

CALIFORNIA PROPOSITION 65

PROP 65
DEFENSIBLE

Prop 65 Compliance for Caffeine Pouches

System-Based Compliance. Not Just Testing.

Presented by: Prop65Compliance.com

Compliance Management by Consultare Inc. Group

Powered by SystemsBuilder.pro

5,000+

NOVs in 2025

~38% Food Share

Why This Matters

California Prop 65 applies to nicotine-free caffeine pouches — oral products with direct mucosal exposure.

⚠️ WARNING

This product can expose you to chemicals known to the State of California to cause cancer, birth defects, or other reproductive harm.
— P65Warnings.ca.gov

Enforcement Is Aggressive

Enforcement is driven by private 'bounty hunter' lawsuits, not regulators — anyone can file.

Penalties Are Real

Non-compliance leads to financial penalties, legal costs, relabeling, and removal from shelves.

Caffeine Pouches Are in Scope

Oral nicotine-free pouches face scrutiny on caffeine metabolites, flavorings, and carrier chemicals.

Documentation Is Your Defense

Without a compliance system, most companies settle. A defensible record is what ends threats cheaply.

Prop 65 Enforcement Trends (2024–2026)

Enforcement is increasing, not slowing down.

~38%

Food & Supplements

Largest single Prop 65 enforcement category in 2025.

~\$86M

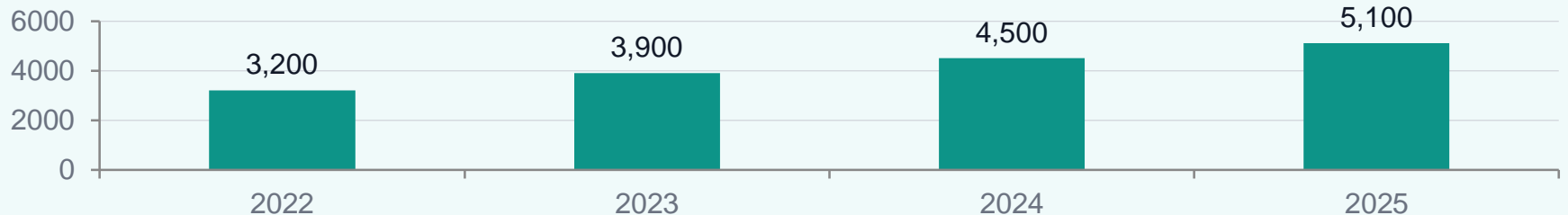
2026 Settlements

Record enforcement activity — majority paid to attorneys.

2 Paths

Caffeine Pouches

Flavor chemicals + caffeine metabolites — stacked risk in one SKU.



Why Caffeine Pouches Are at Risk

From raw material to oral exposure — multiple chemicals can trigger a warning obligation.

1

Caffeine Source

Synthetic or green-coffee caffeine may carry acrylamide or solvent residues from extraction.

2

Flavoring Agents

Flavor chemicals (benzaldehyde, cinnamaldehyde) include Prop 65-listed compounds.

3

Carrier & Filler

Cellulose or plant-based carriers can introduce heavy metals — lead, cadmium.

4

Oral Exposure

Buccal/gum absorption = direct mucosal exposure — highest bioavailability per mg.

Caffeine pouches stack flavor-chemical risk on top of carrier heavy-metal risk — all through buccal delivery.

Business Impact of Non-Compliance

A Prop 65 action hits the balance sheet long before a verdict.

60-Day Notice of Violation

Plaintiff's attorney files with the AG; clock starts immediately on response.

Settlement Exposure

Typical settlements \$20K–\$100K+ per action — plus attorney fees.

Relabeling & Reformulation

Product pulled, warning labels added, ingredient sourcing reviewed.

Retail & Distributor Pressure

Buyers demand evidence of compliance before reinstatement or renewal.

Most companies settle — not because they're guilty, but because their documentation is weak.

Why Prop65Compliance.com

Compliance-focused. Not a law firm. System-based — not one-time testing.

Compliance-Focused



We don't litigate — we build the system that prevents litigation.

System-Based Approach



Testing alone doesn't protect you. A documented program does.

Managed by Consultare Inc.



Operational oversight from a dedicated compliance management team.

Built on SystemsBuilder.pro



Artifact-based system, document control, and AI-assisted workflows.

OUR PROMISE — We build and manage your defensible compliance system. So when a 60-day notice arrives, you already have the answers.

What We Deliver

An end-to-end Prop 65 compliance program — not a one-time report.

