



## FOOD PACKAGING INK STATEMENT OF COMPOSITION

REGULATORY JURISDICTION: United States

Author: HP Sustainability and Product Compliance

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### SECTION A: SUPPLY CHAIN INFORMATION

<p><i>Issued to:</i>  <b>WEBER Marking Systems GmbH</b>          Maarweg 33          DE-53619 Rheinbreitbach          Telefon: + 4 9 (0)2224 7708-0          info@webermarking.de          www.webermarking.de</p> <p><b>24-hour-Emergency-Telephone-Number</b>          (Company/Contract ID code: "BSU")          outside USA/Canada: +49 - 700 - 24 112 112          (BSU)          inside USA/Canada: 011 - 49 - 700 - 24 112 112          (BSU)</p>	<p><i>Issued by:</i>  <b>HP Inc.</b>          1501 Page Mill Road          Palo Alto, CA 94304          United States</p>
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### SECTION B: PRODUCT CLASSIFICATION, IDENTIFICATION, and DESCRIPTION

B1 Product Classification (Choose One)		
Chemical substance <input type="checkbox"/>	Intermediate material <input checked="" type="checkbox"/>	Finished article/material <input type="checkbox"/>
<p>B2 Product Identification</p> <p>HP 2580 Black Solvent Ink-filled cartridges:</p> <ul style="list-style-type: none"> <li>- HP Black 2580 Solvent Print Cartridge (B3F58B)</li> <li>- HP Black 2580 Bulk Solvent Print Cartridge (FOL89B)</li> <li>- HP Black 2580 Bulk Solvent Ink Cartridge (FOL91A)</li> </ul> <p>HP 2590 Solvent Ink-filled cartridges:</p> <ul style="list-style-type: none"> <li>- HP 2590 Solvent Print Cartridge (W3T10B)</li> </ul>		
<p>B3 Product Description</p> <p>HP Solvent Ink-filled cartridges for use with non-HP OEM printers intended for printing product identification text and bar codes on the external surface of various types of flexible film packaging.</p>		

### 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 inks 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 US FDA Title 21 CFR 174.5 general provisions applicable to indirect food additives.

The inks specified in Section B2 are intended for printing on the external surface of various types of flexible film packaging (Section C3), including primary packaging in contact with food, and can comply with US FDA Title 21 CFR parts 170-199 since the ink components fit at least one of the following criteria:

- Is in compliance with the FDA requirements listed in US FDA Title 21 CFR and is within any limitations stated in those regulations
- Components are not food additives or indirect food additives as defined by the Food Additives Amendment of 1958 and the Color Additives Amendment of 1960 of the Federal Food, Drug, and Cosmetic Act if the migration level of the component results in a calculated Dietary Concentration that is below the Threshold of Regulation.
- The component migrates at a minimal level, but a self-determination letter has been completed showing that the component is safe and within industry standards for its intended use
- Substances that, based upon legal opinion, supplier certification, and/or extraction results from food-simulating solvents, are not food additives and are acceptable for food contact applications in full compliance with the Federal Food, Drug, and Cosmetic Act and all applicable food additive regulations
- Substances that are GRAS for direct addition to food or for use in contact with food
- Substances that are "Prior Sanctioned" for use in this application
- Substances that are the subject of applicable Food Contact Substance Notifications

Further information on migration and/or limits of use can be found in Table 2 (HP 2580 ink) and Table 3 (HP 2590 ink) of Section C3.

In accordance with 21 U.S. Code § 342, representative print samples using HP 2580 ink were found to introduce no perceptible odor or taste per EN 1230-2 using SLMB Chap. 47A and Chap. 63B, and DIN EN 4120. HP 2580 was used as a representative of HP 2590, as these inks have similar components and comparable concentrations.

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 inks specified in Section B2 have 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 inks specified in Section B2 are carried out in accordance with the general rules on GMP as provided for in US FDA Title 21 CFR 174.5 General provisions applicable to indirect food additives, 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, a third party has validated the assessment of Non-Intentionally Added Substances 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 in Food Contact Materials and Article (2016) and EuPIA Guidance for Risk Assessment of Non Intentionally Added Substances and Non Listed Substances 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. The azo dyes used are not identified in CLP Regulation (EC) No. 1272/2008.

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

**Organoleptic testing:** HP has conducted organoleptic testing with HP 2580 ink on 25-micron Low-density Polyethylene (LDPE), with an ink laydown of 0.7 mg ink per printed product identification code or mark. Organoleptic testing was performed by an accredited analytical laboratory (ISO 17025) 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. HP 2580 was used as a representative of HP 2590, as these inks have similar components and comparable concentrations.

**Migration testing:** As specified in Table 1, HP has conducted migration testing with HP 2580 ink 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 for simulating ambient storage up to 1 year. HP 2580 was used as a representative of HP 2590, as these inks have similar components and comparable concentrations.

**Table 1**

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

The following information in Table 2 (HP 2580 ink) and Table 3 (HP 2590 ink) identifies the potential for migration of components approved for use within approved limitations and under prescribed conditions as required by the Food Additives Amendment and the Regulations issued by the Food and Drug Administration and, where applicable, the products are within the limitations of the appropriate test for flexible film packaging.

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 HP 2580 ink**

<b>Components</b>	<b>Descriptor</b>	<b>FDA Title 21 CFR Compliance</b>	<b>Method to Establish Compliance</b>
7 components	Proprietary ingredients	Self-Determination Letter Not a “food additive” as defined by migration to the food being packaged per the specific use case as described in Section C3	Confirmed by analytical testing and/or 100% migration calculation
1 component	Ethanol	Listed in US FDA 21 CFR Parts 175.300	Confirmed by analytical testing and/or 100% migration calculation
1 component	Acetone	GRAS	Confirmed by analytical testing and/or 100% migration calculation

**Table 3 HP 2590 ink**

<b>Components</b>	<b>Descriptor</b>	<b>FDA Title 21 CFR Compliance</b>	<b>Method to Establish Compliance</b>
3 components	Proprietary ingredients	Threshold of Regulation (TOR)	Confirmed by analytical testing and/or 100% migration calculation
3 components	Ethanol Ethyl acetate	Listed in US FDA 21 CFR Parts 175.300	Confirmed by analytical testing and/or 100% migration calculation

**SECTION D: FREQUENTLY ASKED REGULATORY MATTERS**

REACH SVHC	As of the date of this Statement, these products do not contain any of the chemicals on the EU’s Candidate List for Authorisation (otherwise known as Substances of Very High Concern) as intentionally added substances.
REACH Annex XVII	These products are 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 Sheets for the United States.
Dual Use Additives	None.
Nestlé Guidance Note on Packaging Inks, October 2018	As of the date of this Statement, these products adhere to the Nestle Guidance Note on Packaging Inks, as applicable to inkjet printing inks.

## 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](http://www.hp.com/environment).

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