



California Proposition 65 Updates and Emerging Issues: What Lies Ahead?

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Introduction



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Overview

- Overview of California Proposition 65 (Prop 65) regulation
- Prop 65 updates
 - Emerging chemicals and trends
 - Testing challenges
 - Disclosure challenges
 - Recommendations
- Final Points




Prop 65: Safe Drinking Water and Toxic Enforcement Act of 1986

- Requires "**clear and reasonable**" **warning** label if use of product may result in exposure to certain chemicals
- >900 chemicals listed, updated frequently
- **Exposure** to chemicals, not chemical **content**
 - Warning labels if exposure is above the Safe Harbor Limit
- Updated August 30, 2018, with new warning label requirements
 - Clarifies warning, notification methods, responsibilities



Safe Harbor Levels (SHLs)



Contents lists available at [ScienceDirect](#)

Regulatory Toxicology and Pharmacology


journal homepage: www.elsevier.com/locate/yrtph



Derivation of an oral Maximum Allowable Dose Level for Bisphenol A

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ABSTRACT

Bisphenol A (BPA) is a high production volume chemical that is used in plastics and epoxy coatings. In 2015, California's Office of Environmental Health Hazard Assessment (OEHHA) added BPA to the Proposition 65 list of chemicals "known to cause reproductive toxicity" based on its Developmental and Reproductive Toxicant Identification Committee's (DART-IC) conclusion that BPA has been shown to cause female reproductive toxicity. A critical factor in determining compliance with Proposition 65 is a Maximum Allowable Dose Level (MADL), which is the exposure level at which a chemical would have no observable reproductive effect even if a person were exposed to 1000 times that level. We performed a comprehensive review of the literature, including the studies reviewed by DART-IC, and derived an oral MADL. Of all the studies we identified, Delclos et al. (2014) is of sufficient quality, has the lowest no observed effect level (NOEL), and results in the most conservative MADL of 157 µg/d. This is generally supported by other studies, including those that were considered by DART-IC. Also, the oral MADL provides a similar margin of safety as OEHHA's dermal MADL and other regulatory guidelines. Taken together, the scientific data support an oral MADL of 157 µg/d.

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- Exposure limits in µg/day
- Reproductive or developmental toxin: maximum allowable dose level (MADL)
 - 1000 x lower than the no observed adverse effect level (NOAEL)
- Carcinogen: no significant risk level (NSRL)
 - Cancer risk of 1×10^{-5} , or 1 in 100,000
- Only ~300 Prop 65 chemicals have SHLs
- Warning required if use of product would result in exposures above the SHL

