



**California's Proposition 65 and Laboratory Chemicals:
Preserving the Out-of-State Manufacturer Exemption for
Workplace Chemical Products**

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Proposition 65 for Laboratory Chemicals: Preserving the Out-of-State Manufacturer Exemption for Workplace Chemical Products

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Proposition 65 Basics

- Warning Requirement
 - Exposure - must be shown, cannot always be inferred due to presence in product or workplace
 - To a “listed” chemical - 900+
- Occupational Warning Method
 - Labels, signs or methods that comply with the Federal Hazard Communication Standard (27 CCR 25604 *et seq.*)
- 60-day notice from plaintiff to defendant and public prosecutors with Certificate of Merit required before private enforcer can bring suit in the public interest
- Burden of defense on defendant
 - No significant risk (cancer)
 - No observable effect (reproductive toxicant)
- Civil penalties of up to \$2500/day/violation, 25% to private enforcer
- Successful private enforcer can recover attorneys’ fees

Proposition 65 for Laboratory Chemicals

- The Out-of-State Manufacturer Exemption for Workplace Chemical Products
- OSHA approved the incorporation of Proposition 65 into the California Hazard Communication Standard
- OSHA imposed three conditions:
 - Warning methods under the HazCom Standard are acceptable for communicating warnings required under Proposition 65.
 - Cal/OSHA is responsible for ensuring that “private enforcement” does not result in inconsistencies in the terms on which the Standard is approved.
 - Proposition 65 may not be enforced against out-of-state manufacturers of workplace chemicals

Interplay with Federal Occupational Safety and Health Act

- Federal OSH Act preempts additional state requirements unless those requirements are part of a State OSHA Plan.
- Federal OSHA approved incorporation of Proposition 65 into State of California OSHA Plan in 1997 (62 Fed.Reg. 31,159 (June 6, 1997)), with three conditions:
 - (1) methods of giving warnings provided under the Hazard Communication Standard could be used to provide any additional warnings required by Proposition 65;
 - (2) the state would take actions to assure that Proposition 65 does not render decisions in private enforcement matters less effective than other matters; and
 - (3) Proposition 65 could not be applied to occupational exposures to products manufactured outside of California.
- Cal/OSHA has adopted a regulation imposing reporting requirements on private persons bringing Proposition 65 actions concerning occupational exposures. (8 CCR § 338.)

As You Sow v. Shell Oil Company

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Date Filed: July 17, 1995

Noticing Party: As You Sow

Alleged Violator: Shell Oil Company

Chemical: Toluene

Source: Bulk sales of toluene

As You Sow v. Shell Oil Company

Civil Complaint:

- Alleged failure to warn on bulk toluene distributed throughout the state for manufacturing other products

Answer:

- No retail sales
- Product shipped into California by the railcar
- Product shipped from storage in California to other states by tank truck
- MSDS travels with product
- Workers trained in HazCom

April 18, 1995

- Coalition of Manufacturers for Responsible Administration of Proposition 65
- Petition to OSHA to Disapprove the Incorporation of Proposition 65 into the California HazCom Standard

May 27, 1997

- Court Issues Preliminary Injunction Against Shell Oil Company
 - Court finds that As You Sow is “likely to prevail.”
 - Court identifies at least five reasons the warnings on Shell’s MSDS for toluene is not “clear” enough to satisfy Proposition 65.
 - Sale of toluene will be unlawful thirty days after ruling if warning is not made “clear.”

June 6, 1997

OSHA Order - 62 Federal Register 31,159

- OSHA Approved the Incorporation of California Hazard Communication Standard, and portions of Proposition 65 incorporated therein, as part of the California State Plan.
- Three conditions:
 1. Warning methods under the HazCom Standard are acceptable for communicating warnings required under Proposition 65.
 2. Cal/OSHA is responsible for ensuring that “private enforcement” does not result in inconsistencies in the terms on which the Standard is approved.
 3. Proposition 65 may not be enforced against out-of-state manufacturers.

