

Developing a Biodegradable, Eco-Friendly Soil Gel Polish as an Alternative to Acrylate UV/LED Coatings in the Context of the 2025 Regulatory Shift

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ABSTRACT

The global nail polish market reached USD 17.35 billion in 2024, while the European Union's ban on the photoinitiator TPO from September 1, 2025 created a precedent for a comprehensive reassessment of the chemical composition of UV/LED coatings. The aim of this study is to systematically analyze the chemical, environmental, and regulatory grounds for developing a biodegradable Soil gel polish based on polylactide (PLA) as a replacement for acrylate-copolymer coatings that accumulate in aquatic ecosystems as persistent microplastics. The methodological framework includes comparative formulation analysis, a systematic review of the scientific literature, content analysis of EU and EAEU regulatory documents, and conceptual formulation design. The study substantiates a HEMA- and TPO-free Soil gel-polish composition, defines target performance indicators for durability (21 days) and biodegradation (at least 60% within 28 days according to OECD 301B), and develops a phased roadmap for product market entry. The analysis indicates that a combination of a PLA matrix, bioplasticizers, and CMR-safe photoinitiators can support the creation of a competitive product aligned with the current requirements of Regulation (EU) 2025/877. The findings are relevant to cosmetic-formulation developers, regulatory specialists, and entrepreneurs in sustainable cosmetics.

Keywords- biodegradable gel polish, polylactide (PLA), acrylate copolymer, microplastic, TPO photoinitiator, HEMA-free, Regulation (EU) 2025/877, sustainable cosmetics, CU TR 009/2011, photopolymerization.

I. INTRODUCTION

The manicure industry is experiencing a period of regulatory instability driven by two simultaneous processes: tighter regulatory control over chemical components in cosmetics and growing consumer demand for environmentally responsible products. According to Grand View Research [1], the global nail polish market was valued at USD 16.23 billion in 2023 and reached USD 17.35 billion in 2024, with a compound annual growth rate (CAGR) of approximately 6.9% and a projected value of USD 29.6 billion by 2032. The gel-polish segment is growing even faster: according to Mordor Intelligence [2], its CAGR for 2025–2030 is expected to be 7.50%, reflecting sustained demand for long-wear coatings among professionals and consumers who have adopted at-home manicure practices.

However, the acrylate-copolymer formulations that dominate the segment create a number of documented environmental and toxicological problems. A study by Rozman and Kalčíková [3], published in *Ecotoxicology and Environmental Safety*, showed that water-soluble polyacrylate polymers are practically non-biodegradable under OECD 301 and exert a significant inhibitory effect on nitrifying bacteria and the bioluminescent organism *Aliivibrio fischeri*. The acrylate copolymer used in most commercial gel polishes is classified as a persistent microplastic [4]: particles generated during coating removal enter wastewater-treatment systems, where no more than 60% of microfibers are retained, and subsequently accumulate in bottom sediments.

At the same time, the regulatory landscape has changed radically. Through Regulation (EU) 2025/877, the European Commission prohibited the use of the photoinitiator TPO (diphenyl(2,4,6-

trimethylbenzoyl)phosphine oxide) in cosmetic products from September 1, 2025, after it was reclassified as a CMR category 1B substance for reproductive toxicity under Delegated Regulation (EU) 2024/197 [5]. The European Commission [6] specified that the rule applies without a transition period: from September 1, 2025, neither sale nor professional use of TPO-containing products is permitted, regardless of the date of purchase. Although HEMA has not been completely prohibited, its use is restricted to professional users with a concentration limit and is accompanied by a sustained market shift toward HEMA-free formulations.

These trends define the research problem: existing eco-alternatives to gel polishes (in particular, the only known commercial brand based on organic corn and potato extracts) do not provide acceptable coating durability beyond three weeks when used with a biodegradable matrix [7]. The theoretical gap lies in the absence of a systematic conceptual formulation design that combines biodegradation, the absence of CMR substances, and professional wear performance.

The aim of the study is to systematically analyze the chemical, environmental, and regulatory conditions for developing a biodegradable HEMA- and TPO-free Soil gel polish based on a polylactide matrix and to formulate a conceptual roadmap for bringing it to market.

The scientific novelty of the work lies in the author's synthesis of a formulation concept for a biodegradable UV/LED gel polish that combines a PLA matrix, a CMR-safe photoinitiator, and biobased plasticizers within a single regulation-compatible composition.

Working hypothesis: replacing the acrylate-copolymer film-forming base with polylactide in combination with a citrate plasticizer and a TPO-free photoinitiator can achieve a coating wear time of 21 days and biodegradation of at least 60% within 28 days according to OECD 301B, without a significant loss of adhesion or aesthetic properties.

