
ASSAYHOUSE

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THE FIELD GUIDES

VOLUME TWO

MAKEUP

Six questions for reading any personal-care label, and eight materials read against them.

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Question Zero — What kind of label am I holding?

Ask this before the other five. It decides which of them apply.

Not everything on a personal-care shelf is a cosmetic in law, and the difference is printed on the pack if you know what to look for. In the US, what a product legally is depends on what it is intended to do.

The three kinds

1 · Cosmetic.

Intended to cleanse or beautify. One ingredient list, in descending order of weight, no percentages disclosed. The FDA does not pre-approve cosmetic products or ingredients — with one important exception, color additives, which matters for Question 1.

Moisturizers, most shampoos, lipstick, nail polish, deodorant, perfume.

2 · Cosmetic and drug.

Intended to cleanse or beautify and to treat or prevent something or affect the body's structure or function. These carry both sets of obligations, and the label shows it.

The structural giveaway: under 21 CFR 701.3(d), a product that is both must identify the drug ingredients as "Active Ingredients" first, before the cosmetic ingredients. The list is split in two — actives at the top with their exact percentages stated, then the inactives in ordinary descending order.

Anti-dandruff shampoo, antiperspirant-deodorants, moisturizers and makeup sold with SPF claims, acne treatments, hand sanitizers.

The cleanest illustration is on one shelf. A deodorant is a cosmetic — it masks odor. An antiperspirant is a drug — it reduces sweating, which affects a function of the body. Same aisle, same format, two legal categories, two different labels.

3 · True soap.

A narrow legal category: consisting primarily of an alkali salt of fatty acids, making no claim beyond cleansing. Products, meeting that definition are not regulated by the FDA at all — they fall to the Consumer Product Safety Commission and are not required to carry a cosmetic ingredient list.

Most things sold as "soap" today aren't true soap in this sense; they're cosmetic cleansing bars, and they do carry a list. If a cleansing bar has no ingredient list, this is usually why — not an oversight.

8. D&C Red No. 27 — the flagship profile

INCI Name: CI 45410 (D&C Red No. 27) • **Formula** $C_{20}H_4Br_4Cl_4O_5$ • **Function Group:** Certified colorant (lake)

Origin. This dye is a direct descendant of one of the oldest synthetic dyes still in use. In 1871, German chemist Adolf von Baeyer combined resorcinol with phthalic anhydride and produced a red crystalline compound that glowed brilliant green in alkaline solution. He named it fluorescein, after the property Sir George Gabriel Stokes had named fluorescence two decades earlier. Baeyer's original interest was the chemistry of dyes; nothing about the discovery involved eyes, lips, or cosmetics.

D&C Red No. 27 is made by taking that same fluorescein scaffold and halogenating it — replacing four hydrogen positions with chlorine and four more with bromine, producing tetrachlorotetrabromofluorescein. The FDA approved it for use in drugs and cosmetics in 1982, under 21 CFR 74.2327.

Why it's used in makeup. On its own, this dye is water-soluble, which makes it difficult to hold in place in a product like a lipstick. Formulators solve this by precipitating it onto an aluminum substrate — converting the soluble dye into an insoluble "lake" that stays put in an anhydrous formula and doesn't bleed or migrate. That is the specific job this material does: it is chosen for how it behaves once fixed to a substrate, not for the color alone.

Elsewhere. The parent compound, plain fluorescein, never left its original field. It is still used today, in essentially the same chemical form Baeyer discovered, as the standard diagnostic dye in ophthalmology — instilled directly into the eye to stain corneal damage and, in its injectable form, to image the blood vessels of the retina. It is also a standard water tracer in hydrology, used to trace groundwater flow and detect leaks, and a forensic reagent for locating trace blood at a scene.

What the framework sees — Question 1, taken further than anywhere else in this volume. Every material in Volume One's Part 2 illustrated one question. This one illustrates the point where Question 1 stops being about *position* and becomes about *permission*.

Color additives are exempt from the ordering rule — that much was established in Volume One. What wasn't yet relevant is that a color additive's approval is also scoped to specific uses, and the scope isn't printed on the pack. D&C Red No. 27 is approved, under its own regulation, "for coloring cosmetics generally." That sounds unconditional. It is not: the regulation contains no language extending that approval to the eye area, and under the FDA's general rule, a color additive approved for general use may not be used near the eye unless its own listing says so. This one's doesn't. It can sit in a lipstick or a blush. It cannot legally sit in a mascara or an eyeshadow.

Start with the limit, not the promise.

The same limit that opened Volume One's Part 3 applies here, for the same reason: an ingredient list cannot separate formulation cost from marketing cost, and nothing about color cosmetics changes that. What *does* change in this category is where the visible cost signals sit. In facial care, packaging was one cost driver among several. In makeup, packaging and mechanism — the compact, the pump, the brush, the wand — routinely account for more of what you're paying than any material inside the formula, because so much of this category's material cost is commodity-cheap mineral pigment and common wax.

What this section does. It shows which of Volume Two's eight materials carry price information, addresses a labeling complication Volume One never had to (this category is sold by weight *and* by volume, and the two aren't interchangeable), and works through what "budget," "premium," "eco," and "BIO" can and can't mean when applied to a shelf built mostly from minerals, synthetic dyes, and silicones.

Walkthrough 1 — A pressed powder with an SPF number

The situation. Two pressed setting powders sit side by side, same brand line, nearly identical packaging. One states "SPF 15" on the front. The other doesn't. Both list titanium dioxide.

Run the questions.

Q0 — first, always. Check for an "Active Ingredients" heading or Drug Facts panel. The SPF powder has one: titanium dioxide appears there, stated at a specific percentage, ahead of the ordinary ingredient list. The plain powder has no such panel — titanium dioxide, if present, sits inside the ordinary cosmetic ingredient list with no percentage disclosed.

What that tells you. The identical INCI name, titanium dioxide, is doing two different jobs on these two labels. On the plain powder it's functioning purely as a pigment — an exempt colorant, ordering-exempt, no percentage required. On the SPF powder, at that same or a similar concentration, it's a drug active, subject to Question 0's cosmetic-and-drug rule: named first, percentage stated.

What you now know. The two products may contain nearly the same material at a similar level, and the only reason one label discloses a percentage while the other doesn't is the claim printed on the front — not a difference in the underlying pigment.

What you still don't know. Whether the stated percentage is adequate protection for your situation, or how it compares to a dedicated sunscreen. Question 0 tells you the number is disclosed and where to find it. It doesn't interpret what that number means for you, and neither does this guide.

THE FIELD GUIDES · FIRST EDITION

Volume Two Makeup

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The same six questions run through every volume. Only the shelf changes.

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