

Photoinitiator Migration and Substitution in Vat Photopolymerisation: Spectral Compatibility, Conversion, Residual Species, Photoproducts and Qualification

From Initiator Replacement to Cured-State Evidence: Why Lower Constituent Hazard or Lower Parent-PI Migration Is Not a Drop-In Qualification

Juan Seguro, PhD

3Dresyns by Resyner Technologies S.L.

Registered tax address: General Etxague 15B, 20003 Donostia / San Sebastián, Gipuzkoa, Spain

VAT number: ESB24827511

Correspondence: info@3Dresyns.com · Website: www.3Dresyns.com

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Statement of Significance

Photoinitiator replacement is frequently discussed as if it were a one-component toxicological substitution. In a vat-photopolymerised system it is instead a coupled material-process-state change: the new initiator must absorb where the printer and post-cure sources emit, generate radicals efficiently in the actual formulation, preserve dimensional and mechanical outcomes, and leave a qualified residual and photoproduct profile in the delivered part. ER-95 defines the evidence chain required to separate lower constituent hazard, lower parent-photoinitiator migration, lower total extractables and finished-part biological suitability. None of these claims is accepted as a surrogate for another.

Keywords: photoinitiator; TPO; photoproducts; migration; extractables; spectral compatibility; degree of conversion; DLP; vat photopolymerisation; ISO 10993; requalification

Abstract

Photoinitiators control the conversion of optical dose into reactive species, but unreacted initiator and photolysis products can remain in cured materials and may migrate under use or extraction conditions. This creates a substitution problem with at least four coupled axes: spectral compatibility, initiation efficiency and conversion, residual parent-photoinitiator and photoproduct inventory, and the intended-use interpretation of chemical release. Direct DLP evidence comparing multiple photoinitiator systems shows that changing the photoinitiator can simultaneously alter cytotoxicity, colour, dimensional accuracy, conversion and mechanical properties. Broader UV-curing literature shows that low-molecular-weight photoinitiators or their photoproducts can migrate, while polymeric, multifunctional and self-anchoring designs can reduce migration in particular coating or ink systems. Those adjacent results are useful mechanism and qualification evidence but are not quantitative VPP transfer rules or a selection guide for alternative photoinitiators. ER-95 therefore proposes a substitution qualification matrix that requires optical-source matching, controlled formulation basis, conversion and print-performance checks, targeted parent-photoinitiator analysis, screening for relevant photoproducts, defined extraction or leaching conditions, and application-specific toxicological interpretation where required. TPO is used only as a bounded regulatory case study: its constituent-level status can motivate substitution, but it does not establish that any replacement is safer or that a cured VPP device is qualified.

1. Scope and controlling boundaries

ER-95 asks a narrow engineering question: **what evidence is required when a photoinitiator system is changed and a claim is made about migration, residual species, performance or improved hazard profile in a vat-photopolymerised material?** It does not rank commercial photoinitiators and does not prescribe a proprietary formulation.

The paper is intentionally distinct from neighbouring reviews. ER-06 controls device-level biological response and the broader biocompatibility framework. ER-27 controls conversion metrology. ER-44 controls cure-depth and optical-attenuation physics. ER-77 controls long-wavelength and superlinear photoinitiation mechanisms. ER-80 controls in-can stability. ER-86 controls analytical extractables/leachables architecture. ER-91 controls evidence-density and SDS asymmetry. ER-92 controls generic residual reactants, impurities and manufacturing conversion. ER-93 controls occupational contact dermatitis, and ER-94 controls intrinsic monomer structure-hazard relationships. ER-98 controls

charge-transfer-complex photoinitiation; ER-95 treats any such system only as a photoinitiator change requiring the same substitution evidence chain. ER-99 controls dispersant molecular and interfacial architecture and its effects on particle interfaces, colloidal state, rheology and optical transport; ER-95 treats dispersant-related changes only as formulation-change variables requiring photoinitiator-specific requalification.

Within those boundaries, ER-95 owns the **photoinitiator-specific substitution chain** from optical absorption and initiation through parent-initiator residuals and photoproducts to migration evidence and requalification. The same measurement may appear in another paper, but the decision question is different.