Prop 65 Warnings



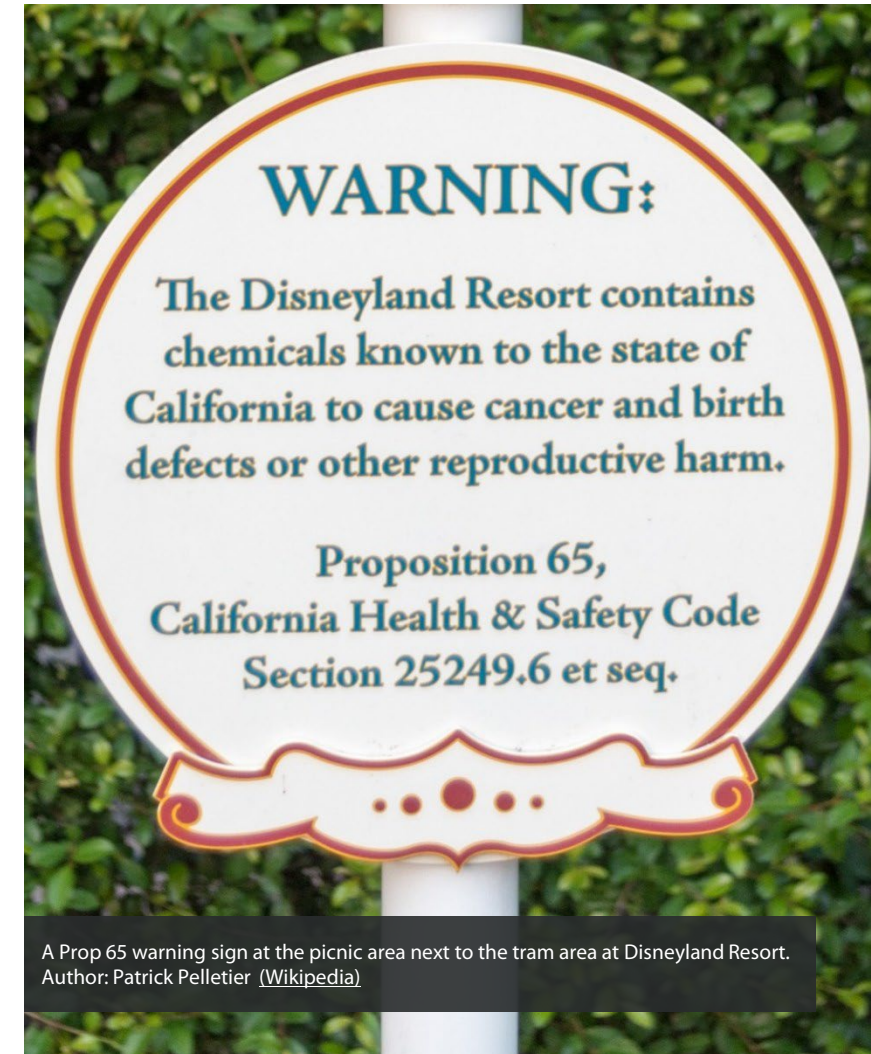
WARNING: This product can expose you to [arsenic], which is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.



WARNING: This product can expose you to [lead], 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 Notification

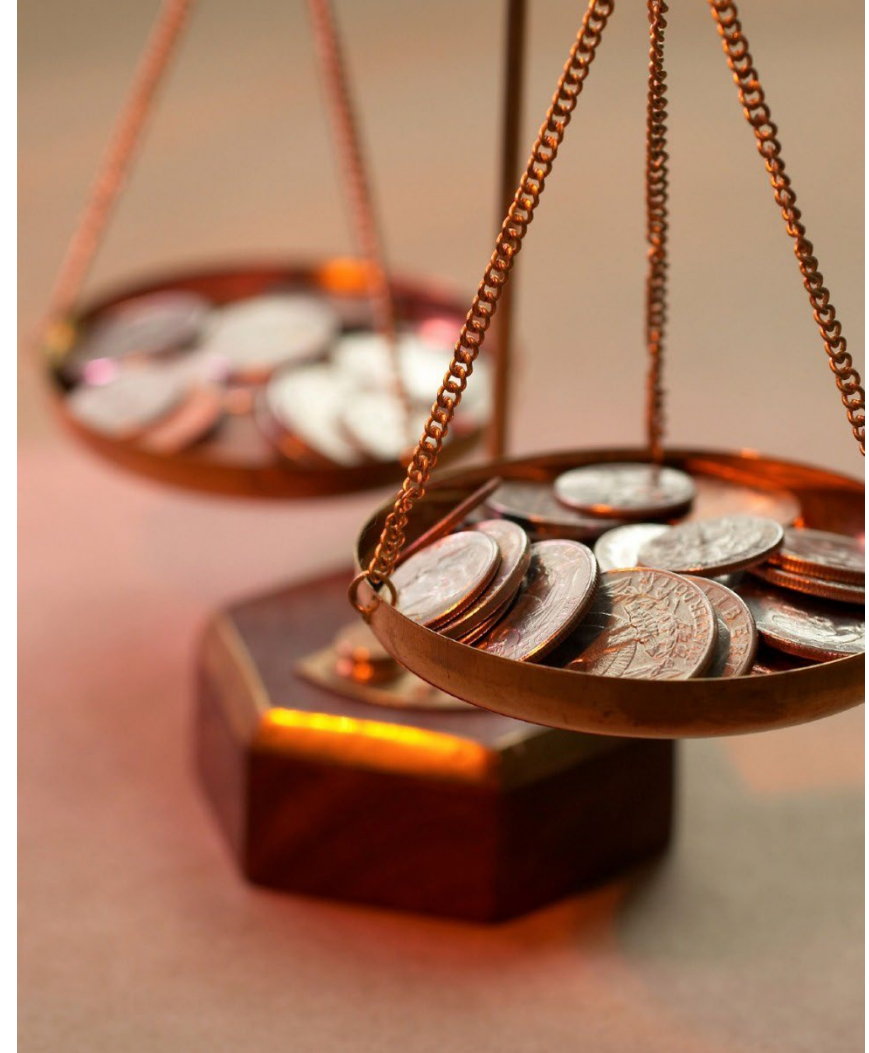
- Case by case and company specific: no single rule of thumb
- Regulation is clear – onus on manufacturer
- Consumer **and** occupational exposures require warnings in CA
- A 'short-form' warning can be used when product packaging is small or there is no room for warning
 - Updated in 2025



