

CALIFORNIA PROPOSITION 65

Prop 65 Compliance

for Mineral Supplements

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

~64%

Food & Supp. Share

W H Y

Why This Matters

Mineral supplements concentrate the very elements Prop 65 targets. And as supplements, they lose the naturally-occurring defense.

WARNING

This product can expose you to chemicals including lead, cadmium, and arsenic, known to the State of California to cause cancer and birth defects or other reproductive harm.

— P65Warnings.ca.gov

Active Enforcement

Nov 2025: 72% of Prop 65 NOVs cited heavy metals. Minerals & 'superfood' blends specifically named.



The Product IS the Mineral

Unlike food or protein powder, contaminants are inherent to source material — zinc ore always carries cadmium; limestone always carries lead.



Source Material Determines Risk

Mining vs seawater vs bone vs coral vs chelated — each source has a predictable heavy metal fingerprint.



Supplement = No Defense

Supplements cannot claim 'naturally occurring' exemption even if the metals came from nature.



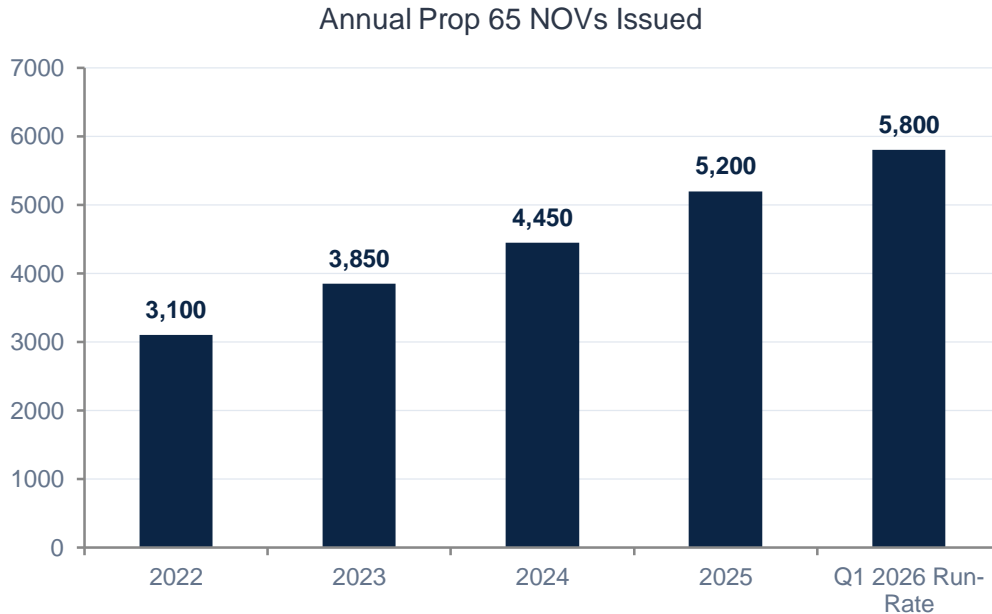
Documentation Is Your Defense

ICP-MS data, source attestations, exposure math — the only evidence that holds up in court.

W H Y

Prop 65 Enforcement Trends (2024–2026)

Enforcement is accelerating — not slowing down.



Source: OAG 60-Day Notice database; Bureau Veritas CPS quarterly summaries.

~64%

Food & Supplements

Largest single category of Prop 65 enforcement in Q1 2026 — record share.

~\$98M

2026 Settlements

Record enforcement activity — majority paid to attorneys.

72%

Heavy Metals

Share of Nov 2025 Prop 65 NOVs citing Pb, Cd, As — dominant and growing.

WHY

Your Mineral Source Is the Risk

Heavy metal load is inherent to source material — and varies by orders of magnitude across formulations.



TIER 1 — HIGHEST RISK

Coral Calcium, Bone Meal, Kelp-Based

Historically driven biggest NOV's. Coral/bone = high lead; kelp concentrates arsenic. Legacy category with settled enforcement history.



TIER 2 — HIGH RISK

Iron, Zinc, Multi-Mineral Blends

Ore-derived. Zinc always co-extracts with cadmium (sphalerite). Iron ore carries lead & cadmium. Blends stack all constituent risks.



TIER 3 — MODERATE RISK

Calcium (Limestone/Dolomite), Selenium

Limestone carries natural lead (~0.8 µg/g OEHHA allowance). Selenium has narrow therapeutic margin — small dose errors = violations.



TIER 4 — LOWER RISK

Magnesium, Chelated Forms (Glycinate, Picolinate)

Seawater magnesium & chelation-purified minerals carry lower metal loads. Quality still depends on parent material source.

Multi-mineral products inherit every tier they contain — a single blend can stack Pb (from Ca), Cd (from Zn), and As (from trace minerals).

W H Y

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 on response.



Settlement Exposure

Supplement-category settlements \$25K–\$150K+ per action. Coral calcium & bone meal NOVs drove industry precedent.



Amazon & Retail Delisting

Amazon, Whole Foods, Sprouts, Vitamin Shoppe, GNC, Costco all require documented compliance.



Brand & Import Hold Risk

FDA import alerts, customs holds, buyer-initiated quality holds can halt shipments for months.

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

WHAT

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

What We Deliver

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



**Product Risk
Assessment**



**Heavy Metal
Test Oversight**



**Exposure
Evaluation**



**Compliance
Determination**



**Warning Label
Strategy**



**Supplier
Compliance Program**



**Documentation
System**



**Ongoing
Monitoring**

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

WHAT

Core Technical Components

The compliance stack underneath every determination we issue.



ICP-MS Heavy Metal Testing

Pb (MADL 0.5 µg/day), Cd (MADL 4.1 µg/day), As, Hg at ISO 17025 labs — finished dosage form, per lot.



