Guidance Note on Packaging Inks

Overview

This document refers to the Nestlé Initiative on Packaging Safety and Compliance and addresses specifically the ink usage for decoration on packaging materials. **This document equally applies to printing inks, lacquers, coatings and varnishes** (shorten to "inks and varnishes" in the rest of this document). It specifies with more details the 4 Standards (Outer printing, UV printing, Inner printing and Ink-jet printing) of the Nestlé Standards on Materials in Contact with Food (GI-80.008) that are mandatory. This document aims at guiding further on the assessment of the composition of inks and varnishes, i.e. information received from packaging vendors via the Certificates of Compliance (CoC). The CoC provided by the converter is based on the composition declaration of the ink maker and varnish manufacturer.

This document **must be shared to Nestlé vendors** and upwards in the packaging value chain (ink makers, coating and overprint varnish manufacturers).

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Main changes compared with the previous version

- This Note has been simplified in many aspects. Main changes are flagged in the margin.
- **Nestlé does not approve inks anymore** but ask suppliers of printed materials to formally declare in the CoC that their materials comply with this Guidance Note on Packaging Inks.

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General requirements

i) Only inks and varnishes that are carefully formulated for food packaging applications can be used. For instance, negative lists must be respected (e.g. EUPiA) and Substances of Very High Concern (according to REACH regulation in the EU) cannot be used (see Nestlé Standard on SVHC). EU Directive 76/769/EEC related to restrictions on the marketing and use of dangerous substances and preparations has to be taken into full consideration.

ii) The principle of low migration must be proved by the converter of packaging materials. The ink and varnish ingredients must comply with either existing restrictions, e.g. specific migration limits, or – when no toxicological evaluation has been made – with the migration limit of 10 µg/kg as stated in the Resolution of the Council of Europe AP(2005)2.

iii) The use of "Fanal"-type pigments must be avoided (see Table 1 in Annex). Also, proper resistance of pigments in the final application must be confirmed.

iv) The use of printed packaging materials at high temperature must be thoroughly evaluated.

v) The sensory impact of inks and vanishes on off-taste- and off-flavour-sensitive products (e.g. chocolate, ice cream, fatty food, cereals) must be thoroughly investigated.

vi) It is the final converter's responsibility to ensure the best combination of inks and varnishes (e.g. upon recommendation of ink makers and varnish manufacturers).

Definition of 'Efficient barrier'

An efficient barrier consists of either glass, plain aluminum, silica, or the following virgin resins: PET, PVDC, and EVOH.

The following examples fall in this category:

- Bag-in-box where the bag is made of a barrier material (with plain Al foil of proven sufficient thickness)
- All types of labels/sleeves on cans, glass jars or rigid containers (e.g. minimum thickness of 90 um) where the plastic is a demonstrated barrier material and only if applied after filling and closing.
- Cans printed by lithography and with UV-varnish on the external face, without inner coating.

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Specific requirements

In addition to the General requirements listed above, the following specific requirements must be respected for the following ingredients/printing processes:

Part 1

UV & EB inks and varnishes (offset and flexo printing techniques)

Both following requirements must be fulfilled:

i) Inks formulation must comply with the approved list of photo-initiators and the restrictions of acrylates (see Tables 2 and 3 in Annex)

ii) Migration must be tested by the converter before the first application and results must be below:
- regulatory limits or
- any other existing limits or
- 10 µg/kg food for non-evaluated substances. (see protocol in Annex for details)

Part 2

Conventional inks and varnishes for offset printing (offset, sheet-fed, typo and letterpress printing techniques)

Many conventional offset inks are available on the market place. Thus, to avoid using inadequate inks (e.g. newspaper inks, non-food grade inks), **only inks that are designed for food packaging and that are recommended by the ink makers must be used**.
Refer to EUPIA customer information note:
http://cepe-myeteam.eudata.be/EPUB//easnet.dll/GetDoc?APPL=1&DAT_IM=101280&DWNLD=090205 EuPIA info sheetfed offset inks for food packaging.pdf

Inks complying with the following two sets requirements will be preferred:

i) Composition:
- No mineral oils are used (traditional offset printing).
- Only selected vegetable oils and fatty acid esters minimizing migrations and off-flavors are used.
- No Cobalt-based drying systems are used.