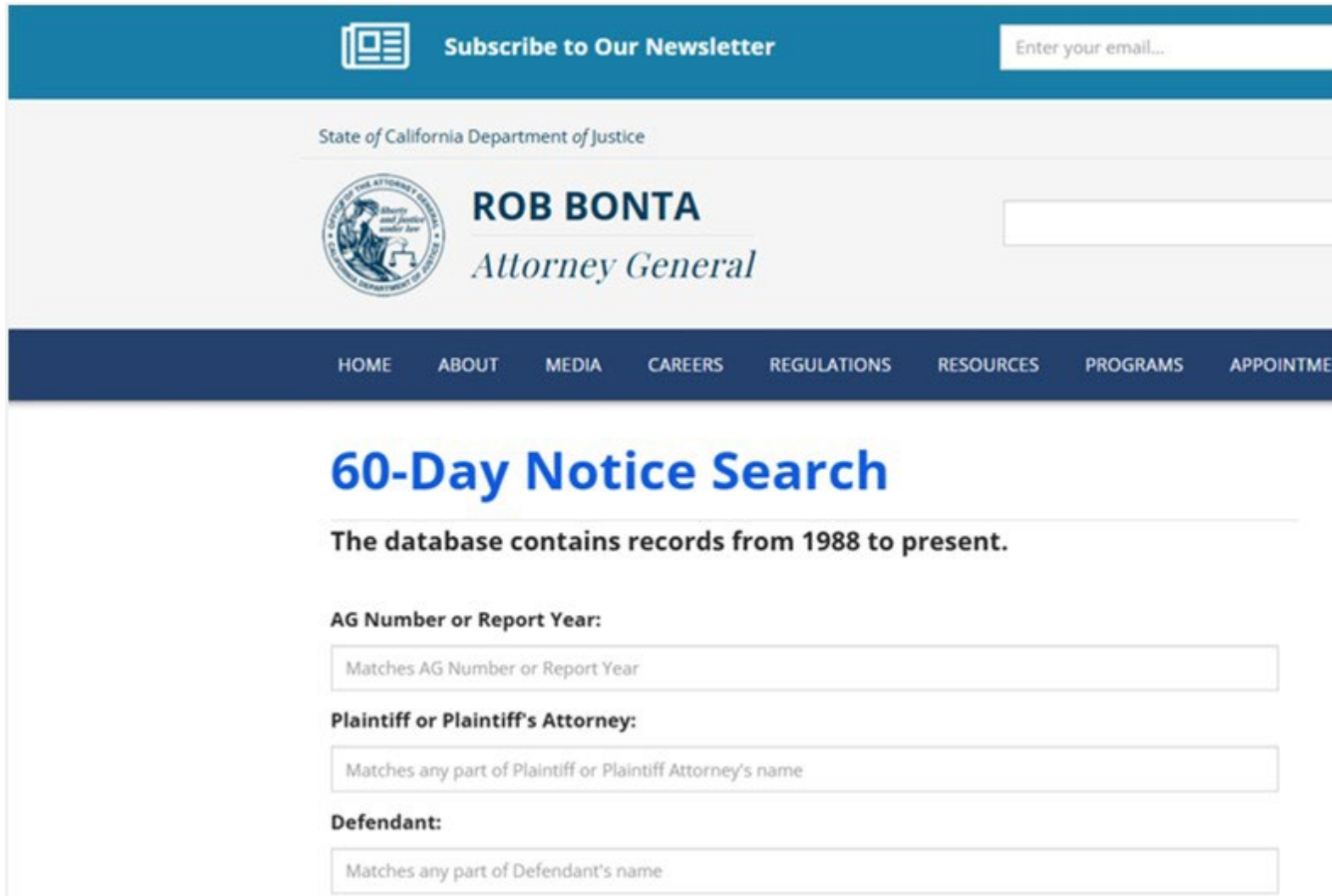
A Prop 65 warning sign at the picnic area next to the tram area at Disneyland Resort.
Author: Patrick Pelletier ([Wikipedia](#))

