

CALIFORNIA PROPOSITION 65

Prop 65 Compliance for Dietary Supplements

The #1 Prop 65 Enforcement Target. Defend Your Brand.

Presented by: Prop65Compliance.com

Compliance Management by Consultare Inc. Group

Powered by SystemsBuilder.pro



#1

Top Category

~38%

Food + Supp

Why This Matters

Dietary supplements are one of the most-sued categories under Prop 65.



⚠️ 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

“Natural” ≠ Safe



Botanical Extracts Carry Metals

Herbs, roots, and greens concentrate lead and cadmium from soil — turmeric, ashwagandha, and chlorella are recurring targets.



Every SKU Is Separately At Risk

A 30-SKU line = 30 separate potential NOVs. One warning label strategy across the catalog isn't enough.



Amazon & Retailers Are Watching

Marketplaces are now requiring Prop 65 documentation as a condition of listing — not just California retailers.



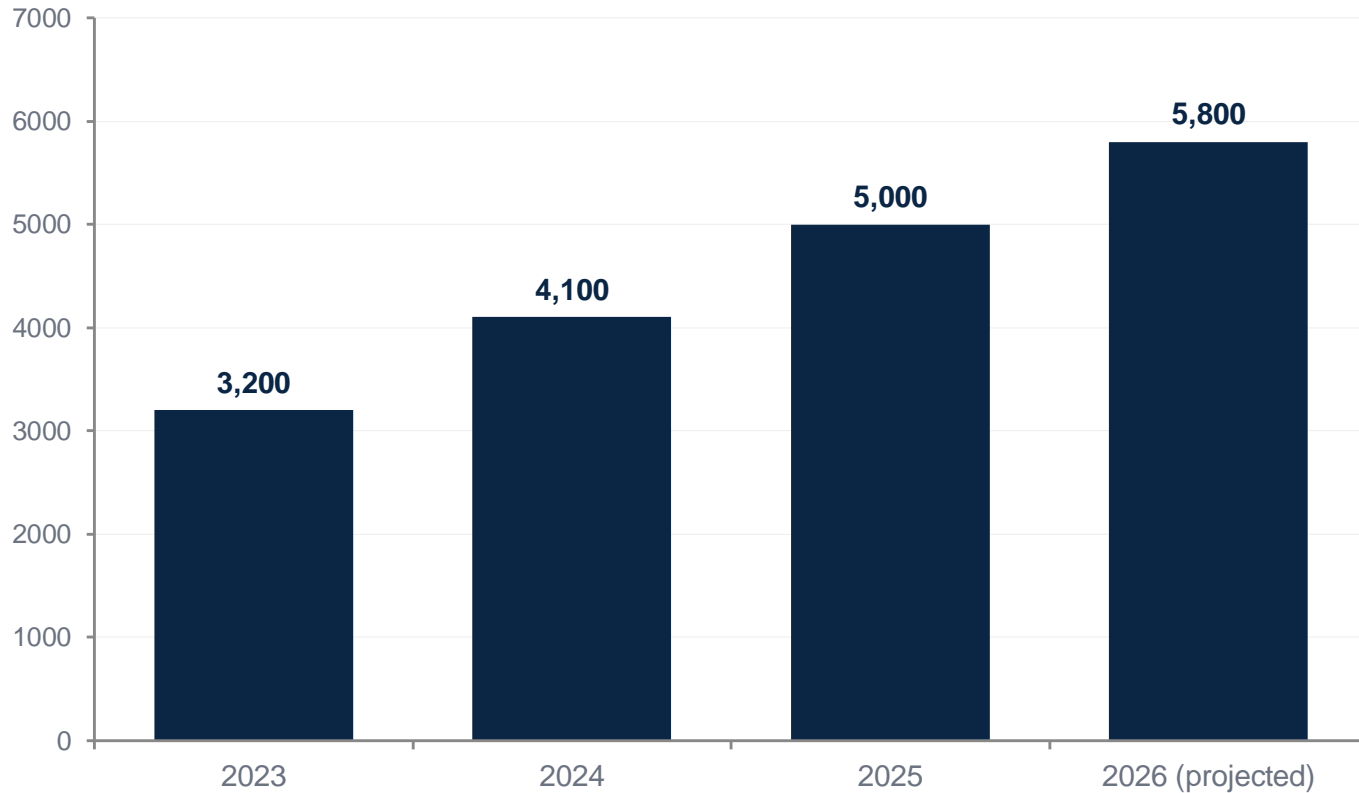
Documentation Is Your Defense

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

Supplements in the Crosshairs

Disproportionately targeted within the food & supplement category.

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.

Turmeric
Herbal
Protein

Top Supplement Targets

Botanicals, protein powders, and greens lead supplement NOV's.

Why Dietary Supplements Are High-Risk

The risk starts in the soil — and concentrates in every capsule.



Herbs and roots absorb lead, cadmium, arsenic from soil

Drying concentrates trace metals into plant material

Extraction concentrates actives — and contaminants — further

Small daily serving = concentrated metal exposure per dose



Extraction amplifies what soil started — small dose, concentrated exposure.

Lead MADL = 0.5 µg/day. A 500 mg turmeric capsule at 0.3 ppm lead already puts you at threshold.

Business Impact of Non-Compliance

For supplement brands, the damage extends far beyond the settlement.



60-Day Notice of Violation

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



Settlement Exposure

Supplement settlements commonly \$30K–\$150K per SKU — per plaintiff.



