

C A L I F O R N I A P R O P O S I T I O N 6 5

Prop 65 Compliance

for Prenatal Vitamins

System-Based Compliance. Not Just Testing.

Presented by: **Prop65Compliance.com**
Compliance Management by **Consultare Inc. Group**
Powered by **SystemsBuilder.pro**



P R O P 6 5
D E F E N S I B L E

5,000+

NOVs in 2025

~45%

Supplement Share

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Why This Matters

California Prop 65's MADLs were written to protect pregnant women — your target consumer IS the test case.

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

Prescription ≠ Exempt

1 in 3 prescription prenatal exceeds the Prop 65 lead MADL per daily dose.



Enforcement Is Aggressive

Private plaintiffs ('bounty hunters') file the majority of 60-Day Notices — the AG doesn't need to lead.



Penalties Are Real

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



MADL Designed for THIS Consumer

Reproductive-toxicant MADLs (Pb 0.5 µg/day, DEHP 410 µg/day) were derived from pregnancy-exposure models. For prenatal, Prop 65 isn't a conservative proxy — it's the actual use case.



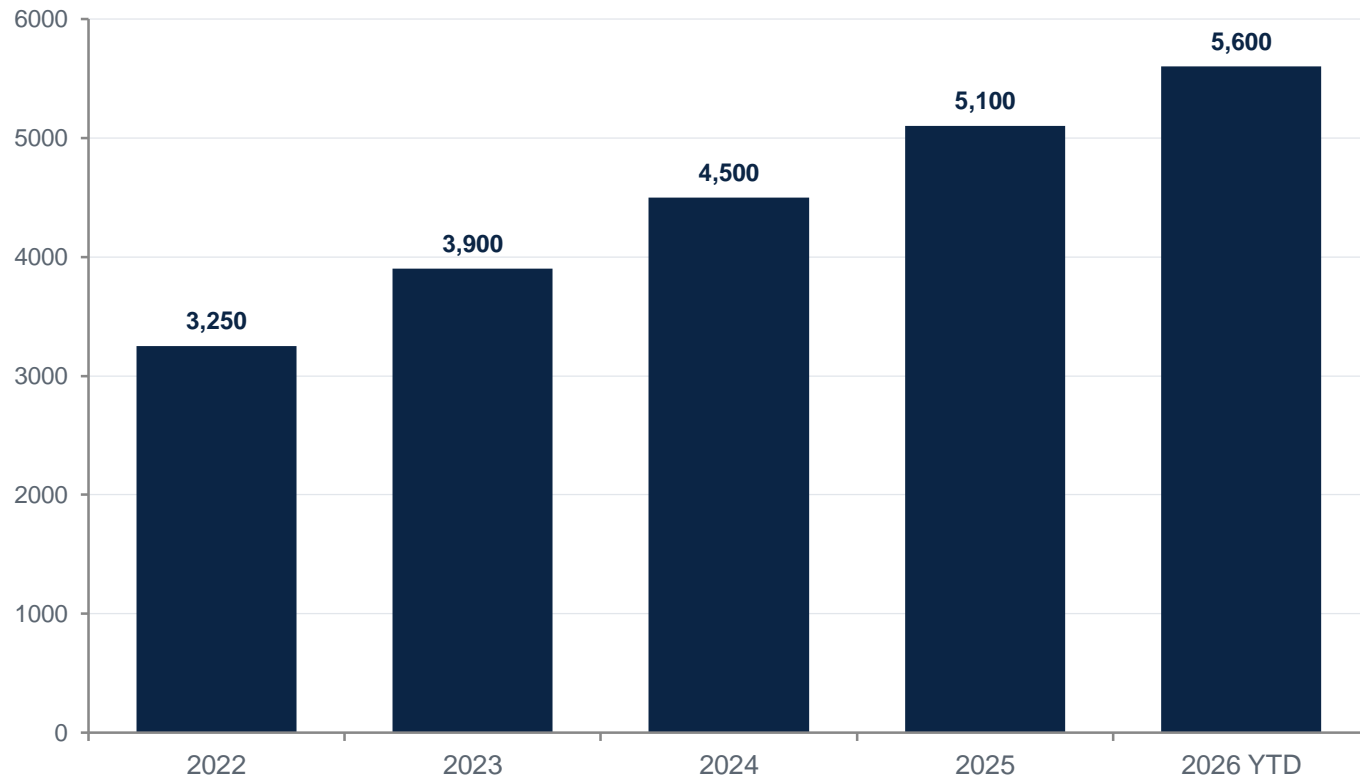
Documentation Is Your Defense

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.

