

ANALYSIS REPORT No. FD-21-002831_English version

Applicant **IRCPack S.r.l.** Via Europa, 6/A - 27041 Casanova Lonati (PV) No. 21LA01007 of 10/06/2021 for:
Customer **Novacart S.p.A.** - Via Europa, 1 - Garbagnate Monastero (LC)
Submitted by Mrs. Federica Ballabio
Customer's Request June 10th, 2021
Date of report July 21st, 2021

1. SAMPLE CHARACTERISTICS

Sample identification	Paper material coupled with plastic signed " GILDED APOLLO "
Provided by	Customer
Samples arrival date	June 10 th , 2021
Sampling and Transport Mode	Transport performed at room temperature, sampling under the responsibility of the customer
Test started on	June 14 th , 2021
Test finished on	July 20 th , 2021

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2. PERFORMED ANALYSIS AND ANALYTICAL METHODS

2.1. OVERALL MIGRATION ANALYSIS

Analysis required	Overall migration determination in aqueous simulants and in olive oil.
Analysis methods	DM 21/03/1973 SO GU n° 104 20/04/1973 + Reg. UE 10/2011 14/01/2011 GU UE L12/1 15/01/2011 + Dir CEE 82/711 18/10/1982 GU CE L297 23/10/198
Contact mode	Single side. Ratio S/V = 1 cm ² /cm ³

RESULTS

Simulant solvent	Test conditions		Overall migration	Uncertainty
Description	Time	Temperature	mg/dm ²	± mg/dm ²
10% of ethanol in deionised water	10 days	40°C	< 1 #	-
3% of acetic acid in deionised water	10 days	40°C	< 1 #	-
Rectified olive oil	10 days	40°C	< 2 #	-

#Quantification limit (LOQ)

Measurement Expanded Uncertainty (± U) associated with the measure with coverage factor K = 2 and a confidence level of 95%

The sample, analysed under the shown test condition, has given values of overall migration below the limits mentioned in the DM 21/03/73 and its subsequent modifications, in the Regulation EU/10/2011: 10 mg/dm².

Consequently this sample may come into contact with food for which are provided the simulant solvents: **10% of ethanol, 3% of acetic acid and rectified olive oil**, on condition that the monomers and additives used are in accordance with the positive lists of the Regulation EU/10/2011 and its subsequent modifications and, where applicable, of the DM 21/03/73 and its subsequent modifications, when the specific migration test aren't required at all, or when required, the values should be within the legal limit.

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2.2. SPECIFIC MIGRATION ANALYSIS OF AMINES

Analysis required Determination of primary aromatic amines in aqueous test simulants.

Analysis methods LMBG S 35L 00.00-6:1995/COR: 2002.

Contact mode Single side. Ratio S/V = 1 cm²/cm³

Date of analysis June 21st, 2021

RESULTS

Simulants		Test conditions		Specific Migration of Primary Aromatic Amines Aniline	Uncertainty
Description	Type	Time	Temperature	mg/Kg	± mg/kg
3% of acetic acid in deionised water	B	2 h	70°C	< 0.002 #	-

Quantification limit (LOQ)

Specific migration limit (DM 21/03/73 and its subsequent modifications - Reg. 10/2011/EU): 0.01 mg/Kg (expressed as aniline).

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2.3. SPECIFIC MIGRATION ANALYSIS OF METALS

Analysis required	Determination of specific migration of aluminium, antimony, arsenic, barium, cadmium, chrome, cobalt, copper, europium, gadolinium, iron, lanthanum, lead, lithium, manganese, mercury, nickel, terbium and zinc in material coming into contact with food.
Analysis methods	UNI EN 13130-1:2005 + P-AM-1475 (Laboratory internal method).
Contact mode	Single side. Ratio S/V = 1 cm ² /cm ³