Product Risk Assessment

Chemical Testing Oversight

Exposure Evaluation

Compliance Determination

Warning Label Strategy

Supplier Compliance Program

Documentation System

Ongoing Monitoring

Each component is documented, traceable, and audit-ready.

Core Technical Components

The compliance stack underneath every determination we issue.

Chemical Testing

Oversight of Acrylamide, Lead (MADL 0.5 µg/day), Cadmium, and flavor-chemical residues at ISO 17025 labs.

Exposure vs MADL Evaluation

Serving-size, daily-exposure, and averaging calculations to determine whether a warning is required for oral-pouch delivery.

Supplier COA Verification

Incoming raw-material Certificates of Analysis cross-checked against screening thresholds — caffeine, filler, and flavor inputs.

Batch-Level Compliance Review

Every lot is logged, reviewed, and tied to a compliance determination on file.

Warning Label Determination

Clear 'warn vs no-warn' logic documented and defensible against private enforcement.

Supply-Chain Compliance Control

Prevent the issue upstream — before it reaches your label.

1

Supplier Attestation

Certification & declarations collected from every raw-material vendor — caffeine suppliers, filler, flavor houses.

2

Raw-Material Risk Mapping

Inputs classified by chemical exposure profile: caffeine source, carrier, and flavor type.

3

COA Tracking

Every batch COA verified against Prop 65 screening thresholds.

4

Corrective Action (SCAR)

Supplier corrective actions logged, verified, and closed out.

Prevent exposure issues before they reach the consumer — and the courtroom.

The SystemsBuilder Approach

Artifact-based compliance — pay for structure, not repetition.

ARTIFACT (you pay)

Testing Program

One document defining how all testing is conducted, reviewed, and documented for caffeine pouches.

Build once. Use forever.

↓ Generates unlimited ↓

RECORDS (no added cost)

Unlimited Batch Test Results

Every lot tested fills out the same framework — no new artifact needed.

→ *Scalable, predictable, cost-efficient.*

How It Works

A three-phase program. Setup once. Monitor continuously.

01

Setup

- Product intake & scoping
- Risk identification by chemical category
- Testing plan creation
- Documentation structure

02

Implementation

- Lab coordination (ISO 17025)
- Exposure & MADL calculations
- Compliance determination
- Warning-label decisions

03

Monitoring

- Monthly compliance oversight
- Batch & lot review
- Trend analysis
- Audit-ready reporting

Setup Pricing — One-Time Investment

Build your defensible Prop 65 compliance system.

COMPLIANCE SYSTEM SETUP

\$1,500

up to 3 finished products

+ \$150 each additional finished product

One-time investment to build your system.

SETUP INCLUDES

- Risk assessment
- Testing program design
- Exposure evaluation framework
- Documentation system setup
- Compliance determination structure

Monthly Monitoring — Ongoing Oversight

Continuous compliance. Keep your system alive.

ONGOING COMPLIANCE OVERSIGHT

\$500

per month — up to 7 finished products

+ \$50 / month per additional finished product

Cancel anytime. No long-term contracts.

MONITORING INCLUDES

- Batch / lot test review
- Compliance verification
- Monthly reporting
- Trend analysis

Testing Monitoring Fees

Per-event oversight — pay only when your product is tested.

\$35

per testing monitoring event

Per lot / batch — lab-report review, threshold comparison, compliance determination & documentation update.

WHAT THE \$35 COVERS

- Lab report review
- Threshold comparison vs MADL
- Compliance determination
- Documentation update

IMPORTANT — LAB FEE EXCLUSION

Laboratory testing fees are NOT included. Testing is conducted by independent ISO 17025 accredited laboratories. All lab costs are billed directly to the client by the laboratory. We provide oversight and compliance review — not laboratory testing services.

Pay only for actual testing events • No markup on lab fees • Independent results ensure defensibility

What You Receive

Every client gets a defensible, audit-ready document package.

Batch Compliance Review Reports

Per-lot review with pass/fail determination, threshold comparison, and reviewer sign-off.

Monthly Summary Reports

Rolling snapshot of all testing events, compliance status, and open action items.

Compliance Monitoring Logs

Date-stamped log of every decision made — the backbone of defensibility.

Supplier Tracking Records

Attestations, COAs, risk ratings, and corrective actions by supplier.

Audit-Ready Documentation

Packaged for OAG inquiries, retailer audits, and legal counsel on 24-hour notice.

