EuPIA Framework for Assessing the Suitability of Photoinitiators and Photosynergists for Food Contact Materials

Background and applicability

EuPIA member companies have long been committed to the manufacture and supply of printing inks for food contact materials. Against this background, EuPIA members active in UV printing inks have developed a framework setting out the criteria and rules used to assess photoinitiators and photosynergists for use in UV printing inks and varnishes applied to the non-food-contact side of food contact materials. EuPIA's Energy Curing Working Group periodically reviews the concepts of the Framework to reflect the current status of technology, regulatory landscape and/or new data.

Suitability is assessed on the basis of toxicological profile and migration potential, in line with EuPIA guidelines and policies.

The framework also includes a dedicated list of commonly used photoinitiators and photosynergists explicitly assessed by EuPIA members active in UV printing inks. This list is voluntary and non-exhaustive. Each company remains responsible for ensuring that its products and applications comply with the applicable legal requirements.

The assessment approach reflected in this document takes account of the general safety requirements of Regulation (EC) No 1935/2004, the principles of Regulation (EC) No 2023/2006 on good manufacturing practice, relevant national provisions such as Swiss Ordinance 817.023.21 and the German Printing Ink Ordinance, the EFSA Note for Guidance and genotoxicity testing strategy[1], as well as relevant EuPIA guidance, including the EuPIA Guideline on Printing Inks applied to Food Contact Materials[2], the EuPIA NIAS/NLS guidance[3] and the EuPIA raw material selection criteria set down in the EuPIA Charter[4].

Important limitations:

The inclusion of a photoinitiator or photosynergist into the annex **does not automatically mean that a cured UV ink or varnish complies with all applicable legal requirements or migration limits.**

- Compliance of the printed article depends on a range of conditions that are in the responsibility of the converter or printer to ensure that the ink film layer is properly cured, the printed article is designed to fit its purpose, and it is produced under Printing Good Manufacturing Practices (e.g. printing speed, UV lamp conditions, colour, substrate, ink layer thickness, the surface-to-food volume ratio, presence of a functional barrier).

- As set out in Regulation (EC) 1935/2004, final verification of migration compliance remains the responsibility of the printer, in line with recognised good manufacturing practice for converters, and of the end user.

[1] Note for Guidance for the Preparation of an Application for the Safety Assessment of a Substance to be used in Plastic Food Contact Materials.
[2] EuPIA-Guideline-on-Printing-Inks-applied-to-Food-Contact-Materials.pdf
[3] EuPIA_NIAS_Guidance.pdf
[4] EuPIA CharterV1

Similarly, and for the same reasons listed above, the fact that a photoinitiator is not included in the annex does not preclude its safe use in accordance with legal requirements.

Responsibility note:

EuPIA members and sponsoring photoinitiator manufacturers are responsible for the data and assessments submitted under this framework. Printers and converters remain responsible for proper curing, GMP, article design and, where relevant, migration verification.

The final food contact material business operator remains responsible for ensuring that the finished article complies with applicable legal requirements.

Criteria and rules for assessing and formulating with photoinitiators and photosynergists for use in UV printing inks and varnishes on the non-food-contact side of food contact materials

Three criteria are used to assess whether a photoinitiator or photosynergist may be considered suitable.

In all cases, materials should only be considered suitable if non-intentionally added substances (NIAS) present can be shown to migrate below the level considered acceptable for the material, based on the EuPIA Guidance for Risk Assessment of Non-Intentionally Added Substances (NIAS) and Non-Listed Substances (NLS) in printing inks for food contact material and the EFSA Note for Guidance for Food Contact Materials.[5]

Criterion 1:

Criterion 1 covers substances with an evaluated status and recognised migration limits in relevant positive lists or national ordinances.

Some photoinitiators and photosynergists combine performance potential for printed food contact materials with supportive toxicological data and an evaluated status that includes recognised migration limits. Examples include substances listed in Annex 10 to Swiss Ordinance 817.023.21 and/or Annex 14 of the German Printing Ink Ordinance (21st Ordinance amending the Consumer Goods Ordinance, December 2021).