Prop 65 Enforcement

- Entire supply chain: manufacturer, distributor, packager, supplier, retailer
- Public enforcer = attorney general
- "Private enforcers" aka "bounty hunters" (anyone)
- All lawsuits are about **failure to provide a warning**
- Starts with a 60-day notice




What Is a Prop 65 60-Day Notice?



The screenshot shows the official website of the State of California Department of Justice, specifically the page for the Attorney General, Rob Bonta. At the top, there is a blue header with a newsletter subscription form. Below this, the department's name and the Attorney General's name and title are displayed. A navigation bar contains links to various sections of the website. The main content area features a large blue heading for the "60-Day Notice Search" tool. Below the heading, a statement indicates that the database contains records from 1988 to the present. Three search criteria are provided: "AG Number or Report Year", "Plaintiff or Plaintiff's Attorney", and "Defendant". Each criterion has a corresponding text input field with placeholder text indicating the type of information to enter.

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Attorney General

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60-Day Notice Search

The database contains records from 1988 to present.

AG Number or Report Year:

Plaintiff or Plaintiff's Attorney:

Defendant:

- Occurs before lawsuit is filed
- Filed by private enforcers “on behalf of the general public”
- 60-day notice contains:
 - Description of the violation
 - Identification of the private enforcer
 - Time period of the violation
 - Listed chemicals involved
 - Route of exposure (inhalation, ingestion, dermal contact)
 - "Certificate of Merit"
- Testing data provided only to attorney general
 - Very low bar – only one data point needed

Prop 65 Product Testing and Sampling Design Considerations

Nearly 1000 Chemicals – Impossible to Test Them All!

- Refine list based on product composition, exposure potential

Product Representativeness is Critical

- Assess precision and variability
- Test multiple samples, batches, manufacturing plants, formulations, colors



Product Testing Strategies

- Exposure defines appropriate test methods
 - Wipe sampling – hand-mouth contact
 - Off-gassing – inhalation exposure
- Total content testing is only useful to verify chemical presence
 - Presence does not equal exposure!
 - Relevance depends on product category
 - Specialized testing may be used in certain cases



Appropriately Evaluating Chemical Exposures

- Who is exposed? How are they exposed? How often are they exposed? How long are they exposed?
- Law focused on the "typical" or "average" exposure
- Receptor: worker, consumer (child, adult)
- Exposure routes:
 - **Ingestion** – hand-to-mouth behavior
 - **Dermal** – absorption through the skin
 - **Inhalation**
- Product testing should focus on relevant exposures
 - *e.g.*, wipe testing to evaluate what gets on the hand from handling the product
 - Accessibility is a consideration



Challenge: Chemicals Lacking SHLs

- Only 300 out of >900 chemicals have SHLs
- May need to derive SHLs to show there is no exposure
- Analysis can vary in complexity
 - Amount of data
 - Consistency of data
 - Relevant route of exposure
- Key considerations:
 - Relevant toxicity studies, appropriate endpoints
 - Mode of action and relevance to humans
 - Extrapolating across route of exposure (dermal vs. inhalation)



Recent Prop 65 Updates and Emerging Chemicals

- Warning label requirements
- New chemicals
- Emerging chemicals
 - Diethanolamine (DEA)
 - Bisphenol S (BPS)
 - Per- and polyfluoroalkyl substances (PFAS) chemicals



