

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 Sunscreens

System-Based Compliance. Not Just Testing.

Presented by: Prop65Compliance.com

Compliance Management by [Consultare Inc. Group](#)

Powered by [SystemsBuilder.pro](#)



78 of 294

Benzene-Positive

Stayed

FDA Monograph

W H Y

Why This Matters

Sunscreens face a stack of compliance regimes that no other personal-care product carries — Prop 65 sits on top of all of them.



THE BENZENE PROBLEM

Valisure (2021) found benzene in 78 of 294 sunscreen batches; J&J recalled 5 Neutrogena/Aveeno brands; class actions still resolving in 2025.

Benzene is a Prop 65 carcinogen with NSRL 1.3 µg/day — and it's a degradation byproduct, not an added ingredient.

Why Sunscreens Are Different

Regulated as OTC Drugs (Not Just Cosmetics)

FDA monograph governs SPF, broad-spectrum, water-resistance claims — entirely separate from Prop 65 obligations.

Stayed Monograph + Pending Order

12 chemical UV filters await FDA GRASE determination. Only zinc oxide and titanium dioxide are confirmed GRASE today.

Benzene Contamination Risk

Forms during degradation of carbomer and other excipients in spray formats; not listed as ingredient — but Prop 65 captures it.

Reef-Safe Patchwork (Hawaii, Caribbean)

Hawaii Act 104, Maui County, Hawaii County, US Virgin Islands, Palau, Aruba — multi-jurisdictional UV-filter restrictions.

PFAS in Water-Resistant Formulas

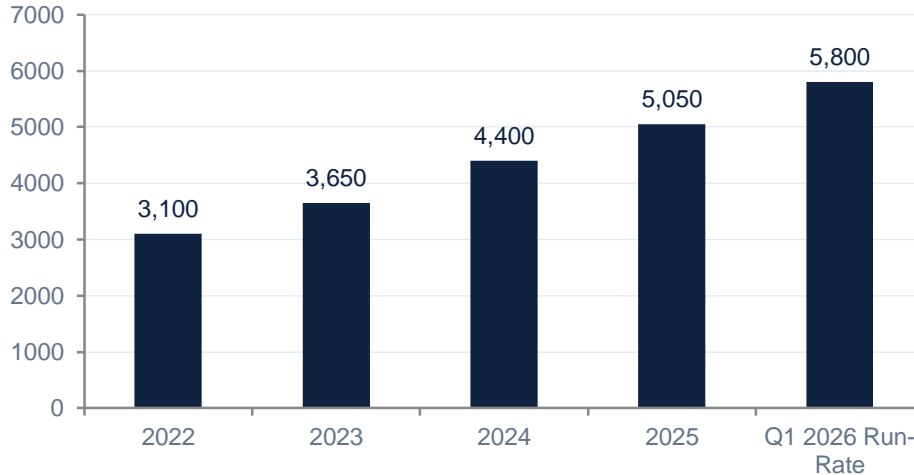
Long-wear and 80-min water-resistant claims often rely on PFAS-derived film-formers — no Prop 65 safe-harbor level.

W H Y

Prop 65 Enforcement Trends (2024–2026)

Sunscreens sit at the intersection of cosmetic, OTC drug, and environmental enforcement.

Annual Prop 65 NOVs Issued



Source: OAG 60-Day Notice database; Valisure citizen petition; FDA enforcement reports.

5 Brands

Recalled by J&J (2021)

Neutrogena and Aveeno aerosols pulled after benzene detection. Class-action settlement still resolving claims through 2025.

16+

Jurisdictions Restrict UV Filters

Hawaii statewide, Maui, Hawaii County, USVI, Palau, Aruba, Bonaire, plus pending state legislation in 2026.

1.3 µg/d

Benzene Prop 65 NSRL

Significant Risk Level for benzene cancer endpoint — exceeds 1.3 µg/day = warning required, no exceptions.

W H Y

Five Regulatory Fronts Converge

Sunscreens carry more parallel obligations than any other personal-care product.



FDA OTC Drug Monograph

Stayed monograph; 12 UV filters await GRASE. Only ZnO and TiO₂ confirmed GRASE. Pending order under CARES Act sec. 505G.



Benzene & Heavy Metals — Prop 65 Carcinogens

Benzene NSRL 1.3 µg/day; Pb MADL 0.5 µg/day; Cd, Cr, As from mineral filters. Independent labs catching what manufacturers miss.



Titanium Dioxide (Enjoined for Cosmetics)

PCPC v. Bonta permanently enjoined Aug 12, 2025 for cosmetics — but sunscreens straddle the cosmetic/drug line.



Reef-Safe Multi-Jurisdiction

Hawaii Act 104, Maui Co. (mineral-only), Hawaii Co., USVI, Aruba, Palau — UV-filter ingredient bans expanding.



