

CALIFORNIA PROPOSITION 65

Prop 65 Compliance for Nootropic 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%

Consumer Share

Why This Matters

California Prop 65 applies to oral consumer products — even herbal and “natural” formulations.



⚠️ 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

Herbal ≠ Exempt



Enforcement Is Aggressive

California requires warnings for exposure to listed chemicals — enforcement is driven by private lawsuits (‘bounty hunters’).



Penalties Are Real

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



Applies to Oral Products

No exemption for natural, herbal, or adaptogenic formulas. If your product is sold in California, you’re in scope.



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.

Annual Prop 65 NOVs Issued



Source: OAG 60-Day Notice database; industry-category tallies.

~38%

Food & Supplements

Largest single category of Prop 65 enforcement in 2025.

~\$86M

2026 Settlements

Record enforcement activity — majority paid to attorneys.

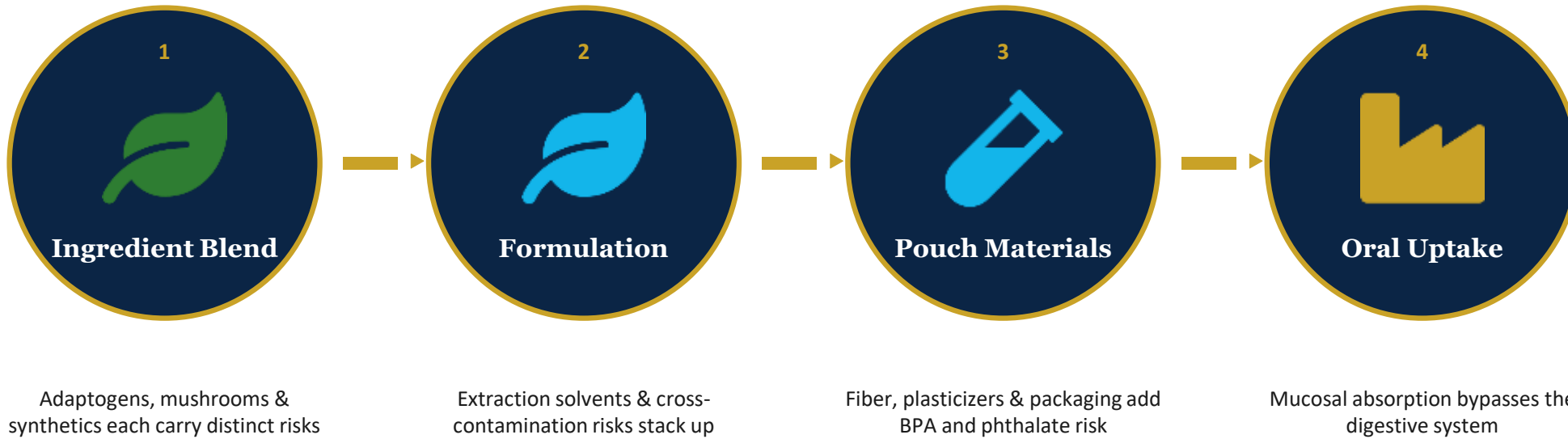
Oral Products Under Scrutiny

Pouches, Gums, Lozenges

Heavy metals in adaptogens, botanical contaminants & packaging chemicals drive enforcement against nootropic products.

Why Nootropic Pouches Are at Risk

Listed chemicals enter through ingredients, processing, and packaging. Oral delivery bypasses digestion.



“Natural” or “herbal” ingredients do not eliminate Prop 65 exposure risk.

Lead, cadmium, arsenic, solvent residues, BPA & phthalates are all listed Prop 65 chemicals — any one can trigger a warning obligation.

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. Group

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 Lead (MADL 0.5 µg/day), Cadmium (MADL 4.1 µg/day), Arsenic, solvent residues, BPA & phthalates at ISO 17025 labs.



Exposure vs MADL Evaluation

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



Supplier COA Verification

Incoming raw-material Certificates of Analysis cross-checked against screening thresholds.



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.



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

The SystemsBuilder Approach

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



ARTIFACTS vs RECORDS

You pay for the structure — not the records.

Build once. Use forever.

Example:

ARTIFACT (you pay)

Testing Program

One document that defines how all testing is conducted, reviewed, and documented.

↓ 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 STEP Setup

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

02 STEP Implementation

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

03 STEP 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

Keeps you continuously compliant.