ii) Migration must be tested by the converter before the first application and results must be below:
- regulatory limits or
- any other existing limits or
- 10 µg/kg food for non-evaluated substances. (see protocol in Annex for details)

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Part 3

Solvent-based & water-based inks and varnishes (rotogravure and flexo printing techniques)

The inks must be formulated taking into account of the following elements:

- Titanium Acetyl Acetonate (TAA) must not be used as an adhesion promoter.
- Phthalate plasticizers must not be used.
- Solvent composition must conform to Nestlé restrictions (see Table 4 in Annex).
- Nitrocellulose inks must not be used in cases where the packaging is heated with food prior to consumption. Exception shall be granted by Nestec.

Part 4

Ink-jet printing technique

For **inner** ink-jet printing (to be differentiated from traditional inner printing with solvent-based inks by means of heliogravure, rotogravure or flexography, as covered by CP-80.202), the following inks have been approved by Nestec:

- Domino 449 RD, 445 RD and 432BL.
- For special application e.g. tear strip, Agfa Agorix Novamod is allowed if the printed surface is covered by a PET layer.

References

- Commission Regulation (EC) 1935/2004
- Directive 2002/72/EC and subsequent amendments
- Commission Regulation (EC) 2023/2006
- Resolution of Council of Europe on packaging inks AP(2005)2
- EUPIA Website: www.eupia.org
- Ultra –Violet Curing, GPMU Safety Reps Handbook, October 2004
- Swiss ordinance 817.023.21 as applied on April 1st, 2010

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Table 1 **Color salts of basic dyes with inorganic complex acids *(Fanal-type* pigments) <u>that must not be used</u>**

Pigments	Color index	CAS number
Pigment Red 81, and Red 81 series	45160:1; 45160:3 45160:x; 45160:y 45161:1; 45161:2 45161:5	12224-98-5
Pigment Red 169	45160:2	12237-63-7
Pigment Red 81 and Red 81 series	45160:1/ (+)	12224-98-5/ (+)
Pigment Red 169	45160:2	12224-98-5
Pigment Green 1	42040:1	1325-75-3
Pigment Green 2	42040:1/ 49005:1	1325-75-3 1326-11-0
Pigment Green 4	42000:2	61725-50-6
Pigment Green 45	Not available	Not available
Pigment Blue 1	42595.2	1325-87-7
Pigment Blue 2	44045:2	1325-94-6
Pigment Blue 9	42025:1	596-42-9
Pigment Blue 10	44040:2	1325-93-5
Pigment Blue 14	42600:1	1325-88-8
Pigment Blue 62	44084	57485-98-0
Pigment Violet 1 and 1:x	45170:2/x	1326-03-0
Pigment Violet 2	45175:1	1326-04-1
Pigment Violet 3	42535:2	1325-82-2 67989-22-4
Pigment Violet 27	42535:3	12237-62-6
Pigment Violet 39	42555:2	64070-98-0

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Table 2 **Authorised photo-initiators (UV printing)**

Important remark: this list of authorised photo-initiators is **exhaustive**. This list will be permanently assessed and subject to changes in the forthcoming updates of this document.

Chemical name	CAS number	MW
2-Benzyl-2-dimethylamino-4'-morpholino-butyrophenone	119313-12-1	366
2-(4-Methylbenzyl)-2-dimethylamino-1-(4-morpholinophenyl)-1-butanone	119344-86-4	380
2-Hydroxy-1-[4-(2-hydroxyethoxy) phenyl]-2-methyl-1-propanone	106797-53-9	224
Phenyl-bis-(2,4,6-trimethylbenzoil)-phosphineoxide	162881-26-7	418
4-Methylphenyl [4-(2-methylpropyl) phenyl]-, hexafluorophosphate (1-), iodonium	344562-80-7	<1000
2-Hydroxy-1-(4-(4-(2-hydroxy-2-methylpropionyl)benzyl) phenyl-2-methyl -2-propanone	474510-57-1	496
Oxy-phenyl-acetic acid 2-[2 oxo-2 phenyl-acetoxy-ethoxy]-ethyl ester Oxy-phenyl-acetic 2-[2 hydroxy-ethoxy]-ethyl ester	211510-16-6 442536-99-4	<1000
Iodonium borate salt	178233-72-2	<1000
2-Ethylhexyl 4-(dimethylamino) benzoate	21245-02-3	277
4-phenyl benzophenone	2128-93-0	258
1-Chloro-4-propoxythioxanthone	142770-42-1	272
2,4,6 trimethylbenzoylphenylphosphinic acid ethyl ester	84434-11-7	316
1-[-(4-Benzoylphenylsulfanyl-2-methyl-2-(4-methylphenyl-sulfonyl)propan -1-one	272460-97-6	510
4-(p-tolythio) benzophenone	83846-85-9	304
Methyl o- benzoyl benzoate	606-28-0	240
Ethyl-4-(dimethylamino)benzoate	10287-53-3	193
Poly{1-[4-(phenylcarbonyl)-4'-(methyldiphenylsulphide)]ethylene}	1010811-98-9	>1000