II. MATERIALS AND METHODS

The study was conducted as a theoretical-analytical investigation using the following methods: a systematic literature review in PubMed/NCBI, ScienceDirect, Springer, USPTO, and open European Commission regulatory registries; comparative analysis of the chemical compositions of commercial gel polishes and potential biopolymer alternatives; content analysis of regulatory documentation (Regulation EC 1223/2009, Regulation EU 2025/877, Delegated Regulation EU 2024/197, and CU TR 009/2011); conceptual formulation design with justification of the functional role of each component; and case studies of commercial solutions (Manucurist Green Flash and Kinetics TPO-free).

The source base was structured into four types. The first comprises academic articles and patents from peer-reviewed sources: a study of the biodegradability of

acrylate polymers (Ecotoxicology and Environmental Safety / ScienceDirect) [3], a USPTO patent on biodegradable PLA-PDMS copolymers for cosmetic use [8], and a study of PLA cosmetic patches [9]. The second type consists of European Commission regulatory documents: the official FAQ on the TPO ban [6], Regulation EU 2025/877 [5], and Delegated Regulation EU 2024/197. The third type comprises market data from analytical agencies: Grand View Research [1], Mordor Intelligence [2], SkyQuest Technology [10], and Fortune Business Insights [11], including 2024 market-size estimates and forecasts through 2032. The fourth type includes manufacturers' technical materials: Kinetics Beauty [12], Manucurist [13], and ProNails [14], describing practical reformulation experience under EU requirements.

Sources were selected according to the following criteria: priority given to peer-reviewed journals and official regulatory acts; limited use of industry analytical reports; and complete exclusion of blogs and press releases. The Soil formulation concept uses INCI data from open databases (CosIng and ECHA) and the OECD 301B (biodegradation), ASTM D3330 (adhesion), and ISO 4892-3 (lightfastness) standards.

III. RESULTS AND DISCUSSION

The following figure presents the dynamics of the global nail polish market from 2020 to 2032, including the forecast period. The data indicate sustained market growth and an increasing share of organic and environmentally oriented products, thereby creating market demand for Soil.



Figure 1. Dynamics of the global nail polish market, 2020–2032 (compiled by the author based on [1, 10])

According to SkyQuest Technology [10], the market reached USD 17.35 billion in 2024, while the UV/LED gel-polish segment is growing faster than the market overall. Fortune Business Insights [11] estimates the adjacent nail-care market at USD 25.76 billion in 2025, rising to USD 40.23 billion by 2034. Importantly, the European market sets the regulatory tone: the EU accounts for 25–28% of the global segment [2], and

tighter regulation directly affects global manufacturers that sell products across multiple jurisdictions.

The TPO ban under Regulation (EU) 2025/877 [5] introduced the CMR 1B (Repr. 1B) classification without a transition period. It is important to emphasize that the rule was triggered not by direct clinical cases but by the automatic application of Article 15(2) of the Cosmetics Regulation [6]. Manufacturers were effectively required to dispose of remaining inventory

without compensation. This creates a precedent demonstrating that formulation dependence on a single photoinitiator represents a commercial risk for any market participant.

To clarify the direction of development, it is useful to compare the component composition of a standard gel polish with the proposed Soil concept. The table below systematizes functional differences across six key positions.

Table 1. Comparative characteristics of the components of standard acrylate gel polish and the Soil concept (compiled by the author based on [3, 7, 8, 9])

Component	Standard gel polish	Soil gel polish (concept)	Key differences
Film former	Acrylate copolymer (does not degrade in soil or water)	Poly lactide (PLA) from corn or sugarcane	PLA degrades within 6–24 months under composting conditions; acrylates persist for >100 years
Photoinitiator	TPO (prohibited in the EU from 01.09.2025)	TPO-R / TPO-L or acylphosphine oxide without CMR status	Eliminates a reproductive toxicant; fully aligned with Regulation EU 2025/877
Crosslinking agent	HEMA (2-Hydroxyethyl Methacrylate)	HEMA-free formulation; alternative HPMA or IBMA	Eliminates skin sensitization associated with HEMA; reduces occupational allergy risk
Plasticizer	Synthetic dibutyl phthalate, TPGDA	Tributyl citrate or biobased sebacate	No endocrine-disrupting plasticizer; REACH-compatible
Solvent	Ethyl acetate + isobutyl acetate (synthetic)	Ethyl acetate from bioethanol (<5% of formulation)	Same solvent, but biobased; reduced carbon footprint
Biodegradability	Not biodegradable (OECD 301 <5%)	Target OECD 301B >60% in 28 days (PLA matrix)	Fundamental change in environmental fate

The principal component of the formulation is polylactide (PLA) as a film former. Adli et al. [9] showed that PLA is non-toxic to HaCaT skin cells, demonstrates antioxidant compatibility, and is suitable for producing thin cosmetic coatings by solvent casting. USPTO Patent 10940106 [8] confirmed the possibility of producing fluid and paste-like cosmetic forms based on PLA-PDMS block copolymers with viscosities ranging from 250 to 190,000 cP, covering the technological range relevant to gel polishes.