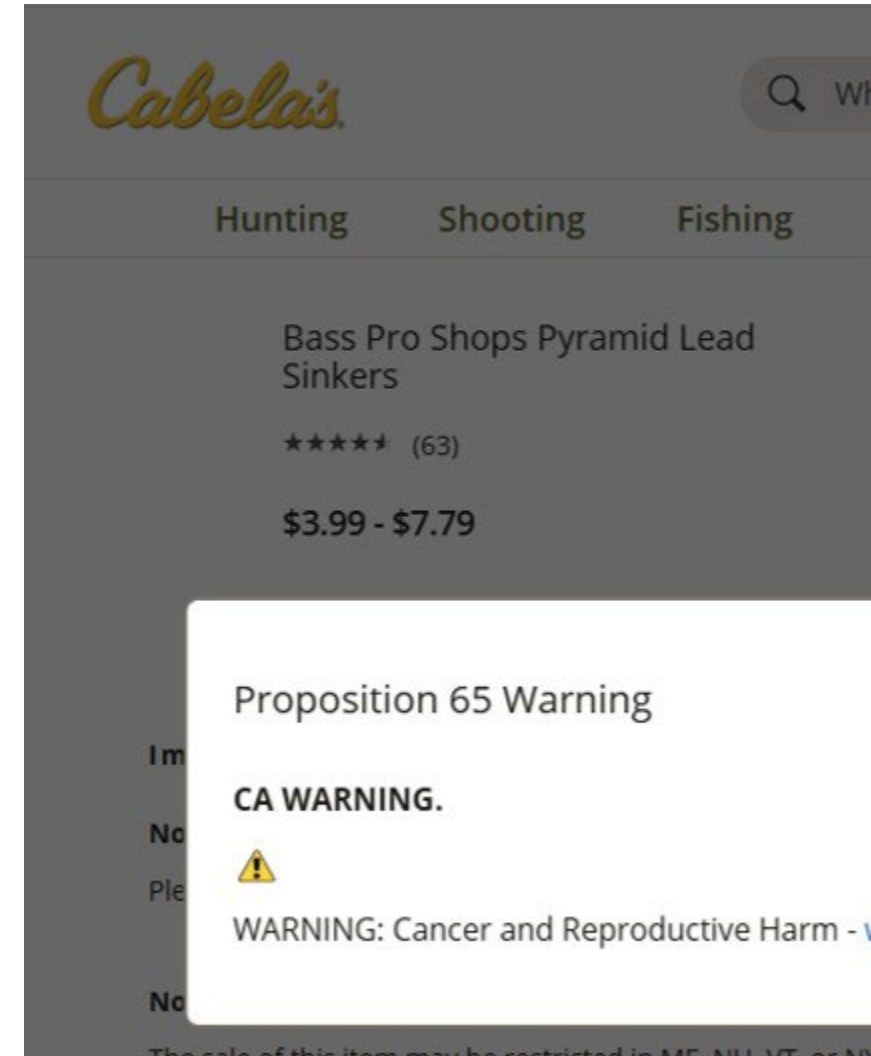
Recent Prop 65 Updates

Short-Form Warning Label

- Effective January 1, 2025
 - Three-year grace period for compliance
- More details required
 - Must include at least one chemical name for each endpoint (cancer and/or reproductive toxicity)
 - Examples: "Cancer risk from exposure to lead" or "Can expose you to arsenic, a carcinogen"

Internet Warnings


- Must be included on the product display page, or
- Use a clearly marked hyperlink with the phrases "warning," "CA warning," or California warning," or
- Other methods for display as long as warning is prominent



Prop 65 Trends: Emerging Chemicals by the Numbers

To Date...

- Over **1,450** 60-day notices filed for DEA (*197 in 2025*)
 - Cosmetics, personal care products
- Over **620** 60-day notices filed for BPS (*all in 2025*)
 - Stickers, receipts
- Over **500** 60-day notices filed for perfluorooctanoic acid (PFOA), perfluorooctane sulfonate (PFOS), and perfluorononanoic acid (PFNA) and its salts (*197 in 2025*)
 - Food packaging, outdoor gear, water-repellant clothing, etc.


