

EuPIA Suitability List of Photoinitiators and Photosynergists for Food Contact Materials

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Some photoinitiators and photosynergists have both Printed Food Contact Material performance potential and, by virtue of supportive toxicological data, an evaluated status with recognized migration thresholds. They are listed in Part A of Annex 10 to the Swiss Ordinance 817.023.21.

In order to make use of the official photoinitiator and photosynergist evaluations, EuPIA members should preferably use photoinitiators with a composition and impurity profile equivalent to those for which the toxicity data were generated, submitted and evaluated by the relevant national body. Photoinitiators are required to be listed when they are intentionally added.

Other materials are not fully evaluated and accordingly are in the Part B list of the above Annex. Depending on the application and packaging structure, compliance of the final package within the accepted migration limits can be achieved.

In all cases these materials should only be considered as suitable for use if Non-Intentionally Added Substances (NIAS) present can be proven to be migrating below the level deemed to be acceptable for that material, based on EuPIA Guidance for Risk Assessment of Non-Intentionally Added Substances (NIAS) and Non-Listed Substances (NLS) in printing inks for food contact materials¹.

It must be remembered that final measurement of migration compliance is the responsibility of the printer, in line with recognised converters' good manufacturing practices, and the end user.

Photoinitiators and photosynergists for use in coatings, inks and varnishes for the non-contact side of food packaging are as follows:

For all printed Food Contact Material types apart from UV inks and varnishes for metal packaging which undergo a thermal-curing step.

Description	CAS N°	SML [mg/kg]
Phenyl bis(2,4,6-trimethylbenzoyl) phosphine oxide	0162881-26-7	3.3
1-(4-[(4-Benzoylphenyl)thio]phenyl)-2-methyl-2-[(4-methylphenyl)sulfonyl]-1-		
propan-1-one	0272460-97-6	0.05
Di-ester of carboxymethoxy benzophenone and polytetramethyleneglycol 250	0515136-48-8	0.05
(Dimethylamino)benzoate, esters with branched polyols	2067275-86-7	0.05
2-Hydroxy-1-(4-(4-(2-hydroxy-2-methylpropionyl)benzyl)phenyl-2-methyl-2-		
propanone	0474510-57-1	0.05
Oligo-[2-Hydroxy-2-methyl-1-((4-(1-methylvinyl)phenyl) propanone]	0163702-01-0	0.05
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	0.05
Poly[oxy(methyl-12-ethandiyl)],alpha-[4-(di-methylamino)benzoyl-omega-butoxy	223463-45-4	0.05

¹ 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, latest version 5th amendment 11-05-2021, <u>Risk Assessment - Eupia</u>



Page 2 of 2

Description	CAS N°	SML [mg/kg]
1-[4-(2-Hydroxyethoxy)phenyl]-2-hydroxy-2-methyl-1-propanone	106797-53-9	0.05
2-(Dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(4-morpholinyl)phenyl]-1-butanone	0119344-86-4	0.05
A mixture of: Oxy-phenylacetic acid 2-[2-oxo-2-phenyl-acetoxy-ethoxy]-ethyl ester	211510-16-6	0.05
andOxy-phenylacetic acid 2-[2-hydroxy-ethoxy]-ethyl ester	442536-99-4	
$\hbox{$2$-Hydroxy-1-[4-(4-(2-hydroxy-2-methylpropionyl)phenoxy)-phenyl]-2-methylpropan-1-one}$	71868-15-0	0.05
tris{4-[(4-acetylphenyl) sulfanyl] phenyl}sulfonium hexafluorophosphate	0953084-13-4	0.05
(Methylimino)diethane-2,1-diyl bis[4-(dimethylamino)-ben-zoate]	925246-00-0	0.05
1,1,1-Trimethylolpropane, ethoxylated, ester with 2-benzoyl-benzoic acid	?	0.05
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-(phenylcarbonyl)benzoylpoly(oxyethylene)-poly[oxy(1-methylethylene)]-poly(oxyethylene)} 2-(phenylcarbonyl)benzoate	1003567-82-5 1003557-16-1	>1000 Da
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	>1000 Da
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-dimethyl-amino)benzoate	1003567-84-7 1003557-17-2	>1000 Da
Polymer based on piperazino compounds of aminoalkylphenone	886463-10-1	>1000 Da
Poly(oxy-1,2-ethanediyl), α -(1-oxo-2-propenyl)- ω -(4-benzo-ylphenoxy)	478549-43-8	Cross-linkable, functional initiator
Derivatized 2-benzoyl-benzoate, esters with linear polyols	3074961-92-2	>1000 Da

The above listed photoinitiators have Food Contact Material performance potential and are supported by appropriate toxicological data. The right-hand column indicates the justification for inclusion (specific migration limits, molecular weight above 1000 Daltons or cross-linkable reactive groups).

EuPIA members may, in addition, choose to use other photoinitiators not listed in this table, but these shall comply with at least one of the following requirements:

- Photoinitiators with an appropriate set of toxicological data showing the absence of CMR properties.
 Migration must be below 10ppb: this must be supported by repeated migration testing.
- Photoinitiators with no potential for migration due to a molecular weight exceeding 1000 Daltons
- Uses where a proven barrier to migration is present (e.g. printing on external glass or metal)

In the first two cases, individual member companies must be able to demonstrate the safety in use of the photoinitiator to customers and competent authorities, on the basis of their own comprehensive assessment of photoinitiator impurities and photolytes, in accordance with the principles laid down in the above mentioned EuPIA NIAS Guidance document.