



## Practical Approaches to California Proposition 65 Testing



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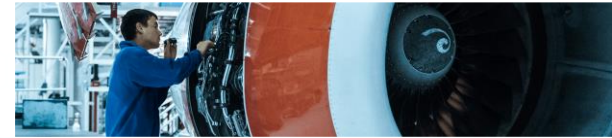
# Example of Proposition 65 Labeling



# NSL Analytical Services

NSL provides independent laboratory testing services to a diverse array of customers where testing **speed**, **accuracy** and **consistency** are mission critical to operations.

Our teams of **chemists**, **engineers** and **metallurgists** provide scientific expertise in materials testing with a focus on metals, polymers and technical ceramics used in critical end markets such as aerospace, oil & gas, energy, chemicals and metallurgy.



|                                  |                           |                       |
|----------------------------------|---------------------------|-----------------------|
| Chemical Analysis                | Thermal Analysis          | Physical Properties   |
| Microscopy & Metallography       | Particle Characterization | Mechanical Testing    |
| Metallurgical / Failure Analysis | Consulting                | Regulatory Compliance |

# What we'll talk about today...



## Introduction to Prop 65

- ➔ Compliance requirements
- ➔ Misconceptions
- ➔ Chemicals and types of materials

## Strategies for Compliance

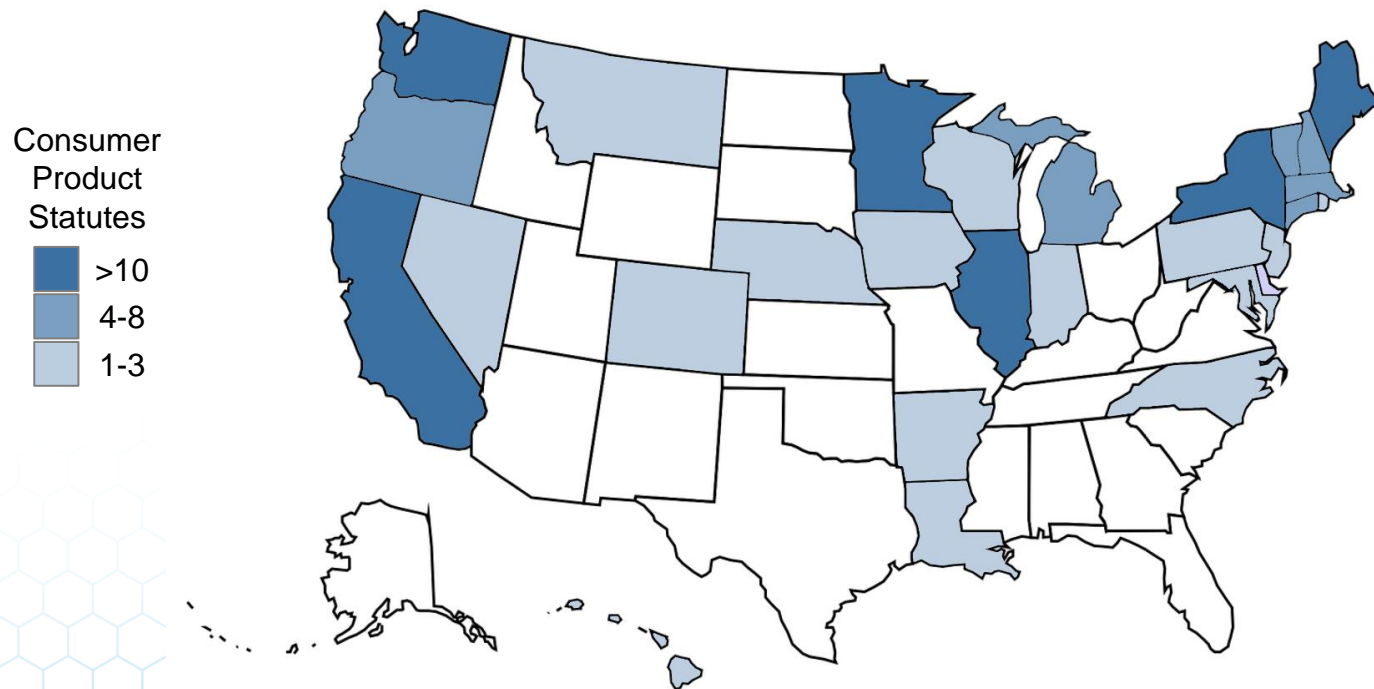
- ➔ Identifying pertinent chemicals
- ➔ Prop 65 exposure vs. product content
- ➔ The role of laboratory test reports