RESULTS

Metal	Unit of measure	Food simulant: 3% of acetic acid in deionised water – Type B Test conditions: 10days/60°C	Uncertainty ± mg/Kg	Specific migration limit (Reg. 10/2011/EU – Annex II) mg/kg
Aluminium	Al mg/Kg	< 0.1 #	-	1
Antimony	Sb mg/Kg	< 0.01 #	-	0.04
Arsenic	As mg/Kg	< 0.002 #	-	ND = 0.01
Barium	Ba mg/Kg	< 0.1 #	-	1
Cadmium	Cd mg/Kg	< 0.002 #	-	ND = 0.002
Chrome	Cr mg/Kg	< 0.01 #	-	ND = 0.01 (¥)
Cobalt	Co mg/Kg	< 0.01 #	-	0.05
Copper	Cu mg/Kg	< 1 #	-	5
Europium	Eu mg/Kg	< 0.01 #	-	0.05 (ψ)
Gadolinium	Gd mg/Kg	< 0.01 #	-	0.05 (ψ)
Iron	Fe mg/Kg	< 1 #	-	48
Lanthanum	La mg/Kg	< 0.01 #	-	0.05 (ψ)
Lead	Pb mg/Kg	< 0.005 #	-	ND = 0.01
Lithium	Li mg/Kg	< 0.1 #	-	0.6
Manganese	Mn mg/Kg	< 0.1 #	-	0.6
Mercury	Hg mg/Kg	< 0.002 #	-	ND = 0.01
Nickel	Ni mg/Kg	< 0.01 #	-	0.02
Terbium	Tb mg/Kg	< 0.002 #	-	0.05 (ψ)
Zinc	Zn mg/Kg	< 1 #	-	5

#Quantification limit (LOQ)

(¥) Based on Reg. 1245/2020 at consideranda No. 20 and remarks No. 3 of Annex II, if on the basis of pre-existing documentary evidence it is shown that hexavalent chromium was not used in the material analyzed or formed during the entire production process, the specific migration value obtained can be considered trivalent chromium. In this case, a limit for the total chromium of 3.6 mg/kg food shall apply.

(ψ) The sum of all lanthanides must not exceed the specific migration limit of 0.05 mg/kg according to Reg. 1245/2020.

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2.4. SPECIFIC MIGRATION ANALYSIS OF AMINES

Analysis required	Determination of specific migration in aqueous simulants of primary aromatic amines listed in entry 43 to Appendix 8 of Annex XVII to Regulation (EC) No. 1907/2006.
Analysis methods	UNI EN 13130-1:2005 + P-FA-2671 (Laboratory internal method) (HPLC-MS).
Contact mode	Single side. Ratio S/V = 1 cm ² /cm ³
Simulant	3% of acetic acid in deionised water (B)
Test conditions	10 days at 60°C

RESULTS

Compound	CAS No.	Value of specific migration ± uncertainty mg/Kg
4,4'-Methylene bis(2-chloroaniline)	101-14-4	< 0.001 #
4,4'-methylenedianiline	101-77-9	< 0.001 #
4,4'-oxydianiline	101-80-4	< 0.001 #
4-chloroaniline	106-47-8	< 0.001 #
3,3'-dimethoxybenzidine	119-90-4	< 0.001 #
3,3'-dimethylbenzidine	119-93-7	< 0.001 #
p-cresidine	120-71-8	< 0.001 #
2,4,5-trimethylaniline	137-17-7	< 0.001 #
4,4'-thiodianiline	139-65-1	< 0.001 #
4-amino azobenzene	60-09-3	< 0.001 #
4-methoxy-m-phenylenediamine	615-05-4	< 0.001 #
4,4'-methylenedi-o-toluidine	838-88-0	< 0.001 #
o-anisidine	90-04-0	< 0.001 #
2-naphthylamine	91-59-8	< 0.001 #
3,3'-dichlorobenzidine	91-94-1	< 0.001 #
biphenyl-4-ylamine	92-67-1	< 0.001 #
Benzidine	92-87-5	< 0.001 #
o-toluidine	95-53-4	< 0.001 #
4-chloro-o-toluidine	95-69-2	< 0.001 #
4-methyl-m-phenylenediamine	95-80-7	< 0.001 #
o-aminoazotoluene	97-56-3	< 0.001 #
5-nitro-o-toluidine	99-55-8	< 0.001 #

Quantitation limit (LOQ)

Specific migration limit for each primary aromatic amines according to Reg. (UE) 2020/1245, which amends and corrects Regulation (EU) No. 10/2011: 0.002 mg/kg.