MONITORING INCLUDES



Batch / lot test review



Compliance verification



Monthly reporting



Trend analysis

Cancel anytime. No long-term contracts.

Testing Monitoring Fees

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

\$35

per testing monitoring event

Per lot / batch — covers 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.



Documented Due Diligence

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



Verified Lab Testing

ISO 17025 independent results — no conflicts of interest.



Traceable Decisions

Supplier → material → batch → determination — fully linked.



Structured System

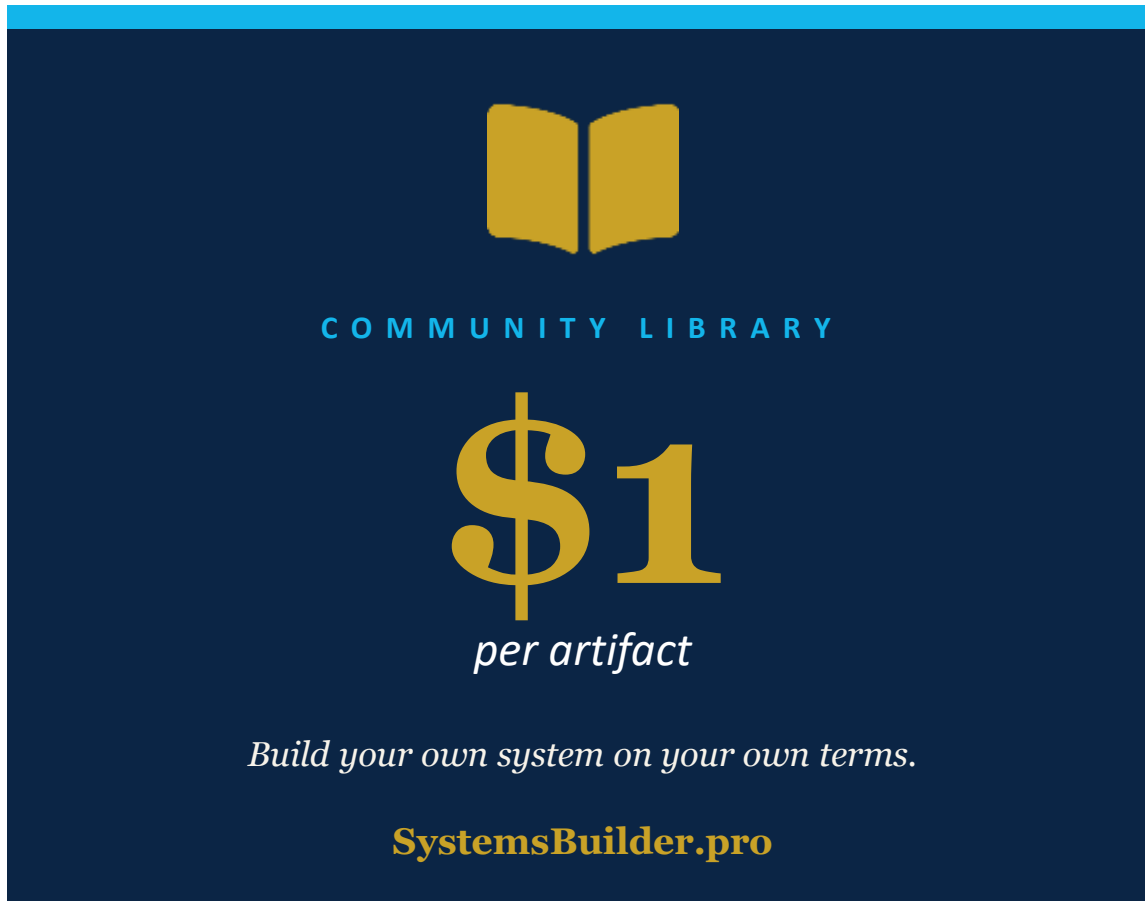
Not ad-hoc — a real management system reviewers recognize.

Critical for lawsuits • Retail audits • Regulatory inquiries

OPTION

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

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



Oral Products

Consumable and oral products face rising Prop 65 enforcement activity.

TOP LITIGATION DRIVER



Multiple Chemicals

Heavy metals, solvent residues, BPA & phthalates all drive enforcement — any one can trigger a notice.

NATURAL EXPOSURE RISK



Nootropic Pouch

Multi-ingredient blends multiply risk; oral-mucosal delivery bypasses digestion.

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.

CALL TO ACTION

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.”

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