## Example Compliance Solution

# Federal Chemical Exposure Regulations

| Environmental Protection Agency     | Food & Drug Administration | Consumer Product Safety Commission (CPSC)       |
|-------------------------------------|----------------------------|---|
| CAA                                 | FDCA                       | Federal Hazardous Substances Act (FHSA)         |
| CWA                                 | FQPA                       |   |
| FIFRA                               |                            | Consumer Product Safety Improvement Act (CPSIA) |
| SDWA                                |                            |   |
| RCRA                                |                            |   |
| CERCLA                              |                            |   |
| Toxic Substances Control Act (TSCA) |                            | Most relevant to consumer products              |

# State Chemical Exposure Regulations



# What is Proposition 65?

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- Safe Drinking Water and Toxic Enforcement Act of 1986
- Regulates roughly 900 chemical species
- Prohibits the release of "significant amounts" of these chemicals into drinking water sources
- Requires businesses operating in California to **provide warnings** to residents of California about **significant exposure** to chemicals that "cause cancer, birth defects or other reproductive harm"
- California is required to update the list of chemical species annually
- Any business that sells or distributes its products in California is required to be Prop 65 compliant

# Proposition 65 Compliance

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- Prop 65 is enforced by the California Attorney General's Office, as well as any district attorney or city attorney for cities whose population exceeds 750,000
- **Private citizens, consumer advocacy groups and law firms may file lawsuits against businesses, alleging them to be in violation of Prop 65**
- Businesses that fail to provide Prop 65 warnings can face penalties up to \$2,500 per violation per day plus attorney's fees



# Question 1 - Plaintiffs

Of the 896 Prop 65 cases closed in 2019, how many were filed by the California Attorney General on behalf of the residents of California?

- A. 1
- B. 56
- C. 128
- D. 598

Nearly all cases are filed by groups of individuals and organizations, represented by about 30 law firms



CA CITIZEN PROTECTION GROUP



# Labeling Requirements

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If a product contains a listed substance that can result in a specified level of exposure:

On Product  
or Packaging



**WARNING:** 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/or birth defects or other reproductive harm]**. For more information go to [www.P65Warnings.ca.gov/product](http://www.P65Warnings.ca.gov/product)

Product  
(very small  
items only)



**WARNING**

Cancer - [www.P65Warnings.ca.gov/product](http://www.P65Warnings.ca.gov/product)

or

Reproductive Harm - [www.P65Warnings.ca.gov/product](http://www.P65Warnings.ca.gov/product)

or

Cancer and Reproductive Harm - [www.P65Warnings.ca.gov/product](http://www.P65Warnings.ca.gov/product)

# Some Common Prop 65 Misconceptions

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## Prop 65...

- ✗ Requires proof that a product does not contain ~900 listed chemicals
- ✗ Dictates the maximum *amount* of listed chemicals in a product
- ✗ Places the same chemical restrictions in all products
- ✗ Compliance can be proven by a “Prop 65 Certificate”

# Proposition 65 Chemical Substance List

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Total number of items: ~950

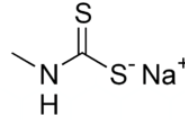
Number of unique chemical substances: ~860

- Includes chemical compounds & individual elements, but also mixtures such as biologics, foods and fuels
- About 1/3<sup>rd</sup> are pharmaceuticals
- About 15% are pesticides, herbicides, etc.
- 25 items are gaseous or particulate emissions
- The list includes items as varied as UV therapies, electronic materials, fungal toxins, wood dust and foods like salted fish

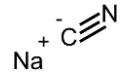
## Question 2 – Elements in Chemicals

Which of these elements is contained in more Prop 65 listed chemical substances?

