INK, HEART & SOUL

SIEGWERK

Statement of Composition
of the following Siegwerk Product

UNICOR POSTPRINT COVERING WHITE
12-010293-4.1470

used in the Manufacture of Food Packaging

Regulation (EC) No 1935/2004, the **Swiss Ordinance 817.023.21** and the **Turkish Food Codex Regulation (No. 30382 of 05.04.2018)** require that materials and articles which, in their finished state, are intended to be brought into contact with foodstuffs, must not transfer any components to the packed foodstuff in quantities which could endanger human health, or bring about an unacceptable change in the composition or deterioration in organoleptic properties.
This means that the manufacturer of the finished article and the filler have the legal responsibility that it is fit for its intended purpose.

Provided that the product listed above is used according to the information given in the Technical Data Sheet, or in equivalent technical communications, and correctly processed, and provided that the food packaging is designed in a way that there is no intended direct food contact with the print, Siegwerk hereby confirms that it will in principle allow compliance of the final product with the Regulation (EC) No 1935/2004, the Swiss Ordinance 817.023.21 and the Turkish Food Codex Regulation.

- Siegwerk products are formulated and manufactured in accordance with the “EuPIA Guideline on Printing Inks applied to Food Contact Materials” (www.eupia.org).

- The product listed above is manufactured in accordance with the EuPIA “Good Manufacturing Practices (GMP) - Printing Inks for Food Contact Materials” (www.eupia.org).

- Based on information provided by raw material suppliers, printed packaging manufactured using the product listed above will contain the following potentially migrating substances in the table below.

For detailed information on the legal background, Siegwerk standard assumptions, risk evaluation and migration testing please refer to:
https://ink-safety-portal.siegwerk.com/regulatory-affairs/statement-of-composition-soc.

In the following table, please find the list of used substances known to be present, that have been subjected to individual risk assessments and as a consequence identified as having the theoretical potential to migrate, including indication whether the substances are restricted under the scope of the Plastics Regulation (EU) No 10/2011, the Turkish Food Codex Regulation Tebliğ No 2019/44, the Swiss Ordinance 817.023.21 Annex 2 or 10 or listed as a food additive in Regulation (EC) No 1333/2008 or in Regulation (EC) No 1334/2008[1]:

CAS No.	PM/Ref No.	FCM No.	Name	Restrictions and specific migration limits (SML) [mg/kg]		Regulation (EC) No 1333/2008 Regulation (EC) No 1334/2008	For non-volatile/non-reactive substances: Maximum amount in dried ink film [%]	WCC[2], S/V ratio 6:1 [mg/kg]	Comment[3]
				Regulation (EU) No 10/2011 Tebliğ No 2019/44	Swiss Ordinance 817.023.21				
56-81-5	18100 / 55920	103	Glycerol	(60)	(60)	E 422	5	9	
9002-88-4	80000	549	Polyethylene waxes	(60)	(60)	-	2	4	
141-43-5	12763/35170	326	2-Aminoethanol	0,05	0,05	-	1,3	2,34	Exemplary migration tests showed that the specific migration limit will not be exceeded for water-based inks.
68441-17-8	80077	811	Polyethylene waxes, oxidized	(60)	(60)	E 914	< 1	1	

[1] The information given in this SoC follows the legal status at the date of the issue.

[2] Standard conditions: 6 dm^2/kg_{food}, with 3 g/m^2 dry ink, 100% area coverage. Depending on the packaging application and the consumer groups (e.g. infants and young children), the exact parameters should be used for the calculation. In rare cases, minor differences in the calculated WCC results can be attributed to carried value roundings.

[3] Risk Assessments based on (Q)SAR Prediction Tools are compliant to the EFSA TTC Guidance (2019).