PFAS in Water-Resistant Formulas

Film-formers in 80-min water-resistant claims often PFAS-derived. CA AB 2771 cosmetic-PFAS ban effective 2027.

Sunscreens are uniquely complex — drug + cosmetic + environmental + Prop 65. The system has to handle all four at once.

▶ YOUR PRODUCT PORTFOLIO

Every Sunscreen SKU

Lotion, spray, stick, mineral, chemical, tinted, kids, baby, sport, face, lip — every form is in scope.

*Five regulatory fronts.
One system to manage them all.*

W H Y

Business Impact of Non-Compliance

Sunscreen recalls have already cost the industry hundreds of millions.



Recall + Class Action Liability

J&J's 2021 benzene recall triggered nationwide MDL; Banana Boat MDL active in 2024–25; settlements still being paid in 2025.



Aerosol & Spray Reformulation

Benzene risk highest in aerosols. Carbomer + propellant chemistry requires full requalification — months, not weeks.



Reef-Safe Reformulation

Hawaii/Caribbean access requires mineral-only or oxybenzone/octinoxate-free formulas — separate SKU lines or single global formula.



Market Already Bifurcating

Major retailers (Sephora, Target, REI) push reef-safe and clean-beauty filters. Brand assortment shrinks if you can't certify.

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.

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.*

W H A T

What We Deliver

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



SKU & Filter-System Risk Assessment



Benzene & Heavy Metals Testing



PFAS & Migration Testing



Exposure Evaluation



Warning Label & Short-Form Strategy



FDA Monograph Cross-Check



Reef-Safe Multi-State Mapping








PCPC Litigation & MoCRA Tracking

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

W H A T

Core Technical Components

The compliance stack underneath every determination we issue.

	Benzene Testing — GC-MS	Headspace GC-MS at finished-good lot level. Prop 65 NSRL 1.3 µg/day. FDA limit 2 ppm. Highest risk: aerosol/spray formats.
	Heavy Metals — ICP-MS	Pb, Cd, Cr, As, Sb on finished sunscreen and on incoming ZnO/TiO ₂ pigments. Mineral filters are the largest metal load.
	PFAS & Migration Screen	Total fluorine + targeted PFOA/PFOS by LC-MS/MS in water-resistant formulas. Packaging migration for DEHP, BPA.
	FDA Monograph Compliance	UV filter inventory vs. deemed final order; SPF/broad-spectrum/water-resistance label substantiation; CARES Act 505G watch.
	Reef-Safe Multi-State Mapping	Hawaii Act 104, Maui Co. (mineral-only), USVI, Palau, Aruba, plus pending state legislation — tracked per SKU/per market.

W H A T

Filter & Component Supply-Chain Control

Prevent the issue upstream — at the UV filter, the formula, and the package.



Filter & Excipient Spec

ZnO/TiO₂ pigment qualification; chemical-filter audit; carbomer source review (benzene risk vector); preservative system.

Formula & Process Validation

SPF substantiation, broad-spectrum testing, water-resistance cycle; thermal stability for benzene formation; reef-safe declaration.

Lot Testing

GC-MS for benzene, ICP-MS for heavy metals, PFAS screening on water-resistant SKUs — per lot, before retail release.

Component Qualification

Aerosol can liner attestation, BPA-free pumps, phthalate-free fragrance, recyclable container claims — supplier signed-off.

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

H O W

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)

Sunscreen Benzene, Heavy Metals & Reef-Safe Compliance Program

One document defining how all benzene GC-MS, heavy metal ICP-MS, PFAS, and reef-safe verification flows through filter qualification, lot release, and multi-state distribution.

↓ Generates unlimited ↓

RECORDS (no added cost)

