



# Proposition 65 and UV/EB

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# Proposition 65

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- Safe Drinking Water and Toxic Enforcement Act of 1986
  - Enacted as a ballot initiative in November 1986
  - “Proposition 65”
  - California Health and Safety Code §§ 25249.5 *et seq.*
  
- Purpose:
  - Inform citizens about chemicals “known” to the State to cause cancer, birth defects, or other reproductive harm
  - Allow California consumers to make informed choices about products
  - Give notice to residents and workers

# The List

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- Governor of California must publish a list of chemicals “known to the state to cause cancer or reproductive toxicity.”
  - Chemicals are chosen by the “state’s qualified experts” such as health professionals and scientists
  - List is updated at least annually
  - Current list contains almost 900 substances
  
- Includes:
  - Dyes
  - Solvents
  - Pesticides
  - Drugs
  - Food Additives
  - By-products or impurities
  - Natural or synthetic
  - Household products

# Warning Requirement

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- Must give “clear and reasonable” warning before exposing person to “significant” amounts of listed chemical
  - “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...” Cal. Health & Safety Code § 25249.6
- Warning is required 1 year after chemical is listed
- Applies to:
  - Consumer Products
  - Workplace Exposures
  - Environmental Exposures
- Suggested warning language for labels:
  - WARNING: This product contains (a) chemical(s) known to the State of California to cause [birth defects or other reproductive harm] [cancer and/or reproductive harm].

# Exemption: Safe Harbor Levels

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- Warning is NOT required if exposure to listed chemical from product or place of establishment is LESS than “safe harbor” level
  - Business can prove that exposure to listed chemical poses “no significant risk,” assuming lifetime exposure at the level in question. Cal. Health & Safety Code § 25249.10(c)
- Safe harbor level for chemical listed as causing cancer:
  - “No significant risk level” (NSRL) is level of exposure that would result in not more than one excess case of cancer in 100,000 individuals exposed to the chemical over a 70-year lifetime. (A person exposed to the chemical at the NSRL for 70 years would not have more than a “one in 100,000” chance of developing cancer as a result of that exposure.)
- Safe harbor level for chemical listed as causing birth defects or reproductive harm:
  - Maximum Allowable Dose Level (MADL) is “no observed effect level” (NOEL) divided by 1,000 to provide ample margin of safety. (A NOEL is the highest dose level which has not been associated with a reproductive effect in humans or test animals.)
- If a source or product causes exposures through multiple routes, the total exposure must be considered in determining whether it falls under the safe harbor level.

# Impact of Prop 65 on UV/EB

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- **Toluene** (Prop 65 listed as reproductive toxicant)
  - Monomers used in UV/EB inks contain 0.1% or less residual toluene
  - Safe harbor level (MADL) for oral exposure is 7,000 µg/day, and for inhalation exposure is 13,000 µg/day
    - [http://oehha.ca.gov/prop65/prop65\\_list/files/P65list052011links.xls](http://oehha.ca.gov/prop65/prop65_list/files/P65list052011links.xls)
  
- **Benzene** (Prop 65 listed as carcinogen and reproductive toxicant)
  - Some cationic photoinitiators generate benzene upon curing
  - Safe harbor level (NSRL) for oral exposure is 6.4 µg/day, and for inhalation exposure is 13 µg/day
    - [http://www.oehha.ca.gov/prop65/law/pdf\\_zip/BenzeneNSRL\\_061303.pdf](http://www.oehha.ca.gov/prop65/law/pdf_zip/BenzeneNSRL_061303.pdf)
  - Safe harbor level (MADL) for oral exposure is 24 µg/day, and for inhalation exposure is 49 µg/day
    - [http://www.oehha.ca.gov/prop65/law/pdf\\_zip/benzene%20MADL.pdf](http://www.oehha.ca.gov/prop65/law/pdf_zip/benzene%20MADL.pdf)

# Impact of Prop 65 on UV/EB

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- **Formaldehyde** (Props 65 listed as carcinogen)
  - Formaldehyde is a component of visibly fluorescent inks and some Hexachrome ink series at extremely low levels (less than 0.1%)
  - Safe harbor level (NSRL) for exposure is 40 µg/day
    - [http://oehha.ca.gov/prop65/prop65\\_list/files/P65list052011links.xls](http://oehha.ca.gov/prop65/prop65_list/files/P65list052011links.xls)
  
- **Barium based red** (Pigment Red 53:1 or D&C Red No. 9) (Prop 65 listed as carcinogen)
  - Present in all PANTONE blends containing Warm Red
  - Safe harbor level (NSRL) for exposure is 100 µg/day
    - <http://www.oehha.ca.gov/prop65/pdf/expcancer.pdf>

# Impact of Prop 65 on UV/EB

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- Benzophenone (on Prop 65's Notice of Intent to List)
  - Photoinitiator in UV curable printing inks and coatings for food packaging
  - Public comments closed April 6, 2012
    - [http://oehha.ca.gov/prop65/CRNR\\_notices/admin\\_listing/requests\\_info/Ext\\_4LC\\_pubcom.html](http://oehha.ca.gov/prop65/CRNR_notices/admin_listing/requests_info/Ext_4LC_pubcom.html)
  
- Other Prop 65 listed chemicals may be present in substrates, fountain solution, press wash, inks/coatings
  - Some **phthalate ester plasticizers** in flexible vinyl
  - **Cobalt compounds** in conventional sheetfed ink
  - **Glycol ethers** in fountain solution and press washes



# Enforcement

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- Civil penalties: \$2,500 per violation per day.
- Injunctive relief and criminal penalties also available.
- Bounty Hunter Provision
  - Private citizen may bring enforcement action if the state declines to do so or does not act within 60 days after it is notified of an alleged violation.
  - If enforcement action is successful, a bounty hunter is entitled to 25% of any penalties.



# Thank you!

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