2. Photoinitiator substitution is not a one-variable change

A photoinitiator participates at the first kinetic step of network formation but its effects propagate through the entire process. Changing PI identity or co-initiator architecture can change absorption, radical yield, oxygen sensitivity, dose response, conversion profile, colour, dimensional accuracy, mechanical response and the identity of residual or cleavage products. A substitution trial that holds only exposure time constant is therefore not a controlled comparison.

Kim et al. compared TPO, TPO-L and BAPO at the same molar concentration in one resin matrix and printed by DLP, followed by evaluation of cytotoxicity, colour stability, dimensional accuracy, degree of conversion and mechanical/physical properties [1]. Those source-specific results establish **multi-endpoint non-equivalence** within that particular system; they do not establish a preferred replacement for TPO or a transferable ranking among photoinitiators.

Older dental-resin studies reinforce the same principle. Meereis et al. studied concentration-dependent polymerisation kinetics and mechanical outcomes for the BAPO system used in their model dental resin [2]. Ikemura et al. linked UV-VIS absorption of acylphosphine-oxide initiators to photo-DSC and degree-of-conversion behaviour [3]. These are source-specific chemistry observations, not recommendations. The relevant comparison variable is therefore not merely the PI name but the full PI $\times$ formulation $\times$ light-source $\times$ dose state.

3. Spectral compatibility and action window

The first substitution gate is spectral. An initiator can be intrinsically efficient yet perform poorly if the installed exposure source does not deliver sufficient irradiance within its useful absorption/action window. Conversely, a broad-spectrum source can activate several systems that appear inequivalent under a narrow-band source.

Oliveira et al. compared TPO, BAPO and camphorquinone/amine combinations under different LED wavelength distributions and found that curing efficiency depended on the interaction between photoinitiator system and light source [4]. Ikemura et al. reported absorption maxima between 365 and 416 nm for the tested acylphosphine oxide and bisacylphosphine oxide derivatives [3]. Those numbers belong to the specific compounds studied; they are not a universal wavelength specification, a preferred operating window or a selection rule for any alternative PI grade.

For VPP qualification, the minimum optical record is the formulation absorption spectrum or otherwise justified PI absorption/action information, the actual printer spectral output, post-cure spectral output where used, irradiance or radiant exposure, layer thickness and geometry. Labels such as “405 nm compatible” are insufficient when the substitution changes the spectral overlap or optical attenuation of the complete resin.

Table 1. Substitution variables and the inferences that must be kept separate.

Variable	Required comparison	What it does not establish
PI / co-initiator identity	Exact chemical system and concentration basis; note whether the matrix is otherwise fixed.	Safety, printability or equivalence from chemical name alone.
Optical absorption / source spectrum	Overlap with printer and post-cure emission under defined irradiance and dose.	Equivalent initiation merely because both systems are described as 405 nm or UV-LED.
Conversion and cure state	Measured conversion and, where relevant, through-thickness or spatial state.	Low extractables, low PI migration or safety by itself.
Parent PI residual	Targeted quantitative result with method, LOD/LOQ and specimen state.	Low total photoproducts or low total extractables.
Photoproduct / co-initiator profile	Targeted or screening evidence appropriate to the chemistry.	That an unidentified peak is toxic, harmless or PI-derived without identification evidence.
Migration / extraction result	Defined medium, ratio, time, temperature, agitation and normalisation.	Universal service release outside those conditions.

Variable	Required comparison	What it does not establish
Colour / dimensions / mechanics	Matched print and post-cure conditions with relevant acceptance criteria.	Biological equivalence.

4. Conversion and residual inventory are related but non-equivalent

Increasing conversion can reduce the population of some unreacted species, but **degree of conversion is not a chemical-inventory measurement**. Two formulations at similar bulk conversion can retain different parent PIs, co-initiators, cleavage products, monomers or oligomers because those species have different reaction pathways, mobility and partitioning.

The DLP comparison reported by Kim et al. is important precisely because conversion was measured alongside biological and dimensional outcomes rather than used as a surrogate [1]. The compounds studied are evidence of system-specific non-equivalence, not a ranking. This is the appropriate discipline for substitution work: conversion verifies network formation; chemical analysis verifies what remains or is released.