Additional note:
Benzophenone, though having been assessed by authorities, has been excluded for quality reasons, as it is proven to be a very strong tainting molecule

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Table 2 **Authorised photo-initiators** (Continued)
(Continued)

Chemical name	CAS number	MW
A mixture of: 1,3-di({α-2-(phenylcarbonyl)benzoylpoly[oxy(1-methylethylene)]}oxy)-2,2-bis ({α-2- phenylcarbonyl)-benzoylpoly[oxy(1-methylethylene)]}oxymethyl) propane And {α-2-(phenylcarbonyl)benzoylpoly(oxyethylene)-poly[oxy(1-methyl-ethylene)]-poly(oxyethylene)} 2-(phenylcarbonyl)benzoate	1003567-82-5 1003557-16-1	1196
Poly{1-[4-(phenylcarbonyl)phenyl]ethylene}	1010811-97-8	>1000
1,3-di({α-[1-chloro-9-oxo-9H-thioxanthen-4-yl)oxy]acetylpoly[oxy(1-methylethylene)]}oxy)-2,2-bis({α-[1-chloro-9-oxo-9H-thioxanthen-4-yl)oxy]acetylpoly[oxy(1-methylethylene)]}oxymethyl) propane	1003567-83-6	1899
A mixture of: 1,3-di({α-4-(dimethylamino)benzoylpoly[oxy(1-methylethylene)]}oxy)-2,2-bis ({α-4- (dimethylamino)-benzoylpoly[oxy(1-methylethylene)]}oxymethyl) propane and{α-4-(dimethylamino)benzoylpoly(oxyethylene)-poly[oxy(1-methylethylene)]-poly(oxyethylene)} 4-dimethyl-amino)benzoate	1003567-84-7 1003557-17-2	1066
(Dimethylamino)benzoate, esters with branched polyols	Not available	N/A
Polymeric thioxanthone derivative	813452-37-8 or equivalent	820
Poly(ethyleneglycol) bis(p-dimethylamino benzoate)	71512-90-8	N/A
Polymeric benzophenonic derivative	515136-48-8 or equivalent	960
Chemistry based upon polymeric derivatives whose molecular weight is above 1000 Da	Various	>1000 (any residuals <1000 Da must be on this list)

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Table 3 **Authorised acrylates (UV and EB printing)**

Acrylates are used in high concentration in UV inks (more than 50% for UV flexo) and EB inks as pre-polymers. They link together with other resins during the curing process. State-of-the-art ink formulations consist generally of high molecular weight compounds to minimise migration potential. The inks may nevertheless be formulated in such a way that they contain low molecular weight acrylates that may easily migrate into the food and might represent a safety concern. Acrylates specially synthesized for food packaging applications should be the preferred option (e.g. "LEO" products from Cytec or equivalent).

To avoid such concern, the following rules must be applied for materials where UV or EB printing is still used:

- **Use only high molecular weight acrylates, preferably at least trifunctional with ethoxylation or propoxylation of ca. MW 400 Dalton.**

- **Do not use the following acrylates:**

Chemical name	CAS number
Butanediol Diacrylate (BDDA)	1070-70-8
Diethylene glycol diacrylate (DEGDA)	4074-88-8
2-Ethyl hexyl acrylate (2EHA)	103-11-7
Iso decyl acrylate (IDA)	1330-61-6
Octyl acrylate (ODA)	2499-59-4
Phenol acrylate	937-41-7
Phenoxy ethyl acrylate	48145-04-6
1, 6-Hexanediol diacrylate (HDDA)	13048-33-4
Mixtures of pentaerythritol tri- and tetra-acrylates (PETA)	3524-68-3
Tetraethylene glycol diacrylate (TEGDA)	17831-71-9

