FOOD PACKAGING INK STATEMENT OF COMPOSITION

REGULATORY JURISDICTION: European Union

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Issue Date: May 24, 2018

Revision History: Revision 1

Period of Validity: 12-months from issue date

SECTION A: SUPPLY CHAIN INFORMATION

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SECTION B: PRODUCT CLASSIFICATION, IDENTIFICATION, and DESCRIPTION

B1 Product Classification (Choose One)		
Chemical substance ☐	Intermediate material ☒	Finished article/material ☐

B2 Product Identification

HP2580 Black Solvent Ink-filled cartridges:

- HP Black 2580 Solvent Print Cartridge (B3F58B)
- HP Black 2580 Bulk Solvent Print Cartridge (F0L89B)
- HP Black 2580 Bulk Solvent Ink Cartridge (F0L91A)

B3 Product Description

HP2580 Black Solvent Ink-filled cartridges for use with non-HP OEM printers intended for printing product identification text and bar codes on the outside surface of various types of flexible film packaging.

SECTION C: FOOD CONTACT COMPLIANCE

All compliance-related statements in this document are made solely on the basis of the Representative Use Case detailed in section C3. It is the responsibility of the customer to perform their own risk assessment and/or further testing to ensure the final product meets all applicable regulatory requirements.

C1 Statement on Regulatory Compliance

This document provides information on the ink specified in Section B2 to customers, to assist them in assessing compliance of their processes and products with legal requirements applicable to the production, marketing and use of materials and articles intended to come into contact with food. Customers must ensure that they apply good manufacturing practices in line with EU Regulation No. 2023/2006 on good manufacturing practices (GMP Regulation).

The ink specified in Section B2 is intended for printing on the non-food contact surface of flexible film packaging (section C3), and can comply with Article 3 of the EU Framework Regulation No. 1935/2004 under appropriate conditions of use. The intentionally added components of the ink specified in Section B2 are manufactured from the substances set out in the applicable sections of the Swiss Ordinance 817.023.21.

Further information on migration and/or limits of use can be found in Table 2 of section C3.

This Statement of Composition is for information purposes only. It is the legal responsibility of the manufacturer of the finished article to ensure the food packaging is fit for its intended purpose.

C2 Statement on Good Manufacture Practice

The ink specified in Section B2 has been manufactured according to Good Manufacturing Practices (GMP) by producing fluids of consistent composition and quality, and by adhering to robust quality assurance & control systems. The manufacturing operations of the ink specified in Section B2 are carried out in accordance with the general rules on GMP as provided for in Article 5, 6, and 7 of the Commission Regulation (EC) No 2023/2006, and with the European Printing Ink Association's *Good Manufacturing Practice: Printing Inks for Food Contact Materials*, 4th completely revised version (2016).

NIAS Management: In addition, HP has commissioned an independent assessment of Non-Intentionally Added Substances (NIAS) in accordance with internationally recognized scientific principles on risk assessment, including ILSI Europe: Guidance on Best Practices on the Risk Assessment of Non Intentionally Added Substances (NIAS) in Food Contact Materials and Article (2016) and EuPIA Guidance for Risk Assessment of Non Intentionally Added Substances (NIAS) and Non Listed Substances (NLS) in printing inks for food contact materials (2017), based on the representative use case, which concluded no resulting human health risks of regulatory concern in the US or EU. Azo pigments are not used, therefore PAAs are not expected to be present.

The intentionally added azo dyes were assessed and it was verified that they do not decompose in the body to the bio-available carcinogenic aromatic amines of Category 1A and 1B according to the CLP Regulation (EC) No. 1272/2008, and listed in Regulation (EC) No 1907/2006 – REACH, Appendix 8: Entry 43 - Azocolourants - List of aromatic amines.

C3 Representative Use Case Test Description and Results (food types, temperature or other variables)

NOTE: Ink is specified in Section B2

Organoleptic testing: HP has conducted organoleptic testing on 25 micron Low-density Polyethylene (LDPE), with an ink laydown of 0.7 mg ink per printed product identification code or mark. Migration testing was performed by an accredited analytical laboratory using protocols identified in DIN 10955, with the unprinted side above water for 10 days at 60 degrees Celsius. The sample material was evaluated by 6 persons, and it was concluded that the ink is compliant with the sensory requirements of Art. 3 (1) c) of Reg. (EC) 1935/2004 for long term contact with food, given the performed testing conditions.

Migration testing: As specified in Table 1, HP conducted migration testing on 12 micron Polyethylene Terephthalate (PET), 15 micron Biaxially Oriented Polypropylene (BOPP), and 30 micron BOPP, using either isooctane or 95% ethanol as food simulants. The ink laydown was 0.7 mg ink per printed product identification code or mark. Migration testing was performed by an accredited analytical laboratory using protocols identified in EU Regulation 10/2011 Annex V simulating ambient storage up to 1 year.

Table 1

Tested Substrate	Tested Temperature	Food Simulant
BOPP 15µ	20C	Isooctane
PET 12µ	20C	95% ethanol
PET 12µ	60C	Isooctane
BOPP 30µ	40C	95% ethanol
BOPP 30µ	20C	Isooctane

The following information in Table 2 identifies the potential for migration of components in order for downstream operators in the supply chain to assess compliance with Article 3 of EU Framework Regulation No. 1935/2004 and applicable parts of Swiss Ordinance 817.023.21.

The information below is provided for information purposes only. The customer must assess the applicability of the Representative Use Case contained in this document to customer's Use Cases of interest, and the potential need for additional assessment to verify compliance with the applicable migration limits or other requirements.

Table 2

Components	Descriptor	Swiss Ordinance 817.023.21	Method to Establish Representative Use Case Compliance
7 components	Other intentionally added ingredients	Annex 2 and/or Annex 10 Part A or B (2 component dossiers submitted, authorized ad interim)	Analytical testing: Not detectable
2 components	Acetone, Ethanol	Authorized by Part A	Analytical testing

SECTION D: FREQUENTLY ASKED REGULATORY MATTERS

REACH SVHC	As of the date of this Statement these products do not have any of the substances on the EU's Candidate List for Authorization (otherwise known as Substances of Very High Concern).
REACH Annex XVII	This product is not subject to a restriction in Annex XVII of Regulation (EC) 1907/2006 as amended through the date of this Statement.
State of California Proposition 65	Refer to HP Ink Safety Data Sheet for United States.
Dual Use Additives	None

SECTION E: ADDITIONAL INFORMATION

HP is committed to providing customers with high quality products and services that have a low environmental impact throughout their lifecycle. HP developed its Design for Environment (DfE) program prior to 2001 with the goal of reducing environmental impact of products and services, in addition to meeting applicable safety and regulatory requirements. For more information about HP's Environmental Programs, HP's General Specification for the Environment (GSE), REACH and RoHS, go to www.hp.com/environment.

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