Post-cure can change both variables. Additional optical or thermal exposure can increase conversion and consume residual PI, but it can also create additional photoproducts. A statement that “post-curing removes the photoinitiator” is therefore chemically incomplete unless parent PI and relevant products are measured in the defined final state.

5. What can migrate: parent photoinitiator, co-initiators and photoproducts

Migration is not limited to the intact starting PI. Type-I photoinitiators are designed to cleave; Type-II systems can involve co-initiators and hydrogen donors; both can generate lower-molecular-weight products whose mobility may differ from that of the starting molecule. Zhou et al. identify migration of low-molecular-weight photoproducts as a major limitation motivating polymeric and multifunctional PI design [5].

Direct leaching studies outside VPP demonstrate why the distinction matters. Ouali et al. measured release of Darocur 1173 from photocrosslinked silicone-acrylate coatings under defined conditions [6], and later showed that accelerated photoageing could change photoinitiator release behaviour [7]. These coating studies are **adjacent evidence**: they prove that cured-state release can depend on matrix, specimen configuration and ageing, but their percentages or kinetics must not be transferred to a printed thermoset.

Food-packaging literature likewise developed dedicated analytical methods because PI migration can contaminate contacting media [8]. ER-95 uses that literature only for measurement architecture and analyte scope. It does not import food-contact limits or simulant requirements into unrelated VPP applications.

Detecting photoinitiator-derived mobile species requires an extraction and analytical method selected for the expected analytes rather than for the parent initiator alone. Photolysis fragments can differ strongly in polarity and thermal stability, so an extraction result is conditional on the declared medium, temperature, specimen-to-medium ratio, duration and specimen state. Exhaustive extraction under a fully declared method can establish a worst-case extractables profile against which simulated-use results are interpreted; no single extraction technique is uniquely required, and no extraction result alone establishes a leachables limit without a declared analytical evaluation threshold and exposure scenario. ER-86 controls the finished-device extractables/leachables qualification architecture.

6. Low-migration photoinitiator design: evidence and transfer limits

One design strategy is to increase PI molecular size or incorporate the initiating chromophore into a multifunctional, polymeric or polymerisable structure. The mechanistic objective is to retain the initiator-derived structure or its products more effectively within the network while preserving initiation efficiency [5].

Fan et al. reported hyperbranched silicone macrophotoinitiators with lower migration than the low-molecular-weight HMPP comparator in a polyurethane-acrylate coating system [9]. Chen et al. reported self-anchoring coumarin oxime-ester PIs in UV-LED-curable coating formulations and found that polymerisable functionality substantially reduced residual-PI migration in their test system [10]. Ren et al. developed a UV-LED-excited PI reported with low migration and low toxicity for photocurable inks [11].

These papers support a **design hypothesis**, not a universal VPP conclusion. Higher molecular weight, polymerisable anchoring or a favourable migration result in a coating or ink does not prove low migration in a different resin, high

conversion under a VPP printer, acceptable viscosity, low photoproduct release or finished-device biological suitability. Each new system must cross the complete qualification chain.

7. TPO substitution as a bounded case study

Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (TPO; CAS 75980-60-8, EC 278-355-8) entered the ECHA Candidate List on 14 June 2023 as toxic for reproduction under REACH Article 57(c) [R1]. Its EU regulatory position has since advanced on several separate tracks. Commission Delegated Regulation (EU) 2024/197 gives TPO the harmonised classifications Repr. 1B (H360Fd) and Skin Sens. 1B (H317), applicable from 1 September 2025 [R2]. Commission Regulation (EU) 2025/877, applicable from 1 September 2025, removed the former cosmetics allowance and added TPO to Annex II of the Cosmetics Regulation as a prohibited substance [R3]. ECHA's final 12th recommendation of 18 November 2025 recommends TPO for inclusion in REACH Annex XIV; the current ECHA record does not show an Annex XIV inclusion date [R4]. Separately, for medical devices within the scope of MDR Annex I 10.4.1, Category 1A/1B CMR substances above 0.1% w/w require the justification specified in §10.4.2 [R5]. These are distinct regulatory mechanisms. None is a finished-part safety test, and none identifies the optimal substitute.

