

Nestlé Guidance Note on Packaging Inks

October 2018

PURPOSE

This document is a part of the Nestlé Packaging Safety and Compliance Program and specifically addresses inks used for the outside of Nestlé packaging materials.

This document equally applies to: **printing inks, primers and overprint lacquers/coatings/varnishes** which are applied by conventional press or digital ink processes. These different ink designations will be referred to as "ink" in this document.

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

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GENERAL REQUIREMENTS

Regulations:

Local legislation for food packaging inks must be followed where one exists. In addition, inks must also be formulated to comply with other local regulations such as environmental laws (e.g. REACH, California's Proposition 65, US-EPA TOSCA, etc.).

In the absence of local legislation, Nestlé requires inks to be formulated using ingredients that are listed in the Swiss Ink Ordinance on Materials and Articles and respect the migration limits contained therein.



Summary of the Swiss Ordinance for food packaging inks requirements:

- Part A lists chemical substances that have been toxicologically evaluated and a Specific Migration Limit (SML) has been set for each substance.
- Part B lists chemical substances which have not been toxicologically evaluated but are still allowed to be used in ink formulations with the default migration limit set at 0.01 mg/kg (10 ppb) for food or food simulant.
- The applicable migration limits must be respected for substances in part A and part B in order to fully comply with the Swiss Ink Ordinance requirements.
- Substances <u>not listed</u> in the Swiss Ink Ordinance are <u>not allowed</u> to be used in any part of a food packaging ink formulation.

Principally, the Swiss inks ordinance must be followed first and foremost. Exceptions may be granted for ink chemicals used outside of Europe which are specifically permitted by local food packaging ink regulations which include a toxicological evaluation (e.g. US-FDA FCN). These ink chemicals are exceptionally allowed for use in Nestlé packaging provided these chemicals are not prohibited elsewhere in this document. For these exceptions, the supplier must include a reference to the specific regulation (e.g. FCN number) as a part of the compliance statement to the Nestlé requirements.

Sustainability and Recyclability for inks:

Nestlé's goals of sustainability and recyclability for food packaging must extend to inks. This means going forward, ink manufacturers must take into consideration and start formulating inks using components which are more environmentally and recyclability friendly.

General exclusions for ink formulations:

This Note has negative lists of components. The components below are allowed by the Swiss Ink Ordinance, but are forbidden for Nestlé ink formulations due to quality and safety concerns.

- Titanium Acetyl Acetonate (TAA) must not be used as an adhesion promoter.
- ortho-Phthalate (commonly called phthalate) plasticizers must not be used.
- Bisphenol A (BPA) and materials manufactured from or incorporating BPA in reacted form as
 part of the chemical structure must not be used where safe suitable alternatives exist. Any BPA
 residue/cross contamination must not be detected in food product from ink above 0.1 ppb.
- SVHC must not be used where suitable alternatives exist.
- Nitrocellulose resins must not be used for ovenable/microwavable packaging that is heated with food prior to consumption due to decomposition concerns.
- Vegetable oils/fatty acid esters with strong odours must not be used (for offset inks)
- Heavy/Toxic metal restrictions and regulations must be followed:
 - Migration limitations are listed in the Swiss inks ordinance for barium, cobalt, zinc, arsenic, and other metals which must be respected.
 - Regulations for metals where a product is sold must be followed and can be significantly lower than 100ppm. Check local regulations to confirm compliance to limits for incidental presence of lead, mercury, chromium⁺⁶, cadmium, and other metals.



 Press washes and fountain solutions must not contain solvents and other chemicals which give off-odour or taint to the food.

PIGMENTS

Rhodamine-based ("Fanal") pigments may contain residual rhodamine, which is a suspected carcinogenic substance. These pigments are generally less stable (visual aspect changes, migrations). The prohibited pigments are listed in Table 1.