As You Sow v. Shell Oil Company

Result

April 27, 1998

- Trial
- Findings:
 - Shell is an ***out-of-state*** manufacturer of toluene.
 - Of other products reviewed at trial, Shell was an “in-state manufacturer” of one; had no sales in California of that product.
 - Of other products reviewed at trial, Shell was an “in-state distributor” of one.
- **Result:** Judgment for Shell

Recent NOVs Raise the Issue

January-February 2020

- Eleven private-enforcer Notices of Intent to Sue served on producers and distributors of laboratory chemicals and associated products.

Alleged Violations:

- All products sold by [manufacturer]
- Via the [manufacturer's] Website
- Which contain a Listed Chemical in a purity of 10 percent or higher, whether in solid form or in solution, and are sold without the prominent display of a Proposition 65-compliant warning prior to completion of the purchase.
- Which contain a Listed Chemical in a purity of 10 percent or higher, whether in solid form or in solution, and are offered via a product display page containing the following language: (1) WARNING: This product contains a chemical known to the State of California to cause cancer, or (2) WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

Proposition 65 for Laboratory Chemicals

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Alleged Products



Lab Fine Chemicals

- Generally single, pure chemical substances that are produced in limited quantities.
- Typically used as starting building block materials or intermediates for other products used in pharmaceutical, food and beverage, cosmetic and personal care manufacturing.
- Product offering of over 45,000 fine chemicals.

April 27, 2020 - Letter to private enforcer from Attorney General

- “We write to inform you of the Attorney General’s belief that there is ***no merit to the action.***
- The exposures you allege are ***to students*** who use the chemicals in academic laboratories, and not to laboratory employees who may be receiving occupational warnings pursuant to the Hazard Communication Standard. . . .
- ***We note that the academic institutions likely follow safety procedures to prevent or minimize the risk of exposures.***
- Even if your allegation is correct that students in California have been exposed . . . ***the students may nevertheless receive a warning from the academic institution*** prior to any exposure.”

September 18, 2020 Cross-Complaint

- Manufacturers alleged causes of action for
 - breach of contract
 - indemnity
 - unfair competition
 - fraud
- “[A]fter conducting extensive due diligence. . . .they learned that [the defendant company identified in the Notice] is not an actual laboratory and had no reason to order Certified Reference Materials other than to falsely represent its business purposes and seek to substantiate an otherwise baseless lawsuit [under Proposition 65.]”

Making sure the Hazard Communication Standard Exemption Survives

- Use it or lose it
- Who will defend the HazCom Standard?
- **“Out of State Occupational Exposures:** To the extent that your notices allege occupational violations against out-of-state manufacturers, they are in violation of California Code of Regulations, title 8, section 38 and the Approval; California State Standard on Hazard Communication incorporating Proposition 65(62 Federal register 31159-31181 (June 6, 1997)), both of which provide that **Proposition 65 may not be enforced against out-of-state manufacturers for occupational exposure that occur outside the State of California.** The regulations incorporating Proposition 65 into the State Plan state that “this approval specifically placed certain conditions with regard to occupational exposure on Proposition 65, including that it **does not apply to the conduct of manufacturers occurring outside the States of California. . . .**”
- Letter from Attorney General, October 30, 2015

Laboratory Standards:

- <https://www.osha.gov/Publications/laboratory/OSHA3404laboratory-safety-guidance.pdf>
 - Laboratory Safety Standards
 - Summarizes OSHA Safety Standards for Laboratories
 - Addresses chemical, biological, physical and safety hazards
- <https://www.ehs.ucsb.edu/labsafety-chp/sec3/a/1-background>
 - Summarizes Cal-OSHA's Laboratory Standard
- <https://blink.ucsd.edu/safety/occupational/hazard/communication.html>
 - Contains the University of San Diego's Laboratory Safety Manual

Questions?

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Thank you for joining the program.



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