
ASSAYHOUSE

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THE FIELD GUIDES

VOLUME FIVE

HAND & NAIL

**Six questions for reading any personal-care label, and
seven 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.

Examples the FDA gives directly: *Anti-dandruff shampoo, antiperspirant-deodorants, moisturizers and makeup sold with SPF claims, acne treatments, hand sanitizers.*

The single cleanest illustration, and it's on one shelf: a deodorant is a cosmetic — it masks odour. An antiperspirant is a drug — it reduces sweating, which is affecting a function of the body. Same aisle, same format, two different legal categories and two different labels.

3 • True soap. A narrow legal category: consisting primarily of an alkali salt of fatty acids and 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 they 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.

MATERIAL 07

7. UNDECYLENIC ACID — THE FLAGSHIP PROFILE

INCI NAME Undecylenic Acid (10-Undecenoic Acid) — commonly used as its zinc salt, Zinc Undecylenate ·
FORMULA $C_{11}H_{20}O_2$ · **FUNCTION GROUP** OTC drug active (antifungal)

Origin: Undecylenic acid was first isolated in 1877, as a byproduct of distilling castor oil — specifically, from the pyrolysis of ricinolein acid, the same fatty acid already profiled in Volume Two's Castor Oil entry. For decades afterward it was an industrial curiosity rather than a medicine: a 1945 paper in the Journal of the American Chemical Society studied it purely as a building block for vinyl polymerization. Its antifungal properties weren't put to therapeutic use until the 1940s — roughly sixty years after its first isolation, and for a purpose nobody was looking for when they first pulled it out of castor oil.

WHY IT'S USED, AND WHAT ITS APPROVAL ACTUALLY COVERS.

Undecylenic acid disrupts fungal cell function and is recognized under the FDA's OTC topical antifungal monograph (21CFR Part 333) as safe and effective — specifically for athlete's foot, jock itch, and ringworm, conditions involving fungal infection of the skin. It is not FDA-approved specifically for onychomycosis — fungal infection inside the nail plate itself.

ELSEWHERE.

The same pyrolysis reaction that produces undecylenic acid also produces its methyl ester, a precursor to nylon-11 — meaning castor oil is feeding this identical industrial pathway from two directions: the whole oil, and this specific fragment cracked out of its ricinoleic acid content. Undecylenic acid is also used in fragrance manufacturing (as a component of musk-type scent compounds) and, unrelated to any of its industrial sourcing, occurs naturally as a minor component of human sweat.

WHAT THE FRAMEWORK SEES — QUESTION ZERO, AND A SCOPE-OF-APPROVAL LESSON FOR A THIRD

TIME IN THIS SERIES: Every FDA-approved treatment specifically for nail fungus — the prescription topical ciclopirox (Penlac, approved 1999), the prescription topicals efinaconazole and tavaborole (both approved 2014), and oral prescription antifungals— requires a prescription. None is available over the counter. What sits on a retail shelf marketed toward nail fungus, including products built around undecylenic acid, carries a monograph approval for a related but distinct condition: fungal infection of skin, not of the nail plate itself, which is a far harder physical barrier to treat topically. This is the same structural lesson D&C Red No. 27's eye-area restriction taught in Volume Two and PPD's eyelash exclusion taught in Volume Four, appearing for a third time in a third completely different context: an approval scoped to one use doesn't automatically extend to an adjacent one, and nothing on the front of the pack is required to tell you where that line sits.

Start with a limit sharper than usual

Every prior Part 3 in this series opened with the same honest limit: an ingredient list can't separate formulation cost from marketing cost. That limit still applies here. But this category adds a second, more consequential one, specific to one product type: **for nail fungus treatment, price comparison itself can be the wrong question**. A \$6 OTC product and a \$60 OTC product built around the same monograph active are still both carrying an approval for a skin condition, not the nail plate — running the price-per-mL math on two products in that situation compares two things that were never going to solve the underlying problem to begin with. Knowing when not to reach for a price comparison is as much a part of this method as knowing how to run one.