~45%

Supplements & Foods

Largest combined category of Prop 65 enforcement in 2025.

~\$86M

2026 Settlements

Record enforcement activity — majority paid to attorneys.

83%

Contain Detectable Lead (U. Miami 2025)

In a 156-product study, 83% had detectable Pb and 15% exceeded the 0.5 µg/day Prop 65 MADL per serving.

Why Prenatal Vitamins Are at Risk

The formulation IS the risk — the very nutrients mother needs are the primary contamination vectors.



Mineral Feedstocks

Calcium carbonate, iron fumarate, Mg oxide — mined minerals carry soil-origin Pb, Cd, As



Herbal & Botanical Add-ons

Ginger, red raspberry, kelp (iodine), choline — each adds its own metal and phthalate exposure



Packaging & Colorants

Capsule shells, film coatings, printing inks — DEHP and DBP phthalate migration into daily-use product



Pre-, During & Post-Natal Dosing

12–24 months of daily exposure during preconception, gestation, and lactation — cumulative not serving-level

Higher Ca and Fe doses correlate with higher Pb and Cd contamination — the formulation decisions ARE the Prop 65 decisions.

Pb (MADL 0.5 µg/day), Cd (MADL 4.1 µg/day), DEHP (MADL 410 µg/day), and DBP are all reproductive-toxicant MADLs — cumulative peri-conception, gestational, and lactational exposure is the real metric.

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.

W H A T

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.

O U R P R O M I S E

*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**



**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.



Reproductive-Toxicant Heavy Metal Testing

Lead (MADL 0.5 µg/day), Cadmium (MADL 4.1 µg/day), inorganic Arsenic (NSRL 10 µg/day), Mercury (MADL 0.3 µg/day) per daily dose at ISO 17025 labs.



Phthalate Testing (DEHP, DBP, BBP)

25% of OTC prenatal products contain detectable DEHP; 13% contain DBP. Testing of capsule shells, coatings, and colorants is non-negotiable.



Mineral-Feedstock COA Discipline

Calcium and iron dose correlate with contamination; Ca carbonate, Fe fumarate, Mg oxide each tested per supplier lot before formulation.



USP Verified / NSF Certified Alignment

Alignment to USP <2232> elemental impurities + NSF/ANSI 173 (dietary supplement) — the industry benchmarks for defensible compliance.



Cumulative-Exposure Math (Pre-, Gest-, Lact-)

12–24 month cumulative dose modeled, not just per-serving — preconception through lactation captures the real fetal/infant exposure.