The inclusion of completely new raw materials in the relevant annexes of the Swiss or German Ordinances depends on the level of toxicological data required by the competent authorities.

Criterion 2:

Criterion 2 covers non-listed substances for which suitability is supported by sufficient toxicological evidence, NIAS/photolysis product assessment and representative migration data.

Materials that have not been fully evaluated by competent authorities and are therefore not officially included in existing legally binding positive lists **may be considered only if all of the following three conditions are met:**

[5] The EFSA Guidance was developed for intentionally added substances and is not formally applicable to NIAS assessments. However, as recognised in the BfR guideline https://www.bfr.bund.de/en/service/databases/bfr-recommendations-on-food-contact-materials/ , it is routinely used as a reference for defining toxicological data requirements and endpoints, and is therefore indirectly applicable to NIAS evaluations.

a) Structural features supporting low migration potential
The substance has a complex molecular structure, although its molecular weight is below 1000 Daltons. Typically, photoinitiators in this group have a molecular weight of around 700 to 1000 Daltons, which may contribute to low migration potential.

b) Toxicological evidence, including relevant CMR endpoints
As part of the internal EuPIA process for adding a new material to the annex list, the EuPIA member or photoinitiator manufacturer sponsoring the application **must provide** the following information to the EuPIA secretariat.

i. Evidence that the photoinitiator is not classified according to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures and does not show evidence of carcinogenicity, genotoxicity, mutagenicity and/or developmental and reproductive toxicity (endpoint-specific hazard assessments required).
To demonstrate the absence of genotoxic concern, including gene mutation and clastogenicity/aneugenicity, at least two *in vitro* genotoxicity tests for the photoinitiator, in line with the EFSA Scientific Committee recommendations on genotoxicity testing strategies and/or the EFSA Note for Guidance, are needed:

- A bacterial reverse mutation test (Ames test, OECD 471)
- An in vitro mammalian cell micronucleus test (OECD 487)

Any positive or equivocal results would need additional testing, typically in vivo. If negative test data are provided that do not directly fulfil the aforementioned test battery, it should be evaluated on a case-by-case basis whether they adequately fulfil the requirements to assess the genotoxicity of the substance, ruling out mutagenicity and clastogenicity/aneugenicity.

ii. Data on the type and levels of NIAS and potential photolysis products associated with the material.

- **If no migration limit is defined for NIAS or photolysis products related to the new material, a risk assessment must be completed to confirm suitability for use.** This should include a toxicological assessment in line with the EuPIA Guidance for Risk Assessment of Non-Intentionally Added Substances (NIAS) and Non-Evaluated or Non-Listed Substances (NLS) in printing inks for food contact materials as well as assessments of clastogenicity.
    - The genotoxic potential must also be assessed for the NIAS. This requires data of acceptable quality showing the absence of gene mutations and structural or numerical chromosome abnormalities, as mentioned in Criterion 2.b.i. When data on DNA reactivity, including mutagenicity and clastogenicity, are available, they may be used. If such data are incomplete or absent, adequate (Q)SAR models may be used to screen for structural alerts for DNA reactivity.
- EFSA guidance on the use of the Threshold of Toxicological Concern approach in food safety assessment requires DNA reactivity to be assessed by applying expert-rule and statistically based models clearly indicating the absence of genotoxicity, as specified in the EFSA Guidance on the TTC concept. Additional supporting information may be used, such as read-across from structurally similar substances or the use of at least a second independent (Q)SAR model based on a different training set or algorithm.

c) Representative migration data confirming that migration levels of the new material are within the migration limits set out in the Swiss Ordinance and/or the German Ordinance.

For the photoinitiator itself, this would be 10 ppb under standard conditions of use in the absence of CMR properties. For NIAS, including photolysis products, other migration levels may apply in accordance with the EuPIA Guidance for Risk Assessment of Non-Intentionally Added Substances (NIAS) and the aforementioned EFSA Guidance documents.

Criterion 3:

Criterion 3 covers high molecular weight or reactive substances where low migration potential may be supported by polymeric size, reactivity and appropriate supporting data.

Photoinitiators may also show compliance potential because of a high molecular weight (above 1000 Daltons) or because they contain reactive groups that allow them to become crosslinked into the cured ink or varnish film.