The durability problem of fully organic formulations is real: the only known commercial brand based on corn and potato extracts provides no more than three weeks of wear. The author’s hypothesis is that the combined use of tributyl citrate as a plasticizer and a titanium-isopropoxide-based adhesion promoter (known from polyester coating systems) can increase this performance to 21–28 days without introducing synthetic crosslinking agents. This is the principal distinction between Soil and existing analogues.

The conceptual Soil gel-polish formulation is shown schematically below, with components distributed according to their functional roles. The figure reflects the author’s view of the formulation architecture, in which

each functional block is independently optimized for biodegradability and regulatory acceptability.

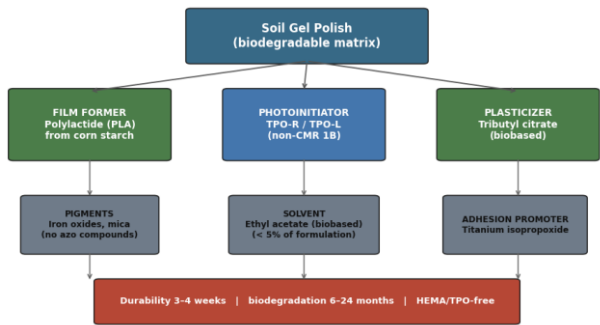


Figure 2. Conceptual diagram of the biodegradable Soil gel-polish formulation (compiled by the author based on [3, 7, 8, 9])

Soil’s ecotoxicological advantage in biodegradability and health safety is achieved at the cost of a moderate reduction in coating durability (6/10 versus 9/10) and a higher formulation cost. This corresponds to the general “green premium” pattern characteristic of first-generation sustainable products.

For comparison, Manucurist Green Flash, the only commercially successful example with an 84% plant-based composition, provides up to 12 days of wear using KeraHCE+ technology [13]. Kinetics Beauty eliminated TPO entirely even before September 2025, replacing it with TPO-R under a different CAS number [12]. These cases demonstrate that industrial-scale substitution of key synthetic components is

technologically feasible; however, no product has yet simultaneously achieved the combination of a “biodegradable matrix + three weeks of wear.”

To assess the feasibility of commercializing Soil gel polish across different jurisdictions, a comparative regulatory matrix is required. Table 2 systematizes requirements for key ingredients and registration procedures in four major markets.

Table 2. Comparative regulatory matrix for biodegradable gel polish in key jurisdictions (compiled by the author based on [5, 6, 14, 15])

Parameter	EU (EC 1223/2009)	Russian Federation / EAEU (CU TR 009/2011)	USA (21 CFR 700)	China (GB/T)
TPO prohibition	From 01.09.2025 (CMR 1B)	Not yet introduced; follows SCCS direction	Not prohibited (wait-and-see)	Not prohibited; some provinces are introducing restrictions
HEMA	Professional use only; limited to 9%	No direct restriction; GOST/ISO standards applied	No prohibition	No prohibition
Registration	CPNP notification	State-registration certificate + EAEU declaration	No FDA premarket approval	NMPA registration (for imports)
Biodegradability	No specific requirement, but eco-labelling is encouraged	No standard; CU TR addresses safety only	No mandatory requirement	No requirement
Priority for Soil	Most stringent market: full CPSR required	Promising: entry can proceed in parallel with the EU	Large market: entry through clean-beauty positioning	Complex NMPA regulation; second priority

The Russian market is strategically relevant for initial product launch: CU TR 009/2011 does not directly prohibit either TPO or HEMA, creating a broader window for formulation experiments before harmonization with international standards. At the same time, Russian consumers are showing growing interest in eco-labeled products, particularly in the professional manicure segment, where technicians experience prolonged cumulative contact with chemical components.

The United States retains a “wait-and-see” approach: the FDA has not prohibited TPO, although BeautyMatter [16] reports growing consumer demand for

TPO-free and HEMA-free products under the influence of media criticism. California prohibited 26 cosmetic chemical ingredients in 2023, and this trend is spreading. For Soil, this creates advantageous “regulatory arbitrage”: a product formulated to EU standards automatically exceeds current U.S. requirements and can be positioned as premium clean beauty.

The figure below schematically presents parallel regulatory pathways for the EU and the Russian Federation, making it possible to visually compare procedural requirements and select the priority market for initial entry.