Amazon & Retail Delisting

Marketplaces suspend listings the moment an NOV is filed against a SKU.



Brand & Review Damage

Prop 65 warnings trigger negative reviews and trust loss that outlast the case.

Most supplement brands 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 + InterlinkIQ

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

What We Deliver

An end-to-end Prop 65 compliance program — tailored to your SKU catalog.



**SKU-Level Risk
Assessment**



**Heavy Metal Testing
Oversight**



**Exposure
Evaluation**



**Compliance
Determination**



**Warning Label
Strategy**



**Ingredient Supplier
Program**



**Documentation
System**



**Ongoing
Monitoring**

Each component is documented, traceable, and audit-ready — per SKU.

Core Technical Components

The compliance stack underneath every supplement determination we issue.



Heavy Metal Panel Testing

Oversight of Lead (MADL 0.5 µg/day), Cadmium (MADL 4.1 µg/day), Arsenic, and Mercury at ISO 17025 labs.



Daily-Serving Exposure Math

Calculations based on actual label-recommended daily serving — not per-gram — to determine warning requirement.



Raw Ingredient COA Review

Botanical, mineral, and excipient COAs verified before they enter the formulation.



SKU-by-SKU Compliance File

Each finished SKU gets its own compliance determination, stored and cross-referenced to batch records.



Warning Label Decision Log

Clear 'warn vs no-warn' logic per SKU — the documented reasoning that stops plaintiff demands.

Ingredient Supply-Chain Control

Most supplement NOVs trace back to one bad botanical lot. Catch it upstream.



Catch the bad ingredient lot before it becomes 50,000 bottles of liability.

The SystemsBuilder Approach

Artifact-based compliance — built once, scales across your entire SKU catalog.



ARTIFACTS vs RECORDS

You pay for the structure — not the records.

Build once. Use for every SKU.

Example:

ARTIFACT (you pay)

Heavy Metal Testing Program

One document defining how every SKU is tested, reviewed, and documented.

↓ Generates unlimited ↓

RECORDS (no added cost)

Per-SKU, Per-Lot Test Records

Every lot of every SKU 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

- SKU intake & catalog scoping
- Ingredient risk classification
- Testing plan per SKU
- Documentation structure

02 STEP Implementation

- Lab coordination (ISO 17025)
- Daily-serving MADL math
- Per-SKU determination
- Warning-label decisions

03 STEP Monitoring

- Monthly compliance oversight
- Per-lot review
- Trend analysis by ingredient
- Audit-ready reporting

Setup Pricing – One-Time Investment

Priced per SKU, because every SKU needs its own compliance file.

COMPLIANCE SYSTEM SETUP

\$1,500

up to 3 finished SKUs

+ \$150
each additional SKU

One-time investment to build your system.

SETUP INCLUDES



SKU-level risk assessment



Heavy metal testing program



Daily-serving exposure framework



Documentation system setup



Compliance determination structure

Monthly Monitoring — Ongoing Oversight

Continuous compliance. Scales with your SKU catalog.

ONGOING COMPLIANCE OVERSIGHT

\$500

per month — up to 7 SKUs

+ \$50 / month

per additional SKU

Keeps you continuously compliant.

MONITORING INCLUDES



Per-lot test review (every SKU)



Compliance verification



Monthly reporting



Trend analysis by ingredient

Cancel anytime. No long-term contracts.

Testing Monitoring Fees

Per-event oversight — pay only when a lot is tested.

\$35

per testing monitoring event

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

WHAT THE \$35 COVERS

- Lab report review
- Threshold comparison vs MADL
- Per-SKU 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 — per SKU.



Per-SKU Compliance Review Reports

Each SKU's lot review with pass/fail determination, MADL comparison, and reviewer sign-off.



Monthly Summary Reports

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



Compliance Monitoring Logs

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



Ingredient Supplier Records

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



Audit-Ready Documentation

Packaged for OAG inquiries, retailer audits, and Amazon compliance requests 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 SKU determination has a record, a reviewer, and a date.



Verified Lab Testing

ISO 17025 independent results — no conflicts of interest.



Traceable Decisions

Supplier → ingredient → lot → SKU → determination — fully linked.



Structured System

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

Critical for lawsuits • Retailer audits • Amazon compliance • 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 Supplement 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 supplement brands scaling SKU count

DIY (SystemsBuilder)

at SystemsBuilder.pro

- Self-managed execution
- \$1-per-artifact library access
- In-house QA team runs the program
- Best for: contract manufacturers & brands with QA depth

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

Supplement Category

Food & supplements = largest Prop 65 enforcement category; supplements lead NOV counts.



TOP LITIGATION DRIVER

Heavy Metals in Botanicals

Lead, cadmium, arsenic, and mercury lawsuits dominate supplement enforcement activity.



INGREDIENT CONCENTRATION

Extract-Based Products

Extraction concentrates metals into dosage form — small daily serving, big exposure per dose.



MARKETPLACE RISK

Retailer Compliance Demands

Amazon and major retailers now require proactive Prop 65 documentation — not just reactive.



If you sell supplements in California, you are already on the target list.

CALL TO ACTION

Don't wait for a 60-Day Notice.

Protect your supplement catalog — today.



MANAGED COMPLIANCE

Let us manage it for you.

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



DIY LIBRARY

Build it yourself.

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

“Build it yourself — or let us manage it for you.”

Prop65Compliance.com • [SystemsBuilder.pro](#)