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2.5. SPECIFIC MIGRATION ANALYSIS

Analysis required Migration of colorants in plastic material coming into contact with food.

Analysis methods Method contained in the D.M. 21/03/73 Annex IV Section 7.

Contact mode Single side. Ratio S/V = 1 cm²/cm³

RESULTS

Simulant solvent	Test conditions		Colorants migration Transmittance (%) (*)	Limit D.M. 21/03/73 Annex IV Sec. 7 Transmittance (%)
Description	Time	Temp.		
10% of ethanol in deionised water	10 days	40°C	> 95	≥ 95
3% of acetic acid in deionised water	10 days	40°C	> 95	≥ 95
Sunflower oil	10 days	40°C	> 95	≥ 95

(*) minimum value of transmittance obtained among 400 and 700 nm.

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2.6. ANALYSIS OF CONTENT

Analysis required: determination of the content of:				
Compound / Element	CAS No.	Ref. No.	FCM No.	Analysis method:
Acetaldehyde	75-07-0	10060	128	P-FA-2672 (**)
Ethylene glycol (EG)	107-21-1	16990 - 53650	227	P-AL-87 (**)
Diethylene glycol (DEG)	111-46-6	13326 - 15760 47680	263	
Terephthalic acid	100-21-0	24910	785	P-FA-2672 (**)
Isophthalic acid	121-91-5	19150	291	P-FA-2672 (**)
2-methyl-4-isothiazolin-3-one	2682-20-4	66755	451	P-FA-2671 (**)
Acrylic acid	79-10-7	10690	147	P-FA-2672 (**)
p-cresol-dicyclopentadiene- isobutylene, copolymer	68610-51-5	45450	732	P-AL-87 (**)
1,3-Butadiene	106-99-0	13630	223	P-AL-83 (**)

(**) Laboratory internal method

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RESULT TABLE No. 1

Compound /Element	Content mg/kg	Uncertainty ± mg/kg	Content mg/dm ²	Theoretical specific migration* mg/kg	Specific migration limit (Reg. 10/2011/EU) mg/kg
Acetaldehyde	<1 #	-	< 0.02	< 0.1	6
Ethylene glycol (EG) Diethylene glycol (DEG)	37.5	± 3.8	0.6	3.6	30
Terephthalic acid	<1 #	-	< 0.02	< 0.1	7.5
Isophthalic acid	<1 #	-	< 0.02	< 0.1	5
2-methyl-4- isothiazolin-3-one	<1 #	-	< 0.02	< 0.1	0.5
Acrylic acid	8.4	± 0.8	0.1	0.6	6
p-cresol- dicyclopentadiene- isobutylene, copolymer	<1 #	-	< 0.02	< 0.1	5

Quantification limit (LOQ)

RESULT TABLE No. 2

Compound	Content mg/kg	Uncertainty ± mg/kg	Limit of content (Reg. 10/2011/EU) mg/kg	Content mg/dm ²	Theoretical specific migration* mg/kg	Specific migration limit (Reg. 10/2011/EU) mg/kg
1,3-Butadiene	< 0.05 #	-	1	<0.0008	< 0.005	NR=0.01

Quantification limit (LOQ)

Note: material weight = 15.5 g/dm².

 * theoretical specific migration: it is assumed a 100% migration of the content of the compound and it is applied the conventional factor equal to 6 dm²/kg.