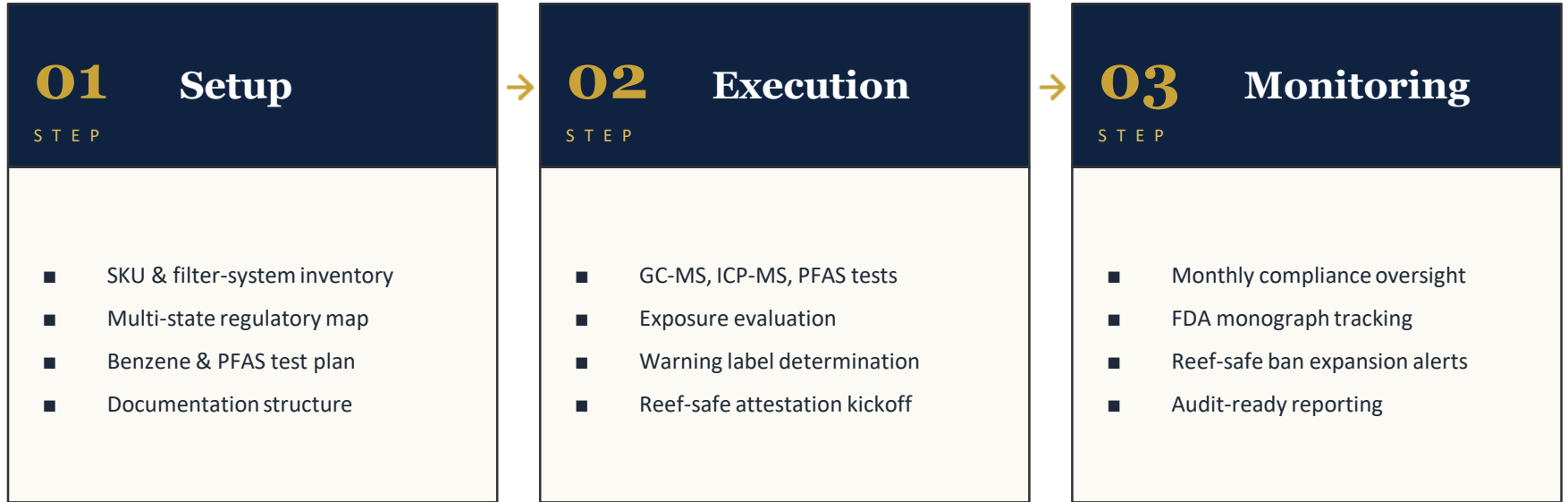
Unlimited Lot Test Results, COAs, Reef-Safe Attestations

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

→ Scalable, predictable, cost-efficient.

How It Works

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



PRICING

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 or SPF level

One-time investment to build your system.

SETUP INCLUDES

- ✓ SKU & filter-system risk assessment
- ✓ Benzene, heavy metals & PFAS test plan
- ✓ Reef-safe multi-state mapping
- ✓ FDA monograph cross-check
- ✓ Reformulation roadmap

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 or SPF level

Keeps you continuously compliant.

MONITORING INCLUDES

- ✓ Lot test review (benzene, metals, PFAS)
- ✓ FDA monograph & PCPC updates
- ✓ Reef-safe legislation tracking
- ✓ Monthly compliance reporting

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 — covers lab-report review, NSRL/MADL/FDA threshold comparison, compliance determination & documentation update.

WHAT THE \$35 COVERS

- ✓ Lab report review (GC-MS, ICP-MS, PFAS)
- ✓ Threshold comparison (NSRL / MADL / FDA)
- ✓ Compliance determination
- ✓ Documentation update

IMPORTANT — LAB FEE EXCLUSION

Laboratory testing fees are NOT included. Testing is conducted by independent ISO 17025 accredited labs. All lab costs are billed directly to the client by the laboratory.

Pay only for actual testing events • No markup on lab fees • Independent results ensure defensibility

W H A T

What You Receive

Every client gets a defensible, audit-ready document package.



Lot 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.



Filter & Component Tracking

UV filter qualifications, ZnO/TiO₂ pigment COAs, packaging attestations, reef-safe declarations by SKU.



Audit-Ready Documentation

Packaged for OAG inquiries, retailer (Sephora, Ulta, REI, Target) audits, and FDA inspections on 24-hour notice.

H O W

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

Filter → formula → fill → release → 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.

M A N A G E D S E R V I C E

by Consultare Inc. Group

- ◆ Hands-off compliance execution
- ◆ Expert-managed monitoring
- ◆ Monthly reporting delivered
- ◆ Best for: indie brands, contract fillers, growth-stage labels

D I Y (S y s t e m s B u i l d e r)

at SystemsBuilder.pro

- ◆ Self-managed execution
- ◆ \$1-per-artifact library access
- ◆ Internal team runs the program
- ◆ Best for: brands with regulatory affairs in-house

Same system. Same artifacts. Same defensibility. — You choose who operates it.

Your Risk Profile

Every one of these factors increases your exposure — independently.

RECALL HISTORY



Benzene Contamination

Valisure 2021 found benzene in 78 of 294 sunscreen batches. J&J recalled 5 brands. NSRL 1.3 µg/day — easily exceeded.

STAYED RULE



FDA Monograph Limbo

12 chemical UV filters await GRASE determination. Only ZnO and TiO₂ confirmed safe & effective today.

MULTI-JURISDICTION



Reef-Safe Bans Expanding

Hawaii, Maui Co., Hawaii Co., USVI, Palau, Aruba — and more states pending. Each ban shrinks your addressable market.

NO SAFE HARBOR



PFAS in Water-Resistant Formulas

PFOA/PFOS and other PFAS in 80-min water-resistant films — no Prop 65 safe-harbor level means trace detection drives NOV's.

Sunscreens carry more parallel obligations than any other personal-care product. Your system has to handle all of them.

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