Built for Defensibility

Documentation is the difference between a quick close-out and a six-figure settlement.

DEFENSIBLE RECORD

Documented Due Diligence

Every decision has a record, a reviewer, and a date.

Traceable Decisions

Supplier → material → batch → determination — fully linked.

Verified Lab Testing

ISO 17025 independent results — no conflicts of interest.

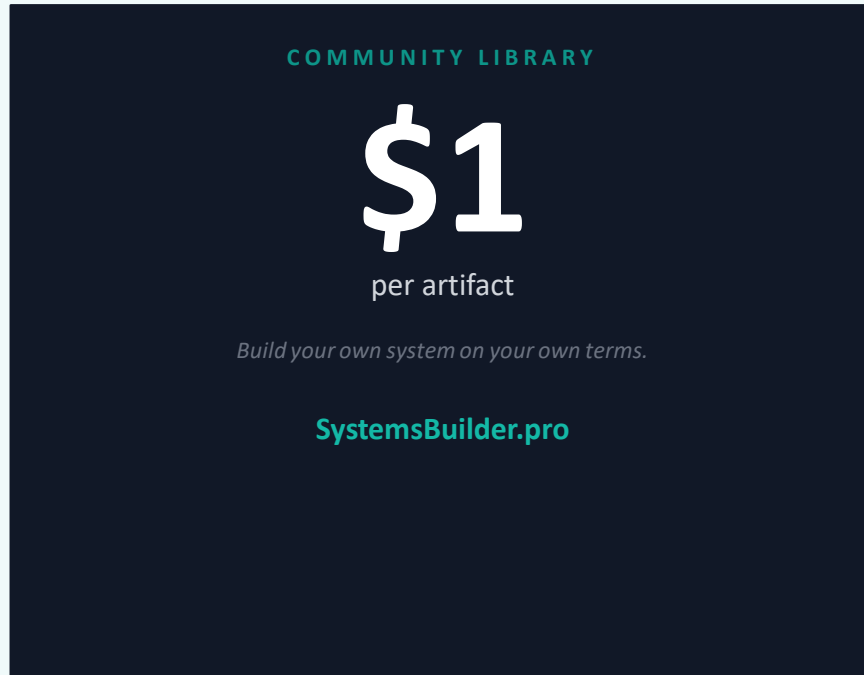
Structured System

Not ad-hoc — a real management system reviewers recognize.

Critical for lawsuits • Retail audits • Regulatory inquiries

DIY Option — SystemsBuilder.pro

Prefer to manage it yourself? The same artifact library, à la carte.



COMMUNITY LIBRARY

\$1
per artifact

Build your own system on your own terms.

SystemsBuilder.pro

ACCESS THE FULL LIBRARY

- Prop 65 Programs
- Policies
- Procedures (SOPs)
- Forms (Artifacts)
- Logs & Templates

Managed Service vs. DIY

Same system. Different execution — you choose who drives.

MANAGED SERVICE

by Consultare Inc. Group

- Hands-off compliance execution
- Expert-managed monitoring
- Monthly reporting delivered
- Best for: growing brands without in-house QA capacity

VS

DIY (SystemsBuilder)

at SystemsBuilder.pro

- Self-managed execution
- \$1-per-artifact library access
- Internal team runs the program
- Best for: teams with existing compliance capability

Same system. Same artifacts. Same defensibility. — You choose who operates it.

Your Risk Profile

Every one of these factors increases your exposure — independently.

#1 ENFORCEMENT TARGET

Food Category

Food & supplements = largest Prop 65 enforcement category in 2025.

TOP LITIGATION DRIVER

Multiple Chemicals

Acrylamide, lead, cadmium, and flavor residues all drive enforcement — any one can trigger a notice.

NATURAL EXPOSURE RISK

Caffeine Pouches

Oral delivery maximizes bioavailability — and regulatory exposure per serving.

STRICT ENVIRONMENT

California

Most aggressive private-enforcement regime in the United States.

Your product is already in a high-risk category — even if you've done nothing wrong.

Don't wait for a 60-Day Notice.

Start your Prop 65 compliance system today.

MANAGED COMPLIANCE

Let us manage it for you.

- End-to-end Prop 65 system setup
- Ongoing monitoring & oversight
- Audit-ready documentation
- Expert-managed execution

DIY LIBRARY

Build it yourself.

- \$1-per-artifact library access
- Community programs & policies
- Forms, logs & templates
- Run it your way, in-house

"Build it yourself — or let us manage it for you."