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Technical Report No. **21LA01007_English version**

Applicant **Novacart S.p.A.** - Via Europa, 1 – Garbagnate Monastero (LC)
Submitted by Mrs. Federica Ballabio
Customer's Request June 10th, 2021
Date of Technical Report August 30th, 2021

1. SAMPLE CHARACTERISTICS

Sample No.	21LA01007
Sample identification	Paper material coupled with plastic signed " GILDED APOLLO "
Provided by	Customer
Samples arrival date	June 10 th , 2021
Sampling and Transport Mode	Transport performed at room temperature, sampling under the responsibility of the customer
Test started on	June 22 nd , 2021
Finished on	July 30 th , 2021

Chemist Dr. Valter Rocchelli

Professional Stamp No. 246 A of the Order of Chemists and Physicists
of the Province of Pavia

2. ORGANOLEPTIC EVALUATION

2.1 Sensory analysis by off-flavour transmission for packages

Analysis method UNI 10192:2000 - part E (indirect contact).
Conditioning: 23±1°C for 48±2h; ambient humidity.
Simulant used: B (grated milk chocolate). Ratio surface/mass (cm²/g): 10
Differentiating and scoring test.

RESULTS

The intensity of the flavour gained by the chocolate after 48 hours in the presence of the sample, **is equal to point 1.6** of the method evaluation scale.

Standard deviation: 0.3

Level of significance α : 0.1%

No. of panelists: 7

Notes:

METHOD EVALUATION SCALE

- 0: no perceptible off-flavour
- 1: just perceptible off-flavour (difficult to define)
- 2: weak off-flavour
- 3: clear off-flavour
- 4: strong off-flavour

3. TOXICOLOGICAL RISK ASSESSMENT

The objective of the study is to identify volatile, semi-volatile and non-volatile organic compounds eventually present in the materials coming into contact with food to evaluate the potential contamination.

Analysis method: UNI/TS 11788:2020 – Packaging: Printed packaging intended to come into contact with food – Method for risk assessment for set-off and migration.

3.1 DESCRIPTION METHOD

Identification of volatile compounds

Sample aliquots are transferred into a 20 ml vial and preconditioned 30' at 150°C, after adding an internal standard (chlorobenzene). The sampling of volatile organic compounds has been carried out by static headspace followed by GC/MS analysis (mass range acquired: 35 – 350 amu).

Analytical sensitivity (in regard to the standard): 1 µg/dm²

The expanded uncertainty for the applied method is: ± 40%

Laboratory: Sepack-lab S.r.l.

Identification of semi-volatile and non-volatile compounds

Sample aliquots were cold extracted for 24 hours with a known volume of n-hexane containing an internal standard (di propyl phthalate) followed by analysis GC/MS (mass range acquired: 45 – 700 amu).

Analytical sensitivity (in regard to the internal standard): 5 µg/dm²

The expanded uncertainty for the applied method is: ± 30%

Laboratory: Sepack-lab S.r.l.

Expression of the results:

In the following figures are reported the tracers in total ion current (TIC) of the samples analyzed, with the relevant tables of the identifications obtained.