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August 15, 2025

Via Certified Mail:

Symphony Beauty Box, Corp. c/o Registered Agent 43 Grand Blvd. Brentwood, NY 11717	Enveco Cosmetic Co., LTD 35 Hwanggeum-ro 323beon-gil Yangchon-eup, Gimpo-si Gyeonggi-do 10049 REPUBLIC OF KOREA
Urban Outfitters, Inc. c/o CSC – Lawyers Incorporating Service 2710 Gateway Oaks Drive Sacramento, CA 91203	Current Chief Executive Officer Urban Outfitters, Inc. c/o Richard Hayne 5000 S Broad Street Philadelphia, PA 19112

Re: Proposition 65 Notice of Violation
This notice amends the original notice of violation AG No. 2025-00077.
This notice adds Enveco Cosmetic Co., LTD as an additional manufacturer.

To Whom It May Concern:

We represent Environmental Health Advocates, Inc., an organization in the State of California acting in the interest of the general public. This letter serves as notice that the parties listed above are in violation of Proposition 65, the Safe Drinking Water and Toxic Enforcement Act, commencing with section 25249.5 of the Health and Safety Code ("Proposition 65"). In particular, the violations alleged by this notice consist of types of harm that may potentially result from exposures to the toxic chemical Diethanolamine ("DEA"). This chemical was listed as a carcinogen on June 22, 2012.

Close-up: Diethanolamine (DEA)

- Listed as a Prop 65 carcinogen in 2012 based on IARC 2B classification (“possibly carcinogenic to humans”)
- Over 1400 60-day notices published
- Cosmetics and personal care products main targets
- May be intentionally or unintentionally present
- No official SHL yet *but* NSRLs have been listed in the literature
 - 5.6 ug/day NSRL derived by Wang *et al.* (2014) (liver and kidney tumors); life-adjusted value of 1.4 ug/day
 - Dermal exposure value of 3,400 ug/day derived by Kirman *et al.*, 2016
- In August 2025, OEHHA proposed an NSRL of **6.4 ug/day** (dermal exposure)



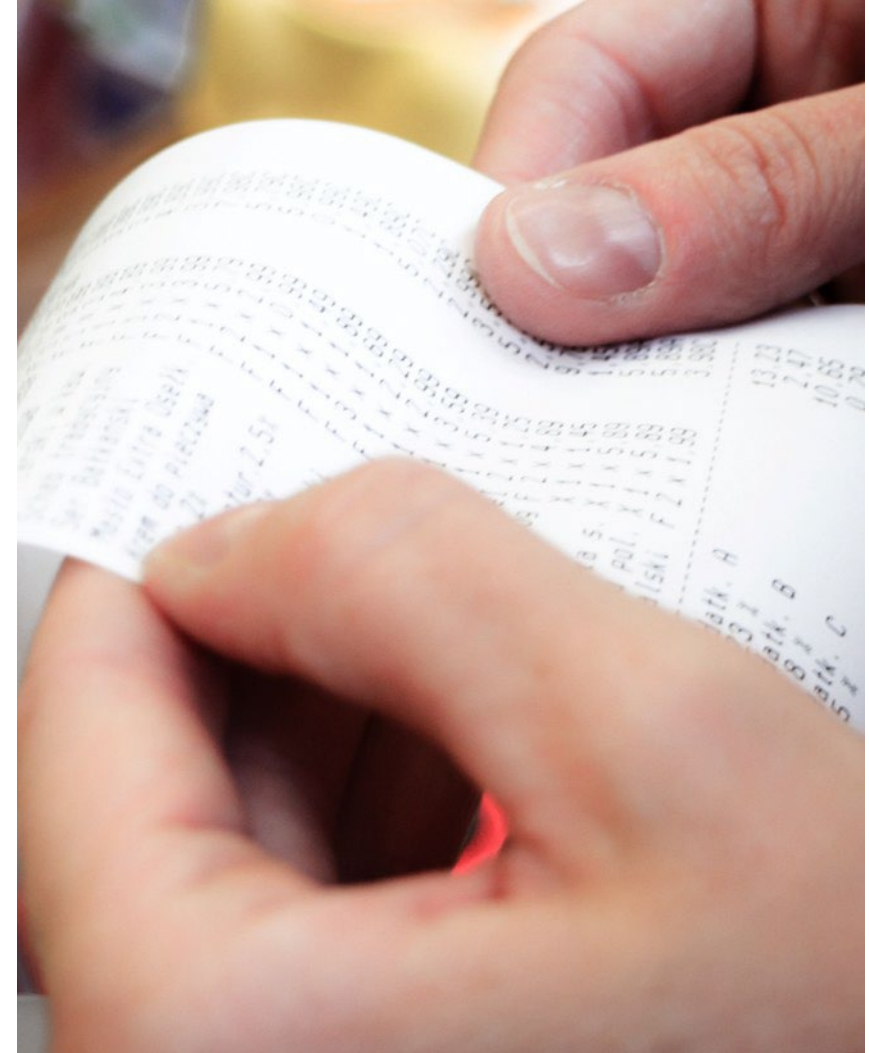
Close-up: Diethanolamine (DEA)