Table 1: Exclusion list for Pigments

Pigments	Color index	CAS number	Swiss Ink Ordinance
Pigment Red 81	45160:1	12224-98-5	В
Pigment Red 81:1	45160:3	80083-40-5	В
Pigment Red 81:2	45161:1	75627-12-2	В
Pigment Red 81:3	45161:2	68310-07-6	В
Pigment Red 81:5	45160:4	63022-06-0	В
Pigment Red 169	45160:2	12237-63-7	В
Pigment Green 1	42040:1	1325-75-3	В
Pigment Blue 1	42595.2	1325-87-7	В
Pigment Blue 62	44084	57485-98-0	В
Pigment Violet 1	45170:2	1326-03-0	В
Pigment Violet 2	45175:1	1326-04-1	В
Pigment Violet 3	42535:2	1325-82-2 67989-22-4	В
Pigment Violet 27	42535:3	12237-62-6	В
Pigment Violet 39	42555:2	64070-98-0	В

Other Pigments that should be minimized* and phased-out where suitable alternatives exist:

Pigments that generate small amounts of polychlorobiphenyls (PCBs) or are manufactured from 3,3'-dichlorobenzidine with different couplers must be minimized or phased-out where suitable alternatives exist.

^{*} Minimized means to use the minimum quantity necessary to achieve expected technical effect.



PHOTOINITIATORS

Nestlé recommends the use of photo-initiators mentioned in List A of the Swiss Ink Ordinance, i.e. those for which toxicological data exist. Additionally, there are photo-initiators listed in the Swiss Inks Ordinance which Nestlé <u>does not allow</u> for its packaging due to negative odour/taint, migration potential, or safety concerns. The prohibited photo-initiators are listed in Table 2.

Table 2: Exclusion list for Photo-Initiators

PhotoInitiator Name	CAS Number	Swiss Inks Ordinance	Reason to exclude
2-Hydroxy 2-methyl propiophenone	7473-98-5	В	Sensory impact Migration /contamination potential
2-(Dimethylamino)ethyl benzoate	2208-05-1	В	Migration /contamination potential
Benzophenone types:			
- Benzophenone	119-61-9	Α	
- 2-Methyl benzophenone	131-58-8	Α	Sensory impact Migration
- 4-Methyl benzophenone	134-84-9	Α	/contamination potential
- 2,4,6-trimethylbenzo phenone	954-16-5	В	
1-Hydroxycyclohexyl phenylketone	947-19-3	В	Sensory impact Migration /contamination potential
2,2-Dimethoxy 2-phenyl acetophenone	24650-42-8	В	Sensory impact Migration /contamination potential
2-Methyl 4'-(methylthio) 2-morpholino-propiophenone	71868-10-5	В	Sensory impact
2- and 4-Isopropyl 9H- thioxanthen-9-one	83846-86-0	А	
(2-ITX and 4-ITX)	5495-84-1	Α	Perceived safety issue
2,4-Diethyl 9H-thioxanthen-9-one	82799-44-8	В	Questionable toxicology
Diphenyl (2,4,6-trimethyl benzoyl) phosphine oxide	75980-60-8	А	Questionable toxicology Perceived issue

Note: This exclusion list is not applicable to UV printing on metal substrates (cans, closures) which undergo a thermal curing process (e.g. oven cured).

Table 3: Minimize list for Photo-Initiators

PhotoInitiator Name	CAS Number	Swiss Ink Ordinance	Reason to Minimize
Irgacure/Omnirad 369	119313-12-1	А	Questionable toxicology
Other monomeric Benzophenones (not forbidden above)	Various	A/B	Potential for migration

^{*} Minimize means to use the minimum quantity necessary to achieve an expected technical effect.

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ACRYLATES

Nestlé recommends the use of acrylates mentioned in List A of the Swiss Ink Ordinance, i.e. those for which toxicological data exist. Additionally, there are acrylates for UV and EB printing which Nestlé **does not allow** for its packaging even though these are listed in the Swiss Ordinance. The prohibited acrylates are listed in Table 4.

Table 4: Exclusion list for acrylates (must not be intentionally used)

Chemical name	CAS number	Swiss Ink Ordinance
Butanediol Diacrylate (BDDA)	1070-70-8	В
Diethylene glycol diacrylate (DEGDA)	4074-88-8	В
Isodecyl acrylate (IDA)	1330-61-6	В
Octyl acrylate (ODA)	2499-59-4	А
Phenoxy ethyl acrylate	48145-04-6	В

There are some acrylates which are allowed by the Swiss ink ordinance and the Nestlé requirements, but have negative quality attributes. These must be minimized* in the ink and varnish formulations so that their residual levels in foods (or food simulants) are below regulatory and sensory thresholds. The acrylates to be minimized are listed in Table 5.