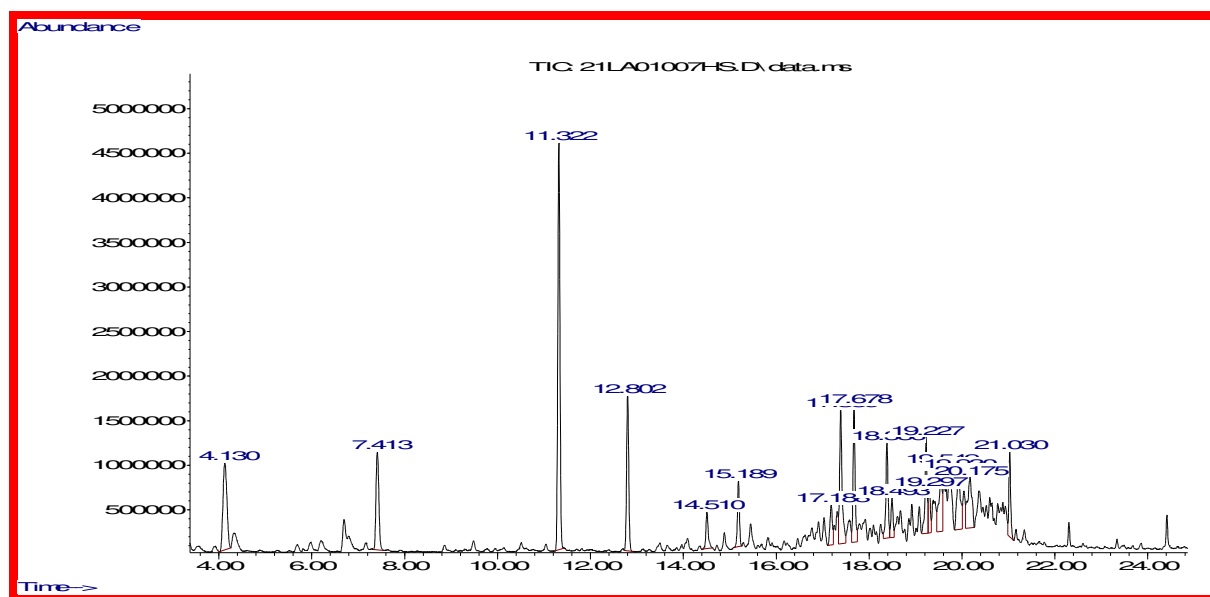
In the tables are reported the following data:

- peak retention time (TR) which appears also on the chromatogram
- identification obtained through comparison of mass spectrums with those ones present in the libraries (Nist05a – W8N05ST - Willey) managed by software of the analytical system.
- qual. = quality namely the index of coincidence between the sample spectrum and the one in the library (maximum 100 - acceptable ≥ 70).
- semiquantitative evaluation: methods are not quantitative but to get an estimate of the concentrations of the compounds, detected in the head space and the extraction solvent, data of "semi-quantitative assessment" are expressed in µg/g or in µg/dm², attributing to various peaks (identified or not) the response factor of added internal standard and calculated on the basis of area of the peaks themselves.

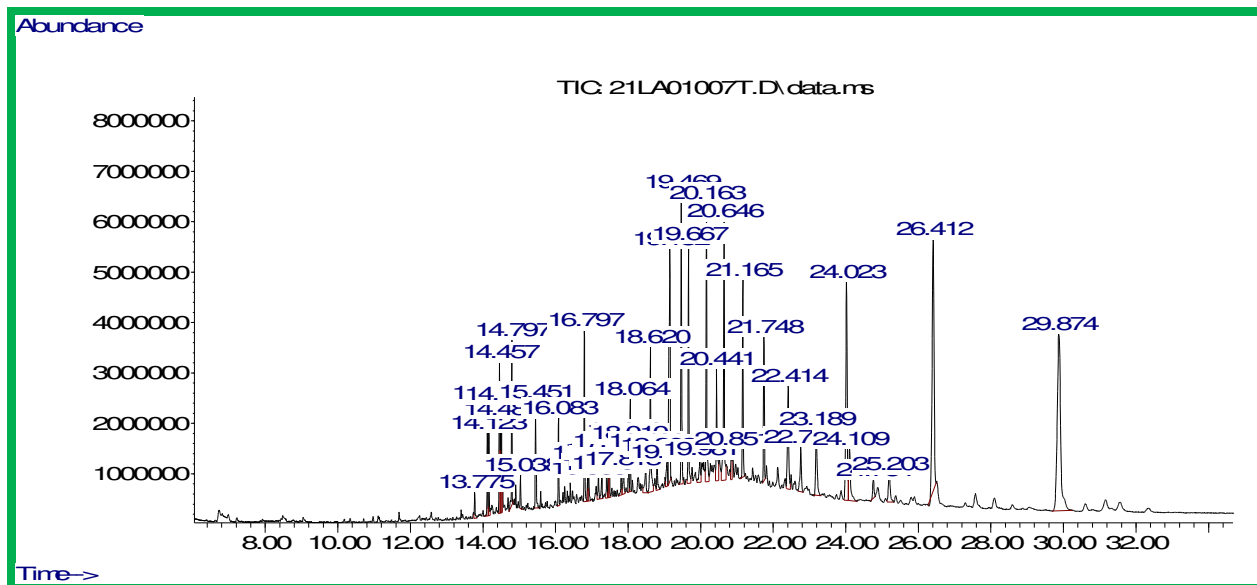
A chromatographic peak is called "unidentified" when its mass spectrum is not comparable with any of those present in the spectra libraries mentioned above and are not available technical documents or information to obtain the identification.