- Coconut oil DEA condensate (cocamide diethanolamine) also listed based on IARC classification 2B
- Ingredient suppliers may need to disclose presence of these compounds in formulations
- Product manufacturers may need to perform analytical testing or exposure assessment to show exposure is below levels of concern



Close-up: Bisphenol S (BPS)

- Listed in 2023 (effective in 2025)
 - Reproductive toxin
- Thermal paper and stickers/adhesives main targets; bisphenol A (BPA) substitute in many applications
- May be intentionally or unintentionally present
- No official SHL defined, but based on CA OEHHA study data for BPS, MADL for reproductive toxicity would likely be extremely low (sub-ppb ug/day)
- Ingredient suppliers may need to disclose presence of BPS
- Product manufacturers may need to perform testing or a quantitative exposure assessment to show BPS exposure is below levels of concern



Close-up: Per- and Polyfluoroalkyl Substances (PFAS) – Perfluorooctanoic Acid (PFOA), Perfluorooctane Sulfonate (PFOS), and Perfluorononanoic acid (PFNA)



PFAS Chemical	No. of 60-Day Notices	Products	Basis for Listing	SHL?
PFOA	454	Clothing, adhesives, food products	Carcinogen, reproductive harm	None defined, but likely to be very low based on OEHHA public health goals
PFOS	63	Clothing, textiles, food	Carcinogen, reproductive harm	None defined, but likely to be very low based on OEHHA public health goals
PFNA	15	Clothing, textiles, food	Carcinogen, male reproductive harm	None defined, but likely to be very low based on OEHHA public health goals