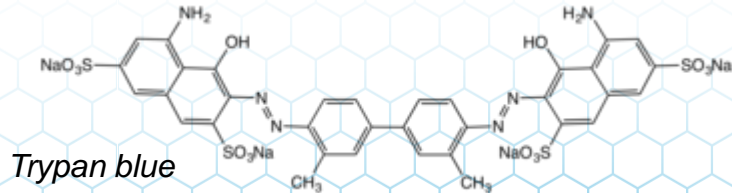
- A. Mercury 3
- B. Sodium 24**
- C. Nickel 10
- D. Phosphorous 13



*dithiocarbamate*



*sodium cyanide*



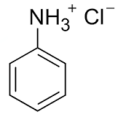
*Trypan blue*

*Values are approximate*

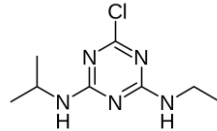
# Question 3 – Elemental Screening

About how many of Prop 65's 860 unique chemicals can potentially be detected by testing for the presence of **chlorine**?

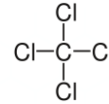
- A. 12
- B. 98
- C. 155
- D. **211 – almost 25% of all listed chemicals**



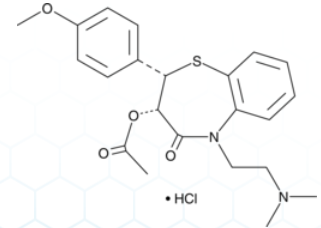
*anilinium chloride*



*atrazine*



*carbon  
tetrachloride*



*Diltiazem HCl*

# Types of Substances on the Prop 65 List

| Product Types   |       |
|-----------------|-------|
| Pharmaceuticals | } 45% |
| Biocides        |       |
| Dyes            |       |
| Emissions       |       |
| Biologics       |       |
| Polymers        |       |
| Fuels/Oils      |       |
| Therapies       |       |
| Edibles         |       |
| Electronics     |       |
| Fibers          |       |
| Industrial      |       |
| Others/Multiple |       |

| Compound Types         |     |
|------------------------|-----|
| Organic (CH) compounds | 90% |
| Inorganic compounds    |     |
| Mixtures               |     |

| Some Specific Elements |     |
|------------------------|-----|
| Nitrogen-containing    | 298 |
| Chlorine-containing    | 211 |
| Sulfur-containing      | 64  |
| Sodium-containing      | 24  |

Values are approximate

# Some Common Prop 65 Misconceptions

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# Identification of Pertinent Chemicals



# Identifying Pertinent Chemicals

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## Potential approaches include:

1. Examination of prior Prop 65 cases for similar products and materials, and/or
2. Process of elimination based on basic knowledge of product and materials, and/or
3. Expert opinion & consultation

## Question 4 – Target Substances

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Of the 860 unique chemical substances on the Prop 65 list, how many were included in CA court cases in 2019?

- A. **21 – about 2.5% of the list!**
- B. 59
- C. 238
- D. 454

# Common Prop 65 Cases: Products & Chemicals

- Plastic-containing household products
  - Phthalates, BPA
- Metal-containing jewelry
  - Heavy metals
- Ceramicwares
  - Heavy metals
- Food, dietary supplements
  - Acrylamide, heavy metals
- Sporting goods, toys, electronic cables
  - Phthalates and heavy metals



# 2019 Prop 65 Cases

## 896 Judgements & Settlements

| Product Type                  | Cases |     |
|-------------------------------|-------|-----|
| Household Products            | 627   | 70% |
| Consumables                   | 137   | 15% |
| Household/Commercial Products | 110   | 12% |
| Commercial Products           | 22    | 2%  |

79% of cases include organic compounds  
22% of cases include inorganic compounds

## 21 Targeted Chemicals

| Target Chemical    | Cases |
|--------------------|-------|
| DEHP phthalate     | 521   |
| Lead               | 165   |
| DINP phthalate     | 131   |
| Cadmium            | 50    |
| Acrylamide         | 35    |
| Bisphenol A (BPA)  | 11    |
| 15 other chemicals | 61    |

*Values are approximate*

# Process of Elimination – Product Type

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Is my product...