3.2 RESULTS

VOLATILES ORGANIC COMPOUNDS – TOTAL HEAD SPACE



TR	Peak identification	qual	SEMIQUANTITATIVE EVALUATION $\mu\text{g}/\text{dm}^2$
4.13	Vinyl acetate + butanal	-	11
7.41	Pentanal	91	9.2
11.32	Hexanal	91	29
12.80	Internal standard (Chlorobenzene)	96	11
14.51	Styrene	97	2.8
5.18	Heptanal	96	4.3
From 17.18 to 20.17	Saturated and unsaturated aliphatic hydrocarbons	>80	37 sum
17.38	2-pentyl, furan	87	11
17.67	Benzaldehyde	97	9.2
18.38	Octanal	94	7.0
21.03	Nonanal	80	5.0

SEMI-VOLATILE AND NON-VOLATILE ORGANIC COMPOUNDS – TOTAL EXTRACTION

TR	Peak identification	qual	SEMIQUANTITATIVE EVALUATION $\mu\text{g}/\text{dm}^2$
13.77	Benzophenone	96	15
From 14.12 to 14.51	Di isopropyl naphthalenes - isomers	>90	288 sum
14.53	Internal standard (Di propyl phthalate)	94	100
15.03	Benzene, 1,1'-[1,2-ethanediylbis(oxy)]bis-	95	10
15.45	Di iso-butyl phthalate	91	49
16.08	Di n-butyl phthalate	91	43
16.79	1-hexadecanol	80	90
From 16.88 to 25.20	Linear saturated aliphatic hydrocarbons	>80	1489 sum
17.41 - 18.48 - 22.76 - 24.76	Natural compounds *	**	120 sum
17.27-17.87	Tributyl acetyl citrate and its compounds decomposition during the analysis phase	>90	58
17.81	Benzene, 1,3-dimethoxy-5-[(1E)-2-phenylethenyl]	99	12
18.01	1-octadecanol	90	26
19.07	Dipropylene glycol dibenzoate	**	24
19.46	Di 2-ethylhexyl phthalate	93	175
20.44	Di 2-ethylhexyl terephthalate	91	87
0.85	Squalene - pollutant of the analytical system	98	-
24.02 - 26.41 - 29.87	Dialkylketones ***	**	767 sum

(*) Natural compounds: are found in cellulosic structures and in some resins (terpene, colophony) as natural products (terpenes dehydroabietic and phenanthrenic acid and derivatives, sitosterols, etc.). Originally present in the raw starting material (wood) or formed in the following the manufacturing process of the cellulose and/or processing of the same.

(**) The identification hypothesis reported is obtained by comparison with a solution of the compound analyzed with the same method or based on information collected from previous studies or in the literature.

(***) Hydrolysis products of the alkyl ketene dimer additive, contemplated in the positive lists of DM 21/03/73 for paper and cardboard.

3.3 CONSIDERATIONS ON THE RESULTS

The analysis performed by GC/MS with the methods described here have pointed out the significant presence of the following organic compounds:

Vinyl acetate (CAS No. 108-05-4): compound contemplated in the positive lists of the DM 21/03/73 and of the EU Reg. 10/2011 with a specific migration limit (SML) of 12 mg/kg or mg/Kg o 2000 µg/dm².

Aldehydes and alkyl-furans: compounds naturally present in the cellulosic structures as they are natural products originally present in the starting raw material (wood) or formed during the manufacturing or transformation process of the cellulose.