The literature illustrates why direct substitution claims require care without establishing a preferred replacement. Meereis et al. studied BAPO in a dental-resin model [2]. Popal et al. reported concentration-dependent cytotoxic effects for both BAPO and TPO and a micronucleus signal for BAPO in V79 cells at 10 μ M, a concentration at which proliferation was also markedly suppressed; the genotoxic signal is therefore interpreted with that cytotoxicity/proliferation caveat [12]. Kim et al. compared TPO, TPO-L and BAPO in one DLP dental-resin matrix and reported formulation-specific differences across biological, optical, dimensional, conversion and mechanical endpoints [1]. These studies identify non-equivalence within their own systems; they do not establish a preferred replacement for TPO or a transferable ranking among photoinitiators.

The defensible conclusion is therefore procedural: a regulatory or hazard concern can justify changing the photoinitiator system, but that system must be requalified for optical response, cure state, residual species, migration, print performance and intended-use endpoints. “TPO-free” is a compositional descriptor, not a universal safety or performance claim.

8. Minimum substitution qualification matrix

A controlled substitution experiment should keep the resin matrix fixed wherever scientifically possible and state every intentional change. Concentration basis matters: equal weight percent and equal molar percent are different comparisons, and equal absorbed photon dose is different again. Where a co-initiator, inhibitor or absorber must change simultaneously, the experiment becomes a system substitution and should be labelled as such.

The final-part specimen state must be explicit. Green prints, washed-but-unpostcured parts, final post-cured parts, aged parts and extracted specimens are chemically different test articles. Parent-PI and photoproduct results must be tied to that state rather than reported as formulation-wide constants.

Table 2. Minimum evidence record for a photoinitiator substitution decision in VPP.

Evidence block	Minimum record	Decision question
Change control	Old/new PI system, concentration basis, matrix changes, lot/version.	What exactly changed?
Optical fit	PI/formulation absorption, printer spectrum, post-cure spectrum, irradiance/dose.	Can the installed light sources activate the replacement under the intended geometry?
Cure state	Working curve or relevant cure response plus conversion in the defined specimen state.	Did network formation remain adequate and spatially controlled?
Print outcome	Dimensions, surface/feature result and application-relevant mechanics or thermal checks.	Did the substitution preserve the required manufactured state?
Targeted chemistry	Parent PI and known critical co-initiator/photoproduct targets; method and LOD/LOQ.	What known species remain or are released?
Screening chemistry	Orthogonal untargeted/semi-targeted coverage where the application warrants it.	Did substitution create new relevant chemical signals?

Evidence block	Minimum record	Decision question
Extraction / leaching	Specimen state, medium, ratio, time, temperature, agitation, normalisation.	Under what test conditions was migration measured?
Risk interpretation	Application-specific chemical/toxicological assessment using applicable standards.	Does the measured exposure support the intended-use decision?

9. Analytical boundary: ER-95 versus ER-86

ER-95 does not create a new extractables/leachables standard. ER-86 controls specimen-state definition, extraction design, analytical coverage, non-detect interpretation and cross-study comparability. ER-95 uses that architecture to answer one PI-specific question: whether substitution changes the parent-PI and photoproduct release profile in a way that matters to the intended use.

For medical-device contexts, ISO 10993-18:2020 together with Amendment 1:2022 provides the chemical-characterisation framework within risk management [S1]. ISO 10993-12:2021 together with Amendment 1:2025 addresses sample preparation and reference materials [S2]. ISO 10993-17:2023 together with Amendment 1:2025 addresses toxicological risk assessment of medical-device constituents using chemical-characterisation information [S3]. These standards are cited **only for their stated medical-device scopes** and are not presented as universal PI-migration methods for industrial VPP parts.

Analytical comparison should report method capability, calibration approach, LOD/LOQ where relevant, extraction blank and material blank strategy, normalisation basis and uncertainty. A lower measured parent-PI concentration is not automatically a lower total-extractables result; a lower total-extractables result is not automatically a toxicological pass.