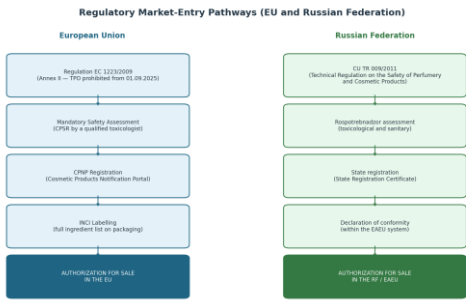


Figure 3. Comparative diagram of regulatory pathways for bringing gel polish to the EU and Russian markets (compiled by the author based on [5, 6, 15, 19, 20])

Based on the preceding analysis, the author developed a phased roadmap for the development and commercialization of Soil gel polish. Table 3 contains six functional stages with approximate time frames and

measurable key performance indicators (KPIs), providing process transparency for a potential manufacturing partner or investor.

Table 3. Author’s roadmap for the development and launch of Soil gel polish (compiled by the author based on [3, 8, 9, 12, 13, 17, 18])

Stage	Approximate timeline	Key tasks	Target KPIs
1. Formulation screening	0–3 months	Select PLA / plasticizer / photoinitiator ratio	Viscosity 800–2000 mPa·s; adhesion at least 2 N/10 mm according to ASTM D3330
2. Photopolymerization	3–6 months	Optimize LED power (405 nm) and curing time	Double-bond conversion at least 80% (FTIR-ATR); curing time no more than 90 s
3. Durability test	6–9 months	Wear on artificial nails; simulation of household loads	21 days without chipping; gloss 85+ GU (60°)
4. Biodegradability	9–12 months	OECD 301B testing (28 days); metabolite analysis (LC-MS)	BOD28/COD at least 60%; no toxic metabolites
5. Regulatory package	12–18 months	Prepare CPSR; register in CPNP (EU) / state registration (RF)	Obtain state-registration certificate; pass Safety Assessment
6. Pilot release	18–24 months	Contract manufacturing (China or CIS), packaging, INCI labelling	Batch of 5,000 units; unit cost no more than USD 3.50

The first author recommendation for organizing development is as follows: at Stages 1–2, it is advisable to engage a Chinese contract manufacturer with an in-house photopolymer laboratory specializing in TPO-free formulations (in particular, several factories in Guangdong Province have already fully reformulated export lines to comply with Regulation EU 2025/877). This can reduce time to market by 3–6 months compared with independent R&D. In parallel, the state-registration procedure in the Russian Federation should be initiated, because its 3–6 month timeline may allow the first certificate to be obtained before completion of the full testing cycle.

The second recommendation is to position the first product release not as a “biodegradable gel polish” (a claim requiring verified OECD 301B data and potentially open to regulatory challenge), but as a “plant-based HEMA-free and TPO-free gel polish.” This positioning is simultaneously accurate (all required components are already technically attainable), commercially attractive to professional nail technicians who experience chronic exposure to sensitizers, and less exposed to regulatory risk associated with environmental claims. Certification under ISO 17516:2014 (microbiological requirements for cosmetics) and ISO 21748 can provide additional professional credibility.

The third recommendation concerns the pilot-release format. Producing the first batch in professional 10–15 mL bottles using a “one-bottle” system (without a separate base coat) and a reduced palette of 12–15 colors minimizes manufacturing costs and regulatory burden

(fewer CPNP notifications). This format is consistent with Manucurist’s launch tactic, which began with a limited Green Flash palette before scaling [13].

IV. CONCLUSION

The analysis confirms the study hypothesis: development of a biodegradable Soil gel polish based on a PLA matrix, a CMR-safe photoinitiator, and a biobased plasticizer is a technically and regulatorily justified task that can be addressed through partnership with a specialized contract manufacturer within an 18–24 month horizon.

The study objective has been achieved: the chemical, environmental, and regulatory grounds for creating Soil have been systematically analyzed; an original conceptual formulation has been developed; a phased roadmap with measurable KPIs has been created; priority markets for initial entry (the Russian Federation and the EU) have been identified; and an optimal positioning strategy has been proposed.

The central conclusion is that the EU ban on TPO from September 1, 2025 is not a barrier but a structural market opening for developers who formulate an alternative in advance. A HEMA- and TPO-free product already represents commercial value for professional nail technicians because of documented risks of sensitization and reproductive toxicity associated with these components.

The practical significance of the study lies in the fact that the developed conceptual roadmap can be used



directly in negotiations with contract manufacturers, preparation of R&D technical specifications, and development of an investment memorandum. Further research should experimentally verify the biodegradation performance of PLA formulations in the presence of typical iron-oxide pigment systems and assess the mechanical properties of the film using nanoindentation methods.

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