California Proposition 65

Day of Wood
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What is Proposition 65?

Proposition 65 is a “right to know” law in California that applies to exposures to listed chemicals.

It does not ban or restrict the use of any listed chemical.

It requires that a warning must be given for listed chemicals unless exposure is low enough to pose no significant risk of cancer or is significantly below levels observed to cause birth defects or other reproductive harm.
Warning:
Chemicals known to cause cancer, or birth defects or other reproductive harm may be present in foods or beverages sold or served here. Cooked potatoes that have been browned, such as french fries, hash browns and baked potatoes, contain acrylamide, a chemical known to the State of California to cause cancer. Other foods sold here, such as hamburger buns, biscuits and coffee also contain acrylamide, but generally in lower concentrations than fried potatoes.

Acrylamide is not added to our foods, but is created whenever potatoes and certain other foods are browned.

The FDA has not advised people to stop eating baked potatoes, fried potatoes or other foods which contain acrylamide. For more information see www.fda.gov.
What Chemicals are Considered?

Over 900 Chemicals

Wide range of naturally occurring and synthetic chemicals known to cause cancer, birth defects or reproductive harm

Naturally occurring: lead, cadmium, nickel, formaldehyde

Synthetic Chemicals: azo dyes, phthalates, flame retardants
How is a Chemical Added to the List?

**Living list** required to be reviewed and updated at a minimum of once per year

Four ways for a chemical to be added

1. Carcinogen Identification Committee (CIC) and/or Developmental and Reproductive Toxicant (DART) Identification Committee

2. Organization Designated as Authoritative Bodies: US EPA, US FDA, NIOSH, National Toxicology Program, and International Agency for Research on Cancer

3. State or Federal Agency requires that the chemical be labeled or identified as causing cancer or birth defects or other reproductive harm (prescription drugs)

4. Meeting certain scientific criteria and identified in the California Labor Code as causing cancer or birth defects or other reproductive harm.
Enforcement by Litigation

Enforcement is carried out through civil lawsuits brought by the California Attorney General, or by a district attorney or city attorney.

Primary enforcement is by private plaintiff’s attorneys (~95% of cases)*
- Send written notice to public prosecutors and violator
- Wait 60 days to make sure no public prosecutor sues

Nearly 20,000 notices have been served since 1986*

In the past 5 years, settlements have totaled about $75,000,000*
- Almost 90% of the settlement money goes to plaintiffs attorney
- Settlements typically require product reformulation and/or labeling

* Statistics compiled from http://oag.ca.gov/prop65
Determining anticipated levels of exposure to listed chemicals can be very complex. Because a business has the burden of proving a warning is not required, you should consider consulting a qualified professional.

(from OEHHA website FAQs)
Step 1 - Product and Supply Chain Risk Assessment

Review information from suppliers related to chemical content of raw materials to determine the potential for listed chemicals to be present.

Review and categorize materials by risk of containing listed compounds and history of enforcement action against specific products and materials.

Identify potential exposure routes for listed chemicals that may be present in your product.
Supply Chain Management Tools

ENTER
- Raw Materials
- Intermediaries
- Sub – Suppliers
- Suppliers

SUPPLY CHAIN

PROCESS
- Automated Compliance Engine
- Robust Regulatory Content
- Industry Standard Methodology
- Multi-lingual
- Professional Review

100K+ Formulations
7000+ Suppliers

SHARE
Storage, Shipping,
Hazard Waste, Restriction,
Custom Data,
GHS SDS, Conflict Minerals
& Additional Data and
Documents

2 Business Days

SUPPLY CHAIN RECIPIENT

WERCSmart™ Web Portal

REQUIRE
- Raw Materials
- Intermediaries
- Sub – Suppliers
- Suppliers
Step 2 - Chemical Testing

Several different types of tests may be required depending on the chemicals of concern associated with the products and potential routes of exposure.