10. Biological and regulatory interpretation boundary

The biological meaning of a photoinitiator substitution belongs to the finished material and intended exposure scenario, not to one isolated ingredient property. Popal et al. provide compound-level cytotoxicity/genotoxicity evidence [12], while Kim et al. provide cured DLP-resin evidence under one dental-oriented workflow [1]. The two evidence levels should not be conflated.

ER-06 retains the broader device-level biological-response question. ER-93 retains occupational dermatitis and prevention. ER-95 may report constituent hazard or biological findings only to explain why substitution needs evidence; it does not convert those findings into a general medical, dental, food-contact or occupational-safety approval.

11. Reporting rules and prohibited shortcuts

Do not report “safer photoinitiator” without naming the compared endpoint and evidence level. A lower hazard classification, lower in-vitro cytotoxicity, lower parent-PI migration and lower total extractables are different claims.

Do not report spectral compatibility from nominal wavelength alone. Record the source and the absorber/PI response actually relevant to the formulation.

Do not infer migration from conversion alone. Conversion and chemical release require separate measurements.

Do not transfer coating, ink or food-packaging migration percentages into VPP. Use those studies as mechanism or method evidence only unless the material and test state are matched.

Do not disclose proprietary formulation rules. ER-95 requires enough information to reproduce the scientific comparison, but it does not publish 3Dresyns PI suppliers, proprietary concentrations, stabiliser packages or formulation-selection heuristics.

12. Limitations and research gaps

The strongest direct VPP comparison located for this version is the 2022 DLP study comparing three photoinitiator systems within one dental-resin matrix [1]. Much of the detailed migration-design literature comes from coatings, inks and food-packaging systems rather than printed VPP thermosets [5–11]. That asymmetry is itself a research gap and is stated explicitly rather than bridged by inference. The named systems in [1] are retained only to identify the experiment; ER-95 does not convert its result into a selection recommendation.

A 2026 paper by Feng et al. addresses next-generation photoinitiation systems with emphasis on safety, migration stability and long-wavelength activation [13]. It strengthens the currency of the migration problem but does not erase the need for VPP-specific specimen-state and process qualification. Long-wavelength mechanism design remains under ER-77; ER-95 uses it only for the migration/substitution context.

Priority experiments are matched old-versus-new PI studies in the same VPP matrix, with spectral characterization, printer-native cure metrics, conversion, dimensional response, targeted parent PI, photoproduct screening, defined final-state extraction and application-specific interpretation. These experiments would allow “low migration” to become a measured VPP property rather than an imported formulation label.

13. Conclusions

Photoinitiator substitution in VPP is a coupled optical, kinetic, chemical and qualification change. A changed photoinitiator system must work with the installed light sources, form the required network state, preserve manufactured performance and produce an acceptable residual and migration profile for the intended use.

The central non-equivalences are decisive: **high conversion $\neq$ low parent-PI migration; low parent-PI migration $\neq$ low photoproducts; low total extractables $\neq$ safety; and constituent regulatory status $\neq$ finished-part qualification.** A defensible substitution claim requires each link to be measured at the evidence level appropriate to that claim.

Accordingly, ER-95 treats TPO-free or low-migration positioning as hypotheses to qualify, not as conclusions to inherit. The deliverable is the substitution evidence chain and reporting architecture, not a commercial ranking, shortlist or recommendation of photoinitiators.

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Version note

Version 0.4 is a format-only correction to the exact reviewed v0.3 candidate. It restores the reference typography and direct hyperlink formatting of [R1], [R2], [S1] and [S2], and restores the front-matter version line to the prior bold 9 pt style. No scientific wording, citation target, regulatory statement, boundary, table content or evidence interpretation was changed. The v0.3 scientific corrections remain controlling. Named alternative photoinitiators remain only where required to identify source-specific experiments or bibliographic titles; this review does not establish or promote a preferred substitute, ranking or commercial selection rule. It does not disclose proprietary 3Dresyns photoinitiator identities, suppliers, concentrations or formulation-selection rules.