WARNING”.
- The word “**WARNING**” is in all capital letters and bold followed by one of the following:
- For carcinogen related exposure

“This product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause cancer. For more information go to [***.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov)”
- For reproductive toxicant exposures related exposures

“This product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause birth defects or other reproductive harm. For more information go to [***.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov)”

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Labeling

- **Warning label contents (continued)**

- For reproductive toxicant and cancer related exposures

“This product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause cancer, and [name of one or more chemicals], which is [are] known to the State of California to cause birth defects or other reproductive harm. For more information go to ***.P65Warnings.ca.gov”

- For chemicals listed as both a carcinogen and reproductive toxicant


“This product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause cancer and birth defects or other reproductive harm. For more information go to ***.P65Warnings.ca.gov”

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Labeling

- **Warning label contents (continued)**
- For on product warning labels (must be on the product, immediate container, box or wrapper of the product)
-  The warning symbol, consisting of a black exclamation point in a white or yellow equilateral triangle. Symbols should be to the left of the warning text and in a size no smaller than the height of the word “WARNING”.
- The word “**WARNING**” is in all capital letters and bold followed by one of the following:

For carcinogen related exposure: “Cancer - ***.P65Warnings.ca.gov”

For reproductive harm related exposure: “Reproductive Harm - ***.P65Warnings.ca.gov”

For carcinogen and reproductive ham related exposure: “Cancer and Reproductive Harm- ***.P65Warnings.ca.gov”

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Labeling

- Warning transmission - General
 - Prior to exposure – Generally before point of purchase
 - Methods
 - On product
 - Online
 - In catalog
 - In store
 - Clear
 - Not obstructed
 - Product specific
 - Not “some items...”
 - Not in in the general content website

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Labeling

- Warning transmission – Online example 1

5246 Florence Ave Apt B
Bell Gardens
California
90201-8509
United States
7165158556

PAYMENT TYPE

 ADD CREDIT/DEBIT CARD

OR

 PAYPAL


 4 EASY PAYMENTS

4 easy payments is only available for orders above \$30.00 and below \$1,000.00

 AFTERPAY

Afterpay is only available for orders above \$30.00 and below \$1,000.00

WE ACCEPT:      

 Warning: One or more of the products in your bag can expose you to chemicals including lead, which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information go to <https://www.p65warnings.ca.gov>

[View affected products](#)

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Labeling

- Warning transmission – Online example 2

REVIEWS

QUESTIONS & ANSWERS

Important notice

Notice--Bulk Item Packaging.

Please note that this item ships in its own packaging, so the contents may be identified.

WARNING: California's Proposition 65



Proposition 65 Warning

CA WARNING.



WARNING: Cancer and Reproductive Harm - <https://www.P65Warnings.ca.gov/product>


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Labeling

- **Proposed short form warning label changes**

- Only allowed for on product warning labels if total surface area for information is less than 5cm **AND** the long form cannot be accommodated
- **Not** allowed for online or catalog warnings
-  The warning symbol, consisting of a black exclamation point in a white or yellow equilateral triangle. Symbols should be to the left of the warning text and in a size no smaller than the height of the word “WARNING”.
- The word “**WARNING**” is in all capital letters and bold followed by one of the following:

For carcinogens: “**Risk of Cancer from [name of one or more chemicals] Exposure** –***.P65Warnings.ca.gov”

For reproductive harm: “**Risk of Reproductive Harm from [name of one or more chemicals] Exposure** - ***.P65Warnings.ca.gov”

For carcinogen and reproductive harm: “**Risk of Cancer and Reproductive Harm from [name of one or more chemicals] Exposure** - ***.P65Warnings.ca.gov”

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Thank You!

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 @PPAIProfDev

Resources

- PPAI: ***.ppai.org
- PPAI Product Responsibility: *****.ppai.org/inside-ppai/corporate-responsibility/product-responsibility/
- Proposed Proposition 65 changes: <https://oehha.ca.gov/media/downloads/crn/p65shortformproposedregtextd2021.pdf>
- Proposition 65 labeling information: https://***.p65warnings.ca.gov/sample-warnings-and-translations-businesses
- TÜV Rheinland: ***.tuv.com
- Questions? mnudell@us.tuv.com

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