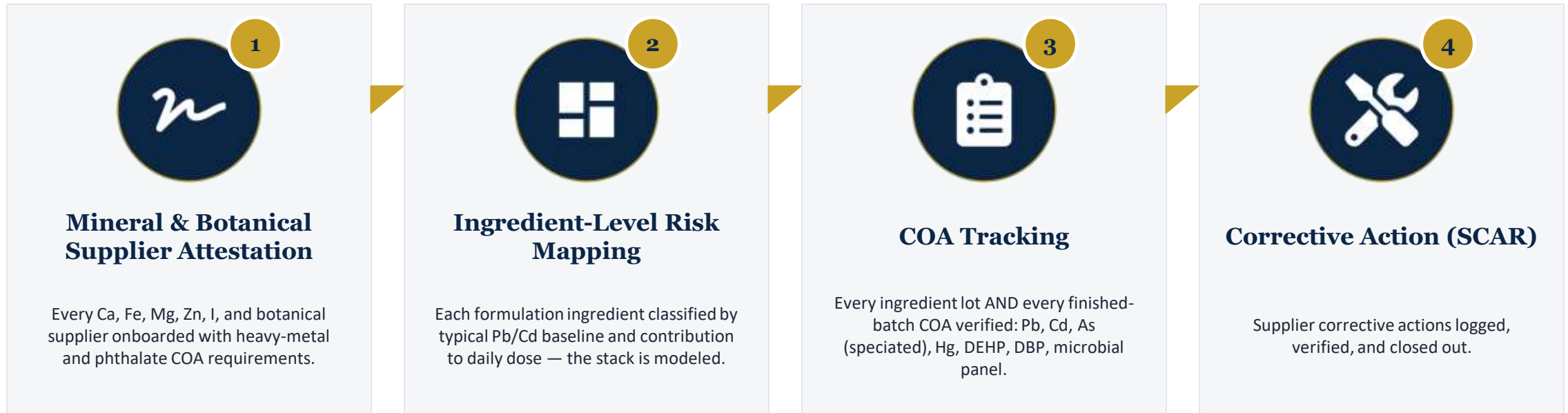


Warning Label Determination

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)

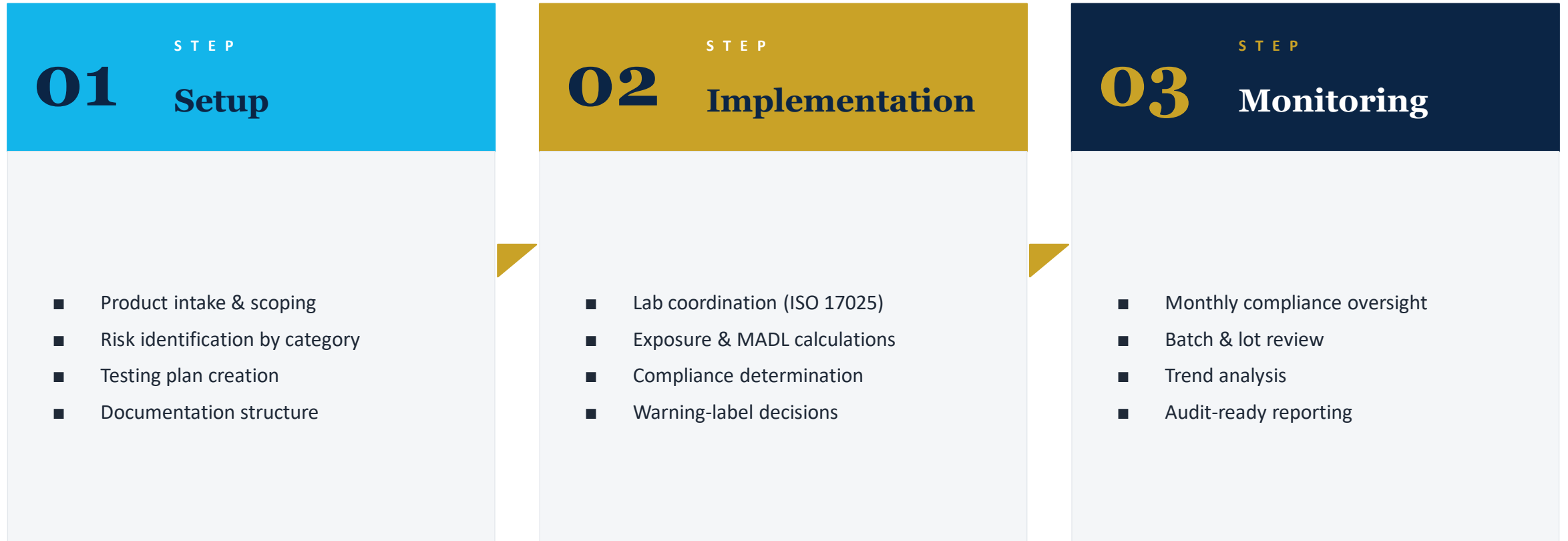
Unlimited Batch Test Results

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.



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 (SKU)

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

Mineral supplier → ingredient lot → formulation → daily dose → determination.



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*

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

Supplement Category

Supplements & foods = largest Prop 65 enforcement category in 2025.



TOP LITIGATION DRIVER

Pb + Cd + Phthalates

Reproductive-toxicant MADLs all triggered: 83% Pb detection, 73% Cd, 25% DEHP in prenats tested.



NATURAL EXPOSURE RISK

Prenatal Vitamins

Pregnant consumers are the exact population MADLs were written to protect — no category has less regulatory margin.



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