Styrene (CAS No. 100-42-5): monomer contemplated in the positive lists for plastics (Reg. 10/2011 UE) without specific restrictions.

Aliphatic saturated and unsaturated hydrocarbons: coming from paper-board coating.

Benzaldehyde (CAS No. 100-52-7): compound included in the list of flavoring substances (ref. EU Implementing Regulation no. 872/2012 of the EC Commission of 01/10/2012).

Benzophenone (CAS No. 119-61-9): photoinitiator for UV varnish and inks; it is also an additive for plastics, contemplated in the positive lists of Reg. 10/2011 EU with a specific migration limit of 0.6 mg/kg or 100 µg/dm².

Di isopropyl naphthalenes (DiPN): used as solvents of the inks of carbonless papers, they are very often present in recovery papers but are not intentionally added. There is currently no regulatory regulation on DiPNs; the German BFR (recommendation 36) asks for the minimization of the content in paper materials containing recovery without, however, indicating limits.

Benzene, 1,1'-[1,2-ethanediylbis (oxy)] bis- (CAS No. 104-66-5): contemplated in the Swiss Ordinance 817.023.21 (status 01/12/2020) - Annex 10 inks part B - substances not evaluated, for which there is a specific migration limit (SML) of 0.01 mg/kg (1.7 µg/dm²). Cramer class = III¹.

Di isobutyl phthalate (CAS No. 84-69-5): specific migration limits are not indicated, it refers to "Di n-butyl phthalate" isomer contemplated in the positive lists for plastics (Reg. 10/2011 EU) with a SML of 0.3 mg/kg or 50 µg/dm².

Di n-butyl phthalate (CAS No. 84-74-2): plasticizer included in the positive lists for plastics (Reg. 10/2011 EU) with a SML of 0.3 mg/kg or 50 µg/dm².

1-hexadecanol (CAS No. 36653-82-4), **1-octadecanol** (CAS No. 112-92-5): aliphatic, saturated, linear, primary mono-alcohols (C4-C22): these compounds are shown in the list positive for plastics intended for contact with food (Reg. 10/2011 UE) (Ref. N. 12375) without specific restrictions.

Linear saturated aliphatic hydrocarbons: n-paraffins.

Tributyl acetyl citrate (CAS No. 77-90-7): plasticizer used for inks, included in the positive lists of additives for plastic materials (Reg. 10/2011 EU) with a specific migration limit (SML) of 60 mg/Kg expressed as the sum of substances (group restriction No. 32).

Benzene, 1,3-dimethoxy-5-[(1E)-2-phenylethenyl] (CAS No. 21956-56-9): Cramer Class = III¹.

Dipropylene glycol dibenzoate (CAS No. 19224-26-1): included in the list of flavoring substances (ref. Implementing Regulation EU No. 872/2012 of the EC Commission of 01/10/2012).

Di 2-ethylhexyl terephthalate (CAS No. 6422-86-2): plasticizer included in the positive lists of additives for plastics (Reg. 10/2011 EU) with a SML of 60 mg/kg expressed as a sum of substances (restriction of group no. 32).

Di 2-ethylhexyl phthalate (CAS No. 117-81-7): plasticizer included in the positive lists for plastics (Reg. 10/2011 EU) with a SML of 1.5 mg/kg or 250 µg/dm².

¹ Substances whose chemical structures do not allow a preliminary presumption of safety or may even suggest significant toxicity or have reactive functional groups that can be potentially considered as a source of toxicity issues; the threshold of toxicological concern is quantified as 90 µg/person/day.

Dialkylketones: hydrolysis products of the alkyl ketene dimer additive, contemplated in the positive lists of DM 21/03/73 for papers and cartons and in the positive lists of Recommendation BFR XXXVI; according to the latter, the dialkylketones must not migrate more than 5 mg/kg or 833 µg/dm².

Based on the analytical assessments carried out and reported in this Technical Report, there are no critical situations for the toxicological risk assessment.