- **The following acrylates must be minimized in the ink and varnish formulations, so that their residual levels in foods (or corresponding authorized food simulants) is below the sensory and regulatory threshold.**

Chemical name	CAS number
Trimethylol propane triacrylate (TMPTA)	15625-89-5
Dipropylene glycol diacrylate (DPGDA)	57472-68-1

Further remark: the US Food Contact Notification 772 on UV inks has not been taken into consideration, as it is not in line with our current stipulations. Indeed, it allows high migration levels (10 ug/in^2) for a given UV ink formulation, even when approved for direct food contact (http://www.cfsan.fda.gov/~dms/opa-fcn.html).

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Table 4 **Solvents submitted to restrictions**

A. Negative list: the following solvents CANNOT be intentionally used

Chemical name	CAS number
2-Methoxyethanol (methyl glycol)	109-86-4
2-Ethoxyethanol (Ethyl glycol)	110-80-5
2-Methoxyethyl acetate	110-49-6
2-Ethoxyethyl acetate	111-15-9
Monochlorobenzene	108-90-7
Dichlorobenzene	Several numbers
Volatile **chlorinated hydrocarbons**, such as [not exhaustive]: - Trichloroethylene - Perchlorethylene - Methylene chloride	 79-01-6 127-18-4 75-09-2
Volatile fluorochlorinated hydrocarbons	
2-Nitropropane	79-46-9
Methanol	67-56-1
Benzene	71-43-2
Toluene	108-88-3
Acety acetone or 2,4 pentanedione	123-45-6
1-methyl-2-pyrrolidone	872-50-4

B. Restriction list: Intentional use of the following solvents is to be strictly minimized

Chemical name	CAS number
Cyclohexane	110-82-7
Methyl ethyl ketone (MEK)	78-93-3
Methyl isobutyl ketone (MiBK)	108-10-1
Mesityl Oxide	141-79-7
Isophorone	78-59-1
Aromatics: Ethylbenzene, Trimethyl benzenes, C10-C13 aromatics, alkyl benzenes	
Pentanols	
Hexanol	111-27-3
2-Ethyl-1-hexanol	104-76-7
n-octanol	111-87-5
Diacetonenalcolhol	123-42-2
Isopropyl glycol	109-59-1
Butyl glycol	111-76-2
Methyl diglycol	111-77-3
Ethyl diglycol	111-90-0
Butyl diglycol	112-34-5
Hexylene glycol	107-41-5
Butoxypropanol	5131-66-8
Methoxy propoxy propanol (DPM)	34590-94-8
Butoxy propoxy propanol	29911-28-2
Ethanediol	107-21-1
Diethylene glycol	111-46-6
Triethylene glycol	112-27-6
Butyl glycol acetate	112-07-2
1-methoxy-2-propylacetate	108-65-6
Butyl diglycol acetate	124-17-4

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Protocol for migration test

Migration from inks and varnishes must be tested by the converter before the first application according to following procedure:

- Tested samples: Packaging materials produced under industrial conditions
- Test conditions: According to EuPIA Guideline (2009)
- Test parameters: Most severe storage, shelf life and process conditions.
- Tested substances: all ink ingredients below 1000 Da of mass must be searched
- Expected report: A clear analytical report which confirms that all substances below 1000 Da of mass were searched and do not migrate above the legal limit (by defaut 10 µg/kg unless otherwise specified). This report shall be made available to Nestlé upon request.

Example :
For a fatty liquid food packed in a plastic flexible pouch, shelf life 6 months, aseptic filling, sold in China and Germany, the following conditions apply:
- European simulant D, 10 days, 40°C, Ethanol 95% or alternatively isooctane, 2 days, 20°C.

We recommend the following independent laboratories (any local laboratory may be used if scientific proficiency is fully proved):

- Kuhlmann institute (www.institut-kuhlmann.de)
- Fraunhofer institute (www.ivv.fraunhofer.de)
- SQTS (www.sqts.ch)
- FABES institute (www.fabes-online.de)

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