

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 Tricalcium Phosphate

System-Based Compliance. Not Just Testing.

Presented by: [Prop65Compliance.com](https://prop65compliance.com)
Compliance Management by [Consultare Inc. Group](https://consultare.com)
Powered by [SystemsBuilder.pro](https://systemsbuilder.pro)



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

5,000+

NOVs in 2025

~42%

Food + Supplements

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Why This Matters

California Prop 65 applies to all mineral ingredients — including tricalcium phosphate.

⚠️ 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

Mineral ≠ Exempt

Rock-phosphate origin means heavy metals travel with the ingredient.



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.



Food, Supplements & Pharma All in Scope

No exemption for food-grade, USP, FCC, or pharma-grade TCP. Every downstream product sold in California is in scope.



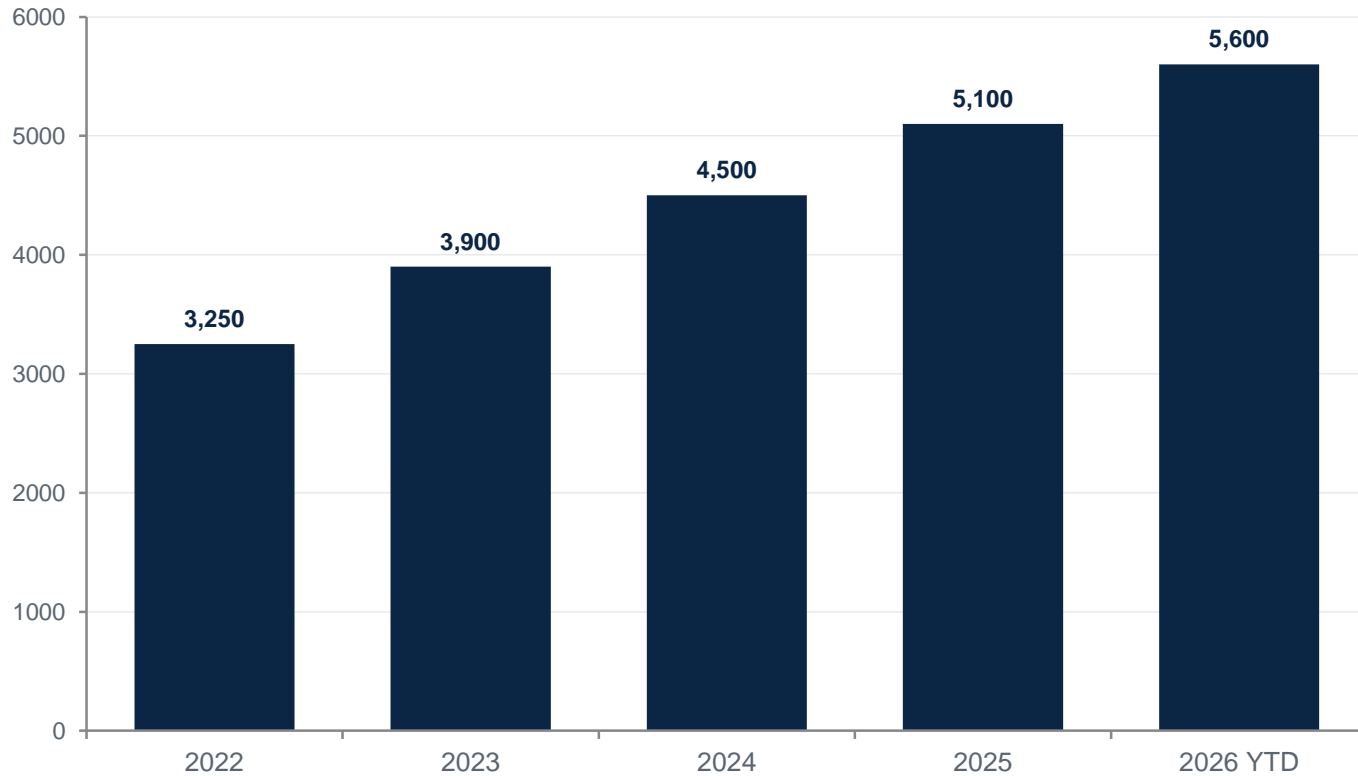
Documentation Is Your Defense

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.

~42%	Food & Supplements Combined, the largest single category of Prop 65 enforcement in 2025.
~\$86M	2026 Settlements Record enforcement activity — majority paid to attorneys.
Phosphate Rock	Mineral-Origin Contamination Cadmium, lead, arsenic & fluoride travel from raw phosphate rock through refining.

Why Tricalcium Phosphate Is at Risk

Heavy metals and fluoride travel with the mineral — from rock to finished product.