Source Fingerprint Analysis

Zn/Cd ratio (sphalerite origin), Pb/Ca ratio (limestone origin), As (kelp origin) — source validation against expected impurity profile.



USP + Prop 65 Dual Evaluation

USP lead limit for supplements is 10 µg/day. Prop 65 MADL is 0.5 µg/day. A USP-compliant product can fail Prop 65 by 20x.



Multi-Mineral Stacking Math

Exposure sums across every mineral ingredient per serving — blends inherit all constituent risks.



Raw Material Source Review

Mine, seawater, bone, coral, chelation — each source has a predictable heavy-metal signature and audit path.

WHAT

Supply-Chain Compliance Control

Prevent the issue upstream — before it reaches your label.



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

HOW

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 defining how all mineral source screening, ICP-MS testing, and multi-mineral exposure evaluations are recorded.

↓ Generates unlimited ↓

RECORDS (no added cost)

Unlimited Batch Test Results

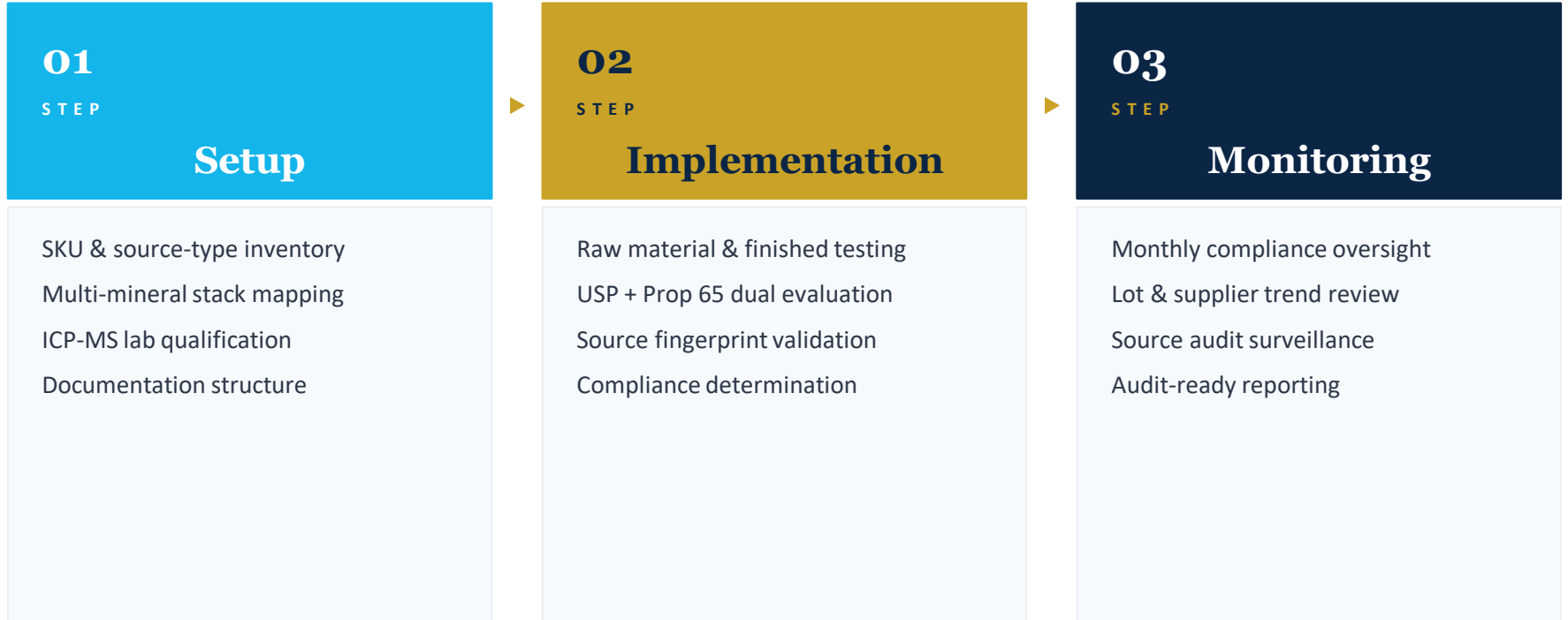
Every lot tested fills out the same framework — no new artifact needed.

→ *Scalable, predictable, cost-efficient.*

HOW

How It Works

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



Setup Pricing — One-Time Investment

Build your defensible Prop 65 compliance system.

COMPLIANCE SYSTEM SETUP

\$1,500

up to 3 finished products (SKUs)

+ \$150

each additional SKU

One-time investment to build your system.

SETUP INCLUDES

- ✓ SKU & source-type risk assessment
- ✓ Multi-mineral stacking analysis
- ✓ Testing program design (ICP-MS)
- ✓ USP + Prop 65 framework
- ✓ Source attestation protocols

PRICING

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 SKU

Keeps you continuously compliant.

MONITORING INCLUDES

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

Cancel anytime. No long-term contracts.

PRICING

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 (0.5 µg/day lead)
- 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

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.

HOW

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.

BOTTOM LINE

Your Risk Profile

Every one of these factors increases your exposure — independently.



STRUCTURAL RISK

The Product IS the Mineral

Contaminants are inherent to source material — zinc always carries cadmium, limestone always carries lead. No reformulation eliminates the risk.



NO DEFENSE AVAILABLE

Supplement Category

Supplements cannot claim 'naturally occurring' exemption even when metals come from nature. 0.5 µg/day triggers a warning.



ENFORCEMENT DOMINATES

72% of NOV's Are Heavy Metals

Nov 2025: Pb, Cd, As accounted for 72% of all Prop 65 NOV's. Minerals and 'superfood' blends specifically named.



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."

Prop65Compliance.com • SystemsBuilder.pro