For these photoinitiators, the same requirements set out under points b. and c. of Criterion 2 apply. This includes the evaluation of potential NIAS and oligomers.

***Applicable if a EuPIA member or photoinitiator manufacturer is sponsoring the addition of the photoinitiator** according to Criterion 2 or 3 **to the annex list:** The above information must be thoroughly reviewed and evaluated by the EuPIA toxicologists in the Hazard Assessment Committee (HAC) in accordance with recognised scientific principles.*

EuPIA members may also choose to use photoinitiators not listed in the annex table, provided they can demonstrate compliance with applicable legal requirements.

- As shown through one or more of the pathways listed above (see criteria 1 to 3)[6], or
- Uses where a proven barrier to migration is present, for example printing on the outside of glass or metal.

Exclusion criteria

Photoinitiators are generally not considered suitable for low-migration applications, and therefore not suitable for inclusion in the annex list, where they:

- do not comply with the general requirements for FCM inks, as defined by the "Addendum to the EuPIA Guideline – General requirements/Raw Material Selection Criteria" of the "EuPIA Guideline on Printing Inks applied to Food Contact Materials"
- are low molecular weight substances with a recognized tendency to migrate[7]

Adjustment of permissible migration limits in the Swiss Ink Ordinance or German Ink Ordinance

The status of materials listed in the Annex should reflect their status under the relevant national ordinances and legislation. If a competent authority re-evaluates a photoinitiator and changes its

[6] Individual member companies must be able to demonstrate safe use of the photoinitiator to customers and competent authorities on the basis of their own comprehensive assessment of the main molecule, impurities and photolyte products.

[7] Examples: 2,4-diethylthioxanthone (CAS 82799-44-8) ; 1-hydroxycyclohexyl phenyl ketone (HCPK CAS 947-19-3); 2-Hydroxy-2-methylpropiophenone (HMPP CAS 7473-98-5) or Isopropylthioxanthone (ITX CAS 83846-86-0)

permissible migration limit, the status of that substance in the annex list should be updated accordingly. Such changes should be made as quickly as possible, in line with EuPIA guidelines and after consultation with the ECWG members.

Removal of materials from the annex list

If a non-polymeric, non-reactive photoinitiator is re-evaluated and is no longer listed in either the Swiss Ordinance or the German Ink Ordinance under Criterion 1, it should be re-assessed by the HAC. Its status in the relevant column should then be updated, or the substance should be removed from the list. This change should be made as quickly as possible, in line with EuPIA guidelines. The ECWG should discuss the substance before any change is made.

Any material listed in the current annex that becomes subject to the EuPIA Charter, whether because of hazard reclassification or because it is identified as a substance of very high concern (SVHC) related to human health, should be reassessed in the ECWG/HAC regardless of whether it remains included in the Swiss Ordinance or the German Ink Ordinance. If a removal from the annex is deemed necessary, it will be determined by the EuPIA Energy Curing Working Group on a case-by-case basis, taking into account the status of the substance under the EuPIA Charter rules.

Disclaimer.

This nonbinding document is provided for general informational purposes only, to support safety and compliance assessments concerning printing inks, coatings and varnishes for the non-food-contact side of food contact materials. It is not a specification, standard, certification, endorsement, approval, positive legal listing, or a recommendation to purchase, sell, use, or avoid any product or supplier. Inclusion of a substance in the annex does not constitute an approval or certification by EuPIA. Companies must make independent decisions and ensure their own products meet legal requirements. EuPIA makes no warranties and assumes no liability for reliance on this document.
In general, any change to this framework and its annex is subject to consensus among the members of the ECWG expert group, in accordance with the association's rules.

EuPIA ECWG, November 2026

Annex: Suitable Photoinitiators and Photosynergists for Food Contact Materials

Based on the criteria above, photoinitiators and photosynergists suitable for use in coatings, inks, and varnishes applied to the non-food-contact side of food packaging are listed in this annex.

These listed substances have performance potential for food contact materials and are supported by appropriate data as outlined in the three criteria. The left-hand column indicates the justification for inclusion.