Phosphate Rock Origin

Cd, Pb, As & fluoride naturally occur in rock phosphate deposits



Wet-Process Acid

Phosphoric acid carries metals forward unless actively removed



Purification & Precipitation

$\text{Ca}^3(\text{PO}_4)_2$ forms — residual metals concentrate without controls



Food / USP Grade TCP

Downstream dose exposure must stay below 0.5 $\mu\text{g}/\text{day}$ Pb MADL

Synthetic or mined — the rock-phosphate supply chain carries listed chemicals into the finished ingredient.

Lead, cadmium, arsenic, and fluoride are all concerns — food/USP-grade documentation is the first line of defense.

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

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.



Heavy Metal Testing

Oversight of Lead (MADL 0.5 µg/day), Cadmium (MADL 4.1 µg/day), and Arsenic (NSRL 10 µg/day) at ISO 17025 labs.



Fluoride & Impurity Profile

Compendial fluoride limits (FCC/USP/Ph. Eur.) plus loss-on-ignition and insolubles verification per batch.



Exposure vs Safe-Harbor Evaluation

Per-serving, daily-exposure, and averaging calculations across end-use applications (food, supplement, pharma).



Grade & Compendial COA Verification

Every lot verified to FCC, USP, Ph. Eur., or customer spec — never industrial-grade routed into food/pharma.



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)

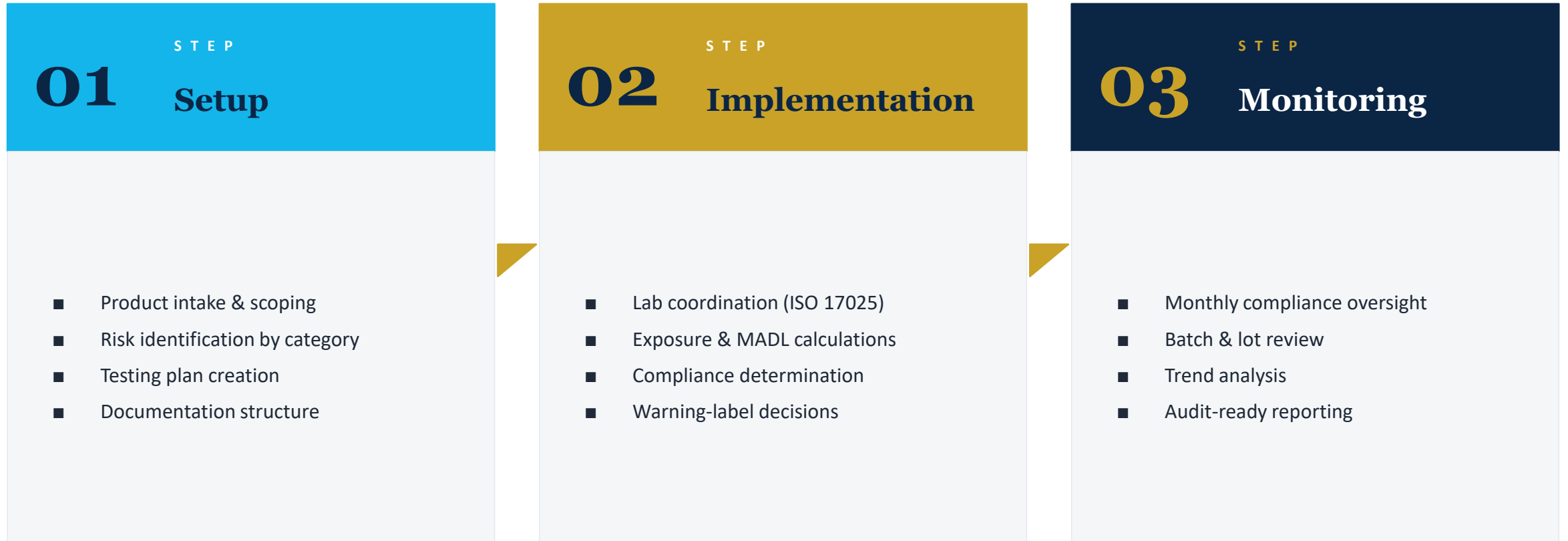
Unlimited Batch Test Results

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.



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

Rock origin → refiner → batch → determination — fully linked.



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

Food & Supplements

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



TOP LITIGATION DRIVER

Mineral-Origin Metals

Lead, cadmium & arsenic from phosphate rock feedstocks drive supplement enforcement.



NATURAL EXPOSURE RISK

Tricalcium Phosphate

Heavy metals and fluoride are inherent to rock-phosphate feedstocks — purification is the only defense.



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