What this section does. Shows which of Volume Five's seven materials carry price information, addresses the nail-fungus pricing trap directly, works through where the money actually goes for the other seven product types, and treats the four positionings with one addition — a fifth category this volume needs that no prior volume did.

Which materials actually carry price information?

MATERIAL	PRICE INFO?	ON LABEL?	WHAT ACTUALLY DIFFERS
Undecylenic Acid	Not in the way price usually works	Yes — name and concentration	See the pricing trap below: price tier says nothing about whether the product can reach the actual site of infection
Nitrocellulose	Barely	Yes — typically the majority ingredient	Commodity film-former; present across every price tier of nail polish
Ethyl Methacrylate	Somewhat	Yes — name and position	EMA-versus-MMA distinction matters more for safety than for price; both are inexpensive commodity monomers
Acetone	Barely	Yes — usually the majority ingredient	Commodity solvent; acetone-free formulations (ethyl acetate based) cost more, a formulation choice rather than a quality signal
Urea	Genuinely, and directly	Yes — concentration usually stated	Concentration changes the product's actual function(humectant vs. keratolytic), making the stated percentage worth checking regardless of price
Formaldehyde	Somewhat	Yes, when present above 0.05%(mandatory disclosure)	Concentration is capped by regulation (2.2% EU maximum), not a driver of premium positioning
Tocopherol	Barely	Partly — acetate form not always distinguished from free tocopherol	The stable ester form costs more to formulate with but isn't always named as such

The pattern. Urea is the standout: its stated percentage is the single most functionally informative number in this entire volume, changing what the product actually does rather than just signaling formulation quality. Undecylenic Acid inverts the usual table entirely — it's the one material where the price question is secondary to a scope question that has to be resolved first.

Three walkthroughs. This is where the framework stops being theory.

Walkthrough 1 — A shelf of "nail fungus" products, and the one question that matters more than any of them

The situation. A shopper stands in front of several OTC products marketed toward nail fungus — creams, brush-on treatments, a product with a nail illustration prominently on the front.

Run the questions. Q0 first: each carries an "Active Ingredients" panel, confirming these are drugs, not plain cosmetics. But the active named — undecylenic acid, tolnaftate, or similar — belongs to the OTC topical antifungal monograph (21 CFR Part 333), whose listed approved indications are tinea pedis, tinea cruris, and tinea corporis. None of those is onychomycosis. The front of the package can picture a nail; the monograph behind the active ingredient cannot approve treatment of one.

What you now know. None of the products on this shelf carry FDA approval specifically for nail fungus, regardless of how directly their packaging addresses the concern. That's not a claim about whether any of them help at all — it's a verifiable fact about what their listed active is actually cleared to treat.

What you still don't know. The label doesn't announce this distinction anywhere; nothing on the front says, "not approved for nail fungus." Finding it requires knowing to check the active ingredient against its own monograph's approved indications —exactly the habit this volume is built to teach.

Walkthrough 2 — A nail salon, a rumor about MMA, and the better question underneath it

The situation. A customer has heard "MMA is illegal" and asks a nail technician whether the salon uses it, intending the question as a safety check.

Run the questions. The premise itself needs checking first: the FDA's own published position states no formal federal regulation bans methyl methacrylate in cosmetic products. What actually governs its use is a patchwork of more than 30 individual state cosmetology regulations — meaning "is MMA illegal" doesn't have one national answer, and a technician correctly saying "it's not federally banned" isn't necessarily saying anything about whether it's legal in that specific state, or whether this specific salon complies with that state's rule.

What you now know. The useful question isn't "is MMA illegal everywhere" — it's "does my state's cosmetology board prohibit this, and does this salon follow that rule." That's a sharper, more answerable question than the popular version, and it's the one actually worth asking a salon directly.

What you still don't know. Whether a given salon is in fact using MMA or its safer replacement, EMA, without a product label or direct disclosure to check — the molecules aren't distinguishable by eye once mixed and applied, and low-cost non-compliant use is precisely why the state-level bans exist in the first place.

THE FIELD GUIDES · FIRST EDITION

Volume Five Hand & Nail

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

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