An industrial process?

An emissions source?

Radioactive?

A therapy?

An electronic?

If not, that eliminates about 50 items



# Process of Elimination – Material Type

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Can it be *reasonably assumed* that my product might contain “significant amounts” of...

A pharmaceutical?

A pesticide or herbicide?

Biologic materials (plants, toxins)?

Fuels or oils?

Alcoholic beverages, salted fish, tobacco or betel quid?



If not, that eliminates about 415 items

# Process of Elimination – Example

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**Practical analysis:** Glazed ceramic products are typically fired in a kiln at temperatures over 1100°C

Organic materials such as most pharmaceuticals, pesticides and biologics can *begin* to decompose into non-active by-products at temperatures as low as perhaps 100°C

(It's conceivably possible that these by-products of partial decomposition may also be regulated materials)

By ~600°C, many organic materials are completely decomposed to CO<sub>2</sub>, H<sub>2</sub>O and other gases, and hence no longer present in the ceramic



# Process of Elimination – Example

Practical analysis: Glazed ceramic products are typically fired in a kiln at temperatures over 1100°C

860 substances

Process of Elimination

Organic materials such as most pharmaceuticals, pesticides and biologics can *begin* to decompose into non-active by-products at temperatures as low as perhaps 100°C

54 substances

(It's conceivably possible that these by-products of partial decomposition may also be regulated materials)

Prior Case Analysis

By ~600°C, many organic materials are completely decomposed to CO<sub>2</sub>, H<sub>2</sub>O and other gases, and hence no longer present in the ceramic

2 substances

**This potentially eliminates 90% of Prop 65 substances  
Combined with an examination of relevant prior cases, only  
two substances remain a concern!**



# Knowledge of Products and Materials

## What is meant by “*reasonably assumed*”?

- A **Certificate of Merit** in with initial complaints
- Typically must include **relevant expert opinion** that there is “**meritorious and reasonable cause**” for the action
- Most plaintiffs employ the same expert to file nearly identical lawsuits targeting specific chemicals known to be found in certain products

**CERTIFICATE OF MERIT**  
Health and Safety Code Section 25249.7(d)

I, \_\_\_\_\_, hereby declare:

1. This Certificate of Merit accompanies the attached sixty-day notice(s) in which it is alleged the party(s) identified in the notice(s) has violated Health and Safety Code section 25249.6 by failing to provide clear and reasonable warnings.
2. I am the attorney for the noticing party.
3. I have consulted with at least one person 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.

## Question 5 – 2019 Cases

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Of the ~896 judgements & settlements reached in 2019  
Prop 65 cases, about how many different plaintiffs account  
for 90% of those cases?

- A. **18 individuals or groups filed ~800 cases**
- B. 57
- C. 113
- D. 240

**~850 Defendants  
\$30M Penalties & Fees**

# Some Common Prop 65 Misconceptions

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## Prop 65...

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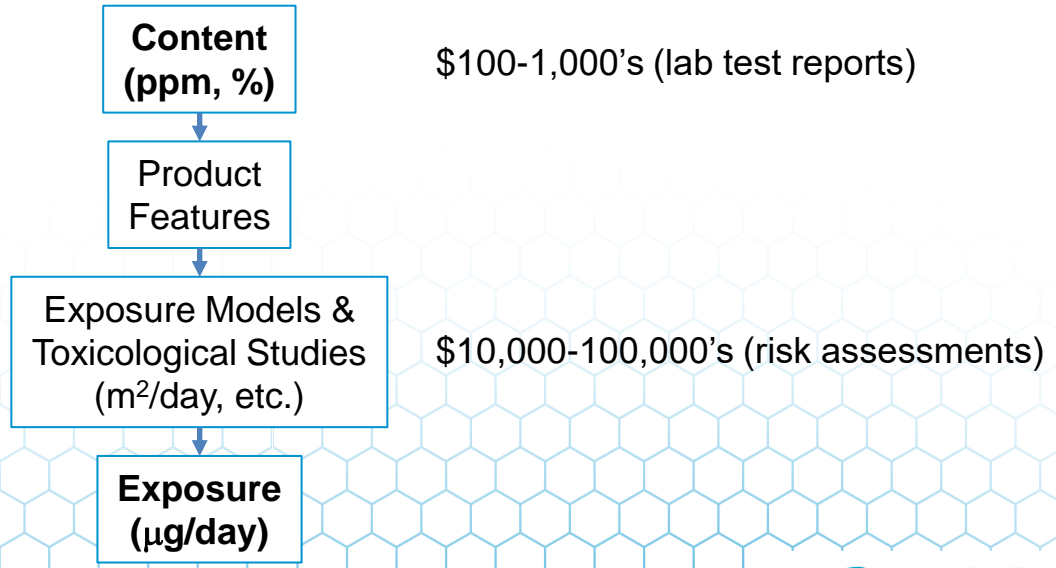
# Exposure Limits vs. Content