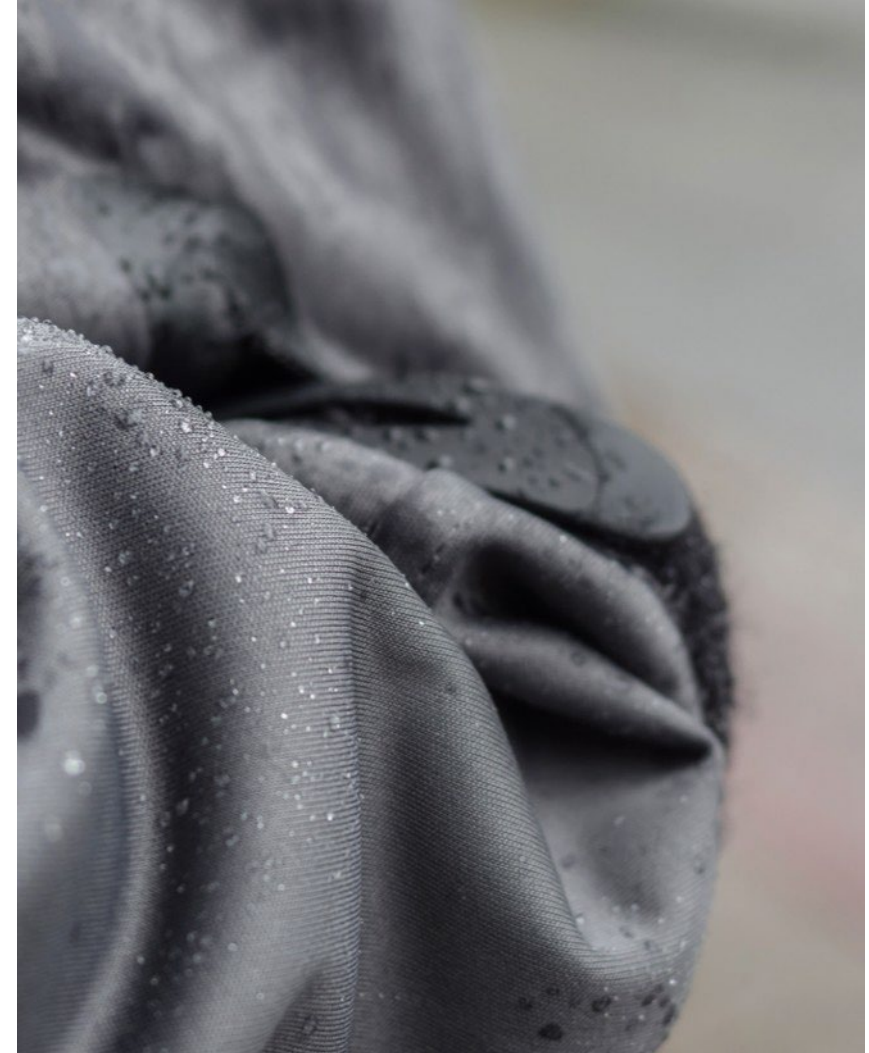
PFOA, PFOS, and PFNA Testing Challenges

- PFAS may be intentionally present or residual
- Targeted methods developed for select matrices, but consumer products pose many challenges
 - Extremely broad range of matrix types
 - Foods, food packaging, personal care products, textiles, hard goods
 - Analytical and sample prep methods are not one size fits all
- Screening vs. targeted testing
 - Total fluorine often used as a proxy for PFAS, but this is not a fail-safe
- Matrix effects
- Detection limits can vary

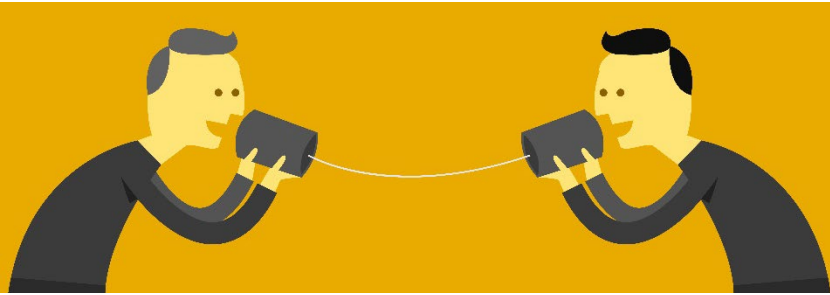


Additional Considerations PFOA, PFOS, and PFNA

- Federal and state regulatory compliance must also be considered
 - Differing definitions, rules
- PFOA Prop 65 settlements
 - Reformulation requirements
 - Total Organic Fluorine (TOF) <100 ppm
 - Intentionally added PFOA not allowed



Navigating Prop 65 Supply Chain Challenges



Good communication up and down the supply chain is critical

- Supply chain and chemical portfolios often very complex
- Retailers can push liability back up the chain to the manufacturers and formulators
- Products can end up being sold in CA even if manufacturer did not intend to do so
- Customers & retailers may require Prop 65 attestations or declarations
- Warnings are key
 - If you need a warning, make sure that the warning follows the product all the way down the chain to retail
- May require legal counsel to understand business implications and liability risks

Prop 65: Final Points

- Be proactive
- Prioritize
- Track regulatory updates
- Know your portfolio and supply chain
 - Product/category, source/raw materials, target products/chemicals
 - Proactive analytical testing program
 - Suppliers/formulators
 - **Your** customers may request disclosures or attestations
 - Manufacturers/buyers
 - Request specific information from suppliers to help to inform regulatory compliance



Questions?

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