Table 5: Minimize* list for Acrylates

Chemical name	CAS number	Swiss Inks Ordinance
Trimethylol propane triacrylate (TMPTA)	15625-89-5	Α
Dipropylene glycol diacrylate (DPGDA)	57472-68-1	В
1, 6-Hexanediol diacrylate (HDDA)	13048-33-4	В
2-Ethyl hexyl acrylate (2EHA)	103-11-7	А
Mixtures of pentaerythritol tri- and tetra- acrylates (PETA)	3524-68-3	В
Tetraethylene glycol diacrylate (TEGDA)	17831-71-9	В

^{*} Minimize means to use the minimum quantity necessary to achieve an expected technical effect.

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SOLVENTS

<u>Table 6:</u> Exclusion list of Solvents: must not be intentionally used in the ink formulation.

Chemical name	CAS number	Swiss Ink Ordinance
2-Methoxyethanol (methyl glycol)	109-86-4	Deleted from Swiss Ord.
2-Ethoxyethanol (Ethyl glycol)	110-80-5	Deleted from Swiss Ord.
Monochlorobenzene	108-90-7	Α
Toluene	108-88-3	А
1-methyl-2-pyrrolidone/ N-Methylpyrrolidone	872-50-4	А

<u>Table 7:</u> Minimize list for Solvents: must be minimized* in the ink formulation to reduce the risk of off-odour and taint.

Chemical name	CAS number	Swiss Inks Ordinance
Methanol	67-56-1	А
Cyclohexane	110-82-7	А
Methyl ethyl ketone (MEK)	78-93-3	А
Methyl isobutyl ketone (MiBK)	108-10-1	А
Hexanol	111-27-3	Α
2-Ethyl-1-hexanol	104-76-7	Α
n-octanol	111-87-5	А
Butyl glycol	111-76-2	А
Ethyl diglycol / Diethyleneglycol ethyl ether	111-90-0	А
Butyl diglycol	112-34-5	А

Chemical name	CAS number	Swiss Inks Ordinance
Hexylene glycol/ 2- Methyl-2,4- penanediol	107-41-5	А
Butoxypropanol	5131-66-8	Α
Butoxy propoxy propanol	29911-28-2	А
Ethanediol	107-21-1	А
Diethylene glycol	111-46-6	А
Triethylene glycol	112-27-6	А
Butyl glycol acetate / Ethyleneglycol butyl ether acetate	112-07-2	А
1-methoxy-2- propylacetate / 2- propanol, 1-methoxy-, acetate	108-65-6	А
Ethylbenzene	100-41-4	А
1-Pentanol	71-41-0	А

^{*} Minimize means to use the minimum quantity necessary to achieve an expected technical effect.



LINKS TO SWISS INK ORDINANCE

ANNEX 6, RS817.023.21

https://www.blv.admin.ch/dam/blv/en/dokumente/gebrauchsgegenstaende/rechts-und-vollzugsgrundlagen/anhang-6-sr-

bedarfsgegenstaende.pdf.download.pdf/130401%20Annex%206_en.pdf (in English)

ANNEX 10:

https://www.blv.admin.ch/dam/blv/en/dokumente/lebensmittel-und-ernaehrung/rechts-und-vollzugsgrundlagen/lebensmittelrecht2017/anhang10-verordnung-materialien-kontakt-lm-gg.pdf.download.pdf/Annex-10-ordinance-fdha-materials-and-articles-intended-to-come-into-contact-with-food-stuffs.pdf (in English)

HOW WERE COMPONENTS IN THE TABLES SELECTED?

Components excluded from or minimized in food packaging inks because of:

- potential or adverse toxicity
- perceived risk by consumers, media, NGO, etc.
- demonstrated migration potential
- negative sensory impact on the packed food or in points of sale

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