The background of the slide features a grid of white ceramic mugs. Each mug is filled with a different colored liquid, ranging from light yellow to deep red. The mugs are arranged in rows, and the background is a solid blue color with a faint, repeating hexagonal pattern. The text 'Exposure Limits vs. Content' is overlaid on the left side of the image in a white, sans-serif font.

# Prop 65 “Safe Harbor Limits”

Prop 65 provides allowable exposure limits (e.g.  $\mu\text{g}/\text{day}$ )

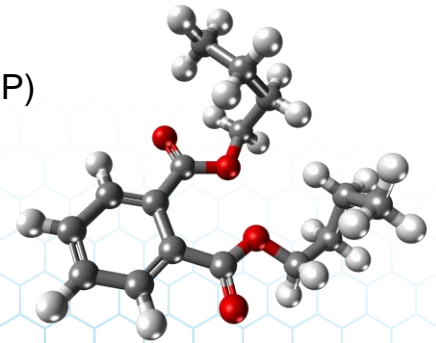
It does not provide content limits (ppm, %)



# Determination of Allowable Content

- The “conversion” from Prop 65 exposure limits into allowable **content levels** in products is not done *a priori* in CA court cases
- The courts generally defer to **composition limits established by well-defined authoritative bodies**; these limits are often also applied in other existing state and federal regulations
- Example: phthalates
  - Prop 65 exposure limits range from 8.7 µg/day (DBP) to 2,200 µg/day (DIDP)
  - But content limits in Prop 65 cases are consistently 1,000 ppm

|                         | U.S. CPSIA          | CA Prop 65 Cases |
|-------------------------|---------------------|------------------|
|                         | Children’s Products | Many Products    |
| DEHP, DINP, DBP, BBP    | <1,000 ppm          | <1,000 ppm       |
| DIBP, DPENP, DnHP, DCHP | <1,000 ppm          | -                |
| DIDP, DnHP              | -                   | <1,000 ppm       |



# Determination of Allowable Content

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- Although content limits established in Prop 65 cases only apply to the specific defendant's products named in judgements or settlements, the CA courts are very consistent in their requirements for *similar* products
- For a given product type, most of these case rulings are nearly identical in their verbiage, specific composition limits and labeling requirements

# Some Common Prop 65 Misconceptions

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## Prop 65...

- ~~\* Requires proof that a product does not contain ~900 listed chemicals~~
- ~~\* Dictates the maximum *amount* of listed chemicals in a product~~
- \* Places the same chemical restrictions in all products
- \* Compliance can be proven by a “Prop 65 Certificate”

# Product-Specific Allowable Content

## Example: Cadmium in ceramicwares

- Prop 65 exposure limit is **4.1 µg/day** (oral)
- Depending on the type of ceramicware, the allowable content varies:

| Ceramic Tableware       | Content Limit (Internal Surfaces) |
|-------------------------|-----------------------------------|
| Flatware                | 3.164 ppm                         |
| Small Hollowware <1.1 L | 0.189 ppm                         |
| Large Hollowware >1.1 L | 0.049 ppm                         |
| Cups & Mugs             | 0.189 ppm                         |
| Pitchers >1.1 L         | 0.049 ppm                         |



# Some Common Prop 65 Misconceptions

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## Prop 65...