Some common testing recommendations include the following:
1. XRF screening and ICP analysis for lead and/or heavy metals
2. GC/MS analysis for listed phthalates
3. GC/MS or HPLC for VOCs and formaldehyde
Step 3 - Exposure Modeling

Estimate Exposure from Skin Contact
- Duration of contact
- Surface Area of Contact of Skin to Phthalate containing Components
- Migration Rate of Phthalate from Component
- Absorption Rate of Phthalate through Skin

Estimate Exposure from Hand-to-Mouth Activities
- Surface Area of Skin that comes into Contact with the Mouth
- Transfer efficiency from hand to mouth

Estimate Exposure from Indoor Inhalation
- Emission rates from product
- Product loading and ventilation in room
- Duration of time indoors with product
- Breathing rate

THIS PRESENTATION IS FOR GENERAL INFORMATION PURPOSES ONLY AND IS NOT INTENDED TO CONVEY LEGAL OR OTHER PROFESSIONAL ADVICE.
**Safe Harbor Levels**

Resulting Exposure is compared to the Safe Harbor Level.

**NSRL**

- Carcinogen Safe Harbor Levels are termed No Significant Risk Levels (NSRL).
- They are based on the most sensitive study meeting certain requirements and calculations described in regulations for an exposure level that results in 1 excess cancer in an exposed human population of 100,000 over a 70-yr lifetime.

**MADL**

- Reproductive Toxin Safe Harbor Levels are termed Maximum Allowable Dose Level (MADL).
- They are based on the most sensitive study meeting certain requirements at a level that is 1,000 fold below the no observable effect level (NOEL) of the study.

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What’s Next for Warning Labels?

Potential Amendments to Article 6 Clear and Reasonable Warnings

**Warning symbol**: warnings must contain the signal word “WARNING” and a pictogram indicating a hazard.

**Identify Chemicals**: warnings must include identification of the listed chemical for which the warning is being provided.

**Hyperlink to website**: almost all warnings will require a link to web pages which contains additional exposure information about specific chemicals and products compiled by OEHHA.

**Additional Languages**: existing regulations require warning only in English, but the proposed revision would require warnings in non-English languages if other product labeling contains information in other languages.
Proposed Labelling Requirements

Many companies will need to revise their warning protocols,

Some companies may want to review their raw materials and risk management strategy avoid labeling.
Furniture Products

www.p65warnings.ca.gov

**Current Warning**

**Proposed Warning**

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

**Fact Sheets**

- Formaldehyde
- Formaldehyde in Furniture Products
- Chlorinated Tris
- Chlorinated Tris in Furniture Products

**Related Websites**

- Office of Environmental Health Hazard Assessment
- Proposition 65 Technical Pages

**Fact Sheets**

- Alcohol and Cancer
- Alcohol and Fetal Alcohol Spectrum Disorders (FASDs)
- Benzene
- Bisfenol A (BPA) (Spanish)
- Bisfenol A (BPA) en Alimentos y Bebidas Enlatados y Embotellados (Spanish)
Styrene Update

Styrene is a building block chemical that is used to make many materials including:

PS, or Polystyrene
EPS, or Expandable Polystyrene
ABS, or Acrylonitrile Butadiene Styrene Copolymer
SAN – Styrene Acrylonitrile Copolymer
UPR, or Unsaturated Polyester Resins
SBR, or Styrene Butadiene Rubber

These materials are used to make everything from building products like carpet and insulation to consumer products like electronics and packaging materials. We all encounter these materials in our day to day lives.
Styrene Added as Known Carcinogen

Effective April 22, 2016, California OEHHA added styrene to the Proposition 65 list of chemicals known to cause cancer.

OEHHA also proposed a No Significant Risk Level (NSRL) for styrene of 27 micrograms per day. Comments on the proposed NSRL were due by June 6, 2016.

Manufacturers of products that may contain styrene have one year to determine if their products could cause significant exposure to styrene and take appropriate action.

Products that can cause styrene exposure greater than the No Significant Risk Level (NSRL) will be required to reformulate or provide a warning label.
Closing

• The amendment is designed to further the "right to know" purposes of Prop 65 and provide manufacturers with more specific guidance on the new product warning label required by the law. The revised regulation has an effective date of August 30, 2018.