

permanent tattoo ink

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Permanent Tattoo Ink

Pigment suspended in a carrier, deposited into the dermis by needle. Tattoo ink sits in FDA's newest primary category — **(16) tattoo preparations**, added by the MoCRA-era category list and absent from the 1974 regulation — and the regulatory gap it occupies is the most striking one in this catalogue.

What it is

Component	Typical
Pigment	Carbon black; azo pigments for reds, yellows and oranges; copper phthalocyanines for blues and greens; titanium dioxide for white
Carrier	Water, ethanol, witch hazel, glycerin, propylene glycol
Additives	Surfactants, binders, preservatives

No colour additive is approved by FDA for injection into the skin. The pigments used are, in the main, **industrial colourants** — the same materials used in printer ink, automotive paint and textiles — because there is no approved cosmetic palette for this use and never has been.

Why the ink stays

The needle deposits pigment into the **dermis**, below the epidermis that continuously sheds. Macrophages engulf the particles; some remain in place, and when a pigment-laden macrophage dies, neighbouring ones take the pigment up again — a **capture–release–recapture cycle** that is why a tattoo persists for a lifetime while individual cells do not.

Pigment also travels: **tattoo pigment has been found in regional lymph nodes**, which is a documented finding rather than a theoretical concern, and is one of the open research questions in the field.

The known problems

- **Allergic reactions**, most often to **red pigments** — historically mercury sulfide, now azo pigments. They can appear **years after the tattoo**, presenting as itching, swelling and raised plaques confined to one colour.
- **Infection**. Bacterial infection from poor technique, and **non-tuberculous mycobacterial outbreaks traced to contaminated ink and to diluting ink with non-sterile water** — the latter has produced multi-state outbreaks and FDA advisories.
- **Granulomas and sarcoid-like reactions**.
- **MRI interaction**. Rare reports of heating or discomfort, mostly with older iron-oxide-containing inks.
- **Obscuring moles**, which makes melanoma harder to detect.
- **Photosensitivity**, particularly yellow pigments.

The regulatory gap

In the US there is no premarket approval of tattoo inks. FDA has historically exercised enforcement discretion, acting on adulteration and contamination rather than approving pigments.

MoCRA changed the framework: tattoo preparations are cosmetics, facilities register and products are listed with FDA, safety substantiation records must be held, and **serious adverse events are reportable within 15 business days**. FDA has also issued **safety advisories on contaminated inks** and has recalled specific products.

The EU went much further. **REACH restriction entry 75, in force from January 2022**, restricts a long list of hazardous substances in tattoo inks and permanent make-up, including many azo pigments and their cleavage products, with concentration limits — and it removed **Pigment Blue 15:3 and Pigment Green 7** from lawful use after a transition period, which materially changed the European colour palette.

Practical advice

Use a licensed studio; **licensing and sanitation are state-level** in the US and are the practical protection. Ask about ink brands and check they are not subject to a recall. **Sterile single-use needles, gloves, and ink poured into single-use caps** are non-negotiable. **Never let anyone dilute ink with tap or bottled water** — that is the documented route to mycobacterial infection.

Patch testing is not reliable for tattoo reactions, and the honest position is that a tattoo carries an irreducible small risk.

Shelf life

Inks carry manufacturer dates. **Once opened, a bottle is a contamination risk**, and professional practice is to pour into single-use caps and never return ink to the bottle. Discard anything past its date, anything that has separated and will not remix, and anything subject to a recall.

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- The rest of *Inks* — [Temporary Tattoo Ink](#) · [Permanent Makeup Pigment](#).
- [Tattoo Aftercare Balm](#) — what comes next.
- Regulatory statements here follow the FDA and EU sources listed on [Cosmetics](#), read 16 August 2026.