- ~~\* Requires proof that a product does not contain ~900 listed chemicals~~
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# There is no “Prop 65 Certificate”

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- The nearest thing is a **test report from an accredited laboratory**
- A lab test report certifies the results of the *specific* chemical substances tested
  - It does *not* certify that those chemical substances on the report are the *only* ones of relevance to Prop 65
- It also does not certify that *all* products from the named manufacturer/distributor/seller are representative of the test samples listed on the report



UNITED STATES OF AMERICA  
CONSUMER PRODUCT  
SAFETY COMMISSION  
Certificate AT-1354



# Elements of an NSL Prop 65 Test Report

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- Results are specific to the product samples tested
- Maximum allowable content specifications are indicated based on citations of prior Prop 65 cases for similar products
  - Quantitative results (usually in ppm or %) are translated into clear PASS or FAIL conclusions
- Test methods and instrumental techniques are specified, with references to external procedures or regulations (when possible)
- Indicates NSL Analytical certifications
  - CPSC
  - ISO 17025

# How Accredited Lab Test Reports Can Be Used

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- During Litigation or Settlement
  - Test reports can support any evidence that a subject product is not an exposure source
- Responding to a Complaint
  - Test reports can be provided as part of a defendant's response to a Prop 65 "60 Day Notice"
- Preemptive Strategies
  - Test reports are posted on retailer/supplier websites to ward off "shill plaintiffs"
  - Test reports are used as part of vendor approval processes (Amazon, HSN, etc.)

## **60-DAY NOTICE OF VIOLATION**

SENT IN COMPLIANCE WITH  
*Cal. Health & Safety Code § 25249.5, et seq.*  
("Proposition 65")

## Question 6 – Judgements & Settlements

Of the approximately 896 Prop 65 cases resolved in 2019, about what portion were **settled out of court**?

- A. 30%
- B. 50%
- C. 70%**
- D. 90%

|                 | Court Judgements | Out of Court Settlements |
|-----------------|------------------|--------------------------|
| Civil Fines     | \$4.1M           | \$1.4M                   |
| Attorney's Fees | \$11.6M          | \$11.0M                  |
| Other           | \$1.6M           |                          |
| Average total   | \$61k/case       | \$20k/case               |

3x more than settling

Values are approximate

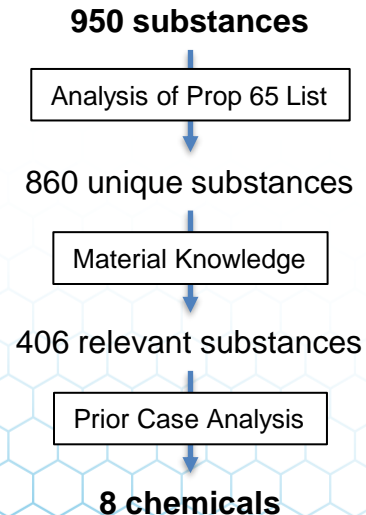
# Example Compliance Solution



# Example: Ophthalmic Products

NSL explored solutions for our ophthalmic customers to inform their compliance requirements, avoid unnecessary Prop 65 labeling and potentially ward off predatory litigation

- Analyzed Prop 65 cases over a 9-year period
  - Identified 157 ophthalmic product cases
  - 164 named defendants - individual retailers, distributors, holding companies, etc.
- Identified affected ophthalmic products
  - Eyeglasses, sunglasses, safety glasses/goggles
  - Eyewear accessories - cases, wipes, leashes, etc.
- **Identified 8 targeted chemicals**
  - 6 phthalates – for products containing polymers
  - Pb and Cd – for metal-containing products
- **Content limits were identical** and corresponded to **CPSC limits** and test methods
  - 1,000 ppm phthalates
  - 100 ppm Pb
  - 300 ppm Cd



# Example: NSL Solution

ISO 17025 & CPSC lab report with references to prior case settlements and/or judgements for ophthalmic products that closely resemble those tested