	80640	79	Polyoxyalkyl(C2-C4)dimethylpolysiloxane	(60)	(60)	-	< 1	< 1	
9003-11-6	79920	551	1,2-Propyleneglycol, ethoxylated and propoxylated	(60)	(60)	-	< 1	< 1	
77-99-6	13380/25600/94960	141	Trimethylolpropane	6	6	-	0,1	0,2	
9046-01-9	79600	578	Polyethylene glycol tridecyl ether phosphate	5	5	-	< 0,1	0,1	
2634-33-5			1,2-Benzisothiazol-3(2H)-one	-	0,5	-	0,04	0,07	
77-85-0			Trimethylolethane	-	0,01	-	0,03	0,06	Based on a toxicological risk assessment conducted by Siegwerk a self-derived SML of 1.80 mg/kg can be applied for the migrant if present as NIAS. Details are available on request.
68611-44-9	86285	87	Silicon dioxide, silanated	(60)	(60)	-	< 1	< 1	
57-55-6	23740 / 81840	109	1,2-Propylene glycol	(60)	(60)	E 1520	< 1	< 1	
55965-84-9			Mixture of 5-Chlor-2-methyl-2H-isothiazol-3-one (CMIT) and 2-Methyl-2H-isothiazol-3-one (MIT) (3:1)	-	0,15	-	< 0,01	< 0,01	

(60) = Overall Migration Limit (OML)

Metals with Restrictions in COMMISSION REGULATION (EU) No 10/2011 Annex II:
The product may contain substances listed in Annex II (1) to the Plastics Regulation (EU) No 10/2011. Such substances are shown in the data table only if the migration of these substances from the final article could exceed the limits specified in the Plastics Regulation.

Primary Aromatic Amines (PAA) with Restrictions in COMMISSION REGULATION (EU) No 10/2011 Annex II (2) are unavoidable impurities possibly present in certain types of pigments. Indicative migration testing and WCC (conducted according to the EU cube) of the PAA listed in entry 43 to Appendix 8 of Annex XVII to Regulation (EC) No 1907/2006 with an individual detection limit of 0.002 mg/kg and PAA not listed in this entry 43 with a detection limit of 0.01 mg/kg (in sum) demonstrated that, in principle, the respective PAA are not released above the detection limit as specified in the Plastics Regulation. If applicable a disclosure of the relevant PAA is provided in the tables below in order to facilitate a proper compliance work.

Please find all PAA listed in entry 43 (so-called “carcinogenic PAA Cat. 1A/B”) known to be possibly present in the liquid ink:

Name (CAS No.)
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Please find all PAA not listed in above mentioned entry 43 known to be possibly present in the liquid ink:

Name (CAS No.)
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General Considerations:
For packaging structures strongly deviating from the WCC assumptions and for specific applications when printing on paper and board and where analysis are performed which are significantly deviating from the methods described in COMMISSION REGULATION (EU) No 10/2011 (e.g. extraction method with cold water; applications falling under BfR recommendation XXXVI), the printer shall inform the ink supplier, who may recommend alternative inks.

In the table below, please find volatile organic solvents used or known to be present in the liquid ink/coating and varnish including an indication, whether the solvents are restricted under the scope of the Swiss Ordinance 817.023.21 Annex 10.

The amount of these organic solvents in the dried ink film and/or the final packaging is under control of the converter.

CAS No.	Name	Restrictions and specific migration limits (SML) [mg/kg] in Swiss Ordinance 817.023.21	Amount in Liquid ink/varnish [%]	Comment
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This information is provided to allow other members of the packaging chain to assess compliance in regard to the Framework Regulation (EC) No 1935/2004, and/or the Plastics Regulation and/or the Swiss Ordinance and/or the Turkish Regulation.

The information may only be used for this purpose. This document must be treated as confidential and must not be transmitted to third parties without prior consent.

Disclaimer

The information contained herein is based upon data regarded to be up-to-date and reflecting the existing level of knowledge at time of issue. Applicable laws and regulations are to be observed. This document is provided to Siegwerk's customers (and/or Analytical Contractors) in order that they are able to comply with all applicable health and safety laws, regulations, and orders. In particular, customers are under an obligation to carry out a risk assessment under relevant Good Manufacturing Practices (GMP) in-line with EU food contact legislation and as a result take adequate risk management measures to protect food consumers.
Since the application and conditions of use are beyond Siegwerk's control, the information provided does not represent a guarantee of any kind for the final printed product. The product's performance and its suitability for the customer's purpose depend on the particular conditions of use and the material being printed. Siegwerk recommends that customers satisfy themselves that each product meets their requirements in all respects before commencing a print run. There is no implied warranty of merchantability or fitness for purpose of the product or products described herein.

Customers are requested to refer to https://ink-safety-portal.siegwerk.com/regulatory-affairs/compliance.html for the Download of "Know How; Customer Guidance: Printing Inks and Coatings for Food Packaging".

Global Product Safety + Responsibility
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