The annex applies to all printed food contact material types except UV inks and varnishes for metal packaging that undergo a thermal curing step.

Criterion for inclusion	Name	CAS Number
1	Phenyl bis(2,4,6-trimethylbenzoyl) phosphine oxide	162881-26-7
1	1-(4-[(4-Benzoylphenyl)thio]phenyl)-2-methyl-2-[(4-methylphenyl)sulfonyl]-1-propan-1-one	272460-97-6
1	Di-ester of carboxymethoxy benzophenone and polytetramethyleneglycol 250	515136-48-8
1	(Dimethylamino)benzoate, esters with branched polyols	2067275-86-7
1	2-Hydroxy-1-(4-(4-(2-hydroxy-2-methylpropionyl)benzyl)phenyl-2-methyl-2-propanone	474510-57-1
1	Oligo-[2-Hydroxy-2-methyl-1-((4-(1-methylvinyl)phenyl) propanone]	163702-01-0
1	Poly(oxy-1,4-butanediyl), .alpha.-[2-[(9-oxo-9H-thioxanthenyl)oxy]acetyl]-.omega.-[[2-[(9-oxo-9H-thioxanthenyl)oxy]acetyl]oxy]-	0813452-37-8
1	Poly[oxy(methyl-12-ethandiyl)],alpha-[4-(di-methylamino)benzoyl-omega-butoxy	223463-45-4
1	1-[4-(2-Hydroxyethoxy)phenyl]-2-hydroxy-2-methyl-1-propanone	106797-53-9
1	A mixture of: Oxy-phenylacetic acid 2-[2-oxo-2-phenyl-acetoxy-ethoxy]-ethyl ester and Oxy-phenylacetic acid 2-[2-hydroxy-ethoxy]-ethyl ester	211510-16-6 442536-99-4
1	2-Hydroxy-1-[4-(4-(2-hydroxy-2-methylpropionyl)phenoxy)-phenyl]-2-methylpropan-1-one	71868-15-0
1	tris{4-[(4-acetylphenyl) sulfanyl] phenyl}sulfonium hexafluorophosphate	953084-13-4
1	(Methylimino)diethane-2,1-diyl bis[4-(dimethylamino)-ben-zoate]	925246-00-0
1	1,1,1-Trimethylolpropane, ethoxylated, ester with 2-benzoyl-benzoic acid	-
3	A mixture of: 1,3-di({a-2-(phenylcarbonyl)benzoylpoly[oxy(1-methylethylene)]}oxy)-2,2-bis({a-2-phenylcarbonyl)-benzoylpoly[oxy(1-methylethylene)]}oxymethyl) propane and {a-2-	1003567-82-5 1003557-16-1

Criterion for inclusion	Name	CAS Number
	(phenylcarbonyl)benzoylpoly(oxyethylene)-poly[oxy(1-methylethylene)]-poly(oxyethylene)} 2-(phenylcarbonyl)benzoate	
3	1,3-di({a-[1-chloro-9-oxo-9H-thioxanthen-4-yl)oxy]acetylpoly[oxy(1-methylethylene)]}oxy)-2,2-bis({a-[1-methylethylene)]}oxymethyl) propane	1003567-83-6
3	A mixture of: 1,3-di({-4-(dimethylamino)benzoylpoly[oxy(1-methylethylene)]}oxy)-2,2-bis({-4-(dimethylamino)-benzoylpoly[oxy(1-methylethylene)]}oxymethyl) propane and {a-4-(dimethylamino)benzoylpoly(oxyethylene)-poly[oxy(1-methylethylene)]-poly(oxyethylene)} 4-dimethylamino)benzoate	1003567-84-7 1003557-17-2
3	Polymer based on piperazino compounds of aminoalkylphenone	886463-10-1
3	Poly(oxy-1,2-ethanediyl), α-(1-oxo-2-propenyl)-ω-(4-benzo-ylphenoxy)	478549-43-8
3	Derivatized 2-benzoyl-benzoate, esters with linear polyols*	3074961-92-2
2	Poly(oxyethylene) bis[3-(phenoxy)-2-hydroxypropyl benzoate]*	3117630-16-4

** Available only for in-house use/not yet commercially available*