- Phthalate analysis by GC-MS (for polymer-containing products)
- Pb analysis by ICP-MS, Cd analysis by GFAA (for metal-containing products)
- Additional options for relevant Prop 65 substances that have not yet been part of ophthalmic litigation

| Prop 65 Chemicals                              | Limit Specification       | Method | Conclusion           |
|--|---------------------------|--------|----------------------|
| Phthalates<br>DEHP, DBP, BBP, DINP, DNOP, DNHP | Prop 65 case reference(s) | CPSC   | Pass/Fail            |
| Pb, Cd   | Prop 65 case reference(s) | CPSC   | Pass/Fail            |
| <b>Optional Additional Analyses</b>            |                           |        |                      |
| BPA  | n/a                       | EPA    | For Information Only |
| Phthalate DIDP                                 | REACH                     | IEC    | For Information Only |
| Fire retardants PBB/PBDE                       | RoHS                      | IEC    | For Information Only |
| Ni release                                     | REACH                     | EN     | For Information Only |

# Summary



- ➔ A manufacturer/distributor/seller does not need to test for ~900 chemicals in their products
  - All parties should have general knowledge about their materials
- ➔ Prop 65 establishes *exposure* limits, not content limits *per se*
  - Content limits are indirectly specified; determined outside the CA court system
  - Content limits are specific to individual product types
  - Although the composition limits specified in cases only apply to the particular products named, the CA courts are very consistent in their rulings for similar products
- ➔ There is no such thing as a “Prop 65 Certificate”

# Summary – Lab Testing



- ➔ Chemical analysis reports from an accredited test laboratory, with references to relevant prior Prop 65 cases, are critical for:
  - Vendor approval processes
  - Comply with labeling requirements
  - Ward off predatory litigation
  - Respond to 60 Day Notices
  - Supporting litigation arguments
- ➔ Normal variations in supply/manufacturing processes may require testing of multiple samples over time

# How NSL Can Help

- ➔ Customized, targeted testing is central to efficient Prop 65 compliance
- ➔ NSL maintains a proprietary database of Prop 65 materials, products and case judgements & settlements
- ➔ Depending on a customer's needs, NSL provides expert consultation services to:
  - Identify relevant chemicals of concern
  - Locate and review relevant Prop 65 prior cases
  - Provide references for composition limits
  - Identify appropriate & acceptable test methods
  - Compose customized Prop 65 test plans and report formats
- ➔ NSL provides authoritative chemical testing & reporting
  - ISO 17025 accredited analysis of polymers, surface-coatings and a wide range of metals, ceramics and other materials
  - CPSC accredited analysis for heavy metals and phthalates

# Resources



## **Proposition 65 - California Office of Environmental Health Hazard Assessment**

<https://oehha.ca.gov/proposition-65>

## **New Proposition 65 Warning Label Requirements**

<https://www.p65warnings.ca.gov/new-proposition-65-warnings>

## **HSN Guide - California Proposition 65 Compliance Requirements**

[https://view.hsn.net/WebDocuments/documents/01\\_Prop65Guide%20Updates%2012-4-2019.pdf](https://view.hsn.net/WebDocuments/documents/01_Prop65Guide%20Updates%2012-4-2019.pdf)

## **Amazon Seller Central - California Proposition 65**

<https://sellercentral.amazon.com/gp/help/external/G202141960>

## **“2020 Regulatory Amendments Attempt to Simplify Proposition 65 Warning Obligations”**

<https://www.jonesday.com/en/insights/2020/07/2020-regulatory-amendment-proposition-65>

## **Regulations, Laws & Standards – Consumer Product Safety Commission**

<https://www.cpsc.gov/Regulations-Laws--Standards>



# Tech Talk

## Let's Talk Tech!

**Dave van der Wiel**

Director of Technology Development

*[dvanderwiel@nslanalytical.com](mailto:dvanderwiel@nslanalytical.com)*

216.438.5215

Join Us For Our Next Tech Talk!

**February 4<sup>th</sup> – 2:00 PM EST**

Discovering the Value of Working with  
an Accredited Commercial Laboratory

Presented by

**Carm D'Agostino, Cynthia Hagan &  
Dave van der Wiel**

NSL Analytical